



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

JUL 06 1995

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 Site Characterization Project
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EVALUATION OF AMENDED RESPONSE TO CORRECTIVE ACTION REQUEST (CAR)
 YM-95-028 RESULTING FROM U.S. DEPARTMENT OF ENERGY/HEADQUARTERS
 QUALITY ASSURANCE DIVISION'S AUDIT HQ-ARC-95-04 OF THE CIVILIAN
 RADIOACTIVE WASTE MANAGEMENT SYSTEM MANAGEMENT AND OPERATING
 CONTRACTOR (SCPB: N/A)

The Yucca Mountain Quality Assurance Division staff has evaluated the amended response to CAR YM-95-028. The amended response has been determined to be satisfactory. Verification of completion of the corrective action will be performed after the effective date provided. Any extension to this date 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 John F. Pelletier at 794-7538.

Robert B. Constable

Richard E. Spence, Director
 Yucca Mountain Quality Assurance Division

YMQAD:RBC-3812

Enclosure:
 CAR YM-95-028

- cc w/encl:
- T. A. Wood, HQ (RW-14) FORS
 - ~~J. G. Spraul, NRC, Washington, DC~~
 - R. L. Robertson, M&O, Vienna, VA
 - Richard Jiu, M&O, Las Vegas, NV
 - R. P. Ruth, M&O, Las Vegas, NV
 - S. W. Zimmerman, NWPO, Carson City, NV
 - 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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CORRECTIVE ACTION REQUEST

1 Controlling Document OCRWM QARD DOE/RW-0333P, Revision 1		2 Related Report No. Audit HQ-ARC-95-04	
3 Responsible Organization CRWMS M&O		4 Discussed With A. Segrest	
5 Requirement: QARD Section 17.0 Paragraph 17.2.2B: "Individuals creating quality assurance records shall ensure that the quality assurance records are legible, accurate, and complete." Paragraph 17.2.2C: "Individuals handling quality assurance records shall protect them from damage or loss until the records are submitted to the records management system." Paragraph 17.2.3E3: "QA Records shall be indexed to ensure retrievability. The indexing system shall include identification of the item or related activity to which the QA records pertain."			
6 Adverse Condition: Contrary to the above requirements, records and record packages associated with drawings, specifications, and analysis are not being properly authenticated for accuracy, and appropriate to the work accomplished, completeness, nor are they being turned over to the LRC reasonably contemporaneous with completion of the individual records and record packages, or protected from deterioration, loss, or damage until turned over to the LRC. Additionally, indexing of records does not adequately provide a cross reference to the documentation or the associated activity. Examples: The following represent examples only. A comprehensive review is required to determine the extent and impact of the deficiencies. Records segment package (LRC-114) for the BAB000000-1717-6300-02341, Revision 02, Steel Sets and Accessories Subsurface (Specification) does not contain a copy of the specification review summary.			
9 Does a Significant Condition Adverse to Quality exist? Yes <u>X</u> No ___ If Yes, Check One: <input checked="" type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E		10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes, Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	
		13 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) Recommend that a performance based surveillance be conducted to determine the extent and impact of the deficiencies. 2) Recommend that record process improvements be communicated through extensive training.			
7 Initiator <u>John F. Pelletier</u> John F. Pelletier		14 Issuance Approved by: <u>[Signature]</u> QADD <u>[Signature]</u> Date <u>3/1/95</u>	
15 Response Accepted QAR <u>John F. Pelletier</u> Date <u>4/10/95</u>		16 Response Accepted QADD <u>[Signature]</u> Date <u>4/10/95</u>	
17 Amended Response Accepted QAR <u>John F. Pelletier</u> Date <u>6/27/95</u>		18 Amended Response Accepted QADD <u>[Signature]</u> Date <u>6.30.95</u>	
19 Corrective Actions Verified QAR _____ Date _____		20 Closure Approved by: QADD _____ Date _____	

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5 Requirements (continued)

M&O QAP-17-1, Revision 3, PO 4

Paragraph 3.2, Authentication: "The act of attesting that the information contained within a record is legible, accurate, complete, and appropriate to the work accomplished."

Paragraph 5.3, Protection of Records and Records-In-Process: "Responsible management and Record Sources shall ensure that records/records-in-process are protected from deterioration, loss, or damage."

Paragraph 5.4.3A: "Records sources shall authenticate individual records and record packages immediately following creation and shall turn them over to the LRC reasonably contemporaneous with completion...individual records and record packages shall be turned over to the LRC no later than 20 working days after completion."

QAP-3-9, Revision 4, Paragraph 6B: "The following QA records generated as a result of this procedure shall be submitted by the LDE to the LRC in accordance with QAP-17-1: Design Analysis Review Summary."

NLP-3-24, Revision 1, Paragraph 5.1.1d: "The drawing or specification Originator shall forward the completed IL to the LDE for transmittal to Local Records Center in accordance with QAP-3-8 or QAP-3-10, after the output (drawing or specification) is approved."

QAP-3-10, Revision 4, Paragraph 6.0: "The following QA Records are generated as a result of this procedure and shall be submitted by the LDE to the Local Records Center in accordance with QAP-17-1:

- A. Approved Drawings (which will be or are baselined)
- B. Drawing Input List
- C. Drawing Review Summary"

6 Adverse Condition (continued)

The TS North Ramp Ground Support Scoping Analysis DI: BAB000000-1717-0200-00010, Revision 01, and Material Dedication Rockbolts, Shotcrete and Accessories DI: BAB000000-1717-00009, Revision 1 have not been sent to the LRC for records processing.

Records package BABEAB000-01717-0200-0002, Structural Steel Sets Analysis, Revision 01 does not contain the Design Analysis Review Summary.

Records packages BABEAB000-01717-6300-02165, Revisions 05 and 06 have not been sent to the LRC for processing.

Records packages were not cross-referenced to the related records packages for proper indexing and ease of retrievability:

BAB000000-01717-6300-01501, "Subsurface General Construction," 2/16/95

Records package for Design Package ID 90% Design Review QA Record Package, 11/28/94

Integrated Data and Control System 90% Design Review QA Record, 1/12/95

The following drawings and the related documentation were not submitted to the LRC as required by NLP-3-24, Revision 1, and QAP-3-10, Revision 4:

Drawings listed by Document Number Description:

BABEAB000-01717-2100-40151, Revision 1, TS North Ramp Ground Support Master Elevation and Sections

BABEAB000-01717-2100-40161, Revision 1, TS North Ramp Alcoves Rockbolts and

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6 Adverse Condition (continued)

Shotcrete Sections

BABEAB000-01717-2100-40162, Revision 1, TS North Ramp Alcoves Rockbolts and Shotcrete Plan and Sections

BABEAB000-01717-2100-40163, Revision 1, TS North Ramp Alcoves Rockbolts and Shotcrete Plan, Sections and Elevation

BABEAB000-01717-2100-41101, Revision 3, TS North Ramp Steel Sets and Lagging Elevation

BABEAB000-01717-2100-41102, Revision 3, TS North Ramp Steel Sets and Lagging Sections and Details

BABEAB000-01717-2100-41103, Revision 3, TS North Ramp Steel Sets and Lagging Sections and Details

13 Recommended Action(s) (continued)

- 3) Recommend that the entire records process be studied and reengineered, both at Las Vegas and Vienna.
- 4) Recommend that indexing methods and structures be devised that allow retrievability of all records pertaining to a given work effort.
- 5) Recommend that the M&O concepts of authentication and validation be evaluated in light of the deficiencies.

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Remedial Action

The following are the examples listed in the CAR.

