Department of Energy
Washington, DC 20585

AUG 21 1991

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

Dear Mr. Linehan,

Subject: Response to Nuclear Regulatory Commission (NRC) Objection #2 Regarding the Site Characterization Plan Section 8.6

The following information is provided to request removal of the NRC Site Characterization Analysis (SCA) Objection #2 on the Quality Assurance Program.

Item: Quality Assurance (QA) Programs

The U.S. Department of Energy (DOE) stands by their original commitment to have an appropriate QA program in place to qualify site exploration data supporting the license application and for site characterization activities including the exploratory studies facility design and construction. The QA Program has been written to meet Subpart G of 10 CFR 60. Based on the agreed upon approach, DOE will obtain Nuclear Regulatory Commission (NRC) acceptance of the QA Program prior to the start of new site characterization activities. In addition, it is intended that each DOE participant's QA program for this project be qualified and accepted by the NRC prior to the start of new site characterization activities, as required. The current status of the DOE QA Program, formally known as the Office of Civilian Radioactive Waste Management (OCRWM) QA Program, and the acceptance of the applicable participants QA programs consistent with the agreed upon approach and milestones are provided below:

OCRWM QA Program

The OCRWM QA Program includes DOE Headquarters and the Yucca Mountain Site Characterization Project Office. In a letter dated March 11, 1991, John J. Linehan to Dwight E. Shelor, the NRC conditionally accepted the OCRWM QA Program for the initiation of new site characterization activities associated with Midway Valley Trenching and Calcite-Silica Activities. OCRWM has resolved the remaining exceptions to the overall NRC acceptance of the OCRWM QA Program. Resolution of these items is discussed in Supplement I of this document. In a letter dated April 15, 1991, the NRC also conditionally accepted the OCRWM QA program for the Transport and Monitored Retrieval Storage of spent fuel and high-level radioactive waste. Supplement I also addresses the actions taken to address the

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NRC comments. Supplement I of this document supports the DOE request that NRC unconditionally accept the OCRWM QA Program to start other new site characterization activities and other quality related activities.

**DOE Participants**

While the QA portion (Section 4.6) of the Overview of the Site Characterization Plan may have been premature in stating, "...all organizations participating in the site characterization program have developed and are implementing a documented quality assurance program that meets the quality assurance requirements of the Nuclear Regulatory Commission.", these programs were written to comply with the QA requirements of the NRC and have been implemented accordingly. This statement was not intended to imply that the NRC had concurred and accepted these QA programs.

In a letter dated October 12, 1990, John J. Linehan to Dwight Shelor, the NRC accepted the QA Programs for Sandia National Laboratories (SNL) and Lawrence Livermore National Laboratory (LLNL) for implementation of new site characterization activities. In addition, in the same letter, the NRC conditionally accepted the QA Programs for Fenix and Scisson of Nevada (FSN), Holmes and Narver (H&N), Reynolds Electrical and Engineering Company (REECo), and U.S. Geological Survey (USGS). The acceptance for the identified participants is conditional upon the satisfactory resolution of the exceptions noted in the DOE's September 12, 1990, letter. The exceptions and related participants are specifically identified in the letters, dated September 12, 1990, sent to the NRC requesting acceptance of the participant QA Programs. As of August 1, 1991, the letters resolving all remaining exceptions for these participants had been issued to the NRC by OCRWM. The letters also requested unconditional acceptance of the respective QA programs by the NRC. It should also be noted that one of these letters also described the transition from FSN and H&N to their replacement participant, Raytheon Services of Nevada (RSN) and the request for the acceptance of the RSN QA Program. In related matters, in a letter dated May 29, 1991, John J. Linehan to Dwight E. Shelor, the NRC accepted the Los Alamos National Laboratory (LANL) QA Program for new site characterization activities. Also, in a letter dated August 1, 1991, Dwight Shelor to John J. Linehan, OCRWM requested unconditional acceptance of the Technical and Management Support Services (T&MSS) QA Program.

**Item: Permanently Fill Top QA Management Positions**

Dr. John Bartlett, DOE Director of the OCRWM Program, announced a proposed reorganization of the program on July 9, 1990. The reorganization resulted from an independent management review and is designed to provide clear lines of responsibility, authority, and accountability of the program and its contractors. As part of this reorganization, Donald G. Horton was named Director, OQA. He reports directly to the OCRWM Program Director and is responsible for developing program QA requirements and overseeing compliance and for

interacting with the NRC on QA requirements. In addition, Donald G. Horton is also acting as the Director, Yucca Mountain Quality Assurance Division (YMQAD). DOE is in the process of filling the position of Director, YMQAD, with a permanent replacement. In addition, the position of Director, Headquarters Quality Assurance Division (HQQAD) has been filled with Robert W. Clark. Both gentlemen have numerous combined years of QA experience both in the Civilian Radioactive Waste Management Program and the commercial nuclear power industry. Both have also previously held QA management positions.

Item: Staff Concerns on the Design Acceptability Analysis (DAA) During Title I Design.

In reviewing the DAA for Title I design, the NRC staff high-lighted two areas of concern: technical aspects and quality assurance. The technical concerns are most closely related to NRC Objection #1 and the quality assurance aspects with NRC Objection # 2.

NRC staff concerns regarding the technical aspects of the DAA of the Title I design have been and continue to be addressed in response to NRC Objection # 1. A letter to provide NRC with the status of the DOE response to the technical concerns related to design as expressed in NRC Objection # 1 is being prepared.

With respect to NRC Objection # 2, DOE believes that NRC staff concerns regarding the quality assurance aspects of the DAA of Title I design are now resolved. DOE has a quality assurance program that has been accepted by the NRC. This QA program includes design control criteria such as input and interface control. In NRC staff review of the data listed in Supplement I to this letter, it should be evident that DOE has taken all the necessary actions to receive unconditional acceptance of its QA program and a lifting of SCA Objection # 2 by the NRC.

Should you have any questions, please contact Linda Desell of my Office at (202) 586-1462.

