



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

WBS 1.2.11
 QA: N/A

JAN 25 1993

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

EVALUATION OF RESPONSE TO CORRECTIVE ACTION REQUEST (CAR) YM-93-015 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD) AUDIT YMP-93-01 OF U.S. GEOLOGICAL SURVEY (USGS)

The YMQAD staff has evaluated the response to CAR YM-93-015. The response to Parts A, B, and C has been determined to be unsatisfactory because:

1. Part A states that there is no remedial action necessary. Based on Items 2 through 3 below, USGS must provide remedial actions to resolve the noted conditions described in CAR YM-93-015.
2. Part B of your response states in part: (1) that a product can be defined as a final data package that is formal input to another investigation, that cannot proceed without the information (data) provided; (2) Administrative Procedure (AP) 5.19Q does not apply to the collegial exchange of scientific information; (3) AP-5.1Q does not apply to the data exchange as cited in the CAR because it is considered raw data and is unchecked; and (4) the exchange cited in the CAR falls under the category of preliminary scientific exchange.

The definitions (i.e., final data package, collegial exchange, and preliminary scientific exchange) for the data which you provided to Los Alamos National Laboratory (LANL) can not be found in either AP-5.1Q or AP-5.19Q.

AP-5.1Q is explicit as to its applicability for the control of technical data. AP-5.1Q, Section 1.1 (Purpose) states: "This procedure establishes requirements and assigns responsibilities for the control and transfer of Yucca Mountain Site Characterization Project (YMP) technical data. Data control and transfer begin at data acquisition, through measurement by YMP Participant Staff, . . . or any other means except for data generated outside the YMP." Section 2.0 (Applicability) states in part: "This procedure applies to the Yucca Mountain Site Characterization Project Office (YMPO) and all YMP Participants who acquire, manipulate, or disseminate technical data."

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ADD: Ken Hooks

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JAN 25 1993

Based on the statement above, any technical data in any form shall comply with the controls specified in AP-5.1Q. Any interpretations to the intent of the requirements in YMPO APs must be established in writing by those who have authority to make the interpretations. AP-5.1Q is clear that data shall be controlled at the beginning of data acquisition. There are no stipulations that data need not be controlled until after the participant makes the decision that it is complete and is checked as stated in AP-5.1Q, Section 3.3 (Data Acquisition). USGS should take immediate action to transmit the data referenced in CAR YM-93-015 to the Participant Data Archive via a Technical Data Information Form as required by AP-5.1Q.

Part B of your response states in part that the data transferred to LANL was unchecked. It appears that another potential violation exists in that the data transferred to LANL was not checked as required by AP-5.1Q, Section 3.3 (Data Acquisition). If this is the case, USGS should take the necessary action to document this condition adverse to quality and implement the necessary corrective action.

3. Part B of your response states in part that AP-5.19Q only applies to the identification, development, approval, control, and changes to Level C and D interfaces. This procedure addresses the control and release of a very specific type of data.

AP-5.19Q, Section 3.3 (Informational/Organizational Interface) states in part: "An informational interface, also referred to as an organizational interface, is a controlled process used to officially request, document, and transfer information between various YMP organizations (Participant) that must share and/or transfer information. This information is usually technical in nature (e.g., scientific data) and is used in technical studies"

AP-5.19Q does not make any reference to the specific type of data you refer to in your response. USGS should take immediate action to finalize the Interoffice Memorandum of Understanding between USGS and LANL for the exchange of technical data.

4. Part D of your response discusses the use of a statement regarding preliminary data. This is not consistent with current requirements. Neither AP-5.1Q nor AP-5.19Q discuss preliminary data.

Based on the YMPO-approved requirements stated in the AP-5.1Q and AP-5.19Q, USGS should take immediate action to bring the transmittal of technical data, as referenced in CAR YM-93-015, into compliance with these requirements or request a revision to AP-5.1Q and AP-5.19Q to be consistent with present practices.

JAN 25 1993

It is requested that USGS management reevaluate their response in light of the aforementioned options, and respond indicating the action taken.

