

U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE

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

SURVEILLANCE NUMBER 92-05

AUGUST 10 - 21, 1992

ON

QUALITY ASSURANCE RECORDS MANAGEMENT

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Headquarters QA Division

Date: 10/02/92

Approved by: D. G. Horton
Donald G. Horton
Director, Office of Quality
Assurance

Date: 10/9/92

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance Surveillance HQ-SR-92-05, the surveillance team determined that some RW offices within the Office of Civilian Radioactive Waste Management are not effectively implementing QAAP 17.1, *QA Records Management*. In addition, QA Program Training for some personnel performing quality affecting activities was found to be deficient as their I&T Matrices did not reflect training to the current revision of QAAP 17.1.

As a result of this surveillance CAR-HQ-92-017 was written to document and track the identified deficiencies. The problems observed during this surveillance appear to result from the lack of training to current revisions of QAAP 17.1 and a misunderstanding of responsibilities by various RW offices in generating and processing QA records packages.

2.0 SCOPE

The Office of Quality Assurance conducted the surveillance to determine compliance with Quality Assurance Administrative Procedure QAAP 17.1, *QA Records Management*.

The surveillance was performed during the week of August 10, 1992, with follow up activity completed during the week of August 17, 1992. The surveillance was performed in accordance with QAAP 18.3, Revision 3, and was conducted at the offices of RW-3, 20, 30, 40 and the Quality Records Center in the Forrestal Building, Washington, DC.

The surveillance team used the following documents as a basis for their activities:

- QAAP 2.1, Revision 2, *Indoctrination and Training*;
- QAAP 17.1, Revision 2, *QA Records Management*.

3.0 SURVEILLANCE TEAM

Team Leader - W.R. Marchand (Weston)
Team Member - V. Montenyohl (Weston)
Team Member - C. Good (CER)

4.0 PERSONNEL CONTACTED

The personnel contacted are listed in Attachment I to this report. A daily meeting was held with management of the organization to be contacted that day. There was no pre-surveillance conference, but prior notice was provided to the organization being reviewed.

5.0 SUMMARY OF SURVEILLANCE RESULTS

The surveillance team concluded that the Quality Assurance Program of the Office of Civilian Radioactive Waste Management was not being fully implemented according to QAAP 17.1, *QA Records Management*. The degree of implementation of this procedure was different for each RW office reviewed. Some offices were found to be creating correct and complete Quality Records Packages (QRPs) and submitting them to the QRC, but did not understand their responsibility for validation and closure of these packages at the QRC. Other offices had various problems with the completeness of QRP's due to their misunderstanding of QAAP 17.1 requirements.

The records packages reviewed for each office are listed in Attachment II. There were a number of generic problems identified on non-validated QRP's transmitted to the QRC which include:

- missing signatures;
- other than black ink used on originals;
- "QA" omitted from record corners;
- correction fluid used on originals;
- pagination errors;
- cut and paste insertions;
- fax paper submitted as records;
- legibility problems.

The reviews performed at the Quality Records Center indicate that very few offices have been validating previously submitted QRP's. A summary of the status of QRP's received by the QRC is listed in Attachment III.

Several offices did not understand the scope of their responsibility, and submitted QRP's that were the responsibility of other RW offices. For example:

- QRP-90-0332.00
- QRP-91-0538.00
- QRP-91-0549.00
- QRP-91-0557.00
- QRP-92-0612.00

One office, RW-20, removed their personnel from the list of people approved to perform quality affecting activities in September, 1991, but continued to submit Study Plans generated under ILP 22.3.1 to the QRC. Submittal of QA records, e.g., Study Plans, to the QRC is a quality affecting activity to be performed in accordance with QAAP 17.1. When this discrepancy was identified, RW-20 committed to reestablish a list of personnel approved to perform quality affecting activities.