Dwight E. Shelor
Associate Director for
Systems and Compliance
Office of Civilian
Radioactive Waste Management

Enclosures:

1) Supplement I - Resolution of Exceptions to the OCRWM Quality Assurance Program
2) Attachment 1 to Supplement I - Software QA Requirements Matrix
3) Attachment 2 to Supplement I - Interim Change Notice (ICN) 4.1 to Quality Assurance Requirements Document, Revision 4
4) Attachment 3 to Supplement I - Interim Change Notice (ICN) 3.1 to Quality Assurance Program Description Document, Revision 3
5) Attachment 4 to Supplement I - Recommended CAR Closure Status
6) Attachment 5 to Supplement I - Recommended Surveillance Status

cc:
R. Loux, State of Nevada
M. Baughman, Lincoln County, NV
D. Bechtel, Clark County, NV
S. Bradhurst, Nye County, NV
P. Niedzielski-Eichner, Nye County, NV
R. Campbell, Inyo County, CA
R. Michener, Inyo County, CA
G. Derby, Lander County, NV
P. Goicoechea, Eureka County, NV
C. Schank, Churchill County, NV
C. Jackson, Mineral County, NV
K. Wipple, Lincoln County, NV
F. Sperry, White Pine County, NV
J. Bingham, Clark County, NV
L. Vaughan, Esmeralda County, NV
B. Raper, Nye County, NV

# SUPPLEMENT I

## RESOLUTIONS OF EXCEPTIONS TO THE U.S DEPARTMENT OF ENERGY (DOE) OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM) QUALITY ASSURANCE (QA) PROGRAM

SUPPLEMENT I

RESOLUTIONS OF EXCEPTIONS TO THE U. S. DEPARTMENT OF ENERGY (DOE)
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM)
QUALITY ASSURANCE (QA) PROGRAM

Reference:(1) Ltr., Linehan to Shelor, dtd. 1/18/91
(2) Ltr., Shelor to Browning, dtd. 12/11/90

This document contains resolution of the remaining exceptions ("U.S. Nuclear Regulatory Commission (NRC) open issues on OCRWM QA Program Documents" and the "Qualification Audit 90-I-01, Recommended Actions" (see Reference 2)) relative to the acceptance of the subject QA Program. The following information addresses the resolution of these exceptions.

OPEN ISSUES ON OCRWM QA PROGRAM DOCUMENTS

NRC Six (6) Open Issues on the QARD and QAPD

A letter (Linehan to Shelor) dated December 3, 1990, regarding review of the Quality Assurance Requirements Document and the Quality Assurance Program Description, listed six open issues with those documents. The resolutions to those six (6) issues are addressed as follows:

NRC Concern Number 1

Sections 1.4 of the Quality Assurance Requirements Document (QARD) and 1.1.16 of the Quality Assurance Program Description Document (QAPD) state that the Office of Civilian Radioactive Waste Management (OCRWM) will develop a system for reporting allegations of inadequate quality. The U.S. Department of Energy (DOE) participant Quality Assurance (QA) Program Plan descriptions state that such allegations are to be resolved in accordance with Yucca Mountain Project Administrative Procedure AP-5.8Q, "Resolution and Report of Quality Concerns." This is an apparent inconsistency which needs to be resolved between DOE and its participants.

Resolution

OCRWM has developed an administrative procedure which provides a system for reporting allegations of inadequate quality. This procedure was issued and became effective on July 1, 1991. All participants will use this system. This administrative procedure describes the system for reporting allegations of inadequate quality referred to in Section 1.4 of the QARD and 1.1.16 of the QAPD. Reference to AP-5.8Q will be deleted as the system is established and implemented.

NRC Concern Number 2

Section 16 of the QARD and QAPD states that identification of root cause will be accomplished by analyzing the information contained in trend analysis reports. The NRC staff recognizes that certain root causes may be uncovered through a trend analysis, whereas others may be uncovered by analyzing the individual condition adverse to quality. The NRC staff also recognizes that there may be isolated instances where the determination of a root cause may be inappropriate or unnecessary due to an obvious nonconforming condition. The NRC staff believes that when a nonconforming condition is discovered, it should be analyzed to determine, where appropriate, what actually caused the nonconforming condition, i.e., "root cause." The QARD and QAPD should describe measures to assurance that the corrective action and reporting systems include provisions to determine the

"root cause" of a condition adverse to quality in order to take timely effective corrective action.

Resolution

Section 16 of the QARD states, in part, that quality information shall be analyzed to identify adverse quality trends and help identify root causes. As stated, quality information includes nonconformance reports, corrective action reports, and other deficiency documents. This section is an amplification of Basic Requirement 16 of NQA-1 which requires cause determination for significant conditions adverse to quality. Section 16.5.1 of the QAPD does require cause determination for significant conditions. This requirement is implemented by Quality Assurance Administrative Procedure QAAP 16.1.

NRC Concern Number 3

Section 17 of the QARD has deleted the reference to DOE/RW-0194, "Records Management Policies and Requirements." This DOE document formed the basis for NRC acceptance of the scope of the DOE QA records program for the geologic high-level waste repository. DOE should provide a description of what the scope of their quality records system consists of, including a listing of typical post-closure and lifetime records most applicable to the geologic high-level waste repository.

Resolution

The QARD contains the requirements for the DOE records program. It has been found to be impractical to provide reference to the RMPR due to all of the non-quality administrative requirements. The QARD does meet all quality requirements of the RMPR as well as the requirements of NQA-1, basic requirement 17 and Supplement 17S-1. It should be noted that although no direct reference is contained in the QARD, the RMPR is still administratively imposed on program participants.

NRC Concern Number 4

The revised Appendix A of the QAPD lists additional support contractors and affected organizations performing work related to the geologic high-level waste repository. Several of these QA programs have not been submitted to the NRC staff not have they have been observed by the NRC staff as being audited by DOE. DOE should state whether it will submit these QA programs to NRC and provide a schedule of when they will be audited by DOE.

Resolution

This concern is assumed to be related to the references in Appendix A to Batelle; Pacific Northwest Laboratories (PNL), Brookhaven National Laboratory (BNL), Lawrence Berkeley Laboratory (LBL), Oak Ridge National Laboratory (ORNL), and Argonne National Laboratory (ANL).

