Department of Energy
Washington, DC 20585

April 12, 1995

Mr. Joseph J. Holonich, Chief
High-Level Waste and Uranium
Recovery Projects Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Holonich:

The enclosed copies of the Office of Civilian Radioactive Waste Management Lessons Learned/Program Clarifications are submitted to the U.S. Nuclear Regulatory Commission as requested in the Nuclear Regulatory Commission letter, Holonich to Milner, dated February 16, 1995. The Nuclear Regulatory Commission Document Control Desk will be added to the distribution of the Lessons Learned/Program Clarifications and those issued to date will also be forwarded to them as requested by that same letter.

Since the inception of this program, six Lessons Learned/Program Clarifications have been issued with direction to the affected organizations to take appropriate action. Currently, only five Lessons Learned/Program Clarifications are still in effect; these are 92-001, 93-001, 93-002, 94-002, and 95-001.

If you have any questions regarding the enclosed materials, please contact either Catherine E. Hampton at (702) 794-7973 or Donald J. Harris at (702) 794-7356.

Sincerely,

Ronald A. Milner

Ronald A. Milner, Director
Office of Program Management and
Integration
Office of Civilian Radioactive
Waste Management

Enclosures:
Lessons Learned/Program
Clarifications 92-001,
93-001, 93-002, 94-002,
and 95-001

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CIVILIAN RADIOACTIVE WASTE MANAGEMENT (CRWM) PROGRAM

OFFICE OF QUALITY ASSURANCE (OQA)

LESSONS LEARNED/PROGRAM CLARIFICATION NO. 92-001

SUBJECT

Criterion 4, Procurement and the Classification of Procurement documents

CONDITION SUMMARY

During the YMQAD YMP-92-03 of Sandia National Laboratories (SNL), it was noted that PR 87-5104 was being processed as "Quality Affecting" in accordance with QAIP 04-01, Procurement. The Quality Assurance Grading Report (QAGR) and the Specification Work Breakdown Structure WBS 1.2.3.6.2.1.6 identifies the activity as "Quality Affecting." The PR was actually a personal Services Contract for a person acting as direct support, monitoring SNL's contract with the National Center for Atmospheric Research, under the direct supervision of the SNL requestor, and in accordance with SNL's QA program and implementing procedures.

RESOLUTION

The procurement documents should be classified as "QA-NA" on all future procurement orders where the contractor will be performing "Quality Affecting" activities under the direct supervision and QA program of the purchaser.

BASIS FOR RESOLUTION

In this case, Criterion 4, Procurement, does not apply because the contractor is acting as direct support capacity as a staff member of the procuring organization. As a staff member, the contractor is under the direct supervision of the requestor and is subject to the requirements of the requesting organization's QA program when the WBS and QAGR indicate the activities are "Quality Affecting."

Donald G. Horton, Director
Office of Quality Assurance
Office of Civilian Radioactive Waste Management

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CIVILIAN RADIOACTIVE WASTE MANAGEMENT (CRWM) PROGRAM

OFFICE OF QUALITY ASSURANCE (OQA)

LESSONS LEARNED/PROGRAM CLARIFICATION NO. 93-001

SUBJECT

QA Program Element 2.0, Quality Assurance Program, specifically: Verification of Minimum Education and Experience.

CONDITION SUMMARY

Some CRWM affected organizations are unaware of the different methodologies of satisfying the requirement for Verification of Minimum Education and Experience.

RESOLUTION

Education Verification

Preferred Method: On company letterhead, request written verification of the highest level of education the employee (or potential employee) had earned from the school Office of the Registrar. Request verification of degree(s) awarded, (or transcript) education major, and dates attended.

Alternate Method: Telephone the school's Office of the Registrar, identify your company and yourself, and request verification of the highest level of education the employee (or potential employee) had earned. Record the following information:

- Date and time
- Telephone number
- Registrar staff member's name providing information
- Degree(s) awarded
- Education major
- Dates attended
- (units toward degree, if a degree was not awarded)
- The signature and date of the requestor

Note: An employee furnished copy of a diploma or transcript is not satisfactory for use as objective evidence in education verification.