- A) BAB000000-01717-6300-02341 Rev 02...review summary missing from record package
- B) BAB000000-01717-0200-00010 Rev 01 and
BAB000000-01717-0200-00009 Rev 01...not in RPC
- C) BABEAB000-01717-0200-00002 Rev 01...review summary missing
- D) BABEAB000-01717-6300-02165 Rev 05 & 06...not in RPC
- E) BAB000000-01717-6300-01501...not cross referenced
ID 90% Review...not cross referenced
IDCS 90% Review...not cross referenced
- F) BABEAB000-01717-2100-40151 Rev 01...not in RPC
- G) BABEAB000-01717-2100-40161 Rev 01...not in RPC
- H) BABEAB000-01717-2100-40162 Rev 01...not in RPC
- I) BABEAB000-01717-2100-40163 Rev 01...not in RPC
- J) BABEAB000-01717-2100-41101 Rev 03...not in RPC
- K) BABEAB000-01717-2100-41102 Rev 03...not in RPC
- L) BABEAB000-01717-2100-41103 Rev 03...not in RPC

These actions listed below will correct all the examples listed above.

Examples B, D, F, G, H and I are complete and in the RPC.

Example A: BAB000000-01717-6300-02341 Rev 02...(Review Summary not in record package.)

Document was created under procedure QAP-3-8 Revision 3, which did not require a review summary and there is no evidence that one was later created to meet the requirements when the specification was actually approved. An IOC from lead with the above information will be added to the record package. This has been completed.

Example C: BABEAB000-01717-0200-00002 Rev 01...(Review Summary not in record package.)

Document was created under procedure QAP-3-9 Revision 3, which did not require a review summary and there is no evidence that one was later created to meet the requirements when the analysis was actually approved. An IOC from lead with the above information will be added to the record package. This has been completed.

Example J: BABEAB000-01717-2100-41101 Rev 03

Example K: BABEAB000-01717-2100-41102 Rev 03

Example L: BABEAB000-01717-2100-41103 Rev 03

Revision 3 of these documents are processed with revision 01 and 02 to keep the records easily retrievable. In compiling the records package Revision 01 (original) was not in EDC but was later located in the records center. The ID Review for Rev 02 of these documents is not available. At the time the ID review took place only the Review Summary sheet was a required record and it was not clear as to whether to keep a copy of the ID Review document. The only comments made were against -41101 by two reviewers who performed a management review and not a technical review. The other two drawings had no comments against them as written on the Review Summary Sheet. An IOC from lead with the above information will be added to the record packages. This has been completed.

Example E: BAB000000-01717-6300-01501; ID 90% Review and the IDCS 90% Review

A supplemental to add needed information to each record package to cross reference the different reviews and the baselining document will be completed. David Parker is the responsible individual for this example.

The completion date for the Remedial Action is May 10, 1995.

11/1/95 11/05/95 DMC 11/10/95

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Extent of Deficiency

M&O QA will conduct a surveillance (Recommendation No. 1) to provide more information that MGDS and IM will then evaluate for extent and impact. The surveillance will include record package completeness and submittal and will be complete by May 10, 1995. D.M. Franks is the responsible individual for this activity.

MGDS Development and IM will then evaluate the results and provide, as required, a supplemental Remedial Action and Extent of Deficiency. David Parker and Terry Mueller are the responsible individuals for this activity.

The following list of documents were verified to be in the records center. During the QA surveillance these record packages will be sampled for problems similar to those listed in the examples.

BABEAD000-01717-2100-40100 Rev 01
BABEAD000-01717-2100-40104 Rev 01
BABEAD000-01717-2100-40110 Rev 01
BABEAD000-01717-2100-40111 Rev 01
BABEAD000-01717-2100-40112 Rev 01
BABEAD000-01717-2100-40113 Rev 01
BABEAD000-01717-2100-40114 Rev 01
BABEAD000-01717-2100-40115 Rev 01
BABEAD000-01717-2100-40116 Rev 01
BABEAD000-01717-2100-40120 Rev 01
BABEAD000-01717-2100-40121 Rev 01
BABEAD000-01717-2100-40122 Rev 01
BABEAD000-01717-2100-40123 Rev 01
BABEAD000-01717-2100-40124 Rev 01
BABEAD000-01717-2100-40125 Rev 01
BABEAD000-01717-2100-40126 Rev 01
BABEAD000-01717-2100-40127 Rev 01
BABEAD000-01717-2100-40128 Rev 01
BABEAD000-01717-2100-40129 Rev 01
BABEAD000-01717-2100-40151 Rev 01
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BABEAD000-01717-2100-40155 Rev 01
BABEAD000-01717-2100-40156 Rev 01
BABEAD000-01717-2100-40157 Rev 01
BABEAB000-01717-2100-40161 Rev 01
BABEAB000-01717-2100-40162 Rev 01
BABEAB000-01717-2100-40165 Rev 01
BABEAC000-01717-2100-41111 Rev 01
BABEAC000-01717-2100-41121 Rev 01
BABEAC000-01717-2100-41130 Rev 01
BAB000000-01717-6300-01500 Rev 00
BAB000000-01717-6300-01501 Rev 03
BAB000000-01717-6300-01600 Rev 01
BAB000000-01717-6300-01800 Rev 00
BABEAB000-01717-6300-02165 Rev 06
BABEAB000-01717-6300-03362 Rev 01
BABEAB000-01717-6300-03363 Rev 01

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Extent of Deficiency (Continued)

The QA surveillance will also include records packages from other M&O departments.

Root Cause and Action to Preclude Recurrence

Completion of Root Cause investigation must be postponed until after the surveillance to properly include all necessary information. Action to Prevent Recurrence will also be developed based on the root cause and will therefore be postponed until after the Root Cause Determination.

The QA surveillance will be completed by May 10, 1995. MGDS Development and IM will then evaluate the surveillance report for further extent of deficiency and impact. A supplemental response containing any additions to the Remedial Actions, Extent of Deficiency, a complete Root Cause and Actions to Preclude Recurrence will be sent to YMQAD by June 2, 1995.

This CAR contained five recommendations. Recommendation Number 1, the QA surveillance, is underway at this time. The other four recommendations will be reviewed based on the results of the surveillance and subsequent root cause determination.

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Remedial Action:

Remedial actions committed by Letter No. LV.ESSD.AMS.4/95.062 and identified as Examples A through L have been completed.

Additional items identified by the surveillance conducted by M&O QA, R. B. Berlien: Table of Contents for LYNX version 3.06 did not include a QA designator and the page count was incorrect. The responsible individual is C. J. Houston.

The transmittal for DIPS version 3.1 included an incorrect page count. The responsible individual is N. Hodgson.

Documents in the DIPS package have the QA designator listed on page 2 rather than page 1. The RTN Matrix included in the records package for Revision 2 of QAP-16-1 did not include a QA designator. The responsible individual is G. S. Abend.

The RTN Matrix included in the records package for Revision 5 of QAP-2-4 did not include a QA designator. The responsible individual is P. R. Dahlberg.

All the identified deficiencies will be corrected and completed on or before July 14, 1995.

Investigation for Extent:

A surveillance was conducted by M&O QA, R. B. Berlien, April 17 through May 3, 1995, as requested by MGDS Development and Records Management. The purpose of the surveillance was to review 1) examples cited by the CAR, 2) additional records submitted to the Records Processing Center (RPC) as listed in the M&O initial response, and 3) records submitted by several M&O departments.

Quoting from the surveillance report (No. 95-NSS-24):

"The results are that the deficiencies identified in the CAR have been satisfactorily resolved except one item, which is scheduled to be completed by May 10, 1995. However, problems similar to those identified in the OCRWM CAR are routinely found with records from various M&O departments."

