Department of Energy
Washington, DC 20585

DEC 2 9 1988

Mr. John Linehan, Director
Repository Licensing and Quality
Assurance Directorate
Division of High-Level
Waste Management
Office of Nuclear Material Safety
and Safeguards
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear: Mr. Linehan:

At the July 7, 1988, meeting between the NRC and DOE on Quality Assurance, the DOE committed (QA-G-2) to provide the NRC with the corrective actions that have been identified in response to the findings of the June 8, 1987, NRC Mini-Audit of Los Alamos National Laboratory (LANL). The DOE also committed to provide the NRC with a monthly report regarding the implementation of the corrective actions.

Enclosed for your information is the report of the Yucca Mountain Project Office (YMPO) QA Surveillance YMP-SR-88-014, which was conducted at LANL on August 15-19, 1988. The purpose of this surveillance was to verify the implementation of the corrective actions taken in response to the deficiencies identified in the June 8, 1987, NRC Mini-Audit. The NRC cited deficiencies and the Los Almos corrective actions necessary to resolve the deficiencies are provided in Enclosure A to the attached report. Enclosure B of the attached report contains the documentation referenced in the surveillance report that supports the status of each corrective action.

Questions regarding this correspondence should addressed to myself, at 586-1462.

Sincerely,

Gordon Appel

Gordon Appel, Chief
Licensing Branch
Office of Civilian Radioactive
Waste Management

cc: R. Stein, RW-30 w/encl
R. Loux, State of Nevada w/encl
S. Zimmerman, " "
D. Betchel, Clark County NV w/encl
S. Bradhurst, Nye County NV " "
M. Baugman, Lincoln County NV " "
S. Kale, RW-20 w/o encl
C. Gertz, YMPO " "
L. Barrett, RW-3 " "

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Enclosure A

Los Alamos NNWSI Project
CORRECTIVE ACTION REPORT

Initiator: Signature/Organization/Phone	CAR No: 024, Rev. 1
H. P. Nunes, N-5, X7-8039	Initiation Date: 26 August 1988
	QA Level: 1

Title of Work to which CAR Applies:

NRC Audit of LANL, June 8, 1987, Appendix B, Page B-1

Condition Requiring Corrective Action:

See attached, Page 1 of 2.

Corresponding Documentation: NRC Mini-Audit Report

Assigned To: H. P. Nunes	Date: 26 August 1988

Cause and Recommended Corrective Action:

See attached response, Pages 1 and 2 of 2.

QAPL Concurrence: DOE ORDER 5000.3, UOR REQUIRED ☐ YES ☒ NO	Date:
Corrective Action Completed:	Date:
Implementation Verified By:	Date:
CAR Closeout:	Date:

RESPONSE TO CAR NO. 024, Rev. 1

REQUIREMENT

LANL-NNWSI-QAPP - Section 1.0, Organization, Subsection 1.1 LANL NNWSI Project:

> "The persons performing QA functions shall have sufficient authority and organization freedom to identify problems; to initiate, recommend, or provide solutions; to verify implementation of solutions; and to stop unsatisfactory work. ...The QAIM has the authority to resolve disputes involving quality."

DESCRIPTION OF FINDING

The audit team examined the LANL-NNWSI-QAPP and implementing Quality Assurance Procedures (QPs) to determine if this requirement was addressed. Table 1.1 in the LANL-NNWSI-QAPP identifies that the Quality Assurance Implementation Manager (QAIM) has the responsibility for "conflict resolution." There appears to be no further reference in the LANL-NNWSI-QAPP or the QPs that address how this requirement is to be implemented.

LANL CORRECTIVE ACTION TAKEN

1. Specific Deficiency Corrective Action

   The LANL QAPP has been extensively revised and reissued as Revision 2. This revision was reviewed and approved by WMPO on April 4, 1988. Section 1.0, "Organization," Table 1-1, Footnote e, clearly states that the Quality Assurance Project Leader (QAPL) will resolve quality-related conflicts. Footnote e, states the following:

   "The QAPL is responsible for resolving quality-related conflicts that have not been resolved at lower levels. Any person involved in the NNWSI Project may appeal a dispute over QA to the LANL TPO. The QAPL may elevate unresolved conflicts to the Project Quality Manager (PQM) at the WMPO. QA personnel can elevate unresolved conflicts through the QAPL to the Program Director of Nuclear Programs at LANL and to the PQM at WMPO."

   In the LANL procedure on Corrective Action, TWS-QAS-QP-21, R0, all NNWSI Project personnel have been identified as having the responsibility and authority to initiate a corrective action report. See QP-21, R0, Section 4.0.

   The mechanism by which all NNWSI personnel have the authority and responsibility to initiate a stopwork order is through an implementing procedure which is under development.

2. Root Cause Determination

   The root cause was failure to establish this requirement in the QAPP, R1, as the dispute resolution mechanism for quality-related matters, and to adequately train LANL staff members.

3. Steps to Prevent Recurrence

A training memorandum will be issued to all LANL NNWSI personnel August 26, 1988, to call their attention to QP-21, R0 which gives them the authority and responsibility to initiate CARs if they observe any activity adverse to quality.

Also, the QAPP training manual has been revised to include information on conflict resolution and initiation of CARs.

The stopwork implementing procedure will be issued September 30, 1988.

4. Schedule for Completion

The memorandum will be issued and the modification to the training guide will be completed by August 26, 1988.

The stopwork procedure will be included in the LANL Quality Assurance Manual by September 30, 1988.

Los Alamos NNWSI Project
CORRECTIVE ACTION REPORT

Initiator: Signature/Organization/Phone	CAR No: 025, Rev. 1
H. P. Nunes, N-5, X7-8039	Initiation Date: 26 August 1988
	QA Level: 1

Title of Work to which CAR Applies:

NRC Audit of LANL, June 8, 1987, Appendix B, Page B-3

Condition Requiring Corrective Action:

See attached, Page 1 of 2.

Corresponding Documentation: NRC Mini-Audit Report

Assigned To: J. J. George	Date: 26 August 1988

Cause and Recommended Corrective Action:

See attached response, Pages 1 and 2 of 2.

QAPL Concurrence: DOE ORDER 5000.3, UOR REQUIRED ☐ YES ☒ NO	Date:
Corrective Action Completed:	Date:
Implementation Verified By:	Date:
CAR Closeout:	Date:

RESPONSE TO CAR NO. 025, Rev. 1

REQUIREMENT

LANL-NNWSI-QAPP - Section 1.0 Organization, Subsection 1.1 LANL NNWSI Project:

"Personnel performing QA Level I and II activities shall be certified to show competence to perform their specific duties, e.g., design verification, document review, surveillance, etc. ...The documentation of certification shall identify the basis for certification. ...Certification shall be evaluated on an annual basis."

DESCRIPTION OF FINDING

The audit team examined the quality assurance (QA) files containing records of personnel certification associated with Scientific Investigation Plan (SIP) No. 86/4.2. The Los Alamos form used to record the various certification appears to be used to certify an individual to selected Quality and Detailed Procedures rather than certifying, for instance, the Quality Assurance Liaison (QAL) as having competence to perform specific duties or responsibilities as identified in Table 1.1. The audit team felt the certifications examined contain minimal information on the qualifications of the LANL staff supporting the SIP No. 86/4.2 and thus may not be adequate for licensing. Similarly, it was noted by the audit team that there were no specific qualifications identified for personnel performing the quality related function of Quality Assurance Implementation Manager (QAIM), Quality Assurance Support and the QAL.

LANL CORRECTIVE ACTION TAKEN

1. Specific Deficiency Corrective Action

   The LANL QAPP has been extensively revised and reissued as Revision 2. This revision was reviewed and approved by WMPO on April 4, 1988. Section 2.0, "Quality Assurance Program," has been revised to include personnel certification, evaluations, and orientation. Subsections 2.4.1 through 2.4.4 establish the overall LANL program requirements and the required documentation. Further, the administrative procedure, QP-02.1, has been issued, and the annual certification process of Project personnel has been completed. The results of this certification process are on file at the file center of the Quality Assurance Support.

2. Root Cause Determination

   Inadequate requirements and procedural direction were established in an effort to accomplish and document the appropriate evaluation and certification of NNWSI personnel.

3. Steps to Prevent Recurrence

   Additional training to the revised QAPP, R2, has been given to all NNWSI participants. A survey will be conducted to ascertain the effectiveness of the above training using the recertification results of 1988. Necessary changes to the training guide and QP-02.1 will be documented as a part of the survey.

4. Schedule for Completion

The survey and additional modifications to the QAPP, R2, training guide, noted in no. 3 above, will be completed on August 30, 1988.

Los Alamos NNWSI Project
CORRECTIVE ACTION REPORT

Initiator: Signature/Organization/Phone	CAR No: 026, Rev. 1
H. P. Nunes, N-5, X7-8039	Initiation Date: 26 August 1988
	QA Level: 1

Title of Work to which CAR Applies:

NRC Audit of LANL, June 8, 1987, Appendix B, Page B-4

Condition Requiring Corrective Action:

See attached, Page 1 of 2.

Corresponding Documentation: NRC Mini-Audit Report

Assigned To: J. J. George	Date: 26 August 1988

Cause and Recommended Corrective Action:

See attached response, Pages 1 and 2 of 2.

QAPL Concurrence: DOE ORDER 5000.3, UOR REQUIRED ☐ YES ☒ NO	Date:
Corrective Action Completed:	Date:
Implementation Verified By:	Date:
CAR Closeout:	Date:

RESPONSE TO CAR NO. 026, Rev. 1

REQUIREMENT

LANL-NNWSI-QAPP - Section 2.0 Quality Assurance Program Subsection 2.2 additional requirements for QA Level I Activities:

"All personnel performing quality-related activities shall have the training (including refresher training, as appropriate) to the extent necessary to perform this specific function. ...The need for training shall be evaluated and documented on an annual basis.,"

DESCRIPTION OF FINDING

The audit team examined the quality assurance (QA) training files for the personnel associated with Scientific Investigation Plan (SIP) No. 86/4.2, Mineralogy/petrology program for the Nevada Nuclear Waste Site Investigation (NNWSI). It was noted that the training records only included names of individuals who have had the QA orientation training. There was no record of a management determination of who needs or requires training or who may be performing quality-related activities. There was no record of an annual training evaluation activity. The training records covered three years.

LANL CORRECTIVE ACTION TAKEN

1. Specific Deficiency Corrective Action

   The LANL QAPP has been extensively revised and reissued as Revision 2. This revision was reviewed and approved by WMPO on April 4, 1988. Section 2.0, "Quality Assurance Program," has been revised to include requirements associated with personnel training. Subsection 2.4.1 through 2.4.4 establish the overall LANL program requirements and the required documentation. QP-02.1, R1, will be revised, see CAR No. 041, and it will include requirements for the review of each NNWSI person and the procedures which affect him/her. Additional training needs for all personnel will be evaluated and documented annually. The LANL-NNWSI-QAPP, R2, resulted in a complete staff retraining using a formal seminar-style training exercise. See QAPP, R2 training records in CAR No. 025.

2. Root Cause Determination

   Inadequate requirements and procedural direction were established in an effort to accomplish and document the appropriate evaluation and certification of NNWSI personnel.

3. Steps to Prevent Recurrence

   A specific administrative procedure will be prepared to address the WMPO training management plan directive, "Nevada Nuclear Waste Storage Investigations Project Training Management Plan," dated May 10, 1988. Once the procedure is completed, training will be conducted to ensure that all responsible managers and principal investigators are aware of the training management plan requirements and documentation.

An index matching NNWSI individuals and the procedures which affect each will be prepared. The QP-02.1 revision will be drafted and issued by November 30, 1988.

4. Schedule for Completion

The QP-02.1 revision will be issued by November 30, 1988, and the index will be prepared and placed in the files by September 30, 1988.

Los Alamos NNWSI Project
CORRECTIVE ACTION REPORT

Initiator: Signature/Organization/Phone	CAR No: 027, Rev. 1
H. P. Nunes, N-5, X7-8039	Initiation Date: 26 August 1988
	QA Level: 1

Title of Work to which CAR Applies:

NRC Audit of LANL, June 8, 1987, Appendix B, Page B-5

Condition Requiring Corrective Action:

See attached, Page 1 of 2.

Corresponding Documentation: NRC Mini-Audit Report

Assigned To: A. M. Pendergrass	Date: 26 August 1988

Cause and Recommended Corrective Action:

See attached response, Pages 1 and 2 of 2.

QAPL Concurrence: DOE ORDER 5000.3, UOR REQUIRED ☐ YES ☒ NO	Date:
Corrective Action Completed:	Date:
Implementation Verified By:	Date:
CAR Closeout:	Date:

RESPONSE TO CAR NO. 027, Rev. 1

REQUIREMENT

LANL-NNWSI-QAPP - Section 4.0 Procurement Document Control Subsection 4.2.2 Procurement Document Review:

"A review of the procurement documents and changes to those shall be made to ensure that documents transmitted to the prospective supplier(s) include appropriate provisions to ensure that items or services will meet the specified requirements. To review shall include, as a minimum, the cognizant technical organization and QAL.

The reviews by the QAL will assure that the following requirements are met:

- QA requirements are correctly stated
- there are adequate acceptance and rejection criteria, and
- procurements documents have been prepared, reviewed, and approved."

DESCRIPTION OF DEFICIENCY

The audit team examined the procurement quality assurance (QA) files at both the Earth and Space Sciences (ESS-1) Group and at the Los Alamos Technical Associates (LATA) office. The method used to record the review results and the subsequent requisition concurrence action by the Quality Assurance Liaison (QAL) is not identified to addressed in the procedure, QP-06 "NNWSI Procurement Procedures."

LANL CORRECTIVE ACTION TAKEN

1. Specific Deficiency Corrective Action

   To reflect the revised requirements of WMPO NVO-196-17, two administrative procedures, QP-04.1, and QP-04.3, were issued to specifically direct procurement activities for the Project. QP-04.1 is directed at the procurement of services and other than engineered items used extensively in research and development. QP-04.3 is directed at the procurement of engineered items through use of an approved vendors listing. These procedures direct the method used to document the review results and the concurrence by the QAL. In addition Change Requests (CRs) have been prepared to specifically address the requirements of QAPP, R2, 4.2.2 as stated above.

2. Root Cause Determination

   Previous procedures involving procurement failed to identify the necessary requirements for documentation.

3. Steps to Prevent Recurrence

   Training will be conducted for each of the above quality procedures to ensure that all NNWSI personnel associated with procurement are aware of Project requirements for documentation.

4. Schedule for Completion

CR 044, which modifies QP-04.1, and CR 045, which modifies QP-04.3, will be issued by August 26, 1988. Training to QP-04.1 has been completed as indicated. Training to QP-04.3, CR 044 and CR 045 will be completed by September 2, 1988.

Los Alamos NNWSI Project
CORRECTIVE ACTION REPORT

Initiator: Signature/Organization/Phone	CAR No: 028, Rev. 1
H. P. Nunes, N-5, X7-8039	Initiation Date: 26 August 1988
	QA Level: 1

Title of Work to which CAR Applies:

NRC Audit of LANL, June 8, 1987, Appendix B, Page B-6

Condition Requiring Corrective Action:

See attached, Page 1 of 1.

Corresponding Documentation: NRC Mini-Audit Report

Assigned To: H. P. Nunes	Date: 26 August 1988

Cause and Recommended Corrective Action:

See attached response, Page 1 of 1.

QAPL Concurrence: DOE ORDER 5000.3. UOR REQUIRED ☐ YES ☒ NO	Date:
Corrective Action Completed:	Date:
Implementation Verified By:	Date:
CAR Closeout:	Date:

RESPONSE TO CAR NO. 028, Rev. 1

REQUIREMENT

LANL-NNWSI-QAPP - Section 5.0 Instructions, Procedures, and Drawings, 5.2.3 Criteria:

"Instruction, Procedures, or drawings shall include appropriate quantitative or qualitative criteria for determining that important activities have been satisfactorily accomplished."

DESCRIPTION OF DEFICIENCY

During the review of the detailed Procedures (DPs), the technical audit team discovered that acceptance criteria are not included in most of the procedures. A few of the procedure (e.g., TWS-ESS-DP-04, R4. Thin section Preparation Procedure, TWS-ESS-DP-06, R2 Carbon Coating of Samples) do include specifications that can be considered to be acceptance criteria. Most of the other procedures, however, do not contain these criteria. Since no specific acceptance criteria are contained in the DPs, it is possible that the principal investigators can use different acceptance criteria when performing the same analysis. An example of this situation was found during the audit, where investigators analyzing zeolites with the electron microprobe use slightly different acceptance criteria during the examination of the same mineral phases. This does not appear to present a problem in this case, however, as it was learned that comparable results are produced using the different criteria. This may not always be the case, however, for all analytical.

LANL CORRECTIVE ACTION

1. Specific Deficiency Corrective Action

   A review of all detailed technical procedures will be made by each group to ascertain the appropriateness of the above stated deficiency. Accept/reject criteria will be included where appropriate to the LANL detailed technical procedures. A memorandum will be issued to each group directing that this review be performed and documented.

2. Root Cause Determination

   The root cause was determined as the inadequate procedural direction given for the preparation and documentation of the detailed technical procedures.

3. Steps to Prevent Recurrence

   A specific lesson plan will be created for DP-05.2, "Preparation of Detailed Technical Procedures," and training will be given to each affected group.

4. Schedule for Completion

   The memorandum directing all groups to review DPs to include accept/reject criteria where appropriate will be issued by August 26, 1988. The list of procedures to be revised is to be returned to the QAPL by September 9, 1988. QP-05.2 lesson plan will be completed August 26, 1988, and training in the use of this procedure will be complete September 30, 1988.

Los Alamos NNWSI Project
CORRECTIVE ACTION REPORT

Initiator: Signature/Organization/Phone H. P. Nunes, N-5, X7-8039	CAR No: 029, Rev. 1 Initiation Date: 26 August 1988 QA Level: 1

Title of Work to which CAR Applies:

NRC Audit of LANL, June 8, 1987, Appendix B, Page B-7

Condition Requiring Corrective Action:

See attached, Page 1 of 1.

Corresponding Documentation: NRC Mini-Audit Report

Assigned To: H. P. Nunes	Date: 26 August 1988

Cause and Recommended Corrective Action:

See attached response, Page 1 of 1.

QAPL Concurrence: DOE ORDER 5000.3, UOR REQUIRED ☐ YES ☒ NO	Date:
Corrective Action Completed:	Date:
Implementation Verified By:	Date:
CAR Closeout:	Date:

RESPONSE TO CAR NO. 029, Rev. 1

REQUIREMENT

LANL-NNWSI-QAPP - Section 5.0 Instructions, Procedures and Drawings

LANL Quality Procedure TWS-MSTQA-QP-14, R1, Research and Development (Experimental) Procedure, Section 3.1.1

"Laboratory notebook entries shall clearly delineate the following:

One time entries for each research and development activity or subset experiments....

- Equipment and materials to be used....

Daily entries--these entries are to be made daily or as important ideas, observations, date, etc., develop....

- Sample (core specimen, section or thin section) identification and history while in experimentor's possession."

DESCRIPTION OF DEFICIENCY

Laboratory notebook TWS-ESS1-12/84-7 was examined and compared to the requirements of QP-14. The audit team found that the requirement for the identification of equipment and materials to be used does not specify what information should be recorded. With respect to the requirement for recording the sample history, the auditors and principal investigators (PIs) did not fully understand the meaning of this requirement. The audit team recommends that QP-14 be revised to clarify these two items.

LANL CORRECTIVE ACTION

1. Specific Deficiency Corrective Action

   A Change Request (CR) 043, has been prepared to clarify the requirements regarding the documentation of equipment and materials used during the conduct of research activities.

2. Root Cause Determination

   The root cause was determined to be inadequate procedural direction given for identification of equipment.

3. Steps to Prevent Recurrence

   Change Request 043 have been prepared as indicated above. A training memo will be prepared and distributed to alert personnel to the exact requirements as indicated by CR 043.

4. Schedule for Completion

   CR 043 and the training memo will be issued August 26, 1988.

Los Alamos NNWSI Project
CORRECTIVE ACTION REPORT

Initiator: Signature/Organization/Phone	CAR No: 030, Rev. 1
H. P. Nunes, N-5, X7-8039	Initiation Date: 26 August 1988
	QA Level: 1

Title of Work to which CAR Applies:

NRC Audit of LANL, June 8, 1987, Appendix B, Page B-8

Condition Requiring Corrective Action:

See attached, Page 1 of 1.

Corresponding Documentation: NRC Mini-Audit Report

Assigned To: J. J. George	Date: 26 August 1988

Cause and Recommended Corrective Action:

See attached response, Page 1 of 1.

QAPL Concurrence: DOE ORDER 5000.3, UOR REQUIRED ☐ YES ☒ NO	Date:
Corrective Action Completed:	Date:
Implementation Verified By:	Date:
CAR Closeout:	Date:

RESPONSE TO CAR NO. 030, Rev. 1

REQUIREMENT

LANL-NNWSI-QAPP - Section 5.0 Instructions, Procedures and Drawings Subsection 5.1 Basic Requirements and 5.2.2 Instructions and Procedures

"If state-of-the-art test procedures, experiments, data acquisition and reduction, and interpretation of results are involved in site characterization studies, then the organization responsible for the activity shall conduct an independent technical review."

"Work ... shall be prescribed in clear, complete and documented instructions...."

DESCRIPTION OF DEFICIENCY

"State-of-the-art" and "independent" are not defined in the LANL-NNWSI-QAPP. The audit team examined numerous Quality Assurance Procedures (QPs) and Detailed (technical) Procedures (DPs). DP-101, "Sample Identification and Control for Mineralogy-Petrology Studies," was written by a supervisor but reviewed by a subordinate. DP-25, "Clay Mineral Separation and Preparation for X-ray Diffraction Analysis," was prepared by a principal investigator (PI) but reviewed by a technician. In both cases, the reviewer is a subordinate of the preparer and thus, would probably not be considered "independent." In addition, the audit team had no criteria by which to determine if these procedures are "state-of-the-art." Also, procedures for technical reviews of procedures have not yet been developed. Thus, the content of the review could be in question at a later time.

LANL CORRECTIVE ACTION

1. Specific Deficiency Corrective Action

   CR 051 is being prepared to modify QP-05.2, R0, and it will define the two terms "independent" and "state-of-the-art," and state the requirements for independent technical review. All technical procedures now in place as well as new procedures will be obliged to meet this requirement.

   LANL letter, TWS-N5/08-88-50, directing independent technical review for procedures reviewed by supervisors or subordinates has been issued.

2. Root Cause Determination

   The root cause was determined to be inadequate procedural direction on independent technical review.

3. Steps to Prevent Recurrence

   All personnel will be trained to the requirements in this procedure.

4. Schedule for Completion

   CR 051 will be prepared and issued by August 26, 1988. A directive memo has been issued to all NNWSI personnel, August 19, 1988, and all DPs will have technical reviews completed by February 28, 1989. Training to QP-05.2, including requirements to CR-051, will be completed by September 30, 1988.

Los Alamos NNWSI Project
CORRECTIVE ACTION REPORT

Initiator: Signature/Organization/Phone	CAR No: 033, Rev. 1
H. P. Nunes, N-5, X7-8039	Initiation Date: 26 August 1988
	QA Level: 1

Title of Work to which CAR Applies:

NRC Audit of LANL, June 8, 1987, Appendix B, Page B-11

Condition Requiring Corrective Action:

See attached, Page 1 of 1.

Corresponding Documentation: NRC Mini-Audit Report

Assigned To: A. M. Pendergrass	Date: 26 August 1988

Cause and Recommended Corrective Action:

See attached response, Page 1 of 1.

QAPL Concurrence: DOE ORDER 5000.3, UOR REQUIRED ☐ YES ☒ NO	Date:
Corrective Action Completed:	Date:
Implementation Verified By:	Date:
CAR Closeout:	Date:

RESPONSE TO CAR NO. 033, Rev. 1

REQUIREMENT

LANL-NNWSI-QAPP - Section 7.0 Control or Purchased Material, Equipment and Services Subsection 7.3.10 Annual Supplier Evaluation

"When required, annual supplier evaluations shall be documented and, if applicable, the following shall be considered:

- review of supplier furnished documents and records such as certificates of conformance, nonconformance reports, audits and receiving inspections..."

DESCRIPTION OF DEFICIENCY

The audit team examined the LANL-NNWSI-QAPP and the implementing Quality Assurance Procedures (QPs) to determine if this requirement was addressed and implemented. Apparently this requirement has not been addressed in the quality assurance (QA) procedural system to date.

LANL CORRECTIVE ACTION

1. Specific Deficiency Corrective Action

   A change request (CR) 047 has been prepared to modify TWS-QAS-QP-04.3 to require the QAPL or his delegate to re-evaluate the Approved Vendor's List to determine which suppliers should be re-evaluated. This information and the evaluations shall be documented.

2. Root Cause Determination

   The root cause was determined as the incomplete application of the NNWSI Project requirements.

3. Steps to Prevent Recurrence

   A review of purchase orders to date found no inappropriate purchase in place. Most items purchased by LANL are commercial-grade laboratory standards, analytical equipment, or laboratory services. To prevent inadvertent procurements from suppliers who are not on the approved vendors list for engineered items or services, specific training will be conducted for QP-04.3.

4. Schedule for Completion

   CR 047 will be issued August 26, 1988. Training will be completed by September 2, 1988.

Los Alamos NNWSI Project
CORRECTIVE ACTION REPORT

Initiator: Signature/Organization/Phone	CAR No: 034, Rev. 1
H. P. Nunes, N-5, X7-8039	Initiation Date: 26 August 1988
	QA Level: 1

Title of Work to which CAR Applies:

NRC Audit of LANL, June 8, 1987, Appendix B, Page B-12

Condition Requiring Corrective Action:

See attached, Page 1 of 1.

Corresponding Documentation: NRC Mini-Audit Report

Assigned To: H. P. Nunes	Date: 26 August 1988

Cause and Recommended Corrective Action:

See attached response, Page 1 of 1.

QAPL Concurrence: DOE ORDER 5000.3, UOR REQUIRED ☐ YES ☒ NO	Date:
Corrective Action Completed:	Date:
Implementation Verified By:	Date:
CAR Closeout:	Date:

RESPONSE TO CAR NO. 034, Rev. 1

REQUIREMENT

LANL-NNWSI-QAPP - Section 7.0 Control or Purchased Material, Equipment and Services Subsection 7.2.5, Control of Documents Generated by Suppliers

"Documentation generated by suppliers shall be controlled, handled, and approved in accordance with LANL implementation procedures."

DESCRIPTION OF DEFICIENCY

The audit team examined the implementing Quality Assurance Procedures (QPs) to determine if this requirement was addressed and implemented. Apparently this requirement has not been addressed in the quality assurance (QA) procedural system to date.

LANL CORRECTIVE ACTION

1. Specific Deficiency Corrective Action

   LANL has recently revised all of the procurement procedures. The revised QP-04.1, R0, specifically addresses the need to specify the form, content, and submission of reports, if required, in the procurement documentation. A change request (CR 046) has been issued to clarify the ways in which documents generated by a supplier are controlled as YMPO Project records. Review of Project resident files and notebooks has shown that supplier-generated documents are being controlled and there are no adverse impacts to the Project.

2. Root Cause Determination

   Change Request CR 046 has been issued to clarify control of documents generated by suppliers.

3. Steps to Prevent Recurrence

   CR 046, which addresses the documentation generated by suppliers, has been prepared. Training to this CR 046 will be held by September 2, 1988.

4. Schedule

   CR 046 will be issued by August 26, 1988. Training for this CR will be held by September 2, 1988.

