

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

SURVEILLANCE REPORT

OF

CRWMS (M&O)

Vienna, VA

SURVEILLANCE NUMBER HQ-SR-93-03

August 4-6, 1993

PRIMARY ACTIVITY EVALUATED

Implementation of the Quality Review Board Process

Prepared by:

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Date:

8/13/93

Approved by:

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Director
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Date:

8/30/93

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1.0 EXECUTIVE SUMMARY

Surveillance HQ-SR-93-03 was conducted to evaluate the implementation of the Quality Review Board (QRB) process. The surveillance was conducted at the M&O offices in Vienna, VA on August 4-6, 1993. The surveillance team consisted of personnel from Headquarters Office of Quality Assurance (OQA). It was determined that the QRB process was being implemented effectively. Nine recommendations were made for management consideration. The evaluation of user acceptance and implementation of QRB processed procedures was inconclusive because the procedures have been issued for only two months or have not reached their effectivity date.

All board members interviewed consider the QRB process of value because it contributes to the integration and consistency of the procedures. The QRB meeting provides a forum for initially presenting the procedure, for communicating past problems, for resolving disputes on mandatory comments, and for providing the necessary efficiency to meet the Transition Plan objectives.

2.0 SCOPE

Surveillance HQ-SR-93-03 was conducted to evaluate the implementation of the M&O QRB process. The surveillance was performance-based, concentrating on five areas:

- a) QRB membership
- b) Review information and criteria
- c) QRB reviews
- d) Comment resolution
- e) Resulting procedure

A table of the objectives and success criteria for each of the areas is presented in Attachment 1. After evaluating pre-determined performance objectives and measurements for these five areas, the surveillance team concluded that the QRB process was effective.

The surveillance team used checklists based upon the performance objectives and the requirements of the following documents:

CRWMS M&O Quality Administrative Procedure, QAP-5-1, Preparation of M&O Administrative Procedures, Revision 2, P01, effective 6/18/93

CRWMS M&O QRB Charter, dated 4/12/93

DOE/RW/0333P, Quality Assurance Requirements and Description (QARD), Revision 0, dated 12/18/92

3.0 SURVEILLANCE TEAM

The surveillance team consisted of the following personnel:

Hugh Lentz	QATSS	Surveillance Team Leader
Patricia White	QATSS	Surveillance Team Member
Walter Coutier	QATSS	Surveillance Team Member

4.0 PERSONNEL CONTACTED

The personnel contacted during the surveillance are listed in Attachment 2.

5.0 SURVEILLANCE RESULTS

The results of the surveillance are presented for each of the five performance-based areas of the QRB process.

5.1 QRB Membership

The evaluation for the appropriate QRB membership was made by comparing the M&O organization chart against the QRB membership list of participants and alternates. The minutes for all meetings conducted by the QRB, since the origination on April 13, 1993, were reviewed to determine if the responsible organizations and designated representatives were actively involved in the review process.

Training record files for QRB members and alternates were reviewed for evidence that the QRB philosophy, process, responsibilities, and procedure requirements had been conveyed to members before they performed QRB activities.

The surveillance team conducted interviews with the QRB chairman and selected board members to evaluate their understanding of the QRB process and their responsibilities as board participants. Interviews were also conducted with selected authors of procedures, currently undergoing changes and processing through the QRB, to evaluate process interfaces and effectiveness.

The QRB membership appears to adequately represent those elements of the M&O organization that have responsibilities for developing, reviewing, and implementing the assigned procedures. The use of the QRB has improved the philosophy of ownership of the QA procedures within the responsible organizations and has focused the comment and resolution cycle within the applicable organizational elements. Ownership would be further enhanced if the responsible manager approved the procedure.

The surveillance team identified a need for the QRB chairman to review administrative controls against current practices and update the authorized QRB membership list, train new members on the QRB charter responsibilities and duties, and submit appropriate training records.

The QRB membership area was considered satisfactory with 3 recommendations. See Recommendations 6.2, 6.3, and 6.4.

5.2 Review Information and Criteria

The surveillance team conducted an evaluation to discover if the correct reviewers were being provided Procedure Review Records (PRRs) with the proper review criteria specified. The evaluation was to determine if the review criteria was adequate and if the appropriate background data was being provided to the reviewers.

The surveillance team reviewed documentation, such as PRRs, draft procedures, and memorandums contained in both in-process and completed record packages, to obtain evidence that the reviewers represented all organizations affected by the procedure. The PRRs were also examined to determine if the specified review criteria was appropriate to each organization as defined by their scope of work. The documentation was reviewed for evidence that related CARs, interfacing documents, related QARD requirements, and rationale for procedure changes were being provided to the reviewers.