The following are deficient items identified as a result of the surveillance:

- 1) The records did not meet the requirement to submit them within 20 work days after completion (identified as "Examples D, F, G, H, and I").
- 2) Drawing packages typically stated there were two pages in the package; actually there were three; the third page was a Special Instruction Sheet. The practice of not identifying the Special Instruction Sheet on the Table of Contents is considered correct

- by records personnel (this item was identified as a result of the review of additional records not cited in the CAR).
- 3) Block 9 of Special Instruction Sheet is not completed; instructions state that one of three entries is valid (this item was identified as a result of the review of additional records not cited in the CAR).
 - 4) Record package for BABEAD000-01717-2100-40152 was compiled 3/31/95 and signed for 4/3/95 by RPC, but Table of Contents had not been authenticated (this item was identified as a result of the review of additional records not cited in the CAR).
 - 5) Writeovers were obvious on Table of Contents for BABEAD000-01717-2100-40125 (this item was identified as a result of the review of additional records not cited in the CAR).
 - 6) Baseline Change Proposals 02-95-0007, 0009, and 0017; Quality Program Status Reports and Trend Reports were requested from RPC: none was retrievable (these items were identified as a result of the review of other departments' records).
 - 7) RPC is reviewing records submitted in November 1994. When current records are reviewed, it may be difficult to correct the problems identified because record sources may not be available to provide the corrections or explanations. In addition, because errors are not identified quickly, more errors are made before the source recognizes the mistake.
 - 8) A signature on Table of Contents (block 11), Authenticated by, is clearly an act of authentication. Interviews of personnel indicated that the approving person does not consider the approval an act of authentication (this item was identified as a result of interviews with record sources and authenticators). The procedure is clear; it is not a matter of interpretation, but one of failure to comply with the procedure.
 - 9) QAP-17-1, 5.3.D states the authenticator submits the record to the RPC. 5.4.2.E states the record source submits. In practice, records are submitted in a variety of ways including secondary distribution (this item was identified as a result of interviews with record sources and authenticators).
 - 10) None of the authenticators interviewed understood the requirement of QAP-17-1, 5.3.C, that the authenticator must determine that the document being authenticated will

- receive no more entries (this item was identified as a result of interviews with record sources and authenticators).
- 11) Protection of records and records-in-progress is not clear. The degree of protection is not specified (this item was identified as a result of interviews with record sources and authenticators).
 - 12) Interpretation of "record segment" varies. CAR Example A had 19 separate documents as part of the records package. The 19 individual documents were submitted as a package. The first of these 19 documents was completed 3/94, yet the package was submitted 4/95 (this item was identified as a result of interviews with record sources and authenticators).
 - 13) Procedures list lifetime and nonpermanent records; yet record packages typically contain additional records (this item was identified as a result of the review of other departments' records).
 - 14) Consistency between organizations and within organizations: example, one person in RPC adds QA:N to transmittals. Another chooses not to add a QA designation to transmittals. (QAP-17-1 does not require identification with QA designator) (this item was identified as a result of the review of other departments' records).
 - 15) Records packages for LYNX version 3.06 included Table of Contents without a QA Designator and page count was incorrect (this item was identified as a result of the review of other departments' records).
 - 16) Transmittal for DIPS version 3.1 record package page count was wrong; documents in the package, such as Life Cycle Plan, have QA Designator on page 2 instead of page 1 (this item was identified as a result of the review of other departments' records).
 - 17) Records packages for QAP-16-1 R2 and QAP-2-4 R5 included RTN record with no QA designator (this item was identified as a result of the review of other departments' records).

Root Cause

The above items 1) through 17) may be categorized and summarized as follows:*

2A-inadequate procedure: 4 cited [contributory causes]: Nos. 2, 3, 9, 11

3B-inattention to detail: 3 cited [contributory causes]: Nos. 15 through 17

3C-failed to follow procedure: 6 cited [root cause]: Nos. 1, 4, 5, 8, 10, 13

6A-inadequate administrative control: 2 cited [contributory causes]: Nos. 7 and 14

Nos. 6 and 12 are addressed below.

*All references to procedure relate to QAP-17-1, "Record Source Responsibilities for Inclusionary Records."

Action to Prevent Recurrence:

To address the cited causes for each item, the following preventive actions are indicated. Where applicable, each includes a completion date or scheduled completion date and responsible individual.

Items No. 1, 4, 5, 8, 10, 13, 15, 16, 17 are not significant if considered singly; however, taken together, they indicate a need to reemphasize the procedure for records sources to follow. Training to QAP-17-1 will be conducted when the QAP is revised. It is currently undergoing revision; completion is scheduled for September 1, 1995. Training on the revised QAP-17-1 will be completed by September 1, 1995. Responsible individuals are: Margaret A. Shepherd (revision of QAP-17-1); and Sandra Y. Bolden (training).

Items 2, 3, 9, and 11 are a result of unclear instruction as provided by QAP-17-1. Revising QAP-17-1 will prevent this problem from recurring. It is currently undergoing revision; completion is scheduled for September 1, 1995. The responsible individual is Margaret A. Shepherd.

Item 6 could not be retrieved because the records had not been submitted to the RPC in Vienna. These records need to be collected and submitted as required, on or before July 14, 1995. The responsible individual is R. Morgan. No further action will be necessary.

Item 7 resulted from inadequate resource allocation to control records in process. In the last several months, several new personnel have been acquired and assigned to the RPC. Records in process have been increasing, because the number of records input has been increasing. However, the addition of RPC personnel and the application of overtime is expected to mitigate records in process. No further action is required at this time.

Item 12 does not represent a deficiency. The 19 records were submitted in full compliance with requirements. A record segment may be held in storage for up to two years in compliance with QAP-17-1. This provision is needed to accommodate systems, components, etc. that take a long period of time from beginning to completion, and the records of which need to be considered part of a collected package. It is up to the record source to define what constitutes a record segment. No further action is necessary.

Item 14 represents the confusion caused by multiple procedures specifying QA designators for a multitude of different records. It is not, and should not, be the responsibility of the RPC staff to verify the correctness of QA designators, but only to verify that a QA designator exists on the first page of the record. The staff will be instructed not to change or add QA designators, but to question the record source when a question exists. The instruction will be documented; completion will be on or before June 9, 1995. The responsible individual is Laura M. Tate.

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Supplemental Response to CAR YM-95-028

REMEDIAL ACTION:

During the initial response (LV.ESSD.AMS.4/95.062, D. Foust), all of the following adverse conditions were addressed:

Example A) Number listed in CAR: BAB000000-01717-6300-02341 Rev 02...review summary not in record package

Action: The number should have been BABEAB000-01717-6300-02341 Rev 02 Document was created under procedure QAP-3-8 Revision 3, which did not require a review summary and there is no evidence that one was later created to meet the requirements when the specification was actually approved. An IOC (LV.ESSB.MET.4/95-043) from the lead with the above information was later added to the record package.

Example B) Numbers listed in CAR: (Item 1)-BAB000000-1717-0200-00010 Rev 01 and (Item 2)-BAB000000-1717-0200-00009 Rev 01...not in RPC

Action: The numbers should have been (Item 1)- BABEA0000-01717-0200-00008 Rev 01 (BABEAB000-01717-0200-00010 Revision 02); Submitted record package. Receipt from the record center dated 03-29-95, Batch # MOY-950329-05 and (Item 2)- BABEAB000-01717-0200-00009 Rev 01; Submitted record package. Receipt from the record center dated 03-30-95, Batch # MOY-950330-08;

Example C) Number listed in CAR: BABEAB000-01717-0200-0002 Rev 01...review summary missing

Action: The number should have been BABEAB000-01717-0200-00002 Rev 01; Submitted record package. Receipt from the record center dated 04-07-95, Batch # MOY-950407-10.

