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DOCUMENT REVISION: N/A DOCUMENT IDENTIFICATION NUMBER: WMPO/88-1

DIRECTIONS

REPLACE - Table of Contents dated April 20, 1989 with  
Table of Contents dated May 31, 1989.

REMOVE - QMP-16-03, Standard Deficiency Reporting System,  
dated March 27, 1987, revision 0.

INSERT - QMP-16-03, Standard Deficiency Reporting System,  
dated 6/5/89, revision 1.

- [\*] Destroy or mark obsolete material "Superseded"
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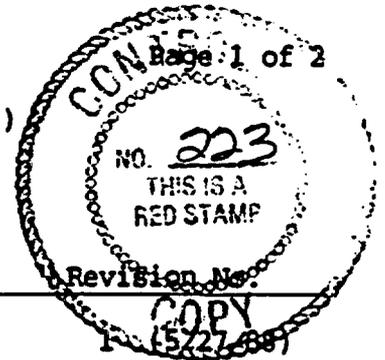
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200	R. S. WATERS	PROJECT OFFICE
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206	J. J. DRONKERS	LLNL
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218	R. E. GATES	MACTEC
219	RANDY SCHREINER	H&N
220	BARBARA HERSH	SAIC
221	R. D. KAISER	PROJECT OFFICE
222	W. C. PATRICK	CNWRA
223	W. L. BELKE	NRC/HQ
**224	S. B. AILES	SAIC
225	DON SCHLICK	PROJECT OFFICE

WMPO Quality Management Procedures (QMPs)

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QMP No.	ICN No.	QMP Title	Revision No.
QMP-01-01		WMPO Organization	1 (5/22/89)
QMP-01-02		Stop Work	0 (4/11/88)
QMP-02-01		Qualification, Proficiency, Indoctrination, and Training of Waste Management Project Personnel	1 (9/2/88)
QMP-02-02		Qualification of Quality Assurance Audit Personnel	1 (2/22/88)
QMP-02-03		Quality Assurance Management Assessment	In Preparation
QMP-02-08		Technical Assessment Review	0 (8/8/88)
QMP-02-08	1		(2/7/89)
QMP-02-09		Development and Conduct of Training	0 (3/31/89)
QMP-03-01		Peer Reviews	1 (1/11/89)
QMP-03-02		Scientific Investigation Control	In Preparation
QMP-03-03		Use of Software	In Preparation
QMP-03-04		Software Development, Maintenance, and Documentations	In Preparation
QMP-03-05		Verification and Validation of Software	In Preparation
QMP-03-06		Software Configuration Management	In Preparation
QMP-03-07		Software Approval	In Preparation
QMP-04-01		Procurement Document Control	0 (4/11/88)
QMP-04-02		Procurement Document Control (Project Office Initiated)	In Preparation

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QMP No.	ICN No.	QMP Title	Revision No.
QMP-05-01		Preparation and Control of Quality Management Procedures	1 (4/11/88)
QMP-05-02		Preparation and Control of Branch Technical Procedures	0 (5/27/88)
QMP-05-03		Preparation and Control of the NWSI Project QAP and the WMPO QAPP	0 (5/27/88)
QMP-06-02		Document Control	1 (12/1/88)
QMP-06-02	1		(4/2/89)
QMP-06-03		Document Review/Acceptance/Approval	1 (2/22/88)
QMP-06-03	1		(5/5/88)
QMP-06-03	2		(8/1/88)
QMP-07-03		Control of Purchased Items and Services	0 (4/11/88)
QMP-07-04		Supplier Surveys	To be Developed
QMP-15-01		Control of Nonconformances	1 (5/27/88)
QMP-16-01		Corrective Action	0 (12/10/88)
QMP-16-02		Trend Analysis	2 (5/27/88)
QMP-16-03		Standard Deficiency Reporting System	1 (6/5/89)
QMP-17-01		Record Source and Record User Responsibilities	0 (1/11/89)
QMP-18-01		Audit System for the Waste Management Project Office	3 (10/3/88)
QMP-18-02		Surveillances	1 (5/27/88)
QMP-18-02	1		(2/6/89)
QMP-18-02	2		(4/2/89)
QMP-18-02	3		(4/20/89)

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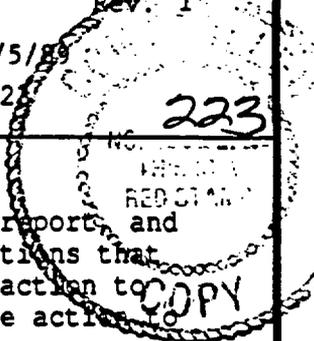
Title  
STANDARD DEFICIENCY REPORTING SYSTEM

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## 1.0 PURPOSE AND SCOPE

The purpose of this procedure is to provide a system to identify, report, and obtain resolution to programmatic deficiencies and procedure violations that require remedial and, if applicable, investigative and corrective action to prevent recurrence. It also provides a system to obtain corrective action to prevent recurrence of repetitive hardware deficiencies.