Interviews were conducted with procedure authors, reviewers, QRB members, and the QRB chairman to understand the basis for assigning review criteria to a particular organization. The surveillance team interviewed the QRB members and reviewers to assess their understanding and use of the review criteria and to determine the adequacy of the background information provided. The individual responsible for the Requirements Traceability Network (RTN) verification process discussed the adequacy of his evaluation to assure that the QARD requirements have been satisfied.

Based on this evaluation, the correct reviewers are being provided PRRs with the proper review criteria specified. The review criteria is being used and is of value because of the focus provided for the procedure review. However, to do a better review, the procedure authors should consistently provide the reviewers background information, such as related CARs, interfacing documents, and rationale for the procedure changes. The RTN verification process is detecting unverified QARD requirements in procedures that have been accepted by the QRB and approved by management. (Note: "Unverified" means that the location of a QARD requirement must be determined through discussion with the procedure author.)

The Review Information and Criteria area was considered satisfactory with one recommendation. See Recommendation 6.5.

5.3 QRB Review

The surveillance team conducted an evaluation, by selecting a sample of procedures processed through the QRB, to assess the methods for determining and selecting appropriate review criteria, for the QRB review itself, and for identifying and resolving reviewer comments.

Interviews were conducted with the QRB chairman and other board members to confirm a consistency among members in their understanding of established procedure philosophy, responsibilities, and commitments.

By attending the QRB meeting conducted on August 5, 1993, the surveillance team observed the QRB process. The meeting addressed board actions for ten procedures in various stages of revision, three procedure change notices (PCNs), two recommended PCNs, and planned actions for the next meeting. The surveillance team observed a need to provide a more effective meeting for the final review and acceptance process by requiring that all QRB members have the necessary documents before the meeting.

The QRB Review area was considered satisfactory with one recommendation. See Recommendation 6.6.

5.4 Comment Resolution

The surveillance team conducted an evaluation to determine if comments were being adequately and satisfactorily resolved prior to approval of the procedures and how this resolution was obtained. The evaluation examined the effectiveness of the dispute resolution process. The surveillance team evaluated the concurrence process to assure that the QRB members had an opportunity to concur with the final procedure.

By reviewing documentation, such as PRRs, comment resolution attachments, and draft procedures contained in both in-process and completed record packages, the surveillance team determined if the QRB members are accepting resolution to mandatory comments prior to approval of the procedures. The documentation was reviewed to assess the nature of the comments provided by the reviewers. The team also questioned how comments that may not meet the mandatory criteria are treated.

Interviews were conducted with procedure authors, reviewers, QRB members, and the QRB chairman to determine how unresolved comments are dispositioned. During the interviews with the QRB members, the surveillance team examined the adequacy of comment resolution process to prevent PCNs.

Based on the evaluation, the surveillance team concluded that comments are being adequately and satisfactorily resolved prior to approval of procedures. Although the resolution has been accepted by the reviewer, the basis for comment resolution is not always documented; and in some cases, the documentation of the resolution is not complete before approval of the procedure. QAP-5-1 has no formal mechanism for upgrading or downgrading the category of a comment. Because no disputed comments have been elevated, the surveillance team cannot determine if this portion of the QRB process is effective. The team discovered that the QRB members are not routinely given the opportunity to review and concur with the final procedure before QRB acceptance. The QRB relies on the chairman to ensure that all procedure commitments and agreements are satisfied.

The Comment Resolution area was considered satisfactory with two recommendation. See Recommendation 6.7 and 6.8.

5.5 Resulting Procedure

Based on an interview with the QRB chairman and review of issued procedures, the QRB acceptance and management approval of procedures was verified as being processed in accordance with QAP-5-1.

To evaluate the objective of implementing procedures that satisfy customer requirements, the surveillance team reviewed the QARD verification process (RTN evaluation) and recent audits, which included QRB processed procedures. The RTN evaluations are identifying unverified QARD requirements, which may require a change to a procedure. The audit, conducted in Charlotte, NC at end of July 1993, did not identify any deficiencies related to 13 QRB processed procedures.

There has been no formal classroom training conducted on the QRB processed procedures to-date. However, an Indoctrination Training class, which includes six specific procedures as denoted by QAP-2-1, was scheduled for August 11, 1993. The training organization keeps current with changes in procedures by participating in the QRB meeting discussions.

