NEI 08-02, Revision 3 (Draft)b

Corrective Action Processes for New Nuclear Power Plants During Construction

January 2010

NEI 08-02, Revision 3 (Draft)~~2a~~

Nuclear Energy Institute

Corrective Action Processes for New Nuclear Power Plants During Construction

January 2010

Nuclear Energy Institute, 1776 I Street N. W., Suite 400, Washington D.C. (202.739.8000)

ACKNOWLEDGEMENTS

This guidance document, *Corrective Action Processes for New Nuclear Power Plants During Construction*, NEI 08-02, was developed by the New Plant Problem Identification and Resolution Task Force and selected members of the New Plant Quality Assurance Task Force. These industry professionals, experts on construction practices and corrective action processes, drawing upon practical lessons learned during the application of corrective action processes, provided valuable insights to this guidance document. We appreciate the time, efforts, and expertise of the individuals who contributed to the development of this guideline.

NOTICE

Neither NEI, nor any of its employees, members, supporting organizations, contractors, or consultants make any warranty, expressed or implied, or assume any legal responsibility for the accuracy or completeness of, or assume any liability for damages resulting from any use of, any information apparatus, methods, or process disclosed in this report or that such may not infringe privately owned rights.

EXECUTIVE SUMMARY

NEI 08-02, "Corrective Action Processes for New Nuclear Power Plants During Construction," provides generic guidance on how the holder of a combined license (COL) or Limited Work Authorization (LWA) issued under 10 CFR Part 52 should implement construction corrective action processes during engineering, procurement and construction activities and until the licensee implements its operational phase corrective action processes. Lessons learned during the construction of the current operating nuclear power plants were considered in the development of this document. The purpose of this document is to establish guidance for roles, responsibilities, and implementation of the construction corrective action processes that will be used during the on-site construction of new nuclear power plants. ~~Additionally, this document will serve as the vehicle for regulatory discussion, resolution, and endorsement of the construction corrective action processes to be used during construction of new nuclear power plants~~

This guidance provides for identification and resolution of conditions adverse to quality and other conditions adverse to meeting specific regulatory requirements in an engineering, procurement, and construction atmosphere where many different organizations and suppliers provide the materials and services needed to construct a new nuclear power plant. The licensee should establish the extent that suppliers and sub-tier suppliers participate in the licensee's construction corrective action processes or implement the supplier's processes. This document identifies the basic elements that are necessary to identify and resolve ~~problems~~ conditions adverse to quality (CAQ) in a fast-paced construction environment.

The process described herein allows any licensee/supplier employee to identify ~~and document~~ a condition that may need to be resolved. The condition is screened to determine if it is a CAQ. The ~~condition~~ CAQ is classified with respect to significance. If classified as a significant CAQ, the condition is analyzed for cause commensurate with its importance to safety. The actions focus on correcting ~~condition~~ CAQ and precluding repetition of significant CAQ.

TABLE OF CONTENTS

EXECUTIVE SUMMARY i

1 INTRODUCTION AND BACKGROUND 1

1.1 DEFINITIONS 2

2 PURPOSE AND APPLICABILITY 6

2.1 PURPOSE 6

2.2 APPLICABILITY 6

3 RESPONSIBILITY 8

3.1 LICENSEE 8

3.2 MANAGEMENT 8

3.3 INDIVIDUAL 9

3.4 SUPPLIER 9

4 CONSTRUCTION CORRECTIVE ACTION PROCESS ELEMENTS 9

4.1 IDENTIFICATION, DOCUMENTATION, AND REPORTING 10

4.2 SCREENING, EVALUATION AND CLASSIFICATION 11

4.2.1 Screening to Identify Conditions that Require Further Review 11
4.2.2 Evaluation to Identify Significant Conditions 12
4.2.3 Evaluating Conditions for Significance to ITAAC Conclusions 13
4.2.4 Classification 14

4.3 CAUSE ANALYSIS 14

4.4 CORRECTIVE ACTIONS 15

4.5 VERIFICATION AND FOLLOW-UP 15

4.6 ANALYZING FOR ADVERSE TRENDS 16

5 IDENTIFICATION AND CORRECTION OF CONDITIONS THROUGH WORK PROCESSES . 17

6 RECORDS 20

7 TRANSITIONING TO THE OPERATIONS CORRECTIVE ACTION PROGRAM 20

ATTACHMENT 1 1

ATTACHMENT 1 2

ATTACHMENT 2 1

CORRECTIVE ACTION PROCESSES FOR NEW NUCLEAR POWER PLANTS DURING CONSTRUCTION

1 INTRODUCTION AND BACKGROUND

Effective identification of problems and resolving them are critical aspects of assuring nuclear plants are constructed in a quality manner. It is also imperative that good documentation is maintained of the identified problems and the actions taken to correct them.

