



Department of Energy
 Office of Civilian Radioactive Waste Management
 Yucca Mountain Site Characterization Office
 P.O. Box 98608
 Las Vegas, NV 89193-8608

MAR 24 1995

Larry R. Hayes
 Technical Project Officer
 for Yucca Mountain
 Site Characterization Project
 U.S. Geological Survey
 101 Convention Center Drive
 Suite 860
 Las Vegas, NV 89109

VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF CORRECTIVE ACTION REQUEST (CAR) YM-94-046 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION'S (YMQAD) AUDIT YMP-94-06 OF U.S. GEOLOGICAL SURVEY (SCPB: N/A)

The YMQAD staff has verified the corrective action to CAR YM-94-046 and determined the results to be satisfactory. As a result, the CAR is considered closed.

If you have any questions, please contact either Robert B. Constable at 794-7945 or Stephen R. Maslar at 794-7762.

Robert B. Constable

Richard E. Spence, Director
 Yucca Mountain Quality Assurance Division

YMQAD:RBC-2638

Enclosure:
 CAR YM-94-046

- cc w/encl:
- J. G. Spraul, NRC, Washington, DC
 - S. W. Zimmerman, NWPO, Carson City, NV
 - T. H. Chaney, USGS, Denver, CO
 - R. W. Craig, USGS, Las Vegas, NV
 - D. D. Porter, USGS/SAIC, Golden, CO
 - D. G. Horton, OQA (RW-3) NV
 - W. E. Barnes, YMSCO, NV

- cc w/o encl:
- W. L. Belke, NRC, Las Vegas, NV
 - D. G. Sult, YMQAD/QATSS, Las Vegas, NV

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

8 CAR NO.: YM-94-046
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CORRECTIVE ACTION REQUEST

1 Controlling Document QARD, Revision 0; YMP-USGS-QMP-16.04, Revision 0		2 Related Report No. YMP-94-06	
3 Responsible Organization USGS		4 Discussed With T. Chaney	
5 Requirement: QARD, Section 16.0 states: "A condition adverse to quality shall be identified when a QARD or implementing document requirement is not met." QMP-16.04, Section 5 states: "The identification of a condition adverse to quality shall be documented by the individual identifying the condition using a Quality Deficiency Report (QDR) or equivalent."			
6 Adverse Condition: Contrary to the above requirements, during a review of USGS internal audit reports 94058-IA and 94031-IA, it appears that of 13 concerns identified, more than half of these concerns met the criteria of the QARD and QMP-16.04 for a conditional adverse to quality without QDRs or equivalent being issued to document these conditions. USGS, per internal memo dated 6/17/94, has defined/interpreted a condition adverse to quality a "a clean or very clear violation of a QMP or technical procedure." This is not in compliance with the QARD or QMP-16.04 definition of a condition adverse to quality in that it does not include noncompliance with quality program requirements other than those specified in procedures.			
9 Does a Significant Condition Adverse to Quality exist? Yes <u>X</u> No <u> </u> If Yes, Circle One: A <u>(B)</u> C D E		10 Does a stop work condition exist? Yes <u> </u> No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C	
3 Response Due Date: 20 Working Days From Issuance			
11 Required Actions: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input checked="" type="checkbox"/> Root Cause Determination			
12 Recommended Actions: 1) USGS should use the wording in the QARD and QMP-16.04 as the basis for determining conditions adverse to quality. 2) Previously identified and future concerns with the associated recommendation need to be formally tracked to insure acceptable closure to USGS-QA.			
7 Initiator S. Maslar <i>C.C. Wam for</i> 6-30-94		14 Issuance Approved by: QADD <i>[Signature]</i> Date 7/5/94	
15 Response Accepted QAR <i>S.R. Maslar</i> Date 8-16-94 <i>N/A</i> <i>CAW</i> 8-16-94		16 Response Accepted QADD <i>N/A</i> Date	
17 Amended Response Accepted QAR <i>C.C. Wam for S.R. Maslar</i> Date 8-16-94 <i>S.R. Maslar 1/31/95</i>		18 Amended Response Accepted QADD <i>[Signature]</i> Date 8/16/94 <i>[Signature]</i>	
19 Corrective Actions Verified QAR <i>S.R. Maslar</i> Date 3/22/95		20 Closure Approved by: QADD <i>[Signature]</i> Date 3-23-95	

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CORRECTIVE ACTION REQUEST (Continuation Page)