## 2.0 APPLICABILITY

This procedure applies to programmatic deficiencies, procedure violations, and repetitive hardware deficiencies for which recurrence control measures are deemed necessary. This procedure applies to deficiencies that are identified on Yucca Mountain Project (Project) Quality Assurance (QA) Level I and II items and activities. These deficiencies may be identified by Yucca Mountain Project Office (Project Office), Science Applications International Corporation/Technical & Management Support Services (SAIC/T&MSS), or U.S. Department of Energy/Nevada Operations Office (DOE/NV) matrix support personnel (hereafter referred to as Project Office staff personnel) during the performance of audits, surveillances, document reviews, or any other Project activities. Assigned responsibilities may be delegated, as appropriate.

## 3.0 DEFINITIONS

### 3.1 STANDARD DEFICIENCY REPORT (SDR)

An SDR is a preformatted form used by the Project Office QA organization to document repetitive hardware deficiencies and deficient, non-hardware related conditions adverse to quality; document remedial/investigative/corrective actions; document evaluation of these actions; and document verification of satisfactory completion of these actions.

### 3.2 NONCONFORMANCE

A nonconformance is a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

### 3.3 ITEM

An item is an all-inclusive term that is used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, and prototype hardware. This term includes magnetic media and other materials that retain or support data.

APPROVED BY

Project Manager, TEMSS  
*W. Macrae*  
Date April 28, 1989

Project Quality Manager  
*James Blyler*  
Date APRIL 28, 1989

Project Manager  
*Ed F. Galt*  
Date 5/20/89

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## 3.4 ACTIVITIES THAT AFFECT QUALITY (i.e., QA Level I and II activities):

Activities that affect quality are deeds, actions, work, or performance of a specific function or task. This applies to activities affecting the quality of any system, structure, or component important to safety, and to the design and characterization of barriers important to waste isolation. These activities include: site characterization, facility and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities as they relate to items important to safety and barriers important to waste isolation.

## 3.5 SEVERITY LEVEL 1

Severity Level 1 is assigned to significant deficiencies considered of major importance. These deficiencies require remedial, investigative, and corrective actions to prevent recurrence (see Section 5.2.1.1 for a description of conditions that characterize Severity Level 1 deficiencies).

## 3.6 SEVERITY LEVEL 2

Severity Level 2 is assigned to a deficiency that requires remedial and corrective action to prevent recurrence, and possibly investigative actions to determine the extent of the deficiency, but does not exhibit the severe attributes of a Level 1 deficiency (see Section 5.2.1.1 for a description of conditions that characterize Severity Level 2 deficiencies).

## 3.7 SEVERITY LEVEL 3

Severity Level 3 is characterized by a minor deficiency requiring only remedial action. These deficiencies are generally isolated in nature or have a very limited scope. In addition, the integrity of the end result of the activity is not affected, nor does the deficiency affect the ability to achieve those results (see Section 5.2.1.1 for a description of conditions that characterize Severity Level 3 deficiencies).

## 3.8 REMEDIAL ACTION

Remedial actions are taken to correct the specific deficiencies noted on the SDR.

## 3.9 INVESTIGATIVE ACTION

Investigative actions are taken to further examine the deficient condition to determine its extent and depth. This action should identify all conditions similar to the examples listed on the SDR.

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## 3.10 CORRECTIVE ACTION

Corrective actions are taken to identify the cause of the deficiency and to prevent recurrence of the deficiency identified on the SDR.

## 3.11 QUALITY VERIFICATION

The QA activities of reviewing, monitoring, inspecting, testing, checking, auditing, or otherwise verifying that items, designs, processes, or documents conform to established criteria and requirements. Independent quality verification is performed by individuals other than those who performed or supervised the activity, but who may be from the same organization.

## 3.12 OBSERVATION

The recognition or perception of a weakness in a technical area or in the Quality Assurance Program that, if left unaddressed, could result in a condition adverse to quality.

## 4.0 RESPONSIBILITIES

### 4.1 PROJECT OFFICE STAFF PERSONNEL

It shall be the responsibility of Project Office personnel to identify programmatic deficiencies, procedure violations, and significant repetitive hardware deficiencies. These shall be reported to the Project Office QA organization for evaluation and possible issuance of an SDR.

### 4.2 PROJECT OFFICE QA ORGANIZATION

The Project Office QA organization shall be responsible for following this procedure when initiating, processing, and closing an SDR.

