



OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

Title: CORRECTIVE ACTION PROCESS (for OCRWM/HQ Deficiency Reports and Corrective Action Reports Issued Prior to 10/15/90)

Procedure No.: QAAP 16.9	Revision: 0	Date: 10/17/90	Page 1 of 16
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Concurrence <i>[Signature]</i>	Date: 10/17/90	Approval <i>[Signature]</i>	Date: 10/17/90
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1.0 PURPOSE

This procedure prescribes the responsibilities and methods for identifying, correcting, preventing recurrence, and closure of deficiencies.

2.0 SCOPE

This procedure replaces QAAP 16.1 Revision 0, and applies only for the continued processing and closure of those Deficiency Reports (DRs) and Corrective Action Reports (CARs) initiated at OCRWM Headquarters under QAAP 16.1, Revision 0 prior to October 15, 1990. The current revision of QAAP 16.1 applies CARs (deficiency reports) initiated after October 15, 1990.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

- 3.1.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", (QARD) DOE/RW-0214.
- 3.1.2 "Quality Assurance Program Description for the Civilian Radioactive Waste Management Program," (QAPD) DOE/RW-0215.

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 Corrective Action - measures taken to rectify conditions adverse to quality and, where necessary, to prevent recurrence. Corrective action includes remedial action and investigative action as defined below.
- 3.2.3 Corrective Action Report (CAR) - a document used by the Director, OQA, to report and/or elevate deficiencies that are determined to be significant or of importance sufficient to warrant the attention of the Director, OCRWM.



- 3.2.4 Deficiency - a condition of an item or activity, attribute, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.
- 3.2.5 Deficiency Report (DR) - a document used to report deficiencies in activities or products discovered by OCRWM personnel or OCRWM support contractor personnel, and to record the corrective actions.
- 3.2.6 Investigative Action - actions taken to determine the overall extent, depth, and root cause of a deficiency, including identification of similar deficiencies related to those specifically identified.
- 3.2.7 Product - includes items, as defined in reference 3.1.1; documents that result from PROGRAM activities and software.
- 3.2.8 Remedial Action - actions taken to correct specifically identified deficiencies.
- 3.2.9 Root Cause - the most fundamental circumstances that are manifest by an observed deficiency, i.e., where the deficiency is but a symptom of a more basic problem.
- 3.2.10 Significant Deficiency - a significant condition adverse to quality that, were it to remain uncorrected, could seriously affect safety or waste isolation.

4.0 RESPONSIBILITIES

4.1 DIRECTOR, OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM)

The Director, OCRWM, or designee is responsible for:

- 4.1.1 Approving the issuance, resolution, and closeout of Corrective Action Reports.

4.2 OCRWM MANAGERS

OCRWM Managers (i.e., the Cognizant Branch Chief, Division Director, Associate Director, or Director) or their designees, are responsible for:



- 4.2.1 Controlling activities and/or the use of products identified as deficient until resolution is reached;
- 4.2.2 Taking immediate action to correct deficiencies where threat of degradation or irretrievable loss to the OCRWM PROGRAM exists;
- 4.2.3 Taking remedial action to correct identified deficiencies;
- 4.2.4 Investigating deficiencies to determine the overall extent of the problem and root cause; and
- 4.2.5 Implementing measures to prevent recurrence of deficiencies.

4.3 OCRWM PERSONNEL

OCRWM and OCRWM support contractor personnel are responsible for:

- 4.3.1 Identifying and reporting deficiencies observed in the conduct of PROGRAM activities or in the characteristics of PROGRAM products;
- 4.3.2 Initiating a Deficiency Report (DR), as necessary; and
- 4.3.3 Providing support in resolving deficiencies.

4.4 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA, or designee is responsible for:

- 4.4.1 Preparing and maintaining this QAAP;
- 4.4.2 Assuring that activities and/or products identified as deficient are controlled until resolution is reached;
- 4.4.3 Determining the significance of deficiencies and initiating a Corrective Action Report (CAR), as required;
- 4.4.4 Tracking the status of all OCRWM DRs and CARs;
- 4.4.5 Investigating and validating reported deficiencies;
- 4.4.6 Evaluating proposed corrective actions;
- 4.4.7 Verifying implementation of corrective actions; and
- 4.4.8 Closing out the DR or CAR upon verification of corrective actions.



