EVALUATION RESEARCH CORPORATION

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COMANCHE PEAK RESPONSE TEAM

PROJECT PROCEDURE FOR ALL ISSUE SPECIFIC ACTION PLANS

PROCEDURE NO: CPP-011

REVISION: 0

ISSUE DATE: 10-11-85

EVALUATIONS OF ADVERSE TREND ANALYSES, SAFETY SIGNIFICANT DEFICIENCIES, AND QA/QC PROGRAM DEFICIENCIES

Prepared by: _____ Date: 10/9/85

Approved by: _____ Date: 10-10-85
On-Site QA Representative

Approved by: _____ Date: 10/11/85
QA/QC Review Team Leader

1.0 PURPOSE

This procedure establishes the methods to identify potentially safety significant adverse trends, determine their root cause and generic implication, and to evaluate each safety significant deficiency and QA/QC program deficiency for root cause and generic implications.

Moreover, this procedure establishes the methods to conduct additional reinspections/documentation reviews of the deficient population/work activity/item should there be a report of safety significant deficiency, a QA/QC program deficiency, or an indication of a potentially safety significant adverse trend.

2.0 APPLICABILITY

This procedure is applicable to safety related hardware constructed at Comanche Peak Steam Electric Station, Units 1, 2, and areas common to both units and the associated QA/QC program.

3.0 REFERENCES

3.1 CPP-016, Safety Significance Evaluations of Deviation Reports

3.2 CPP-006, Sample Selection

3.3 CPP-009, Performance of Reinspections and Documentation Reviews

4.0 GENERAL

Each safety significant deficiency and QA/QC program deficiency is evaluated to determine its root cause and generic implication. Potentially safety significant adverse trends that are apparent in deviations are also analyzed to determine their root cause and generic implication.

Upon the issuance of a safety significant deficiency, the affected population/work activity/item is further evaluated/reinspected. Additional evaluations/reinspections will, when coupled with a root cause and generic implication analysis, establish whether the safety significant deficiency was an isolated occurrence. Any additional evaluation/reinspections may include a portion of or the entire deficient population/work activity/item. Similarly, the population/work activity/item is evaluated/reinspected should a potentially safety significant adverse trend be evident in non-safety significant deficiencies.

4.1 Responsibilities

4.1.1 QA/QC Issue Coordinators/Lead Discipline Engineers

QA/QC Issue Coordinators/Lead Discipline Engineers review appropriate data to identify each potentially safety significant adverse trend, its root cause, and generic implication. As required, they prepare plans/analyses and initiate sample expansion plans and reinspections of deficient/susceptible populations or work activities.

4.1.2 QA/QC Supervisors and the QA/QC Review Team Leader

The responsible QA/QC Supervisor and the QA/QC Review Team Leader review and approve plans/analyses.

4.1.3 QA/QC Records Administrator

The QA/QC Records Administrator distributes and controls plans/analyses in accordance with this procedure.

4.2 Policy

Activities performed under this procedure shall conform to the policies contained in the latest Comanche Peak Response Team Program Plan, ERC Management Program Plan, and applicable QA/QC Issue Specific Action Plans (ISAPs).

Should an activity be designated the responsibility of a QA/QC Issue Coordinator/Lead Discipline Engineer, or higher, it may be delegated by that individual to an individual under his or her supervision.

4.3 Conflicts

In the case of a conflict between this procedure and the documents referenced in Section 4.2, the latter shall govern.

4.4 Definitions

4.4.1 Adverse Trend (Programmatic Construction Deviation)

The recurrence of deviations with similar characteristics that may result in a safety significant deficiency in that portion of the population/work activity/item or another population/work activity/item.

4.4.2 Root Cause

The feature(s) of the procedure, instruction, or activity in effect at the time the work was performed that permitted the deficiency or adverse trend to occur.

4.4.3 Generic Implication

A deduction based upon a review of the root cause of an adverse trend, safety significant deficiency, or QA/QC program deficiency that links the deficient population/work activity/item with another in which the same condition may exist, or otherwise indicates a QA/QC program weakness.

4.4.4 Safety Significant Deficiency

A deviation in the construction of an item, which if uncorrected, would result in the loss of capability of the affected system, structure, or component to perform its intended safety related function. Credit is not allowed for redundancy at the component, system, train, or structure level.

4.4.5 QA/QC Program Deficiency

A violation of a requirement of 10CFR50, Appendix B.

5.0 PROCEDURE

5.1 Adverse Trending

Deviation Reports, Safety Significance Evaluations, Data Base Summaries, and other data which results from implementation of an ISAP, are reviewed to identify any potentially safety significant adverse trend.