The support to MGDS provided by the above organizations is limited and in most cases does not affect near-term site characterization. The one area that does affect near-term site characterization is review of study plans and for this task the organizations (in accordance with procurement requirements) were utilized as direct support contractors implementing the OCRWM QA Program. In some cases, these organizations were utilized as subcontractors to Yucca Mountain participants. These situations do not require "qualification" or submittal of programs to the NRC.

NRC Concern Number 5

In Appendix E, "Glossary," of the QARD , the definition of "Procurement Document" indicates that revisions to procurement documents that do not modify the scope of an item or activity to which the QA program is applied to, are not subject to the procurement controls of the QA program. Those revisions that add quality assurance of technical requirements to procurement documents, are subject to QA or technical review. It is not clear in appendix E of the QARD or in any other sections of the QARD or QAPD, what individual(s) or organization(s) are responsible for determining whether a review of revisions to procurement documents necessitates involvement of the QA or technical organizations.

Resolution

This is a level of detail appropriate for an implementing document rather than as requirement to be included in the QARD. The reason for the statement in the definition is to preclude the necessity for reviews that are not required. For example, a work authorization letter that allows work to be initiated based on a procurement document that has already undergone QA and technical review does not require another review. QAAP 4.1, Section 6.1.1 requires that the procurement "preparer organization" decide if any technical or quality review is necessary.

NRC Concern Number 6

During its review of the QARD and QAPD, the NRC requested clarification from DOE concerning where certain of the RP criteria pertaining to software QA controls were addressed. In response to the NRC concern, DOE has stated, that a matrix will be provided to the NRC staff specifically delineating how and where the QARD and QAPD meet the RP criteria concerning software QA controls. This matrix will be required for final review by the NRC staff for verifying the acceptability of the software QA controls of the QARD and QAPD.

Resolution

A copy of the completed matrix can be found in Attachment 1 of this supplement and is provided for your information.

NRC Three (3) Concerns on Appendix A - Transport of Nuclear Fuel and High-Level Waste

A letter (Linehan to Shelor) dated April, 15, 1991 identified additional concerns with the Transportation Appendix of the QARD. The resolutions to those issues are addressed as follows:

NRC Concern Number 1

The QARD and QAPD are acceptable as meeting the requirements of Appendix H of 10 CFR Part 71, provided the six open issues identified in the NRC letter of December 3, 1990, are satisfactorily resolved.

Resolution

See resolution to the six issues listed above

NRC Concern Number 2

Section 1.0 a. of Appendix B of the QAPD should read, "Transportation operations planning, Scheduling ..." (instead of shielding)

Resolution

The corrections have been made as indicated on page 6 of ICN 3.1 (Attachment 3 of this Supplement)

NRC Concern Number 3

Section 1.0 of Appendix B in the next to last paragraph should read, "... Systems and Compliance ..." (instead of "Systems Compliance")

Resolution

The corrections have been made as indicated on page 6 of ICN 3.1 (Attachment 3 of this Supplement)

NRC Two (2) Concerns on Appendix B - MRS System

The April, 15, 1991 letter also identified concerns with the MRS System Appendix of the QARD. The resolutions to those issues are addressed as follows:

NRC Concern Number 1

Sections 1 through 19 of the QARD appear generally acceptable. Appendix D of the QARD should be modified similar to the way Appendices A and B amplify the QARD for the mined geologic disposal system and waste acceptance process. Examples of such modifications would include, but not be limited to, considerations in the areas of the QA Program Scope, readiness reviews, graded QA, peer reviews, etc.

Resolution

It is agreed that the items described above, such as QA Program Scope, graded QA, peer reviews, etc. should also apply to the MRS element of the OCRWM Program. However, instead of adding these amplifications to each of the QARD Appendices, these requirements have been moved back into the main body of the QARD. Therefore, the requirements will apply PROGRAM-wide. The changes have been made as indicated on ICN 4.1 (Attachment 2 of Supplement I)

Additional changes such as the implementation of DOE System 80 requirements and qualification of data of indeterminate quality have also been added to the main body of the document and are reflected in the ICN. Since the subject of readiness reviews is already present in the main body of the document, no further amplification of this requirement is necessary in Appendix C or D.

NRC Concern Number 2

Similarly for the QAPD, the NRC staff also finds it to be generally acceptable. However, as in aforementioned comment (1) for the QARD, consideration should also be given to modifying Appendix C of the QAPD similar to the way Appendices A and B amplify the QAPD.

Resolution

See resolution of Comment number 1 above, and ICN 3.1 (Attachment 3 of Supplement I)

QUALIFICATION AUDIT 90-I-01, RECOMMENDED ACTIONS

The resolution of this exception, which involves completion of recommended actions, is documented on Attachments 4 and 5. It should be noted that all the actions have been satisfactorily completed with the exception of the closure of a Severity Level 3 Corrective Action Request (CAR) YM-91-005 (see Attachment 4). This CAR has been allowed to remain open while OCRWM is consolidating Headquarters and site procedures, as well as the Quality Assurance Requirements Document and the Quality Assurance Program Description Document. These efforts are intended to resolve the deficiencies identified by the matrix and complete the required corrective action.

There were two CARs identified while performing the recommended surveillances. These CARs and other deficiency documents that have been identified on the OCRWM QA Program remain open. Even though this condition exists, it is the Office of Quality Assurance's (OQA's) position that this is an inherent characteristic of a properly implemented QA Program and is to be expected. Therefore, since this condition is limited, it has no significance in regard to the acceptance of the overall OCRWM QA Program.

Based on this information, the OQA concludes that the OCRWM QA Program is acceptable for implementation of new site characterization activities and other quality related activities with no exceptions.