Los Alamos NNWSI Project
CORRECTIVE ACTION REPORT

Initiator: Signature/Organization/Phone H. P. Nunes, N-5, X7-8039	CAR No: 035, Rev. 1 Initiation Date: 26 August 1988 QA Level: 1

Title of Work to which CAR Applies:

NRC Audit of LANL, June 8, 1987, Appendix B, Page B-13

Condition Requiring Corrective Action:

See attached, Page 1 of 1.

Corresponding Documentation: NRC Mini-Audit Report

Assigned To: H. P. Nunes	Date: 26 August 1988

Cause and Recommended Corrective Action:

See attached response, Page 1 of 1.

QAPL Concurrence: DOE ORDER 5000.3, UOR REQUIRED ☐ YES ☒ NO	Date:
Corrective Action Completed:	Date:
Implementation Verified By:	Date:
CAR Closeout:	Date:

RESPONSE TO CAR NO. 035

REQUIREMENT

LANL-NNWSI-QAPP - Section 7.0 Control or Purchased Material, Equipment and Services Subsection 7.2.4 Supplier Performance Evaluation

"The requests of items and services shall establish measures to interface with the supplier and to verify supplier's performance as deemed necessary by the requester."

LANL-NNWSI-QAPP - Section 5.0, Instructions, Procedures and Drawings Subsection 5.1 Basic Requirements

"Activities that affect quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances..."

DESCRIPTION OF DEFICIENCY

The audit team examined the implementing Quality Assurance Procedures (QPs) to determine if this requirement was addressed and implemented. Apparently this requirement has not been addressed in the quality assurance (QA) procedural system to date.

LANL CORRECTIVE ACTION

1. Specific Deficiency Corrective Action

   LANL has issued QP-04.1, R0, "NNWSI Procurement Procedures," in which Subsection 5.1 addresses preparation of procurement documents to include means by which supplier performance will be evaluated. Procurement documents will contain, as appropriate, right-of-access provisions allowing LANL personnel to conduct inspections, surveys, and audits of work in progress and documentation provisions specifying required information such as confidence limits on analysis. Subsection 5.1.2 addresses the need to include in procurement documents for items any requirement on hold-for-inspection points, procedures for verification of materials specification, and definitions of nonconformance and resolution.

   To evaluate the performance of service suppliers, LANL has issued QP-04.2, R0, "Acceptance of Procured Service Performance." Evaluation for acceptance is performed according to criteria stated in Subsection 5.1, including an independent technical verification of data generated, a survey and/or audit of the service activity, a review of objective evidence to determine conformance to the procurement document requirements, and the satisfactory implementation of any CAR.

2. Root Cause Determination

   Inadequate procedural details were contained in the original procurement procedure, QP-22.

3. Steps to Prevent Recurrence

   Procedures QP-04.1, R0, and QP-04.2, R0, were approved and issued on March 29, 1988, and June 27, 1988, respectively. Training to QP-04.1 has been held. Training to QP-04.2 will be completed by September 30, 1988. All procurements for items

were made for commercial-grade stock for which the evaluation of supplier performance is not required. Procurements for services have been reviewed and were found to contain evaluation criteria. By September 2, 1988, a memorandum stating that procurement documents were reviewed and that no adverse trends were noted will be issued to the NRC audit file.

4. Schedule

Training will be completed by September 30, 1988.

Los Alamos NNWSI Project
CORRECTIVE ACTION REPORT

Initiator: Signature/Organization/Phone H. P. Nunes, N-5, X7-8039	CAR No: 036, Rev. 1 Initiation Date: 26 August 1988 QA Level: 1

Title of Work to which CAR Applies:

NRC Audit of LANL, June 8, 1987, Appendix B, Page B-15

Condition Requiring Corrective Action:

See attached, Page 1 of 4.

Corresponding Documentation: NRC Mini-Audit Report

Assigned To: H. P. Nunes	Date: 26 August 1988

Cause and Recommended Corrective Action:

See attached response, Pages 1 and 2 of 4.

QAPL Concurrence: DOE ORDER 5000.3, UOR REQUIRED ☐ YES ☒ NO	Date:
Corrective Action Completed:	Date:
Implementation Verified By:	Date:
CAR Closeout:	Date:

RESPONSE TO CAR NO. 036

REQUIREMENTS

LANL-NNWSI-QAPP - Section 10.0 Inspection/Surveillance
Subsection 10.1 Basic Requirements

"Measures for the surveillance of site activities and contracted services shall be established and executed. . . . Surveillance shall be conducted based on the activity's relative impact and/or importance to the LANL NNWSI Project. . ."

LANL-NNWSI-QAPP - Section 18.0 Audits
Subsection 18.1 Basic Requirement

"A system of planned and periodic audits shall be made to verify compliance with all aspects of the LANL NNWSI Project QA program and to determine the effectiveness of the program. . . . The audit program shall be supplemented by random surveillances."

Subsection 18.2 Additional Requirements for QA Level I and II Activities

"Regularly scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage. . ."

DESCRIPTION OF DEFICIENCY

The audit team examined the Los Alamos audit and surveillance schedule for FY-87. There was only one audit scheduled and performed for the Earth and Space Sciences (ESS-1) Group program area. Based on a comparison of the significance and the number of problems identified in the LANL internal audit (Feb. 18-20, 1987), the Waste Management Project Office (WMPO) audit of LANL (April, 1987), and this audit by NRC, it appears the LANL audit/surveillance program is not adequate. The internal LANL audit did not cover all aspects (Sections of the QAPP) as required by Section 18.1.

It was noted that three surveillances were conducted within ESS-1 to date. These were, however, of minor coverage in the total scope of the LANL-NNWSI-QAPP requirements. In addition, none of the three surveillances performed were of a technical nature (i.e., no surveillances of in-process work or testing).

LANL CORRECTIVE ACTION

1. Specific Deficiency Corrective Action

   LANL is dedicated to the concept of conducting audits and surveys to ascertain program effectiveness. The LANL effort is continuously directed at this portion of the program to improve overall program effectiveness. Attached are copies of LANL FY 1988 audit and survey schedules. Each group is audited annually to all applicable requirements of the QAPP which includes all applicable requirements of the QAPP which includes all applicable critieria of 10 CFR 50, Appendix B. This is recorded in the formal audit report. Surveys are conducted for work or experiments in progress, and the Survey Log is also included here to indicate that many surveys and have been conducted in the past eight months.

   In addition the auditing procedure was revised to address some requirements that had been not adequately addressed in past implementing procedures, particularly

the documenting of the inclusion of all 18 criteria. Training was conducted to this draft on June 11, 1988. Training record is included. Due to time constraints, this procedure was not issued, but a CR 032 which addressed these issues was approved and issued June 17, 1988.

2. Root Cause Determination

   Currently approved audit and survey procedures were found to be inadequate for NNWSI Project needs.

3. Steps to Prevent Recurrence

   CR 032 has been issued and auditing personnel were trained to the requirements.

4. Schedule for Completion

   CR 032 has been completed and was issued on June 6, 1988.

Los Alamos NNWSI Project
CORRECTIVE ACTION REPORT

Initiator: Signature/Organization/Phone	CAR No: 037
H. P. Nunes, N-5, X7-8039	Initiation Date: 26 July 1988
	QA Level: 1

Title of Work to which CAR Applies:

NRC Audit of LANL, June 8, 1987, Appendix B, Page B-16

Condition Requiring Corrective Action:

See attached, Page 1 of 1.

Corresponding Documentation: NRC Mini-Audit Report

Assigned To: N/A	Date: N/A

Cause and Recommended Corrective Action:

See attached response, Page 1 of 1.

QAPL Concurrence: DOE ORDER 5000.3, UOR REQUIRED ☐ YES ☒ NO	Date:
Corrective Action Completed:	Date:
Implementation Verified By:	Date:
CAR Closeout:	Date:

RESPONSE TO CAR NO. 037

REQUIREMENT

LANL-NNWSI-QAPP - Section 10.0 Inspection/Surveillance

LANL Quality Procedure TWS-MSTQA-QP-11, RI, NNWSI Surveillance Procedure Section 5.3

"The QAIM shall review and sign all surveillance reports for completeness and adequacy of actions taken or recommended."

DESCRIPTION OF DEFICIENCY

Of the three surveillances conducted within the Earth and Space Sciences (ESS-1) Group this fiscal year, two completed surveillance reports were not reviewed and signed by the Quality Assurance Implementation Manager (QAIM) at the time of this audit.

LANL CORRECTIVE ACTION

1. Specific Deficiency Corrective Action

   The survey files have been reviewed, and all completed surveys are now signed by the QAPL. No adverse impacts were found as a result of the procedural noncompliance by the QAPL.

2. Root Cause Determination

   Root cause was determined as an isolated case of procedural noncompliance. No specific root cause can be identified.

3. Steps to Prevent Recurrence

   No steps are required.

4. Schedule for Completion

   Specific actions as stated above have been completed.

Los Alamos NNWSI Project
CORRECTIVE ACTION REPORT

Initiator: Signature/Organization/Phone H. P. Nunes, N-5, X7-8039	CAR No: 038, Rev. 1 Initiation Date: 26 August 1988 QA Level: 1

Title of Work to which CAR Applies:

NRC Audit of LANL, June 8, 1987, Appendix B, Page B-17

Condition Requiring Corrective Action:

See attached, Page 1 of 1.

Corresponding Documentation: NRC Mini-Audit Report

Assigned To: H. P. Nunes	Date: August 26, 1988

Cause and Recommended Corrective Action:

See attached response, Page 1 of 1.

QAPL Concurrence: DOE ORDER 5000.3, UOR REQUIRED ☐ YES ☒ NO	Date:
Corrective Action Completed:	Date:
Implementation Verified By:	Date:
CAR Closeout:	Date:

RESPONSE TO CAR NO. 038, Rev. 1

REQUIREMENTS

LANL-NNWSI-QAPP, Section 12.0 Control of Measuring and Test Equipment
Subsection 12.2 Selection

"Each device shall have a unique identification number."

DESCRIPTION OF DEFICIENCY

The NRC audit team examined the Megadigital Thermometer #4273 at Building TA-3 which includes three probes and a digital readout. The audit team found that one of the probes was labeled 4237 instead of 4273. The team recognizes that this inconsistency is an isolated case. However, in tracing the calibration records to MEC-8, the Metrology lab, the team found that although the folder was labeled 4273 it was misfiled under 4237.

LANL CORRECTIVE ACTION

1. Specific Deficiency Corrective Action

   The folder and probe identifications were corrected at the time of the audit. MEC-8 personnel review the identifications to ensure accuracy. No further instances of mislabeling were found by MEC-8.

2. Root Cause Determination

   The root cause was determined as an isolated case.

3. Steps to Prevent Recurrence

   This is always a part of continuing audits and surveys.

4. Schedule of Completion

   All actions have been completed.

Los Alamos NNWSI Project
CORRECTIVE ACTION REPORT

Initiator: Signature/Organization/Phone	CAR No: 039, Rev. 1
H. P. Nunes, N-5, X7-8039	Initiation Date: 26 August 1988
	QA Level: 1

Title of Work to which CAR Applies:

NRC Audit of LANL, June 8, 1987, Appendix B, Page B-18

Condition Requiring Corrective Action:

See attached, Page 1 of 1.

Corresponding Documentation: NRC Mini-Audit Report

Assigned To: P. M. Tillery	Date: 26 August 1988

Cause and Recommended Corrective Action:

See attached response, Page 1 of 1.

QAPL Concurrence: DOE ORDER 5000.3, UOR REQUIRED ☐ YES ☒ NO	Date:
Corrective Action Completed:	Date:
Implementation Verified By:	Date:
CAR Closeout:	Date:

RESPONSE TO CAR NO. 039, Rev. 1

REQUIREMENTS

LANL-NNWSI-QAPP - Section 12.0 Control of Measuring and Test Equipment.

LANL Quality Procedure TWS-MSTQA-QP-15, R0, Calibration Control
Section 6.3

"A calibration card (see Attachment 1) shall be sent to the QAS by the QAL when an instrument requiring calibration is brought into the system or after an instrument requiring periodic calibration has been calibrated."

DESCRIPTION OF DEFICIENCY

The calibration records for the XRD-LAB Weight Set in Building TA-3 were traced to the Los Alamos Technical Associates (LATA) file. LATA personnel examined the file in the presence of the NRC audit team and discovered that the card was not present. In addition, LATA personnel telephoned LANL personnel and discovered that the calibration procedure for the weights did not require a card to be sent to LATA. Thus, the specific calibration procedure is not in compliance with QP-15 requirements. The calibration information, however, is recorded in the lab notebook for these weights.

LANL CORRECTIVE ACTION

1. Specific Deficiency Corrective Action

   LANL has revised its M&TE procedure, TWS-QAS-QP-12.1, and the "card system" has been eliminated. There is now a calibration form for every piece of calibrated equipment on file in the QAS resident file. The new procedure requires an issuance of a monthly reminder of items to be calibrated during the month, and this system helps to ensure calibration, corresponding activities, and documentation.

2. Root Cause Determination

   Root cause was determined as a failure to properly train Project staff members in the full implementation of M&TE Project requirements.

3. Steps to Prevent Recurrence

   Appropriate LANL NNWSI staff members will be trained to the revised M&TE procedure, QP-12.1.

4. Schedule of Completion

   The training memo will be issued by August 26, 1988.

Los Alamos NNWSI Project
CORRECTIVE ACTION REPORT

Initiator: Signature/Organization/Phone	CAR No: 040, Rev. 1
H. P. Nunes, N-5, X7-8039	Initiation Date: 26 August 1988
	QA Level: 1

Title of Work to which CAR Applies:

NRC Audit of LANL, June 8, 1987, Appendix B, Page B-19

Condition Requiring Corrective Action:

See attached, Page 1 of 1.

Corresponding Documentation: NRC Mini-Audit Report

Assigned To: M. F. McGowan	Date: 26 August 1988

Cause and Recommended Corrective Action:

See attached response, Page 1 of 1.

QAPL Concurrence: DOE ORDER 5000.3, UOR REQUIRED ☐ YES ☒ NO	Date:
Corrective Action Completed:	Date:
Implementation Verified By:	Date:
CAR Closeout:	Date:

RESPONSE TO CAR NO. 040, Rev. 1

REQUIREMENTS

LANL-NNWSI-QAPP - Section 13.0 Handling, Shipping, and Storage.

LANL Quality Procedure TWS-MSTQA-QP-04, R2, Handling, Storage, and Shipping Procedure, Sections 6.1 and 8.0.

"Periodic inspections shall be performed to assure that storage areas are being maintained in accordance with specified storage requirements."

"Approved procedures, reports, personnel qualifications, test equipment calibration records, test deviation or exception records, and inspection and examination records shall be prepared and maintained in accordance with the NNWSI Records Control Procedure (TWS-MSTQA-QP-09)."

DESCRIPTION OF DEFICIENCY

QP-04, Sections 6.1 and 8.0, requires periodic inspections of storage areas and that records will be maintained according to QP-09, "Records Control Procedure." Through interviews with one of the principal investigators, the NRC audit team determined that informal inspections of the sample storage room are conducted frequently but these inspections are not documented.

LANL CORRECTIVE ACTION

1. Specific Deficiency Corrective Action

   TWS-QAS-QP-13.1, Handling, Storage, and Shipping Procedure has been approved and issued April 5, 1988. This QP-13.1 address the NRC concern for sample storage requirements by directing that all appropriate DPs address the storage requirements as specified by QP-13.1. CR 048 is being prepared to require documentation and immediate corrective action to these DPs as necessary to bring the DPs into compliance.

2. Root Cause Determination

   Personnel were not trained to properly implement the requirements of QP-04, R2, as stated in the NRC deficiency description.

3. Steps to Prevent Recurrence

   CR 048 is being prepared, and it will address the issue of bringing DPs into compliance with the requirements of QP-13.1. A training memo will be issued to alert PIs to the necessity for an immediate review of DPs for compliance.

4. Schedule of Completion

   CR 048 to QP 13.1 will be issued August 26, 1988. A training memo will be issued September 26, 1988 to alert PIs to their responsibilities for review of the DPs. Review of DPs will be completed November 30, 1988.

Enclosure B.1.a

TABLE 1-1

DIVISION OF LANL NNWSI QUALITY ASSURANCE RESPONSIBILITIES[a]
(concluded)

Function[b]	QAPL	QAS	QAL
Maintenance of documents before transfer to the LANL Records Processing Center (RPC)	X	X	X
Internal Survey and Audits (Coordination with PIs and QALs)		X	

a. Individuals supervising or performing QA functions are the QAPL, QAS, and QAL--all from participating organizations. The QAPL will play a major role in all QA functions for the LANL NNWSI Project.

b. The QAPL reports to the TPO; the QAS reports to the QAPL; and the QAL reports to the QAPL or to the line supervisor.

c. The QAL coordinates all reviews and approvals.

d. The QAPL compiles the responses to external audits and surveys with substantial input from the QAS and QAL.

e. The QAPL is responsible for resolving quality-related conflicts that have not been resolved at lower levels. Any person involved in the NNWSI Project may appeal a dispute over QA to the LANL TPO. The QAPL may elevate unresolved conflicts to the Project Quality Manager (PQM) at the WMPO. QA personnel can elevate unresolved conflicts through the QAPL to the Program Director of Nuclear Programs at LANL and the PQM at WMPO.

ENCLOSURE 3

Enclosure B.1.b

CORRECTIVE ACTION

Effective Date ~~JANUARY~~ 5, 1987

H P Nunes — 12/30/86

QA Support
H. P. Nunes, QAS

Paul R. Guthals — 12/30/86

QA Implementation Manager
P. R. Guthals, WM

R. T. Hurst Jr. — 12/31/86

Technical Project Officer
D. T. Oakley, WM

Date

CORRECTIVE ACTION

1.0 Purpose

The purpose of this procedure is to assure that Significant Conditions Adverse to Quality are promptly identified and corrected.

2.0 Scope

The provisions of this procedure are applicable to all Los Alamos NNWSI Project quality assurance Level I and II items or activities.

3.0 Responsibilities

3.1 The Quality Assurance Support person (QAS) shall review all Nonconformance Reports, Audit Reports, and Unusual Occurrence Reports and identify Significant Conditions Adverse to Quality. The QAS shall determine the need for, method of, and persons responsible for, determination of cause and recommended corrective action(s).

The QAS shall maintain a log of Corrective Action Reports initiated, including status.

3.2 When requested by the QAS, the cognizant Project Leader shall determine cause and shall recommend appropriate corrective action.

3.3 The QAL shall concur with any cause determination or corrective action recommended by the Project Leader.

The cognizant Quality Assurance Line person (QAL) shall report any condition identified during surveillance, inspection, or observation that require corrective action to the QAS.

3.4 The QAIM shall distribute copies of Corrective Action Reports to Los Alamos NNWSI management. Copies of Corrective Action Reports for QA Level I and II activities shall be sent to WMPO and the QASC. The QAIM shall determine appropriate distribution.

3.5 Any Los Alamos NNWSI Project person shall initiate a Corrective Action Report whenever Significant Conditions Adverse to Quality are identified.

4.0 Procedure

Any Los Alamos NNWSI Project person has authority and responsibility to initiate a Corrective Action Report whenever situations are identified which have a potential for reducing confidence that required quality is achieved and/or maintained. These situations or conditions are considered Significant Conditions Adverse to Quality as defined in Section 6.0 below.

Initiation, processing, completion, and internal distribution of CARs shall be accomplished in accordance with the instructions on the back of the Corrective Action Report form (see Attachment 2 to this procedure).

It is not intended that a Corrective Action Report be issued as a companion to each Nonconformance Report.

5.0 Records

Copies of completed CARs and CAR Logs shall be maintained by the QAS.

Completed records shall be forwarded by the QAS to the Los Alamos Records Center Manager for submission to the NNWSI Project Records Center.

6.0 Definitions

CONDITIONS ADVERSE TO QUALITY - Failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances.

CORRECTIVE ACTIONS - Measures taken to rectify significant conditions that are adverse to quality and, to preclude repetition.

SIGNIFICANT CONDITIONS ADVERSE TO QUALITY - Situations with potential for reducing confidence that required quality is achieved and/or maintained. These situations or conditions may exist when:

- Deficiencies are found in Quality Assurance Programs and/or their implementation, including flagrant violations of codes, standards, or specifications;

SIGNIFICANT CONDITIONS ADVERSE TO QUALITY (Continued)

- Quality related problems occur which are similar or repetitive;
- A particular quality related problem may apply to more items or activities than those specifically identified on a Nonconformance Report, Audit Report, or Unusual Occurrence Report; or
- Problems are identified at other locations or on other projects which may be applicable to Los Alamos NNWSI Project activities.

NONCONFORMANCE - A deficiency in characteristics, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

Los Alamos NNWSI Project
CORRECTIVE ACTION REPORT

Initiator: Name/Organization/Phone	CAR No: Initiation Date:
Condition Requiring Corrective Action:	
Corresponding Documentation:	
Assigned To:	Date:
Cause and Recommended Corrective Action:	
QAIM Concurrence:	Date:
Implementation Verified By:	Date:
CAR Closeout:	Date:

LOS ALAMOS NNWSI PROJECT

INSTRUCTIONS FOR PROCESSING CORRECTIVE ACTION REPORTS

1. The Originator of a Corrective Action Report (CAR) must complete the Initiator, Initiation Date, and Condition Requiring Corrective Action blocks of the CAR. The Condition Requiring Corrective Action should be described in adequate detail to allow independent investigation and verification of the condition.

2. If the Originator is a Los Alamos NNWSI Project person other than the QAL or QAS, the Originator should have the QAL initial and date the Condition Requiring Corrective Action to indicate the QAL's concurrence. The Originator or the QAL shall then forward the CAR to the QAS.

3. If the QAS determines that Corrective Action is required, the QAS shall assign a CAR Number, identify any Corresponding Documentation, and assign responsibility for Recommended Corrective Action. If the QAS determines that Corrective Action is not required, the QAS shall return the CAR form to the Originator with an explanation.

4. The Cause shall be identified and Recommended Corrective Action shall be described in adequate detail to ensure complete implementation and allow independent verification of implementation. The person responsible for implementation and required completion date shall be identified.

5. The QAIM shall concur with the Recommended Corrective Action prior to implementation.

6. The cognizant QAL, or other person selected by the QAIM, shall verify adequate implementation of the Corrective Action.

7. The completed CAR shall be forwarded to the QAS for review and closeout.

Enclosure B.1.c

Los Alamos
Los Alamos National Laboratory
Los Alamos, New Mexico 87545

memorandum

TO: Distribution

DATE: August 19, 1988

FROM: H. P. Nunes, QAPL

MAIL STOP/TELEPHONE: J521/7-8039

SYMBOL: TWS-N5/08-88-51

SUBJECT: TRAINING—INITIATING CORRECTIVE ACTION REPORT

Enclosed for your signature is a training receipt acknowledgment form. Please return the signed form within 10 working days of receipt of this memo.

If you have any questions, please call me at 667-8039 or Jim George at LATA, 662-1753.

JJG/meg

Attachment: a/s

Distribution:

P. L. Aamodt, ESS-1, MS D462
M. J. Aldrich, ESS-1, MS D462
W. S. Baldridge, ESS-1, MS D462
J. A. Barber, ESS-1, MS D462
D. W. Barr, INC-DO, MS J515
S. Barr, ESS-5, MS F665
R. J. Beckman, A-1, MS F600
K. Birdsell, ESS-5, MS F665
S. Birdsell, ESS-4, MS J981
D. L. Bish, ESS-1, MS D462
S. Bolivar, ESS-1, MS D462
D. E. Broxton, ESS-1, MS D462
E. A. Bryant, INC-7, MS J514
E. J. Bustos, MAT-11, MS P274
F. Byers, ESS-1, MS D462
(Distribution continued on reverse side)

Training Receipt Acknowledgment
August 19, 1988

Return To: K. L. Foster
Los Alamos National Laboratory
LATA QAS, MS-M321
Los Alamos, NM 87545

Name: _____
(Please Print)

SUBJECT: INITIATING CORRECTIVE ACTION REPORTS

All NNWSI Project personnel have the authority to initiate a corrective action report concerning existing conditions that have the potential for reducing confidence in quality. (Please refer to TWS-QAS-QP-21, R0, Corrective Action Procedure).

I have read and understand who has the authority to initiate corrective action reports.

_____ _____
Signature Date

Enclosure B.1.d

4c

Los Alamos

Los Alamos National Laboratory
Los Alamos, New Mexico 87545

memorandum

TO: Distribution

DATE: August 18, 1988

FROM: H. P. Nunes, QAPL

MAIL STOP/TELEPHONE: J521/7-8039

SYMBOL: TWS-N5/08-88-41

SUBJECT: QUALITY CONFLICT RESOLUTION

Please sign the enclosed receipt acknowledgement form stating that you understand how to implement the project quality conflicts resolution requirement. Training of this type, will be a feature of the NNWSI overall training effort and is in keeping with the NNWSI/88-9 QA Plan.

If, for any reason, you are dissatisfied with any QA decision, I can be contacted to attempt to resolve the matter. Any needed documentation will be issued by this office.

If you have any questions, please call me at 7-8039.

JJG/ldc

Enclosure: a/s

Distribution:
P. L. Aamodt, ESS-1, MS D462
M. J. Aldrich, ESS-1, MS D462
W. S. Baldridge, ESS-1, MS D462
J. A. Barber, ESS-1, MS D462
D. W. Barr, INC-DO, MS J515
S. Barr, ESS-5, MS F665
R. J. Beckman, A-1, MS F600
K. Birdsell, ESS-5, MS F665
S. Birdsell, ESS-4, MS J981
D. L. Bish, ESS-1, MS D462
S. Bolivar, ESS-1, MS D462
D. E. Broxton, ESS-1, MS D462
E. A. Bryant, INC-7, MS J514
E. J. Bustos, MAT-11, MS P274
F. Byers, ESS-1, MS D462
(Distribution continued on reverse side)

Training Receipt Acknowledgement
August 18, 1988

Return To: K. L. Foster
Los Alamos National Laboratory
LATA QAS, MS-M321
Los Alamos, NM 87545

Name: _____
(Please Print)

SUBJECT: QUALITY CONFLICT RESOLUTIONS

Footnote E of Table 1-1 in Section 1 of the LANL-NNWSI-QAPP, R2, states:

The QAPL is responsible for resolving all quality-related conflicts that have not been resolved at lower levels. Any person involved in the NNWSI Project may appeal a dispute over QA to the LANL TPO. The QAPL may elevate unresolved conflicts to the Project Quality Manager (PQM) at WMPO. QA personnel can elevate unresolved conflicts through the QAPL to the Program Director of Nuclear Programs at LANL and the PQM at WMPO. The QAPL also reviews and approves the WMPO PQM's comments on the QAPP and QPs.

I have read and understand the above on the resolution of quality conflicts.