5.0 GENERAL

- 5.1 All OCRWM and support personnel are required to report deficiencies in execution of QL1 or QL2 activities or in characteristics of QL1 or QL2 products, upon discovery. The OQA shall be contacted as soon as practical upon discovery of a deficiency. This procedure may also be used to address deficiencies in QL3 activities or QL3 products that are considered important to PROGRAM objectives. Deficiencies may be discovered through audits, surveillances, reviews, observation of work in-process, trend analysis, or examination and testing of products or software.
- 5.2 If an apparent deficiency in the OCRWM PROGRAM is identified by an outside organization (for example the NRC), and reported to the OCRWM, the Director, OQA, shall initiate the required actions in accordance with this procedure.
- 5.3 A Deficiency Report (DR) (Attachment I) shall be prepared in accordance with Section 6.0 of this procedure upon detection of programmatic or implementation deficiencies (e.g., procedure violations or inadequacies), for OCRWM product deficiencies, and for Participant-product deficiencies identified by OCRWM personnel.
- 5.4 The Director, OQA, shall evaluate reported deficiencies to determine whether or not a CAR is warranted, and initiate a CAR as appropriate. A DR is not necessarily required to initiate a CAR. The CAR is needed for significant deficiencies, as described below, and for other deficiencies that are repetitive and for which previous corrective action has been ineffective.
- 5.5 The Director, OQA, shall determine whether or not the deficiency is significant, based on the criteria given below. This determination may be changed by the Director, OQA, as determined through investigation of a deficiency. Examples of significant deficiencies are:
- 5.5.1 Serious errors in design, construction, or fabrication which were detected subsequent to formal quality verification and acceptance (e.g., a significant design error discovered during an OCRWM design review of a previously verified design that impacts a Q-List item);
- 5.5.2 Serious errors in the execution or results of scientific investigations, performance assessments, or performance confirmation, that were detected subsequent to acceptance of the resulting data (e.g., deficiencies in the conduct of activities which are included on the Quality Activities List that have a potential for impact on waste isolation);



5.5.3 A breakdown in a QA program (i.e., failure of an organization to establish and implement prescribed QA and technical requirements, plans, and procedures); and/or

5.5.4 Deficiencies that may require a stop work order (SWO) in accordance with QAAP 16.2, "Stop Work".

5.6 The status of each DR and CAR shall be tracked by the OQA from submittal to closure.

5.7 DRs and CARs shall be analyzed for trends by the OQA, in accordance with QAAP 2.9, "QA Program Status Reporting".

6.0 PROCEDURE

6.1 DEFICIENCY REPORTING

6.1.1 OCRWM or OCRWM support contractor personnel, upon discovering an apparent deficiency, shall determine the appropriate course of action based upon the criteria of Section 5.0. If a DR is warranted, the OCRWM or OCRWM support contractor personnel shall notify the Director, OQA, of the condition within one work day and initiate a DR. The DR shall be signed and submitted to the OQA.

6.1.2 If a deficiency is a result of an audit or surveillance, the Lead Auditor or surveillance leader shall monitor the DR/CAR status and ensure that adequate corrective actions are implemented.

6.1.3 The Director, OQA, and responsible management shall determine whether immediate corrective measures are needed to prevent degradation or loss to the PROGRAM. These measures shall be recorded on the DR.

6.1.4 Where products are suspect as being deficient, the Director, OQA, and the management responsible for the product shall take action to mark, segregate, or otherwise control use of these products to preclude their inadvertent use until disposition is final and approved.

6.1.5 Where an activity is conducted in a deficient or improper manner, the Director, OQA, and the management responsible for the activity shall take action to control the activity and its effects until permanent corrective measures are implemented.



6.2 INITIAL EVALUATION

- 6.2.1 The OQA shall enter the DR into a status tracking system.
- 6.2.2 The OQA shall initially investigate the reported deficiency to determine whether a deficiency exists. Other OCRWM organization(s) shall support the OQA in the investigation, as necessary. If no deficiency exists, the OQA shall take steps to cancel the DR in accordance with Section 6.7 of this QAAP.
- 6.2.3 The Director, OQA, shall determine whether a CAR is required based upon the criteria of Sections 5.4 and 5.5.

6.3 CORRECTIVE ACTION REPORT

- 6.3.1 For deficiencies requiring a CAR as prescribed in Sections 5.4 and 5.5, the Director, OQA, shall initiate a CAR.
- 6.3.2 The basis of the CAR may be one or more DRs or major concerns otherwise brought to the attention of the Director, OQA. Where applicable, the DRs shall be included and processed with the CAR.
- 6.3.3 The Director, OQA, shall evaluate the need to suspend affected work activities in accordance with QAAP 16.2, "Stop Work", and take appropriate actions. Reference to the SWO shall be recorded on the CAR.
- 6.3.4 The Director, OCRWM, shall sign the CAR as concurrence with the CAR and as direction to pursue corrective actions.