Experience Verification

Preferred Method: On company letterhead, request written verification of work experience from the employee's previous employer(s) for the dates and position descriptions cited on the employee' resume`.

ENCLOSURE

Alternate Method: Telephone the employee's previous company personnel department or previous department manager. Identify your company and yourself and request verification of the employee's work experience. Record the following information:

- Date and time
- Company name, address and telephone number, personnel staff member name or previous department staff member providing the information.
- Dates employed
- Position description
- The signature and date of the requestor,

In the event that the employee's previous company is out of business or personnel records are no longer available, due to time duration since being employed by the company, it is permissible to contact person(s) that have personal knowledge of the employee's work history for a specified time frame. Record the following information:

- Date and time
- Persons name, address and telephone number providing the information
- Confirmation of the dates provided on employee's resume. Record actual time frame being evaluated
- Position description title, or job title
- The signature and date of the requestor.

Note: Objective evidence accumulated or generated for the purpose of education and experience verification is subject to surveillance and audit.

BASIS FOR RESOLUTION

DOE/RW/0333P, Rev.#0 QARD, QA Element 2.0, Quality Assurance Program. Paragraph 2.2.11 Personnel Selection, Indoctrination, Training and Qualification. Item F. states "Ensure minimum education and experience are verified or, when minimum education and experience cannot be specifically verified, provide a statement and justification for the personnel assignment."

5/11/93

Donald G. Horton — Date
Director
Office of Quality Assurance

CIVILIAN RADIOACTIVE WASTE MANAGEMENT (CRWM) PROGRAM

OFFICE OF QUALITY ASSURANCE (OQA)

LESSONS LEARNED/PROGRAM CLARIFICATION NO. 93-002

93--002 Supersedes 92-002

SUBJECT

QA Program Element 2.0, Quality Assurance Program, specifically Management Assessments and, QA Program Element 18.0, Audits, specifically Internal Audits

CONDITION SUMMARY

Condition: Some CRWM affected organizations appear to have a misunderstanding of Lessons Learned/Program Clarification No 92-002, on the QA organizations not requiring Annual Management Assessment.

REQUIREMENT:

DOE/RW/0333P, Rev. 0, Section 2.0 Quality Assurance Program, Paragraph 2.2.6 Management Assessments, "Senior Management of an affected organization shall perform or direct the performance of management assessments by personnel outside the QA organization. A. Management assessments shall be planned and documented, and performed annually".

RESOLUTION:

Annual Management assessments for the QA organization and /or independent internal audits of the QA organization are not required for those years that the CRWM Office of Quality Assurance performs a QA Program Audit for adequacy and effectiveness.

Note: This does not relieve other internal organizations from planning and performing an Annual Management Assessment to determine how well their organizations are performing their QA functions. Personnel performing the management assessment may be either internal company personnel (Non-QA) or external personnel.

BASIS FOR RESOLUTION:

The CRWM Office of Quality Assurance audits determine the adequacy and effectiveness of QA program implementation, including QA organizational activities such as indoctrination, training, planning, procedural controls, management information tracking, implementation of non-conformance and corrective action system and performance of audits. The CRWM Office of Quality Assurance audit organization and QA program are totally independent of the organizations they are auditing and the auditors are knowledgeable of the requirements.

5/10/93

Donald G. Horton — Date

Director

Office of Quality Assurance

ENCLOSURE

CIVILIAN RADIOACTIVE WASTE MANAGEMENT (CRWM) PROGRAM
OFFICE OF QUALITY ASSURANCE (OQA)
LESSONS LEARNED/PROGRAM CLARIFICATION NO. 94-002

SUBJECT:

Quality Assurance (QA) Program Element 2.0, "Quality Assurance Program," specifically: Quality Assurance Requirements and Description (QARD) 2.2.8, "Peer Reviews," existing data not collected under an approved QA program and QARD Supplement III, "Scientific Investigations," specifically: QARD III.2.4, "Data Validation and Qualification."