Example D) BABEAB000-01717-6300-02165 Rev 05 & 06...not in RPC

Action: Submitted record package. Receipt from the record center dated 02-27-95, Batch # MOY-950227-23

Example E) *

Example F) BABEAB000-01717-2100-40151 Rev 01...not in RPC

Action: Submitted record package. Receipt from the record center dated 02-24-95, Batch # MOY-950224-31

Example G) BABEAB000-01717-2100-40161 Rev 01...not in RPC

Action: Submitted record package. Receipt from the record center dated 03-08-95, Batch # MOY-950309-13

Example H) BABEAB000-01717-2100-40162 Rev 01...not in RPC

Action: Submitted record package. Receipt from the record center dated 03-01-95, Batch # MOY-950301-03

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Example I) BABEAB000-01717-2100-40163 Rev 01...not in RPC

Action: Submitted record package. Receipt from the record center dated 02-27-95, Batch # MOY-950227-24

Example J) BABEAB000-01717-2100-41101 Rev 03...not in RPC

Action: Submitted record package. Receipt from the record center dated 04-07-95, Batch # MOY-950407-12

Example K) BABEAB000-01717-2100-41102 Rev 03...not in RPC

Action: Submitted record package. Receipt from the record center dated 04-13-95, Batch # MOY-950413-18

Example L) BABEAB000-01717-2100-41103 Rev 03...not in RPC

Action: Submitted record package. Receipt from the record center dated 04-14-95, Batch # MOY-950414-01

All of the above actions have been completed.

* The only additional item still needing action after the initial response was:

Example E) BAB000000-01717-6300-01501...not cross referenced

ID 90% Review...not cross referenced

IDCS 90% Review...not cross referenced

Response: The date the action was required to be completed was May 10, 1995. The information was presented to the RPC via a lotus notes. During the verification the action had been completed by EDC it was discovered there was a misunderstanding as to what was to be done.

Action: NEW- Submit a supplemental to the BAB000000-01717-6300-01501 dated 2/16/95, ID 90% Review and the IDCS 90% review with a list to cross reference all the review documents contained within and another list of all applicable review packages for the document i.e., DAR #, BCP #, 90% Review Package #. This action has been completed.

RECOMMENDED ACTIONS:

Item 1) recommends a performance based surveillance be conducted.

Information Management and MGDS Development requested M&O QA to conduct a performance-based surveillance to determine whether 1) original findings of CAR YM-95-018 are valid, and 2) extent of the findings was limited to MGDS Development. The findings of the surveillance were reported in Surveillance No. 95-NSS-24 (see Attachment A) and are addressed in the root cause determination elsewhere in the response. The following results were noted in the Summary of Surveillance Results, section IV:

Example A) The use of an IOC was questioned appropriate.

Response: Sometimes procedural requirements change very rapidly and in trying to keep up with the changes we may overlook a prior revision which may not have had the same exact requirements as the effective procedure and we may not meet all the requirements. When such occurrences happen it would be very helpful for someone going back in time to know that a document didn't exist. As this was the case, we submitted an I.O.C. as objective evidence.

Action: No further action required

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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

Example B) Additional deficiencies were noted as below:

- 1) Table of Contents (TOC) for the two packages did not have the SCPB number.
- 2) The page count on the Table of Contents was incorrect.
- 3) One of the records listed is a marked-up copy of the analysis.
- 4) Actual document is not clearly identified, does not have QA or SCPB designations, and is not paginated. The record is not required by the current procedure.

Remedial Action: The following action has been completed:

- 1) SCPB number has been added.
- 2) Corrected page count on the TOC.
- 3) Verified the markup was a needed record and include an explanation in TOC what this document was for.
- 4) Checked document and inserted QA and SCPB designation and paginate. (Although the record is not required by current procedure, the intent is to provide objective evidence to provide adequate traceability.)

Example C) The use of an IOC was questioned appropriate.

Response: See example A) above.

Action: No further action required

Examples D) through I) Records did not meet the 20-day requirement, but are now in the Records Processing Center.

Response: The 20-day requirement to submit "completed" records was met for all Engineering Design Records. Design Packages are completed when the Table of Contents is authenticated complete and will receive no more entries. All of the examples in the CAR met the requirements. The interpretation of what is a "complete" record created another issue of when the 20 day time period starts. A PAR will be initiated and submitted to address the need for clarification to QAP-3-8, QAP-3-9 and QAP-3-10 for records submittal and when a record can be considered "completed records" and be submitted to the RPC.

Preventive Action: David Parker will submit a PAR before July 14, 1995 for the above QAP's to request clarification on completed records/record packages.

Example E) Provided the RPC the information required to cross reference these records and incorporate into the record system.

Response: The record sources need to understand the importance of cross referencing their record packages to all contained documents within.

Preventive Action: A Lesson Learned Training for the discrepancies found for cross referencing will be developed and conducted by E. Iverson before August 7, 1995.

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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

Example J, K, L) Records did not meet the 20-day requirement but they are now in the RPC. An IOC was created explaining the confusion regarding whether a review document needed to be kept.

Response for J, K, L:

An I.O.C. to the RPC was submitted to document the fact that a review document would not be included in these packages because of the change in procedure which changed the records required at the time the review took place.

Action: No further action is required.

In addition to the documents referenced in the CAR the following documents or deficiencies were noted in the surveillance:

Example 1) Records did not meet the requirement to submit them within 20 work days after completion.

Response: See Example D) through I) above

Action: See Example D) through I) above

Example 2) BABEAD000-01717-2100-40152 Rev 00, 01;

- a) The only package found in the RPC was revision 00
- b) The package contains three sheets but only two were noted, the Special Instruction Sheet for one of a kind documents is not listed on the Table of Contents
- c) Block 9 of the Special Instruction Sheet (SIS) was not filled in
- d) The Table of Contents had not been authenticated
- e) Writeovers were obvious on the TOC for BABEAD000-01717-2100-40125

Preventive Action: David Parker will write a PAR to QAP-17-1 before July 14, 1995 requesting clarification for the requirements for the page count and Special Instruction Sheet on the TOC. The drawing BABEAB000-01717-2100-40152 Rev 01 was submitted to the RPC on 2/24/95. The TOC was not authenticated for BABEAD000-01717-2100-40154 Rev 0D because the record was created as a none QA record. The CI number had been changed during the review process. The TOC and SIS have been corrected and authenticated.

Example 3) Drawing packages typically stated there were two pages in the record package, page 1 was the Table of Contents and page 2 was the drawing. There were actually three pages in the packages, the third page was a Special Instruction Sheet.

Action: Required action see above: Example 2)

Example 4) Software records package for LYNX, Version 3.06 had the following concerns:

- a) not submitted to the RPC within the 20 days required
 - b) Table of Contents did not have a QA designator
 - c) page count was incorrect
- Software records package for DIPS, Version 3.1 had the following concerns:
- d) error in the page count
 - e) Documents in the Life Cycle Plan, have the QA designator listed on page 2 of the document rather than page 1

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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

Response:

- a) *The 20-day start time for record package submittal IAW QAP-17-1 begin upon the date the record package authenticator provides signature concurrence on the Table of Contents. The record package was verified by the authenticator on April 3, 1995, the record package was re-verified by the Record Processing Center (RPC) on April 3, 1995. There is no 20-day violation.*
- b) *The person that performed audit HQ-ARC-95-04 used an information only copy of the record package submittal for verification, the original record package submittal to the RPC has the proper QA designator.*
- c) *The page count of the record package was checked by the record package compiler, the authenticator then re-checked twice and corrected by the RPC during pre-acceptance. The page count is correct.*
- d) *The person that performed said audit used an information only copy instead of the original for page count verification. The page count is correct.*
- e) *The QA designator is listed on every page of the Life Cycle Plan excluding the cover page. This violates QAP-17-1 which requires the opposite.*

Remedial Action: The QA designator has been added to the first page of the Life Cycle Plan.