6.4 INVESTIGATION

- 6.4.1 The Director, OQA, shall transmit the DR and/or CAR to the responsible organization within the OCRWM, or reporting directly to OCRWM, who has responsibility for implementing corrective actions. Where more than one organization may be considered responsible, a lead shall be designated by the Director, OQA.
- 6.4.2 The responsible management shall investigate to determine extent, magnitude, and overall effects of the reported deficiency, and the remedial actions that will be taken to resolve the deficiency. For a CAR, the responsible management shall determine the root cause of the deficiency and what actions will be taken to prevent recurrence of the problem. As applicable, the remedial actions, root cause, extent and effects of the problem, and actions taken to prevent recurrence shall be recorded on the DR and/or CAR.



- 6.4.3 Where deficiency resolution is to accept the results of a technical activity or products, wherein the activities or products do not conform to the original requirements, technical justification for acceptance of the results or products shall be documented on the DR/CAR.
- 6.4.4 If the deficiency disposition requires rejection of a product or other results of activity, planned actions for recovery, in addition to the specific disposition for the product or result, shall be documented on the DR/CAR.
- 6.4.5 If a deficiency involves a breach of the OCRWM technical baseline, and remedial action does not fully restore the activity or product to specified requirements, the baseline shall be modified to reflect the deviation in accordance with QAAP 3.4, "Configuration Management". This action shall be initiated by the management of the organization responsible for corrective action and shall be documented on the DR/CAR.
- 6.4.6 The DR and/or CAR shall be signed by the responsible manager(s), the Project Manager for non-OCRWM organizations, the cognizant Associate Director for internal OCRWM deficiencies, and returned to the OQA for evaluation.

6.5 RESOLUTION

- 6.5.1 The Director, OQA, shall evaluate the DR and/or CAR response received from the responsible organization. He shall ensure that the remedial action is adequate, that the problem was investigated to sufficiently determine its extent, effects, and root cause, and that adequate measures will be taken to prevent recurrence, as applicable. The extent of the evaluation may range from a review of the documented response to an independent field investigation by the OQA, depending on the significance and complexity of the problem.
- 6.5.2 The Director, OQA, shall record the results of the evaluation of the DR/CAR response, sign, and return the DR/CAR to the responsible organization(s).
- 6.5.3 If the planned corrective action is determined to be inadequate, further instructions shall be provided to the responsible organization. The DR/CAR may be reissued as the next sequential revision at this time. The responsible organization shall conduct further investigations, modify the response as necessary, and resubmit the DR/CAR to the OQA.



- 6.5.4 If the corrective action is determined to be adequate, the responsible organization shall continue with implementation of the corrective action.
- 6.5.5 If agreement between the Director, OQA, and the responsible management cannot be reached, the issue shall be elevated in the management hierarchy until resolved. Resolution of the DR/CAR shall then proceed per management directives.
- 6.5.6 The responsible management shall notify the Director, OQA, upon completion of the corrective action by submitting the DR/CAR with the actual completion date and corresponding management signatures. The actual corrective action taken, and any deviations from the planned corrective actions, shall be recorded on the DR/CAR.

6.6 VERIFICATION

- 6.6.1 The Director, OQA, shall evaluate the completed corrective action, as stated on the DR/CAR, to assure that the specific deficiencies were corrected, as well as any underlying root causes of CAR-type deficiencies.
- 6.6.2 The Director, OQA, shall ensure adequate implementation of the corrective action for identified deficiencies by conducting independent verification, such as surveillance or audits at the responsible organization's facility. Verification should be performed within thirty (30) days of notification of corrective action completion although additional follow-up audits may be scheduled. Results of the verification shall be documented and included with the DR/CAR. If the Director, OQA, determines that OQA verification is not necessary, justification for this decision shall be recorded on the DR/CAR.
- 6.6.3 If the corrective action is adequately completed, the DR/CAR shall be signed and closed by the Director, OQA. The CAR shall be signed by the Director, OCRWM, prior to closure. A copy of the closed DR/CAR shall be transmitted to the originator.
- 6.6.4 If the corrective action is inadequate, the responsible management shall be notified by the Director, OQA, to take further actions and the corrective action process shall be reiterated in accordance with this procedure. The DR/CAR shall be reissued as the next sequential revision.