CONDITION SUMMARY:

A clarification and interpretation has been requested on the use of existing data not collected under an approved QA program in planning and conducting site characterization activities and related scientific investigations.

The QARD DOE/RW-0333P Glossary defines existing data as "Data developed prior to the implementation of a quality assurance program that meets Office of Civilian Radioactive Waste Management (OCRWM) requirements and data that are not information accepted by the scientific and engineering community as established fact." This definition is consistent with U.S. Nuclear Regulatory Commission (NRC) staff guidance provided in NUREG-1298, "Qualification of Existing Data for High-Level Nuclear Waste Repositories." Examples of existing data are: (1) any data collected by a Project participant prior to OCRWM acceptance of its QA program; (2) data obtained through a literature search of scientific journals; or (3) data obtained from an unpublished thesis or dissertation. Data found in technical handbooks are considered to be ":information accepted by the scientific and engineering community as established fact," and thus are recognized to be acceptable sources of data.

RESOLUTION:

Existing data may be used at any time during the planning and conduct of site characterization investigations and supporting activities. This includes Test Interference Evaluation (TIE), Waste Isolation Evaluation (WIE), and Determination of Importance Evaluation (DIE) evaluations performed during planning of surface-based and underground testing, as well as performance assessment calculations used to support test planning and prioritization. Existing data also may be used as corroborative evidence in support of the license application provided it is not directly relied upon to support conclusions regarding safety or waste isolation. However, Traceability shall be maintained and data indicated accordingly for any existing data used as described herein. In addition existing data must be qualified according to Administrative Procedure AP-5.9Q if it will be directly relied upon to address safety and waste isolation issues (QARD III.2.4.D).

BASES FOR RESOLUTION:

Supplement III of the QARD was intended to provide controls on site characterization and scientific investigations that would be analogous to controls placed on the design process. The controls on scientific investigations were not intended to be more restrictive than Criterion 3, which applies to design control. It is recognized in QARD III.2.4.E.2 that "In some cases (such as when insufficient data exist) it may be necessary to release unverified designs to other organizations to support schedule requirements. Unverified portions of the design shall be clearly identified...." In contrast, Section 2.4.D of Supplement III states that "Existing data relied upon to address safety and waste isolation issues shall be qualified...." Inadvertently, the QARD was silent on the use of existing data in site characterization planning activities such as WIE and TIE and DIE evaluations. This will be remedied in future revisions to the QARD.

It is the intent of the QARD that the traceability requirements applicable for design data should apply to scientific investigations data as well. The QARD defines traceability as "The ability to trace the history, application, or location of an item, data, or sample using recorded documentation." This definition of traceability implies that data must be both traceable backward (trace and history) and forward (trace the use and application). Regardless of the stage at which data are used in quality-affecting activities, all data (existing and qualified) must be traceable (Supplement III, Section 2.3). The QARD criteria states that "Data shall be identified to provide traceability, indicate useability, and document validation status." It further states that "identification and traceability shall be maintained throughout the lifetime of the data." The approach to be followed to meet this requirement is analogous to the use of "to be verified" labels for design input. Regular systematic reviews should then be conducted of the products developed using existing data to establish if earlier results should be changed in light of the most current site data and theories (e.g., conceptual repository design, waste package corrosion, and groundwater travel time). These periodic reviews should consider the cumulative effects of the changes in the input data and current conclusions should be revised and remediation undertaken as needed. Thus, these reviews would verify at different stages that the evaluations are still valid.

12/17/93

Donald G. Horton — Date
Director
Office of Quality Assurance

CIVILIAN RADIOACTIVE WASTE MANAGEMENT (CRWM) PROGRAM
OFFICE OF QUALITY ASSURANCE (OQA)
LESSONS LEARNED/PROGRAM CLARIFICATION NO. 95-001

SUBJECT:
Quality Assurance Program Element 17.0, Quality Assurance Records, specifically: Classification and Retention of Quality Assurance Records.