- 5) **QAP-16-1 Revision 2 and QAP-2-4 Revision 5 did not have Impact Review Forms in the packages or did not identify the marked-up Requirements Traceability Network record with a QA designator.**

Response: Impact review forms are not required for these two procedures because once the new revision went into effect, the old procedures was not "grandfathered" Work in both trending and corrective action is performed solely with the current effective procedure.

Remedial Action: RTN Matrices for QAP-2-4 and QAP-16-1 have been corrected by adding a QA designator.

- 6) **BCP's 02-95-0007, 0009, 0017 were not found in the RPC nor any records associated with Quality Program Status Reports and Trend Reports.**

Response: BCP's-02-95-0007, -0009, -0017 are processed IAW QAP-3-4. QAP-3-4 requires the Baseline Change Control Board (BCCB) closeout report to be finished prior to any record package submittal of change paper. The QAP-3-4 closeout report is in-process, and upon completion will start the record package submittal process. No procedural requirement has been violated.

Action: No further action at this time

- 7) **RPC is currently reviewing records as far back as November 1994. When current records are screened, it may be difficult to address identified errors.**

Response: The backlog resulted from inadequate resource allocation to control records in process. In the last several months, several new personnel have been assigned to the RPC. The quantity of unprocessed records in the RPC has increased. However, the additions to RPC personnel and the application of overtime is expected to mitigate records in process. Overtime began June 12, 1995, and is planned to continue for 12 weeks.

Action: No further action at this time.

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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

- 8) Interviews with record sources and authenticators raised several issues.
- a) A signature on a records package Table of Contents in block 11 is an act of authentication. Individuals approving a document, such as QA approval or Manager approval do not consider this to be an act of authentication. If the approval is authentication, individuals need to be made aware of that interpretation and the associated responsibilities.
 - b) QAP-17-1 Section 5.3 D. states that the authenticator submits the record to the RPC. Section 5.4.2 E. states the record source submits the record to the RPC.
 - c) None of the interviewed authenticators understood the requirement in QAP 17-1, Section 5.3 C that after authentication the document will receive no more entries.

Preventive Action: David Parker will write a PAR to QAP-17-1 before July 14, 1995 requesting clarification for authenticators requirements. There will be a Lessons Learned Training for the discrepancies found in this CAR developed and conducted by E. Iverson before August 7, 1995.

- 9) Protection of records and records-in-progress is not clear.

Response: Section 5.2, Protecting Records and Records-In-Progress refers to the handling needed to ensure records are "protected", i.e., caution is taken to preclude damage that may occur due to extreme temperatures or excessive light, due to eating or drinking while preparing or handling records, improperly stacking media that is pressure sensitive, or having magnetic media kept by sources of magnetic fields. Protection refers to these general handling instructions, as stated in the procedure, as opposed to temporary storage (i.e., dual storage or one hour fire rated safe storage).

Records are required to be protected throughout their entire life cycle. Prior to submittal to the RPC, protection may take the form of storing records, or items that will become records, in file cabinets or desk drawers. The intent is to ensure that Record Sources are handling these records to avoid loss or damage that can result from a multitude of situations.

Preventive Action: Additional clarification will be provided via a Records Coordinators' bulletin from Jan Verden by July 14, 1995.

- 10) The interpretation of record segments varies.

Response: Record package segments are defined in Section 3.19 as follows: A subset or component of a records package; usually an individual record that is intended to become part of a completed records package.

The intent of records package segments is to allow the RPC to safeguard records that are going to become part of a records package. Records package segments are tracked (i.e., logged into a data base - the Records Log - to enable timely retrieval), but are not indexed or reviewed until the records package is submitted by the Record Source to the RPC for processing. They are retrievable through the Record Source or the RPC while in process, but in fact, they are not formally submitted for processing (i.e., review, discrepancy resolution, indexing, and imaging). The RPC maintains a title given by the Record Source along with a tracking number, author, date, etc., to enhance retrievability. These segments are not required to be reviewed by the RPC, in accordance with Records Management procedures, until the activity is complete.

Once the activity is complete, the Record Source compiles a records package by including the information necessary to support the work performed, and by preparing a table of contents that lists the information in the records package. The Record Source then has 20 working days to submit the records package to the RPC for processing. At this time, the RPC will review the records package for completeness (i.e., legibility and accurate page counts), and resolve any discrepancies with the Record Source. After discrepancies are resolved, the records package is indexed into the records data base and forwarded to the Imaging Center to be imaged.

Action: No further action at this time.

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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

11) Record packages contain a number of additional records.

Response: The addition of non-required records to those records required by the governing procedure(s) is used as objective evidence. In the case of QAP-16-1, for example, the prescribed instruction is: Lifetime QA records include . . .S supporting documentation. Other procedures include similar instruction. It is the M&O's contention that this objective evidence is useful for reasons of explanation and comprehensiveness and should not be discouraged.

Action: No further action is necessary.

Recommended Actions continued from CAR:

Item 2) recommends that a record process improvements be communicated through extensive training.

Preventive Action: Many of the concerns being addressed in the surveillance and CAR can be resolved by revising the QAP-17-1 as stated previously. Interim training will be initiated on the existing QAP-17-1 and CAR YM-95-028 and the surveillance report by E. Iverson before August 7, 1995.

Item 3) recommends the entire records process be studied and reengineered, Both in Las Vegas and Vienna.

Preventive Action: Where necessary, the M&O plans to implement improvements, as indicated elsewhere in this response. Evaluation of the process and associated problems has been completed (see Root Cause Determination, elsewhere in this response). The actions committed to will correct the identified problems.

Item 4) recommends that indexing methods and structures be devised that allow retrievability of all records pertaining to a given effort.

Response: This item was identified in adverse conditions listed in CAR YM-95-028 and confirmed in Surveillance No. 95-NSS-24. Indexing methods permitting retrievability of all records pertaining to a given work effort have existed since the data base was first set up. The cause of the identified problems is the failure of the records source to give the records management organization, at the time of submittal, enough information (cross references) to permit tying the records together. The applicable, implementing procedure, QAP-17-1, addresses this point (5.1.1.B: "The Record Source...shall create a title (subject) that identifies the contents of the record and the item or activity to which the record applies in order to facilitate indexing of the record for future identification and retrievability). However, because of the importance of the need to assure retrievability, we believe improvement of the procedure's guidance on this point would enhance the understanding by records sources of the ways in which titles should include the appropriate information to permit retrievability by cross references. The commitment to improve QAP-17-1 has been noted elsewhere in this response.

Preventive Action: There will be a Lessons Learned Training for the discrepancies found in this CAR developed and conducted by E. Iverson before August 7, 1995.

Item 5) recommends that the M&O concepts of authentication and validation be evaluated in light of the deficiencies.

Preventive Action: Revising QAP-17-1 on the concepts of authentication should clarify the scope. A PAR will be generated as stated previously and Lessons Learned Training will be developed and conducted before August 7, 1995.

CAR YM-95-028

(Records)

ROOT CAUSE DETERMINATION

June 22, 1995

ADVERSE CONDITION

The adverse condition is detailed in the CAR which was issued to the M&O by means of DOE letter YMQAD:RBC-2368 dated March 8, 1995 by Mr. Richard E. Spence.