1. AMENDED CORRECTIVE ACTION RESPONSE FOR CAR No. YM-94-046

- A. REMEDIAL ACTION:** The issues, documented as Concerns and Recommendations rather than deficiencies, will be formally tracked to ensure acceptable resolution of the issues.
- B. EXTENT OF THE DEFICIENCY:** The approach for using Concerns was initiated as a result of significant revisions to QMP-16.04, Control of QDRs, and QMP-18.01, Audits, which procedurally eliminated the "Observation" as a tool to document weaknesses or recommendations for improvement in the program. The effective date of the QMPs was September 29, 1993. The first of the 73 Concerns was initiated on January 12, 1994. All potential QDR conditions are identified in the Concerns.
- C. ROOT CAUSE DETERMINATION:** The USGS tries to avoid creating unnecessary paperwork whenever possible by concentrating on documenting those conditions in the program that clearly impact the results of our work. When a condition that may potentially be adverse to quality is identified, the appropriate QA and technical staff members make a determination as to whether a true deficient condition exists and if quality is enhanced by initiating a QDR. As a result, the verification group chose a conservative interpretation of a Condition Adverse to Quality and, to minimize conflict after the loss of the Observation tool, the Verification Group established a means to document potential or difficult quality issues in the form of Concerns and Recommendations, with the understanding that Management would recognize the intent of the identified concern and responsibly initiate corrective action. The Verification Group, clearly understanding what a Condition Adverse to Quality is, proceeded with this alternative approach as a means to attain compliance with the USGS QA Program.
- D. CORRECTIVE ACTION TO PRECLUDE RECURRENCE:** Corrective Actions will consist of two elements:
- (1) Effective immediately, the Verification Group will utilize a strict interpretation of the QARD definition for Conditions Adverse to Quality to identify deficiencies (QDRs).
 - (2) QMPs 16.04 and 18.01 will be changed to include a provision for documenting Concerns that encompass weaknesses and suggestions for improvement.

2. For each action above, identify the name of the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date.

1.A. L.L. McInroy, Verification Supervisor	08/01/94
1.D.(1) L.L. McInroy, Verification Supervisor	08/01/94
1.D.(2) L.L. McInroy, Verification Supervisor	10/01/94

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CORRECTIVE ACTION REQUEST (Continuation Page)

1. CORRECTIVE ACTION RESPONSE FOR CAR No. YM-94-046

- A. **REMEDIAL ACTION:** The issues, documented as Concerns and Recommendations rather than deficiencies, will be tracked to ensure appropriate resolution of the issues.
- B. **EXTENT OF THE DEFICIENCY:** The approach for using Concerns was initiated as a result of significant revisions to QMP-16.04, Control of QDRs, and QMP-18.01, Audits, which procedurally eliminated the "Observation" as a tool to document weaknesses or recommendations for improvement in the program. The effective date of the QMPs was September 29, 1993. The first of the 73 Concerns was initiated on January 12, 1994. All potential QDR conditions are identified in the Concerns.
- C. **ROOT CAUSE DETERMINATION:** The USGS tries to avoid creating unnecessary paperwork whenever possible by concentrating on documenting those conditions in the program that clearly impact the results of our work. When a condition that may potentially be adverse to quality is identified, the appropriate QA and technical staff members make a determination as to whether a true deficient condition exists and if quality is enhanced by initiating a QDR. As a result, the verification group chose a conservative interpretation of a Condition Adverse to Quality and, to minimize conflict after the loss of the Observation tool, the Verification Group established a means to document potential or difficult quality issues in the form of Concerns and Recommendations, with the understanding that Management would recognize the intent of the identified concern and responsibly initiate corrective action. The Verification Group, clearly understanding what a Condition Adverse to Quality is, proceeded with this alternative approach as a means to attain compliance with the USGS QA Program.
- D. **CORRECTIVE ACTION TO PRECLUDE RECURRENCE:** Corrective Actions will consist of two elements:
- First, effective immediately, the Verification Group will utilize a strict interpretation of the QARD definition for Conditions Adverse to Quality to identify deficiencies (QDRs).
- Second, QMPs 16.04 and 18.01 will be changed to include a provision for documenting Concerns that encompass weaknesses and suggestions for improvement.

2. For each action above, identify the name of the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date.

L.L. McInroy, Verification Supervisor

09/12/94

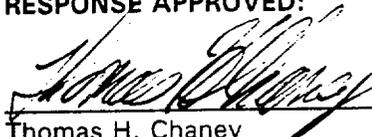
8/1/94 Ltn. Hayes & Spence

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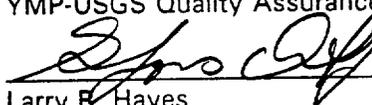
CORRECTIVE ACTION REQUEST (Continuation Page)

3. RESPONSE APPROVED:



Thomas H. Chaney
YMP-USGS Quality Assurance Manager

8/1/94
Date



Larry R. Hayes
Chief, Yucca Mountain Project Branch

8/1/94
Date

For

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CORRECTIVE ACTION REQUEST (Continuation Page)

3. RESPONSE APPROVED:



Thomas H. Chaney
YMP-USGS Quality Assurance Manager

8/9/94

Date



Larry R. Hayes
Chief, Yucca Mountain Project Branch

8/9/94

Date

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CORRECTIVE ACTION REQUEST (Continuation Page)

