

U. S. Department of Energy
Carlsbad Field Office

MANAGEMENT PROCEDURE

CBFO MP 3.2, Rev. 1

Effective: June 25, 2007

Expires: June 25, 2009

SUBJECT: DEFICIENCY TRENDING AND REPORTING

Manager, Carlsbad Field Office: Signature on File

Date:

1.0 PURPOSE

The purpose of this procedure is to describe the responsibilities and processes used to identify, track, analyze, and report deficiency trends resulting from Carlsbad Field Office (CBFO) internal and external audits and surveillances.

2.0 SCOPE

This procedure encompasses analyses of deficiencies generated during audits and surveillances of CBFO, Sandia National Laboratories – Carlsbad Program Group (SNL – CPG), Los Alamos National Laboratory – Carlsbad Operations (LANL – CO), Washington TRU Solutions (WTS), and other organizations participating in the Transuranic (TRU) Waste Program that are subject to CBFO and regulator audits and surveillances. The trend report resulting from analyses of deficiencies is issued semiannually to CBFO management, applicable regulators, and affected organizations to provide identification of items, services, and processes needing improvement, and trends adverse to quality. This procedure supersedes Management Procedure (MP) 3.2, Revision 0, *Deficiency Trending and Reporting*.

3.0 REFERENCES AND DEFINITIONS

3.1 References

- DOE O 414.1C, *Quality Assurance*
- DOE/CBFO-94-1012, *Quality Assurance Program Document (QAPD)*
- CBFO Management Procedure (MP) 3.1, *Corrective Action Reporting*
- NM4890139088-TSDF, WIPP Hazardous Waste Facility Permit

3.2 Definitions

- **Adverse Trend** – A trend of deficiencies with the potential to result in a condition adverse to quality if not corrected.
- **Corrective Action Report (CAR)** – A document utilized to identify and document conditions adverse to quality (CAQ) and track the associated corrective actions.
- **Corrected During the Audit/Surveillance (CDA/CDS)** – Isolated, non-significant deficiencies that do not require a root cause determination, procedure revision or actions to preclude recurrence, and correction of the deficiency can be verified prior to the end of an audit or surveillance.
- **Deficiency** – CARs, CDAs, and CDSs reported during a CBFO audit or surveillance.

AVAILABLE ONLINE AT:

<http://bellview/cbfo/Procedures/ProcedureManualTOC.htm>

INITIATED BY:

CBFO Quality Assurance Manager

- **Trend** – A trend is identified where numbers of deficiencies reported in specific categories are evaluated and determined to be sufficient in number to indicate an adverse trend.

4.0 RESPONSIBILITIES

4.1 CBFO Quality Assurance Manager (QAM)

Prepare and maintain this procedure. Has overall responsibility for trending deficiencies and reporting quality problem areas.

4.2 CBFO CAR Coordinator

Review, track, and analyze deficiencies to determine and report program trending results to the CBFO QAM and responsible organizations.

4.3 CBFO QA Specialist

Provide documented and trend coded deficiencies to the CAR Coordinator for evaluating responses from responsible organizations that detail corrective actions for identified trends, and for notifying the QAM and CAR Coordinator when corrective actions are completed.

4.4 Responsible Organization

Investigate and respond to the CBFO QA Specialist for trends and potential adverse trends identified and reported to the organization.

5.0 PROCEDURE

5.1 Trend Codes

5.1.1 Trend codes for deficiencies will be determined and assigned to CARs by the initiator of the corrective action report.

5.1.2 Trend codes may be amended by the initiator after the acceptance of the corrective action plan if actions to be performed under the plan indicate another appropriate activity or deficiency category.

5.1.3 Trend codes for deficiencies will be determined and assigned to CDAs and CDSs during the audit/surveillance.

NOTE: Trend codes are denoted by entering the Activity Category code number, followed by the Deficiency Category code number (numbers are listed in Attachment 1). For example, an organization was identified as having four cases of use of incorrect measuring and test equipment (M&TE) due to incorrect M&TE being listed in the associated procedure. The first entry is “MT,” and the second entry is “01,” resulting in an adverse trend code of “MT-01.”

5.1.4 The QA Specialist will verify trend codes assigned to deficiencies.

5.1.5 The CAR initiator or CDA/CDS initiator will be informed by the QA Specialist of any trend codes amended by the QA Specialist.

5.2 Deficiency Summary and Trending Data Collection

- 5.2.1 The CAR Coordinator will perform a semiannual analysis of deficiencies identified during the previous six-month period.
- 5.2.2 The CAR Coordinator will perform a semi-annual analysis of the status of CARS that were initiated prior to the six-month reporting period and that are still open, or that were closed during the reporting period.
- 5.2.3 Nonconformance reports (NCRs) received by CBFO from generator sites will be summarized on a monthly basis and transmitted to the New Mexico Environment Department (NMED). NCRs received from TRU waste generator sites are not considered in the trending report.