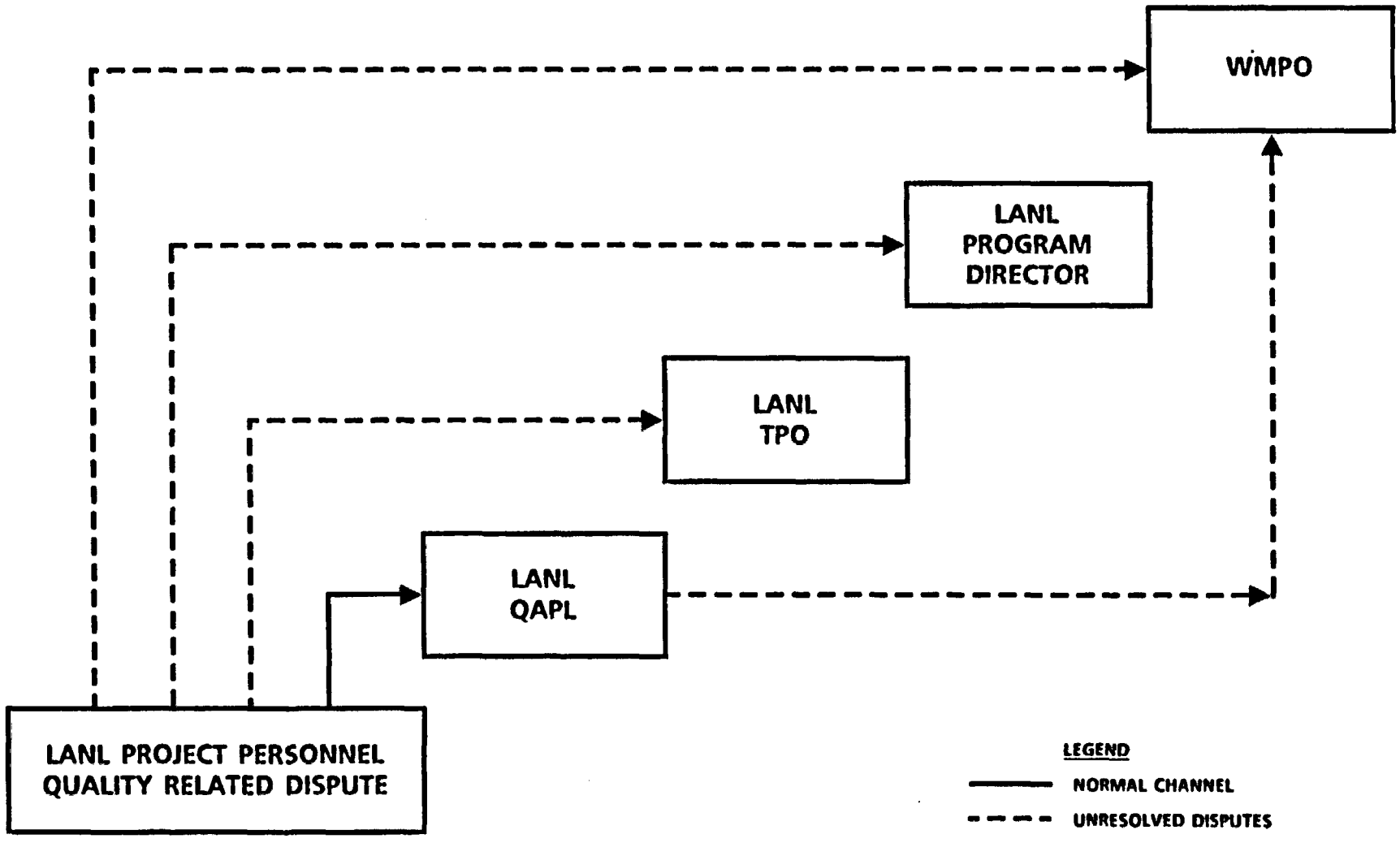
_____ _____
Signature Date

REQUIREMENT 1.0
(CONTINUED)

CONFLICT RESOLUTION

- THE QAPL SHALL RESOLVE LOWER LEVEL QUALITY RELATED CONFLICTS
- NNWSI PROJECT PERSONNEL MAY APPEAL A DISPUTE OVER QA TO THE TPO
- THE QAPL MAY ELEVATE CONFLICTS TO THE PQM AT WMPO
- QA PERSONNEL CAN EVALUATE CONFLICTS THROUGH THE QAPL TO THE PROGRAM DIRECTOR OF NUCLEAR PROGRAMS AT LANL, AND TO THE PQM AT WMPO

Enclosure 1...



Los Alamos

August 18, 1988 3:46 PM
02 TRG/VGS/MISC LS06503 (G01)

REQUIREMENT 16.0
(CONTINUED)

CORRECTIVE ACTIONS

Q: WHO MAY FORMALLY IDENTIFY A CONDITION "ADVERSE TO QUALITY" ON THE NNWSI PROJECT?

A: ANY NNWSI PROJECT PERSON HAS THE AUTHORITY AND RESPONSIBILITY TO INITIATE A CORRECTIVE ACTION REPORT (CAR) WHEN A CONDITION EXISTS WHICH HAS A POTENTIAL FOR REDUCING CONFIDENCE IN QUALITY

Enclosure B.2.a

2.0 QUALITY ASSURANCE PROGRAM

2.1 Basic Requirements of the Los Alamos National Laboratory Nevada Nuclear Waste Storage Investigations Quality Assurance Program

LANL's QA program is based on the contents of the LANL QAPP, which is approved by WMPO, and the LANL implementing procedures. The implementing procedures provide and implement control over activities affecting quality. The QAPP and implementing procedures will be applied in a way that is consistent with the importance of the activity. This QAPP applies to all items and activities important to repository licensing, safety, and waste isolation.

This QAPP complies with the requirements of WMPO NNWSI-NVO-196-17, Nevada Nuclear Waste Storage Investigations Project Quality Assurance Plan (QAP). The LANL NNWSI Project and subtier activities are carried out in accordance with this QAPP and LANL implementing procedures. Both WMPO and TPO signoffs of this QAPP are required before its implementation.

This QAPP applies to all LANL activities associated with the NNWSI Project, including nuclide migration studies; geochemistry; mineralogy; petrology studies; and Exploratory Shaft (ES) planning and design review for ES construction, technical direction, and the ES testing program. LANL also provides assistance in accordance with this QAPP to other project organizations in areas of specialized expertise as directed by Waste Management Project Office (WMPO).

The activities covered by this QAPP are delineated in the LANL NNWSI Project Work Breakdown Structure (WBS), which is maintained at the TPO's office. The LANL QAPP includes the following basic provisions for activities affecting quality.

- Activities affecting quality are planned and documented to ensure a systematic approach. Planning results in the documented identification of methods and organizational responsibilities. Planning is begun as early as practicable and is completed no later than the start of those activities.

- Activities affecting quality are accomplished under controlled conditions, which include the use of appropriate equipment, the maintenance of environmental conditions suitable for accomplishing the activity, the use of formal procedures for the given activity, and the ensurance that all prerequisites for the given activity have been satisfied.

- Procedures for activities affecting quality will specify any special controls, processes, test equipment, tools, and technical skills necessary to achieve the required quality for that activity.

- Procedures for activities affecting quality will specify the means to verify quality by inspection, test, peer reviews (WMPO directed), technical review, or a combination of these.

- All LANL NNWSI Project personnel performing activities affecting quality will be trained in both technical and QA requirements of their assigned task; QA auditors are trained and qualified in accordance with NNWSI Project requirements. Project personnel will be certified, and the certification will be documented.

- LANL NNWSI Project management will assess the adequacy and implementation of this QAPP regularly and will formally report the results on an annual basis.

- LANL participants are responsible for interfaces with other NNWSI major participants as specified in the Work Breakdown Structure (WBS). These responsibilities are outlined in Section 1 (LANL NNWSI QAPP).

2.1.1 Verification of the Quality Assurance Program Plan

The QAPL or his appointee will conduct internal audits of all phases of the application of this QAPP for all LANL NNWSI activities affecting quality. These internal audits will assess the continuing implementation, effectiveness, compliance, and adequacy of the QA program.

2.1.2 Use of Data Not Generated Under Quality Assurance Controls

For use in licensing activities, the QA program for the LANL NNWSI Project provides primary data or primary data interpretations that were not generated under the NNWSI Project QA controls. Specific methods for acceptance of this information are in WMPO NNWSI APs. These methods apply to the following types of data:

- primary data or primary data interpretations and reports that were generated by LANL or LANL's subcontractors for the NNWSI Project before August 1980 (QAP, Rev 0);

- primary data from reports, books, and theses generated by non-NNWSI Project participants; and

- primary data or data interpretations from a technical journal.

2.1.3 Q-List

The Q-List is a list of geologic repository structures, systems, components, and activities that have been determined to be important to safety or waste isolation, or both, and are thereby subject to the highest QA level (QA Level I) of the NNWSI QA program.

At this time, LANL does not have prime responsibility for any Q-List items. If LANL becomes responsible for such items, a procedure will be generated to define the determination and documentation of such items.

2.1.4 Approach to Quality Assurance

The NNWSI Project uses an approach to QA, known as the graded approach, that recognizes the differences between items and activities that affect radiological health and safety and those that do not. The graded approach is designed to ensure that each item or activity is assigned a QA level consistent with its potential impact on, or importance to, radiological health and safety, waste isolation, nonradiological health and safety, achievement of DOE mission objectives, NRC licensing process, and operability and maintainability of the repository, including its costs and schedules. LANL or WMPO will identify QA levels for all items and activities affecting quality that are associated with site characterization, facility and equipment construction, facility operations, performance confirmation, permanent closure, and decontamination and dismantling of

surface facilities. QA levels assigned by LANL are subject to WMPO approval before work begins on the item or activity.

2.2 Application of Graded Quality Assurance

2.2.1 Extent of Application

Graded QA applies throughout the life of the NNWSI Project in accordance with the established policies, procedures, and instructions and controls activities affecting quality of the identified structures, systems, and components to an extent consistent with their importance. The QAPP applies to all items and activities affecting quality during site characterization of the geologic repository, facility and equipment design, procurement and construction, facility operation, performance confirmation, closure, decommissioning, and dismantling of surface facilities.

It may be necessary to exempt certain NNWSI items and activities from QALAs. Requests for exemptions must be documented and contain sufficient justification to support the exemption request. Such exemptions are subject to approval by the QAPL, TPO, and the WMPO PQM.

2.2.2 Method of Application

Graded QA in the LANL NNWSI Project is applied according to a LANL implementing procedure, which defines the responsibility, method, and criteria for assigning and documenting QA levels to the LANL activities and items involved in the NNWSI Project. This procedure ensures that

- all NNWSI activities and items affecting quality are evaluated for QALA;
- QA levels are assigned in a manner consistent with the WMPO APs and the NNWSI Project QAP;
- the justification for the QALA is documented; and
- once a QALA has been made, it will be applied equally to the particular item or activity associated with the QALA by any participant involved therein.

The LANL QAPP applies to QA Levels I and II. Good engineering and scientific practices apply to QA Level III unless other requirements are specified. Definitions for each level are contained in Appendix A. Deviations within applicable criteria are permissible for QA Level II items and activities, provided that adequate justification is documented and approved by WMPO.

QA Level I is the most stringent level and will be applied to those items and activities that may affect the ability of the repository to meet the preclosure and postclosure performance objectives specified by the NRC and the EPA. QA Level I control and documentation is applied to all activities (i.e., those activities involving near-term safety and long-term isolation) specifically concerned with the protection of the public's health and safety with respect to radiological hazards. Therefore, QA Level I will be applied to

- items or activities that affect preclosure radiological health and safety of the general public;
- items or activities that provide site-characterization data;

- items or activities that affect the retrievability of waste up to the time of repository closure;
- items or activities that provide the primary data used to support public radiological health and safety issues for a license application; and
- items or activities whose failure would cause the failure of a QA Level I item, irretrievable loss of a QA Level I item, or irretrievable loss of QA Level I data.

Items and activities important to safety are those engineered structures, systems, components, and related activities essential to the prevention or mitigation of an accident that could result in a radiation dose either to the whole body or to any organ of 0.5 rem or greater either at or beyond the nearest boundary of the unrestricted area at any time until the completion of the permanent closure of the repository.

QA Level II is the second most stringent level and will be applied to those items and activities specifically concerned with the nonradiological operation of the exploratory shaft facility and repository and the radiological safety of the repository worker. Therefore, QA Level II will be applied to items and activities that could have a major impact on the nonradiological health and safety of the public and repository worker and items and activities whose failure would cause repository workers to be exposed to radiation or radioactive contamination levels in excess of the limits expressed in 10 CFR 20. Additionally, activities that have a major impact on Project costs or schedules, which delay the achievement of DOE/Office of Geologic Repositories (OGR) milestones, will be controlled as QA Level II.

2.3 Management Assessment

Management assessments are conducted at least annually to verify that the QA program is being effectively implemented; that the system and management control, which are established to achieve and ensure quality, are effective; that the resources and personnel provided to the QA program are adequate; and that personnel are trained to the QA requirements of the program. These assessments are performed and reported in accordance with WMPO directives, which include the minimum requirements for planning, organizing, performing, and documenting the results.

The assessment procedure will specify that results be analyzed for quality trends and that reports and recommendations be tracked. Copies of the LANL management assessment report will be transmitted to the WMPO Project Manager and WMPO PQM.

2.4 Personnel Orientation and Training Procedures

LANL has established requirements for the orientation and training of personnel performing or verifying activities that affect quality. Position descriptions will establish minimum personnel qualifications and the necessary orientation or training or both before a person starts work on activities that affect quality. In addition, personnel performing activities that specifically require certification by applicable codes and standards (e.g., lead auditors, inspectors, testers, and nondestructive examiners) will be certified in accordance with those codes and standards.

2.4.1 Position Description and Personnel Qualification Evaluation

For the NNWSI Project, a LANL implementing procedure requires job descriptions that specify relevant education and experience. The minimum requirements for formal education and experience are established and documented in NNWSI position descriptions for personnel performing and verifying activities that affect quality. NNWSI personnel shall have skills commensurate with NNWSI position descriptions. The education, experience, and training of personnel will be verified. The NNWSI personnel qualification evaluation will be performed by managers or supervisors responsible for the activities performed.

2.4.2 Orientation

Personnel assigned to perform activities affecting quality will first be oriented to the purpose, scope, methods of implementation, and applicability of the following documents as they relate to the work to be accomplished:

- QAPPs,
- implementing procedures and work instructions (applicable to the individual's responsibilities),
- regulations, and
- Project-level documents.

Orientation may be effected through the use of a mandatory reading list, classroom presentations, video presentation, or other instructional methods.

2.4.3 Training

Before being assigned complex activities affecting quality (i.e., assignments where it is deemed necessary to develop and demonstrate initial proficiency), personnel will undergo training to gain the required proficiency. This training will encompass the principles, techniques, and requirements of the activity. Such instruction may include classroom sessions, workshops, on-the-job training, or other instructional methods.

2.4.4 Records

NNWSI personnel files shall contain the orientation and training records, position descriptions, annual certification forms, initial qualification evaluations for work on the LANL NNWSI program, and supervisors' documentation of the annual NNWSI proficiency evaluations. These documents are to be retained as QA records.

Training or orientation records, which include the object and content of the training or orientation, dates of training or orientation, the name of the instructor, attendees, results of any NNWSI proficiency evaluations, the initial evaluation, and any other applicable information, are maintained as lifetime QA records. The evaluation documents for the proficiency of NNWSI personnel will include the name of the employee, the name of the evaluator, evaluation results, date, and activities covered by the evaluation.

The evaluation documents for the qualification of NNWSI personnel will include the verification and evaluation of employee education, experience, and training as compared to those required for the position.

Enclosure B.2.b

NNWSI PERSONNEL SELECTION, TRAINING, AND CERTIFICATION

EFFECTIVE DATE: March 29, 1988

Patricia M. Tillery
Patricia M. Tillery
QA Support

March 16, 1988
Date

Karen A. West
Karen A. West
Acting QA Project Leader

March 25, 1988
Date

D. T. Oakley
D. T. Oakley
Technical Project Officer

3/29/88
Date

1.0 PURPOSE

The purpose of this procedure is to establish and document the requirements used for the selection, orientation, and training of NNWSI Project personnel.

2.0 SCOPE

This procedure shall apply to all personnel performing NNWSI Project activities that affect quality. The procedure establishes the documentation requirements for position descriptions, job assignments, personnel selection, and annual evaluations. It also establishes the requirements and documentation for certification and training, including training that becomes necessary during the year. These requirements shall be established for all NNWSI Project personnel. Personnel selected for these positions shall have education and experience commensurate with the minimum requirements specified for a given job assignment. Personnel shall be given a Project orientation before they start work on NNWSI activities. Inexperienced or otherwise unqualified personnel shall also be trained before they begin technical activities.

3.0 DEFINITIONS

3.1 Orientation

As used in this procedure, orientation refers to a brief overview of the NNWSI Project, including Project objectives, and an introduction to the licensing application process and the Project's incumbent Quality Assurance (QA) program.

3.2 Training

As used in this procedure, training refers to any special technical or QA training commensurate with the complexity of the activity and/or responsibilities.

4.0 RESPONSIBILITIES

4.1 Principal Investigator

Principal Investigators (PIs) shall define and document job assignments for each position and each job activity for which they are responsible.

4.2 Supervisor

Supervisors of NNWSI personnel shall be responsible for determining and documenting that the personnel selected have education and experience commensurate with the minimum requirements specified in the position description; ensuring that personnel who perform activities have received adequate technical training; and conducting proficiency evaluations and documenting these evaluations annually.

4.3 Quality Assurance Project Leader

The Quality Assurance Project Leader (QAPL) shall ensure that LANL NNWSI Project personnel who perform quality-related activities have been trained in the scope, purpose, and technical objectives of their QA activities. The QAPL, with the help of the QAS, shall also provide position descriptions of all categories to each QAL for resident files.

4.4 Quality Assurance Liaison

Quality Assurance Liaisons (QALs) shall conduct training to the Quality Procedures (QPs) for the groups to which they are assigned. The QALs also help prepare and update the NNWSI Certification and Training Form (Attachment 2), which replaces the TWS-MSTQA-QP-08, R3, NNWSI Personnel Certification Form.

4.5 Quality Assurance Support

The Quality Assurance Support (QAS) person shall provide training as required by the QAPL. The QAS shall also maintain training and certification files.

4.6 NNWSI Employee

The NNWSI employee shall be responsible for performing the work activities according to the appropriate detailed technical procedures (DPs) and QPs; providing correct information on the NNWSI Resume Form (Attachment 1) and keeping that information up to date; and signing the Certification and Training Form to acknowledge training.

5.0 PROCEDURE

Requirements for NNWSI employees, PIs, supervisors, QALs, and the QAPL are delineated in the following subsections and are summarized on the Requirements Chart (Attachment 4).

5.1 NNWSI Employee Requirements

The NNWSI employee shall provide correct information on the NNWSI Resume Form or any resume format that provides the necessary information and shall keep the resume up to date, as necessary. Also, the employee annually signs the Certification and Training Form to acknowledge training to the Quality Assurance Program Plan (QAPP) and appropriate QPs and DPs. The employee performs the assigned work activities according to the appropriate DPs and QPs.

5.2 Principal Investigator and/or Supervisor Requirements

5.2.1 Job Assignments

NNWSI job assignments shall specify and generally describe the activities performed for each NNWSI Project position that involves the performance of activities affecting quality. These job assignments may conform to LANL's requirements for personnel positions and may be the same as the LANL job assignment. These assignments shall be documented and held in the Resident File with copies in the QAPL and QAS file.

5.2.2 Personnel Selection

Personnel selected for NNWSI job assignments must have education and experience that conform to the requirements as specified in NNWSI position description. Resumes of employees or potential employees are

verified for accuracy, and the requirements of position descriptions are compared to resumes for conformance. Supervisors indicate that both requirements are met by their signature on the resumes following a statement that indicates the employees are qualified. Resumes and job assignments are kept in the Resident File with copies in the QAPL and the QAS file. Updates to resumes are verified by supervisors in the same manner as above and attached to the original resumes in the Resident File and the QAS file.

5.2.3 Training for Technical Activities

Before beginning NNWSI Project activities, an employee shall receive special technical training needed to accomplish the activity. The QAL, PI, and supervisor shall establish the training required and either conduct the training or designate a trained person to do so.

An employee can meet training requirements through a study of the appropriate DPs or QPs; through on-the-job training, workshops, classroom instructions, or verbal instructions; or through a combination of all these methods. It is the responsibility of the PI, supervisor, and QAL to document that the required training has been completed on the NNWSI Project Training Form (Attachment 3). If job assignments change during the year, additional training, which may be required, shall be noted on the Project Training Form.

Training shall be re-evaluated annually. Previous training may be forwarded to the new Certification and Training Form if the QAL, PI, and supervisor consider it appropriate. The Certification and Training Form shall be updated to reflect the re-evaluation within the first 90 days of the calendar year. Other requirements for the completion of the Certification and Training Form are listed below under Subsection 5.2.4, Proficiency Evaluations. The training forms are kept in the Resident File and copies are kept in the QAS file.

5.2.4 Proficiency Evaluations

Acknowledgement of satisfactory proficiency evaluations are required annually. The supervisor verifies that the employee has had a satisfactory performance appraisal for NNWSI activities and acknowledges this by circling the appropriate response on the Certification and Training Form and then by signing the form. A copy of the form is kept in the Resident File and the QAS file.

5.3 QAL Requirements

5.3.1 Brief Orientation

The QAL shall provide a brief orientation to employees who are new to the NNWSI activities. The orientation shall include information as to the purpose, scope, and methods of implementation of the QAPP and its incumbent procedures and of regulations and Project level documents.

5.3.2 Group Training to QPs

As directed by the QAPL, the QALs shall provide detailed training to their assigned groups on new QPs or on QPs that are not well followed.

5.3.3 Preparation of Certification and Training Forms

The QAL helps prepare the annual Certification and Training Forms. The QAL may have informal input from the PI, supervisor, and employee as to the necessity and appropriateness of DPs and QPs.

5.4 QAPL Requirements

5.4.1 Training of All NNWSI Employees to the QAPP

The QAPL shall be responsible for training NNWSI Project personnel to use the QAPP and its supporting procedures. The QAPL shall annually re-evaluate the need for personnel to update their training in the QAPP and/or supporting procedures; training shall be conducted if there is a significant change in the QAPP or supporting procedures.

Training to the QAPP and/or its implementing procedures provided by the QAPL or his designee shall address the scope, purpose, objectives, and requirements of the NNWSI Project QA program. This training may include presentations (formal or informal), video tapes, or a mandatory reading list, and it shall be documented on the Project Training Form and signed by the person conducting the training. The Project Training Form will be kept in the QAS file with copies in the Resident File and QAPL file.

5.4.2 QAL Training to New, Revised, or Problematic QPs

The QAPL or designee shall train QALs to new or revised QPs as they are implemented in the program. Also, the QAPL shall review audit findings and CARs to determine if additional training to specified QPs is appropriate to prevent more problems of a similar nature. The QAPL or designee shall train the QALs and/or the employees to the specified QPs. Training shall be documented on the Project Training Form and signed by the person conducting the training. The Project Training Form will be kept in the QAS file with copies in the Resident File and QAPL file.

5.4.3 Directing Special Training Activities

The QAPL shall ensure that personnel who perform activities that require certification specified by applicable codes and standards be certified in accordance with those codes and standards. Records of certification for these activities shall be maintained in the QAS file. Requirements for lead auditors, auditors, and technical specialists are addressed in another LANL NNWSI QP. These requirements shall be documented on the Certification and Training Form.

The QAPL shall also ensure that QALs have training commensurate with their responsibilities. This training shall include special courses that become available and are recommended by the QAPL. QAL training that pertains to the purpose and scope of the NNWSI Project shall include methods for determining the applicability and implementation of the procedures specified by the following documents:

- the QAPP,
- QPs and DPs,
- regulations, and
- Project-level QA documents.

These and all additional requirements shall be documented on the Certification and Training Form by the QAPL or his designee. The Certification and Training Form shall be held in the Resident File, and a copy shall be sent to the QAS. QAL training status shall be evaluated and documented annually by the QAPL.

5.4.4 Preparing Position Descriptions

The QAPL, with the assistance of the QAS, shall prepare position descriptions for NNWSI work. The position descriptions shall specify minimum education and experience requirements for each NNWSI Project position category that involves the performance of activities affecting quality. These descriptions shall be documented and held in the resident file with copies in the QAPL and QAS file.

6.0 QUALITY ASSURANCE REQUIREMENTS

6.1 Records

6.1.1 Position Descriptions

Position descriptions shall be completed by the QAPL and QAS for each NNWSI position category. After initial preparation the description will only be changed if position responsibilities or definitions change. Copies of the position descriptions will be in the Resident File, the QAPL file, and the QAS file.

6.1.2 Resume

A resume shall be completed by each NNWSI employee and verified by the line supervisor. It shall be signed by the employee and supervisor as indicated on the NNWSI Resume Form. The NNWSI Resume Form in this procedure or another form that contains the same information may be used for this requirement. Copies of the resume will be in the Resident File, the QAPL file, and the QAS file.

6.1.3 Job Assignment

The job assignment for each employee is prepared by the PI or designee. After initial preparation, it will only be changed if the employee's job assignment changes. Copies of this job assignment will be in the Resident File, the QAPL file, and the QAS file.

6.1.4 Certification and Training Forms

The Certification and Training Form or equivalent form, thereof, will be completed within the first 90 days of the calendar year for each NNWSI employee. Information from the previous year may be brought forward to the Certification and Training Form in addition to the updated information from Project Training Forms. The employee verifies the information and signs the form. The appropriate supervisor signs the form verifying adequate training and satisfactory performance evaluation for NNWSI activities. Copies of the Certification and Training Form will be in the Resident File, the QAPL file, and the QAS file.

6.1.5 Project Training Forms

Project Training Forms will be completed by following the instructions included on the forms and will be signed by the person conducting the training. Copies of Project Training Forms will be in the Resident File, the QAPL file, and the QAS file.

7.0 REFERENCES

"Los Alamos National Laboratory Quality Assurance Program Plan for Nevada Nuclear Waste Storage Investigations," prepared for Los Alamos National Laboratory by Los Alamos Technical Associates, Inc., Los Alamos, NM, January 1988.

8.0 ATTACHMENTS

NNWSI Resume Form
NNWSI Certification and Training Form
NNWSI Project Training Form
Requirements Chart

LOS ALAMOS NATIONAL LABORATORY
NNWSI RESUME

Participant Data *(please print)*

Name _____

Occupation _____ Work Phone _____

Relevant Educational Background
(Begin with most recent education)

School	Location	Major Field	Dates	Degree

Employment Record
(Begin with most recent relevant employment)
(List relevant past employment)
(Use additional sheet if required)

Most Recent Employer _____ From _____ To _____

Address _____

Name and Title of Supervisor _____

Position Held _____

Responsibilities _____

NNWSI RESUME *(continued)*

GENERAL INFORMATION

List professional/scientific NNWSI-relevant publications of which you are author or co-author or patents that you hold.

List relevant professional or trade licenses, giving type of license, date issued, and expiration date.

List additional training, giving name and date of training.

Approximate total of relevant years of experience _____ .

I hereby certify the correctness of the above information and authorize its release as required by the Nevada Nuclear Waste Storage Investigations Project and applicable codes and standards.

_____ _____
Employee's Signature Date

I have reviewed relevant education and experience of _____ and find him/her qualified to perform his/her NNWSI job assignment.

_____ _____
Supervisor's Signature Date

_____
Print Supervisor's Name

LOS ALAMOS NATIONAL LABORATORY
NNWSI
CERTIFICATION AND TRAINING FORM

(Use additional sheets if necessary.)

The completion of this form, together with previously completed forms for _____, documents that he/she has received appropriate orientation and has been trained to the administrative and technical procedures that are required in the performance of activities that affect quality on the NNWSI Project.

Quality Assurance Training

Procedure #	Title

Technical Procedures Necessary to Perform Job Assignment

Procedure #	Title

NNWSI CERTIFICATION AND TRAINING FORM *(continued)*

_____ has become familiar with the above listed procedures through implementation, on-the-job training, and training as specified on the enclosed Project Training Forms. Further training will be documented on Project Training Forms and included with this form.

I hereby acknowledge that the above training has been received and authorize the release of the above information as required by the NNWSI and applicable codes and standards _____.

Proficiency evaluation does/does not indicate satisfactory performance of NNWSI activities.