### 4.3 PROJECT QUALITY MANAGER (PQM)

It shall be the responsibility of the PQM to concur with severity levels and to provide final approval of SDRs for issuance and closure.

### 4.4 QA VERIFICATION DEPARTMENT

The QA Verification Department shall be responsible for tracking all SDRs initiated by the Project Office QA Organization via a Standard Deficiency Report Log, assuring committed corrective actions have been properly implemented, and reporting the status of SDRs to the Project Office QA organization. The QA Verification Department shall be copied on all documentation generated in association with SDRs.

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## 5.0 PROCEDURE

### 5.1 IDENTIFICATION OF DEFICIENT CONDITIONS

5.1.1 Potential deficient conditions identified by Project Office personnel outside the Project Office Quality Assurance organization shall be documented on a YMP Deficiency Evaluation Report (DER), (refer to Figure 1 for form and preparation instructions) and evaluated by the Project Office QA organization to determine the following:

1. Validity of deficiency.
2. Type of deficiency.
3. Effect on quality.
4. Scope of deficiency.

5.1.1.1 Based on the evaluation of the above points, deficient conditions will be handled by one of the following methods:

5.1.1.1.1 If the deficiency is a nonconformance related to an item (hardware), the responsible Project participant shall be directed to generate a nonconformance report (NCR) in accordance with their internal procedures. If the responsible Project participant is reluctant to generate this NCR or does not do so in a timely manner, an SDR shall be generated in accordance with this procedure. This SDR shall direct the responsible Project participant to generate the subject NCR and identify the cause(s) for the failure to follow their nonconformance control system.

5.1.1.1.2 If the deficiency is not a hardware nonconformance but is a minor deficiency that can be corrected "on-the-spot" (i.e., missing signatures, missing dates, incorrect log entries, etc.), and correction is verified, issuance of an SDR is not required. A written statement attesting to the correction of the deficiency will be entered in the DER, and the DER will be returned to the respective Branch Chief or Department Manager.

5.1.1.1.3 An SDR will be generated in accordance with this procedure for programmatic and implementation deficiencies (procedure violations) which cannot be corrected "on-the-spot" as described above, and for significant and repetitive hardware nonconformances.

5.1.1.1.4 If the Project Office QA evaluation does not conclude that the identified deficiency warrants an SDR, an explanation will be provided on the DER, which will then be returned to the respective Branch Chief or Department Manager.

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5.1.1.2 In all cases the action taken shall be documented on the DER. The DER shall be returned to the originator, and a copy retained by the QA Administrative Assistant.

5.1.2 SDR conditions identified by Project Office QA personnel during the performance of audits, surveillances, document reviews, or any other Project activity shall be documented on SDRs and processed in accordance with this procedure.

5.1.3 Programmatic weaknesses that may warrant additional consideration but do not constitute a deficiency will be recorded by Project Office QA personnel as observations utilizing the Observation form (see Figure 4 for form and completion instructions).

5.1.3.1 Observations shall be transmitted via cover letter from the Project Office PQM to the applicable organization and require a response within 20 working days from the date of the transmitting correspondence.

## 5.2 SDR INITIATION

5.2.1 Project Office QA personnel shall document identified SDR conditions on an SDR format sheet (Figure 2) by completing Blocks 1, 3, 3A, 5, 6, 8, 9, and 10. Instructions for completion of these blocks are contained in Figure 3.

5.2.1.1 Assignment of the severity level (Block 2 on the SDR) shall be accomplished through the conduct of an SDR review meeting. The SDR review meeting shall be attended by the PQM and cognizant QA staff members, and shall result in the completion of an SDR Severity Level Checklist (Figure 5). This checklist shall serve as the documented basis for assigning SDR severity levels. The SDR Severity Level Checklist shall be signed and dated by the QAE/Lead Auditor, responsible QA Manager, and the PQM. There are three severity levels of deficiencies with Severity Level 1 being the most serious and significant and Severity Level 3 being the least serious and minor in nature.

A description of conditions that characterize severity levels are as follows:

Severity Level 1 - These deficiencies require remedial, investigative, and corrective actions to prevent recurrence and meet one or more of the following conditions:

1. Significant damage to natural barriers, structures, systems, or components which will require extensive evaluation, extensive redesign, or extensive repair in order to assure public health and safety.
2. Loss of essential data or information needed for licensing.

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3. Significant deficiencies in design, construction, testing, or performance assessment that were detected subsequent to formal quality verification and acceptance.
4. A significant deficiency in design as approved for construction such that the design deviates extensively from design criteria and bases.
5. A significant deviation from performance objectives or specification which will require extensive evaluation, extensive redesign or extensive repair to establish the adequacy of a natural barrier, structure, system, or component to meet design criteria and bases.
6. A significant error detected in a computer program after it has been released for use.
7. Significant deficiencies such as a breakdown in a participant QA program (i.e., failure of an organization to establish and implement appropriate QA and technical requirements, plans, and procedures) and/or repetitive programmatic and hardware deficiencies for which previous corrective action has not been reasonably prompt or effective.