SUPPLEMENT I
Attachment 1

# SOFTWARE QA REQUIREMENTS MATRIX

| Software QA Plan | QARD/QAPD | | NRC Standard Review Plan |
|---|---|---|---|
| Section 2.1 | QARD, Section 19; 19.1.1.1 | 2.4 | Criteria are established and documented for determining and identifying structures, systems, components, software and activities which are to be controlled by the QA program. Guidance for determining these items and activities is provided in NUREG-1318, "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program, Subject to Quality Assurance Requirements." (See Ref. 4) |
| Section 2.1; 4.4.3; 6.0 | QARD, Section 19.0a; 19.1 (19.1.1) | 2.9 | The QA program includes a commitment that all development, control, and/or use of computer programs will be conducted in accordance with the QA program. Guidance for the content of documentation of computer codes is provided by NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management." (See Ref. 5) |
| | This is only in NRC Review Plan, Sec. 2.9. OCRWM does not have this in the QARD | | NUREG/CR-4640 "Handbook of Software Quality Assurance Techniques Applicable to the Nuclear Industry," (see Ref. 6) may be used as a reference for developing software QA programs. |
| SQAP in Total | QARD, Section 19.1; App. A, Section 19.1 | 3.1 | Design information and design activities refer to data collection and analyses activities and computer codes that are used in supporting design development and verification. |
| Section 5.1 | QARD, Section 19.1 (Section 19.1.1, 2nd bullet) NQA-1, BR-3; Supplement 3S-1, Paragraphs 2, 3, and 4 | 3.3 | Measures are established to assure that those applicable regulatory requirements, design bases and design features developed through the site characterization phase activities for those structures, systems, components, and software to which this appendix applies are correctly translated into specifications, drawings, plans, procedures, and instructions. |

# SOFTWARE QA REQUIREMENTS MATRIX
(continued)

| Software QA Plan | QARD/QAPD | | NRC Standard Review Plan |
|---|---|---|---|
| SQAP in Total | QARD, Section 19, especially 19.1; 19.1.1; 19.1.2b; 19.2; NQA-1, Supplement 3S-1, Paragraphs 2, 3, 4 | 3.4 | Design control measures are established and applied to: a) the design of engineered items important to safety or waste isolation; b) the description of the geologic setting and plans for data collection and analysis activities that will generate information pertinent to the repository design and that will be relied on in licensing; c) computer codes. These design control measures apply to the design inputs, outputs and implementation of the Site Characterization Plan into scientific investigation plans and study plans. |
| | QARD Section 3.0 | 3.5 | Design control measures are established and applied to conceptual design, or parts thereof which may at a later time become part of the final design. |
| Section 5.1 | QARD, Section 19.0a; 19.0c; 19.1; 19.2; 19.3; 19.4; 19.6; 19.8; NQA-1, BR-3; Supplement 3S-1, Paragraphs 2, 3, and 4 | 3.6 | Organizational responsibilities are described from preparing, reviewing, approving, verifying and validating design and design information documents. |
| Section 5.1; 8.0 | QARD, Section 19.1, bullets 3 and 4; 19.5; NQA-1, BR-3; Supplement 3S-1, Paragraph 6 | 3.8 | Design interfaces and interface controls among organizations or groups involved in design development and other design activities such as the review, approval, release, distribution and revisions of documents involving design interface are described and procedurally controlled. |
| Section 6.2; 7.2; 10.2; 5.2 | QARD, Section 19.8; 19.1.2d; 19.2; 19.12 | 3.10 | Procedural controls provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculation methods, or by the performance of a suitable testing program. |

# SOFTWARE QA REQUIREMENTS MATRIX
(continued)

| Software QA Plan | QARD/QAPD | | NRC Standard Review Plan |
|---|---|---|---|
| Section 6.2 | QARD, Section 19.8<br>QARD, Section 3.3 | 3.12 | Procedures for a design or technical review require, where applicable, the identification of the reviewers, the area or features reviewed, and the resolution methods for resolving comments. |
| Section 7.0; 5.2.7 | QARD, Section 19.1; bullet 6; 19.2; 19.3; 19.4; 19.1.1.4; 19.7d | 3.13 | Design verification procedures assure the following:<br>a. criteria for determining the method of verification are established; |
| | QARD, Section 19.2c<br>NQA-1, Supplement 3S-1, Paragraph 4 | | b. the persons performing verification and validation are qualified and not directly responsible for the design; |
| Section 5.2.7 | QARD, Section 19.2a; 19.6; NQA-1, Supplement 3S-1, Paragraph 4 | | c. the verification and validation are completed before release for procurement, manufacturing, construction, or use; |
| Section 7.1; 7.2 | QARD, Section 19.1.1.2 | | d. the responsibilities of the persons performing the verification or validation are defined; |
| Section 7.1; 7.2 | QARD, Section 19.2; 19.2b; 19.3 | | e. the areas and features to be verified are specified; and |
| Section 6.0 | QARD, Section 19.2; 19.1, 3rd bullet; 19.1.1.3; 19.7 | | f. the extent of documentation is designed. |
| Section 5.2.7 | QARD, Section 19.2 (especially Paragraph C)<br>NQA-1, Supplement 3S-1, Paragraph 4 | 3.14 | Procedures are established and described for verification of designs and design activities. Individuals verifying designs should be qualified and not directly responsible for the design (i.e. not the performer or his immediate supervisor). In exceptional cases, the designer's immediate supervisor can, however, perform the verification, provided:<br>a. The supervisor is the only technically qualified individual. |