An amended response to Parts A, B, and C is required to be submitted to this office within ten working days of the date of this letter. Send the original of your response to Nita J. Brogan, Science Applications International Corporation, Las Vegas, Nevada. If an extension to the due date is necessary, it must be requested in writing, with appropriate justification, prior to that date.

If you have any questions, please contact either Robert B. Constable at 794-7945 or Richard L. Maudlin at 794-7290.



Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-1856

Enclosure:
CAR YM-93-015

cc w/encl:

~~K. R. Hooks, NRC, Washington, DC~~
S. W. Zimmerman, NWPO, Carson City, NV
T. H. Chaney, USGS, Denver, CO
R. W. Craig, USGS, Las Vegas, NV
B. J. Verna, YMP, NV
A. V. Gil, YMP, NV

cc w/o encl:

J. W. Gilray, NRC, Las Vegas, NV
N. J. Brogan, SAIC, Las Vegas, NV
D. D. Porter, SAIC, Golden, CO

ORIGINAL
THIS IS A RED STAMP

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

8 CAR NO.: YMP-93-015
DATE: 10-22-92
SHEET: 1 OF 2
QA

CORRECTIVE ACTION REQUEST

1 Controlling Document AP 5.19Q, R2 AP5.1Q, R2	2 Related Report No. YMP-93-01
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3 Responsible Organization USGS	4 Discussed With Ardell Whiteside, R. Spangler
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5 Requirement:

AP 5.19Q, Step 8b, stated in part: "Data Supplier-If IMOU and/or PIRN have no impact on controlled documents and are acceptable, sign and return original signature document... to the processor."

AP 5.19Q, Step 11, states in part: "Data Supplier-Compile and send data to the requester (send and control data per AP-5.1Q....)"

AP 5.1Q, Step 2, states in part: "YMP Participant- Submit the DPS to the appropriate participant data archive... Include a TDIF...."

AP 5.1Q, Section 3.12 states in part: "The TDIF... is used to provide input to the ATDT System. The form is included with DPSs and Data Transmittal Packages."

6 Adverse Condition:
Contrary to the above:

(A) Acquired Data has been transmitted to LANL without documented evidence of processed IMOU.

(B) Acquired Data has been transmitted to LANL without evidence of a TDIF being prepared and Data entered into the Participant Data Archive.

Example: 6-10-91 "Potential Sr-Isotope Stratigraphy High-Silca Rhyolite."
10-12-92 "Isotope Stratigraphy in the Topopah Springs High-Silica Rhyolite"

9 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; if Yes - Attach copy of SWO If Yes, Circle One: A B C D	11 Response Due Date: 20 working days from issuance
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12 Required Actions: Remedial Extent of Deficiency Preclude Recurrence Root Cause Determination

13 Recommended Actions:

(A) Process IMOU and get number assigned prior to transmittal of Data

(B) Transmit Acquired Data to PDA with TDIF

(C) Evaluate status of all IMOUS between USGS and other participants. Assure all have been processed and have been assigned a number per AP 5.19Q

7 Initiator R. L. Maudlin <i>R. Maudlin</i> Date <u>10-22-92</u>	14 Issuance Approved by: QADD <i>R. Spangler</i> Date <u>11/3/92</u>
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15 Response Accepted QAR Date	16 Response Accepted QADD Date
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17 Amended Response Accepted QAR Date	18 Amended Response Accepted QADD Date
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19 Corrective Actions Verified QAR Date	20 Closure Approved by: QADD Date
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ENCLOSURE

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
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WASHINGTON, D.C.

8 CAR NO.: YMF-93-015
DATE: 10-22-92
SHEET: 2 OF 2
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

13 Recommended Action(s) (continued)

- (D) Evaluate all Data Transmitted to date and determine:
 - (1) is there a valid IMOU for transmittal of this data
 - (2) has data been transmitted to PDA via TDIF prior to being sent to participant
- (E) Determine cause of condition and what action would be taken to preclude recurrence

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CAR NO. YM-93-015
DATE: _____
SHEET: _____ OF _____

CORRECTIVE ACTION REQUEST
(continuation sheet)

1. **YMP-USGS CORRECTIVE ACTION RESPONSE FOR CAR # YM-93-015**

- A. **Remedial Actions** - Remedial actions are not necessary for Corrective Action Request (CAR) YM-CAR-93-015.
- B. **Investigative Action** - In order to examine the extent of the potential deficiency, the YMP-USGS has reevaluated the requirements of AP-5.19Q and AP-5.1Q; investigated various types of data releases; and coordinated and confirmed the results of the evaluation with the USGS Interface Control Working Group Representative (ICWG), USGS Data Management Coordinator, and Deputy Director of Regulatory and Site Evaluation Division, Yucca Mountain Project Office.