This document provides guidance for meeting the requirements of Criterion XVI of Appendix B to 10 CFR Part 50, *Quality Assurance for Nuclear Power Plants and Fuel Reprocessing Plants*, that are identified in a licensee's approved QA program that is based on NQA-1-1994, or other NRC endorsed QA standard, as it relates to the processes necessary to develop effective construction corrective action processes for new nuclear power plants up to the point in time determined by the licensee that the operations phase Corrective Action Program is to be implemented. ~~This document outlines corrective action principles that are intended to address adverse conditions adverse to quality (CAQ) with respect to regulatory compliance with 10 CFR Part 50, Appendix B.~~ It will also be applied to the activities related to ITAAC compliance in accordance with 10 CFR Part 52, regardless of the quality classification of the equipment associated with the ITAAC. ~~and certain environmental issues as described in Subsection 2.2, below.~~ It was not written for use in correcting industrial safety, security, environmental, or other non-quality related conditions; however, the principles may be applied to those areas as deemed appropriate by the implementing organization. ~~Implementation of this guidance document provides the 10 CFR Part 50, Appendix B, basis for Nuclear Regulatory Commission (NRC) endorsement of the construction project construction corrective action processes.~~

Current operating plants have established effective corrective action processes for the operating environment, and many suppliers have established and effective programs for implementing the applicable requirements of 10 CFR Part 50, Appendix B. New nuclear plant construction projects use similar corrective action elements, but methods for documenting corrective actions may differ. ~~during the construction-related activities of engineering, procurement, and construction, but may differ in the processes utilized to document corrective actions.~~

The 10 CFR Part 52 licensing process provides the regulatory framework for constructing and operating new nuclear power plants. This regulatory environment is different from that under which the current operating nuclear power plants were built. These construction corrective action process guidelines account for the two key differences in the licensing processes between Part 50 and Part 52: construction of safety-related SSCs is conducted after the combined license (COL), or Limited Work Authorization (LWA), is issued; Part 52 inspections, tests, analyses, and acceptance criteria (ITAAC) are used to verify that the completed plant was constructed in accordance with license requirements.

The licensee is responsible for assuring that conditions adverse to quality (CAQ) are identified, corrected, and managed in accordance with the requirements and commitments of the facility quality assurance program (QAP). The processes defined in this guidance document outline one method of satisfying NRC regulatory corrective action requirements. ~~Conditions adverse to quality~~CAQ are identified through implementation of elements of the QA program. The construction corrective action processes implement the requirements of Criterion XVI of Appendix B to 10 CFR Part 50, as identified in NRC Regulatory Guide 1.206, NUREG-0800 Standard Review Plan, Section 17.5, and ASME/ANSI Consensus Standard NQA-1-1994, through defined processes that address failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances that are documented as specified in NQA-1-1994. The licensee will need to determine the extent to which this document is delegated to their contractors. Attachment 1 provides an illustration of the construction corrective action processes. When an onsite safety-related supplier demobilizes and leaves the site, the supplier will review all open CAQs related to that specific supplier for correct disposition and ensure that responsibility is appropriately transferred.

Management promotes prompt identification of conditions and appropriate evaluation, tracking, trending, and correction in a timely manner commensurate with the condition's safety significance and complexity. It is important on a construction site for Management to establish an environment where all workers feel free to identify problems. The Safety Conscious Work Environment program, e.g., Employee Concerns Program, establishes the means by which that environment is administered. The construction corrective action processes are the primary means for workers to identify problems. There are additional processes that can be used by workers to identify problems including reporting to management, reporting to QA, Employee Concerns Program, reporting to NRC, etc.

1.1 DEFINITIONS

The following definitions are provided to assure a uniform understanding of select terms as they are used in this document.

Combined license (COL) – means a combined construction permit and operating license with conditions for a nuclear power facility issued under Subpart C of 10 CFR Part 52. (Based on 10 CFR 52.1, Definitions.)

Condition – the existence, occurrence, or observation of a situation that requires further review, evaluation, or action for resolution to ensure regulatory compliance. (Defined specific to the usage in this document.)

Condition Adverse to Quality (CAQ) – an all inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, deviations, defective items, and non-conformances. (Based on ASME NQA-1-1994, Part 1, Section 1, Introduction; and, 10 CFR 50, App. B, Criterion XVI.)