Severity Level 2 - These deficiencies require remedial and corrective actions to prevent recurrence, and possibly investigative actions to determine the extent of the deficiency. A level 2 deficiency does not exhibit the severe attributes of a Level 1 deficiency. Severity Level 2 deficiencies must meet one or more of the following conditions:

1. Failure to correct deficiency may have an adverse impact on the health or safety of operations personnel.
2. Operating outside the scope of the quality program or approved quality procedures where both remedial and corrective actions are required.
3. Repetitive hardware deficiencies for which no previous corrective action measures exist.

Severity Level 3 - These deficiencies are minor requiring only remedial action that cannot be corrected during the course of an audit or surveillance activity, and meet one or both of the following conditions:

1. The integrity of the end results of the activity is not affected nor does the deficiency affect the ability to achieve those results.
2. The deficient condition is an isolated occurrence or very limited in scope.

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5.2.2 Once Blocks 1, 2, 3, 3A, 5, 6, 8, 9, and 10 are completed the draft SDR will be assigned a sequential SDR number obtained from the Project Office QA Administrative Assistant. Once the draft SDR is finalized, the responsible Quality Assurance Engineer (QAE) or Lead Auditor signs and dates the SDR in block 11 and obtains the approval of the appropriate Project QA Division Manager. If approved, the SDR is then sent to the PQM for approval and subsequent issuance.

5.2.3 If the responsible QA Division Manager or the PQM does not approve the SDR, documented justification shall be provided and the SDR shall be returned to the responsible QAE/Lead Auditor for processing into the QA records system.

5.2.4 For Severity Level 1 deficiencies that may require a stop work order, the responsible QAE/Lead Auditor shall initiate appropriate action to suspend the affected activity in accordance with QMP-01-02, Stop Work Order.

5.2.5 If any SDR continuation sheets (Figure 3) attachments, or any other documentation to support the SDR are necessary, the responsible QAE/Lead Auditor shall ensure that they are traceable to the SDR by SDR number.

## 5.3 SDR ISSUANCE

5.3.1 When approved by the Project Office PQM, the SDR shall be forwarded by letter to the responsible Project participant Technical Project Officer (TPO) or organization management for response. SDRs that have been generated as a result of audits or surveillance activities may be issued independent of the related audit or surveillance report. If issued independently, an information copy of the SDR shall be attached to the appropriate audit or surveillance report. The SDR response due date shall be 20 working days from the date of the transmittal letter. A copy of each SDR that identifies a Severity Level 1 deficiency shall be forwarded to the Office of Civilian Radioactive Waste Management for information.

Additionally, a copy of all SDRs with the cover letter shall be forwarded to the QA Verification Department for entry into the SDR tracking system.

5.3.2 The QA Verification Department shall track and maintain the status of all SDRs and coordinate the processing of the SDR(s) between the initiating QAE/Lead Auditor and the responding organization.

5.3.2.1 An SDR log shall be maintained by the QA Verification Department. At a minimum this log shall contain the following:

1. SDR number.
2. Severity level.

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3. Issue date and the affected organization.
4. Initiating QAE/Lead Auditor.
5. Status (i.e. response due date, effective date for completion of remedial and investigative/corrective action).

## 5.4 SDR RESPONSE

5.4.1 SDR responses are reviewed and approved/rejected by the responsible QAE/Lead Auditor within 20 working days of response receipt. The following items are reviewed, as appropriate:

5.4.1.1 To ensure that the REMEDIAL ACTION specifies appropriate actions to correct the specific condition(s) identified.

5.4.1.2 To ensure that the INVESTIGATIVE ACTION has determined the extent and depth of the deficient condition identified and that all conditions similar to the examples listed on the SDR are identified and corrected.

5.4.1.3 To ensure that the CORRECTIVE ACTION has identified the cause of the condition and that actions necessary to properly and completely implement the required corrective action are specified, and that these actions shall prevent recurrence of the problem.

5.4.2 When the QAE/Lead Auditor has determined that the response to the SDR is acceptable, Block 19 of the SDR is signed and dated by the QAE/Lead Auditor. Responses to SDRs shall also be approved by the respective QA Division Manager and the PQM. Upon approval of the response, a notification letter will be sent to the responsible Project participant or organization to advise them of the status. This letter of notification is initiated by the QAE/Lead Auditor and issued along with an information copy of the SDR by the PQM. The correspondence number of the notification letter shall be recorded in the remarks section of the SDR (Block 21).