# SOFTWARE QA REQUIREMENTS MATRIX
(continued)

| Software QA Plan | QARD/QAPD | | NRC Standard Review Plan |
|---|---|---|---|
| | This is only in NRC Review Plan, Section 3.14. OCRWM does not have this in QARD. | | b. The need is individually documented and approved in advance, with the concurrence of the QA Manager. |
| Section 5.2.7; 10.1; 10.2 | QARD, Sec. 19.2a; 19.2c; 19.7d; NQA-1, Supplement 3S-1, Paragraphs 3 and 3.1. Approval of computer codes meet the intent of "certification". | 3.18 | Procedures are established to assure that verified computer codes are certified for use and that their uses are specified. |
| | QARD, Section 19.6; 19.11; NQA-1, BR-7; Supplement 7S-1, Paragraphs 5.2, 8, and 10 | 7.1 | Measures are established and described to assure that purchase items and services, including software, whether purchased directly or through contractors and subcontractors, conform to procurement documents. |
| Section 9.0 | QARD, Section 19.11; NQA-1, BR-7; Supplement 7S-1, Paragraph 2 | 7.2 | Organizational responsibilities are described for the control of purchased items, services and software. |
| Section 9.1; 9.2 | QARD, Section 19.6; 19.11; NQA-1, BR-7; Supplement 7S-1 | 7.3 | Procedures governing procurement of items or services provide for: a) evaluation and selection of suppliers; b) objective evidence of quality furnished by suppliers; c) inspections and audits of suppliers' activities, items, services and software; and d) receiving inspections. |
| Section 8.0 | QARD, Section 19.5a | 8.2 | Procedures are established which assure that identification is maintained either on the item, software and samples or on records and containers traceable thereto. |
| Section 9.1; 5.2; 6.9; 6.10; 7.0 | QARD, Section 19.1.2d; 19.2; 19.3; 19.4; QARD Section 3.3 | 11.1 | A test program is established to assure that all testing associated with items, software, scientific investigations, and acquiring data from samples is identified and performed in accordance with written test procedures incorporating, as appropriate, the requirements and acceptance limits contained in applicable design documents. |

# SOFTWARE QA REQUIREMENTS MATRIX
(continued)

| Software QA Plan | QARD/QAPD | | NRC Standard Review Plan |
|---|---|---|---|
| Section 8.0 | QARD, Section 19.5 | 14.1 | Procedures are established to indicate by the use of markings the status of inspections and tests, and the operating status of individual items and software. |
| Section 8.0 | QARD, Section 19.5 and 19.9 | 15.2 | Procedures are established for identifying, documenting, tracking, segregating, reviewing, dispositioning, and notifying affected organizations of nonconforming or defective items, software, procedures, records and activities. The procedures identify positions authorized to dispose of and close out nonconformances. |
| Section 6.0; 6.2 | QARD, Section 19.7; 19.8; 19.0a; 19.1, 3rd and 4th bullet; 19.1.1.3; 19.1.1 | 17.6 | Procedures are established describing methods of documenting recording, reviewing, and confirming accuracy of records, which include laboratory and field notebooks and log books, data sheets, data reduction documents and software. |

# OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.

## INTERIM CHANGE NOTICE

| AFFECTED DOCUMENT (Including Revision): | EFFECTIVE DATE: | ICN NO. |
|---|---|---|
| Quality Assurance Requirements Document (QARD) Revision 4 | September 3, 1991 | 4.1 |

INTERIM CHANGE AND RATIONALE:

PAGES AFFECTED

I QARD Main Body

The following changes are made for clarity and correctness or to add additional requirements.

1.0 Paragraph 2.5.1 — 2-2

Change title to "Classification".

Change first sentence to read:

"Items shall be classified to determine applicability of the quality assurance (QA) program to the items and their related activities. The QA program shall apply to items important to radiological safety and waste isolation."

2.0 Paragraph 2.5.2 — 2-3

Add "(Grading)" to title after the word "Controls".

3.0 Section 2.8, Personnel Selection, Indoctrination, Training, and Qualification — 2-4

Add new paragraph between existing paragraphs 4 & 5 to identify the need to collect and maintain certain records as privileged records:

"Records on individuals generated by affected organization training and qualification programs shall be collected and maintained as privileged records according to the Privacy Act of 1974 as defined in Section 17."

4.0 Subsection 2.12 and Paragraph 2.12.1 — 2-6

Add new Subsection 2.12 and Paragraph 2.12.1 as follows:

"2.12 QUALIFICATION OF DATA OF INDETERMINATE QUALITY

Data that will be needed to be qualified to support a license application and that was not collected under the control of a QA program meeting the QA program requirements of 10 CFR 60, 71, 72 or this document, shall be qualified in accordance with the approach provided in NUREG-1298, prior to use in support of license application activities.

| TYPE OF CHANGE: Major X Minor ___ | REQUIRED TRAINING: Read X Classroom ___ |
|---|---|
| PREPARER OF ICN — DATE 8/7/91 | DIRECTOR, OQA — DATE 8/8/91 |
| APPROVAL: DIRECTOR, OQA — DATE 8/8/91 | APPROVAL: DIRECTOR, OCRWM — DATE 8/9/91 |

# OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.

## INTERIM CHANGE NOTICE (Continuation Sheet)

| AFFECTED DOCUMENT (Including Revision): | EFFECTIVE DATE: | ICN NO. |
|---|---|---|
| Quality Assurance Requirements Document (QARD) Revision 4 | September 3, 1991 | 4.1 |

INTERIM CHANGE AND RATIONALE:

PAGES AFFECTED

4.0 Subsection 2.12 and Paragraph 2.12.1 (continued)

2-6

a. Data may include information collected from such sources as professional journals, technical reports, and symposia proceedings; such data does not include design reference codes and standards, for example, ASME Boiler and Pressure Vessel Code, ASTM standards, and CRC Handbooks.

b. The organization using the data shall define the data qualification process that describes how data will be assessed for quality characteristics, such as accuracy, precision, completeness, representativeness, and comparability.

c. Acceptable qualification methods include any one, or a combination of, peer review, corroborating data, or confirmatory testing.

d. Consideration shall be given to the following factors when available and measurable:

1. Qualifications of personnel or organizations generating the data.
2. Technical adequacy of the equipment and procedures used in the scientific investigation.
3. Laboratory conditions.
4. Confidence level associated with the corroborating data based upon the quality and reliability of the measurement control program under which the data was generated.
5. Amount of corroborating data or confirmatory testing.
6. Extent to which data demonstrates properties of interest (for example; physical, chemical, geologic, mechanical.
7. Extent to which conditions generating the data may partially meet requirements of this document.
8. Prior uses of the data and associated verification process.
9. Prior professional reviews of the data.
10. Extent and reliability of the documentation associated with the data.
11. Degree to which data-generating processes were independently audited.
12. Importance of the data to show that performance objectives were met.

e. The results of data qualification activities shall be documented.

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4.0 Subsection 2.12 and Paragraph 2.12.1 (continued)

2.12.1 Qualification of Data by Use of Corroborating Data — 2-6

Reports of data qualification by use of corroborating data shall include the following elements:

a. Identification of the corroborating data source.

b. Tabulation of the corroborating data.

c. Description of the corroborating data relationship to the data being qualified.

d. Technical justification for use of the corroborating data.

e. Identification of the corroborating data reviewers.

f. Test results."