1. AMENDED CORRECTIVE ACTION RESPONSE FOR CAR No. YM-94-046 (Dated 11/30/94)

- A. **REMEDIAL ACTION:** No change. The issues, documented as Concerns and Recommendations rather than deficiencies, will be formally tracked to ensure acceptable resolution of the issues.
- B. **EXTENT OF THE DEFICIENCY:** No change. The approach for using Concerns was initiated as a result of significant revisions to QMP-16.04, Control of QDRs, and QMP-18.01, Audits, which procedurally eliminated the "Observation" as a tool to document weaknesses or recommendations for improvement in the program. The effective date of the QMPs was September 29, 1993. The first of the 73 Concerns was initiated on January 12, 1994. All potential QDR conditions are identified in the Concerns.
- C. **ROOT CAUSE DETERMINATION:** No change. The USGS tries to avoid creating unnecessary paperwork whenever possible by concentrating on documenting those conditions in the program that clearly impact the results of our work. When a condition that may potentially be adverse to quality is identified, the appropriate QA and technical staff members make a determination as to whether a true deficient condition exists and if quality is enhanced by initiating a QDR. As a result, the verification group chose a conservative interpretation of a Condition Adverse to Quality and, to minimize conflict after the loss of the Observation tool, the Verification Group established a means to document potential or difficult quality issues in the form of Concerns and Recommendations, with the understanding that Management would recognize the intent of the identified concern and responsibly initiate corrective action. The Verification Group, clearly understanding what a Condition Adverse to Quality is, proceeded with this alternative approach as a means to attain compliance with the USGS QA Program.
- D. **CORRECTIVE ACTION TO PRECLUDE RECURRENCE:** Added new paragraph: Corrective Actions will consist of two elements:
- (1) Effective immediately, the Verification Group will utilize a strict interpretation of the QARD definition for Conditions Adverse to Quality to identify deficiencies (QDRs).
 - (2) New Paragraph: As committed in 1A., Remedial Action, the Concerns and Recommendations have been tracked and will continue to be tracked with follow through to ensure acceptable resolution of the issues. In cases where further evaluation indicates a deficiency exists, QDRs will be issued. It is not believed, however, that it is necessary to persist in implementing the approach at this time due, principally, to the recent DOE Transition Plan which will soon require all participants to utilize DOE deficiency documents and tracking systems.

It is, therefore, recommended that Corrective Action Item 1.D(2) and responsibility Item 2, 1.D.(2) be deleted.

11/30/94 LTR. HAYES TO SPENCE

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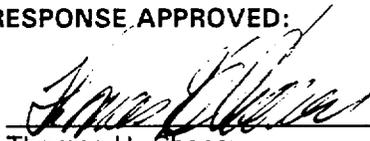
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2. For each action above, identify the name of the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date.

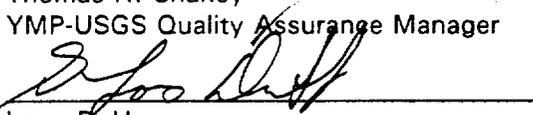
1.A. L.L. McInroy, Verification Supervisor 08/01/94
1.D.(1) L.L. McInroy, Verification Supervisor 08/01/94

3. RESPONSE APPROVED:



Thomas H. Chaney
YMP-USGS Quality Assurance Manager

11/30/94
Date



Larry R. Hayes
Chief, Yucca Mountain Project Branch

11/30/94
Date

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CORRECTIVE ACTION REQUEST (Continuation Page)

1. SUPPLEMENTAL RESPONSE FOR CAR No. YM-94-046

This supplemental response provides a reassessment of a specific provision for documenting Concerns that encompass weakness and suggestions for improvements.

QMP-16.01, R1, will be completed and effective prior to 3/10/95. A review of QMP-18.01, R7, indicates no changes are appropriate for that procedure. It does not discuss deficiencies but only refers the reader to QMP-16.04.

2. RESPONSIBLE INDIVIDUAL:

L.L. McInroy, Verification Supervisor

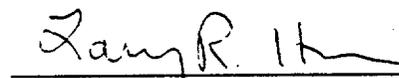
03/10/95

3. SUPPLEMENTAL RESPONSE APPROVED:



Thomas H. Chaney
YMP-USGS Quality Assurance Manager

1/24/95
Date



Larry R. Hayes
Chief, Yucca Mountain Project Branch

1/25/95
Date

MANAGEMENT PROCEDURES MANUAL

CHAPTER 16 - CORRECTIVE ACTION

**SECTION 4 - CONTROL OF QUALITY DEFICIENCY REPORTS
AND QUALITY CONCERNS**

1. **PURPOSE.** The purpose of this Quality Management Procedure (QMP) is to document a method for reporting, validating, responding to, and verifying conditions or conditions potentially adverse to quality discovered by Yucca Mountain Project - U.S. Geological Survey (YMP-USGS) personnel and support organizations.
2. **SCOPE OF COMPLIANCE.** This procedure is applicable to all conditions or conditions potentially adverse to quality associated with quality-affecting activities performed by YMP-USGS personnel and support organizations unless an alternate method for documenting the control of the condition adverse to quality has been approved by the YMP-USGS Quality Assurance (QA) Manager.