Although the surveillance team interviewed seven users of approved and issued procedures, the evaluation to determine if the QRB process accomplishes the intended objective to issue an implementable procedure was conducted too early. The evaluated procedures have been issued for only two months. Both the Quality and Systems organizations plan to evaluate the implementation of their procedures and to measure the effectiveness of the QRB process.

The Resulting Procedure area was considered satisfactory with one recommendation. See Recommendation 6.9.

6.0 RECOMMENDATIONS

- 6.1** The M&O should continue to build on the QRB process. The surveillance team observed the QRB process as possessing the following good attributes:
- a) active participation
 - b) acceptance of responsibility
 - c) integration of functions
 - d) more consistent product
 - e) forum to resolve issues
 - f) efficiency to meet commitments
- 6.2** Because the QRB minutes are QA records, the surveillance team recommends that the QRB secretary identify board representatives in the meeting minutes, especially when the QRB has accepted procedures.
- 6.3** Training for QRB members, and especially alternates, should be reviewed and updated to reflect training on the QAP philosophy and QRB charter.
- 6.4** According to QAP-5-1, responsible managers develop particular QAPs related to their functional activity. To further enhance the ownership of these particular QAPs, the responsible manager should approve the procedures and QA should only concur.
- 6.5** To obtain a better review of procedures, the procedure author should provide reviewers with document histories and identification of interfacing procedures, and related CARs.
- 6.6** Also observed at the meetings were procedures that were not ready for QRB discussion. Each member does not have all the information or revisions necessary to conduct an efficient and cost effective meeting. The QRB could improve meeting efficiency by requiring that all QRB members have the necessary documents before the meeting.
- 6.7** QAP-5-1 does not provide a process for changing the category of a comment. A mandatory designated comment must be resolved even if the comment is editorial, unless the procedure author gets the reviewer to withdraw the comment. The surveillance team suggests that QAP-5-1 be revised to include a formal mechanism for changing the category of a comment (either downgrade or upgrade).
- 6.8** As observed at the meetings, the QRB members do not have a completely revised procedure when final acceptance is decided. The QRB should develop a system for ensuring that the entire QRB reviews and concurs with the final draft prior to board acceptance and management approval.

- 6.9** The surveillance team recommends that the M&O move the QARD verification process upstream to provide more interface with the review process. This would allow incorporation of missing requirements prior to approval and issue of the procedure.

7.0 LIST OF ATTACHMENTS

- Attachment 1: Table of Objectives and Success Criteria for the QRB Process
Attachment 2: List of Personnel Contacted During the Surveillance
Attachment 3: List of Objective Evidence Reviewed During the Surveillance

ATTACHMENT 1

Table of Objectives and Success Criteria for the QRB Process

OBJECTIVE: Is the QRB effective?		SURVEILLANCE HQ-SR-93-03	Date: 7/30/93
FLOWCHART	OBJECTIVE	SUCCESS CRITERIA	
QRB membership QAP-5-1 Para. 3.11 5.1.8 5.3.3	Procedure consistency Group compatibility Organization accountability Better product (procedure) Expertise from each organization Efficient review cycle	Qualification and training User feedback - other organizations Verification process	
Review information and criteria QAP-5-1 Para. 5.3.1 5.3.2 5.3.3 Att. III Att. IV	Adequate information Specified review criteria PRR form/draft procedure Other issues provided at QRB meeting Procedure flowchart Expedite information flow Specific QARD Requirements CAR HQ-93-013	Training QRB requests (reviewers) Verification process User feedback QA Manager evaluation	

ATTACHMENT 1

Table of Objectives and Success Criteria for the QRB Process (continued)

OBJECTIVE: Is the QRB effective?		SURVEILLANCE HQ-SR-93-03	Date: 7/30/93
FLOWCHART	OBJECTIVE	SUCCESS CRITERIA	
QRB review QAP-5-1 Para. 5.3.6 Att. I-SEC 5 Att. IV	Meet customer requirements/other requirements Practical procedure Interface with other procedures	QRB acceptance Procedure trial run RTN evaluation Number of subsequent PCNs Verification process	
Comment resolution QAP-5-1 Para. 5.3.8	Documented resolution of comments (traceability) Enhancement of procedure User ownership Incorporation of comments	Concurrence No disputes (escalation) No Quality concerns QA records PRR acceptance Verification process	
Resulting procedure QAP-5-1 Para. 5.3.9	QA Mgr/Gen Mgr approval Traceable back to requirements OCRWM Acceptance Adequate training plans	RTN evaluation Verification process OCRWM acceptance Feedback from users Training plan/trainee problems	