NOTE: Block 19 of the SDR is signed only when the response has been determined to be acceptable. If the actions indicated in Paragraphs 5.4.3, 5.4.4 or 5.4.5 are required, Block 19 remains unsigned until such time as an acceptable response has been achieved.

5.4.3 An amended response shall be requested if it is deemed necessary to clarify remedial and/or corrective action. The request for an amended response shall be initiated by the responsible QAE/Lead Auditor and issued by the PQM.

5.4.3.1 The request for an amended response shall include the rationale for the request, recommendations of specific actions necessary to achieve

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satisfactory resolution and a response due date of not more than ten (10) working days from the date of issue.

5.4.3.2 The correspondence number of the request for an amended response shall be recorded by the responsible QAE/Lead Auditor in the Remarks section of the SDR (Block 21).

5.4.3.3 Upon receipt of an acceptable amended response, the QAE/Lead Auditor shall initiate those actions prescribed in paragraph 5.4.2 of this procedure.

5.4.4 If the SDR response is unacceptable and an amended response is not appropriate, the QAE/Lead Auditor shall initiate a letter to the responding organization advising them of the unsatisfactory response. This letter requires the same level of review and approval as the original SDR and is issued along with an information copy of the SDR by the Project Office PQM.

5.4.4.1 The correspondence required by Paragraph 5.4.4 shall include, as a minimum, the reason(s) the original response was found to be unacceptable recommendations of specific actions necessary to achieve a satisfactory response and a response due date of not more than ten working days from the date of issue.

5.4.4.2 The correspondence number of the request for a new response shall be recorded by the responsible QAE/Lead Auditor in the Remarks section of the SDR (Block 21).

5.4.4.3 Upon receipt of an acceptable response, the QAE/Lead Auditor shall initiate those actions prescribed in Paragraph 5.4.2 of this procedure.

5.4.5 If, by the response due date (whether it be original response, amended response, or revision to original response), the required response or a written request for extension has not been received, the QAE/Lead Auditor shall prepare a separate SDR in accordance with Paragraph 5.2 of this procedure and the following specific instructions.

5.4.5.1 Block 9 shall cite, "Failure to respond to SDR \_\_\_ \_\_\_ \_\_\_ by the established due date of \_\_\_/\_\_\_/\_\_\_," as the deficiency.

5.4.5.2 Block 8 shall cite the NNWSI Project QA Plan, 88-9, Section XVI, Paragraph 1.0, which states in part, "that conditions adverse or potentially adverse to quality are identified promptly and corrected as soon as practical," as the violated requirement.

5.4.5.3 The new SDR, a copy of the original SDR and a cover letter are then forwarded to the Project Office PQM for issuance. The response due date for both SDRs shall be not more than seven (7) working days from date of issue.

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5.4.5.4 The recipients next higher level of management shall receive a copy of all documents cited in Paragraph 5.4.5.3 above, to assure appropriate responses are expediently dispatched.

5.4.5.5 The correspondence number and new SDR number shall be recorded by the responsible QAE/Lead Auditor in the Remarks Section (Block 21) of the original SDR.

5.4.5.6 Upon receipt of acceptable responses to both SDRs the QAE/Lead Auditor shall initiate those actions prescribed in Paragraph 5.4.2 of this procedure.

5.4.5.7 Should violations of established due dates continue to persist, the matter shall be formally elevated by the Project Office PQM to the management level necessary to achieve prompt resolution.

## 5.5 SDR VERIFICATION

5.5.1 Committed corrective actions should be verified within 45 days of the effective date.

5.5.1.1 When the QAE/Lead Auditor determines that the committed corrective actions have been properly instituted and completed, the QAE/Lead Auditor shall sign and date Block 20 of the SDR and annotate any supporting documentation in the Remarks Section (Block 21) of the SDR. Completion of corrective action is authenticated by the signature of the respective QA Division Manager and the PQM.

Note: Block 20 of the SDR is signed only when the verification of committed corrective action is satisfactory and complete. If the actions indicated in Paragraphs 5.5.2, 5.5.3 or 5.5.4 are required, Block 20 remains unsigned until such time as satisfactory verification is achieved.

5.5.2 Requests for extensions of the effective date for completion of committed corrective actions shall be made in writing by the responsible organization and must be submitted prior to the due date. These extension requests must contain sufficient justification for the extension.

5.5.2.1 Upon receipt of extension requests, the responsible QAE/Lead Auditor shall evaluate the rationale for the request, accept or reject the request, initiate a formal reply to the requestor, and forward the request to the responsible QA Division Manager and the PQM for signature and issuance.

5.5.2.2 The QAE/Lead Auditor shall reference by correspondence number both the request for extension and the reply in Block 21 of the SDR.