Supervisor's Signature _____ Date _____

_____
Print Supervisor's Name

NNWSI PROJECT TRAINING FORM

TITLE: _____

DURATION: _____ DATE: _____

INSTRUCTOR: _____ ORG: _____ PHONE: _____

ATTENDEES

PRINT NAME	SIGNATURE	GROUP	PHONE

QP-02.1

REQUIREMENTS CHART

5.0 Procedures	5.1 NNWSI Employee Submits resume Receives and acknowledges DP & QP training Performs work activities according to procedures	
	5.2 PI/Supervisor 5.2.1 Job Assignments 5.2.2 Personnel Selection 5.2.3 Training for Technical Activities (Annual Training Evaluation) 5.2.4 Proficiency Evaluations	
	5.3 QAL 5.3.1 Brief Orientation 5.3.2 Group Training to QPs	
	5.4 QAPL 5.4.1 Training of all NNWSI Employees to the QAPP 5.4.2 QAL Training to New, Revised, or Problematic QPs 5.4.3 Directing Special Training Activities 5.4.4 Preparing Position Descriptions	
6.0 QA Requirements	6.1 Records	Location
	6.1.1 Position Descriptions	Resident File QAPL File QAS File
	6.1.2 Resume Signed by employee Verified by supervisor	Resident File QAPL File QAS File
	6.1.3 Job Assignment Prepared by PI or designee	Resident File QAPL File QAS File
	6.1.4 Certification and Training Form Prepared by QAL, PI, and Supervisor Signed by the appropriate supervisor	Resident File QAPL File QAS File
	6.1.5 Project Training Form Prepared by person conducting training	Resident File QAPL File QAS File

Enclosure B.2.C

LOS ALAMOS NATIONAL LABORATORY
NNWSI TRAINING PROGRAM

Class Title: LANL Quality Assurance Program Plan for NNWSI

Class No.: QAPP,R2 Instructor: H.P. Nunes Phone: 667-8039

Date taught: 04/18/88 For 1.5 Hours

Attendee's List

Trainee	Group	Phone
K.M.Cambern	ESS-1	667-8815
H.N.Kalia	LANL-LV	667-8815
L.W.Maassen	ESS-1	667-1691
R.D.Oliver	ESS-1	667-8815

LOS ALAMOS NATIONAL LABORATORY
NNWSI TRAINING PROGRAM

Class Title: LANL Quality Assurance Program Plan for NNWSI

Class No.: QAPP,R2 Instructor: H.P. Nunes Phone: 667-8039

Date taught: 04/20/88 For 3.0 Hours

Attendee's List

Trainee	Group	Phone
K.H.Birdsell	ESS-4	667-4318
S.L.Bolivar	ESS-1	667-1868
F.M.Byers	ESS-1	667-8753
R.J.Crowley	WX-4	667-7459
C.Dicke	ESS-5	667-1055
K.L.Foster	LATA	662-1763
S.D.Francis	WX-4	667-0050
D.Hall	WX-4	667-7459
M.D.Helland	N-5	667-9768
G.Y.Hollen	LATA	662-1762
P.M.Hummer	LATA	662-1814
M.A.Jones	ESS-1	667-7590
S.S.Levy	ESS-1	667-9504
D.A.Mann	ESS-1	667-7508
T.J.Merson	WX-4	667-5726
C.Montoya	ESS-1	667-7508
P.M.Tillery	LATA	662-1752
P.T.Trexler	LATA	662-1809
D.A.York	WX-4	667-8458

LOS ALAMOS NATIONAL LABORATORY
NNWSI TRAINING PROGRAM

Class Title: LANL Quality Assurance Program Plan for NNWSI

Class No.: QAPP,R2 Instructor: H.P. Nunes Phone: 667-8039

Date taught: 04/28/88 For 3.0 Hours

Attendee's List

Trainee	Group	Phone
J.Aldrich	ESS-1	667-1495
P.Auchampaugh	ESS-1	667-7590
J.Barber	ESS-1	667-7590
S.Barr	ESS-5	667-5648
S.A.Birdsell	ESS-4	667-4318
D.L.Bish	ESS-1	667-1165
D.Broxton	ESS-1	667-2492
K.Campbell	A-1	667-2799
B.Carlos	ESS-1	667-6879
S.J.Chipera	ESS-1	667-1110
M.R.Cisneros	INC-11	667-9164
K.Coen	ESS-5	667-6384
C.J.Duffy	INC-7	667-5154
M.H.Ebinger	HSE-12	667-3147
S.Gonzales	HSE-12	667-3331
R.C.Hagan	ESS-1	667-4225
C.D.Harrington	ESS-1	667-0078
A.R.Jenkins	MAT-3	665-0872
A.A.Kirby	LATA	662-9080
S.D.Knight	INC-11	667-4578

LOS ALAMOS NATIONAL LABORATORY
NNWSI TRAINING PROGRAM

Class Title: LANL Quality Assurance Program Plan for NNWSI

Instructor: H.P. Nunes Phone: 667-8039

Date taught: 04/28/88 For 2.0 Hours

Attendee's List Continued

Trainee	Group	Phone
D.H.Kraig	LATA	662-1820
F.O.Lawrence	INC-11	667-4578
G.M.Lopez	HSE-12	667-2426
L.L.Lopez	N-5	665-1425
G.Luedemann	ESS-1	667-7674
R.M.Morely	LATA	662-1812
W.A.Morris	ESS-1	667-7590
B.Neuman	HSE-12	667-2426
A.E.Norris	INC-7	667-4542
D.Norton	N-5	667-0916
G.Ortiz	N-5	667-0599
M.A.Ott	INC-11	667-4085
A.M.Pendergrass	LATA	662-1755
W.L.Polzer	HSE-12	667-3073
J.Poths	INC-7	667-1506
R.Raymond	ESS-1	667-4580
B.A.Robinson	ESS-4	667-4318
E.L.Romero	N-5	667-9768
M.G.Snow	ESS-1	667-8005
V.Starquist	ESS-1	667-6879

LOS ALAMOS NATIONAL LABORATORY
NNWSI TRAINING PROGRAM

Class Title: LANL Quality Assurance Program Plan for NNWSI

Instructor: H.P. Nunes Phone: 667-8039

Date taught: 04/28/88 For 3.0 Hours

Attendee's List Continued

Trainee	Group	Phone
K.Tanaka	ESS-1	667-1110
J.L.Thompson	INC-11	667-4559
K.A.West	N-5	667-1033
M.L.Wheeler	LATA	662-1806

LOS ALAMOS NATIONAL LABORATORY
NNWSI TRAINING PROGRAM

Class Title: LANL Quality Assurance Program Plan for NNWSI

Class No.: QAPP,R2 Instructor: H.P. Nunes Phone: 667-8039

Date taught: 05/10/88 For 3.0 Hours

Attendee's List

Trainee	Group	Phone
	UTEP	915-747-5464
D.J.Burton	HSE-5	665-1458
L.Clifton	LATA	662-1810
B.M.Crowe	INC-7	667-3965
Z.Dash	ESS-4	662-1923
S.Dye	INC-7	667-5487
K.Eggert	ESS-5	667-5200
B.Feary	INC-7	665-2423
H.R.Fuentes	UTEP	915-747-5464
A.L.Gauler	MEC-8	667-4864
D.Janecky	INC-7	665-0253
G.Langhorst	HSE-12	667-3300
G.A.Martinez	ESS-5	667-6384
M.R.Martinez	WX-4	667-7378
A.Meijer	INC-7	667-0625
A.Mitchell	INC-11	667-4085
L.Mitchell	INC-11	667-0829
E.Nuttall	ESS-5	667-1581
D.T.Oakley	N-5	667-1310
P.D.Palmer	INC-11	667-5313

LOS ALAMOS NATIONAL LABORATORY
NNWSI TRAINING PROGRAM

Class Title: LANL Quality Assurance Program Plan for NNWSI

Instructor: H.P. Nunes Phone: 667-8039

Date taught: 05/10/88 For 3.0 Hours

Attendee's List Continued

Trainee	Group	Phone
K.J.Partin	ESS-5	667-1581
F.Perry	INC-UNM	505-277-6528
A.R.Pratt	N-5	667-4308
P.Z.Rogers	INC-7	667-1765
R.S.Rundberg	INC-11	667-4559
B.J.Skaggs	HSE-5	665-0071
E.P.Springer	HSE-12	667-9836
B.J.Travis	ESS-5	667-1254
I.R.Triay	INC-11	667-5313
E.A.Vigil	HSE-5	667-0858

LOS ALAMOS NATIONAL LABORATORY
NNWSI TRAINING PROGRAM

Class Title: LANL Quality Assurance Program Plan for NNWSI

Class No.: QAPP,R2 Instructor: H.P. Nunes Phone: 667-8039

Date taught: 05/27/88 For 1.5 Hours

Attendee's List

Trainee	Group	Phone
S.Bhatia	LS-2	667-2779
E.D.Essington	HSE-12	667-3057
L.E.Hersman	LS-2	667-2779
S.Kelkar	ESS-4	667-4318
J.A.Salazar	LS-2	667-2779
D.T.Vaniman	ESS-1	667-1803
G.Zyvoloski	T-3	665-0977

LOS ALAMOS NATIONAL LABORATORY
NNWSI TRAINING PROGRAM

Class Title: LANL Quality Assurance Program Plan for NNWSI

Class No.: QAPP,R2 Instructor: H.P. Nunes Phone: 667-8039

Date taught: 06/08/88 For 1.5 Hours

Attendee's List

Trainee	Group	Phone
M.F.Butler	ESS-5	
Y.Kosaka	LS-2	667-6779
F.Marcinowski	LS-2	667-2779
J.R.Neergaard	ESS-5	667-8799
D.M.Updegraff	LS-2	

LOS ALAMOS NATIONAL LABORATORY
NNWSI TRAINING PROGRAM

Class Title: LANL Quality Assurance Program Plan for NNWSI

Class No.: QAPP,R2 Instructor: H.P. Nunes Phone: 776-8039

Date taught: 06/20/88 For 1.5 Hours

Attendee's List

Trainee	Group	Phone
P.L.Aamodt	ESS-1	667-7960
R.J.Beckman	A-1	667-1443
J.A.Canepa	N-5	667-4109
W.R.Daniels	INC-11	667-4546
L.Dimas	ESS-5	667-3175
A.Gancarz	INC-DO	667-2606
T.E.Hakonson	HSE-12	667-3331
R.J.Herbst	N-5	667-9286
T.J.Hirons	N-DO	667-5590
B.Isom	HSE-5	667-6170
D.E.Morris	INC-11	665-0008
C.W.Myers	ESS-DO	667-6722
C.A.Navarro	WX-4	667-7332
J.M.Ortega	HSE-5	667-7782
L.W.Ortiz	HSE-5	667-5231
R.Vigil	N-5	667-9768

Enclosure B.4.a

NNWSI PROCUREMENT PROCEDURES

Effective Date March 29, 1988

Ann Pendergrass
Prepared by:
Ann Pendergrass

March 29, 1988
Date

Karen A. West
Karen A. West
Acting QA Project Leader

March 29, 1988
Date

D. T. Oakley
D. T. Oakley
Technical Project Officer

3/29/88
Date

NNWSI PROCUREMENT PROCEDURES

1.0 PURPOSE

This quality procedure (QP) documents the requirements for the initiation, review, approval, and control of procurement documents.

2.0 SCOPE

This procedure applies to the procurement of items and services for the LANL NNWSI Project from suppliers who are external to the Laboratory. Procurements made through LANL stores for items that are stocked routinely by research groups and that are used as general office or laboratory supplies are exempt from the requirements of this procedure.

3.0 DEFINITIONS

3.1 Approved Vendors List

The Approved Vendors List (AVL) is a listing of those suppliers who are qualified to fill the Quality Assurance (QA) Level I and II procurements for engineered items. The AVL is addressed in another administrative procedure.

3.2 Commercial-Grade Item

A commercial-grade item must fulfill the following criteria. The item is

- not subject to design or specification requirements that are unique to mined geological systems and
- used in applications other than mined geological disposal systems and
- to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., catalog).

An item classified as commercial grade may be accepted for use in QA Level I or II activities.

QA Level I or II purchased services and built-to-order or prototype QA Level I or II items cannot be classified as commercial grade.

3.3 Equipment Acceptance Plan

An equipment acceptance plan sets forth criteria developed by the requestor to ascertain that a QA Level I or II analytical standard, item of measuring or test equipment, or analytical equipment meets stipulated technical requirements. An equipment acceptance plan must be prepared and implemented to determine the acceptance/rejection of all QA Level I and II analytical standards, items of measuring and test equipment, or analytical equipment except for

- rulers, tape measures, and other such devices if normal commercial equipment provides adequate accuracy, and

- standards supplied by the manufacturer with NBS-traceable or similar-certification, or documentation of analysis.

For these exceptions, an equipment acceptance plan may be used at the discretion of the requestor. The complete equipment acceptance plan documents the performance of the item or standard under test conditions. If the item or standard performs satisfactorily, it can be accepted for NNWSI Project work.

3.4 MAT Division

At LANL, the MAT Division is responsible for performing the contractual aspects of procurements. Personnel in the MAT Division place all procurement orders external to LANL and maintain the contract-related documentation.

3.5 Receiving Reports

Orders placed through regular LANL procurement procedures for the NNWSI Project are inspected when received to determine the completeness and correctness of orders received and freedom from damage using one of the following forms.

3.5.1 MAT-14 Receiving Report

The MAT-14 Receiving Report (Attachment 1) is computer-generated by the MAT-14 Receiving Section and accompanies most delivered orders. The order is checked by the requestor or user, and any discrepancies are reported to MAT.

3.5.2 Delivery Sheet

A Delivery Sheet (Attachment 2) is sent to the requestor by MAT Division when a QA Level I or II noncommercial-grade item or radioactive material is received and under some other conditions. The Delivery Sheet is completed by the requestor or user, and a copy is returned to the MAT Division.

3.5.3 NNWSI Receiving Inspection Report

An NNWSI Receiving Inspection Report (Attachment 3) is used to document the receipt of an order if neither a MAT-14 Receiving Report nor a Delivery Sheet accompanies a delivery.

3.6 Nonconformance

A nonconformance is a deficiency in characteristics, documentation, or procedures that renders the quality of an item or activity indeterminate or unacceptable. The existence of a nonconforming item and a decision on its disposition is documented on a nonconformance report (NCR); a nonconforming service or activity is identified and resolved through use of a corrective action report (CAR).

3.7 Purchase Order

The purchase order (PO), LANL Form 688-7, is completed by the MAT Division. The PO with the PR and any other supporting documentation are the contract document package for procurement.

3.8 Purchase Request

A purchase request (PR), LANL Form 838 (Attachment 4), initiates the procurement process and provides documentation of the requestor's technical specifications, the suggested supplier(s), and QA information.

3.9 Quality Assurance Level I, II, and III

Quality Assurance Levels I, II, and III are defined fully in Appendix A of the QAPP. Quality Assurance Level I (or II) items and services are defined as those items or services that are critical in producing measurements or other data required for QA Level I (or II) activities. Quality Assurance Level III items and services may be used in QA Level I and II activities but shall not be critical in producing measurements or other data required for these activities.

3.10 QA Level Assignment and Commercial-Grade Checklist

The QA Level Assignment and Commercial-Grade Checklist (Attachment 5) provides documentation of the Quality Assurance Liaison's (QAL) decision on the applicable quality level of items or services to be procured. The checklist also documents the decision as to whether or not a QA Level I or II item meets all criteria for commercial-grade classification.

3.11 Standing Order

A standing order, or blanket agreement, specifies items or services to be procured at intervals over the course of one year and may be placed with a supplier. Purchase requests may be placed against the standing order with the MAT Division, as needed, during the year. The MAT Division can order releases from the supplier after the initial blanket agreement has been completed. Only items or services specified in the original PR are covered.

4.0 RESPONSIBILITIES

4.1 Requestor Responsibilities

The requestor shall be responsible for the technical aspects of procurement procedures. He/she shall

- state the scope of work to be performed by the supplier;
- identify all appropriate technical specifications and required documentation for the item or service, including catalog numbers, NBS certificates, instructions, tolerances, and analysis requirements for the PR form;
- identify appropriate supplier(s) where possible;

- have sent to the MAT Division only those PRs that have been approved by the QAL;
- document review and concurrence with the QAL on procurement specifications, including any changes to the procurement, and place documentation on or with the PR in the Resident File;
- send a copy of each PR and QA Level Assignment and Commerical-Grade Checklist to the Quality Assurance Support (QAS) group;
- prepare, execute, and document results of an equipment acceptance plan, if appropriate; and
- complete receiving documentation.

4.2 QAL Responsibilities

The QAL shall be responsible for review of the procurement documentation. He/she shall

- review the technical specifications of PRs;
- review, complete, approve, sign, and date PRs and the QA Level Assignment and Commercial-Grade Checklist, with assistance, as needed, from the requestor;
- stamp all NNWSI PRs for QA Level I and II noncommercial-grade items "NNWSI-QA Required;"
- review with the requestor and approve any changes to the procurement documents that were made by the MAT Division as a result of bids received from suppliers; and
- review copies of the Request for Quotation (RFQ) and the PO for QA Level I and II noncommercial items against the PR to ensure that all original technical and QA requirements and changes are included in the final order and to inform the MAT Division of any discrepancies.

4.3 QAS Responsibilities

The QAS shall be responsible for QA aspects of procurement procedures. He/she shall

- perform QAL functions as requested by the QA Project Leader (QAPL) and
- maintain QA control of procurement documents by establishing files for copies of completed PRs and QA level assignments.

4.4 MAT Division Responsibilities

The MAT Division shall be responsible for the purchasing contract aspects of procurement procedures. The MAT Division shall

- ensure that the scope of work and technical requirements specified on the PR are contained in the contract;
- place contracts with suppliers as specified by the requestor where possible;
- ensure that the requestor reviews a bid to determine that the technical requirements have been met, reach agreement with the requestor and the QAL in case of exceptions taken by the bidder, and document the agreement before placing the PO;
- include all notes of telephone conversations between MAT personnel and vendors and between MAT personnel, QALs, and requestors in procurement documentation;
- coordinate all visits by LANL, DOE, and LANL-authorized personnel to the contractor and vendor facilities;
- send required documentation of closed QA Level I and II procurements to the QAPL; and
- send copies of the RFQs and POs for QA Level I and II, non-commercial items to the requestors.

4.5 QAPL Responsibilities

The QAPL shall send a copy of the procurement documents for each QA Level I and II order to WMPO QA.

5.0 PROCEDURES

The procedures to be followed and elements to be considered in preparing procurement documents are presented for each procurement category. Procurement documents will contain the following information, as appropriate:

- a scope-of-work description;
- the technical requirements for the work, including technical specifications or catalog number reference;
- QA program requirements;
- a right-of-access provision;
- subcontracting requirements;
- documentation requirements;
- nonconformance provisions; and
- provisions for spare and replacement parts.

This information is defined in Section 4 of the QAPP.

All procurements shall be documented with completed PRs (LANL Form 838) and QA Level Assignment and Commercial-Grade Checklists. The QAL shall review, complete, date, and sign all PRs and QA Level Assignment and Commercial-Grade Checklists before the PRs are further processed.

PRs may be written against standing orders; the original RFQ, PO, and support documentation apply to subsequent PRs.

A receiving report or delivery sheet (Attachments 1, 2, and 3) must be checked, completed as appropriate, and a copy placed in the Resident File with other procurement documents by the requestor or user for each order received.

Service procurements do not require the completion of a receiving report or delivery sheet.

5.1 QA Level I and II Items and Services

These requirements address the procurements of QA Level I and II services and of QA Level I and II items that do not qualify as commercial-grade items. These PRs shall be stamped "NNWSI-QA Required."

QA Level I and II procurements shall be fully documented. The PR shall be supplemented with additional documentation addressing the requirements specified above in Section 5, as appropriate. Particular attention shall be paid to the following points:

- QA Program Requirements. The supplier's QA program documents should be requested in advance and reviewed to determine the adequacy for program needs. If the suppier's QA program is not adequate, the requestor and the QAL shall specify additional requirements as a part of the statement of work to meet LANL NNWSI QA program requirements. A supplier may elect the option to use the LANL NNWSI Quality Assurance Program. If this option is chosen, the requestor shall include this requirement as a part of the statement of work.

- Right-of-Access Provision. A right-of-access provision, which allows designated LANL personnel entry to suppliers' facilities to conduct inspections, surveys, and QA audits, shall be guaranteed. The MAT Division will coordinate, with suppliers, all LANL-authorized personnel and DOE visits to the suppliers' facilities before contract award and during contract performance. External surveys and/or audits may be performed by the QAS during the service contract interval.

- Subcontracting Requirements. Subcontracting by contractors or vendors shall only be allowed through LANL review and documented agreement.

- Documentation Requirements. The form and content of reports, including confidence limits on analyses, technical review, and periodic submission of all original documents to the LANL requestors' groups, shall be considered.

The PR must include a list of suggested suppliers. If a sole source is requested, the requestor must provide justification by stating information

needed for LANL Form 866 (Attachment 6), which is found in the Laboratory Administration Manual, Subject 1002.34-.36.

Standard QA terms and conditions, any of which may be added to the requirements of QA Level I and II noncommercial grade procurements, are shown in Attachment 7.

The MAT Division sends out a request for bids, listing all appropriate terms and conditions, and evaluates all bids for technical and QA requirements with the requestor. Any exceptions taken by a bidder shall be discussed by the buyer with the requestor and the QAL. The final decision on exceptions shall be noted in MAT's procurement documentation. The PO is placed after the requestor has reviewed and accepted the final technical and QA terms of the contract.

5.1.1 Services

In addition to the points listed above, particular attention shall be paid to the following points in preparing the statement of work:

- QA Program Requirements. Chain of custody, sample identification, and storage provisions should be reviewed with particular care.

- Nonconformance. What constitutes a nonconformance and how the nonconformance for a service contract will be resolved, through a CAR, shall be defined in the statement of work, as required.

- Corrective Action. Corrective action is the measures taken to rectify conditions that are adverse to quality and, where necessary, to preclude repetition of such adverse conditions. In service procurement, corrective action is required to resolve a procedural violation--a failure to fulfill the requirements contained in procurement documents. Requirements to implement corrective actions promptly shall be included in the statement of work as required.

5.1.2 Items

Quality Assurance Level I or II noncommercial-grade items include one-of-a-kind items built to the requestor's specifications and prototypes that are currently under development. Acceptance for NNWSI Project work is contingent upon satisfactory performance, as evaluated by an equipment acceptance plan, conducted in-house. Full documentation is required on PRs, including the documentation of the QA requirements specified above, as appropriate. In addition to the points listed in Section 5.1 above, particular attention shall be paid to the following points in preparing the statement of work:

- QA Program Requirements. Hold-for-inspection points and procedures for the verification of materials specification should be reviewed with particular care.

- Nonconformance. What constitutes a nonconformance and how the nonconformance will be resolved shall be defined in the statement of work, as required.

5.2 QA Level I and II Commercial-Grade Items

Items that fulfill the commercial-grade criteria (Section 3.2) may be procured with minimum documentation and time; however, the requestor is responsible for documenting technical aspects of the procurement to NNWSI program standards. Acceptance for NNWSI Project work is based on inspection of the item and, if needed, an evaluation following an equipment acceptance plan that has been developed, performed, and documented by the requestor.

The QA level assignment on the PR shall state "QA Level I (or II), Commercial Grade Acceptable." This statement relieves MAT Division of the requirement of implementing additional QA procedures in procurement.

5.3 QA Level III Items and Services

Items and services that are not QA Level I or II, as determined by the QA Level Assignment and Commercial-Grade Checklist, may be procured following standard MAT non-QA procedures and LANL policies. Procurement specifications shall be made following good scientific and/or engineering practices and judgement. No additional QA consideration is required for procurement.

5.4 Procurement Document Changes

Any changes to procurement documents shall be subject to the same degree of review control used in preparing the original documents. Changes made as a result of bid evaluation or precontract award negotiations shall be incorporated into procurement documentation. The requestor shall review any changes, evaluate the effects, and document the findings and decision. Those changes and the decision documentation shall be reviewed by and concurred with the requestor and the QAL before the MAT Division awards the contract. The requestor and the QAL may concur by telecon with the buyer. Written evidence of the review and concurrence reached shall be documented in the Resident File and in the MAT buyer's file.

Review of changes to procurement documents shall consider the following, as appropriate:

- inclusion of information listed in Section 5.0,
- addition or modification of design or site investigation criteria,
- analysis of exceptions or changes requested, and
- determination of the effects such changes may have on the intent of the procurement documents and quality or suitability of the item or service to be furnished.

5.5 Procurement Quality Disagreement

In the event that the requestor and the QAL fail to agree on QA requirements or QA level assignments, the next higher level of technical and QA management shall jointly make the decision. This decision shall be documented as a part of the procurement record in the requestor's group Resident File.

6.0 QUALITY ASSURANCE REQUIREMENTS

6.1 Records

6.1.1 Purchase Request

The requestor's group office personnel shall process PRs according to LANL procurement procedures. Copies of PRs shall be retained in group Resident Files. Duplicates of the Resident File PR copies shall be sent to the QAS.

6.1.2 QA Level Assignment and Commercial-Grade Checklist

QA Level Assignment and Commercial-Grade Checklists, which have been completed, reviewed, and signed, shall be attached to the PR documents in the group Resident Files, and copies shall be attached to the PR copies sent to the QAS.

6.1.3 Purchase Order

The designated buyer at the MAT Division retains copies of the procurement documentation, which is processed as permanent records according to MAT procedures. At the time an order is placed, the MAT Division sends copies of RFQs and POs for QA Level I and II non-commercial-grade items and services to the QAS and the requestor. The requestor shall attach the RFQ and PO copies to the corresponding PRs in the group Resident Files. All approvals and concurrence to the final order shall be documented by the requestor and the buyer on or with their copies of the PO.

For each QA Level I and II order, the QAPL shall send a copy of the procurement documents to the following address:

Waste Management Project Office
Project Quality Manager
P.O. Box 98518
Las Vegas, NV 89193-8518

6.1.4 Equipment Acceptance Plan

When an equipment acceptance plan is used, the requestor shall develop one and place it with the PR copy in the Resident File. When the equipment is received, the equipment acceptance plan shall be implemented and the outcome and documentation of the plan shall be placed by the requestor in the Resident File with the other procurement

documentation for the equipment. The executed plan documents acceptance of equipment for use in the NNWSI Project.

6.1.5 Receiving or Delivery Report

Each order of items received is checked to ascertain correctness and completeness of the order and the items' freedom from damage. ~~One of~~ the following forms is used to document this check:

- a MAT-14 Receiving Report,
- a Delivery Sheet, or
- an NNWSI Receiving Inspection Report.

The appropriate form is initialed and dated (MAT-14 Receiving Report only) or completed, signed, and dated by the requestor or user, and a copy is placed in the Resident File attached to the other procurement documentation for the order. ~~When the Delivery Sheet is used, the requestor or user returns a completed copy to the buyer at MAT.~~

6.1.6 NNWSI Project Records

The completed procurement records become part of the NNWSI Project documentation. Completed procurement records from the group Resident Files shall be sent to the LANL Records Processing Center for processing.

For each QA Level I and II order, MAT shall send a copy of the closed procurement file, including the PR and final PO, to the QAPL, marked to the attention of "NNWSI."

6.2 Nonconformances

Nonconformances in equipment and services shall be resolved according to LANL NNWSI Program procedures and following specifications stated in the applicable contract. Contract specifications are discussed in Sections 5.1.1 and 5.1.2.

6.3 Document Control

This quality procedure is to be issued, controlled, and revised in accordance with the LANL implementing procedures for document control.