This QMP does not apply to the control of supplier deficiencies as described in QMP-7.01, the control of non-conforming samples as described in QMP-8.01, nor the control of deficient or nonconforming measuring and test equipment as described in QMP-12.01. Quality concerns formally identified prior to the effective date of this procedure and currently awaiting resolution and closure will be assigned a unique identification number and tracked in accordance with this procedure.

3. **DEFINITIONS.** For the purposes of this procedure, the following definitions shall prevail:
 - 3.1 **Actions to Prevent Recurrence:** Actions taken that are intended to preclude repetition of a condition adverse to quality.
 - 3.2 **Condition Adverse to Quality:** A state of noncompliance with quality assurance program requirements.
 - 3.3 **Corrective Action:** Actions taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.
 - 3.4 **Investigative Actions:** Actions taken to determine the extent and potential impact of a condition adverse to quality.
 - 3.5 **Quality Deficiency:** A document initiated for purposes of tracking the disposition of a condition adverse to quality.
 - 3.6 **Quality concern:** A condition potentially adverse to quality, including those which may stem from interpretation of governing documents.
 - 3.7 **Remedial Actions:** Actions taken to correct identified conditions adverse to quality.

3/10/95 Chaney to Spence

- 3.8 Response: The documentation of proposed corrective actions, any supplemental annotated documents, and, as applicable, the root cause, remedial actions, investigative actions, and actions to prevent recurrence.
- 3.9 Root Cause: The identified cause of a condition adverse to quality that, if corrected, will preclude recurrence or greatly reduce the probability of recurrence of the same or similar condition adverse to quality.
- 3.10 Significant Condition Adverse to Quality: A condition adverse to quality which, if uncorrected, could have a serious effect on safety or the ability of the proposed repository to isolate waste.
- 3.11 Validation: The YMP-USGS QA Manager's concurrence that the described condition constitutes a state of noncompliance with quality assurance program requirements.
- 3.12 Verification: The process that is performed to determine by investigation of objective evidence the adequacy of and compliance with established implementing documents and the effectiveness of implementation.
- 4. RESPONSIBILITIES.**
- 4.1 The YMP-USGS QA Manager is responsible for coordinating, processing and validating quality concerns and Quality Deficiency Reports (QDRs); assigning severity levels; issuing QDRs to the appropriate organization or person for response; evaluating proposed responses or extension requests; verifying corrective action implementation; and preparing Record Packages. Any of the above responsibilities may be assigned to QA Office staff members.
- 4.2 The QA Audit/Surveillance Team Leader assigned to conduct an audit or surveillance is responsible for identifying and documenting any condition discovered during the course of an audit or surveillance which is adverse or potentially adverse to quality; assisting the QA Manager in assigning QDR severity levels; assisting the QA Manager in evaluating QDR responses; and verifying completion of approved responses.
- 4.3 YMP-USGS and Support Personnel are responsible for initiating QDRs, providing responses, and implementing approved corrective actions.
- 5. PROCEDURE.** During the course of an audit (reference QMP-18.01), surveillance (reference QMP-18.02), verification, trending (reference QMP-16.03), or other routine operations, conditions adverse to quality may be discovered. The identification of a condition adverse to quality shall be documented by the individual identifying the condition using a Quality Deficiency Report (QDR), or equivalent. If deficiencies identified during the course of an audit or surveillance (QMP-18.01 or QMP-18.02) can be corrected expediently and there is no impact on data, then a QDR does not need to be generated. These corrected deficiencies shall be documented in the applicable audit or surveillance report or by memorandum to appropriate management, including the YMP-USGS QA Manager.

Conditions potentially adverse to quality (quality concerns) may also be discovered that do not warrant issuance of a QDR, justify further investigation and/or improvement, and

are of concern to the YMP-USGS and support personnel. These quality concerns shall be documented on the Quality Concern Form (Attachments 3).

5.1 QDR Initiation: The QDR initiator shall complete the Initiation portion, Part I, of the QDR (Attachment 1 or equivalent).

5.1.1 The QDR initiator shall identify how the condition adverse to quality was identified, i.e., audit, surveillance, verification, trending, or other routine operations; and shall identify the associated SCP Activity, if applicable.

5.1.2 The QDR initiator shall specify the requirement violated, state the specific deficiency, and provide other pertinent information and/or recommendations as applicable.

5.1.3 The initiator shall forward the QDR to the QA Manager for validation.

5.2 QDR Validation: The QA Manager shall review Part I of the QDR to ascertain if it is valid and properly documented.

5.2.1 If the QDR is valid and properly documented, the QA Manager checks "Valid" and signs the QDR in Part II.

5.2.2 If the QDR is valid, but not properly documented, the QA Manager shall discuss the QDR with the initiator. Either the initiator or the QA Manager shall make the needed corrections.