Some validated QRP's were on hold (RW-30) in the QRC pending a decision as to whether "Personnel Requirement Forms" and "Qualification Reviewer Forms" are to be considered System 80 Records which require additional controls. For example:

- QRP-90-0329.00
- QRP-90-0331.00

In many offices, the final transmittal of the QRP's to the QRC was conducted by someone other than the records originator. In most of those cases, transmittal was conducted by a department secretary who was not listed as personnel authorized to perform quality affecting activities. Other offices had one or more people responsible for assembling and transmitting QRP's who were not trained to QAAP 17.1, Revision 2. Transmitting QRP's to the QRC is a quality affecting activity that must be performed according to QAAP 17.1.

With the exception of RW-3 and RW-30, the other RW offices did not maintain the required list of the types of QRP's that they are responsible for transmitting to the QRC as required by QAAP 17.1.

Only RW-323 and RW-3 maintained a log of the QRP's previously transmitted to the QRC. A QRP log is a requirement of QAAP 17.1.

Several offices have submitted large QRP's to the QRC without providing a detailed table of contents with page counts for individual documents as required by QAAP 17.1. Without such a list, the packages cannot be reviewed for completeness and neither the QRC personnel nor the QRP validators can provide accurate QRP status. For example:

- QRP-90-0010.00 504 pages;
- QRP-90-0331.00 665 pages.

As a result of this surveillance CAR-HQ-92-017 was written to document and track the identified deficiencies.

6.0 RECOMMENDATIONS

- 6.1** It is recommended that each RW office review Attachment III of this report and determine the completion status of those quality records packages submitted to the Quality Records Center. Packages that are determined to be complete should then be validated by the cognizant RW office. Final validation of the QRP's by the responsible RW offices will allow the Quality Records Center personnel to process the completed QRP's in accordance with QRC procedures.
- 6.2** It is recommended that a meeting be held between RW-3, RW-10 and RW-30 to determine if "Personnel Requirement Forms" and "Qualification Reviewer Forms" are considered System 80 Records.

Attachment I

<u>Office</u>	<u>Personnel Contacted</u>	<u>Date</u>
RW-3	R. Clark/C. Goode	August 11, 1992
RW-20	S. Brocoum J. Stockey D. Stucker	August 10, 1992 August 13, 1992 August 14, 1992
RW-321	M. Betancourt M. Senderling	August 10, 1992 August 11, 1992
RW-323	T. Van S. Peterson	August 11, 1992 August 11, 1992
RW-331	C. Macaluso S. Skuchko	August 12, 1992 August 12, 1992
RW-421	P. Kumar J. Jones D. Meck S. Davis	August 14, 1992 August 14, 1992 August 17, 1992 August 17, 1992
RW-431	W. Lake	August 12, 1992
QRC	G. Ruffin	August 10-14, 1992

QRPs Reviewed by Office

QRP NUMBER	RW	TITLE	COMMENTS
QRP-90-0010.00	RW-20	Excavation Investigations (ESF) Study Plan 8.3.1.15.1.5	Transmitted 10/04/90 by J.Stockey. 504 pages not broken down into individual documents. Not closed.
QRP-90-0059.00	RW-20	Characterization of YM Regional Ground-Water Flow System Study Plan 8.3.1.2.1.3	Transmitted 08/17/90 - 11/30/90 by J. Stockey and T. Switzer. Not closed. Table of Contents is itemized (see above).
QRP-90-0069.00	RW-20	Characterization of the Vertical & Lateral Distribution of Stratigraphic Units within the site area 8.3.1.4.2.1	(no specific comments)
QRP-90-0085.00	RW-20	Detachment Faults at or Proximal to YM Study Plan 8.3.1.17.4.10	First transmittal 6/10/90 by J. Kimball. Last transmittal on 8/5/92 by J. Stockey. BT initialed correction on transmittal. (Contents include signature by Berusch acting for Brocum certifying reviewer qualifications. Comment resolution by J. Stockey.)
QRP-90-0141.00	RW-40	Draft MRS Site Requirements and Considerations (QAAP 3.5)	Contains Proficiency Review Reports with personnel qualification data.
QRP-90-0152.00	RW-20	Technical Review of App. E to the Generic Requirements for MGDS (OGR/B-2)	Contains Proficiency Review Reports with personnel qualification data.
QRP-90-0319.00	RW-323	Program Change Control Procedure, Rev. 3	Transmitted 4/26/91. Not closed. Various record review items incomplete (review draft not marked draft, QA not in upper corner of all records, Page 1 of __ not filled in)