7.0 REFERENCES

7.1 Los Alamos National Laboratory Administration Policies and Procedures Manual

8.0 ATTACHMENTS

8.1 MAT-14 Receiving Report

~~8.2 Delivery Sheet~~

8.3 NNWSI ~~Receiving Inspection Report~~

8.4 Purchase Request, LANL Form 838

8.5 QA Level Assignment and Commercial-Grade Checklist

8.6 Justification for Sole Source or No Substitution Procurement, LANL Form 866

8.7 Typical QA Terms and Conditions for QA Level I and II Procurements

LOS ALAMOS NATIONAL LABORATORY
MAT-14 RECEIVING REPORT

R251005

BUYER: CD
EXPEDITOR: C

TIME: 1615

VENDOR: COORS CERAMICS COMPANY
RECEIVING REPORT NO: 205792

PURCHASE ORDER: 2-YCC-54C7K-1
SUBSEQUENT RECEIPT: 001

GROUP: MST-6 REQUESTOR: GIBBS MS: G770 PIECES: 2 WEIGHT: 981

SITE: 3 BUILDING: 66 ROOM: R100 ROUTE: 3 PHONE: 7-8750

ROUTING: 03 DATE DOCKED: 01-19-95

****
* WARNING *
* NOTE TO REQUESTOR: RECEIVING REPORT MADE ACCORDING TO *
* PACKING LIST. CHECK MATERIAL RECEIVED AND REPORT DISCREPANCIES *
* TO MAT 14 RECEIVING WITHIN 15 DAYS. PHONE 667-4186 *
****

CLERK: ALAN VAN VESSEM DATE WORKED: 01-20-95

CARRIER: Yellow Freight System FREIGHT BILL #: 063007169

FOB: FREIGHT CHARGES: COLLECT

TERMS: 2 20 PACKING LIST: 89756

SHIPPING MEMO #: DELIVERY RECEIPT #:

****

ITEM	DESCRIPTION	REC'D	REJ'D	UNIT	UNIT COST
001		3.00	0.00	EA	3881.00
	TARGET, BALLISTIC, ALUMINA CERAMIC (AD-85S), 17.625" X 17.625" X 7.88" THICK, PRODUCED BY FACE BONDING TWO (2) MONOLITHIC 3.94" THICK BLOCKS. ACCT CODE: 6106 R56G C 1 10				
	********** RECEIVING REPORT TOTAL **********				$11643.00

DELIVERY SHEET

UNIVERSITY OF CALIFORNIA
LOS ALAMOS NATIONAL LABORATORY

Person	Site	Bldg	Group	Purchase Request	Purchase Order
Carrier	Waybill or BSL			Pcs Wt	Chgs ppd / coll
Vendor	Address				
Receiving Clerk	Date Received				Date Delivered

QUANTITY	DESCRIPTION

NNWSI Receiving Inspection Report
QA Level I and II Items

Item Description _____ Identification Number/ Property Number _____

_____ User Group _____

PR No. _____

MAT-14 Receiving Report No. _____

	Sat	Unsat	N/A
1. No physical damage			
2. Correct part number(s)			
3. Correct serial number(s)			
4. Operator's manual(s) provided			
5. Handling instructions complied with			
6. Special conditions complied with			
7. All parts or components identified on packing slip and PO present			
8. Correct and complete documentation, including calibration and analysis information			
9. Item received in good working order			

☐ The item is ACCEPTED for NNWSI Project.

☐ The item is REJECTED for NNWSI Project.

- Contact the buyer at MAT for resolution.
- Contact the QAL.

☐ An Equipment Acceptance Plan must be implemented to determine Acceptance/Rejection for the NNWSI Project.

Comments:

Inspected By _____ Date _____

*U.S. GOVERNMENT PRINTING OFFICE: 1984-781-317

UNIVERSITY OF CALIFORNIA — LOS ALAMOS NATIONAL LABORATORY

PURCHASE REQUEST

Date of Request

INSTRUCTIONS Requester retains pink copy and sends all other copies to MAT-10, MS P274 Return unused or unused copies to MAT-10, MS P274 DO NOT DESTROY DO NOT USE FOR STOCK ISSUE ITEMS IN LABORATORY WAREHOUSES

Requested By	Telephone	Group	Mail Stop	Realistic Date Req.

Acct. Code	Program Code	Exp. Code	Job Order No.	Cap. Equip. Code	Correspondence to	Telephone	Mail Stop

Deliver to (Name)	Area	Building	Room	Telephone	Mail Stop

KNOWN AVAILABLE EXCESS LISTS HAVE BEEN REVIEWED
Purchase approved by (Signature) Date Z Number

Typed Name

Title

Auth. Level $ K

Foreign Country

ACT-1 Use Only

SHADED AREAS FOR MATERIALS MANAGEMENT USE ONLY

Screened for Excess Date	Date Assigned	Buyer	Telephone (505) 667-

Invoice Terms	Required Shipping Date	Date of Order

TO

PURCHASE REQUEST NUMBER

0519L

Quoted By	Telephone	Date	Quote Number

F.O.B.	Ship Via:

Ship From

ITEM	TYPE COMPLETE DESCRIPTION OF REQUIREMENTS OR SPECIFICATIONS	QTY.	UNIT	UNIT PRICE	EXTENSION
	Use Purchase Request Supplementary page if additional space is required.				

PAGE OF PAGES

SUGGESTED SOURCES (Sole source over $2.5K requires written justification)

Total Estimated Cost

Previous P.O. Number

Important handling or delivery information. QA? Hazards? Remarks.

Telephone Contact

Items	Total Cost	Account	Program	Loc.	Bor.	Exp.	Perm.	Job Order	Ord.	Proc.	Wt.	Bump.	Source	Accept

Bids Requested				Bids Received				Bids Rejected			Seller's Number	Ex.	Due Date	Ship Date
S	S	D	W	S	S	D	W	Small	Disadvantaged	Women				

Form Number 538 (6-84)

BUYER FILE/ACT TO MAT-14

EXAMPLE

QA LEVEL ASSIGNMENT AND COMMERCIAL GRADE-CHECKLIST

PR No. _____

QA LEVEL CHARACTERISTICS	QA LEVEL	(CIRCLE)
1. Is the item or service critical in producing data (measurements) that could predict radiologic health and safety?	☐ NO ↓ ☐ YES →	I
2. Is the item or service critical in producing data that could predict duration or extent of waste isolation?	☐ NO ↓ ☐ YES →	I
3. Is the item or service critically involved with retrievability?	☐ NO ↓ ☐ YES →	I
4. Is the intended purpose of this service or data produced by this item critical in providing data for a license application?	☐ NO ↓ ☐ YES →	I
5. Can failure of the item or inadequately performed service cause a failure of a QA Level I item or irretrievable loss of QA Level I data?	☐ NO ↓ ☐ YES →	I
6. Does the service or item involve a design phase which is to be conducted immediately prior to application for a NRC license, major procurement, or start of construction?	☐ NO ↓ ☐ YES →	I
7. Can the item or service have a major impact on nonradiological or occupational health and safety through the faulty generation of data or measurements or through failure of an item or service?	☐ NO ↓ ☐ YES →	II
8. If the item were to fail or the service were performed inadequately, could repository workers be exposed to radiation or radioactive contamination levels in excess of the limits expressed in 10 CFR 20?	☐ NO ↓ ☐ YES →	II
9. Does the item or service have a major impact on the nonradiological operation, reliability or maintainability of engineered systems, structures, or components and therefore affect nonradiological or occupational health and safety?	☐ NO ↓ ☐ YES →	II
10. Does the item or service involve a design phase for which the principle purpose is to conduct a comparative technical analysis of alternatives?	☐ NO ↓ ☐ YES →	II
11. Can failure of the item or inadequately performed service cause major cost overrun or schedule slippage?	☐ NO ↓ ☐ YES →	II
LEVEL III – WHEN THE ANSWERS TO ALL QUESTIONS ABOVE ARE "NO"	☐ →	III

LEVEL I OR II COMMERCIAL GRADE ITEM CHARACTERISTICS	COMM	NON-COMM	
1. Item is not subject to design or specification requirements that are unique to mined geological disposal systems?	☐ YES ↓	☐ NO →	_____
2. Item is used in applications other than mined geological disposal systems?	☐ YES ↓	☐ NO →	_____
3. Item is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, catalog)?	☐ YES ↓	☐ NO →	_____
COMMERCIAL GRADE – WHEN THE ANSWERS TO ALL QUESTIONS ABOVE ARE "YES"	☐		

SIGNATURE OF QAL _____ DATE _____

☐ EQUIPMENT ACCEPTANCE TEST REQUIRED/WANTED

☐ COMMENTS ON REVERSE

JUSTIFICATION FOR SOLE SOURCE OR NO SUBSTITUTION PROCUREMENT

Instructions: Complete the form, or write a memo of justification using the form as an outline.

Purchase Request Number _____

Federal and DOE procurement regulations and good business practices mandate that competition be maximized whenever practicable. Sole source procurement is permitted only as an exception when properly justified.

Do *not* use this form for research and development subcontracts. Contact MAT-* at *-8582 for assistance in preparing the sole source or no substitution justification.

The following information *must* be provided when the total cost of order is over $5000.

A. Check one of the following:

- ☐ Sole Source Procurement (specific item or service available from only one source)
- ☐ No Substitution Procurement (specific item or service available from various sources)

B. If this product or service must be acquired by sole source or no substitution, check the reason(s) and provide written justification based on outline below (space provided in Section C).

REASON	JUSTIFICATION OUTLINE
☐ Compatibility	Indicate system, make, model, and *detailed* explanation of compatibility requirement
☐ Unique repair or replacement item	Identify item to be used with, purchase request number the item was purchased under, property number, and warranty period
☐ Supplementary or accessory part required from same manufacturer	Identify in-house equipment and use with existing system. Provide detail about why only the same manufacturer's items are required.
☐ Unique item	Identify project, program, equipment, or unique design (make and model). Include reason required and *detailed* explanation of uniqueness. What other makes or sources were considered?
☐ To comply with standards program	Identify criteria for standards program project and why others will not meet requirements
☐ For test and evaluation	For what system and what others will be tested and evaluated? What is the estimated total quantity expected eventually for the project?
☐ Directed procurement by DOE or other agencies	Attach copy of letter directing procurement. Letter must stipulate justification. Contact MAT-* at *-8582 for special procedures
☐ Unique service	In what area is facility, equipment, or expertise unique? Include reason required and *detailed* explanation of uniqueness
☐ Other reasons - if not shown above	Explain in detail.

C. JUSTIFICATION Explain the justification. Attach extra sheets if necessary.

_____

_____

_____

_____

_____

D Signatures Provide all requested. Final approval rests with the Materials Management Division.

_____

Requester Group Date

_____

Requesting Group Approving Authority Division Date

Signature authorization must be commensurate with the value of the purchase request.

_____

Materials Management Approving Authority Signature Authority Date

Form 866 (Rev 12/89)

TYPICAL STANDARD QA TERMS AND CONDITIONS FOR QA LEVEL I AND II PROCUREMENTS

Numbers in parentheses refer to MAT reference numbers for the preparation of contracts.

Code 1 - "Seller shall have an approved quality assurance program that complies with the applicable section of ANSI/ASME NQA-1." (SPC 677)

Code 2 - "Seller shall provide a Certificate of Conformance (C of C) with the seller's product." (SPC 678)

Code 3 - "Seller shall provide a Certified Material Test Report (CMTR) with the seller's product." (SPC 679)

Code 4 - "Seller shall provide a certification that American Chemical Society (ACS) specifications are met." (SPC 680)

Code 5 - "Seller shall supply a copy of the procedures used for all analyses applicable to this order." (SPC 681)

Code 6 - "Seller shall supply with the product a copy of all Certificates of Calibration traceable to National Bureau of Standards." (SPC 682)

Code 7 - "Seller shall maintain records that provide traceability of analytical results and/or instrument calibrations to the National Bureau of Standards or other documented standard." (SCP 684)

Code 8 - "The seller's personnel and staff shall have the necessary qualifications and certifications to perform the required task." (SPC 685)

Code 9 - "Los Alamos personnel or authorized representatives shall have the right to visit the seller's facilities, to review records, and to perform any necessary inspections or audits applicable to this order to ensure compliance with quality assurance criteria." (SPC 686)

Code 10 - "Seller shall mark the outside of all packages as follows: Quality Assurance Order - To Be Opened By Requestor Only." (SPC 639)

Code 11 - "Seller must have an approved quality assurance program, or a preaward survey must be performed and the seller qualified before placement of this order." (Note on RFQ only)

ACCEPTANCE OF PROCURED SERVICES PERFORMANCE

Effective Date 6/27/88

A. M. Pendergrass
Preparer

June 27, 1988
Date

H. P. Nunes
QA Project Leader

June 27, 1988
Date

D. T. Oakley
Technical Project Officer

6/27/88
Date

ACCEPTANCE OF PROCURED SERVICES PERFORMANCE

1.0 PURPOSE

This procedure specifies the requirements for and methods by which the performance of procured services is accepted and the means by which acceptance is documented.

2.0 SCOPE

This quality procedure (QP) applies to acceptance of Quality Assurance (QA) Level I and II services procured and performed for the Los Alamos National Laboratory (LANL) Nevada Nuclear Waste Storage Investigations (NNWSI) Project. Acceptance of Quality Assurance (QA) Level I and II items and equipment is addressed in TWS-QAS-QP-04.1, "NNWSI Procurement Procedures."

The extent to which the performance of services is evaluated must be consistent with relative importance, complexity, and amount of service procured.

3.0 DEFINITIONS

3.1 Corrective Action

Corrective action is the measures taken by the supplier to rectify significant conditions that are adverse to quality and, where necessary, to preclude repetition of such conditions. The condition requiring corrective action, the cause, the recommended corrective action, and the verification that corrective action has been implemented are documented on a Corrective Action Report (CAR) (Attachment 1).

3.2 Nonconformance

A nonconformance in a service procurement is a failure of the supplier to fulfill the requirements contained in the procurement documents such that the quality of the service rendered is unacceptable or indeterminate. A nonconformance in a service procurement is reported and the resolution is documented through a CAR.

3.3 Services

Services that may be procured by LANL in support of the NNWSI Project are performance by subcontractors of activities such as analysis, third party inspections, engineering and consulting, installation, repair, overhaul, and maintenance work.

4.0 RESPONSIBILITIES

4.1 Requester Responsibilities

The requester of the service will be responsible for the technical aspects of accepting the performance. The requester will, as applicable,

- prepare the statement of work to include conditions of service acceptance;
- select the method(s) to determine acceptance and review the information produced by implementing the method(s);
- issue CARs, if appropriate;
- document acceptance or nonacceptance of the service performance;
- request the QAS or Waste Management Project Office (WMPO) to conduct surveys, surveillances, and/or audits of service suppliers; and
- document acceptance or rejection of the results of procured services.

4.2 QAS Responsibilities

The QAS is responsible for documenting on a CAR the nonconforming conditions and corrective actions required for procured services, if required, and for performing QA oversight activities. The QAS will

- review the requester's documentation on acceptance or nonacceptance of the service performance, if requested,
- conduct surveys and/or audits of service suppliers, as needed,
- prepare and complete CARs, as needed,
- obtain the QAPL's concurrence on recommended corrective action of a CAR before sending it to the supplier to be implemented,
- send a copy of the CAR to the MAT buyer who placed the service contract, and
- provide the QAPL with a copy of the closed CAR.

4.3 QAPL Responsibilities

The QAPL is responsible for concurring with the recommended corrective action of a CAR before it is implemented.

4.4 WMPO Responsibilities

WMPO is responsible for conducting surveillance of a participating organization or Nevada Test Site (NTS) support contractor used by another participating organization or NTS support contractor, when requested by the organization using such a contractor or participating organization.

5.0 PROCEDURES

5.1 Acceptance

Acceptance of the performance of a service procurement is made by one or more of the following methods, as specified by the requester of the service:

- technical verification of data generated,
- survey and/or audit of the activity,
- review of objective evidence for conformance to the requirements contained in the procurement documents (statement of work), and/or
- satisfactory implementation of CARs.

The service procurement will be accepted unless unacceptable conditions are documented by the requester and sent to the QAS. Either of these individuals will then prepare and compile a CAR.

5.1.1 Technical Verification of Data

The requester of the service will, when appropriate, provide for technical verification of data generated. Standard or known samples and duplicate samples may be submitted for analysis; duplicate samples may be submitted to another anlysis laboratory for independent analysis. The requester will document these verification activities on the Acceptance of Results of Procured Services form (Attachment 2) and place it in the group resident file with the other service procurement documents.

5.1.2 Survey and/or Audit

The QAS will perform surveys and/or audits of the supplier's activities consistent with the importance and complexity of the service and as needed when the requester has reason for concern about potential nonconforming conditions. The outcomes of these activities will be documented by the QAS in accordance with LANL NNWSI implementing procedures. The QAS will send copies of all audit and survey reports to the requester, who will place them in the group resident file with the other service procurement documents.

When a participating organization or NTS support contractor uses another such organization to provide services, the user organization will request WMPO to conduct a WMPO surveillance (survey) of the organization performing the service to determine that the work is being performed in accordance with requirements. The surveillance report will be sent to the requester who will place it in the group resident file with the other service procurement documents.

5.1.3 Review for Conformance to Procurement Documents

The requester will review objective evidence that shows whether the supplier's work conforms to specifications contained in the statement-of-work section of the procurement documents. The requester will document these verification activities on the Acceptance Results of Procured Services form (Attachment 2) and will place it in the group resident file with the service procurement documents.

5.2 Nonconformance

5.2.1 Identification of Supplier Nonconformance

The requester and QAS will determine supplier nonconformance based on implementation of one or more of the acceptance methods listed above. The nonconforming condition will be identified on a CAR issued to the supplier by the requester or QAS. A copy will be sent by the QAS to the MAT buyer who placed the contract.

5.2.2 Control of Supplier Nonconformance

Nonconforming services performed by the supplier will be controlled through prompt corrective action taken by the supplier. Upon

receiving a CAR, the supplier must identify appropriate corrective action measures taken to correct the nonconforming condition and, where necessary, to prevent repetition. The supplier will obtain concurrence of the QAPL for proposed corrective actions before implementing them and will implement them promptly after receiving concurrence.

5.2.3 Verification of Corrective Action

The QAS will verify the QAPL's concurrence with the supplier's proposed corrective actions and will take appropriate action, such as a survey or audit, to verify the implementation of corrective actions.

5.2.4 Acceptance of Service Following Nonconformance

As a part of closing out a CAR, the QAS and requester must determine acceptance or rejection of services performed before the corrective action was implemented by the supplier. This decision will be documented as a part of the CAR action, and a copy of the decision will be sent by the QAS to the MAT buyer who placed the contract.

6.0 QUALITY ASSURANCE REQUIREMENTS

6.1 Records

Records that document acceptance or rejection of results and any corrective actions for a service procurement consist of some or all of the following:

- technical verification of generated data, which is documented on the Acceptance of Results of Procured Service form,
- review of objective evidence, which shows conformance to procurement document specifications,
- survey and/or audit reports covering the supplier's activities, and
- CARs.

The Acceptance of the Results of Procured Services form, when completed, will be attached to the purchase request and other procurement documents in the resident file. The completed form becomes part of the Project's permanent procurement records.

6.2 Document Control

This QP will be issued, controlled, and revised in accordance with LANL NNWSI Project implementing procedures.

7.0 ATTACHMENTS

Attachment 1, Los Alamos NNWSI Project Corrective Action Report
Attachment 2, Acceptance of Results of Procured Services form

Los Alamos NNWSI Project
CORRECTIVE ACTION REPORT

Initiator: Signature/Organization/Phone	**CAR No:** **Initiation Date:** **QA Level:**
Title of Work to which CAR Applies:	
Condition Requiring Corrective Action:	
Corresponding Documentation:	
Assigned To:	**Date:**
Cause and Recommended Corrective Action:	
QAPL Concurrence:	**Date:**
Corrective Action Completed:	**Date:**
Implementation Verified By:	**Date:**
CAR Closeout:	**Date:**

Los Alamos
Los Alamos National Laboratory
Los Alamos, New Mexico 87545

ACCEPTANCE OF THE RESULTS OF PROCURED SERVICE

ATTACH TO SERVICE PROCUREMENT DOCUMENTS

PR No.: _____ REQUESTOR OR EVALUATOR: _____

SERVICE PERFORMED: _____

ACCEPTANCE METHOD

1. TECHNICAL VERIFICATION OF DATA GENERATED ☐ ACCEPT ☐ REJECT ☐ N.A.

COMMENTS:

_____ REQUESTOR OR EVALUATOR _____ DATE

2. SURVEY / AUDIT OF SUPPLIER'S ACTIVITIES ☐ ACCEPT ☐ REJECT ☐ N.A.

SR OR AUDIT REPORT NUMBER(S): _____

COMMENTS:

_____ REQUESTOR OR EVALUATOR _____ DATE

3. REVIEW OF OBJECTIVE EVIDENCE THAT SHOWS CONFORMANCE TO STATEMENT OF WORK ☐ ACCEPT ☐ REJECT ☐ N.A.

COMMENTS:

_____ REQUESTOR OR EVALUATOR _____ DATE

4. CAR IMPLEMENTATION ☐ ACCEPT ☐ REJECT ☐ N.A.

CAR NUMBER: _____

COMMENTS:

_____ REQUESTOR OR EVALUATOR _____ DATE

QUALIFICATION OF SUPPLIERS FOR ENGINEERED ITEMS AND SERVICES

Effective Date 6/27/88

A M Pendergrass
Preparer
A. M. Pendergrass

June 27, 1988
Date

H.P. Nunes
QA Project Leader
H. P. Nunes

June 27, 1988
Date

D T Oakley
Technical Project Officer
D. T. Oakley

6/27/88
Date

QUALIFICATION OF SUPPLIERS FOR ENGINEERED ITEMS AND SERVICES

1.0 PURPOSE

This quality procedure (QP) describes the need, methods, and documentation requirements for qualifying suppliers of engineered items and services and for maintaining an Approved Vendors List (AVL) of qualified suppliers.

2.0 SCOPE

This QP applies to suppliers of Quality Assurance (QA) Levels I and II engineered items and services for the Los Alamos National Laboratory (LANL) Nevada Nuclear Waste Storage Investigations (NNWSI) Project. Because LANL's scope of work is for scientific investigations and not for engineered items, these requirements are set forth for use by the LANL subcontractor responsible for procurement of engineered items and for future use by LANL in the event that LANL becomes responsible for engineered items.

3.0 DEFINITIONS

3.1 Approved Vendors List

The AVL documents suppliers who have been qualified to fill QA Levels I and II procurements for engineered items and services.

4.0 RESPONSIBILITIES

4.1 Requester

The requester will specify in the procurement documents a vendor previously qualified to provide engineered items or services, as appropriate.

If no supplier has previously been qualified to provide the items or services being considered, the requester will ensure that options by which suppliers may be qualified are specified in the procurement documents.

The requester will ensure that suppliers are capable of providing the required items or services in accordance with the requirements stated in the applicable procurement documents before the award of the contract.

The requester may prepare supplier qualification plans.

4.2 Quality Assurance Liaison

The Quality Assurance Liaison (QAL) may prepare supplier qualification plans and will ensure that these plans are documented. The QAL will review and concur with the supplier qualification plans prepared by the requester and will obtain concurrence from the Quality Assurance Project Leader (QAPL) before plans are implemented. The QAL will coordinate the implementation of all supplier qualification plans with the Quality Assurance Support (QAS) contractor.

The QAL will attempt to qualify a supplier when requested by LANL NNWSI Project personnel and will prepare a summary report documenting the qualification process and outcome.

4.3 Quality Assurance Support

The QAS will maintain an AVL for suppliers of engineered items and services for the NNWSI Project. Based on information from users of the AVL, the QAS will update and reissue the AVL at least annually.

The QAS will assist the QALs in performing supplier qualification activities, as needed.

4.4 Quality Assurance Project Leader

The QAPL will review and concur with all supplier qualification plans before they are implemented.

4.5 Survey Team Leader

The survey team leader will plan, direct, and report any onsite preaward survey performed to qualify a supplier after a purchase request (PR) has been submitted and before the procurement contract has been awarded. The survey team leader must be a member of the LANL NNWSI Project staff or the QAS organization.

The survey team leader will not have technical responsibility for the items or services that are to be produced by the surveyed organization.

4.6 MAT Division

MAT Division will forward a questionnaire to a potential supplier if asked by a requester and will arrange for an onsite preaward survey team to visit a supplier's facility.

5.0 PROCEDURE

5.1 Supplier Qualification

A requester may ask the QAL to attempt to qualify a supplier at any time.

Supplier qualification activities result in an evaluation of the capability of the supplier to provide engineered items or services in accordance with the technical and QA requirements of the procurement. The qualification process used and the outcome obtained in a summary report will be documented by the QAL.

A supplier may be qualified by the QAL using one (or more) of the following methods:

- in-house quality assurance survey,
- onsite preaward survey,
- letter of recommendation, and
- evidence of prior acceptance.

After evaluating the supplier, the QAL will make one of the following recommendations:

- The supplier is fully qualified.

- The supplier is conditionally qualified; the limitations on procurement will be explicitly indicated, including the additional requirements for full qualification.

- The supplier is not qualified; the reasons for this recommendation, and the corrective actions necessary before this recommendation can be reconsidered, will be indicated.

5.1.1 In-House Quality Assurance Survey

A supplier evaluation will be performed by the appropriate QAL and will begin with an in-house survey. Depending on the significance and complexity of the product, process, or service, an onsite preaward survey may also be required, as described in Subsection 5.1.2 below.

The in-house survey will take into account any letters of recommendation, the supplier's documented history in providing acceptable identical or similar products or services, previous preaward surveys, the supplier's current QA program and records, and/or other pertinent information submitted by the supplier. Letters of recommendation will address the supplier's capabilities to meet the specific technical and/or QA requirements of the applicable procurement documents or the supplier's history of providing identical or similar products or services that have proved satisfactory in actual use. At the direction of the requester and with the QAL's concurrence, a questionnaire may be sent to the supplier by the appropriate Materials Management (MAT) Division representative to elicit specific information. Evaluations performed by other DOE contractors may be accepted if the appropriate codes and standards were used as the basis for qualification.

5.1.2 Onsite Preaward Survey

If a preaward survey is required to approve a supplier after the PR has been submitted, the requester must make arrangements for the survey team to visit the supplier's facility through the appropriate MAT Division representative. The survey team will

- review with the supplier pertinent issues that may include but are not limited to
  - the purpose of the survey,
  - the supplier's organization and facilities,
  - qualifications of special process personnel,
  - the instrument and equipment calibration procedures and certification system,
  - product and service delivery capabilities,
  - design requirements of the products or services,
  - process procedures followed,

- content and implementation of the supplier's QA program, and
- documentation of satisfactory product performance;

- conduct the survey using appropriate checklists to cover the technical and QA requirements of the procurement documents; and

- conduct a postsurvey session with the supplier to summarize and review
  - survey findings and/or observations,
  - the supplier's lack of compliance with specified requirements or lack of capabilities, if any, and
  - any further corrective action necessary to attain full qualification, including required completion dates, in writing, from responsible supplier management.

5.1.3 Evidence of Prior Acceptance

If another branch of the Waste Management Project Office has previously accepted a supplier to provide engineered items or services that meet technical and QA requirements similar to those under consideration, evidence of such acceptance may serve as a recommendation for qualifying the supplier.

5.2 Supplier Disqualification

If a supplier fails to fulfill the technical or QA requirements (as documented by survey reports, audit reports, nonconformance reports, or corrective action reports), a requester will ask the QAS to disqualify the supplier. The QAS will then remove the supplier's name from the AVL. The supplier is eligible for requalification as described in Subsection 5.1.