5.1.1 Analysis

Upon the completion of reinspections/reviews for a population/work activity/item, the QA/QC Issue Coordinator/Lead Discipline Engineer reviews Deviation Reports, Safety Significance Evaluations, Data Base Summaries, etc., to identify any unacceptable characteristic which appears to be repetitive and which may cause a safety significant deficiency in that or another population/work activity/item. For example, a hypothetical trend of significantly undersized welds, although determined not to be safety significant for the sample evaluated, may have the potential to be a safety significant deficiency in another population/work activity/item. The QA/QC Issue Coordinator/Lead Discipline Engineer documents the analysis in accordance with Attachment 6.1.

Should the Coordinator/Lead conclude that there is the potential for a safety significant deficiency, a determination is made as to the root cause and generic implication.

5.2 Root Cause and Generic Implication

Upon the identification of 1) a potentially safety significant adverse trend, or 2) a safety significant deficiency, or 3) a QA/QC program deficiency, the QA/QC Issue Coordinator/Lead Discipline Engineer performs a review to determine the root cause and to identify populations/work activities/items that are susceptible to the same condition. Attachment 6.2 may be used as a guide to identify common root causes. However, the QA/QC Issue Coordinator/Lead Discipline Engineer should postulate any additional root causes that are appropriate.

5.2.1 Analysis

Based upon the root causes of the potentially safety significant adverse trend, QA/QC program deficiency, or safety significant deficiency, the QA/QC Issue Coordinator/Lead Discipline Engineer analyzes the generic implications to determine other populations/work activities/items that are susceptible to the same condition. For example, there may be evidence which links an adverse trend to inadequate inspection. That is, one or more inspectors may have accepted welds that were subsequently determined to be significantly undersized. It can be deduced that the same inspector(s) may have accepted welds in other populations/work activities/items that exhibit the same unacceptable characteristic.

The QA/QC Issue Coordinator/Lead Discipline Engineer ensures that the result of the root cause and generic implication analysis is documented in accordance with Attachment 6.3.

5.3 Additional Evaluations/Reinspections Due to Deficiencies or Adverse Trends

Should a safety significant deficiency or QA/QC program deficiency be reported, or should a potentially safety significant adverse trend be evident in non-safety significant deviations, additional evaluations/reinspections of any deficient and/or suspect populations/work activities/items are conducted and the results evaluated.

The scope of additional evaluations/reinspections will, when coupled with the results of the root cause and generic implication analyses (Refer to Section 5.2) be of sufficient size to reasonably ensure that no other safety significant deficiency exists in the population/work activity/item.

If safety significant deficiencies are not found in the additional evaluation/reinspection, no further evaluation/reinspection is required.

5.3.1 Initial Sample Expansion Due to a Safety Significant Deficiency for ISAP VII.c

Should a safety significant deficiency be issued in accordance with Reference 3.1, the responsible QA/QC Lead Discipline Engineer ensures that additional items within the deficient population/work activity/item are randomly selected, reinspected, and evaluated. The selection of an expanded sample is conducted in accordance with Reference 3.2, except the preparer of the Random Sample Identification (Form CPP-006) enters "EXPANDED" in lieu of "FIRST" or "SECOND".

Initial reinspection/documentation review of the expanded sample due to one or more safety significant deficiencies is conducted with the same instructions that were used previously. (See Reference 3.3.) Table 5.3-1 indicates the total number of items to be reinspected based on the number of safety significant deficiencies.

For example, should 1 safety significant deficiency be evident in a sample of 60 items from a population of 101, an additional 35 items should be reinspected to attain the total number of 95.

TABLE 5.3-1

SAMPLE SIZE FOR ADDITIONAL REINSPECTIONS

Population Size	Total Number of Samples		
	One Safety Significant Deficiency	Two Safety Significant Deficiencies	Three or More Significant Deficiencies
46 - 100	All or 65*	All or 81*	All
101 or More	95	All or 126*	All

* Whichever is less.

5.3.2 Additional Sample Expansion Due to a Safety Significant Deficiency in the Initial Sample Expansion for ISAP VII.c.

Should one or more safety significant deficiencies be evident in the expanded sample, the QA/QC Issue Coordinator/Lead Discipline Engineer initiates additional reinspections/documentation reviews based upon their root cause. (Refer to Section 5.2)

If the deficiencies are of the same root cause type, only the attributes necessary to identify deficiencies of that type are verified by reinspection/reviews.

If the deficiencies are determined to have different root causes or be of different types, all of the attributes which were used for the original reinspection are verified by reinspection/review.

The QA/QC Issue Coordinator/Lead Discipline Engineer consults with the Comanche Peak Response Team (CPRT) engineering statistics advisor to determine the expanded sample size, then submits the analysis and sample expansion plan for review and approval in accordance with Section 5.4.