AP-5.19Q only applies to the identification, development, approval, control, and changes to Level C & D interfaces. This procedure addresses the control and release of a very specific type of data. An appropriate application of AP-5.19Q is when a product from one Level C and/or D system is requested as input to another Level C and/or D system or subsystem. A product can be defined as a final data package that is formal input to another investigation that can not proceed without the information (data) provided. For example, soil and rock properties data must be provided to RSN prior to the design of the surface facilities. AP-5.19Q does not apply to the collegial exchange of scientific information.

AP-5.1Q is utilized to control and ensure technical data to support the license application for repository construction are complete and retrievable. Technical data are defined in AP-5.1Q as data resulting from data acquisition or data development activities. Acquired technical data are further defined to be data that have been recorded and checked. Developed technical data are the results of reducing, analyzing, or interpreting acquired data. AP-5.1Q addresses the control and release of these specific types of data. AP-5.1Q does not apply to the data exchange cited in the CAR because the data were raw and unchecked. AP-5.1Q requires that data be checked before they are submitted to the Participant Data Archive (PDA).

There are additional types of data and data releases that do not fall under the control of AP-5.1Q or AP-5.19Q. Investigative actions have identified various types of data releases and their controls. It has been determined that the exchange of information cited in YM-CAR-93-015 fall under a category of preliminary scientific exchange. This type of scientific exchange is specified in Study Plan (SP) 8.3.1.4.2.1. The SP Section 1.1 (Information to be obtained and how that information will be used) states in part, "Some of the data necessary to determine rock correlation and spatial variability in this study plan is similar to data being collected at Los Alamos National Laboratory (Study 8.3.1.3.2.1, Mineralogy, petrology and rock chemistry of transport pathways; Study 8.3.1.3.2.2, History of mineralogical and geochemical alteration of Yucca Mountain). Likewise, geological interpretations from this study are essential

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CORRECTIVE ACTION REQUEST
(continuation sheet)

1. YMP-USGS CORRECTIVE ACTION RESPONSE FOR CAR # YM-93-015 (Continued)

B. Investigative Action (Continued) -

for adequate characterization of the transport pathways being investigated elsewhere. Therefore, we envision close communication and information exchange with scientists at Los Alamos in areas of potential overlap (mineralogy, petrology and diagenesis) so that data sets collected by each group are unique and complementary."

During DOE Audit 93-01 discussions, the YMP-USGS stated that an AP-5.19Q IMOU existed to address scientific exchanges between the USGS and Los Alamos National Laboratory (LANL). Subsequent investigations confirmed that the draft IMOU to control this exchange was canceled by the USGS ICWG Representative and therefore was never fully approved. During the approval process it was determined that the IMOU was inappropriate.

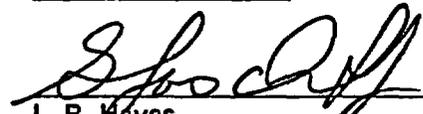
C. Root Cause Determination - The requirements of AP-5.19Q were misunderstood by YMP-USGS staff.

D. Corrective Action to Preclude Recurrence - 1) The YMP-USGS QA Manager and the YMP-USGS Data Management Coordinator have received clarification of the requirements pertaining to AP-5.1Q and AP-5.19Q from YMPO officials. 2) Through involvement with this CAR the investigator is aware that future written communications should have a statement such as, "data are preliminary and should not be used in quality affecting work".

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

T.H. Chaney completed investigative actions November 3, 1992.
P.W. McKinley completed investigative actions November 4, 1992.

3. Response Approved:


For L. R. Hayes 12/1/92
Chief, Yucca Mountain Project Branch Date


T. H. Chaney 12/1/92
YMP-USGS Quality Assurance Manager Date