Construction Corrective Action Processes (CCAP) – An umbrella concept ~~overarching processes~~ used to identify, document, and correct conditions adverse to quality or adverse

to certain other regulatory requirements. CCAP encompasses the Corrective Action Program and the corrective action elements of the work processes. (Defined specific to usage in this document.)

Corrective Action – measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition. (Based on ASME NQA-1-1994, Part 1, Section 1, Introduction.)

Corrective Action Program (CAP) – a construction corrective action process that serves as a management process or tool for collecting information concerning Significant Conditions Adverse to Quality and other significant adverse conditions, and tracking implementation of causal determination and corrective action. (Defined specific to usage in this document.)

Design Acceptance Criteria (DAC) – a set of prescribed limits, parameters, procedures, and attributes upon which the NRC relies, in a limited number of technical areas, in making a final safety determination to support a design certification. (Based on the definition from NEI-08-01; also see SECY-92-053, page 3.)

Deviation – a departure from the technical requirements included in a procurement document, or specified in early site permit information, a standard design certification, or standard design approval (Based on 10 CFR 21.3); a departure from specified requirements. (Based on ASME NQA-1-1994, Part 1, Section 1, Introduction.)

Extent of Condition – the extent to which the actual condition exists in other processes, programs, or equipment. For significant conditions adverse to quality, the extent of condition review should assess the degree that the actual condition, and cause of the condition, may exist for other processes, programs, or equipment. (Defined specific to usage in this document.)

Inspection, Test, Analysis, and Acceptance Criteria (ITAAC) – as identified within the combined license, the inspections, tests, and analyses, including those applicable to emergency planning, that the licensee shall perform, and the acceptance criteria that, if met, are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's rules and regulations. (Based on 10 CFR 52.97(b).) (For additional information on ITAAC, refer to NEI 08-01.)

ITAAC Closure Letter (also known as ITAAC closure notification) – the letter the licensee sends to notify the NRC that an ITAAC is complete in accordance with 10 CFR 52.99(c)(1). (Based on the definition in NEI 08-01.)

ITAAC Closure Package – the information and records documenting the work performed to verify and close an ITAAC. Once completed, the ITAAC Closure Package will be available for NRC inspection at the plant site. (Based on the definition in NEI 08-01.)

ITAAC Finding – a regulatory violation that is: greater than minor, associated with a specific ITAAC for which the licensee has issued the ITAAC closure letter, and material

to the ITAAC acceptance criteria. This type of finding could prevent the ITAAC from being closed out by the NRC and could require that previously closed ITAAC be re-opened. An ITAAC finding may be related to a single ITAAC or a family of ITACC. (~~Based on the definition in NEI 08-01~~From IMC-0613.)

ITAAC-Related Construction Finding (IRCF) – a regulatory violation that is: greater than minor, associated with a specific ITAAC for which the licensee has not yet issued the ITAAC closure letter, and material to the ITAAC acceptance criteria. This type of finding could prevent the ITAAC from being closed out and therefore must be corrected and addressed in the licensee's ITAAC closure letter. An ITAAC-Related Construction finding may be related to a single ITAAC or a family of ITACC. (~~Based on the definition in NEI 08-01~~From IMC-0613.)

Item – an all inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit. (Based on ASME NQA-1-1994, Part 1, Section 1, Introduction.)

Licensee – a person who is authorized to conduct activities under a license issued by the Commission. (Based on 10 CFR 50.2, Definitions, and 10 CFR 52.1, Definitions.)

Management – personnel from the first line of supervision through senior management positions. (Defined specific to usage in this document.)

Nonconformance – a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate. (Based on ASME NQA-1-1994, Part 1, Section 1, Introduction.)

Nonconforming Item – means an appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit that does not conform to specified requirements. If a nonconforming item is not rejected define or cannot be reworked to satisfy the original design requirements, a technical justification for the acceptability of the nonconforming item (e.g. repair, use-as-is) shall be documented and subject to design control measures commensurate with those applied to the original design and the as-built records, if such records are required, shall reflect the accepted deviation. (Based on usage in ASME NQA-1-1994, Supplement 15S-1.)

Quality-Related – a generic term used to indicate structures, systems, and components (SSCs) and associated activities for which the QA Program applies. (Defined specific to the usage in this document.)

Repair – the process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement. (Based on ASME NQA-1-1994, Part 1, Section 1, Introduction.)

Rework – the process by which an item is made to conform to original requirements by completion or correction. (Based on ASME NQA-1-1994, Part 1, Section 1, Introduction.)

Significant Condition Adverse to Quality – a condition adverse to quality that, if uncorrected, could have a serious effect on safety or operability. (Based on ASME NQA-1-1994, Part 1, Section 1, Introduction.)