5.2.3 If the QDR is not considered valid, the QA Manager shall discuss the QDR with the initiator. After discussion, if the QDR is still not considered valid, the QA Manager checks "Invalid" to document the rejection and signs Part II. Justification of the action and a copy of the invalidated QDR are returned to the initiator.

5.3 QDR Severity Level: The QA Manager, in consultation with the QDR originator, shall assign a severity level based on the following guidelines. Severity levels decrease in significance from 1 to 3. The QA Manager shall check the appropriate boxes in Part II of the QDR to identify necessary parts of a response based upon the following guidance.

5.3.1 Severity level 1 is assigned to significant conditions adverse to quality. Severity level 1 conditions are generally applicable when it is likely that results from an entire SCP Activity would be in jeopardy if the condition is not corrected. An example of a severity level 1 condition would be conducting a data gathering activity without either a technical procedure or scientific notebook, without personnel instruction, and without documentation of personnel qualifications. Responses to severity level 1 deficiencies are required to address impact on data, root cause, action(s) to prevent recurrence, remedial actions, investigative actions, and annotated documents (documents with critical explanations or analysis; commentary). Severity level 1 deficiencies shall be evaluated by the QA Manager to determine if a stop work condition exists in accordance with QMP-16.02, Control of Stop Work Orders. The result of the evaluation shall be documented in Part II of the QDR.

5.3.2 Severity level 2 is assigned to conditions adverse to quality that are considered likely to have an affect on the acceptability of resultant data or that are identified trends of severity level 2 and/or 3 deficiencies. Examples of severity level 2 deficiencies would be equipment found to be out of calibration, use of a vendor that was not qualified, or a trend on late submittals of documentation. Responses to severity level 2 deficiencies shall generally address impact on data, root cause, action(s) to prevent recurrence, remedial actions, investigative actions, and annotated documents (documents with critical explanations or analysis; commentary).

5.3.3 Severity level 3 is assigned to minor deficiencies that are not likely to have an adverse impact on data and that are not initially recognized as a trend. Usually, severity level 3 responses are only required to address impact on data and remedial action(s). If the condition has already been corrected and Part I of the QDR provides this information under "Other Pertinent Information/Recommendations," then no response may be necessary.

- 5.4 QDR Numbering and Tracking: After validation, the QA Manager shall assign a unique number to each QDR. QDR numbers and status are tracked in accordance with QMP-16.03.
- 5.5 Issuance for Response: The QA Manager shall issue the QDR for response to the appropriate organization or person based on the scope and severity level of the deficiency. For severity level 1 QDRs, the QA Manager shall notify the management responsible for the condition and their upper management. The distribution of QDRs shall include DOE, Yucca Mountain Quality Assurance Division (DOE/YMQAD).
- 5.6 QDR Response Due Date: The QA Manager shall assign a response due date, which shall not exceed 30 calendar days from the validation date.
- 5.7 QDR Response: Upon receipt of the validated QDR, the person assigned responsibility for the QDR response shall complete and sign the response (Part III) on a QDR continuation sheet (Page 1 of Attachment 2 or equivalent). The proposed response shall address the response parts indicated on Part II of the QDR. If the deficient condition has an impact on data, the actions taken to flag the data shall be included in a QDR response. (Examples of actions taken to flag data are notations in the comment section of the Technical Data Information Forms and reference to the QDR in a scientific notebook, calibration document, or other record.) The QDR continuation sheet shall be submitted to the QA Manager by the assigned due date and shall include, as necessary, scheduled and/or anticipated completion date(s) for the action(s) to be taken.
- 5.8 Response Evaluation: As appropriate, the Audit Team Leader, Surveillance Team Leader, and/or QA Manager shall evaluate the proposed response to the QDR. The evaluation shall consider the adequacy, timeliness, and effectiveness of the actions to be taken. The evaluation shall be documented by marking the appropriate box and signing and dating the QDR continuation sheet.
- 5.8.1 The organization responding to the QDR shall be notified by the YMP-USGS QA Manager that a response is either approved or rejected. For the responses that

are rejected, the QA Manager shall provide appropriate rationale to support the rejection and a new response due date shall be assigned.

5.8.2 If the proposed response is rejected, the responsible organization shall provide the QA Manager with an amended or supplemental response on a QDR continuation sheet prior to or on the response due date assigned in Para. 5.8.1.