6.7 CANCELLATION

6.7.1 If it is determined through OQA investigation that no deficiency exists, the following steps shall be taken:

- a) The Director, OQA, shall record the justification for cancellation on the DR and return the DR to the originator for concurrence;
- b) The originator shall sign the DR to indicate concurrence with the cancellation. The DR shall be returned to the OQA, closed; or
- c) If the originator does not concur, the Director, OQA, shall elevate the matter to the appropriate management level, until resolution is reached.

6.7.2 If the decision to cancel the DR stands, the Director, OQA, shall record the justification and close the DR.

6.7.3 If it is determined that corrective action is required, the corrective action process shall proceed in accordance with this procedure.

7.0 RECORDS

7.1 Documentation generated as a result of this procedure is collected and maintained in accordance with requirements specified in QAAP 17.1, "Records Management". At a minimum, attachments I and II are considered QA Records.

8.0 ATTACHMENTS

- 8.1 Attachment I - OCRWM Deficiency Report.
- 8.2 Attachment II - OCRWM Corrective Action Report.
- 8.3 Attachment III - QAAP Flowchart



ATTACHMENT I (Typical)

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.			SHEET _____ OF _____ WBS NO. _____ DR. NO. _____ REVISION NO. _____
DEFICIENCY REPORT			
AUDIT/SURVEILLANCE (4)	RESPONSIBLE ORGANIZATION (5)	REFERENCE DOCUMENTS (6)	
REQUIREMENTS (7)			
DESCRIPTION OF CONDITION (8)			
RECOMMENDED ACTIONS TO CORRECT CONDITION (9)			
ORIGINATOR (10) _____ Signature Date		BRANCH/DIVISION/OFFICE (11)	
YES NO <input type="checkbox"/> <input type="checkbox"/> SIGNIFICANT (12) <input type="checkbox"/> <input type="checkbox"/> REPETITIVE (13)		CAR NO. (14)	
(15) RESPONSE DUE	(16) OOA _____ Signature Date	DIRECTOR, OOA _____ Signature Date	
REMEDIAL ACTIONS (18)			
EXTENT (19)			
PLANNED COMPLETION (20)	RESPONSIBLE MANAGER (21) _____ Signature Date	PROJECT MANAGER/ASSOCIATE DIR. (22) _____ Signature Date	
RESPONSE (23) <input type="checkbox"/> ACCEPT <input type="checkbox"/> REJECT	OOA SIGNATURE (24) _____ Signature Date	DIRECTOR, OOA (25) _____ Signature Date	
COMPLETION DATE (26)	RESPONSIBLE MANAGER (27) _____ Signature Date	PROJECT MANAGER/ASSOCIATE DIR. (28) _____ Signature Date	
OOA VERIFICATION (29) <input type="checkbox"/> SATISFACTORY <input type="checkbox"/> UNSATISFACTORY	OOA (30) _____ Signature Date	DIRECTOR, OOA (31) _____ Signature Date	

*DOCUMENT JUSTIFICATION FOR REJECTION ON CONTINUATION SHEET



OCRWM QA
ADMINISTRATIVE
PROCEDURE

Procedure No.:

QAAP 16.9

Revision:

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ATTACHMENT I cont'd

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

SHEET _____ OF _____
ABS NO _____

DEFICIENCY REPORT (continuation sheet)

DR. NO. _____ REVISION NO. _____ DATE _____



OCRWM QA
ADMINISTRATIVE
PROCEDURE

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ATTACHMENT II (Typical)

<input type="checkbox"/> SIGNIFICANT (1) <input type="checkbox"/> REPETITIVE (2)		OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		SHEET _____ OF _____ 3) WBS NO _____ 4) CAR NO _____ 5) REVISION NO _____	
CORRECTIVE ACTION REPORT					
DR. NO. (6)		RESPONSIBLE ORGANIZATION (7)		STOP WORK ORDER NO. (8)	
DESCRIPTION OF CONDITION (9)					
RECOMMENDED ACTION (10)					
(11) RESPONSE DUE	(12) OQA _____ Signature _____ Date _____	(13) DIRECTOR, OCRWM _____ Signature _____ Date _____			
REMEDIAL ACTION (14)					
ROOT CAUSE/EXTENT (15)					
MEASURES TO PREVENT RECURRENCE (16)					
PLANNED COMPLETION DATE (17)		RESPONSIBLE MANAGER (18) _____ Signature _____ Date _____		PROJECT MANAGER/ASSOCIATE DIR. (19) _____ Signature _____ Date _____	
RESPONSE (20) <input type="checkbox"/> ACCEPT <input type="checkbox"/> REJECT		DIRECTOR, OQA (21) _____ Signature _____ Date _____		DIRECTOR, OCRWM (22) _____ Signature _____ Date _____	
COMPLETION DATE (23)		RESPONSIBLE MANAGER (24) _____ Signature _____ Date _____		PROJECT MANAGER/ASSOCIATE DIR. (25) _____ Signature _____ Date _____	
OQA VERIFICATION (26) <input type="checkbox"/> SATISFACTORY <input type="checkbox"/> UNSATISFACTORY		DIRECTOR, OQA (27) _____ Signature _____ Date _____		DIRECTOR, OCRWM (28) _____ Signature _____ Date _____	