6.0 QUALITY ASSURANCE REQUIREMENTS

6.1 Supplier Qualification Reports

The survey team leader will report to the QAL the results of a preaward survey, including actions pending and recommendations relating to qualification of the supplier.

The QAL will prepare a summary report for the QAS that documents each qualification process used and outcome obtained, including the recommendations made for qualifying the supplier. Copies will be sent to the requester and the QAPL. A copy will also be sent to the MAT buyer if an onsite survey has been performed after a PR was submitted and before a procurement contract was awarded.

When a supplier is qualified, the QAS will provide written notice to all AVL holders and will update the AVL master listing.

Copies of qualification plans of approved suppliers, survey reports, and necessary commitments for corrective action, and closeout documentation will be maintained by the QAS.

6.2 Qualifications of Survey Team Members

The survey team leader will be a member of the LANL NNWSI Project staff or an auditor qualified following the requirements of the LANL NNWSI Project implementing procedures. The survey team need not include an auditor.

The technical expert(s) will have adequate training and/or experience to determine the capability of the surveyed organization to satisfy the technical requirements of the applicable procurement documents.

6.3 Approved Vendors List

The QAS will maintain and keep current an AVL for NNWSI Project activities. The QAS will revise and reissue the AVL at least annually. The AVL will be issued as a controlled distribution document. This list will include

- the supplier's name and address and
- products or services to which the approval applies, including any special processes.

The QAS will maintain additional information, including

- survey date, type, QAL, and survey team leader (if applicable) on which the evaluation is based; and
- results of evaluations--that is, full approval, conditional approval, or disapproval (if approval is conditional, the stipulations will be included).

6.4 Completed Records

Completed records will be forwarded by the QAS to the manager of the Los Alamos Records Center for submission to the NNWSI Project Records Center.

7.0 REFERENCES

None

8.0 ATTACHMENTS

None

LOS ALAMOS NATIONAL LABORATORY
NNWSI
CHANGE REQUEST

Change Request No. 044

Date 8-18-88

Procedure No. TWS-QAS-QP-04.3 "Qualification of Suppliers for Engineered Items and Services"

Change Requested:

Add Section 5.3 Procurement Documentation

All procurements for engineered items and services must be made following the requirements contained in TWS-QAS-QP-04.1. In particular, the QAL will review procurement documents to determine whether the following requirements are met:

- QA requirements are correctly stated,
- there are adequate acceptance and rejection criteria, and
- procurement documents have been prepared, reviewed, and approved by an appropriate technical individual.

If the procurement is for QA Level III or commercial grade, the QAL's signature and date on the PR documents review and concurrence with these requirements.

If the procurement is not commercial grade or QA Level III, the QAL's review will be documented using NNWSI Project document review sheets which will become QA records. Concurrence will be documented by the QAL's signature and date on the purchase request form after resolution of all comments on the document review sheets.

Reason for Change:

Response to CAR No. 027 from NRC Mini-audit.

Change Requested By Patricia M. Tillery **Date** August 18, 1988

Reviewed By H P Jones **Date** 8/20/88

QAPL Approval H P Jones **Date** 8/20/88

TPO Approval D F Miller **Date** 8/22/88

Effective Date August 22, 1988 **Date** 8/22/88

Enclosure B.4.C

LOS ALAMOS NATIONAL LABORATORY
NNWSI
CHANGE REQUEST

Change Request No. 045

Date 8-18-88

Procedure No. TWS-QAS-QP-04.1 R0 "NNWSI Procurement Procedures"

Change Requested:

Add Section 5.3 Procurement Documentation

All procurements for engineered items and services must be made following the requirements contained in TWS-QAS-QP-04.1. In particular, the QAL will review procurement documents to determine whether the following requirements are met:

- QA requirements are correctly stated,
- there are adequate acceptance and rejection criteria, and
- procurement documents have been prepared, reviewed, and approved by an appropriate technical individual.

If the procurement is for QA Level III or commercial grade, the QAL's signature and date on the PR documents review and concurrence with these requirements (on Attachment 4).

If the procurement is not commercial grade or QA Level III, the QAL's review will be documented using NNWSI Project document review sheets which will become QA records. Concurrence will be documented by the QAL's signature and date on the purchase request form after resolution of all comments on the document review sheets.

Reason for Change:

Response to CAR No. 027 from NRC Mini-audit.

Change Requested By Patricia M Tillery **Date** August 18, 1988

Reviewed By HPJames **Date** 8/20/88

QAPL Approval HPJames **Date** 8/20/88

TPO Approval DTDelligatti **Date** 8/22/88

Effective Date August 23, 1988 **Date** 8/22/88

LOS ALAMOS NATIONAL LABORATORY
NNWSI TRAINING PROGRAM

Class Title: NNWSI Procurement Procedures

Class No.: Q04.1R0 Instructor: A.M. Pendergrass Phone: 662-1755

Date taught: 02/12/88 For 0.5 Hour

Attendee's List

Trainee	Group	Phone
S.Dye	INC-7	667-5487
A.R.Jenkins	MAT-3	665-0872
L.W.Maassen	ESS-1	667-1691
H.P.Nunes	LATA	667-8039
A.M.Pendergrass	LATA	662-1755
D.F.Sterner	LATA	662-9080
P.M.Tillery	LATA	662-1752
M.L.Wheeler	LATA	662-1806

LOS ALAMOS NATIONAL LABORATORY
NNWSI TRAINING PROGRAM

Class Title: NNWSI Procurement Procedures

Class No.: Q04.1R0 Instructor: A.M. Pendergrass Phone: 662-1755

Date taught: 05/05/88 For 1.0 Hour

Attendee's List

Trainee	Group	Phone
K.A.West	N-5	667-1033

LOS ALAMOS NATIONAL LABORATORY
NNWSI TRAINING PROGRAM

Class Title: NNWSI Procurement Procedures

Class No.: Q04.1R0 Instructor: A.M. Pendergrass Phone: 662-1755

Date taught: 05/25/88 For 0.5 Hour

Attendee's List

Trainee	Group	Phone
R.J.Crowley	WX-4	667-7459
D.Hall	WX-4	667-7459
M.R.Martinez	WX-4	667-7378
T.J.Merson	WX-4	667-5726

LOS ALAMOS NATIONAL LABORATORY
NNWSI TRAINING PROGRAM

Class Title: NNWSI Procurement Procedures

Class No.: Q04.1R0 Instructor: A.M. Pendergrass Phone: 662-1755

Date taught: 06/22/88 For 0.5 Hour

Attendee's List

Trainee	Group	Phone
M.H.Ebinger	HSE-12	667-3147
E.H.Essington	HSE-12	667-3057
S.M.Gonzales	HSE-12	667-3331
G.Langhorst	HSE-12	667-3300
G.M.Lopez	HSE-12	667-2426
B.D.Neuman	HSE-12	667-2426
W.L.Polzer	HSE-12	667-3073
E.P.Springer	HSE-12	667-9836
D.A.York	WX-4	667-8458
M.H.Ebinger	HSE-12	667-3147
E.H.Essington	HSE-12	667-3057
S.M.Gonzales	HSE-12	667-3331
G.Langhorst	HSE-12	667-3300
G.M.Lopez	HSE-12	667-2426
B.Neuman	HSE-12	667-2426
W.L.Polzer	HSE-12	667-3073
E.P.Springer	HSE-12	667-9836

Enclosure B.5.a

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Los Alamos

Los Alamos National Laboratory
Los Alamos, New Mexico 87545

memorandum

TO: Distribution

DATE: August 19, 1988

FROM: H. P. Nunes, QAPL

MAIL STOP/TELEPHONE: J521/7-8039

SYMBOL: TWS-N5/08-88-45

SUBJECT: ACCEPTANCE CRITERIA IN DETAILED TECHNICAL PROCEDURES, NRC MINIAUDIT, DEFICIENCY B-6 (CAR NO. 028)

During the NRC miniaudit, the audit team discovered that acceptance criteria, by which it is determined that important activities have been satisfactorily accomplished, had not been included in most detailed technical procedures (DPs). This memorandum is being issued to direct all groups participating in the NNWSI Project to immediately review their DPs to see that acceptance criteria have been included. If acceptance criteria have not been included, please revise the DPs to meet this requirement. Submit a list of procedures to be revised, along with completion dates, by September 9, 1988, or a statement that none needs to be revised.

For specifics on the inclusion of acceptance criteria, please refer to TWS-QAS-QP-5.2, R1, "Preparation of Detailed Technical Procedures." We are required to bring all DPs into compliance by November 30, 1988.

MFM/kkk

Distribution:
S. Dye, INC-7, MS J514
K. G. Eggert, ESS-5, MS F665
E. H. Essington, HSE-12, MS J495
H. R. Fuentes, HSE-12, MS J495
J. J. George, LATA, MS M321
L. E. Hersman, LS-3, MS M890
L. W. Maassen, ESS-1, MS D462
G. Ortiz, N-5, MS J521
B. A. Robinson, ESS-4, MS J981
B. J. Skaggs, HSE-5, MS K494
E. H. Springer, HSE-12, MS J495
QAS file, MS M321
RPC (3), MS J521

Cy: D. T. Oakley, N-5, MS J521

Los Alamos
NATIONAL LABORATORY

PREPARATION OF
DETAILED TECHNICAL PROCEDURES
TWS-QAS-QP-05.2, R0

NNWSI
QUALITY ASSURANCE PROGRAM TRAINING

PREPARATION OF A DETAILED TECHNICAL PROCEDURE
TRG / QPS-QP-05.2, R0

INDEX OF VIEWGRAPHS

VG-00 LEAD-IN
VG-01 PURPOSE
VG-02 SCOPE
VG-03 PRINCIPLES
VG-04 DEFINITIONS
VG-05 RESPONSIBILITIES
VG-06 ALPHANUMERIC IDENTIFIER ASSIGNMENT
VG-07 TITLE PAGE
VG-08 PROCEDURE
VG-09 CONCLUDED
VG-10 QUALITY ASSURANCE REQUIREMENTS
VG-11 PAGINATION
VG-12 REVIEW PROCESS
VG-13 QUALITY ASSURANCE REQUIREMENTS
VG-14 DOCUMENT REVIEW SHEET

PURPOSE

TO STATE THE REQUIREMENTS FOR

- WRITING,
- APPROVING, AND
- REVISING

DETAILED TECHNICAL PROCEDURES (DPs)

SCOPE

THIS QP APPLIES TO THE WRITING OF ALL DPs IN SUPPORT OF LANL RESEARCH ACTIVITIES FOR THE NNWSI PROJECT.

PRINCIPLES

- THIS SECTION COULD INCLUDE AN OVERVIEW OF THE ACTIVITY AND THE RELATIONSHIP OF THE DP TO THE SCIENTIFIC INVESTIGATION INVOLVED.

- IF NOT OF PARTICULAR USE, THIS SECTION WILL BE LABELED N/A.

DEFINITIONS

DPs DEFINE TECHNICAL REQUIREMENTS, CONSTRAINTS, AND PROCEDURAL STEPS OF REPETITIVE SCIENTIFIC ACTIVITIES.

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RESPONSIBILITIES

- TPO HAS FINAL APPROVAL AUTHORITY FOR EACH DP.
- QAS ASSIGNS A BLOCK OF NUMBERS FOR EACH LANL PARTICIPATING GROUP AND MAKES CONTROLLED DISTRIBUTION OF DPs.
- QAPL REVIEWS AND APPROVES COMPLETED DPs.
- PRINCIPAL INVESTIGATOR (PI) IS RESPONSIBLE FOR DPs AND INITIATES CHANGE REQUESTS (CR) FOR REVISIONS TO DPs.
- DP PREPARER FOLLOWS THE QP, IS RESPONSIBLE FOR TRAINING TO DPs WRITTEN, AND INITIATES CRs FOR DEFICIENCIES NOTED.
- DP USERS ADHERE TO DP AND NOTIFY PI OR PROJECT LEADER OF INADEQUACIES OR NECESSARY REVISIONS.

ALPHANUMERIC IDENTIFIER ASSIGNMENT

QAL WILL ASSIGN AN IDENTIFIER SUCH AS

TWS-INC-DP-99, R0, WHERE

- TWS SIGNIFIES NNWSI,
- INC IDENTIFIES THE LANL GROUP,
- DP IDENTIFIES DOCUMENT AS A DETAILED TECHNICAL PROCEDURE,
- 99 IS THE PROCEDURE NUMBER ASSIGNED BY THE QAL FROM A BLOCK ISSUED BY THE QAS, AND
- R0 IS THE REVISION NUMBER.

TITLE PAGE

- ALPHANUMERIC IDENTIFIER IN THE UPPER RIGHT CORNER
- PROCEDURE TITLE
- SPACE FOR DATE SIGNED BY TPO
- SPACES FOR SIGNATURES OF THE
  - PREPARER,
  - REVIEWER(S),
  - QAPL, AND
  - TPO

    (NAME OF PERSON AND TITLE TYPED UNDER EACH SIGNATURE SPACE).

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PROCEDURE

- PURPOSE EXPLAINS WHAT THE DP IS DESIGNED TO DO.
- SCOPE DEFINES THE EXTENT OF THE APPLICATION OF THE DP.
- PRINCIPLE EXPLAINS HOW THE DP RELATES TO THE SCIENTIFIC INVESTIGATION.
- DEFINITIONS, WHERE NECESSARY, AVOID AMBIGUITY.
- RESPONSIBILITIES DESIGNATE WHO (GIVE SPECIFIC TITLE) IS ACCOUNTABLE FOR IMPLEMENTING THE VARIOUS REQUIREMENTS.
- IN THE PROCEDURE, A DP WILL ADDRESS THE FOLLOWING ITEMS IN THEIR APPROPRIATE SEQUENCE:
  - EQUIPMENT BEING USED;
  - RELEVANT ENVIRONMENTAL CONDITIONS;
  - VERIFICATION THAT CRITICAL PREREQUISITES HAVE BEEN COMPLETED;
  - DEFINITIONS OF THE PARAMETERS TO BE RECORDED, METHOD OF DATA DOCUMENTATION, AND CRITERIA FOR ACCEPTANCE OF DATA;

PROCEDURE

(CONCLUDED)

- INSTRUCTIONS FOR SAMPLE / SITE TRACEABILITY;
- THE COMPUTER HARDWARE AND SOFTWARE THAT WILL BE USED;
- WRITTEN INSTRUCTIONS FOR INSPECTION;
- DEFINITIONS OF MATHEMATICAL OPERATIONS THAT WILL BE PERFORMED; AND
- A LIST OF APPLICABLE REFERENCE DOCUMENTS.

- IF A DEFICIENCY IS OBSERVED IN A DP, THE USER MAY CONTINUE TO USE THE DP AFTER NOTIFICATION OF THE PREPARER OR PI. WHILE THE CR IS IN PROCESS, THE PROCEDURE CHANGE SHALL BE DOCUMENTED BY THE DP USER IN THE LABORATORY NOTEBOOK OR LOGBOOK WITH EACH USE OF THE DP.

QUALITY ASSURANCE REQUIREMENTS OF DPs

INCLUDE ANY CONSIDERATIONS OF UNIQUE QUALITY REQUIREMENTS. AT A MINIMUM, THE FOLLOWING SHOULD BE INCLUDED:

- HANDLING, SHIPPING, AND STORAGE REQUIREMENTS IN ACCORDANCE WITH QP 13.1;
- RECORDS;
- DOCUMENT CONTROL;
- TRAINING TO USE THE DP (THE PREPARER AND TECHNICAL REVIEWER OF THE DP ARE CERTIFIED IN ITS USE);
- REFERENCE DOCUMENTS; AND
- SUPPLEMENTARY MATERIAL THAT GIVES USEFUL INFORMATION.

PAGINATION

THE DP SHALL BE PAGINATED AS SHOWN IN QP-05.2, INCLUDING PROCEDURE APLHANUMERIC IDENTIFIER AND THE PAGE NUMBER.

REVIEW PROCESS

- THE DRAFT DP SHALL BE SUBMITTED FOR INDEPENDENT TECHNICAL REVIEW.
- THE REVIEW PROCESS SHALL BE DOCUMENTED BY MEANS OF THE DOCUMENT REVIEW SHEET, VIEWGRAPH VG-14.
- ANY REQUIRED REVIEWS AND APPROVALS SHALL BE STIPULATED AS THEY PERTAIN TO SAFETY AND HEALTH PHYSICS.

QUALITY ASSURANCE REQUIREMENTS OF QP 05.2

- HANDLING, SHIPPING, AND STORAGE REQUIREMENTS
  - HANDLING, SHIPPING, AND STORAGE REQUIREMENTS MUST MEET THE REQUIREMENTS AS SPECIFIED IN QP-13.1, R0.
- RECORDS
  - TWS-QAS-QP-05.2, R0 IS THE RECORD GENERATED BY THIS PROCEDURE.
- DOCUMENT CONTROL
  - THIS QP BECOMES A PART OF THE LANL QAM, ISSUED AND CONTROLLED IN ACCORDANCE WITH LANL DOCUMENT CONTROL PROCEDURES.

LANL

DOCUMENT REVIEW SHEET

PROJECT: _____

DOCUMENT No.: _____ REVISION _____ DATE _____

DOCUMENT TITLE: _____

DATE RECEIVED: _____ COMMENTS REQUIRED DATE: _____

REVIEWED BY: _____ GROUP _____ MS _____

COMMENT SHEET FORWARDED TO: _____ ON _____

COMMENTS RESOLVED BY: _____ ON _____

REVIEWER'S COMMENTS			RESOLUTION		
ITEM No.	LOCATION: PAGE, PARAGRAPH, LINE	COMMENTS	ACCEPT	REJECT	REASON

Los Alamos

LOS ALAMOS NATIONAL LABORATORY
NNWSI
CHANGE REQUEST

Change Request No. 043

Date 8-18-88

Procedure No. TWS-MSTQA-QP-14.R1

Change Requested: In section 3.1.1

1. After ". Equipment and material to be used," add "When referencing the equipment used use the property number (preferable) or the serial number. Equipment and materials should be identified to an extent that the identification will allow others to identify the equipment used."

2. Under "Daily Entries... . Sample... identification..." delete "and history... experimentor's possession."

Reason for Change:

In response to the NRC-Mini Audit, auditors and principal investigators had difficulty in understanding what information was actually being requested.

Response to CAR No. 029 from NRC Mini-audit.

Change Requested By Patricia McKinney **Date** 8/19/88

Reviewed By J P James **Date** 8/20/88

QAPL Approval J P James **Date** 8/20/88

TPO Approval J P Roll **Date** 8/22/88

Effective Date August 22, 1988 **Date** 8/22/88

Los Alamos
Los Alamos National Laboratory
Los Alamos, New Mexico 87545

memorandum

TO: Distribution

DATE: August 29, 1988

FROM: H. P. Nunes, QAPL

MAIL STOP/TELEPHONE: J521/7-8039

SYMBOL: TWS-N5/08-88-73

SUBJECT: TRAINING-CHANGE TO TWS-MSTQA-QP-14, R1 "RESEARCH AND DEVELOPMENT (EXPERIMENTAL) PROCEDURE," CR 043

Enclosed for your signature is a training receipt acknowledgment form. Please return the signed form within 10 working days of receiving this memo to indicate that you have read the change in wording and understand how items of equipment must be identified in the research notebook. Also enclosed is a copy of CR 043.

If you have any questions, please call me at 667-8039 or Jim George at LATA, 662-1753.

KLF/kkk

Attachments: a/s

Distribution:

P. L. Aamodt, ESS-1, MS D462
M. J. Aldrich, ESS-1, MS D462
W. S. Baldridge, ESS-1, MS D462
J. A. Barber, ESS-1, MS D462
D. W. Barr, INC-DO, MS J515
S. Barr, ESS-5, MS F665
R. J. Beckman, A-1, MS F600
K. Birdsell, ESS-5, MS F665
S. Birdsell, ESS-4, MS J981
D. L. Bish, ESS-1, MS D462
S. Bolivar, ESS-1, MS D462
D. E. Broxton, ESS-1, MS D462
E. A. Bryant, INC-7, MS J514
E. J. Bustos, MAT-11, MS P274
F. Byers, ESS-1, MS D462
(Distribution continued on reverse side)

Training Receipt Acknowledgment
August 29, 1988

Return To: K. L. Foster
Los Alamos National Laboratory
LATA QAS, MS M321
Los Alamos, NM 87545

Name: _____
Please Print

SUBJECT: CR 043 ON IDENTIFICATION OF ITEMS OF EQUIPMENT, CHANGE TO QP-14, R1

Research and development (experimental) procedures are documented in the research notebook according to requirements specified in TWS-MSTQA-QP-14, R1. One of the requirements is to identify equipment and material to be used. Change Request (CR) 043 specifies that equipment be identified by property number or serial number where possible and that equipment and materials be identified to an extent that others are able to identify the equipment used. The CR also deletes the requirement to document sample history as a daily entry.

I have read CR 043. I understand the requirement that equipment and material must be adequately identified and that sample history is not a daily entry requirement.

_____ _____
Signature Date

LOS ALAMOS NATIONAL LABORATORY
NNWSI
CHANGE REQUEST

Change Request No. 051

Date 8-22-88

Procedure No. TWS-OAS-OP-05.2, R0, "Preparation of a Detailed Technical Procedure"

Change Requested: Add the following definitions:

4.2 Independent

For a technical review to be independent, it must be conducted by qualified personnel outside the WBS under which the work had been performed, or it must be conducted by personnel not directly involved in the particular activity that produced the work, document, or procedure.

4.3 State of the Art

Refers to a technique, approach, or equipment used in scientific investigations that is not yet widely documented or widely used by scientists working in the discipline but that is expected to produce better results than older techniques, approaches, or equipment.

Insert:

6.5 "independent" before "technical review" in the first sentence.

Reason for Change:

Response to CAR No. 030, R1, from the NRC miniaudit.

Change Requested By Patricia M Tillery **Date** Aug 29, 1988

Reviewed By [signature] **Date** 8.29.88

QAPL Approval [signature] **Date** 8.29.88

TPO Approval [signature] **Date** 8/30/88

Effective Date August 30, 1988 **Date**

Enclosure B.7.b

13.

Los Alamos
Los Alamos National Laboratory
Los Alamos, New Mexico 87545

August 18, 1988

TWS-N5/08-88-50

Multiple Addressees:

SUBJECT: INDEPENDENT REVIEW OF TECHNICAL PROCEDURES NRC MINIAUDIT DEFICIENCY B-8

To resolve the deficiency identified during the NRC miniaudit involving DPs prepared by supervisors and reviewed by subordinates, all DPs reviewed in this manner must be reviewed again. The QAL for each group must prepare a list of all affected procedures, which, in turn, will be technically reviewed where appropriate (reference Appendix A of the QAPP, R2, Technical Review definition).

Your response is due by September 16, 1988. If you have any questions, please call me at 667-8039.

JJG/meg

Sincerely,

H. P. Nunes

Multiple addressees:
K. Campbell, A-1, MS F600
S. Dye, INC-7, MS J514
K. G. Eggert, ESS-5, MS F665
E. H. Essington, HSE-12, MS J495
H. R. Fuentes, U of T, El Paso, TX
A. L. Gauler, MEC-8, MS D474
L. E. Hersman, LS-2, MS M890
A. R. Jenkins, MAT-3, MS P274
L. W. Maassen, ESS-1, MS D462
H. Nitsche, LBL, Berkeley, CA
F. Perry, UNM, Albuquerque, NM
B. A. Robinson, ESS-4, MS J981
B. J. Skaggs, HSE-5, MS K494
P. M. Tillery, LATA, MS M321
CRM-4, (2) w/o att., MS A150
QAS file, MS M321
RPC (3), MS J521

Cy: D. T. Oakley, N-5, MS J521

LOS ALAMOS NATIONAL LABORATORY
NNWSI
CHANGE REQUEST

Change Request No. 047

Date 8-19-88

Procedure No. TWS-QAS-QP-04.3 R0

Change Requested:

Add to last of Paragraph 4.3:

The QAPL or his delegate shall review the Approved Vendors List (AVL) annually to determine which suppliers should be re-evaluated. The need for re-evaluation shall be based on the relative importance, complexity, and quality of the item or service procured, as well as on the supplier's performance as measured by audits and surveillances. The QAPL or delegate shall record this evaluation by issuing a list of suppliers requiring re-evaluation.

The results of evaluations and re-evaluations shall be recorded and shall become a QA record.

Reason for Change:

Response to CAR No. 033 from NRC mini-audit

Change Requested By Patricia M Tillery **Date** 8/19/88

Reviewed By HP Nunes **Date** 8/20/88

QAPL Approval HP Nunes **Date** 8/20/88

TPO Approval J R Dalla **Date** 8/22/88

Effective Date Aug. 22, 1988 **Date** 8/22/88

LOS ALAMOS NATIONAL LABORATORY
NNWSI
CHANGE REQUEST

Change Request No. 046

Date 8-26-88

Procedure No. TWS-QAS-QP-04.1 R0, "NNWSI Procurement Procedures"

Change Requested:

Renumber the present Section 6.1.6 as 6.1.7

Add: 6.1.6 Documents Generated by Suppliers

Any form, content, and submission requirements that apply to documents generated by suppliers are stipulated in procurement documents. After being received by the requestor, these documents become a part of the LANL NNWSI Project records. Documents generated under a service procurement are evaluated following procedures described in TWS-QAS-QP-04.2 and are controlled following the administrative procedure on document control. Analysis sheets and certificates of calibration are placed in the group resident file. Single analysis sheets may be attached in scientific notebooks at the discretion of the requestor.

Reason for Change:

Response to CAR No. 034, REV. 1 from NRC miniaudit.

Change Requested By [signature] **Date** August 29, 1988

Reviewed By [signature] **Date** 8.29.88

QAPL Approval [signature] **Date** 8.29.88

TPO Approval [signature] **Date** 9/30/88

Effective Date August 30, 1988 **Date**

Enclosure B.13.a

INTERNAL/EXTERNAL
FY-1988

LANL NNWSI AUDIT SCHEDULE

Audit Date	Organization		Activity
11-87	INC-7/11	I	Isotope and Nuclear Chem & Volcanism Dynamic Transport Process
12-87	WMPO to Audit LANL		INC-7 and HSE-12
1-88	UNM-GEO	E	Mineralogy/Petrology
2-88	ESS-1 (WX-4)	I	Mineralogy/Petrology/ESF
2-88	UTEP	E	Support Study for HSE-12 (Computer Modeling)
3-88	EG&G	E	IDS
4-88	HSE-12 (CLS-1)	I	Reactive Tracer Tests in C-Wells
5-88	Hydrogeochem	E	Support Study for Solubility Determination
5-88	LS-3	I	Biological Sorption and Transport
6-88	HSE-5	I	Prototype Air-Coring
7-88	ESS-4/5	I	Retardation Sensitivity Analysis
8-88	LBL (INC)	E	Support Study for Solubility Determination
9-88	WMPO to Audit LANL		

March 7, 1988 4:17 PM
02 SP/TXT LS86383 (G01)

E - External Audit
I - Internal Audit

LANL NNWSI SURVEY SCHEDULE
FY 1988

Date	Organization	Subject
10-87	HSE-5, ESS-1, HSE-12 (CLS-1)	Work in progress & applicable basic requirements
11-87	ESS-5, LS-3, ESS-1 (WX-4)	Work in progress & applicable basic requirements
1-88	ESS-4, INC-7, INC-11	Work in progress & applicable basic requirements
2-88	HSE-5, ESS-1, HSE-12	Work in progress & applicable basic requirements
3-88	ESS-5, LS-3, ESS-1 (WX-4)	Work in progress & applicable basic requirements
4-88	ESS-4, INC-7, INC-11	Work in progress & applicable basic requirements
5-88	HSE-5, ESS-1, HSE-12	Work in progress & applicable basic requirements
7-88	ESS-5, LS-3, ESS-1 (WX-4)	Work in progress & applicable basic requirements
8-88	HSE-5, ESS-1, HSE-12	Work in progress & applicable basic requirements
9-88	ESS-4, INC-7, INC-11	Work in progress & applicable basic requirements

NNWSI QUALITY ASSURANCE AUDITS

Effective _____

_____	_____
M. F. McGowan **Preparer**	**Date**
_____	_____
H. P. Nunes **QA Project Leader**	**Date**
_____	_____
D. T. Oakley **Technical Project Officer**	**Date**

NNWSI QUALITY ASSURANCE AUDITS

1.0 PURPOSE

This quality administrative procedure (QP) defines the auditing functions of the Los Alamos National Laboratory (LANL) Nevada Nuclear Waste Storage Investigations (NNWSI) Project. This QP states the requirements for establishing an audit program, for conducting audits, and for tracking follow-up activities of audit findings. The purpose of audits is to ensure LANL management and the Waste Management Project Office (WMPO) that the Quality Assurance Program Plan (QAPP) is implemented satisfactorily.

