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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

Title: OCRWM QUALITY CONCERNS PROGRAM			
Procedure No.: QAAP 1.2	Revision: 0	Date: 07/01/91	Page 1 of 14
Concurrence: [signature] Date: 6/26/91		Approval: [signature] Date: 6/26/91	

1.0 PURPOSE

This procedure describes the Office of Civilian Radioactive Waste Management (OCRWM) Quality Concerns Program (QCP) that provides personnel the opportunity to confidentially report concerns or conditions either adverse to quality or to the radiological health and safety of PROGRAM participant personnel and the general public. This is an action-oriented management system designed to assure each employee, and others, that positive steps are taken by OCRWM management to resolve any reported concerns.

The QCP encourages employee/contractor participation in the achievement of quality. An important provision of the QCP is to guarantee the confidentiality of the identity of individual(s) reporting concerns and to ensure that the individual is protected from reprimand, harassment, retaliation, duress, or reprisal.

2.0 SCOPE

This procedure establishes an OCRWM-wide program for identifying and reporting quality concerns that will be available to PROGRAM participants.

The QCP is not intended to handle allegations of waste, fraud, theft, mismanagement, criminal acts, or concerns involving industrial safety or personnel-related issues, etc., as there are established systems to address these issues. However, if such concerns are received through the QCP, they will be directed to the appropriate organization for investigation.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

3.1.1 *Quality Assurance Requirements Document* (QARD), DOE/RW-0214.

3.1.2 *Quality Assurance Program Description Document* (QAPD), DOE/RW-0215.

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3.2 DEFINITIONS

3.2.1 The definitions of standard terms may be found in the Glossary contained in reference 3.1.1.

3.2.2 Interviewer - The individual who:

a) has direct contact with the originator of a concern;

b) is responsible to investigate the information provided by the originator to determine its validity, and

c) verifies that actions taken to resolve the concern are complete.

This individual shall be independent of the affected activity (i.e., neither have performed the activity nor reports to an individual responsible for the activity).

3.2.3 Originator - The individual who identifies the concern to the QCP for investigation and resolution.

3.2.4 PROGRAM - U.S. Department of Energy, Office of Civilian Radioactive Waste Management Program

3.2.5 PROGRAM participant - All organizations performing work on the PROGRAM

3.2.6 TPO - Individuals responsible for management of work assigned to organizations supporting the Office of Geologic Disposal.

3.2.7 Quality Concern - A problem or, a perceived problem, which indicates that PROGRAM activities have not met either the technical or quality requirements for the PROGRAM and may adversely affect:

a) the radiological health and safety of the public during the processing, handling, transportation, storage or the safe disposal of high-level radioactive waste; or

b) work that either provides direct input into the license application or the radiological safety sections of the environmental impact statement or indirectly supports the technical arguments in the license application or the radiological safety sections of the environmental impact statement.

3.2.8 Quality Concerns Hotline - A PROGRAM-wide telephone message and mail system designed to allow PROGRAM personnel and others to express quality concerns in confidence and obtain feedback on resolutions if desired.

3.2.9 Exit Interview Package - A package of Quality Concerns Program material consisting of:

a) Quality Concerns Disclosure Statement (Attachment II) with pre-paid QCP-addressed envelope;

b) Exit Interview Form for Transferring/Departing Employees (Attachment III); and

c) other explanatory material providing details on how to contact the QCP office.

4.0 RESPONSIBILITIES

4.1 DIRECTOR, OCRWM

4.1.1 The Director, OCRWM, or designee has overall responsibility for:

4.1.1.1 Establishing, implementing and monitoring a Quality Concerns Program (QCP) to process concerns as described in this procedure.

4.1.1.2 Acting in place of the Director, Office of Quality Assurance (OQA), as described in this procedure, when a quality concern specifically questions the actions of, or describes a problem within, the Office of Quality Assurance.

4.2 ASSOCIATE DIRECTORS/OFFICE DIRECTORS, OCRWM

The Associate Directors/Office Directors are responsible for:

4.2.1 Assigning a QCP Coordinator to interface with the Quality Concerns Program Manager.

4.2.2 Providing prompt support of the QCP process by investigating, evaluating, responding to, and correcting any condition determined to be a quality concern.

