MANAGEMENT PROCEDURES MANUAL

CHAPTER 16 - CORRECTIVE ACTION

SECTION 3 - TREND ANALYSIS

1. PURPOSE. This procedure defines the requirements and responsibilities incumbent upon the YMP-USGS QA Office regarding tracking/monitoring of open items and trend analysis of conditions adverse to quality.

2. SCOPE OF COMPLIANCE. This procedure applies to all USGS and USGS contractor personnel working on the Yucca Mountain Project whose work may potentially impact quality. This procedure particularly applies to QA and technical management in their effort to ensure that conditions adverse to quality are identified, corrected and that root causes are eliminated.

3. DEFINITIONS.

   3.1 Condition Adverse to Quality: An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if not corrected, could have a serious effect on safety or operability.

   3.2 Root Cause: A specific problem that can be determined through trend analysis to have generated one or more conditions adverse to quality.

   3.3 Trend: Any series of conditions adverse to quality, or potentially adverse to quality, that point to a given root cause, or a series of conditions that indicate a marked improvement in a given area.

   3.4 Trend Analysis: The act of reviewing QA documents (e.g., CARs, NCRs, AFRs, Observations, Audit Reports and Surveillance Reports) to determine if a trend exists. This activity is computer aided through the use of data base management.

   3.5 Status of Open Items and Trend Analysis Report: A periodically prepared listing of all externally and internally generated open deficiency documents, and an analysis of all identified deficiencies, used as a management tool for the trending process.

4. RESPONSIBILITIES.

   4.1 The Chief, Branch of YMP, is responsible for assigning cognizant personnel the tasks of determining and carrying out the necessary corrective actions to resolve any open items related to technical activities.

   4.2 The QA Manager is responsible for monitoring all potential trends, analyzing trends for root causes, keeping technical management informed of any trend adverse to quality and assigning QA or Records personnel to resolve open items involving QA or Records. In addition, the QA Manager, or delegate, is responsible for the periodic publication of the Status of Open Items and Trend Analysis Report.

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5. **PROCEDURE**.

5.1 Analysis of Open Items:

5.1.1 All deficiency documents issued by or to the USGS shall be reviewed by the QA Manager, or delegate, to determine:

- o QMP chapter, section, and subsection cited;
- o Subject of deficiency;
- o Root cause;
- o If any current open items already cover the same subject;
- o QA Level;
- o Severity level;
- o Division/Individual assigned responsibility; and
- o Date initiated.

This review shall be documented by completion of a Trend Analysis Log Sheet (Attachment 1) for each corrective action document upon QA Office receipt.

5.1.2 An adverse trend shall be considered to exist when three or more deficiencies are determined to have the same root cause.

5.1.3 When a potentially adverse trend is identified, appropriate management shall be informed via the Status of Open Items and Trend Analysis Report. At this time a Corrective Action Report (CAR) shall be generated by the QA Manager, or delegate, in accordance with QMP-16.01.

5.2 Status of Open Items and Trend Analysis Report:

5.2.1 The QA Manager, or delegate, shall prepare and distribute the Status of Open Items and Trend Analysis Report to technical management on a monthly basis, as a minimum.

5.2.1.1 The Status of Open Items and Trend Analysis Report shall take the form of a table listing brief information about each open item, a bar chart depicting the number of deficiencies related to a specific type of problem, and a textual report describing trends and potential trends. The report shall also provide technical management with recommended corrective actions.

5.2.1.2 The specific items tracked by this report include internally and externally generated open items, such as:

- o USGS Stop Work Orders (USGS-SWO);
- o USGS Nonconformance Reports (USGS-NCR);
- o USGS Audit Finding Reports (USGS-AFR);
- o USGS Corrective Action Reports (USGS-CAR);
- o USGS Audit/Surveillance Observations;
- o YMPO Stop Work Orders;
- o YMPO Standard Deficiency Reports (SDR);
- o YMPO Nonconformance Reports (YMPO-NCR);
- o YMPO Corrective Action Reports (YMPO-CAR); and
- o YMPO Audit/Surveillance Observations.

6. **RECORDS MANAGEMENT.**

6.1 Controlled Documents: None.

6.2 Records Center Documents: All transmittal memos and letters concerning trending as well as the Status of Open Items and Trend Analysis Report shall be submitted to the USGS Records Center in accordance with YMP-USGS-QMP-17.01.

7. **RELATED DOCUMENTS.**

7.1 Superseded Documents: None

7.2 References Cited:

YMP-USGS-QAPP-01, YMP-USGS Quality Assurance Program Plan

YMP-USGS-QMP-16.01, Control of Corrective Action Reports

YMP-USGS-QMP-17.01, YMP-USGS Records Management

8. **ATTACHMENTS.**

Attachment 1: Trend Analysis Log Sheet

9. **APPROVALS AND EFFECTIVE DATE.**

EFFECTIVE DATE: Upon Approval.

J.R. Willmon — 10/11/88
YMP-USGS Quality Assurance Manager — Date

Larry R. Hayes — 10/11/88
Chief, Branch of YMP — Date

TREND ANALYSIS LOG SHEET

DOCUMENT TYPE	DOCUMENT NUMBER	INIT DATE	QMP #	QA LEVEL/ SDR LEVEL	RESPONSIBLE DIVISION/PERSON	ACTION DATE	ACTION TYPE*	EXT. #

* R = Response I = Implementation C = Closure A = Actions Complete