- 5.9 QDR Amended/Supplemental Response: If the QDR assigned responder recognizes that a proposed response is no longer correct or appropriate, an amended or supplemental response may be submitted at any time on a QDR continuation sheet. The amended or supplemental response should clearly state what parts of the previous response it is superseding.
- 5.10 Completion of Actions: All corrective actions shall be implemented by the responsible organization as committed to in the approved response unless an extension request has been approved (see Para. 5.10.1 below). When the actions are complete, the responsible organization shall notify the QA Office on a QDR continuation sheet that actions are complete.
- 5.10.1 In the event that corrective actions cannot be completed by the scheduled due date, an extension request shall be documented on a QDR continuation sheet and submitted to the YMP-USGS QA Manager no later than the due date for the corrective action. Extension requests shall include a justification for the delay, a statement of progress achieved, and an evaluation of impact due to failure to maintain the approved schedule. Examples of acceptable justifications are unexpected extended absence by key personnel involved with the actions, or rescheduling of anticipated events or actions which impacted the corrective actions and which were beyond the control or influence of the responders.
- 5.10.2 Extension requests shall be evaluated by the Audit Team Leader, Surveillance Team Leader, and/or QA Manager, as applicable, and the acceptance or rejection shall be documented on the continuation sheet. For those extension requests that are rejected, the YMP-USGS QA Manager shall contact appropriate management of the responsible organization to develop an acceptable schedule for completion of the corrective actions.
- 5.11 Request to Void a QDR: If, during the course of investigating the deficient condition, it is determined through objective evidence that the condition is not a violation, the responsible person may request that the QA Manager void the QDR. The request to void a QDR should be documented on a QDR continuation sheet. The QA Manager will view the evidence and accept or reject the request. Acceptance will be processed in accordance with Para. 5.13.
- 5.11.1 If the request to void a QDR is rejected, the QA Manager will provide on a QDR continuation sheet appropriate rationale to support the rejection and the request for an amended response.
- 5.12 QDR Verification: QDRs are generally closed by verification of corrective actions. See Para. 5.13 for alternate closures.

- 5.12.1 Follow-up actions shall be taken or assigned by the Audit Team Leader, Surveillance Team Leader, or QA Manager, as appropriate, to verify completion of corrective actions in a timely manner after their completion if an alternate basis for closure is not identified. Verification shall be performed by persons or organizations not directly responsible for implementing the corrective actions.
- 5.12.2 The results of the verification shall be detailed on a QDR continuation sheet or in an audit or surveillance report with appropriate reference recorded in Part IV. If the verification determines that the corrective actions were not completed adequately or were not effective, the QA Manager, Audit Team Leader or Surveillance Team Leader, as appropriate, shall notify responsible management. The notification shall be documented on a QDR continuation sheet and should indicate the next course of action; i.e., amended response, new verification date, etc.
- 5.12.3 Upon closure, Part IV of the QDR shall be signed and dated by the Audit Team Leader/Surveillance Team Leader, if appropriate, and by the QA Manager. A copy of the closed QDR shall be distributed to the responsible organization and to DOE/YMQAD. Severity level 1 QDRs shall also be distributed to the offices of the Director of the U.S. Geological Survey and the Assistant Chief Hydrologist for Technical Support.
- 5.13 Alternate QDR Closure: The QA Manager shall explain the alternate basis for closure, such as duplicate corrective actions recognized in other existing deficiency documents, or basis for voiding the QDR in Part IV of the QDR with further explanation on a QDR continuation sheet, if necessary. Upon closure, Part IV of the QDR shall be signed and dated by the QA Manager and the Audit Team Leader/Surveillance Team Leader, if appropriate. A copy of the closed QDR shall be distributed to the responsible organization and to DOE/YMQAD. Severity level 1 QDRs shall also be distributed to the offices of the Director of the U.S. Geological Survey and the Assistant Chief Hydrologist for Technical Support.
- 5.14 Identification of Quality Concern: Quality Concerns may be identified by all YMP-USGS personnel, but shall be reported to the QA Office. When appropriate, QA Office personnel will initiate and process Quality Concern Forms.
- Upon report of a new quality concern, and prior to initiating a new Quality Concern Form, the existing Quality Concern Forms shall be tracked (see para. 5.16) to ensure against duplication.
- If a reported quality concern relates to, or is a duplicate of, an existing quality concern; the extent of the relationship will be examined and a decision will be made regarding the need for generating a new Quality Concern Form.
- 5.15 Completion of Quality Concern Form: All Quality Concerns shall be documented and processed in accordance with the instructions provided on the backside of the Quality Concern Form (see Attachment 3). Information which constructively contributes to closure of the quality concern(s), may be documented on the Quality Concern Form Continuation Sheet (see Attachment 4) provided all completed continuation sheets are securely attached to the original Quality Concern Form.

5.15.1 **INITIATION** (Section 1 of Attachment 3): When appropriate, the QA Office shall initiate a form for quality concerns that have been identified..

5.15.2 **REVIEW, RESOLUTION AND/OR CLOSURE ACTION** (Section 2 of Attachment 3): QA Office reviewers shall perform quality Concern Form reviews, document personnel contacts, ensure affected personnel are adequately notified of the concern and its implications and contribute to follow-up actions. Reviews shall be performed by persons or organizations not directly responsible for the quality concern.

5.15.3 **FOLLOW-UP RESULTS** (Section 3 of Attachment 3): Based on the follow-up results, the QA Office shall recommend closure or further follow-up action(s) and sign and date the form. Further follow-up action(s) are documented on the form continuation sheet(s).