5.3 Trending Report

- 5.3.1 The CAR Coordinator will prepare a semiannual draft Deficiency Summary that identifies the number of deficiencies by Activity Category code number and Deficiency Category code number. See Attachment 1 for a list of trend codes.
- 5.3.2 The CAR Coordinator will prepare a draft Trending Report, on a semiannual basis, that identifies trends in the number of deficiencies by activity and deficiency trend codes and includes a comparison to previous reporting periods.
- 5.3.3 The CAR Coordinator will prepare draft notification letters that address adverse trending information relative to individual responsible organizations and will transmit the notification letters, draft Deficiency Summaries, and draft Trending Reports to the QA Specialist at the individual responsible organization for review and concurrence.
- 5.3.4 The QA Specialist will submit the draft Deficiency Summaries, Trending Reports, and trend notification letters to the QAM for review and approval.
- 5.3.5 The QAM will review the drafts and once approved, will authorize the QA Specialist to distribute the documents to the following as a minimum:
 - CBFO Manager
 - CBFO Deputy Manager
 - Responsible CBFO Office Director(s)
 - Responsible Organization(s)

5.4 Trend Report Response and Closure

- 5.4.1 The responsible organizations/office directors that receive notification of an adverse trend within their program shall conduct an investigation to appropriately determine the impact of the identified adverse trend and shall provide a response to the QA Specialist detailing the action taken to correct the trend.
- 5.4.2 The QA Specialist shall evaluate the response(s) by the responsible organization(s) for acceptability, return rejected corrective action responses to the responsible organization(s), and evaluate revised responses for acceptability.
- 5.4.3 The QA Specialist shall provide status of corrective action response to the QAM and the CAR Coordinator.

5.4.4 The QA Specialist shall track completion of responsible organizations corrective actions, determine when actions taken by responsible organizations satisfactorily correct the adverse trend, and inform the QAM, responsible organizations, and the CAR Coordinator when the corrective actions are complete.

5.4.5 The CAR Coordinator shall assemble and submit trending records in accordance with MP 4.9, *Quality Assurance Records*.

6.0 RECORDS

The following documents are generated as a result of this procedure. They are nonpermanent QA records and shall be maintained in accordance with MP 4.9.

- Deficiency Summary
- Notification Letters
- Site Responses
- Response Acceptance/Rejection Correspondence
- Trending Report