ATTACHMENT 2
Personnel Contacted During The Surveillance

NAME	ORG.	TITLE
Karin Baxter	M&O/Secretariat	Records Management Assistant
R.J. Brackett	M&O/QA	M&O QA Manager
George A. Carruth	M&O/SI	Manager, Systems Integration
Eugene T. Chulick	M&O/Training	Manager, Training
James R. Clark	M&O/S&T	Deputy Mgr., Storage and Transportation
Hubert Dameron	M&O/QA	Senior Technical Specialist
Bill Farmer	M&O/QA	QA Engineer
Christopher Kelly	M&O/Training	Database Specialist
Jeffrey Lim	M&O/SI	MTS Systems Engineer
Robert A. Morgan	M&O/QA	Vienna QA Manager
Frank Nash	M&O/QA	QA Staff
Peter H. Schlereth	M&O/QA	QA Engineer (Senior)
Michael D. Vance	M&O/QA	QA Engineer
Glenn Vawter	M&O/NV Site	Deputy Site Manager

ATTACHMENT 3

Objective Evidence Reviewed During Surveillance

Quality Review Board Meeting Minutes for:

<u>Meeting No.</u>	<u>Dated</u>
1	4/15/93
2	4/22/93
3	5/11/93
4	5/14/93
5	5/21/93
6	5/26/93
7	6/7/93
8	6/15/93
9	6/17/93
10	7/3/93
11	7/7/93
12	7/14/93
13	7/22/93
14	7/28/93

Quality Review Board Membership List, dated April 1993

Quality Review Board Membership List April 1993 (Update August 5, 1993)

Quality Administrative Procedure Development Philosophy April 1993

QRB Charter April 12, 1993

M&O Organization Chart February 10, 1993

Training Attendance Record on QAP and QRB Briefing, dated April 13, 1993

Training Records Reviewed

Brackett, R.J.
Carruth, G.A.
Clark, J.R.
Dameron, H.C.
Lim, J.J.
Schneider, W.
Shepherd, M.
Standley, W.
Stringer, J.B.
Morgan, R.A.
Tierney, J.L

ATTACHMENT 3 (continued)

Objective Evidence Reviewed During Surveillance

QAP In Process Records

QAP 1-1, Rev. 2, PRRs
QAP 2-3, Rev. 4, PRRs for 1st and 2nd Review Cycles
QAP 3-12, Rev. 2, PRRs
QAP 5-1, Rev. 2, P01, PRRs for 2nd Review Cycle
QAP 19-4, Rev. 1, Preliminary Draft w/QARD reference attachment

QAP Record Packages

QAP 2-3, Rev. 3, Classification of Items
QAP 2-7, Rev. 0, Management Assessment
QAP 3-1, Rev. 2, Technical Document Review
QAP 3-4, Rev. 0, Baseline Control
QAP 3-9, Rev. 1, Engineering Calculations and Analysis
QAP 3-12, Rev. 0, External Transmission of Design Input Data
QAP 6-1, Rev. 2, Document Control
QAP 19-2, Rev. 2, Software Configuration Management

Resulting Procedures

QAP 2-1 Rev. 4, Indoctrination and Training
QAP 2-7, Rev. 0, Management Assessment, effective date 4/26/93
QAP 5-1, Rev. 2, P01, Preparation of M&O Quality Administrative Procedures, effective date 6/18/93
QAP 6-1, Rev. 2, Document Control, effective date 6/18/93
QAP 18-2, Rev. 2, Audits, effective date 6/18/93

RTN Status Report, dated 7-28-93, issued by Michael Vance

RTN Status Report, dated 8-5-93, issued by Michael Vance

Memo to Jim Brackett from Tom Colandrea, Management Assessment Procedure QAP-2-7, dated 3-10-93

Flowchart for QAP-2-7, as presented to the QRB meeting, dated 4-13-93

M&O MGDS Design Control Improvement Plan, Preliminary Draft Rev. 0, 30 July 1993 (no signatures)

Interoffice Correspondence memo, dated 7/20/93, R.J. Brackett to File.

CRWMS M&O Quality Assurance Report (draft), Report Number: 93-MRA-01, MRS/MPC Design, Charlotte, NC, conducted 7/13-15/93, dated 7/29/93 by ATL.

Draft plan for Measuring Effectiveness of QRB dated 8-5-93