

memorandum

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'87 JUL 17 P2:29

DATE: JUL 14 1987

REPLY TO RW-24
ATTN OF:

SUBJECT: NRC Findings During LANL Audit

TO: QACG Members (List Attached)

Attached are copies of the handouts provided by NRC at the June 12, 1987 exit meeting following their audit of LANL.

Carl Newton, Chairman
Quality Assurance Coordinating Group

Attachments

87714742

WM Project: WM-1
PDR w/encl
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WM Record File: 405
LPDR w/encl

H

WM Record File
405

WM Project 1
Docket No. _____
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Deficiency #1

1. The detailed procedures do not include or reference acceptance criteria. However, according to Section 5.1 of the LANL-NNWSI QAPP, instructions, procedures, or drawings shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that important activities have been accomplished satisfactorily.

Observation #1

1. The resident file for milestone report R345 was examined to determine if it is in compliance with QP-07 (3/4/85), Procedure for Technical Review of Publications. It was found that the file was in compliance with this procedure. However, the following was found:

- a. The reviewer had comments beyond editorial ones; the comments were incorporated but the reviewer did not sign off on the final manuscript to indicate his approval of the incorporation.
- b. The comments were in the margins of the report and the only way to determine if the comment was resolved is by comparison to the published paper. This is satisfactory for editorial comments but it is suggested that substantive comments be placed on separate sheets and a comment response accompany it.
- c. The reviewed manuscripts were not clearly identified. The reviewer's name and date of the review should be noted on each manuscript.
- d. QP-07 requires that Attachment C be contained in the file. This form was present but not completed. QP-07 should require that attachments be filled out completely.

This procedure has been updated. The revision addresses (a) above since the reviewer or TPO must sign Attachment 2. The other items above are not addressed in the revision.

Deficiency #2

- 2. Lab notebook TWS-ESS-1-12/84-7 was examined and a comparison made of the one time and daily entry requirements from QP-14. The following was found:
 - a. Both one time and daily entries were incomplete. For example, the objective of the activity for the one time entry and the identification of the activity on a daily entry were not recorded.
 - b. The requirement for identifying the equipment utilized does not specify what information from the equipment should be recorded. The requirement for daily entries specifies sample history and neither the PIs nor NRC could determine the meaning of this requirement.
 - c. There were notations concerning some ongoing experiments scattered throughout the notebook pages examined. It was not clear as to what experiment these notations referred.

There are two basic conclusions from the above. First some clarifications in QP-14 need to be made. Second, there is evidence that QP-14 is not being fully implemented. Portions of this deficiency were previously identified by LANL in its internal audit.

Deficiency #3

3. QP-04, sections 6.1 and 8 requires periodic inspections of the storage areas and that records will be maintained according to Records Control Procedure (QP-09). Documented inspections have not been made of the sample storage facility.

Deficiency #4

4. A box of thin sections was examined in TA-3 to determine if work was being conducted on the materials described in the SIP. In the process it was found that one box is labeled J-13 but the notations on the thin sections are JA. It is considered that this inconsistency is not in compliance with Item 3 of DP-101 and could lead to confusion later in the program and that it should be corrected.

Deficiency #5

5. QAPP, section 5.1 requires that procedures have an "independent technical review." DP-101 was reviewed by the author's subordinate. DP-25 was reviewed by the author's technician. In both cases, it would be difficult to make a case for independence even though the reviewers did not prepare or were not involved in the preparation of the procedure. Thus, "independence" may need to be defined or this requirement reviewed to determine if it is appropriate. In addition, there are no procedures for "technical reviews" which a reviewer should follow. The team, however, was informed that these procedures are in progress.

Deficiency #6

6. QP-15 Section 6.3 requires that a card to be sent to the QAS when an instrument requiring periodic calibration has been calibrated. The calibration records for the XRD-Lab weight set in TA-3 were traced to LATA. The required card was not in the file. The team was informed that the requirement to forward a card to LATA was not in the calibration procedures for these weights. These procedures were not examined. However, there is an apparent discontinuity between procedure QP-15 requirements and the detailed procedures.