5.0 Subsection 3.5 — 3-2

Add "new" Subsection 3.5 as follows:

"3.5 PEER REVIEWS

Peer Reviews shall be performed in accordance with the approach provided in NUREG-1297"

6.0 Section 17, Quality Assurance Records — 17-1

Add new Section 17.2 to identify the requirements for compliance with the Privacy Act of 1974 using DOE System 80:

"17.2 QA TRAINING AND QUALIFICATION RECORDS (DOE SYSTEM 80)

17.2.1 QA records that contain personnel training and qualification information, including certification records, shall be collected and maintained as a special system of records in accordance with the requirements of the *Privacy Act of 1974; Proposed Establishment of a New System of Records*, 55 FR 32288, August 8, 1990 (DOE System 80).

17.2.2 DOE System 80 shall be managed by the Director, Office of Quality Assurance, OCRWM. The system manager shall delegate responsibility for management of DOE System 80 at PROGRAM Participant locations.

17.2.3 DOE System 80 records shall be processed, maintained, and controlled at OCRWM Headquarters and PROGRAM Participant locations as privileged records with appropriate restrictions on availability and distribution, according to each affected organization's Quality Assurance Program Description and established procedures for processing QA records.

17.2.4 Access to DOE System 80 records is restricted to authorized personnel and those provided access under a routine use as defined in DOE System 80. Requests for access to DOE System 80 records shall be directed to the appropriate system manager."

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|---|---|
| II QARD, Appendix A | |
| Appendix A, Subsection 2.1 | A-1 |
| Change to read: "The classification process to determine the applicability of the QA program to items and their related activities and the grading process shall be consistent with the guidelines provided in NUREG 1318, "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements," April 1988." | |
| Appendix A, Subsections 3.0 and 3.1 | A-1 |
| Delete. | |
| Appendix A, Subsection 20.10 and Paragraph 20.10.1 | A-13 & A-14 |
| Delete. | |
| III QARD, Appendix B | |
| Appendix B, Subsection 2.5 | B-2 |
| Change reference from Section "2.8" to "2.10". | |
| Appendix B, Sections 3.1, 3.2, and Paragraphs 3.2.1, 3.2.2, 3.2.3, and 3.2.4 | B-2 & B-3 |
| Delete existing Section 3.1 and renumber remaining sections and paragraphs as 3.1, 3.1.1, 3.1.2, 3.1.3 and 3.1.4 | |
| Appendix B, Paragraph 3.2.5, 3.2.6 and Section 3.3 | B-3, B-4 & B-5 |
| Delete existing Paragraph 3.2.5 and renumber existing paragraph 3.2.6 as 3.1.5. Renumber Section 3.3 as 3.2. | |

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| Quality Assurance Program Description (QAPD) Revision 3 | September 3, 1991 | 3.1 |

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I QAPD Main Body

The following changes are made for clarity and correctness or to add additional requirements.

1-4

1. Section 1.1, OCRWM Organization

Add new paragraph 1.1.2.1.n to assign new responsibility for DOE System 80 to the Director, OQA:

"n. Manage DOE System 80 for QA training, qualification, and certification records in accordance with the Privacy Act of 1974 as described in Section 17."

2.0 Paragraph 2.1.8 — 2-4

Change title to "Classification and Graded Quality Assurance."

Change first sentence to read:

"OCRWM has adopted a quality assurance approach which classifies items to determine applicability of the QA program and in which the extent of the program and procedural controls are selectively applied to the items and related activities depending on the relative importance of the item to radiological safety, waste isolation, or PROGRAM objectives."

3.0 "Delete" the existing last sentence of Section 2.1.8. — 2-5

4.0 Section 2.1, OCRWM Quality Assurance Program — 2-6

Add new paragraph 2.1.9.e to identify the need to collect and maintain certain records as privileged records for DOE System 80:

"e. QA Training and Personnel Qualification Records

Documentation generated for the purpose of verifying that personnel have the appropriate education and experience for qualification and have received appropriate training shall be maintained as a special system of records within the OCRWM records management system to meet the requirements of DOE System 80 of the Privacy Act of 1974."

| TYPE OF CHANGE: Major X Minor ___ | REQUIRED TRAINING: Read X Classroom ___ |
|---|---|
| PREPARER OF ICN — DATE 8/7/91 | DIRECTOR, OQA — DATE 8/8/91 |
| APPROVAL: DIRECTOR, OQA — DATE 8/8/91 | APPROVAL: DIRECTOR, OCRWM — DATE 8/9/91 |

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5.0 Paragraph 2.1.13 — 2-7

Add new Paragraph 2.1.13 to read as follows:

"2.1.13 Qualification of Data

Data that will be needed to be qualified to support a license application and that was not collected under the controls of a QA program meeting the QA program requirements of 10 CFR 60, 71, 72 or this document, shall be qualified in accordance with the approach provided in NUREG 1298, prior to use in support of license application activities."

6.0 Paragraph 3.1.10 — 3-4

Add new Paragraph 3.1.10 to read as follows:

"3.1.10 Peer Review

Peer reviews are required when adequacy of the information (e.g., data, interpretations, test results, design assumptions, etc.) or suitability of essential procedures and methods cannot be confirmed by testing, alternate calculations, or reference to previously established standards and practices.

OCRWM establishes and implements, when appropriate, procedures in accordance with approach specified in NUREG 1297.

Documents generated during the peer review process are quality assurance records."

7.0 Section 8.0 — 8-1

Change to read:

"The identification and control of materials, parts, components, and samples are implemented in accordance with approved procedures."

8.0 Section 12.0 — 12-1

Change to read as follows:

"12.0 GENERAL

This section applies the requirements necessary to ensure that tools, gages, instruments, and other measuring and test equipment (M&TE) used in activities that affect quality are properly controlled, adjusted, and calibrated at specified periods to maintain accuracy within necessary limits. OCRWM Managers are responsible for the implementation of an effective calibration program in accordance with approved procedures.