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5.5.3 If details of the committed corrective action are determined to be incomplete at the time of verification, the QAE/Lead Auditor shall note those conditions that were corrected on the spot in the Remarks section (Block 21) of the SDR. Request (verbally) immediate corrections that would complete the required corrective actions on the spot.

5.5.4 If it is determined by the QAE/Lead Auditor that the committed corrective actions have not been implemented or achieved, a letter shall be initiated by the QAE/Lead Auditor indicating that verification of the committed corrective action was unsatisfactory and is rejected.

5.5.4.1 The letter shall contain specific details of the corrective actions found to be unsatisfactory, recommendations for correcting these conditions, and a due date of not more than ten working days from the date of issue by which the violating party must respond and establish a new completion date.

5.5.4.2 The letter, with a copy of the SDR and any other applicable documentation, shall be forwarded to the PQM for issuance.

5.5.4.3 The correspondence number of the rejection letter shall be recorded by the responsible QAE/Lead Auditor in the Remarks section (Block 21) of the SDR.

5.5.4.4 If the violating party has not responded by the established due date, the QAE/Lead Auditor shall elevate the matter to the appropriate management for action.

## 5.6 SDR CLOSURE

Upon satisfactory verification, the SDR is signed by the initiating QAE/Lead Auditor and is forwarded to the appropriate QA Division Manager and the PQM for closure signatures. A copy of the closed SDR shall be forwarded to the QA Verification Department and a notation of closure made on the SDR log.

The closed SDR along with other supporting documentation shall be processed in accordance with QMP-17-01, Record Source and Record User Responsibilities. Notification will be sent to the responsible Project participant/organization informing them of the closure of the SDR.

## 5.7 EXCEPTIONS

For deficiencies identified as Severity Level 3, the following exceptions apply to the initiation of, response to, and acceptance/closeout of the SDR:

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5.7.1 By the definition of a minor deficiency, only remedial action is required, thus Blocks 16 and 17 are "N/A".

5.7.2 Unsatisfactory responses and/or verifications shall be evaluated by the PQM to determine whether the SDR should remain a Level 3 or be escalated to a Level 2.

## 5.8 DISPOSITION OF PRIOR OPEN QA ITEMS

5.8.1 Previous NCRs that are open as of the effective date of this procedure will be evaluated, verified, and closed in accordance with QMP-15-01, Non-conformance Control. If the NCR needs to be revised due to rejection of a response or an unsatisfactory verification, the QA Verification Department Manager shall cause it to be "rolled-over" to an SDR in accordance with this procedure, unless the deficiency relates to an item (hardware).

5.8.2 Previous Audit Finding Sheets (AFS) or Corrective Action Requests (CAR) that remain open as of the effective date of this procedure shall continue to be processed and closed in accordance with either QMP-18-01, Audits, or QMP-16-01, Corrective Action, as appropriate. If the Audit Finding Sheets or Corrective Action Requests are revised and reissued due to rejection of the response or unsatisfactory verification, the responsible QAE will "roll it over" to an SDR in accordance with this procedure.

## 5.9 TREND ANALYSIS

SDRs shall be trended by Project Office QA in accordance with QMP-16-02, Trend Analysis.

## 6.0 REFERENCES

QMP 01-02, "Stop Work."

QMP-15-01, "Nonconformance Control."

QMP-16-01, "Corrective Action."

QMP-16-02, "Trend Analysis."

QMP-17-01, "Record Source and Record User Responsibilities."

QMP-18-01, "Audit System for the Waste Management Project Office."

QMP-18-02, "Surveillances."

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## 7.0 FIGURES

- Figure 1. Deficiency Evaluation Report (DER) Format Sheet and Completion Instructions.
- Figure 2. Yucca Mountain Project Office Standard Deficiency Report Format Sheet and Completion Instructions.
- Figure 3. SDR Continuation Sheets
- Figure 4. Yucca Mountain Project Office Observation Form and Completion Instructions
- Figure 5. SDR Severity Level Checklist.

## 8.0 QA RECORDS

QA records resulting from this procedure shall be maintained in accordance with QMP-17-01, Record Source and Record User Responsibilities. Applicable QA records are as follows:

Standard Deficiency Report and supporting documentation.

SDR Continuation Sheets.

DER.

SDR Severity Level Checklist.

Observation Forms.