5.15.4 **CLOSURE** (Section 4 of Attachment 3): After final follow-up action is completed, the QA Manager (or delegate) shall provide closure approval.

5.15.5 **DISTRIBUTION**: The completed Quality Concern Form shall be distributed to QA Office personnel who were responsible for initiating the quality concern, and affected others.

5.16 **Maintenance of Quality Concern Tracking System**: The QA Office shall maintain a tracking system for quality concerns in accordance with QMP-16.03. This tracking system will include a status-history of each quality concern, including initiation and closure dates.

6. **RECORDS MANAGEMENT.**

6.1 **Controlled Documents**: None.

6.2 **Records Center Documents**: The following QA records shall be submitted by the QA Manager to the YMP-USGS Local Records Center as complete record packages in accordance with QMP-17.01:

- Completed YMP-USGS Quality Deficiency Reports (or equivalent) and supporting documentation
- Invalidated Quality Deficiency Reports and the justification for invalidation
- Quality Concern form(s) and support documentation

7. **RELATED DOCUMENTS.**

7.1 **Superseded Documents**: This QMP supersedes YMP-USGS-QMP-16.04, R0, Control of Quality Deficiency Reports and Modifications QMP-16.04,R0-M1, -M3, -M4, and -M5.

7.2 **References Cited**:

- YMP-USGS-QMP-7.01, Receipt of Purchased Items and/or Services
- YMP-USGS-QMP-8.01, Identification and Control of Samples
- YMP-USGS-QMP-12.01, Instrument Calibration

- YMP-USGS-QMP-16.02, Control of Stop Work Orders
- YMP-USGS-QMP-16.03, Tracking, Trending, and QA Management Information Reporting
- YMP-USGS-QMP-17.01, YMP-USGS Records Management for Records Sources
- YMP-USGS-QMP-18.01, Audits
- YMP-USGS-QMP-18.02, Surveillances

8. ATTACHMENTS.

- Attachment 1: YMP-USGS Quality Deficiency Report
- Attachment 2: YMP-USGS Quality Deficiency Report Continuation Sheet
- Attachment 3: Quality Concern Form and Instructions
- Attachment 4: Quality Concern Form Continuation Sheet

9. APPROVALS AND EFFECTIVE DATE.

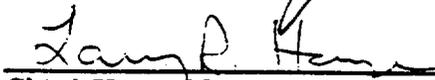
EFFECTIVE DATE: 03/10/95



 YMP-USGS Quality Assurance Manager

3/9/95

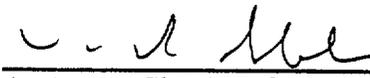
 Date



 Chief, Yucca Mountain Project Branch

3/9/95

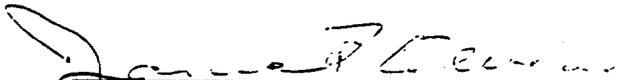
 Date



 Assistant Chief Hydrologist for Technical Support

3/10/95

 Date



 Science Advisor for Science Applications

MAR 10 1995

 Date

10. HISTORY OF CHANGES.

<u>Revision/Modification No.</u>	<u>Effective Date</u>	<u>Description of Changes</u>
R0	09/29/93	Initial Issue.
R0-M1	04/22/94	Changed to support compliance with paras. 18.2.9, 18.2.10, and 18.2.11 of the QARD.
R0-M2	10/07/94	Procedure modified to provide a revised way to address unsatisfactory verifications.
R0-M3	11/10/94	Supersedes Modification 2; editorial change to History of Changes.

<u>Revision/ Modification No.</u>	<u>Effective Date</u>	<u>Description of Changes</u>
R0-M4	12/09/94	Procedure modified as a result of corrective actions during DOE Audit YMP-95P-04.
R0-M5	02/21/95	Procedure changed to exclude the use of the QDR process for documenting deficient or nonconforming M&TE.
R1	03/10/95	This revision incorporates all Modifications to R0 and the identification of concerns as committed to in DOE CAR YM-94-046.

19 25 3/7/95



YMP-USGS QUALITY DEFICIENCY REPORT Continuation Sheet

USGS-QDR- _____

QDR Page ____ of ____

(To be filled out by Responder[s]):

Page 1 of ____

- Response
- Amended/Supplemental Response
- Extension Request
- Notification of Completion of Actions
- QDR Void Request

Submitted by: _____
Signature Date

(To be filled out by QA Office:)

Approved Rejected Basis for Rejection: _____

Amended/Supplemental Response Due Date _____

ATL/STL: _____
Signature Date

QA Manager: _____
Signature Date



YMP-USGS QUALITY DEFICIENCY REPORT Continuation Sheet

QA: L
SCP: NA
WBS #: 1.2.11

USGS-QDR- _____

QDR Page ____ of ____

(To be filled out by QA Office):

Page 1 of ____

- Evaluation Results
- Approval/Rejection of Extension Request
- Request for Supplemental/Amended Response
- Request for Notification of Completion of Actions
- Verification Results
- Alternate QDR Closure

Submitted by: _____
Signature Date

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DS/KS/KS



YMP-USGS
QUALITY ASSURANCE
VERIFICATION

QUALITY CONCERN FORM

Concern No: _____
Page 1 of _____

SECTION 1 - INITIATION

Associated Oversight Number: _____ Issue Date: _____ Due Date: _____

Subject (Include QMP, technical procedure, etc.): _____

SECTION 2 - RESOLUTION AND/OR CLOSURE ACTION

Contacts: _____

Comments: _____

SECTION 3 - FOLLOW-UP RESULTS

Close, based on above comments.