The adverse condition from the CAR is quoted below:

"Contrary to the above requirements [QARD Section 17.0], record packages associated with drawings, specifications, and analysis are not being properly authenticated for accuracy, and appropriate to the work accomplished, completeness, nor are they being turned over to the LRC reasonably contemporaneous with completion of the individual records and record packages, or protected from deterioration, loss, or damage until turned over to the LRC. Additionally, indexing of records does not adequately provide a cross reference to the documentation or the associated activity.

"Examples:

"The following represents examples only. A comprehensive review is required to determine the extent and impact of the deficiencies.

"Records segment package (LRC-114) for BAB000000-1717-6300-02341, Revision 02, Steel Sets and Accessories Subsurface (Specification) does not contain a copy of the specification review summary.

"The TS North Ramp Ground Support Scoping Analysis DI: BAB000000-1717-0200-00010, Revision 01, and Material Dedication Rockbolts, Shotcrete and Accessories DI: BAB000000-1717-00009, Revision 1 have not been sent to the LRC for records processing.

"Records package BABEAB000-01717-0200-0002, Structural Steel Sets Analysis, Revision 01 does not contain the Design Analysis Review Summary.

Records packages BABEAB000-01717-6300-2165, Revisions 05 and 06 have not been sent to the LRC for processing.

"Records packages were not cross-referenced to the related records packages for proper indexing and ease of retrievability:

BAB000000-01717-6300-01501, 'Subsurface General Construction' 2/16/95

Records package for Design Package 1D 90% Design Review QA Record Package, 11/28/94

Integrated Data and Control System 90% Design Review QA Record Package, 1/12/95

"The following drawings and the related documentation were not submitted to the LRC as required by NLP-3-24, Revision 1, and QAP-3-10, Revision 4:

"Drawings listed by Document Number Description:

BABEAB000-01717-2100-40151, Revision 1, TS North Ramp Ground Support Master Elevation and Sections

BABEAB000-01717-2100-40161, Revision 1, TS North Ramp Alcoves Rockbolts and Shotcrete Sections

BABEAB000-01717-2100-40162, Revision 1, TS North Ramp Alcoves Rockbolts and Shotcrete Plan, Section and Elevation

BABEAB000-01717-2100-40163, Revision 1, TS North Ramp Alcoves Rockbolts and Shotcrete Plan, Section and Elevation

BABEAB000-01717-2100-41101, Revision 3, TS North Ramp Steel Sets and Lagging Elevation

BABEAB000-01717-2100-41102, Revision 3, TS North Ramp Steel Sets and Lagging Sections and Details

BABEAB000-01717-2100-41103, Revision 3, TS North Ramp Steel Sets and Lagging Sections and Details"

WHAT IS EXPECTED?

A. The requirements come from the OCRWM QARD DOE/RW-0333, Revision 1, according to the CAR, however the current QARD is DOE/RW-0333P Revision 2.

The requirements come from QARD Section 17.0. The requirement specific to this CAR are quoted below:

"Paragraph 17.2.2B: 'Individuals creating quality assurance records shall ensure that the quality assurance records are legible, accurate and complete.'

"Paragraph 17.2.2C: 'Individuals handling quality assurance records shall protect them from damage or loss until the records are submitted to the records management system.'

"Paragraph 17.2.3E3: 'QA Records shall be indexed to ensure retrievability. The indexing system shall include identification of the item or related activity to which the QA records pertain.'

"M&O QAP-17-1, Revision 3, P04 (NOTE: The procedure in effect as of February 20, 1995 was Revision 4.)

"Paragraph 3.2, Authentication: 'The act of attesting that the information contained within a record is legible, accurate, complete, and appropriate to the work accomplished.'

"Paragraph 5.3, Protection of Records and Records-In-Process: 'Responsible management and Record Sources shall ensure that records/records-in-process are protected from deterioration, loss, or damage.'

"Paragraph 5.4.3A: 'Records sources shall authenticate individual records and record packages immediately following creation and shall turn them over to the LRC reasonably contemporaneous with completion...individual records and record packages shall be turned over to the LRC no later than 20 working days after completion.'

"QAP-3-9, Revision 4, Paragraph 6B: 'The following QA records generated as a result of this procedure shall be submitted by the LDE to the LRC in accordance with QAP-17-1: Design Analysis Review Summary.'

"NLP-3-24, Revision 1, Paragraph 5.1.1d: 'The drawing or specifications Originator shall forward the completed IL to the LDE for transmittal to Local Records Center in accordance with QAP-3-8 or QAP-3-10, after the output (drawing or specification) is approved.'

"QAP-3-10, Revision 4, Paragraph 6.0: 'The following QA Records are generated as a result of this procedure and shall be submitted by the LDE to the Local Records Center in accordance with QAP-17-1:

- A. Approved Drawings (which will be or are baselined)
- B. Drawing Input List
- C. Drawing Review Summary'"

For purposes of this root cause analysis the above is

summarized as:

Records shall be:

- legible
- accurate
- complete
- protected from loss
- protected from damage
- indexed to ensure retrievability
 - indexed records to include identification of item or activity
- sent to RPC within 20 working days after completion
- properly authenticated

WHAT ACTUALLY HAPPENED?

B. Records are not being properly authenticated for accuracy and appropriate to the work accomplished. Records are not complete. Records are not "being turned over to the LRC reasonably contemporaneous with completion of the individual records and record packages.

INVESTIGATION:

A surveillance was conducted by the M&O and the conclusions and recommendations contained therein form substantial basis for this Root Cause Analysis. The surveillance report entitled Quality Assurance Surveillance Report, Report Number 95-NSS-24, April 17 through May 3, 1995, covering M&O Records is referenced. The surveillance confirmed the adverse condition documented in the original CAR.

PERSONNEL

WHO WAS INVOLVED?

This CAR covers organizations and is not restricted to individuals. Attention should focus on the responsible line organizations rather than individual personnel.

WHICH ORGANIZATIONS CONTRIBUTED TO THE DEFICIENCY?

The primary responsible parties for this CAR are MGDS Development and Information Management. However, the surveillance found that there are problems elsewhere in the M&O organization.

WAS THERE A LACK OF AWARENESS OF THE REQUIREMENTS?

Yes, in some cases, as determined by the original CAR and later by the surveillance, there was an apparent lack of awareness of the requirements.

WAS THERE A LACK OF KNOWLEDGE?

Yes: see the paragraph above. There needs to be a clear understanding of what an authenticators are and what they do. It is clear that this lack of understanding of definitions and functions are a significant part of the deficiency.

WAS THERE A LACK OF ATTENTION TO THE TASK?

Yes.

WAS THERE A LACK OF PERSONNEL?

Staffing for Engineering Document Control in MGDS Development was only half the estimated requirement at the beginning of FY '95. This contributed to the findings in the CAR and in the subsequent surveillance.

The backlog of records at the LRC at the end of calendar year 1994 and at the beginning of 1995 points to insufficient personnel.

SUMMARY

To summarize the PERSONNEL section the following are evident:

1. The problem affects the M&O generally and not just MGDS Development.
2. Knowledge of requirements is lacking.
3. Shortages of personnel were evident because of hiring freezes, budgets, difficulty in hiring, finding qualified people.

TRAINING

WAS ADEQUATE TRAINING AVAILABLE OR PERFORMED?

Training is provided for all new personnel on the project regarding general records requirements. Other training related to records is available, on an individual or supervisory directed basis. Training for records requirements for specific groups has not been available. Training related to problems encountered and the necessary remediation generally has not been used.

INDICATE IF ANY OF THE FOLLOWING APPLY:

MISSING OR INADEQUATE VERIFICATION OF EXPERIENCE/EDUCATION

This is not an issue.

MISSING OR INADEQUATE POSITION DESCRIPTION

This is not an issue.

LACK OF INDOCTRINATION

This is not an issue.