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8.0 Section 12.0 (continued)

12.1 APPLICABILITY AND SCOPE OF THE M&TE CONTROL PROGRAM

Controls noted in this section apply to M&TE (tools, gages, instruments, etc:). However, controls of M&TE are also applied to activities used to calibrate, measure, gage, test, or inspect for the purpose of either: (1) controlling or acquiring data to verify conformance to a specified requirement; or (2) establishing characteristics or values not previously known. The methodology for control of M&TE is described in approved procedures.

12.2 M&TE REQUIREMENTS

12.2.1 Selection

Selection of M&TE is controlled to ensure that such equipment is of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements. Each device has a unique identification number. The type, range, accuracy and tolerance of a measuring device is specified in approved procedures. This number is recorded on the data sheet, log, or equivalent, along with the measurement taken, to ensure traceability of the measurement to the device used to take the measurement.

12.2.2 Calibration

Measuring and test equipment is calibrated against certified equipment having known valid relationships to the National Institute of Standards and Technology or other nationally recognized standards and is calibrated, adjusted, and maintained at prescribed intervals. If no nationally recognized standards exist, the acceptability of the calibration standard used is justified. Calibrating standards have equal or greater accuracy than equipment being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible PROGRAM personnel.

12.2.3 Control

The method and interval of calibration for each M&TE item is defined, based on the type of equipment, stability characteristics, required accuracy, precision, intended use, degree of usage, and other conditions that affect measurement control. M&TE is labeled, tagged, or otherwise documented in a manner that indicates the due date of the next calibration and provide traceability to calibration data. If M&TE is found to be out of calibration, an evaluation is made and documented on the validity of previous results obtained, on acceptability of items previously inspected or tested or on data gathered since the last calibration. Out of calibration devices require the condition be documented in accordance with Section 15 of this QAPD, tagged or segregated, and not used until they have been dispositioned and corrective action has been satisfactorily verified. If any M&TE is found to be consistently out of calibration, it is repaired or replaced. Calibration is performed when the accuracy of equipment is suspect.

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12.2.4 Commercial Devices

Calibration and control measures are not required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy.

12.2.5 Handling and Storage

M&TE is handled properly and stored to maintain accuracy in accordance with requirements specified by either the manufacturer or responsible PROGRAM personnel.

12.2.6 Records

M&TE records are maintained and identify the calibration procedure (including revision) used to perform the calibration. These records are processed in accordance with Section 17 of the QAPD."

9.0 Section 13.0 — 13-1

Change to read as follows:

"13.0 GENERAL

This section applies the requirements for controlling the packaging, handling, storage, shipping, cleaning, and preservation of items or samples subject to quality assurance program controls to prevent damage, loss, or deterioration.

13.1 IMPLEMENTING DOCUMENTS

Handling, shipping, and storage activities are conducted in accordance with procedures, specifications, drawings, instructions, or other pertinent documents specified for use.

13.2 REQUIREMENTS

13.2.1 Special Equipment and Protective Environments

When required for particular items or samples, technical documents specify controls for use of special equipment and special environments. These documents also require special equipment and environments to be provided and existence verified.

13.2.2 Specific Procedures

When required for critical, sensitive, perishable, or exceptionally expensive articles, specific procedures for handling, storage, packaging, shipping, and preservation are used. Where appropriate, qualification of special lifting equipment, slings, and hoists is explicitly addressed.

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13.2.3 Inspection and Testing of Special Tools and Equipment

When used, special handling tools and equipment are controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment are inspected and tested in accordance with procedures at specified time intervals, to verify that the tools and equipment are adequately maintained.

13.2.4 Operators of Special Equipment

Operators of special handling and lifting equipment are experienced or trained to use the equipment; related training activities are conducted and documented in accordance with procedures.

13.2.5 Procedures

Procedures used for marking, labeling, packaging, shipping, handling, and storage of items or samples include provisions addressing adequate identification, maintenance, and preservation of the items, including indication of the need for special environments or the need for special controls."

10. Section 17, Quality Assurance Records — 17-3

Add new section 17.9 to identify the requirements for compliance with the Privacy Act of 1974 using DOE System 80:

"17.9 QA TRAINING AND QUALIFICATION RECORDS (DOE SYSTEM 80)

A special system of records is established for QA training, qualification, and certification records. Requirements for this records system are described in the Federal Register notice, *Privacy Act of 1974; Proposed Establishment of a New System of Records*, 55 FR 32288, August 8, 1990 (DOE System 80).

DOE System 80 is managed by the Director, OQA at OCRWM Headquarters. Responsibility for maintaining the system is delegated to the QA Training Officer at Headquarters and to the Training Officer at the Project Office.

DOE System 80 records are turned over to the LRCs and subsequently to the CRFs for processing, control, and maintenance in accordance with approved QA records management procedures.

DOE System 80 records are classified as privileged records in the OCRWM records management system. Appropriate restrictions on availability and distribution of privileged records are described in approved procedures and instructions.

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| | 17-3 |
| Access is limited to authorized supervisory, QA, records management processing personnel, and those provided access under a routine use. DOE System 80 permits disclosure of records to state and local agencies, the NRC, and other Federal agencies for audit purposes. Requests for access to DOE System 80 records are directed to the Director, OQA, OCRWM." | |
| II QAPD, Appendix A | |
| Appendix A, Section 2.0 first sentence and Paragraphs 2.0.c, -d and -f | A-6 |
| Change "items and activities" (1st sentence); "activities" (paragraphs c&d); "items or activities" (paragraph f) | |
| to "... items and their related activities..." | |
| Appendix A, Paragraph 3.2.1 | A-8 |
| "Delete" first paragraph on the top of page A-8. | |
| Appendix A, Paragraphs 12.0 through 12.3.6<br>Delete in its entirety. | A-10 & A-11 |
| Appendix A, Paragraphs 13.0 through 13.3.5<br>Delete in its entirety. | A-12 & A-13 |
| Appendix A, Paragraph 20.4.2 | A-14 |
| Delete. | |
| III QAPD, Appendix B | |
| Appendix B, Subsection 1.0 | B-1 |
| Change the word "shielding" in Paragraph 1.0.a to "scheduling". | |
| Revise Paragraph immediately following Paragraph 1.0.d by inserting the word "and" between "Systems" and "Compliance". | |