4.3 ASSOCIATE DIRECTOR, OFFICE OF PROGRAM AND RESOURCES MANAGEMENT (OPARM) AND ASSOCIATE DIRECTOR, OFFICE OF GEOLOGIC DISPOSAL (OGD) are responsible for:

4.3.1 Coordinating OCRWM-HQ employee exit interviews and YMPO employee exit interviews, respectively.

4.4 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA, is responsible for:

4.4.1 Providing general supervision of the Quality Concerns Program Manager.

4.4.2 Maintaining and providing resources for implementation of the system described in this procedure.

4.4.3 Conducting periodic surveillances and audits to assess the implementation of the Quality Concerns Program.

4.5 QUALITY CONCERNS PROGRAM MANAGER

The Quality Concerns Program Manager has the overall responsibility for:

4.5.1 Notifying the Director, OCRWM, when the quality concern involves OQA.

4.5.2 Preparing and maintaining this QAAP.

4.5.3 Establishing and maintaining the telephone and mail-in system for the identification of quality concerns.

4.5.4 Assuring that each quality concern is documented, assigned an identification number, logged, screened, and investigated as described herein.

4.5.5 Concurring with quality concern investigation activities and corrective actions.

4.5.6 Maintaining confidentiality with respect to access to quality concerns investigation documentation and files.

4.5.7 Coordinating the investigation and feedback on the status of PROGRAM participant concerns from PROGRAM Participant coordinators.

4.5.8 Assigning a QCP interviewer to lead, coordinate or participate in the investigation of a quality concern.

4.5.9 Monitoring the progress of recommended actions and closure of any corrective action associated with a quality concern.

4.5.10 Issuing a monthly status report regarding investigations in-progress to the Directors, OCRWM and OQA, and the organizations involved in, or affected by, a quality concern.

4.5.11 Closing the Quality Concerns Program files when actions have been completed and processing designated QA records per Section 7.0.

4.5.12 Providing Quality Concerns Program promotional material (e.g., posters, brochures, videos, prepaid mailers, forms, etc.), as appropriate, to PROGRAM participant employees.

4.5.13 Providing indoctrination and training to PROGRAM participant employees including:

a) Employee indoctrination

b) Interviewer and Participant Coordinator training

4.6 QUALITY CONCERNS INTERVIEWER

4.6.1 A Quality Concerns Interviewer is responsible for manning the Hotline phone during normal working hours, reviewing Hotline recorded telephone messages every working day, and taking appropriate action to incorporate reported concerns into the Quality Concerns Program.

4.6.2 The Quality Concerns Interviewer is responsible for conducting an investigation of quality concerns, documenting results, and verifying that corrective actions have been taken to satisfactorily resolve the expressed concern. The interviewer shall not investigate non-quality concerns, but shall be responsible for follow-up to ensure evaluation is made and to obtain a response from the responsible organization.

4.6.3 A summary report shall be prepared by the Quality Concerns Interviewer and approved by the QCP Manager for submittal to appropriate management. The report shall include:

a) a concise statement of the concern with the identifying number;

b) action taken to resolve the concern;

c) a statement verifying that corrective action has been completed; and

d) signature of the interviewer.

4.7 QUALITY CONCERNS PROGRAM (QCP) PARTICIPANT COORDINATOR

QCP Participant Coordinator activities shall be limited to coordinating the Exit Interview Program; assisting the Quality Concerns Interviewer as requested; assisting in training, installation, and maintenance of QCP promotional material; acting as point of contact between Participant and the QCP Manager; and maintaining the follow-up of Corrective Action Requests to obtain timely response. Any additional support activity beyond that noted above shall be requested from and approved by responsible PROGRAM Participant management.

5.0 GENERAL

5.1 An important provision of the QCP is to guarantee confidentiality of the identity of the concern originator to ensure that the individual is protected from reprimand, harassment, retaliation, duress, or reprisal.

5.2 Promotional materials and training provide a means to communicate the goals and objectives of the QCP to employees at PROGRAM participant locations. QCP training shall be provided in order to:

a) Acquaint employees with the QCP and allow them to ask questions about the program; and

b) Train interviewers and coordinators on how to perform their respective responsibilities.

5.3 Sources of quality concerns may include:

5.3.1 Information received from the QCP Hotline.

5.3.2 Concerns identified during exit or other personal interviews.

5.3.3 Notification from the NRC or other outside agency or interest (e.g., states, tribes).

5.3.4 Prepaid mailers or letters from any source.

5.4 Upon receipt of a call that identifies a quality concern, the Originator shall be provided with a unique concern identification number as described in Section 6.1. At no time shall the name of the Originator be recorded, nor shall it appear in any file, work papers, or reports unless specifically requested or agreed to by the Originator. Any request by the Originator for status of the quality concern investigation or any results must be made using the concern's unique identification number.