ADEQUATE INSTRUCTION

See the first response in this section.

QUALIFICATIONS

This is not an issue.

SUMMARY

The current training is inadequate because:

1. Training including the initial indoctrination and the training specific to procedures, is not effective considering the findings of both the CAR and the Surveillance. The training does not reach the specific details that the records package generators need to provide satisfactory records and record packages. Reliance on Reading/Self Study is not working.
2. Training is not specific to the task nor to the individual procedure.
3. The present training does not deal with past mistakes and the ways to prevent them.

PROCEDURE

WAS A PROCEDURE A FACTOR?

Procedures are a significant factor in the deficiencies covered by this CAR.

1. The procedures do not always have clear definitions.

2. The frequent procedure revisions have not allowed the procedures to integrate with one another.

3. Records generators have not worked with a single set of procedures enough times to have gained a thorough understanding and confidence of the procedures to be error free yet.

WAS THERE AN APPLICABLE PROCEDURE?

Yes.

WHICH PROCEDURE?

The following procedures are factors in this evaluation:

1. M&O QAP-17-1
2. M&O QAP-3-9
3. M&O QAP-3-10
4. M&O NLP-3-24

The above were cited in the CAR, but the following also have an impact on this CAR Root Cause:

1. M&O QAP-3-0
2. M&O QAP-3-2
3. M&O QAP-3-4
4. M&O QAP-3-8
5. YAP-17-1

WERE THEY FOLLOWED?

Yes; however, there were many instances where procedures were not followed exactly. Both the CAR and the surveillance uncovered areas where the procedures were not rigorously followed.

WAS THE CURRENT REVISION USED?

Yes.

IS THE PROCEDURE LEGIBLE?

Yes, legible procedures were and are available.

IS THE PROCEDURE MISLEADING?

Yes, these procedures need clarifications particularly in the area of definitions and in the area where they interface with other procedures. Specific definitions for completed records and for authenticators need to be provided. All of the procedures identified in the CAR and listed as having an impact are potential candidates for revision.

IS THE PROCEDURE CONFUSING?

Yes, see the paragraph above.

IS THE PROCEDURE ADEQUATE TO DO THE TASK?

Yes, with some difficulty.

SUMMARY

The conclusion is that procedures are difficult to use and are confusing.

SUMMARY

As a result of the above analysis the following items are considered to be contributing causes:

1. There is a lack of awareness and knowledge of the requirements.
2. Personnel shortages were a contributing factor to the problem at the time of the CAR and when the records packages were stored. This problem is considered solved and therefore is not presently a cause.

The overall root cause of the adverse condition, as determined by this analysis, is that the procedures are inadequate and confusing. This manifests itself mainly in two ways--1) training does not convey what is expected and what the definitions are in terms of this project, and 2) the procedures themselves could be written in a clearer, more integrated manner.

jjc
June 22, 1995
rtcau28d.wp5

Interoffice Correspondence
Civilian Radioactive Waste Management System
Management & Operating Contractor

ATTACHMENT A



TRW Environmental
Safety Systems, Inc.

QA: N/A
SCP: N/A

Subject
Surveillance 95-NSS-24

Date
May 12, 1995
LV.QA.RBB.5/95.163

From *RBBerlin*
D.M. Franks

To
L.D. Foust
R L. Robertson

cc
Distribution

Location/Phone
TES1/6561
(703) 204-8872

Attached for your information is the subject report documenting a surveillance covering M&O Records. The surveillance was conducted on April 17 through May 3, 1995, in response to OCRWM Corrective Action Request YM-95-028.

- cc:
- G. S. Abend
 - R. B. Berlien
 - E. T. Chulick
 - P. G. Jones
 - C. L. Kelly
 - T. L. Mueller
 - M. F. Penovich
 - A. M. Segrest
 - R. M. Sandifer
 - H. C. Stafford
 - J. D. Verden
 - J. W. Willis

Rec'd.
MAY 18 1995

QA: L
SCPB: N/A

CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM

MANAGEMENT AND OPERATING CONTRACTOR

QUALITY ASSURANCE SURVEILLANCE REPORT

Report Number: 95-NSS-24

Surveillance Dates: April 17 through May 3, 1995

Organization(s) Under Surveillance: M&O

Activities Under Surveillance: Records

Surveillance Leader:

R. B. Berlien

RBB

5/11/95

Printed Name/Signature/Date

Surveillance Report Approval:

DM

5/12/95

QA Surveillance Manager Signature/Date

I. EXECUTIVE SUMMARY

The purpose of this surveillance is to fulfill a commitment in the response to OCRWM Corrective Action Request (CAR) YM-95-028. The surveillance provides more information to enable MGDS and IM to evaluate the deficiencies reported in the CAR for extent and impact. The scope included a review of the examples cited as deficient in the CAR, a review of additional records submitted to the Records Processing Center (RPC) listed in the response, and a review of records submitted by several M&O departments.

The results are that the deficiencies identified in the CAR have been satisfactorily resolved except one item, which is scheduled to be completed by May 10, 1995. However, problems similar to those identified in the OCRWM CAR are routinely found with records from various M&O departments.

II. DESCRIPTION OF THE SURVEILLANCE FINDINGS

Deficiencies identified during this surveillance will be addressed in the supplemental response to the OCRWM CAR.

III. DEFICIENCIES CORRECTED DURING THE SURVEILLANCE

None.

IV. SUMMARY OF SURVEILLANCE RESULTS

The M&O response dated April 5, 1995, to OCRWM CAR YM-95-028, stated actions being taken to resolve the specific deficiencies identified in the CAR, listed documents verified to be in the records center and to be sampled during this M&O surveillance and stated that records submitted by other M&O departments would be reviewed. During this surveillance records reviewed included drawings, specifications, analyses, procedure preparation documentation, software qualification documentation, and baseline change control submittals. In addition, interviews were conducted with record sources, authenticators and RPC staff.

The deficiencies listed in the CAR were identified as examples A through L in the response. The response indicated the resolution to the deficiency stated. This surveillance verified that all but one of the actions has been satisfactorily completed. Each is commented on below.

Example A. The deficiency noted in the CAR for this example was that the record did not have the required Review Summary in the package. The response pointed out that the summary required by the current revision to the procedure was not required in the revision to the procedure in effect at the time of submittal. An IOC was added to the package stating this fact. (Note: both the CAR and the response referenced an incorrect record identification prefix: BABOOO000

instead of the correct BABEAB000.)

Example B. This deficiency concerned two packages not in the RPC. The packages are now in the RPC.

Like Example A, B was also referenced with the incorrect prefix. The Table of Contents for the packages did not have an SCPB designation; the majority of records reviewed during the surveillance did not have this designation as required by Section 5.1.1 C. of QAP-17-1. There is also an error in the page count in the Table of Contents. One of the records listed in the Table of Contents is a marked-up copy of the analysis. The actual document is not clearly identified, does not have a QA or SCPB designation, and is not paginated. The record is not required by the current procedure.

Example C. This item was the same issue and resolution as Example A. (The item had been properly identified however.)

Examples D, F, G, H and I. These records were not in the RPC at the time of the OCRWM audit. They are there now but the requirement to submit records within 20 working days after completion, Section 5.4.2 E. 1. of QAP-17-1, was not met.

Example E. The record involved is to be supplemented to cross reference other records. The supplement was not in the RPC files as of April 27, 1995. It is due by May 10, 1995.

Examples J, K, and L. These records were also not in the RPC at the time of the OCRWM audit. The records and an IOC from the lead explaining the situation regarding these records is in the RPC now. (The IOC states there was confusion regarding whether a review document needed to be kept.)