5.3.3 Sample Expansion Due to a Potentially Safety Significant Adverse Trend for ISAP VII.c

Should a potentially safety significant adverse trend (i.e., a Programmatic Construction Deviation) be identified in accordance with Section 5.1, the responsible QA/QC Issue Coordinator/Lead Discipline Engineer consults with the CPRT engineering statistics advisor, then develops a sample expansion plan that focuses on the populations/work activities/items susceptible to the effects of the adverse trend.

The sample expansion plan defines the number of additional reinspections, as agreed to by the CPRT engineering statistics advisor, and the specific attributes(s) which are appropriate to the expanded sample.

The QA/QC Issue Coordinator/Lead Discipline Engineer determines the specific attribute(s) by identifying the previously reported unsatisfactory attribute(s) and any related attribute(s). For example, should the items be deficient with regard only to bolted connections attributes, it is necessary to reinspect the expanded sample only for the specific attributes relative to bolted connections. It is unnecessary to reinspect the same expanded sample for any attribute relative to those attributes that were previously found to be satisfactory, e.g., welded connections.

The Coordinator/Lead signs the plan as preparer, then sends it to the appropriate QA/QC Supervisor, and Review Team Leader (RTL) for review and approval in accordance with Section 5.4.

Approved plans are sent to the QA/QC Records Administrator for control in accordance with Section 5.5.

5.3.4 Additional Evaluations/Reinspections for ISAPs Other Than ISAP VII.c

Should a QA/QC program deficiency, safety significant deficiency, or adverse trend be identified in accordance with an ISAP other than ISAP VII.c, the Issue Coordinator shall initiate a reinspection/-documentation review of the deficient and/or suspect populations/work activities/items in accordance with the applicable ISAP, and shall develop a plan which describes how the evaluation is to be conducted. The plan is reviewed and approved in accordance with Section 5.4.

5.4 Review and Approval

Analyses and plans are reviewed and approved prior to any additional evaluations/reinspections. Upon the completion of a satisfactory review, the reviewers endorse the analysis/plan, then send it to the QA/QC Records Administrator for distribution and control in accordance with Section 5.5.

5.4.1 QA/QC Supervisors

QA/QC Supervisors review the analyses/plans to ensure that they are logical and are adequately supported by the referenced documentation; there are reasonable justifications for the stated conclusion and any recommended actions.

5.4.2 QA/QC Review Team Leader

The QA/QC RTL reviews analyses/plans approved by the responsible QA/QC Supervisor to ensure that they are consistent with the policies and intent of the CPRT.

5.5 Distribution and Control

The QA/QC Records Administrator distributes approved adverse trend and root cause and generic implication analyses to the TUGCO Coordinating Engineer, Design Adequacy Program (DAP) RTL, the CPRT Program Director, the Collective Evaluation Engineer, and the Coordinator for Programmatic Issues. Adverse trend, root cause, and generic implication analyses with design concerns are sent to the DAP RTL for action by the DAP.

The QA/QC Records Administrator maintains:

- Adverse Trend Analyses (refer to Section 5.1) in the file marked ISAP (Number) - 5.
- Root Cause and Generic Implication Analyses (refer to Section 5.2) in the file marked ISAP (Number) - 5.

- Additional reinspections/documentation reviews and sample expansion plans (refer to Section 5.3) in the file marked ISAP (Number) - 5.

6.0 ATTACHMENTS

6.1 Adverse Trend Analysis (Sample and Instruction)

6.2 Common Root Causes

6.3 Root Cause and Generic Implication Analysis (sample and Instruction)

ADVERSE TREND ANALYSIS

COMANCHE PEAK RESPONSE TEAM
ADVERSE TREND ANALYSIS

POPULATION/WORK ACTIVITY/ITEM DESCRIPTION

(1)

RECORDS REVIEWED, E.G., DEVIATION REPORTS, SAFETY SIGNIFICANCE EVALUATIONS, DATA BASE SUMMARIES, ETC.

(2)

ANALYSIS

(3)

CONCLUSION

☐ NO APPARENT POTENTIALLY SAFETY SIGNIFICANT ADVERSE TREND.

☐ AN ADVERSE TREND THAT IS NON-SAFETY SIGNIFICANT. (EXPLAIN)

☐ A POTENTIALLY SAFETY SIGNIFICANT ADVERSE TREND. (EXPLAIN)

(4)

(5) ☐ A CONST. CONCERN EXISTS (6) ☐ ADDITIONAL EVALUATION/REINSPECTION IS REQUIRED DUE TO THE POTENTIAL FOR SAFETY SIGNIFICANT DEFICIENCIES. (REFER TO CPP-011, PARA. 5.1.1)

(5) ☐ A DESIGN CONCERN EXISTS

(5) ☐ NO CONCERN EXISTS (6) ☐ NO ADDITIONAL EVALUATION/REINSPECTION IS REQUIRED.