5.5 The initial contact with a concern's originator may be the only opportunity to obtain information about the quality concern. This information is necessary to permit an appropriate investigation of a reported concern. Therefore, the following information may be obtained during the initial interview in order to fully define the quality concern:

a) the location,

b) characteristics,

c) nature,

d) impact on quality and safety,

e) personnel to contact, and

f) any other specifics.

6.0 PROCEDURE

6.1 REPORTING QUALITY CONCERNS

6.1.1 The Quality Concerns Program Manager shall establish and maintain the interview, telephone, and mail-in system for the identification of quality concerns.

The system shall provide for posted notification throughout the Program explaining the purpose, availability, instructions for use, the address of the QCP office and the telephone number of the Quality Concerns Hotline.

6.1.2 PROGRAM personnel who have quality concerns, or knowledge of quality concern matters that have not been resolved to their satisfaction through normal channels or that require anonymity, may report them through the Quality Concerns Program outlined in this procedure.

6.1.3 Quality concerns may be reported in a personal interview; via telephone, using a mail-in form; through the exit interview process, or any other appropriate method.

6.1.4 Concerns will be given a unique identification number by the QCP office and placed on a logging system. When possible, the concern originator will be given the identification number which must be used if information on the resolution of the concern is requested. Feedback shall depend on establishing an acceptable means of communication between the QCP and the originator of the concern.

6.1.5 The identity of originators shall not be revealed during the course of any actions involved with the investigation, follow-up and resolution of a quality concern.

NOTE: However, in cases where a quality concern may result in duly authorized legal investigations or legal actions, identification of an originator may be required by a specific legal procedure/order.

6.1.6 A complete description of the quality concern should be provided by the originator. When possible descriptive information should include: the location, responsible individual(s), concise/ specific details regarding the condition, when the condition occurred, and other individuals who may provide additional information.

6.1.7 When utilizing the QCP Telephone Hotline method, the originator should follow the recorded instruction. The telephone system will be available on a 24-hour basis. The Hotline number and instructions on its use will be posted at Program participant locations.

6.1.8 The Exit Interview Package is designed to provide departing individuals an opportunity to express a concern directly to the Quality Concerns Program Office, either by letter or personal interview. This letter or interview is independent of the knowledge of respective management, if so desired. This may also be accomplished by using the Hotline or the Quality Concerns Program Letter described in Attachment I. In addition, the signed acknowledgment of receipt of the Exit Interview Package (Attachment III) provides a record that the departing employee was made aware of the Quality Concerns Program.

6.1.9 The Exit Interview Package processing may be performed in a manner deemed appropriate by the PROGRAM participant. Completed Exit Interview Forms will be submitted to the QCP for processing per Section 7.0.

6.2 RESOLVING QUALITY CONCERNS

6.2.1 Upon receipt of a concern, the Quality Concerns Program Manager shall determine whether it is a quality concern, as defined in Paragraph 3.2. If not, the concern will be referred to the appropriate DOE organization (i.e., Security, Personnel, Safety, etc.), but the Quality Concerns Program Manager shall retain responsibility for follow-up to obtain a response and report back to the originator the action taken by the responsible organization.

6.2.2 The quality concern will be assigned to a Quality Concerns Interviewer. The interviewer shall prepare an investigation plan for approval by the QCP Manager. This plan may, as appropriate include support provided via paragraph 4.2.2. An appropriate investigation of all the information provided by the originator shall be conducted.

6.2.3 When the QCP Manager and the interviewer concur that a quality concern is substantiated and the need and responsibility for corrective action is established, the interviewer shall prepare a Corrective Action Request (CAR) per QAAP 16.1. The CAR shall be transmitted to the respective Participant TPO and the Quality Concerns Coordinator of the organization responsible for action. A copy shall be sent to the cognizant Associate Director (AD)/Office Director (OD).

6.2.4 The CAR response shall include the plan for achieving corrective action and the schedule for completion. The response shall be transmitted to the Quality Concerns Program Office within ten (10) working days from receipt. Delinquent responses shall be referred to the cognizant AD/OD for assistance in obtaining corrective action.

6.2.4.1 The cognizant AD/OD shall respond within five (5) working days. If the response is not received, the concern shall be referred by the Quality Concerns Program Manager, via the Director, OQA, to the Director, OCRWM for resolution.