With regard to the additional records listed in the response that were not cited in the CAR, eleven of the thirty-nine were reviewed during this surveillance. The records did not meet the requirement to submit them within 20 working days after completion. In two instances involving drawings, the title of the record stated that it covered Revision 00 and 01 of the drawing but there was only documentation for Rev 00 in the package. The response stated that Rev 01 was in the RPC for BABEAD000-01717-2100-40152. The only package found in the RPC for this drawing was Rev 00. Drawing packages typically stated there were two pages in the record package; Page 1 was the Table of Contents, and Page 2 was the drawing. There were actually three pages in the packages, the third page was a Special Instruction Sheet (identified as QA: L, Page 1 of 1). The practice of not identifying the Special Instruction Sheet on the Table of Contents is considered correct by records personnel. In addition, block 9 of the Special Instruction Sheet is not completed, the instructions for completing block 9 state that one of three entries is valid. The record package for BABEAD000-01717-2100-40152 was compiled on 3/31/95 and signed for on 4/3/95 by the RPC, but the Table of Contents had not been

authenticated. Writeovers were obvious on the Table of Contents for BABEAD000-01717-2100-40125.

As committed, records were also reviewed for other M&O departments. The following problems were encountered during that review. The information is provided to the Records group to help determine the extent and impact of the problems identified by the OCRWM QA CAR.

Records packages for software qualification were reviewed for LYNX Version 3.06 and DIPS Version 3.1. The package for LYNX had not been submitted to the RPC within the 20-day requirement; the package for DIPS met the requirement. The Table of Contents for LYNX was not identified with a QA designator and the page count was incorrect. The transmittal for DIPS had an error in the page count. Documents in the package, such as the Life Cycle Plan, have the QA designator listed on Page 2 of the document rather than Page 1 as required by Section 5.1.1 D of QAP-17-1.

Records packages regarding procedure preparation were reviewed for Revision 2 of QAP-16-1 and Revision 5 of QAP-2-4. Neither had identified the marked up Requirements Traceability Network record with a QA designator. Both were submitted within the 20-day time requirement.

Records were requested for Baseline Change Control documents, specifically Baseline Change Proposals 02-95-0007, 0009, and 0017 that have been processed to QAP-3-4 and are required records. Also requested were any records associated with issued Quality Program Status Reports and Trend Reports, which are records required by QAP-2-4 (these records are created and submitted to the RPC in Vienna, but should be retrievable through the Las Vegas records system). None were retrievable by the RPC with the information provided.

It is recognized that most of the omissions or errors identified in this report would be identified by the RPC screening process, but the RPC is currently reviewing records submitted in November of 1994. When current records are screened, it may be difficult to correct the problems identified, and record sources may not be available to provide the appropriate corrections or explanations. In addition, because errors are not identified quickly, more errors are made before the source recognizes the mistake.

During interviews with record sources and authenticators, several questions were raised that need resolution. The resolution may require procedure modification and/or additional or more detailed training of individuals implementing the procedure. The issues include:

1. A signature on a records package Table of Contents in Block 11 (Authenticated By) is clearly an act of authentication. However, interviews conducted during this surveillance indicated that when individuals approve a document, such as QA approving a Software Life Cycle Plan or a Manager approving an employee's technical output document, the approving person does not consider the approval an act of authentication. If the approval is authentication, individuals need to be made aware of that interpretation and the associated responsibilities of it.

2. Section 5.3 D. of QAP-17-1 states that the authenticator submits the authenticated record to the RPC. Section 5.4.2 E. states the record source submits the record to the RPC. In practice, records are submitted in a variety of ways including secondary distribution, which is allowed, but the submittal may be by individuals other than the record source or authenticator.
3. None of the authenticators interviewed during this surveillance understood the requirement in Section 5.3 C. of QAP-17-1, that the authenticator is to determine the document they are authenticating will receive no more entries. They felt the requirement should either be eliminated or clarified.
4. Protection of records and records-in-progress is not clear. Sources are to secure them when unattended, but the degree of protection is not specified. Fireproof files are not specified, but it may be prudent to store records in desk drawers or file cabinets when unattended.
5. It is recommended in QAP-17-1 that records be submitted in record segments instead of record packages. However, the interpretation of a record segment varies. For example, drawings, specs and analyses are segments of Package 2C. They are submitted as segments. However, within these segments are a number of other segments. CAR Example A, a specification, had nineteen separate documents as part of the records package. These nineteen individual documents were submitted as a package rather than as segments. The first of these nineteen documents was completed in March of 1994, yet the package was submitted in April of 1995.
6. The various procedures list those records that are to be maintained as lifetime or nonpermanent records. Typically, record packages contain a number of additional records. They are generally included because the source felt the information pertinent. The practice of providing additional records should be addressed in terms of providing guidelines for the allowance of additional records, recognizing the additional reviews required, additional microfilming that may be required, and the value added.
7. Consistency between organizations and within organizations may need addressing. As an example, one person in the RPC adds QA: N to Transmittals. Another person chooses not to add a QA designation to transmittals. (QAP-17-1 does not require them to be identified with a designator.)

A meeting was held on May 3, 1995, to present and discuss the results of the surveillance. In attendance were:

G. Abend
T. Badredine
J. Clark
E. Ferguson
T. Mueller
M. Prater
L. Tate
J. Verden

V. IDENTIFICATION OF SURVEILLANCE PERSONNEL

R. Berlien - Surveillance Leader

VI. PERSONNEL CONTACTED DURING THE SURVEILLANCE

C. Bartley
I. Blackwell
N. Hodgson
C. Houston
P. Jones
T. Mueller
R. Saunders
L. Tate
J. Willis

APPENDIX A

EVIDENTIAL DOCUMENTS REVIEWED DURING THE SURVEILLANCE

CAR YM-95-028

Letter dated 4/5/95, L. Foust to W. Barnes, Response to CAR YM-95-028

Record Packages Identified as CAR Deficiencies:

BABEAB000-01717-6300-02341 Rev 01, 02, 03
BABEAB000-01717-0200-00010 Rev 01
BABEAB000-01717-0200-00009 Rev 01
BABEAB000-01717-0200-00002 Rev 01
BABEAB000-01717-6300-02165 Rev 00, 01, 02, 03, 04, 05, 06
BABEAB000-01717-6300-01501
BABEAB000-01717-2100-40151 Rev 00, 01
BABEAB000-01717-2100-40161 Rev 00, 01
BABEAB000-01717-2100-40162 Rev 00, 01
BABEAB000-01717-2100-40163 Rev 00, 01
BABEAB000-01717-2100-41101 Rev 00, 01, 02, 03
BABEAB000-01717-2100-41102 Rev 00, 01, 02, 03
BABEAB000-01717-2100-41103 Rev 00, 01, 02, 03

Record Packages Referenced in the CAR Response:

BABEAD000-01717-2100-40100 Rev 00, 01
BABEAD000-01717-2100-40110 Rev 00, 01
BABEAD000-01717-2100-40112 Rev 00, 01
BABEAD000-01717-2100-40114 Rev 00, 01
BABEAD000-01717-2100-40116 Rev 00, 01
BABEAD000-01717-2100-40121 Rev 00, 01
BABEAD000-01717-2100-40123 Rev 00, 01
BABEAD000-01717-2100-40125 Rev 00, 01
BABEAD000-01717-2100-40127 Rev 00, 01
BABEAD000-01717-2100-40129 Rev 00, 01
BABEAD000-01717-2100-40152 Rev 00

Record Packages for Software Qualification:

DIPS Version 3.1, Batch MOY-950303-10
LYNX Version 3.06, Batch MOY-950406-14

Record Packages for Procedure Preparation:

QAP-2-4 Revision 5
QAP-16-1 Revision 2