Deficiency #7

7. QAPP Section 12.2 requires that each device have a unique identification number. We examined the Megadigital Thermometer #4273 at TA-3, which includes three probes and a digital readout. We found that one of the probes was labeled 4237 instead of 4273.

LANL AUDIT

Requirement:

The NNWSI QAP (NVO-196-17, Rev. 4) Section 1.10 states that "all quality assurance personnel across the entire project shall report to management levels such that they have sufficient authority and organizational independence to identify quality problems; to initiate, recommend, or provide solutions; to verify implementation of solutions; and to stop unsatisfactory work."

Finding: #2

Section 1.1 of the LANL QAPP states this requirement but there is no identified procedure for implementation of the requirement.

In the LANL QAPP, Rev. 1, Table 1.1 indicates the QAIM has responsibility for "conflict resolution." There appears to be no further reference as how this is implemented. Also, Table 1.1 does not identify responsibility for the QAIM, QAS, or the QAL to identify quality problems, to initiate, recommend or provide solutions ---

Table 1.1 states the QAIM/QAS and QAL have responsibility for "approval of disposition of NCRs and CARs" only.

QP-16, Rev. 0, Control of Nonconformances does not address this requirement.

QA-21, Rev. 0, Corrective Action states in paragraph 3.5 that "any Los Alamos NNWSI Project person shall initiate a Corrective Action Report whenever significant conditions adverse to quality are identified. The term "significant conditions adverse to quality" has a particular meaning in NQA-1. It does not adequately address the requirement to identify quality problems---.

LANL AUDIT

Requirement:

NQA-1, Section 2 requires indoctrination and training of personnel. The NNWSI QAP, NVO-196-17, Rev. 4, Section 2.2 states that "All personnel performing quality-related activities shall have training to the extent necessary to perform their specific function. ... the need for training shall be evaluated and documented on an annual basis"

Finding:

#3

In reviewing the training files it was observed that the training records only identified the individuals who have had QA training. However, there is no record of a determination of who needs/requires training (quality and/or technical). There is also no record of the need for training being evaluated and documented on an annual basis.

LANL AUDIT

Requirement:

The LANL QAPP, Rev. 1, Section 2.1 states that "Personnel performing QA Level I and II activities shall be certified to show competence to perform their specific duties."

Finding: (#4)

The LANL form used to record the certifications appears to be used to certify an individual to selected Quality Procedures rather than certifying, for instance, the QAL as having competence to perform specific duties (ref. Table 1.1 responsibilities). Also, the certifications contain minimal information on the qualifications of LANL staff and may not be adequate for licensing. The need for detailed information for demonstrating the qualifications of staff was also addressed in observation # _____. Memo dated September 27, 1985, Morris to Barber, clearly identifies J. Barber's duties. However, this memo causes confusion over the responsibility of the QAL in ESS-1. It was observed there are no specific qualifications identified for the personnel performing quality related functions, i.e., QAIM, QAS, and QAL.

LANL AUDIT

Requirement:

The LANL QAPP, Rev. 1, Section 4.2.2., Procurement Document Review states that ... "A review of the procurement documents shall be made to ensure that appropriate provisions have been included ... that the review shall be documented and that the review shall include, as a minimum, the cognizant technical organization and the QAL. The reviews by the QAL will assure that the following requirements are met:

- 1) QA requirements are correctly stated,
- 2) there are adequate acceptance and rejection criteria, and
- 3) procurement documents have been prepared, reviewed and approved ..."

Finding:

#5

A method of recording the results and concurrence action of the QAL review is not identified or addressed in the QP-06 procedure.

10/16

LANL AUDIT

Requirement:

The LANL QP-06, Rev. 2 procedure, NNWSI Procurement Procedures, Section 4.13, "QA Program Requirements" states that ... Procurement documents shall require that the supplier have a documented QA program that implements either portions or all of the requirements of the NNWSI quality assurance program.