QRPs Reviewed by Office

QRP NUMBER	RW	TITLE	COMMENTS
QRP-90-0329.00	RW-321	Physical System Requirements - Overall System, Rev. 0	Package validated by M. Senderling 07/15/92. Contains Proficiency Review Reports (System 80 records). Further processing by QRC on hold pending outcome of Surveillance HQ-SR-92-07. Individual records named by TDMP not clearly itemized on Table of Contents.
QRP-90-0331.00	RW-321	Physical System Requirements - Transport Waste, Rev. 0	Package validated by M. Senderling 07/15/92. Contains Proficiency Review Reports (System 80 records). Further processing by QRC on hold pending outcome of Surveillance HQ-SR-92-07. Last transmittal submitted 665 pages containing several individual records not itemized on Table of Contents.
QRP-90-0332.00	RW-321	Physical System Requirements - Store Waste, Rev. 0	Record transmitted on 7/7/92 to inappropriate package. (Concurrence on MRS Conceptual Design Report)
QRP-91-0372.00	RW-40	Lists of Typical Records and Record Package Types and Validators	Generic list of technical document and technical document review records.
QRP-90-0378.00	RW-50	Statement of Work for M&O, QAAP 4.1 and 7.1 Review	Last transmittal 10/91. Not closed. Contains records on heat sensitive fax paper that will fade. Pages incorrectly numbered (pages 2-9 of 9 page document labeled "2 of 2." One page documents labeled "1 of 2.")
QRP-91-0445.00	RW-321	ORNL FY 1991 QAPD Review and Approval	Contains draft QAPD Rev. 1 with request for review memo to RW-3. See comment on QRP-91-0535.00
QRP-91-0461.00	RW-10	Annual QA Management Assessment	Closed 7/2/92 by J. Bresee.

QRPs Reviewed by Office

QRP NUMBER	RW	TITLE	COMMENTS
QRP-91-0471.00	RW-40	Peer Review of Initiative 1 Task Design Requirements and Interface Specifications	Records transmitted by B. Lake. Task still in progress, Package current to date.
QRP-91-0478.00	RW-323	WMSR, Volume IV, Rev. 1	Transmitted as complete 7/8/91. Not closed. Duplicate package title (QRP-90-0339) for same document contains 1 record transmitted 2/22/91 (did not review this package).
QRP-91-0535.00	RW-321	ORNL FY 1992 QAPD Review and Approval	Contains RW-3 comments and acceptance of QAPD, Rev. 1, while QRP-91-0445.00 contains records requesting review and draft document.
QRP-91-0538.00	RW-50	FY1992 Program Guidance Letters to Oak Ridge Field Off.	RW-321 transmitted records on 6/15/92 to an RW-50 package.
QRP-91-0549.00 QRP-91-0557.00 QRP-92-0612.00	RW-30	1) Corrective Action Requests, 2) 10/91 Audit Responses to CARS, 3) FY92 CARS	RW-30 packages for records that are RW-3's responsibility.
QRP-91-0572.00	RW-323	Physical System Requirements - Store Waste, Initial Issue	Transmitted as complete 5/22/92. Not closed.
QRP-91-0573.00	RW-40	MRS Design Requirements	No specific comments.
QRP-91-0581.00	RW-323	Programmatic Physical System Requirements - Overall System, Rev. 0	Transmitted as complete 5/22/92. Not closed.
QRP-92-0632.00	RW-323	Program Change Control Procedure, Rev. 4	Transmitted as complete 6/26/92. Not closed.

Attachment III

ORC
OA Records Packages

<u>Office</u>	<u>Open ORPs</u>	<u>Complete ORPs</u>	<u>Validated ORP</u>
RW-1/2	1	1	0
RW-3	339	314	257
RW-10	18	18	4
RW-20	52	45	0
RW-30	7	5	0
RW-321	44	35	2(H)
RW-322	2	2	0
RW-323	17	8	0
RW-331	5	1	0
RW-332	5	0	0
RW-40	10	5	0
RW-50	25	22	5
TOTAL	_____	_____	_____
	525	465	265

(H) Packages on hold.