2.0 SCOPE

This QP applies to all Quality Assurance (QA) Levels I and II work performed by LANL and LANL suppliers in support of the NNWSI Project. Each LANL participating group and external supplier will be audited annually. Internal and external QA audits will be scheduled in a manner that will provide coverage and coordination with ongoing program activities.

3.0 DEFINITIONS

3.1 Audit

An audit is a planned and documented activity performed through investigation, examination, or evaluation of objective evidence to determine the effectiveness of the QA program. Internal audits directly involve LANL groups or Work Breakdown Structure (WBS) elements. External audits involve organizations that provide supplies and services to LANL groups.

3.2 Audit Plan

An audit plan is a formal statement of the scope of work to be covered by the audit. The audit plan includes a listing of the personnel assigned to perform the audit, the audit schedule, and any designated document to be used.

3.3 Audit Program

The audit program outlines which LANL internal and external organizations will be audited and when those audits will take place.

3.4 Audit Schedule

The audit schedule is the detailed timetable for the activities that will take place during a specific audit.

3.5 Audit Scope

The audit scope is a formal statement of the program elements or activities that are to be covered by the audit team.

3.6 Audit Team

An audit team consists of a group of individuals who will conduct an audit. The audit team has a general understanding of the programmatic and technical areas being audited. The audit team must include a lead auditor and may include auditors, auditors in training, audit observers, and technical observers. More than one audit team may be involved in an audit.

3.7 Corrective Action

Corrective action includes measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition of such conditions.

3.8 Deficiency

A deficiency is a condition adverse to quality, including failures, malfunctions, defective items, and nonconformances. A significant condition adverse to quality is one that, if left uncorrected, could have a serious effect on the validity of the data or computer model.

3.9 Finding

A finding is the recognition by the audit team of a deficiency in characteristics, documentation, or procedures that renders the quality of an item or activity unacceptable or indeterminate.

3.10 Finding Report

The Finding Report is the documentation of a finding discovered during an audit and its subsequent correction (i.e., the subsequent corrective actions undertaken to resolve the finding). The Finding Report contains the requirement and deficiency that resulted in the finding, the response by the audited organization, and verification that the finding has been corrected.

3.11 Objective Evidence

Objective evidence includes any documented statement of fact; other information; or record, either quantitative or qualitative, that pertains to the quality of an item or activity. Objective evidence is based on observations, measurements, or tests that can be verified.

3.12 Observation

An observation is the recognition by the audit team of a weakness in a QA program that, if left uncorrected, could result in a condition adverse to quality.

3.13 Observation Report

The Observation Report is the documentation made by the audit team of an observation made in the course of an audit.

3.14 Root Cause

Root cause is the determination of the basic reason for a deficiency.

3.15 Supplier

A supplier is any individual or organization under contract to provide items or services for NNWSI Project activities to either WMPO, a participating organization, or a Nevada Test Site Support Contractor such as LANL.

4.0 RESPONSIBILITIES

4.1 Audit Observer

The audit observer is not an active participant in the audit process but may be involved with any audit to observe how the audit is conducted or to become familiar with the audited organization and its activities.

4.2 Audit Team Contact

The audit team contact is a person from the audited organization selected to escort the audit team.

4.3 Audited Organization

The audited organization will provide an audit team contact and arrange for the meeting and caucus areas during the audit.

4.4 Auditor

An auditor is a member of the audit team who performs the activities of an audit. Auditor activities can include functions related to the lead auditor, auditor, and technical observer.

4.5 Lead Auditor

The lead auditor is responsible for planning, directing, and reporting the audit and for tracking follow-up activities, as required. This individual will oversee the development of the audit checklist (Attachment 1). In addition, the lead auditor will conduct the team conferences and the preaudit and postaudit meetings.

The lead auditor assembles and orients the audit team members. Certification of lead auditors is addressed in TWS-QAS-QP-02.1, "NNWSI Personnel Selection, Certification, and Training."

4.6 Quality Assurance Liaison

The cognizant Quality Assurance Liaison (QAL) will support the audited organization in responding to auditors' requests and in determining the corrective actions needed to rectify audit findings and/or observations.

4.7 Quality Assurance Project Leader

The Quality Assurance Project Leader (QAPL) will assist in preparing the audit program, recommend (when requested and in writing) qualified technical observers for the audits, and ensure that corrective actions to audit findings are implemented.

4.8 Quality Assurance Support

The QAS develops and implements an audit program to include at least one annual audit of each participating group (or WBS element). The QAS will develop audit schedules and plans and will execute the audit program for all LANL groups. The QAS may develop special QA audit programs and/or audit plans for external audits. This development and maintenance may be done on a "case-by-case" basis in coordination with the requestor, the QAPL, and the appropriate QAL for the particular supplier.

4.9 Technical Observer

The technical observer will be familiar with, or have reviewed, the technical procedures to be audited and will serve as an advisor to the audit team on technical matters. This individual will participate in audit preparation activities and in the audit.

4.10 Technical Project Officer

The Technical Project Officer (TPO) will review and approve the audit program to ensure that the review objectives of the program management are met by the audit program.

5.0 PROCEDURE

5.1 Audit Program

Through consultation between the QAPL and QAS, an audit program will be developed and documented on a yearly basis. The audit program will be submitted to the TPO for approval. Audits for participating LANL groups and subcontractors will be scheduled annually. These audits will be arranged and initiated in a timely manner to ensure an effective QA program. An evaluation of the audit program will be conducted periodically to maintain current coverage. Revisions to the program will be documented. The evaluation of the effectiveness of the audit program will include a review of

- previous audits and corrective actions,
- nonconformance reports, and
- information from other sources, such as the Nuclear Regulatory Commission.

Supplemental audits may be required to provide adequate coverage and will be conducted

- when significant changes are made in functional areas of the QA program, such as significant reorganization or revisions to procedures;
- when the quality of an item or service is suspected to be in jeopardy because of deficiencies in the QA program;
- when assessment of the program effectiveness is considered desirable; or
- after the award of a contract if sufficient time has elapsed for implementing the QA program to determine its effective implementation.

Random surveys are conducted as needed to augment the audit program.

5.2 Audit Preparation

Audit preparation revolves around the formulation of the audit plan. The audit plan includes the scope, the schedule, and the selection of the audit team.

The audit plan is prepared by the lead auditor in consultation with the QAL and QAPL. If an external audit is being planned, the cognizant buyer at the Materials Management (MAT) Division will be notified. The QAS will notify the audited organization of the audit plan through an audit notification letter. The plan should provide sufficient information so that the audited organization will be able to identify personnel, procedures, and equipment available for the audit.

5.2.1 Scope

The audit scope will be designed by the lead auditor to evaluate adherence to all QAPP requirements as applicable to the scope of work in progress. The audit scope will be developed by the QAS in consultation with and approval by the QAPL. Any QAPP element not specifically applicable to the work in progress may be waived for the purpose of the audit. This decision will be documented in the Audit Report.

The scope of the audit will consider

- applicable documents and procedures,
- results of previous audits and surveys,
- the nature and frequency of identified deficiencies,
- significant changes in personnel or the organization,
- the work in progress, and/or
- applicable requirements.

5.2.2 Audit Schedules

The audit schedules will be initially discussed with the cognizant management of the audited organization before the audit notification letters are issued. These schedules will provide the audited organization with the dates and times of personnel interviews and preaudit and postaudit meetings.

5.2.3 Selection of the Audit Team

The QAS selects auditors who are not directly responsible for performing activities that will be audited. Audit personnel will have sufficient authority and organizational freedom to make audits meaningful and effective. The audit team will be identified before the audit and will be listed in the audit notification letter. The lead auditor will be the audit team leader; this individual will select technical observers and will ensure that the team is prepared for the audit. Audit team members will have the appropriate technical expertise and QA background to conduct the audit. Technical observers will be selected for audits involving technical work.

5.2.4 Audit Notification Letter

An audit notification letter will be sent to the audited organization at least 30 calendar days before the audit. The letter includes a confirmation of the audit dates; it also includes requests that all appropriate personnel are notified of the audit dates and that rooms are reserved for audit team caucuses and the preaudit and postaudit meetings.

5.3 Team Conferences

The auditing organization will conduct a series of preaudit team conferences to meet with and orient audit team members. This meeting should be led by the lead auditor. At the preaudit conference, audit team members will

receive their assignments for preparing checklists, which will be used as guidelines for conducting the audit. Checklists will facilitate the examination of the objective evidence that will determine if aspects of the audit scope are adequate for effective controls and whether or not the QA program has been implemented effectively. At these meetings, the lead auditor will ensure that the auditors understand the audit plan and checklists. The QAS staff will have reviewed the checklists before the preaudit meeting.

5.4 Audit Performance

5.4.1 Preaudit Meeting

The lead auditor conducts the audit. At the preaudit meeting of the audit, the lead auditor will introduce the audit team to the audited organization, review the schedule, and coordinate the interview process with the audited organization's personnel. The lead auditor will explain how the audit will proceed. An Audit Record of Attendance (Attachment 2) form will be circulated at this meeting. Personnel attending this meeting will be reminded of the postaudit meeting.

5.4.2 Interview Process

The audit team, with assistance from the audit team contact, will locate the audited organization's personnel with whom the auditors are scheduled to interview. Using the checklists, auditors will interview personnel, observe procedures, and verify documented evidence that substantiates an effective QA program. Auditors will document their investigations and observations on the audit checklist. Proper audit conduct and professionalism is expected of all audit team members.

5.4.3 Audit Team Caucuses

The audit team may have to confer and discuss potential deficiencies at the end of the day. These discussions are called caucuses. If

conditions require prompt corrective action, the management of the audited organization will be asked to attend these caucuses to receive reports.

5.4.4 Postaudit Meeting

A postaudit meeting will be conducted by the lead auditor. At this meeting, a review of the findings and observations of the audit team will be held. Drafts of Finding Reports and Observation Reports will be made available to the responsible management and individuals of the audited organization. Questions should be encouraged. An attendance record will also be circulated at this meeting.

5.5 Audit Report

The lead auditor, with assistance from the audit team, will prepare a formal, written Audit Report. The report will include the identification, purpose, and scope of the audit; names of the auditors and contacts; a description of audit findings or observations sufficiently detailed to enable the implementation of corrective action; the effectiveness of the activities audited; conclusions and recommendations of the audit team; an executive summary of the results; and the signature of the lead auditor. The Audit Report will be approved by the QAPL.

Findings will be recorded in a Finding Report (Attachment 3). Observations will be recorded in an Observation Report (Attachment 4). Unusual occurrences will be reported in the Finding Report.

Within 30 calendar days after the postaudit meeting, the QAS or lead auditor will issue the original Audit Report and any Finding Report or Observation Report to the audited organization's responsible management and QAL, the TPO, and the QAPL. A copy of each document will be retained by the QAS.

5.6 Audit Response

5.6.1 Response by the Audited Organization

The QAL, in conjunction with the audited organization, will determine the corrective actions that need to be made as a result of the audit findings and observations. The root cause of any finding will be determined and its corrective action will be stated to prevent recurrence. An implementation schedule will be established as a part of the response. These proposed corrective actions will be recorded in the Finding Report that will be returned to the QAS within 30 calendar days of receipt of the report. The Finding Report will be implemented as soon as practical and within the time specified in the response.

5.6.2 Evaluation

The audit response must be accepted by the lead auditor before its implementation. The lead auditor will evaluate the adequacy of the response as criteria for acceptance.

5.6.3 Follow-Up Activities

The QAPL and QAS are responsible for reviewing and verifying the implementation of corrective actions as described in the Finding Report. The review will evaluate the effectiveness of corrective actions and will assess the need for revising the QA program. After the corrective action has been implemented, the original Finding Report and any Observation Report will be signed by the audited organization's responsible management and will be returned to the QAS.

Audit results will be analyzed by the QAS to identify trends in quality assurance. The results of this analysis are reported to the QAPL for review and appropriate action.

6.0 QUALITY ASSURANCE REQUIREMENTS

6.1 Records

The following records will be generated by using this procedure:

- audit plans,
- audit schedules,
- Audit Record of Attendance forms,
- audit checklists,
- Finding Reports,
- Observation Reports,
- Audit Reports,
- written responses to the Audit Reports,
- verification of the completion of corrective actions, and
- the status of audit findings.

6.2 Document Control

6.2.1 The QAS will send copies of audit plans, Audit Reports, and deficiency documents to the audited organizations, the QAPL, the TPO, and the Records Processing Center. The QAS will maintain the official audit files.

6.2.2 The QAPL will send copies of external and internal audit schedules, including revisions, external Audit Reports, and close-out notifications to the WMPO and the WMPO QA.

6.2.3 This QP is distributed and maintained according to LANL NNWSI document control procedures.

6.3 Audit Personnel Certification

All audit personnel are certified according to TWS-QAS-QP-02.1, R0, "NNWSI Personnel Selection, Certification, and Training." The certification

requirements for lead auditors and auditors are specifically addressed in Appendix E of the QAPP.

7.0 REFERENCES

NNWSI/88-9
LANL NNWSI QAPP
NNWSI Personnel Selection, Certification, and Training
Document Control Procedures

8.0 ATTACHMENTS

Attachment 1 - Audit Checklist
Attachment 2 - Audit Record of Attendance
Attachment 3 - Finding Report
Attachment 4 - Observation Report

AUDIT CHECKLIST

NNWSI ORGANIZATION _____ DATE _____

AUDIT NO. _____ PAGE _____ OF _____

Number	Description	Reference	Criteria					
			PR #	STAMP	QALA	QAL REVIEW	SIGNATURE	Observations
			1.					
			2.					
			3.					
			4.					
			5.					
			6.					
			7.					
			8.					
			9.					
			10.					
			11.					
			12.					
			13.					
			14.					

PERSONNEL CONTACTED _____

_____

_____

AUDITOR _____ DATE _____

June 13, 1988 9:20 AM
QS SP/QP 18.1 1506101 (G01)

LOS ALAMOS NATIONAL LABORATORY
AUDIT RECORD OF ATTENDANCE

AUDIT NO.: _____

AUDIT DATE: _____

PREAUDIT MEETING

POSTAUDIT MEETING

NAME	ORGANIZATION	TELEPHONE / EXTENSION

Page 1 of 2

Los Alamos
N-5, MS J521
Los Alamos National Laboratory
Los Alamos, New Mexico 87545

LOS ALAMOS NNWSI QUALITY ASSURANCE FINDING REPORT

FINDING SECTION: (TO BE FILLED OUT BY AUDITOR)

AUDITED ORGANIZATION: _____

AUDIT No.: _____ FINDING No.: _____ AUDIT DATE(S): _____

LEAD AUDITOR: _____ REPORT DATE: _____

AUDITORS: _____ _____

_____ _____

UNUSUAL OCCURRENCE REPORT REQUIRED? ☐ YES ☐ NO (DOE ORDER 5000.3)

REQUIREMENT:

DEFICIENCY:

_____ _____
LEAD AUDITOR DATE

FINDING CORRECTION HAS BEEN VERIFIED BY:

SURVEY No.: _____ REAUDIT No.: _____ LEAD AUDITOR: _____
INITIALS

COMMENTS:

_____ _____
LEAD AUDITOR OR DESIGNEE DATE

June 13, 1988 8:47 AM
18 FRM LS06503 (G01)

Los Alamos
N-5, MS J521
Los Alamos National Laboratory
Los Alamos, New Mexico 87545

LOS ALAMOS NNWSI QUALITY ASSURANCE FINDING REPORT

RESPONSE SECTION: (TO BE FILLED OUT BY THE AUDITED ORGANIZATION; ATTACH ADDITIONAL NUMBERED PAGES WHEN NECESSARY.)

1. THE ROOT CAUSE(S) OF THIS DEFICIENCY IS (ARE):

2. THE STEPS TO BE TAKEN TO CORRECT THIS AUDIT DEFICIENCY ARE:

3. THE DATE BY WHICH THIS CORRECTIVE ACTION WILL BE COMPLETED: _____

4. THE STEPS TO BE TAKEN TO PREVENT RECURRENCE OF THIS DEFICIENCY ARE:

5. THE DATE BY WHICH STEPS TO PREVENT RECURRENCE WILL BE COMPLETED: _____

COMMENTS:

AUDIT RESPONSE ACCEPTANCE:

GROUP LEADER OR PRINCIPAL INVESTIGATOR	LEAD AUDITOR	DATE

LOS ALAMOS NATIONAL LABORATORY
QUALITY ASSURANCE
OBSERVATION REPORT

Audit No.: _____ Date: _____

Audited Organization: _____

Auditors: _____

_____

Observation No.: _____ This observation does not require formal response but should be considered by the audited organization.

Discussion

Technical Management	Date	Lead Auditor	Date

FORM - LANL - QA - 86 - REV. - 6

Enclosure B.13.d

16:

NNWSI PROJECT TRAINING FORM

TITLE: AUDITS, QP-18.1, RØ (DRAFT)

DURATION: 1 1/2 HRS DATE: 5/11/88

INSTRUCTOR: [illegible] ORG: QAS PHONE: 662-1753

ATTENDEES

PRINT NAME	SIGNATURE	GROUP	PHONE
PATRICIA TILLERY	Patricia M Tillery	LATA	662-1752
Grace Hollen	Grace Hollen	LATA	662-1762
ANN PENDERGRASS	Ann Pendergrass	LATA	662-1755
Karen West	Karen A. West	LANL	667-1033
Michael McGowan	Michael F. McGowan	LATA	662-1731

12 FR/M LS06503 (G01)

Enclosure B.13.e

LOS ALAMOS NATIONAL LABORATORY
NNWSI
CHANGE REQUEST

Change Request No. 032

Date May 13, 1988

Procedure No. TWS-QAS-QP-17.R0

Change Requested:

1. 4.1 Start the fourth paragraph with the following sentence: "Random surveys will be performed as needed to augment the audit program."
2. 4.2 Add the following information as the first bulleted phrase: "• All elements of the 18 requirements as listed in the QAPP (however, elements not specifically applicable to the work in progress may be waived for the purpose of the audit, and this decision must be documented in the audit report)."
3. 4.4 Replace the entire section with the following information: "The QAL, in conjunction with the audited organization, shall determine the corrective action, measures taken to prevent recurrence, and the implementation schedule for each corrective action, as a result of any audit findings. (See the audit finding report, CR Attachment 1.) Responses to audit findings must be made and sent to the lead auditor within 30 calendar days of the audit report date. The lead auditor, with the concurrence of the QAPL, must assess the responses for acceptability and shall concur with acceptable responses by signing the appropriate place in the audit finding report and returning it to the management of the audited organization.

   A monthly status report will be issued by the QAS and sent to the affected organizations to report the status of open audit findings."

Reason for Change:

1. To bring this portion of this procedure into compliance with LANL QAPP 18.3.
2. To bring this portion of this procedure into compliance with LANL QAPP 18.2.7.
3. To bring this portion of this procedure into compliance with LANL QAPP 18.2.9.

Change Requested By Henry Paul Dunes Date 6/13/88

Reviewed By Patricia M. Tillery Date 5/13/88

QAPL Approval R. J. Herbst for KAW Date 5/17/88

TPO Approval D. Dobbs Date 5/17/88

Effective Date May 17, 1988 Date 5/17/88

Los Alamos
MS J521
Los Alamos National Laboratory
Los Alamos, New Mexico 87545

LOS ALAMOS NNWSI QUALITY ASSURANCE AUDIT FINDING REPORT

FINDING SECTION: (TO BE FILLED OUT BY AUDITOR)

AUDITED ORGANIZATION: _____

AUDIT No.: _____ **FINDING No.:** _____ **AUDIT DATE(S):** _____

LEAD AUDITOR: _____ **REPORT DATE:** _____

AUDITORS: _____ _____

_____ _____

UNUSUAL OCCURRENCE REPORT REQUIRED? ☐ YES ☐ NO (DOE ORDER 5000.3)

REQUIREMENT:

DEFICIENCY:

_____ _____
LEAD AUDITOR DATE

FINDING CORRECTION HAS BEEN VERIFIED BY:

SURVEY No.: _____ **RE-AUDIT No.:** _____ **LEAD AUDITOR:** _____
INITIALS

COMMENTS:

_____ _____
LEAD AUDITOR DATE

Los Alamos
S, MS J521
Los Alamos National Laboratory
Los Alamos, New Mexico 87545

LOS ALAMOS NNWSI QUALITY ASSURANCE AUDIT FINDING REPORT

RESPONSE SECTION: (TO BE FILLED OUT BY AUDITEE. ATTACH ADDITIONAL NUMBERED PAGES WHEN NECESSARY)

1. THE ROOT CAUSE(S) OF THIS DEFICIENCY IS (ARE):

2. THE STEPS TO BE TAKEN TO CORRECT THIS AUDIT DEFICIENCY ARE:

3. THE DATE BY WHICH THIS CORRECTIVE ACTION WILL BE COMPLETED: _____

4. THE STEPS TO BE TAKEN TO PREVENT RECURRENCE OF THIS DEFICIENCY ARE:

5. THE DATE BY WHICH STEPS TO PREVENT RECURRENCE WILL BE COMPLETED: _____

COMMENTS:

AUDIT RESPONSE ACCEPTANCE:

GROUP LEADER OR PRINCIPAL INVESTIGATOR	LEAD AUDITOR	DATE

Enclosure B.14.9

LOS ALAMOS NATIONAL LABORATORY
NEVADA NUCLEAR WASTE SITE INVESTIGATION

QA SURVEILLANCE REPORT SR-0001

Organization/Location ESS-1 TA-3 Date: 2/12/87

Personnel contacted David Bish, Steve Chipera
w Larry Maassen as QAL

This report results from a walk-through surveillance of the above group for Materials and Testing Equipment to ascertain if equipment used for NNWSI meets the requirements of QP-15.

Property Number		Location	Calibration Date
487066	Siemons X-Ray Diffractometer (DP-24) User calibrates ~4 x/yr to standards - Calibration due date is only a formality and perhaps misleading.	105	11/20/86
706907	Cameca Inst - Spectrometer (part of above)	105	11
716050	Siemons - Att X-Ray Diffractometer (not yet unpackaged)	105	N/A
624829	Mettler Balance (Calibration sticker on back - difficult to access)	105	4/24/87
671322	Thermocouple indicator - (Thermometer to be used to calibrate ovens)	105	9/9/87
707059	Thermolyne Oven User calibrated with thermocouple indicator.	102	N/A
OV35025	Thermolyne Oven User calibrated with thermocouple indicator.	102	N/A
603248	Dupont Denemour - Analyzer Moisture DP is not yet written to detail operation and calibration. User calibrated	102	N/A

Continued on page 2

Patricia M Tillery — April 15 1987
Surveillance by QAS — Date

Larry W. Maassen — 4-16-87
QAL Acknowledgement — Date

Paul Guthals QAPL — 10/9/87

QA SURVEILLANCE REPORT SR# 0006

Organization/Location ESS-1

Personnel contacted L. Maasen, ESS-1 QAL

Description of items and operations reviewed and observed. Include procedure number, item number, and identification:

Review of Audit responses, Audit No. 86-3, Nos. 2, 3 and 4. The following was noted:

a. Finding No. 2, Draft procedure is available. Storage cabinets are locked and area access is controlled. Lab area cleanliness was adequate

b. Finding No 3, The attached memo and Change Request are satisfactory corrective actions.

c. Finding No. 4. The Change Request attached is a satisfactory corrective action.

On the basis of this surveillance, Audit No. 86-3, Findings 2, 3 and 4, are closed

Henry Paul Nunes	9/19/86
Surveillance By QAS	Date
Larry W. Maasen	9/29/86
QAL Acknowledgment	Date
N/A	
QAIM Reviewer	Date
Paul Sanchez, QAL	10/9/87

Enclosure B.16.a

NNWSI INSTRUMENT CALIBRATIONS

Effective Date 1/28/88

P. M. Tillery
QA SUPPORT
P. M. TILLERY

1/27/88
DATE

Paul Guthals
QA PROJECT LEADER
P. R. GUTHALS

1/28/88
DATE

D. T. Oakley
TECHNICAL PROJECT OFFICER
D. T. OAKLEY

1/28/88
DATE

165

NNWSI INSTRUMENT CALIBRATIONS

1.0 PURPOSE

The purpose of this procedure is to establish a calibration system for measuring and test equipment (hereafter referred to as instruments) to ensure that instruments affecting quality are properly identified and calibrated at specific intervals to maintain established accuracy.

2.0 SCOPE

This procedure applies to all instruments used in Quality Assurance (QA) Level I or II activities for the acceptance of material or equipment, the control of processes or tests, or the collection of scientific data or samples for analysis.

When specific instruments are determined by the Principal Investigator (PI) to be exempt from the requirements of this procedure, the PI shall document the specific exemptions and the reasons for these exemptions. These exemptions must be approved by the responsible Quality Assurance Liaison (QAL). The documentation supporting these approved exemptions will be maintained in the group's Resident File, and a copy will be sent to the Quality Assurance Support (QAS).

Also, calibration and control measures are not required for rulers, tape measures, levels, and other such devices if normal commercial grade instruments or equipment provide adequate accuracy.

3.0 DEFINITIONS

3.1 Calibration Group

The calibration group referred to here is the Los Alamos National Laboratory's (LANL) Standards and Calibration Group, which provides National Bureau Standards (NBS) traceable calibration to other LANL groups and maintains the documentation for traceability.

3.2 Service Organization

A service organization is a group internal or external to LANL that is capable of providing calibration using standards and procedures provided or approved by LANL's calibration group.

3.3 Controlled Calibration

Controlled calibration is calibration performed according to written procedures and done at specified intervals to standards that are traceable to nationally recognized standards or natural physical constants. Calibration by the calibration group, service organization, or operator/custodian is controlled calibration. Where no recognized standards exist, the basis for calibration shall be documented in a scientific notebook. These calibration procedures shall be described in detailed technical procedures (DPs) when they are used during activities controlled by DPs or within the DPs for that instrument.

3.4 Commercial Grade Instruments

Commercial grade instruments are rulers, tape measures, levels, and other commercial equipment that provide adequate precision and accuracy.

3.5 QA-Calibration Form

The QA-Calibration Form (Attachment 1) provides records of the identification number and calibration requirements of individual instruments.

The QA-Calibration Form provides notification information to the QAS so that the QAL of the user organization can be notified regarding instruments due to be calibrated each month. For every instrument used in this program, a QA-Calibration Form will be completed and filed with the QAS. Instructions for completing the QA-Calibration Form are included as Attachment 1.