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## FIGURE 1 (Continued)

Instructions for completion of Deficiency Evaluation Report (DER) Form

- Block 1
- Enter the PQM as the recipient of the DER
  - Enter the dated signature of the individual whom identified the deficiency
  - Enter the dated signature of the appropriate Branch chief or Department Manager after concurrence.
- Block 2
- Quote or paraphrase the requirement violated noting the document violated with revision and paragraph number. As a general rule, use the lowest tiered document violated e.g., quote from the implementing procedure rather than the QA Program Plan.
- Block 3
- As briefly as possible, state the condition adverse to quality. Include a discussion that supports this statement and include examples of the adverse condition.
- Block 4
- Enter the dated signature of the QAE who evaluated the DER for possible issuance of an SDR
  - Enter the surveillance number performed by the QA organization if applicable.
- Block 5
- If the DER is approved, enter the dated signature of the responsible QA Division Manager and the SDR number to be issued.
  - Enter the number of the SDR issued as a result of DER approval.
- Block 6
- If the DER is disapproved, enter the dated signature of the responsible QA Division Manager and the reason for disapproval.

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FIGURE 2

YMPO STANDARD DEFICIENCY REPORT				N-QA-038 4/89
Completed by Originating QA Organization	1 Date		2 Severity Level <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3      Page      of	
	3 Discovered During		3a Identified By	
			4 SDR No. _____ Rev. _____	
	5 Organization		6 Person(s) Contacted	
Completed by Organization in Block 5	7 Response Due Date is 20 Working Days from Date of Transmittal			
	8 Requirement (Audit Checklist Reference, if Applicable)			
	9 Deficiency			
	10 Recommended Action(s): <input type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input type="checkbox"/> Corrective			
	Apr. 11 QAE/Lead Auditor/Date      12 Division Manager/Date      13 Project Quality Mgr./Date			
Completed by Org. QA Org.	14 Remedial/Investigative Action(s)      15 Effective Date _____			
	16 Cause of the Condition & Corrective Action to Prevent Recurrence      17 Effective Date _____			
	18 Signature/Date			
19 Response Accepted		QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
21 Remarks				
22 QA CLOSURE		QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date

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## FIGURE 2 (Continued)

### Instructions for Completion of SDR Form

- |                             |   |
|-----------------------------|---|
| Block 1 Date                | - Enter the date that the deficiency is discovered.   |
| Block 2 Severity Level      | - Check the appropriate box based on paragraph 5.2.1.1 of this procedure.   |
| Block 3 Discovered During   | - Identify whether the deficiency was discovered during an Audit or Surveillance and enter the Audit or Surveillance Report Number; or if appropriate, enter "N/A."   |
| Block 3A Identified By      | - Name of individual who identified the deficient condition.  |
| Block 4 SDR Number          | - Obtain the next sequential number from the QA Administrative Assistant in accordance with paragraph 5.2.2.  |
| Block 5 Organization        | - Enter the name of the organization expected to respond to the SDR e.g., Los Alamos, USGS, etc.  |
| Block 6 Person(s) Contacted | - Enter the name(s) of person(s) within the organization identified in Block 5 who was contacted for discussion of the SDR prior to issuance.   |
| Block 7 Response Due Date   | - Specify due date in accordance with paragraph 5.3.1 of this procedure.  |
| Block 8 Requirement         | - Quote or paraphrase the requirement violated noting the document violated with revision and paragraph number. As a general rule, use the lowest tiered document violated e.g., quote from the implementing procedure rather than the QA Program Plan. If the deficiency was discovered during the performance of an audit, reference the audit checklist item number. |

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## FIGURE 2 (Continued)

- |   |  |
|---|--|
| Block 9 Deficiency                      | - As briefly as possible, state the condition adverse to quality. Include a discussion that supports this statement and include examples of the adverse condition.   |
| Block 10 Recommended Action(s)          | - Check the appropriate box(es) based on the severity level and scope of the deficiency.   |
| Block 11 QAE/Lead Auditor               | - Enter the dated signature of the responsible QAE or Lead Auditor.  |
| Block 12                                | - Enter the dated signature of the appropriate QA Division Manager.  |
| Block 13 Project Quality Manager        | - Enter the dated signature of the PQM.  |
| Block 14 Remedial/Investigative Actions | - Enter the actions which were taken, or will be taken to: (a) Correct the examples noted in Block 9 and, (b) as necessary, investigate, identify, and correct similar conditions.   |
| Block 15 Effective Date                 | - Enter the date that all actions in Block 14 were completed or are expected to be completed.  |
| Block 16 Cause of the Condition         | - Enter the cause of the adverse condition noted in Block 9 and describe the corrective action that will be taken to prevent recurrence. If procedure must be revised, describe the interim plan to be used until the revised procedure is approved and implemented. |
| Block 17 Effective Date                 | - Enter the date that all actions in Block 16 were completed or are expected to be completed.  |

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## FIGURE 2 (Continued)

- Block 18 Signature - Enter the dated signature of the individual(s) responsible for assuring completion of Blocks 14 and 16. This name should also be printed or typed in this Block.
- Block 19 Response Accepted - The response is evaluated by the responsible QAE and acceptance/rejection decision concurred on by the PQM and responsible Division Manager, and dated signatures are entered.
- Block 20 Corrective Action Verification Satisfactory - Indicate satisfactory corrective action verification by entering the required dated signatures.
- Block 21 Remarks - Enter a description of verification actions taken. If the response is not accepted or corrective action verification is not satisfactory, enter the reason for rejection or unsatisfactory verification of the SDR. This block may also be used to record any other pertinent remarks related to the SDR.
- Block 22 Closure - Enter the dated signatures required.