Deficiency:

#8

On examination of three ESS-1 initiated procurements for QAL review (UNM, Case Western, and University of California-Riverside) indicated the Quality Levels of II, I, and I were applicable. The applicable portions of the LANL QAPP (NQA-1) requirements were not recorded. A review of the three vendor supplied QA plans was made and it was apparent that not all criteria were applicable or appropriate. There was not a record of the basis for the QAL/QAS determination that the three vendor QA programs were determined acceptable.

LANL AUDIT

Requirement:

The LANL QP-22, Rev. 0 procedure, NNWSI Supplier Qualification, paragraph 4.4, Reporting, states that "the survey team leader shall furnish the QAS, QAIM, and the QAL/Requestor with a summary report of the supplier qualifications and/or pre-award survey results, including actions pending and recommendations relative to qualifications of the supplier. A copy of all related subsequent correspondence shall be furnished to the QAS, QAIM, and the QAL/Requestor."

Deficiency:

#9

In reviewing the Procurement package for the UNM (PO U9012, dated 10/1/84) a survey was performed by the QASM (lead) and the QAL on January 28, 1987. However, the ESS-1 Resident File or the LATA QA file did not contain a summary report as required.

LANL AUDIT

Requirement:

The LANL QAPP, Section 7.2.4, Supplier Performance Evaluation requires the establishment of measures to verify suppliers' performance ---

The LANL QAPP, Section 5.1 states that activities that affect quality shall be prescribed by documented instructions, procedure ...

Deficiency:

#10

There does not appear to be a procedure to accomplish this QAPP requirement.

Requirement:

The LANL QAPP, Section 7.2.5, Control of Document Generated by Suppliers require that vendor generated documentation be controlled ... in accordance with LANL implementation procedures

Deficiency:

#11

There does not appear to be a procedure to meet this requirement.

Requirement
Deficiency:

#12

The LANL QAPP, Section 7.2.10, Annual Supplier Evaluation, requires that when required an annual supplier evaluation be documented.

Deficiency
Observation:

#12
#13

There does not appear to be a procedure developed for the annual supplier evaluation.

Deficiency

#13

1. QP-11 section 5.3 requires the QAIM to review and sign all surveillance reports (SR). Of the three surveillances conducted within ESS-1, two complete SRs were not reviewed and signed.
2. QAPP section 18.1 states, "a system of planned and periodic audits shall be made to verify compliance with all aspects of the LANL NNWSI Project QA programs and to determine the effectiveness of the program."

QAPP section 18.2.1 states, "Regularly scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage."

The adequacy of the LANL audit/surveillance program is questionable when compared to the number of deficiencies identified by the WMPO and NRC audits. To date, only one internal audit has been performed ^{this year} within ESS-1. This was a two-day audit consisting of three auditors - one of which was an auditor-in-training. In addition, the audit checklist was predominantly programmatic in nature and limited in detail and coverage of the QA program. *

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LANL AUDIT

~~XXXXXXXXXX~~Requirement:

The LANL QP-16 Procedure, paragraph 3.0, Responsibilities, states that "the Technical Project Officer (TPO) shall ensure that the nonconformances are promptly dispositioned."

Observation:

#2

It was observed that of the six NCRs issued since October 1986, only about half were sent to the TPO.

LANL AUDIT

Observation:

#5

The LANL QAPP, Rev. 1, Figure 1.1 appears to need revision to properly reflect the role and responsibility of the QAS and the QAL. For example, the QAL has an administrative line (dotted) to the QAS and not to the QAIM. The QAS has a line management line to the Project Manager-Geochemistry and the Project Manager-Exploratory Shaft. It appears this should be dotted.

LANL AUDIT

Observation:

#4

The LANL CAR form does not include a place for the entry of the appropriate Quality Level. Since the NNWSI QAP and the QAPP require QA Level I CARs to be sent to WMPO, it would appear this would be appropriate.

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