Close, based on action(s) taken and verified.

Further follow-up action(s): _____

Follow-up due date: _____

Signature, QA Office

Date

SECTION 4 - CLOSURE APPROVAL

Signature, QA Office

Date

Copy to:

22 23
4/5/95

QUALITY CONCERN FORM INSTRUCTIONS

HEADER

Concern No.: Contact the QA Office for number (e.g., CON-94089). If a quality concern is identified during an oversight activity, include this tracking number in the applicable audit/surveillance report.

Pagination: Complete appropriate pagination for the entire pack of forms applicable to the quality concern, prior to submission to the YMP-USGS Local Records Center. Include attachments as necessary.

SECTION 1 - INITIATION

Associated Oversight Number (if applicable): Audit or surveillance number. If not applicable, enter "NA".

Issue Date: Date of initiation, or date of issuance of oversight report (if applicable).

Due Date: Due 90 days after initiation date.

Subject: Brief description of quality concern; include appropriate QMP, technical procedure, or other related document.

SECTION 2 - RESOLUTION AND/OR CLOSURE ACTION

Contacts: Personnel contacted; add date if different from date of signature in Section 3 on form. If resolution and subsequent closure recommendation consist of several actions taken on separate dates, use the form continuation page (Attachment 4) to document these actions.

Comments: Describe resolution, action, justification for closure recommendation; reference attachments, if applicable.

SECTION 3 - FOLLOW-UP RESULTS

Closure/Further Follow-up Action Recommendation: Check appropriate block.

- Close, based on above comments.
- Close, based on action(s) taken and verified.
- Further follow-up action(s):
 - Add explanation.
 - Follow-up due date; 30 days after date of signature in Section 3 of form.

Signature, QA Office, Date: Resolution step completed or closure recommended.

SECTION 4 - CLOSURE APPROVAL

Signature, QA Manager or delegate, Date: Closure approval.

FOOTER

Copy to: List recipients; include as a minimum: QA Manager, QA Verification Manager, YMP-USGS and support personnel primarily involved in resolution; LRC File for applicable audit or surveillance file.

VERIFICATION OF CORRECTIVE ACTION FOR CAR YM-94-046

Reviewed revised procedure, QMP-16.04, Revision 1, and found it acceptable. As a result of this verification, CAR YM-94-046 is considered closed.

S. R. Maslar
Stephen R. Maslar, QAR

3/22/95
Date

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

CAR NO. YM-94-046
 DATE: 7/1/94
 PAGE: 1 OF 1
25 QA 25 DS
 4/5/95

CAR SUMMARY SHEET

	<u>Date</u>	<u>Letter Reference</u>
<u>Issuance Letter/Memo</u>	<u>7/5/94</u>	<u>YMQAD:RBC-4160</u>
<u>Response Extension Request</u>	<u>N/A</u>	<u>N/A</u>
Acceptance	↓	↓
<u>Response Received</u>	<u>8/2/94</u>	<u>Ltr. Hayes to Spence</u>
Acceptance	<u>N/A</u>	<u>N/A</u>
<u>Request Amended Response</u>	<u>verbal</u>	<u>Madlar/McInroy</u>
Response	<u>8/9/94</u>	<u>Ltr. Hayes to Spence</u>
Acceptance	<u>8/16/94</u>	<u>YMQAD:RBC-4685</u>
<u>Request Amended Response</u>	<u>N/A</u>	<u>N/A</u>
Response	<u>11/30/94</u>	<u>LTR. HAYES TO SPENCE</u>
Acceptance	<u>N/A</u>	<u>N/A</u>
<u>C/A Extension Request</u>		
Acceptance		
<u>C/A Extension Request</u>		
Acceptance		
<u>Unsatisfactory Verification</u>	<u>1-13-95</u>	<u>YMQAD:RBC-1677</u>
Response	<u>1/25/95</u>	<u>Hayes to Spence</u>
Acceptance	<u>2/6/95</u>	<u>YMQAD:RBC-1973</u>
<u>Closure Letter</u>	<u>2/24/95</u>	<u>YMQAD:RBC-2638</u>
Other	<u>Request Amended Resp. 12/21/94</u>	<u>YMQAD:RBC-1349</u>
	<u>Verification information Recd. 3/10/95</u>	<u>Chaney to Spence</u>