*DOCUMENT JUSTIFICATION FOR REJECTION ON CONTINUATION SHEET



OCRWM QA
ADMINISTRATIVE
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ATTACHMENT II cont'd

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

SHEET _____ OF _____
WBS NO _____

CORRECTIVE ACTION REPORT (continuation sheet)

CAR NO. _____

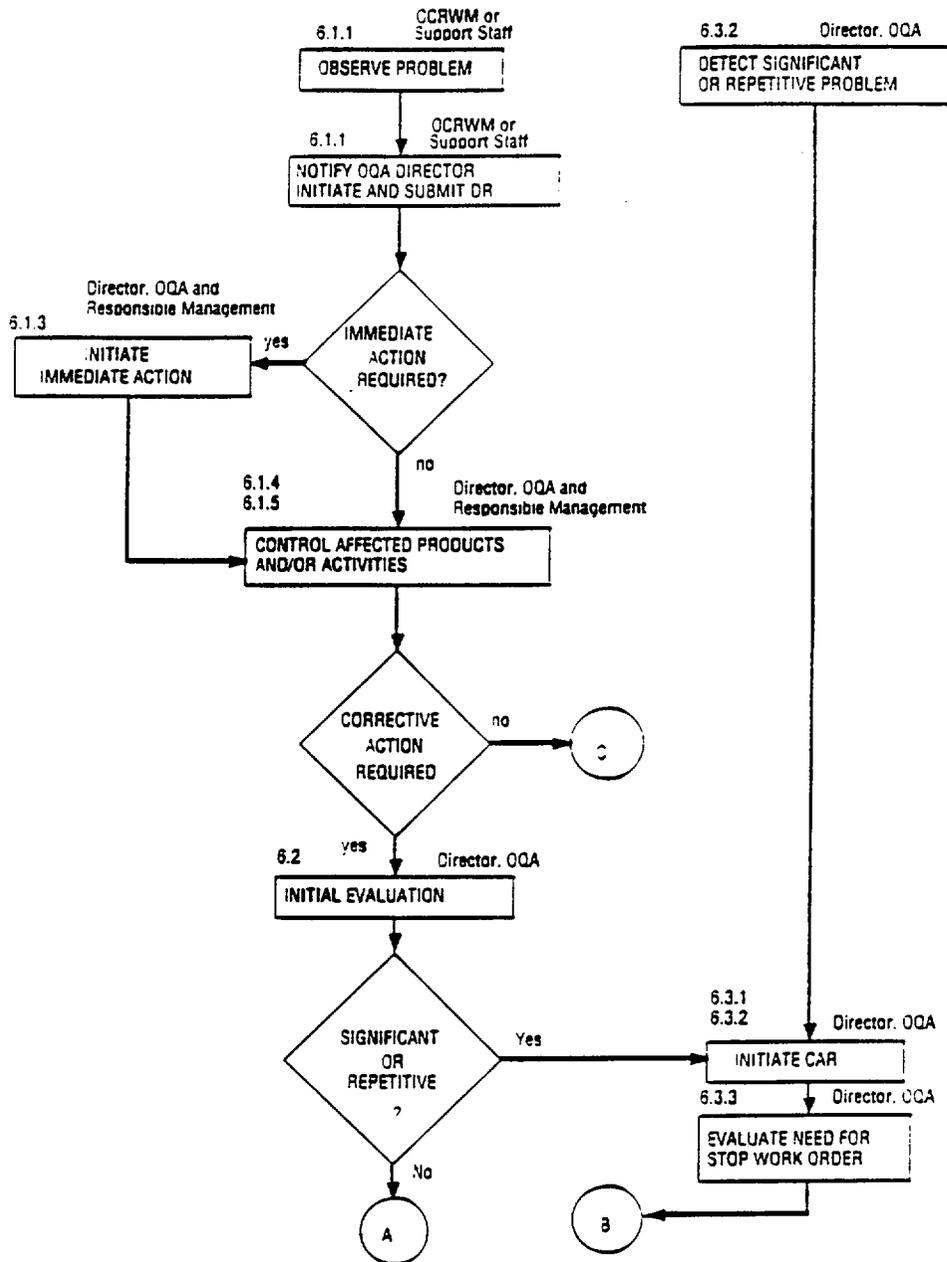
REVISION NO. _____

DATE _____



ATTACHMENT III

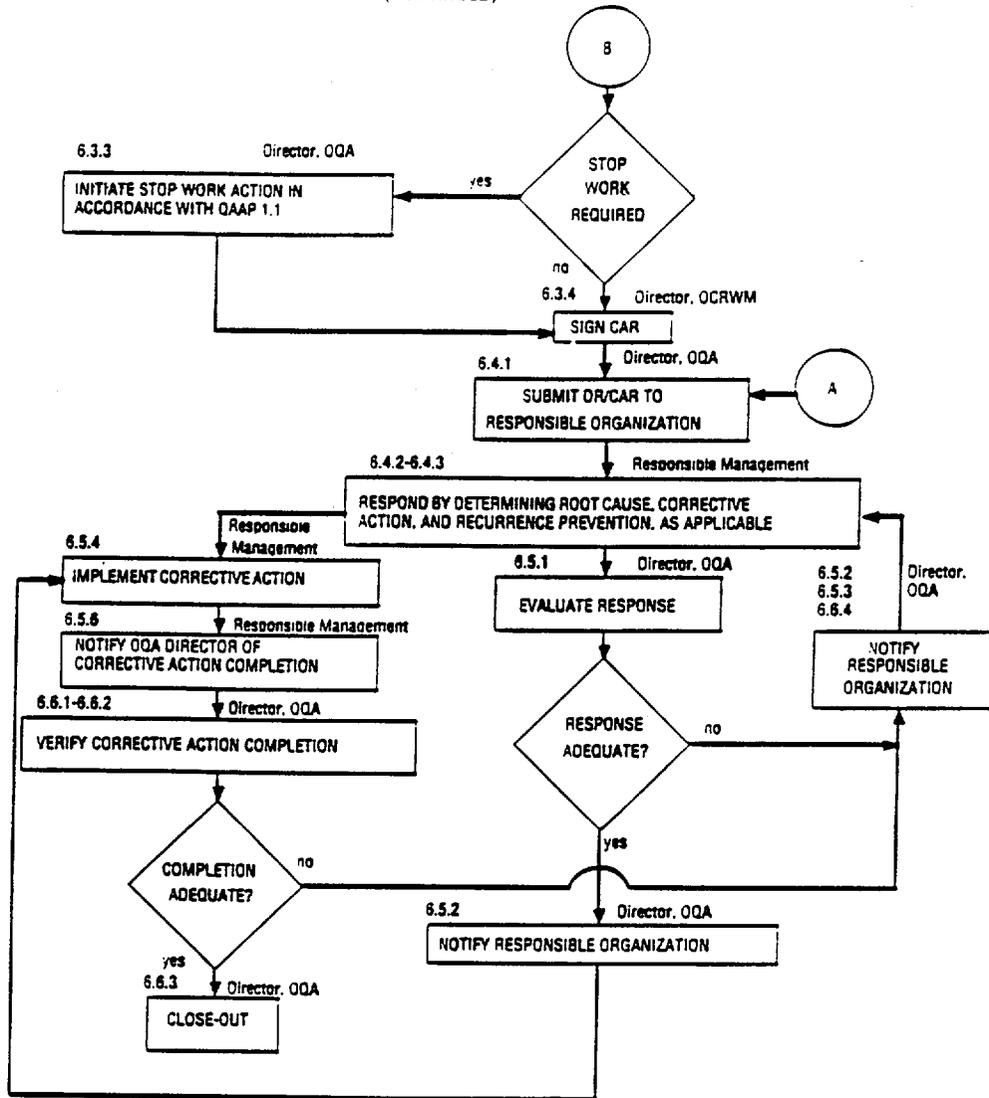
CORRECTIVE ACTION





ATTACHMENT III cont'd

CORRECTIVE ACTION (CONTINUED)





ATTACHMENT III cont'd

CORRECTIVE ACTION (CONTINUED)