If additional space is required for any of the above blocks, use the SDR continuation sheet. Additional information shall be traceable to the SDR Form by SDR Number.

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FIGURE 3

YMPO STANDARD DEFICIENCY REPORT  
CONTINUATION SHEET

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SDR No.	Page	of
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FIGURE 4

YUCCA MOUNTAIN PROJECT OFFICE		N-QA-012	
1 YMPO OBSERVATION NO. _____		4/89	
Completed by Originating Organization	2 Noted During:	3 Identified By:	4 Date:
	5 Organization:	6 Person(s) Contacted:	7 Response Due Date is 20 Days from Date of Transmittal
	8 Discussion:		
	9 QAE/Lead Auditor	Date	10 Branch Manager
Completed by Responder	11 Response:		
	12 Signature: _____ Date: _____		
Completed by QA Org.	13 Response Receipt Acceptable <input type="checkbox"/>		
	Initiator	Date	QA/Lead Auditor      Date
14 Remarks:			

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## FIGURE 4 (Continued)

### INSTRUCTIONS FOR COMPLETION OF OBSERVATION FORM (SEE FIGURE 4 FOR CORRESPONDING BLOCK NUMBERS)

1. Obtain observation number from Q.A. Administrative assistant.
2. Enter activity (audit/surveillance, etc.) during which the observation was noted.
3. Enter the name of the individual making the observation.
4. Enter the date the observation was noted.
5. Enter the name of the organization required to respond to the observation.
6. Enter the name(s) of the individual(s) of the responding organization contacted for discussion of observation prior to issuance.
7. Self Explanatory
8. Enter details and particulars of observation.
9. Enter signature and date of responsible QAE/Lead Auditor.
10. Enter signature and date of responsible branch manager.
11. Responding organization enters response to observation.
12. The responsible individual of the responding organization enters signature and date.
13. Indicate acceptable response by entering required dated signatures.
14. If the response is not acceptable, describe reason for rejection. This block may also be used to record any pertinent remarks related to the observation.

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FIGURE 5

## SDR SEVERITY LEVEL CHECKLIST

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**I. ASSIGN A SEVERITY LEVEL OF 1 IF ONE OR MORE OF THE FOLLOWING IS TRUE.**

	Yes	No
1. Did the deficiency result in significant damage to natural barriers, structures, systems, or components that will require extensive evaluation, extensive redesign, or extensive repair in order to assure public health and safety?	—	—
2. Does the deficiency involve loss of essential data or information needed for licensing?	—	—
3. Does the deficiency constitute a significant deficiency in design, construction, testing, or performance assessment that were detected subsequent to formal quality verification and acceptance?	—	—
4. Does the deficiency constitute a significant deficiency in design as approved for construction such that the design deviates extensively from design criteria and bases?	—	—
5. Does the deficiency constitute a significant deviation from performance objectives or specifications that will require extensive evaluation, extensive redesign, or extensive repair to establish the adequacy of a natural barrier, structure, system, or component to meet design criteria and bases?	—	—
6. Does the deficiency constitute a significant error detected in a computer program after it has been released for use?	—	—
7. Does the deficiency constitute a significant breakdown in a participant's QA program and/or repetitive, programmatic and hardware deficiencies for which previous corrective action has not been reasonably prompt or effective?	—	—

**II. ASSIGN A SEVERITY LEVEL OF 2 IF THE ANSWERS TO ALL QUESTIONS IN PART I ARE NO AND ONE OR MORE OF THE FOLLOWING IS TRUE:**

	Yes	No
1. Could failure to correct deficiency have a potentially adverse impact on the health or safety of operations personnel?	—	—
2. Does the deficiency constitute operating outside the scope of the quality program or approved quality procedures where both remedial and corrective actions are required?	—	—
3. Does the deficiency constitute a repetitive hardware deficiency for which no previous corrective action measures exist?	—	—

**III. ASSIGN A SEVERITY LEVEL OF 3 IF THE ANSWERS TO ALL QUESTIONS TO PARTS I AND II ARE NO.**

QAE/Lead Auditor

QA Division Manager

PQM

\_\_\_\_\_  
Signature/Date

\_\_\_\_\_  
Signature/Date

\_\_\_\_\_  
Signature/Date