CONDITION SUMMARY:
Some CRWM affected organizations do not understand why quality assurance records need to be classified as lifetime or nonpermanent. A need for instructions in identifying quality assurance records and classifying them as lifetime or nonpermanent has been identified.

RESOLUTION:
The purpose of the classification of quality assurance records and associated retention periods is to identify the value or importance of the records from a quality assurance perspective. This perspective focuses on the ability of the record to provide evidence of, and potentially be used to maintain, the quality of items or activities affecting quality from a safety or waste isolation perspective. It is not the intent of the quality assurance classification requirements to address retention requirements that may be required by other federal, state, or agency regulations. The retention of quality assurance records beyond the minimum time frame needed to satisfy the quality assurance value will be governed by the OCRWM Records Inventory and Disposition Schedule approved by the National Archives and Records Administration.

The first step in identifying quality assurance records is determining whether or not the item or activity to which the document pertains is quality-related. Refer to QARD Section 2.2.3, Classifying Items and Applying Quality Assurance Controls, which identifies the applicability of the quality assurance program. If the item or activity is quality-related, the associated document shall be classified as a quality assurance record.

Once the document has been identified as a quality assurance record, the next step is to classify it as a lifetime or nonpermanent record. If the document satisfies one or more of the criteria of QARD Section 17.2.1A. it shall be classified as a lifetime record. If it does not meet any of these criteria but provides evidence that the quality assurance program has been properly executed, it shall be classified as a nonpermanent record. Any document that is generated by a quality-related procedure for a quality-related item or activity and is not classified as a lifetime record is deemed to provide evidence that the quality assurance program has been properly executed and shall be retained as a nonpermanent quality assurance record.

Documents generated as a result of using quality-related procedures for nonquality-related activities or items should not be considered quality assurance records.

Record identification and classification should be done during the development of the implementing document that will generate the record. QARD section 17.2.2A.1. states implementing documents shall "Identify those documents that will become quality assurance records". QARD section 5.2.2, H. states that implementing documents shall include "Identification of the lifetime or nonpermanent quality assurance records generated by the implementing document." It is important to identify, before an activity begins, what records will be generated to provide for the adequate documentation of the activity

ENCLOSURE

and to provide for proper record completion, protection, and preservation. QARD section 2.2.4, F. states that work planning elements shall include "Identification of, or provisions for the identification of, required records and the recording of objective evidence of the results of the work performed."

BASIS FOR RESOLUTION:

Lifetime Records:
NQA-1-1989, Supplement 17S-1, addresses the classification of records as lifetime or nonpermanent. Section 2.7.1 of this document identifies that records meeting one or more of the following criteria are lifetime records:

1. Those which would be of significant value in demonstrating capability for safe operation.
2. Those which would be of significant value in maintaining, reworking, repairing, or modifying an item.
3. Those which would be of significant value in determining the cause of an accident or malfunction of an item.
4. Those which provide required baseline data for in-service inspections.

These criteria along with other related record requirements from 10CFR50, 10CRF71, 10CFR72, and the NRC Review Plan were used to develop the OCRWM-specific criteria for the classification of lifetime records in QARD Section 17.2.1.

Nonpermanent Records
NQA-1-1989, Supplement 17S-1, Section 2.7.2 states: "Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records."

NQA-1-1989, Supplement 17S-1, Section 2.8 states: " . . . The retention period for nonpermanent records shall be established in writing."

QARD Section 17.2.7 specifies the minimum retention time and conditions for nonpermanent records. The three years minimum retention time, given that other specified conditions are satisfied, is based on a triennial audit schedule. This would allow the "evidence that an activity was performed in accordance with the applicable requirements" to be reviewed during the audit process.

RC Spence For 12/28/94
Donald G. Horton, Director Date
Office of Quality Assurance