Attachment 4

Recommended CAR CLOSURE STATUS
(from Qualification Audit 91-I-01)

| CAR NUMBER | ASSIGNED TO | DESCRIPTION | STATUS |
|---|---|---|---|
| HQ-91-002 | Headquarters (RW-30) | Deficiencies with interface control. | Closed |
| HQ-91-007 | Headquarters (RW-30) | Improper document control of WMSR and WMSD. | Closed |
| HQ-91-008 | Headquarters (RW-3) | Untimely actions for open items relative to CAR/DR/OBS. | Closed |
| HQ-91-009 | Headquarters (RW-10) | Inadequate description of the records storage facility. | Closed |
| HQ-91-011 | Headquarters (RW-3) | Lack of HQ internal or external audits. | Closed |
| YM-91-005 | Project Office (QAD) | No approved matrix for OCRWM procedures and QARD/QAPD. | Response Accepted (In Process) |
| YM-91-006 | Project Office (Training) | Training system does not ensure adequate training. | Closed |
| YM-91-007 | Project Office (EDD) | Flow down of technical requirements not clear. | Closed |
| YM-91-008 | Project Office (EDD) | Inputs to YMP/CM-007 not always traceable. | Closed |
| YM-91-009 | Project Office (EDD) | Inappropriate reviewer selection. | Closed |

**Recommended Surveillance Status
(from Qualification Audit 91-I-01)**

| SURVEILLANCE NUMBER (DATE | SUBJECT | SUMMARY OF RESULTS | DEFICIENCY REPORTS ISSUED |
|---|---|---|---|
| | SURVEILLANCES FOR: Control of the Technical Baseline (including the change control process). (HQ) | | |
| HQ-91-001 (1/22-29/91) | The review/comment process for the WMSR Vol. IV, Revision 1, and the Technical Document Management Plan. Also, the preparation, review, and approval of the Technical Document Management Plan for the Physical System Requirements/Functional Analysis and implementation of the plan. | This surveillance determined that the documents listed in the scope of this surveillance were developed, reviewed, and commented on in accordance with applicable procedures. In addition, the qualification and training of personnel involved were found to be in accordance with approved documents. | HQ-91-021 (Open) |
| HQ-SR-91-002 (2/4-6/91) | The process used in developing, reviewing, issuing, and controlling Revision 1 of WMSR, Vol. 1. | DCP 29, Revision 1 of WMSR, Vol. 1, was prepared and processed in accordance with the requirements of DOE/RW-0223, Revision 3P, Program Change Control Procedure. The DCP documentation was revised against the requirements stipulated in the appropriate procedures and was found to follow these requirements | None |

**Recommended Surveillance Status**
**(from Qualification Audit 91-I-01)**

| SURVEILLANCE NUMBER (DATE | SUBJECT | SUMMARY OF RESULTS | DEFICIENCY REPORTS ISSUED |
|---|---|---|---|
| | SURVEILLANCE FOR: Quality Records Center | | |
| HQ-SR-91-003 (3/5-7/91 | The origination, collection, packaging, verification, and control of the QA record packages identified in the surveillance report. | Based upon the documents reviewed during this surveillance and discussions with the personnel contacted, it has been determined that the appropriate requirements of QAAP 17.1 are being met by the originating organizations. | None |
| | SURVEILLANCE FOR: Corrective Action System | | |
| HQ-SR-91-007 (4/22-25/91) | This surveillance covered activities associated with the OCRWM Corrective Action System in order to determine the effectiveness of implementation of QA Administrative Procedures (QAAPs) 16.1 and 16.9. Open and closed deficiency documents issued during 1990 and 1991 were reviewed during the surveillance. | The surveillance team concluded that QAAP 16.1 is being effectively implemented for the HQ activities of OCRWM. One CAR was issued as a result of this surveillance which identifies an inconsistency between QAAPs 16.1 and 18.2 regarding the requirements for determining extent of a deficiency, root cause, and action to prevent recurrence when responding to CARs. | HQ-91-023 (Open) |
| HQ-SR-91-006 (4/9-11/91) | Review QAAP 18.1, Qualification of Audit Personnel, Revision 1, dated 2/22/91, and determine the effectiveness of implementation. | QAAP 18.1 was determined to be effectively implemented, although the implementation of System 80 will result in a simpler, more concise filing system. | None |

**Recommended Surveillance Status**
**(from Qualification Audit 91-I-01)**

| SURVEILLANCE NUMBER (DATE | SUBJECT | SUMMARY OF RESULTS | DEFICIENCY REPORTS ISSUED |
|---|---|---|---|
| HQ-SR-91-015 (7/15-19/91) | Implementation of QAAP 18.2, Audit Program, Revision 3 and QAAP 18.3, Surveillance Program, Revision 1. | These procedures were found to be effectively implemented. However, one CAR was issued to resolve minor inconsistencies in auditor qualification records where one auditor was qualified, however, the documentation for this qualification was not properly signed. | HQ-91-031 (Open) |
| | SURVEILLANCE FOR: Preparation and Review of YMP/SM-0007, Revision 2 | | |
| YMP-SR-91-006 (11/29/90 and 12/3-4/90) | Yucca Mountain Site Characterization Project Office and Sandia National Laboratories (SNL) preparation and review of "Technical Requirements for the Yucca Mountain Project (Midway Valley Trenching and Calcite-Silica Activities), "YMP/CM-0007, (R-2). (Project Office) | The preparation and review of YMP/CM-0007, Revision 2, was satisfactorily performed in accordance with applicable SNL and Project Office procedures. | None |
| | SURVEILLANCE FOR: Training. (Project Office) | | |
| YMP-SR-91-003 (10/20-11/26/90) | Training for technical, regulatory, management, and quality assurance reviews of YM/CM-0007, Revision 2. | This surveillance determined that individuals assigned to perform a technical, regulatory, management or quality assurance review of YMP/CM-0007, Revision 2, had the requisite training. | None |