6.2.5 Upon completion of the investigation and verification of any required corrective action, the interviewer shall prepare a Quality Concerns Program Investigation Report, including applicable references and supporting documents.

6.2.5.1 The report shall be summarized stating the concern and any appropriate corrective action taken. Copies of the summary shall be sent to the Director, OCRWM, the cognizant Associate Director, Office Director, Director OQA, and the responsible Participant's TPO.

6.2.6 The interviewer shall notify the originator of the actions taken to resolve the reported concern if appropriate avenues of communication have been established. If the originator is not satisfied with and rejects the resolution, the matter shall be referred to the QCP Manager and the Director, OQA for direction.

6.2.7 A system shall be developed to provide tracking and status of quality concern resolution activities.

7.0 RECORDS

7.1 QA records shall be processed in accordance with QAAP 17.1, *QA Records Management*. At a minimum, the following are considered QA Records:

7.1.1 Exit Interview Form for Transferring/Departing employees;

7.1.2 Corrective Action Request (CAR); and

7.1.3 Relevant correspondence associated with the CAR.

8.0 ATTACHMENTS

8.1 Attachment I - Quality Concerns Program Letter

8.2 Attachment II - Quality Concerns Disclosure Statement

8.3 Attachment III - Exit Interview Form for Transferring/ Departing Employees

8.4 Attachment IV - Flowchart

ATTACHMENT I

QUALITY CONCERNS PROGRAM LETTER

QUALITY CONCERNS PROGRAM LETTER

QUALITY CONCERNS PROGRAM
OCRWM
U. S. Department of Energy
Mail Stop RW-3
1000 Independence Ave.
Washington, DC 20585

Date_____

I have the following concern:

Please describe the concern in detail and include the following: (1) condition/concern; (2) location of the concern; (3) procedure or system affected, (4) activities affected, (5) dates and times, (6) possible impact, (7) how the QUALITY CONCERNS PROGRAM can learn more about the condition, and (8) names of others who can help us.

(Additional sheets may be added, if necessary)

I want to be informed of the results of the investigation. Yes ☐ No ☐
If your answer is yes, please let us know how we can contact you:

Name_____ Address_____

Telephone (____)_____

Signature_____ Access Code_____

THE ABOVE PERSONAL INFORMATION WILL REMAIN CONFIDENTIAL

BLOCK TO BE COMPLETED BY QUALITY CONCERNS PROGRAM REP:
CONCERNS FILE NO._____
DATE RECEIVED:_____

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ATTACHMENT II

QUALITY CONCERNS DISCLOSURE STATEMENT

QUALITY CONCERNS PROGRAM

QUALITY CONCERNS DISCLOSURE STATEMENT

I, _____, employed by _____
acknowledge that: (Check one of the items below)

☐ I know of no existing quality problems not currently identified which could 1) affect the safe operation for this Program, and/or 2) affect the radiological health and safety of the general public or Project site personnel.

☐ The quality problem(s) listed below, in my opinion affect either 1) the safe operation of, and/or, 2) the radiological health and safety of the general public or site personnel of the Program. Please describe the concern in detail. Include the following: Location of the concern, procedure or system affected, activities affected, dates and times, possible future problems, how the QUALITY CONCERNS PROGRAM can learn more about the problem, and names of others who can help us.

(Use additional pages as needed)

I may be contacted at:

_____ _____
_____ _____
_____ _____
_____ _____

Telephone (_____) _____

It would be appreciated if you would return this completed form to the QUALITY CONCERNS PROGRAM. A prepared envelope is provided in the Exit Interview Package for this purpose. Your name will remain confidential.

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ATTACHMENT III

EXIT INTERVIEW FORM FOR TRANSFERRING/DEPARTING EMPLOYEES

QUALITY CONCERNS PROGRAM

EXIT INTERVIEW FORM FOR TRANSFERRING/DEPARTING EMPLOYEES

Date _____ Position Title _____

Employee Name _____ Badge Number _____

Employer _____

Permanent Address _____

_____

_____

Phone Number _____

☐ I was given the Exit Interview Package

_____
Employee Signature

☐ Employee was not on site or unavailable

☐ An Exit Interview Package was mailed

QUALITY CONCERNS COORDINATOR _____
Signature Date

QACERNP 129/5-31-91

ATTACHMENT IV

FLOWCHART