3.6 Calibration Certificate

A calibration certification, which is provided either by the NBS, the instrument's supplier, or calibrating organization, attests to the accuracy of a calibration and specifies the period of validity for that calibration.

3.7 Custodian/Operator

The custodian/operator of a particular instrument is a member of a group internal to LANL who has the sole responsibility within that group to maintain and calibrate that instrument. Calibrations shall be documented in the instrument logbook or TWS project notebook by the operator/custodian.

3.8 Operator Calibration

Operator calibration is any calibration performed routinely by certified personnel and documented in the instrument logbook or TWS project notebook.

Calibration may be performed as a check to verify an instrument's accuracy or may be done to standardize the instrument.

4.0 RESPONSIBILITIES

4.1 Quality Assurance Project Leader

The Quality Assurance Project Leader (QAPL) shall ensure that a master inventory of instruments requiring calibration is maintained.

4.2 Quality Assurance Support Contractor

The QAS shall maintain the master inventory of instruments and shall notify the QAL of the user organization of the required calibration, as applicable. The QAS shall verify that the appropriate calibration labels have been placed on all instruments.

4.3 Principal Investigator

The PI shall ensure that all instruments that are used for QA Level I or II work are calibrated to acceptable traceable standards. The PI shall inform the QAS of all instruments that are to be entered on, or removed from, the master inventory. The PI shall send a copy of each calibration certificate and completed QA-Calibration Form to the QAS.

4.4 Calibration Group

The calibration group, as defined in Subsection 3.1, will provide the requested calibration. The group will follow its internal procedures and record and keep the information on file for future reference. When calibration is completed, a calibration certificate will be given to the individual who requested the calibration.

4.5 Service Organization

The service organization will provide the requested calibration using its internal procedures. The QA-Calibration Form that has been provided by the QAS will be completed by a member of this group and will be returned to the individual who requested the calibration upon completion of the calibration.

4.6 Custodian/Operator

The custodian/operator of a specific instrument is responsible for the maintenance and calibration of that instrument and determines the calibration intervals of that instrument. The custodian/operator shall provide documentation of compliance to calibration procedures by completing the QA-Calibration Form and returning it to the QAS. If the instrument is new to the system it is the responsibility of the PI, through the custodian/operator, to initiate the QA-Calibration Form the first time and then forward the form to the QAS for this one time operation. In addition, the custodian/operator will affix an "Operator Calibrated" label to the instrument.

4.7 Operator

The operator may check or calibrate instruments that require frequent calibration before, during, or after experiments or runs. These instruments may or may not specifically require controlled calibration in order to be calibrated by the operator. In addition, the operator may check and calibrate instruments that do require, by DPs or manufacturer recommendations, regular custodian/operator calibration or other calibration service. The operator will provide documentation of compliance to calibration procedures.

5.0 PROCEDURE

5.1 Calibration Procedures

Calibration procedures may refer to published standard practice or the manufacturer's calibration procedure. If an instrument is custodian/operator or operator calibrated, the calibration method shall be defined in either an NNWSI DP, a laboratory notebook, or a instrument logbook. For instruments calibrated by LANL's calibration group or service organization, the method

shall be defined by that group's procedures. When necessary, the PI shall provide special calibration requirements, the calibration method to be used, and the calibration interval. These procedures will include

- the instrument's nomenclature, manufacturer, and model number and
- clear descriptions of the measurement standards used to calibrate the instrument (if applicable).

5.2 Calibration Intervals

Calibration intervals must be determined before the instrument is used for QA Level I or II work.

For calibrations performed by the calibration group, the calibration intervals are established by that group. Requests for interval changes for instruments calibrated by the calibration group will be granted only in accordance with their internal procedures.

For calibrations performed by service organizations or the custodian/operator, the calibration interval is established in consultation with the PI and QAL. This decision should consider

- the manufacturer's recommendations,
- maximum limitations imposed by government and industry codes or standards,
- the frequency of use,
- the environment of the instrument,
- the inherent design characteristics of the instrument,
- the desired accuracy and/or precision of the instrument, and
- the stability of the instrument.

Interval changes for the calibrations performed by service organizations or the custodian/operator will be made by the PI after review of the above-listed considerations, any extenuating circumstances, and instrument use and history.

5.3 Corrective Action

If the instrument is found to be out of tolerance during calibration, the custodian, operator, and the QAL shall be notified immediately of the inaccuracy. In such a case, a corrective action report is required. Measures shall be taken and documented to determine the validity of measurements made since the last calibration and to determine the acceptability of items, processes, or data that have previously been collected, verified, inspected, or tested using this instrument. In addition, the cause of the instrument inaccuracy will be determined, if practical, and appropriate corrective action shall be implemented.

If any instrument is found to be out of calibration consistently, it shall be repaired or replaced. A calibration shall be performed when the accuracy of the instrument is in question.

5.4 Special Items Requiring Outside Calibration Service

Some items may have calibration requirements that are outside the scope of LANL's calibration group, service organization, or custodian/operator calibrations. In this case, provisions shall be made for outside calibration service. The supplier of the calibration service shall be an approved vendor, and any storing, handling, or shipping of items must be done in accordance with written procedures.

5.5 List of Calibrated Instruments and Recall Notification

A master list of instruments requiring calibration is maintained by the QAS. The QAL shall be notified on a monthly basis of all instruments due for calibration.

If an instrument is not calibrated by its expiration date, the QAL shall remove it from service. It may be returned to use after calibration.

5.6 Handling and Storage of Calibrated Instruments

Instruments shall be handled and stored to maintain instrument integrity and specified accuracy.

5.7 Special Designs

Instruments that are of special design for a particular investigative activity will be designed, developed, and manufactured under the control of the PI or another designated individual. Before use, such instruments shall be calibrated per approved procedures generated from the design requirements. Calibration shall be documented and the information placed in the group Resident File and a copy sent to the QAS.

6.0 QUALITY ASSURANCE REQUIREMENTS

6.1 Calibration Records

A calibration record for each instrument shall be initiated and maintained by the group performing the calibration and shall include the following:

- the instrument's nomenclature, manufacturer, model number, and serial or property number;
- the expected performance tolerance limits of the instrument;
- the nomenclature, manufacturer, model number, and serial or property number of the measurement standards used to calibrate the instrument;
- the owner, custodian, or user group;
- the calibration procedure number and revision;
- the date the instrument was calibrated, the next calibration due date or expiration date;
- data showing the degree of accuracy and/or precision of the instrument before calibration; and
- the calibration technician's signature and date.

A calibration certificate or the QA-Calibration Form shall be sent to the cognizant QAL, and a copy will be maintained in the group's Resident File. The original shall also be sent to the QAS. If a calibration certificate (e.g., from the calibration group) is returned to the QAS without the QA-Calibration Form, the appropriate information will be transferred to the QA-Calibration Form by the QAS and attached to a copy of the calibration certificate in the QAS file.

When an instrument that is not custodian/operator or operator calibrated is initially brought into the system, the QA-Calibration Form shall first be initiated by the PI or by the calibrator after an instrument has been calibrated. This form shall be sent to the QAS, and a copy will be maintained in the group's Resident File. After an instrument is in the system, the QAS will initiate the updated QA-Calibration Form to notify the QAL that calibration will be due.

6.2 Document Control

Quality Procedure 12.1, R0 becomes part of the LANL QAPP and will be issued and controlled in accordance with LANL implementing procedures.

6.3 Labels

All instruments covered by this procedure shall be labeled with one of the following designations or functional equivalent:

- OPERATOR CALIBRATED (QA-CL-21)
- SCHEDULED CALIBRATION (QA-CL-20)
- CERTIFIED (MEC-8) (horizontal or vertical format)
- CERTIFICATION LIMITED (MEC-8)
- CALIBRATION VOID IF SEAL IS BROKEN

See Attachment 2 for facsimiles of these labels. The individual performing the calibration will affix the calibration labels to those instruments that require these labels.

6.3.1 Operator Calibrated

The OPERATOR CALIBRATED label identifies the instrument and the procedure used to calibrate it.

6.3.2 Scheduled Calibration

The SCHEDULED CALIBRATION label identifies the instrument, the date the instrument was calibrated, the date for when the next calibration is due, and the procedure used to calibrate the instrument. This label shall be completed and displayed on the instrument by the calibrator and may be used either by personnel from the calibration group or service organization or by the custodian/operator.

6.3.3 Certified

The CERTIFIED label identifies an instrument that has been calibrated by the calibration group against primary, secondary, or working standards or by other certified equipment. This label shall be completed and attached to or displayed conspicuously in the vicinity of an instrument or standard that requires periodic calibration.

6.3.4 Certification Limited

The CERTIFICATION LIMITED label is used by the calibration group to identify a limited calibration of functions, ranges, or attributes. All limitations shall be described on the calibration certificate.

6.3.5 Calibration Void if Seal is Broken

The CALIBRATION VOID IF SEAL IS BROKEN label shall be used by the calibration group when required to prevent adjustment that would affect calibration. The person responsible for the calibration shall initial the label and apply it in such a manner that any attempt to repair or adjust the instrument will result in breaking the seal.

7.0 REFERENCES

None

8.0 ATTACHMENTS

Attachment 1: QA-Calibration Form and Instructions for Completing the QA-Calibration Form

Attachment 2: Examples of Calibration Labels

17

DATE [1]

LOS ALAMOS NATIONAL LABORATORY
NNWSI
QA – CALIBRATION NOTIFICATION

GROUP	[2]
LOCATION	[3]
INSTRUMENT DESCRIPTION	[4]
IDENTIFICATION NUMBER	[5]
DATE CALIBRATION DUE	[6]
DATE OF NEXT CALIBRATION DUE	[7]
DETERMINE IF INSTRUMENT IS WITHIN GIVEN TOLERANCE PRIOR TO ADJUSTMENT	[8]
CALIBRATION PROCEDURE	[9]
NBS TRACEABLE	[10]
MEC-8 FILE NUMBER	[11] EXP [12]
CALIBRATION RANGE	[13]
CALIBRATION REFERENCES	[14]
COMMENTS	[15]
CALIBRATED BY (SIGNATURE, GROUP & PHONE	[16]

Fill in all blanks. If some are not applicable, please denote by N/A. If given information is incorrect, please correct.

17.

INSTRUCTIONS FOR COMPLETING THE QA-CALIBRATION FORM

Items [2] through [6] will be furnished to your QAL by the QAS with information as recorded in the files. Please correct any misinformation or add information not included, such as room number.

The QAL will forward the form to the calibrator. This form will serve as a notice for when calibration is due, as well as a record of completed calibration, out-of-tolerance information, and NBS traceable information.

The calibrator should return the completed and dated form to the QAL who then will return it to the QAS for retention. No other cards or forms will be used for this purpose.

[7] Date to be entered by calibrator.

[8] Calibrator to make this determination and record the information before calibration.

[9] Procedure or DP number to be recorded here.

[10] Record certification information. If traceable to MEC-8, indicate by "yes."

[11] & [12] Record file number and expiration date.

[13] Record calibration range, if pertinent. If not, indicate by N/A.

[14] Indicate instrument operating manual, if applicable.

[15] General comments may be recorded here.

[16] & [1] Calibrator to sign, as indicated, and date the form.

17

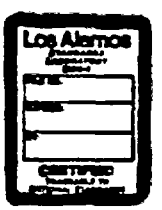
EXAMPLES OF CALIBRATION LABELS

SCHEDULED CALIBRATION
For QA Work
Ident. _____
Date Calibrated _____
Recalibration Due _____
Procedure No. _____
Calibrator _____
QA-CL-20

For QA Work
Ident. _____
OPERATOR TO CALIBRATE
Procedure No. _____
QA-CL-21

CALIBRATION VOID IF SEAL IS BROKEN

Los Alamos
STANDARDS LABORATORY
MEC-8
FILE NO.
OTHER ID
EXPIRES
BY:
CERTIFIED
TRACEABLE TO NATIONAL STANDARDS



CERTIFICATION LIMITED
TRACEABLE TO NATIONAL STANDARDS
FILE NO | OTHER ID
EXPIRES | BY
Los Alamos STANDARDS LABORATORY MEC-8

CERTIFIED
TRACEABLE TO NATIONAL STANDARDS
FILE NO | OTHER ID
EXPIRES | BY
Los Alamos STANDARDS LABORATORY MEC-8

Los Alamos
Los Alamos National Laboratory
Los Alamos, New Mexico 87545

memorandum

TO: S. Dye, INC-7, MS J514

DATE: June 30, 1988

FROM: H. P. Nunes, QAPL

MAIL STOP/TELEPHONE: J521/667-8039

SYMBOL: TWS-N5/06-88-55

SUBJECT: CALIBRATIONS DUE IN JULY 1988

According to our records, the following items are due for calibration in July 1988.

Mettler Balance	PN 318834	07/01/88	TA-48 308
Mettler Balance	PN 310954	07/01/88	TA-48 305
Ainsworth Balance	PN 318476	07/01/88	TA-48 315
Metric Weight Set	Mec 8 File 001662	07/01/88	TA-48 408

Please have the calibrator complete the enclosed forms and return them to this office.

MFM:meg

Enclosures: a/s

Cy: M. F. McGowan, LATA, MS M321
RPC (3), N-5, MS J521
QAS file, LATA, MS M321

DATE 6-27-88

LOS ALAMOS NATIONAL LABORATORY
NNWSI
QA CALIBRATION FORM

GROUP	INC 7-11
LOCATION	TA 48 Rm 408
INSTRUMENT DESCRIPTION	Metric Weight Set
IDENTIFICATION NUMBER	Mec 8 File 001662
DATE CALIBRATION DUE	7/1/88
DATE OF NEXT CALIBRATION DUE	
DETERMINE IF INSTRUMENT IS WITHIN GIVEN TOLERANCE PRIOR TO ADJUSTMENT	
CALIBRATION PROCEDURE	
NBS TRACEABLE	
MEC-8 FILE NUMBER	EXP
CALIBRATION RANGE	
CALIBRATION REFERENCES	
COMMENTS	
CALIBRATED BY (SIGNATURE, GROUP, AND PHONE)	

Fill in all blanks. If some are not applicable, please denote by using N/A.
If given information is incorrect, please correct it.

DATE 6-27-88

LOS ALAMOS NATIONAL LABORATORY
NNWSI
QA CALIBRATION FORM

GROUP	INC 7-11
LOCATION	TA 48 Rm 315
INSTRUMENT DESCRIPTION	AINSWORTH BALANCE
IDENTIFICATION NUMBER	PN 3184-76
DATE CALIBRATION DUE	7/1/88
DATE OF NEXT CALIBRATION DUE	
DETERMINE IF INSTRUMENT IS WITHIN GIVEN TOLERANCE PRIOR TO ADJUSTMENT	
CALIBRATION PROCEDURE	
NBS TRACEABLE	
MEC-B FILE NUMBER	EXP
CALIBRATION RANGE	
CALIBRATION REFERENCES	
COMMENTS	
CALIBRATED BY (SIGNATURE, GROUP, AND PHONE)	

Fill in all blanks. If some are not applicable, please denote by using N/A.
If given information is incorrect, please correct it.

DATE 6-27-88

LOS ALAMOS NATIONAL LABORATORY
NNWSI
QA CALIBRATION FORM

GROUP	INC 7-11
LOCATION	TA 48 Rm 308
INSTRUMENT DESCRIPTION	Mettler Balance
IDENTIFICATION NUMBER	PN 318834
DATE CALIBRATION DUE	7/1/88
DATE OF NEXT CALIBRATION DUE	
DETERMINE IF INSTRUMENT IS WITHIN GIVEN TOLERANCE PRIOR TO ADJUSTMENT	
CALIBRATION PROCEDURE	
NBS TRACEABLE	
MEC-8 FILE NUMBER	EXP
CALIBRATION RANGE	
CALIBRATION REFERENCES	
COMMENTS	
CALIBRATED BY (SIGNATURE, GROUP, AND PHONE)	

Fill in all blanks. If some are not applicable, please denote by using N/A.
If given information is incorrect, please correct it.

DATE 6/27/88

LOS ALAMOS NATIONAL LABORATORY
NNWSI
QA CALIBRATION FORM

GROUP	INC 7-11
LOCATION	TA 48 Rm 305
INSTRUMENT DESCRIPTION	Mettler Balance
IDENTIFICATION NUMBER	PN 310954
DATE CALIBRATION DUE	7/1/88
DATE OF NEXT CALIBRATION DUE	
DETERMINE IF INSTRUMENT IS WITHIN GIVEN TOLERANCE PRIOR TO ADJUSTMENT	
CALIBRATION PROCEDURE	
NBS TRACEABLE	
MEC-8 FILE NUMBER	EXP
CALIBRATION RANGE	
CALIBRATION REFERENCES	
COMMENTS	
CALIBRATED BY (SIGNATURE, GROUP, AND PHONE)	

Fill in all blanks. If some are not applicable, please denote by using N/A.
If given information is incorrect, please correct it.

NNWSI PROJECT TRAINING ATTENDANCE

TITLE: NNWSI Instrument Calibrations QP-12.1 / QAL Meeting

DURATION: _____ DATE: 12/8/87

INSTRUCTOR: P. Tillery ORG: LATA PHONE: 662-1752

ATTENDEES

PRINT	SIGNATURE	GROUP	PHONE
PATRICIA M TILLERY	Patricia M Tillery	LATA-QAS	662-1752
PAUL GUTHALS	Paul Guthals	N-5	Z-8039
Grace Hollen	Grace Hollen	LATA-QAS	662-1762
Michael McGowan	Michael F. McGowan	LATA-QAS	662-1731
Suzann Dye	Suzann Dye	INC-7	7-5487
Kimberly W. Thomas	Kimberly W. Thomas	INC-11	7-4546
Merlin Wheeler	Merlin Wheeler	LATA-GAL	7-1806
~~Flo Butler~~			
Flo Butler	Flo Butler	LATA	7-1806

Enclosure B.17.C

Los Alamos
Los Alamos National Laboratory
Los Alamos, New Mexico 87545

memorandum

TO: Distribution

DATE: August 19, 1988

FROM: H. P. Nunes, QAPL

MAIL STOP/TELEPHONE: J521/7-8039

SYMBOL: TWS-N5/08-88-53

SUBJECT: TRAINING - TWS-QAS-QP-12.1, R1

Enclosed for your signature is a training receipt acknowledgment form.

Please return the signed form within 10 working days of receipt of this memo.

JJG/pmf

Attachment: a/s

Distribution:
P. L. Aamodt, ESS-1, MS D462
M. J. Aldrich, ESS-1, MS D462
W. S. Baldridge, ESS-1, MS D462
J. A. Barber, ESS-1, MS D462
D. W. Barr, INC-DO, MS J515
S. Barr, ESS-5, MS F665
R. J. Beckman, A-1, MS F600
K. Birdsell, ESS-5, MS F665
S. Birdsell, ESS-4, MS J981
D. L. Bish, ESS-1, MS D462
S. Bolivar, ESS-1, MS D462
D. E. Broxton, ESS-1, MS D462
E. A. Bryant, INC-7, MS J514
E. J. Bustos, MAT-11, MS P274
F. Byers, ESS-1, MS D462
K. M. Cambern, LANL/LV, MS J900/527
K. Campbell, A-1, MS F600
J. A. Canepa, N-5, MS J521
B. A. Carlos, ESS-1, MS D462
S. J. Chipera, ESS-1, MS D462
M. R. Cisneros, INC-11, MS J514
B. M. Crowe, LANL/LV, MS J900/527
R. J. Crowley, WX-4, MS G787
W. R. Daniels, INC-11, MS J514
R. B. Demuth, ESS-5, MS F665
L. J. Dimas, ESS-5, MS F665
C. J. Duffy, INC-7, MS J514
S. Dye, INC-7, MS J514
(Distribution continued on reverse side)

Training Receipt Acknowledgement
August 19, 1988

Return To: K. L. Foster
Los Alamos National Laboratory
LATA QAS, MS-M321
Los Alamos, NM 87545

Name: _____
(Please Print)

SUBJECT: TRAINING TO TWS-QAS-QP-12.1, R1

All M&TE used on the NNWSI Project is subject to the requirements of Procedure QP-12.1, R1. Because the old card tracking system has been replaced by a QA calibration notification system, it is necessary for you to understand the latter procedure. Your attention should be directed to Paragraphs 3.5, 6.1, and 8.0 of the referenced procedure.

I have read and understand that I am required to be familiar with TWS-QAS-QP-12.1, R1.

_____ _____
Signature Date

HANDLING, STORAGE, AND SHIPPING PROCEDURE

EFFECTIVE DATE: 4/5/88

Michael F. McGowan — 4-1-88
M. F. McGowan — **Date**
Preparer

Karen A. West — 4/5/88
K. A. West — **Date**
Acting QA Project Leader

D. T. Oakley — 4/5/88
D. T. Oakley — **Date**
Technical Project Officer

HANDLING, STORAGE, AND SHIPPING PROCEDURE

1.0 PURPOSE

The purpose of this procedure is to prevent or avoid loss or deterioration of samples and/or equipment when such effects have the potential of adversely affecting Quality Assurance (QA) Levels I and II material or activities associated with the Nevada Nuclear Waste Storage Investigations (NNWSI) Project at Los Alamos National Laboratory (LANL).

2.0 SCOPE

This quality procedure (QP) defines the generic QA requirements related to the handling, marking, preservation, storage, packaging, shipping, record keeping, and documentation of samples and/or equipment.

These requirements must be addressed when developing or revising detailed technical procedures (DPs) for the NNWSI Project. The requirements stated in Section 5 of this QP must be addressed in either a DP developed specifically for the purposes of an entire group or included in existing Project DPs.

Procedures for the handling, storage, and shipping of data, records, and/or documents are addressed in the Records Management Procedure, TWS-QAS-QP-17.1, R0.

3.0 DEFINITIONS

3.1 Data

Data include hard copies or electronic representations of the results of scientific investigations, tasks, tests, experiments, reports, or publications.

3.2 Equipment

Equipment includes special tools, machinery, or laboratory apparatus or items used in the handling, storage, accumulation, shipping, measurement, and processing of samples.

3.3 Handling

Handling includes the care, transportation, and use of samples and equipment at LANL after arrival from the field or from other outside sources.

3.4 Marking

Marking is the process of uniquely identifying samples, including an indication of a need to maintain special environments or other special controls, in a manner that promotes sample identification as to its source and end use.

3.5 Packaging

Packaging refers to the preparation of samples for handling, shipping, and storage, including the cleaning, care, and marking of samples.

3.6 Preservation

Preservation refers to the maintenance of the samples in the same condition as they are procured or as their original state.

3.7 Samples

A sample is a small part of a material used for the NNWSI to show the quality, style, or nature of a larger portion of the experimental whole. The sample may have a critical, sensitive, perishable, or high-value nature as related to cost and/or rarity. Examples include surface or ground water samples, hand or core rock samples, and gaseous samples.

3.8 Shipping

Shipping refers to the movement of samples to and from LANL and within the laboratory.

3.9 Storage

Storage refers to the facilities used to ensure the preservation of samples.

4.0 RESPONSIBILITIES

The principal investigator (PI) or an individual designated by the PI shall have the responsibility for including these requirements in the appropriate DPs.

All persons involved in the LANL NNWSI Project should be suitably trained and cognizant of the appropriate procedures for the handling, marking, preservation, storage, packaging, shipping, record keeping, and documentation of samples and/or equipment.

5.0 REQUIREMENTS

5.1 Handling

Detailed instructions shall be included in the appropriate DPs for all samples that require special handling. Conditions, which may be considered in these procedures, include weight, height, fragility, or susceptibility to environmental influence.

Equipment operators, who are involved in the handling of samples, shall be suitably trained or experienced. This training information shall be documented as stated in Personnel Selection, Training, and Certification, TWS-QAS-QP-02.1, R0.

5.2 Preservation

If a PI determines that samples may incur damage or deterioration, he/she shall include methods in the DP to ensure preservation of the sample. If there is a life expectancy for the sample, it should also be noted on the sample or container. Examples of conditions requiring attention may include inert gas atmospheres, specific levels of moisture content, or temperature controls.

If sample deterioration is a possibility, the DP must describe the PI's responsibility for evaluating the usefulness of the sample. Subsequently, the PI shall document the results of the evaluation and make recommendations on the suitability of the sample for other experimental use.

5.3 Storage

Each participating LANL NNWSI group responsible for the storage of samples shall include specific storage information in the DP, if appropriate. The storage portion of the DP shall

- be coordinated with the sample preservation section of the DP;
- include an organizational plan of the storage area, which addresses access control, security, filing and location systems, cleanliness, housekeeping, and marking and/or labeling;
- provide for periodic reviews of storage procedures and facilities; and
- provide for written records of sample locations, reviews, and protective methods used at the facility.

5.4 Packaging and Shipping

The packaging portion of the DP ensures that samples are protected from corrosion, contamination, physical damage, or any effect that may lower their quality or cause their deterioration. Proper selection of containers must take into account shock absorption, cleanliness, and marking and/or labeling.

Caps, plugs, tapes, and adhesives shall consist of materials that enable them to perform their intended function adequately without causing deleterious effects on samples or equipment.

The shipment portion of the DP shall specify requirements for sample transportation where environmental protection, fragility, identification, and inspection are important. Shipping procedures and documentation shall be addressed in the DP. These procedures should be coordinated with the organizations responsible for the transportation of samples, as appropriate.

5.5 Marking and/or Labeling

Marking and/or labeling of samples is required. Proper documentation of the marking and/or labeling shall be made in Project logbooks. Investigators' and sample collectors' notebooks must provide traceability of samples using unique identifiers. The PI shall also take into consideration unique sample identification procedures as prescribed by the Sample Management Facility or the LANL group responsible for sampling activities. These procedures should assist in the retrievability and traceability of samples and in the facilitation and coordination of future work.

5.6 Exceptions for Use

In the event that samples have been damaged or deteriorated according to specifications outlined in the DP, the PI may determine if exceptions for

the use of samples are appropriate. Such exceptions must be recorded in the PI's laboratory notebook.

6.0 QUALITY ASSURANCE REQUIREMENTS

6.1 Records

Records that may be generated through the implementation of this QP are DPs.

6.2 Document Control

Approved DPs and QPs are maintained by the QAS in the Quality Assurance Manual. Personnel qualifications and certifications are maintained in accordance with TWS-QAS-QP-02.1, R0, NNWSI Personnel Selection, Training, and Certification Procedure. Notebooks are maintained in accordance with TWS-MSTQA-QP-14, R1, Research and Development Procedure.

7.0 REFERENCES

TWS-QAS-QP-02.1, R0--NNWSI Personnel Selection, Training, and Certification Procedure
TWS-QAS-QP-17.1, R0--Records Management Procedure
TWS-MSTQA-QP-14, R1--Research and Development Procedure

8.0 ATTACHMENTS

None.

Enclosure B.17.b

19:

LOS ALAMOS NATIONAL LABORATORY
NNWSI
CHANGE REQUEST

Change Request No. 048

Date 8-19-88

Procedure No. TWS-OAS-OP-13.1 R0

Change Requested:

Delete from Section 5.3:

"• provide periodic reviews of storage procedures and facilities;"

Add to Section 4.0:

If the provisions of this QP should be addressed in a currently active DP and are not, the PI responsible for the DP shall issue a corrective action report to document the deficiency and to initiate remedial measures. The PI is responsible for having corrective action implemented in a timely fashion.

Reason for Change:

- Reviews are not required in NNWSI/88-9
- Remedial measures are not addressed in the procedure
- Response to CAR No. 040 from NRC mini-audit

Change Requested By _____ **Date** _____

Reviewed By _____ **Date** _____

QAPL Approval _____ **Date** _____

TPO Approval _____ **Date** _____

Effective Date _____ **Date** _____