7.0 ATTACHMENTS

Attachment I: Trend Codes

Attachment II: Process Flow Chart

Attachment III: Trend Code Guidance Examples

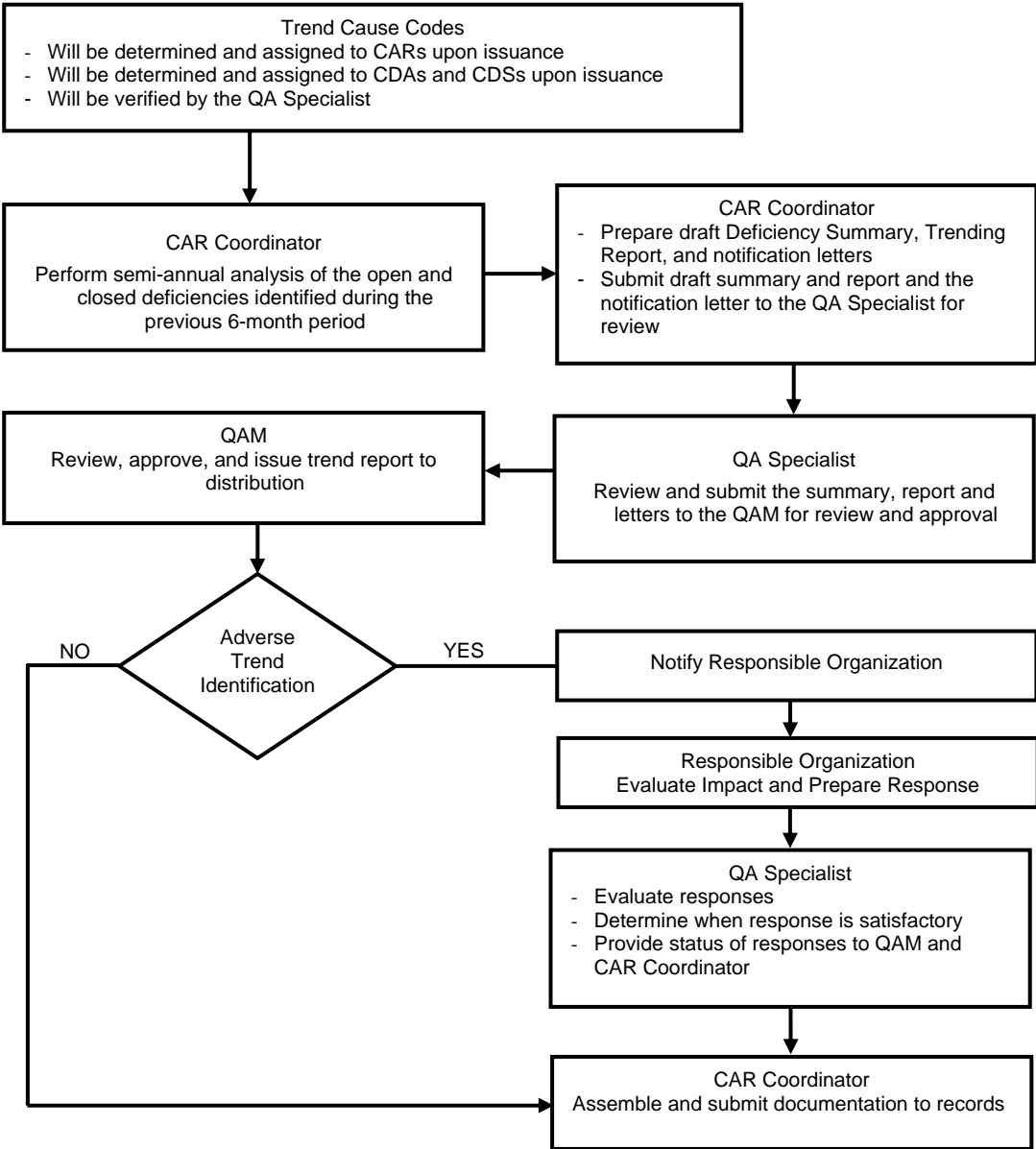
ATTACHMENT I

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TREND CODES	
ACTIVITY CATEGORY	Code Number
Acceptable Knowledge (AK)	AK
Audits and Assessments	AA
Control of Measuring and Test Equipment (M&TE)	MT
Corrective Action Program (CARs and NCRs)	CA
Characterization Data	CD
Data Validation	DV
Design Control and Engineering	DE
Document Control	DC
Gas Generation Testing (GGT)	GG
Headspace Gas Sampling and Analysis (HGAS)	HG
Management	MA
Non-Destructive Assay (NDA)	ND
Organization and Resources	OR
Performance Demonstration Program (PDP)	PD
Procurement	PS
QA Program and Implementation	QA
Real-Time Radiography (RTR)	RT
Receiving / Receipt Inspection	RI
Records Management	RM
Safety/Operations	SA
Sampling Techniques	ST
Software	SW
Training and Qualifications	TQ
Transportation	TR
TRUPACT-II Leak Testing	TL
Visual Examination (VE)	VE
Waste Handling Operations	WH
Work Processes	WP

DEFICIENCY CATEGORY	Code Number
Definition of Work Process and Proceduralization	01
Identification of Work Steps	02
Training Materials and/or Training Presentations	03
Untrained Personnel	04
Performance of Work	05
Documentation of Work	06
Records Processing	07

Flow Chart



LEGEND
 CA – Corrective Action
 CAR – Corrective Action Report
 CDA – Corrected During Audit
 CDS – Corrected During Surveillance
 QA – Quality Assurance
 QAM – Quality Assurance Manager

Trend Code Guidance Examples

The following items on the CAR form should be considered during assigning trend codes.

- Block 2: Activity Report No.: Was the deficiency identified during a surveillance, audit, or outside of a formal activity? This block can give you an idea of the scope of what was being evaluated during the time that a deficiency was identified.
- Block 4: Controlling Document: What is the highest level of requirement governing the identified deficiency? Don't always have to go to the highest-level requirement, but use the requirement to help decide on an activity category.
- Block 6: Responsible Organization: Use the organization name to help define the specific types of work that are being performed by specific organizations.
- Block 8: Requirement that was violated: Use in conjunction with Block 4 to give details of the requirement that was violated.
- Block 9: Condition Adverse to Quality:
- Block 10: Suggested Action (Optional): Consider this block if actions are stated at time of identification of the deficiency.

Information on NCR, CDA, and CDS forms regarding as many of the items listed above should be considered when assigning trend codes for deficiencies identified and addressed under these other formats.

Example 1: Headspace Gas equipment calibration was not performed properly (the procedure for calibration omitted a step in the process sequence):

- Assign Activity Code "WP – Work Processes" (you may have considered the "HG" code for headspace gas, but you want to associate this one with not having an adequate definition of work)
- Assign a Deficiency Code of "02 – Identification of Work Steps".

Example 2: AK Summary not up-dated and information not communicated to the DNA personnel:

- Assign an Activity Code of "AK – Acceptable Knowledge" (this issue is closely associated with AK).
- Assign a Deficiency Code of "05 – Performance of Work" (choose this because the procedure was violated where it requires up-date of the AK summaries and distribution).

Example 3: The Leak Tester performed work on a TRUPACT-II, but the worker had not completed the required training.

- Assign an Activity Code of "TL – TRUPACT-II Leak Testing" (you may consider the "TQ – Training and Qualifications" activity code, but the activity is more closely related to the TRUPACT-II leak testing).
- Assign a Deficiency Code of "04 – Untrained Personnel".

Example 4: The job descriptions found in the Project Plan are out of date. Responsibilities have changed for several organizations and functional positions. The document has not been up-dated since it was originally issued two years ago. Responsibilities are no longer consistent with actual practices. The plan does not provide an explanation of duties as required by regulator:

- Assign an Activity Code of "MA – Management" (it is managements responsibility to maintain the document and show actual organizational structure as it is revised or evolves).
- Assign a Deficiency Code of "01 – Definition of Work Processes and Proceduralization" (choose this because the document did not include the accurate definition of the work positions).