DRAFT

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

CAR NO. CAR HQ-92-017
DATE: _____
PAGE _____ OF _____
QA

CORRECTIVE ACTION REQUEST

¹ Controlling Document QA Records Management QAAP-17.1 Rev. 2		² Related Report No. HQ-SR-92-05
³ Responsible Organization RW-20, RW-30, RW-40		⁴ Discussed With W. Lemeshewsky, T. Van, W. Lake, P. Kumar
⁵ Requirement:		
1. PARA 4.5.3 Record originators are responsible for "ensuring that QA record packages are assembled, reviewed, and validated on a timely basis upon completion of the associated activity."		
2. PARA 6.3.4 "Subsequent to a satisfactory review and any necessary corrections the record originator shall prepare a QA record transmittal and submit the QA records to the QRC"		
⁶ Adverse Condition:		
1. PARA 4.5.3 Contrary to the above requirement, most RW's are opening packages and transmitting records to the QRC but are not timely in assembling, reviewing and validating same.		
2. PARA 6.3.4 Contrary to the above requirement, QA record transmittals are being prepared and transmitted to the QRC by various RW secretaries. Example: QRP 90-0331.00 QRP 90-0059.00 Additionally, some records originators preparing and transmitting records to the QRC are not trained to the current revision of QAAP-17.1		
⁸ Does a significant condition adverse to quality exist? Yes ___ No ___ If Yes, Circle One: A B C	¹⁰ Does a stop work condition exist? Yes ___ No ___; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	¹¹ Response Due Date:
¹² Required Actions: <input type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
¹³ Recommended Actions:		
1. RW-20, 30, and 40 are to review the status of records/records packages generated to date and take the actions necessary to assure compliance with QAAP-17.1 "QA Records Management," including required training.		
⁷ Initiator Date	¹⁴ Issuance Approved by: QADD Date	
¹⁵ Response Accepted QAR Date	¹⁶ Response Accepted QADD Date	
¹⁷ Amended Response Accepted QAR Date	¹⁸ Amended Response Accepted QADD Date	
¹⁹ Corrective Actions Verified QAR Date	²⁰ Closure Approved by: QADD Date	

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

CAR NO. CAR-HQ-92-017
DATE: _____
SHEET: _____ OF _____

**CORRECTIVE ACTION REQUEST
(continuation sheet)**

5. Requirement (con't)

3. PARA 6.3.4b "The QA record transmittal shall include, for each record being submitted, the QA record title or subtitle, identifying number if any (i.e., DOE/RM XXXX), the record date, number of pages, the assigned QRD identification number, special instructions/comments if appropriate, and name and location.
4. PARA 4.1.4 Responsible directors are responsible for "ensuring that QA records originated within their organizations that are considered privileged are properly identified, marked and handled prior to submittal to the QRC."

6. Adverse Condition (con't)

3. PAPA 63.4b Contrary to the above requirement some offices are submitting large packages to the QRC without providing a detailed table of contents with page counts for individual documents. (Without such a list the validator cannot review for completeness.)
Example: QRP 90-0331.00 (665 pages)
QRP 90-0010.00 (504 pages)
4. PARA 4.1. Contrary to the above requirement, records packages reviewed in the QRC contain privileged records examples:
QRP-90-0152.00 contains proficiency review reports with personnel qualification data
ORP-90-0329.00 contains proficiency review reports

13. Recommended Actions

2. It is also recommended that each RW office consider appointing a "Records Originator" to be responsible for assuring that QA records are identified and transmitted to the QRC when completed and subsequently assembled, reviewed and validated on a timely basis upon completion for the associated activity.
3. Additionally RW-3 is to come up with a position and determine if proficiency review reports are to be considered privileged records. (Some quality records packages containing these reports have been placed on hold by the QRP validators while others make no mention of this issue.)