PREPARED BY:		APPROVED BY:		APPROVED BY:	
(7)	(7)				
	DATE	SUPERVISOR	DATE	REVIEW TEAM LDR	DATE

INSTRUCTION FOR COMPLETING FORM CPP-011.1 "ADVERSE TREND ANALYSIS"

The QA/QC Issue Coordinator/Lead Discipline Engineer enters:

(1) The description of the applicable population/work activity/item.

(2) The identification of the applicable records reviewed.

(3) The methodology used to identify adverse trends. For example:

> "The referenced documents were reviewed to identify unacceptable attributes in non-safety significant deviations that appear to be repetitive and which may cause a safety significant deficiency in the same, or another population/work activity/item."

(4) The conclusion based on a review of the referenced records reviewed.

(5) A check to indicate whether a construction, design, or no concern exists.

(6) A check to indicate whether additional evaluation/reinspection is (un)necessary.

(7) Signature as preparer and date.

The appropriate QA/QC Supervisor and the QA/QC Review Team Leader review the analysis as specified in Section 5.4. Upon completion of a satisfactory review they enter their signatures and approval date(s) in the appropriate blocks on the form.

COMMON ROOT CAUSES

•PROGRAM/PROCEDURE RELATED

No procedure
Outdated Procedure
Procedural Technical Content
Contradictory Procedures
Inadequate Procedure

•MANAGEMENT/QA RELATED

Training
Manpower
Timeliness/Scheduling
Supervision
Personnel Cert/Qualification
Housekeeping
Inadequate Dept. Interface

•DOCUMENTATION RELATED

Document Control
Missing Documentation
Incomplete Documents
Misfiled Documents
Incomplete Records

•PERSONNEL RELATED

Typo's/Illegibility
Inaccuracy
Procedural Noncompliance
Work on Wrong Component
Personnel Error

•DESIGN/MFG/INSTALLATION

Craftmanship
Improper Equipment
Incorrect Material
Contamination
Abnormal Wear
Lubrication
Weld Related
Abnormal Temperature
Abnormal Pressure
Abnormal Flow
SET PT Drift
Valve Misalignment
Open Circuit
Short/Ground
Bad Controls
Defective Connection
Overload
Defective Circuit
Cyclic Fatigue
Vibration/Cavitation
Obstruction
Dirt/Crud
Corrosion/Erosion
Natural End of Life
Hi-Rad Environment
Hi-Humidity
Poor Maintenance
Design Error

ROOT CAUSE AND GENERIC IMPLICATION ANALYSIS

COMANCHE PEAK RESPONSE TEAM
ROOT CAUSE AND GENERIC IMPLICATION ANALYSIS

POPULATION/WORK ACTIVITY/ITEM DESCRIPTION

(1)

IDENTIFICATION AND DESCRIPTION OF ADVERSE TREND, SAFETY SIGNIFICANT DEFICIENCY, OR QA/QC PROGRAM DEFICIENCY.

(2)

ROOT CAUSE ANALYSIS

(3)

GENERIC IMPLICATION ANALYSIS

(4)

PREPARED BY:	APPROVED BY:	APPROVED BY:
(5) (5)		
DATE	QA/QC SUPERVISOR DATE	QA/QC RTL DATE

INSTRUCTION FOR COMPLETING
FORM CPP-011.2
"ROOT CAUSE AND GENERIC IMPLICATION ANALYSIS"

THe QA/QC Issue Coordinator/Lead Discipline Engineer enters:

(1) The description of the applicable population/work activity/item in which the potentially safety significant adverse trend, safety significant deficiency, or QA/QC program deficiency occurred.

(2) Provide the identification and description of the adverse trend or deficiency being analyzed. This may be accomplished by reference to other documents which may be attached to this form.

(3) Document the root cause analysis results in this section. Attachment 6.2 of CPP-011 contains a list of common potential root causes which are to be used as a starting point for the analysis. Additional potential root causes should be added as a part of the analysis as appropriate. Supplementary pages may be added as required.

(4) Document the generic implication analysis results in this section. The postulated root cause(s) are to be considered in this analysis. The purpose of the analysis is to determine whether the deficiency being analyzed could occur in other populations/work activities/-items and, in the case of a QA/QC program deficiency, what the impact might be on the acceptability of installed hardware. The following factors should be considered when analyzing the potential scope of the concern:

- Time period in which the deficiencies occurred.
- Procedure(s) used.
- Personnel who performed the work.
- QC or other personnel who checked the work.
- Area of the plant.
- System(s) involved.
- Type of component or commodity involved.

Supplementary pages may be added to document the analysis as required.

(5) The preparer signs and dates the analysis. The appropriate QA/QC Supervisor and the QA/QC Review Team Leader review the analysis as specified in Section 5.4 of CPP-011. Upon the completion of a satisfactory review, they enter their signatures and approval date(s) in the appropriate blocks on the form.