Standard Design Certification or Design Certification – means a Commission approval, issued under Subpart B of 10 CFR Part 52, of a final standard design for a nuclear power facility; this design may be referred to as a certified standard design (Based on 10 CFR 52.1, Definitions.)

Supplier – any individual or organization who furnishes items or services in accordance with a procurement document. An all inclusive term used in place of any of the following; vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels. (Based on NQA-1-1994, Part 1, Section 1, Introduction.)

Trending – an analysis to detect repetition of conditions adverse to quality, as well as the relationship or similarity between different conditions in order to assure adverse trends that could result in a significant condition adverse to quality are identified and evaluated for appropriate correction (Defined specific to the usage in this document.)

Use-as-is – a disposition permitted for a nonconforming item when it has been established that the item is satisfactory for its intended use (Based on ASME NQA-1-1994, Part 1, Section 1, Introduction.)

Work Processes – ~~Design Control, Inspection, and other~~ processes affecting quality such as design control, control of purchased material,, etc., that are performed in accordance with 10 CFR 50 Appendix B and the licensees Quality assurance Program, and including appropriate corrective action elements, (e.g. identification , documentation, and correction of the condition. ~~defined processes controlling activities (e.g., designing, constructing, procuring, fabricating, installing, inspecting, etc.) performed to implement in accordance with the Ccriteria of 10 CFR Part 50, Appendix B, as identified in NQA-1 Part I and Part II (subparts) and as identified in the implementing organization's quality assurance program.~~ (Defined specific to the usage in this document).

References

The following references were used to assist in the development of this guidance document.

- 10 CFR Part 21, *Reporting of Defects and Noncompliance*~~; and, 10 CFR 50.55, Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses – paragraph (e) regarding reporting to the NRC of deviations and failures to comply to the NRC~~
- 10 CFR Part 50, *Domestic Licensing of Production and Utilization Facilities*; including

Formatted: Font: Not Italic

Formatted: Font: Not Italic

- 10 CFR 50.55, *Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses* – paragraph (e) regarding reporting to the NRC of deviations and failures to comply
- 10 CFR 52.6, *Completeness and Accuracy of Information*~~; including 10 CFR 50.55, *Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses* – paragraph (e) regarding reporting to the NRC of deviations and failures to comply~~
- 10 CFR Part 52, *Licenses, Certifications, and Approvals for Nuclear Power Plants*
- ASME NQA-1-1994, *Quality Assurance Requirements for Nuclear Facility Applications*
- ANSI N18.7-1976, *Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants*
- NEI 08-01, *Industry Guideline for the ITAAC Closure Process Under 10 CFR Part 52*
- NUREG-0800, Standard Review Plan, Section 17.5, *Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants*
- NUREG-1055, *Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants*
- *Principles for Effective Self-Assessment and Corrective Action Programs*, December 1999 INPO
- RIS 2005-20, *Revision to Guidance Formerly Contained in NRC Generic Letter 91-18, "Information to Licensees Regarding two NRC Inspection Manual Sections on Resolution of Degraded and Nonconforming Conditions and on Operability"*

Formatted: Indent: Left: 1", Tab stops: 1.25", List tab + Not at 1"

2 PURPOSE AND APPLICABILITY

2.1 PURPOSE

The purpose of this document is to establish guidance for roles, responsibilities, and implementation of the construction corrective action processes used during the on-site construction of new nuclear power plants. This document outlines the important elements of the construction corrective action processes to guide the development of administrative processes, procedures, and instructions that the licensees and/or suppliers utilize to implement corrective actions. Where this document uses CCAP it applies to the corrective action process (CAP) as well as the work process corrective action elements.

2.2 APPLICABILITY

This document is applicable to the identification and correction of conditions adverse to quality. Corrective action may be implemented by using either a single (umbrella) corrective action process or multiple processes performed in accordance with 10CFR Part 50, Appendix B as described in the quality assurance program. When multiple processes are used to implement corrective action then interface measures shall be defined and

implemented. These interface measures shall ensure identified problems are adequately and appropriately evaluated. The measures shall ensure that conditions adverse to quality are addressed in accordance with 10 CFR 50, Appendix B, Criterion XVI. ~~and environmental issues related to the information submitted in the Environmental Report affecting Final Environmental Impact Statement (FEIS) determinations (e.g., water use assumptions, population predictions, discharge water temperature limits)~~. ~~This document does **not** address requirements for reporting to the NRC of deviations, failures to comply, or other reportable occurrences in accordance withunder 10 CFR 50.55, 10 CFR Part 21, or 10 CFR Part 52; however, the licensee and safety-related suppliers at all levelsof quality-related materials and services must ensure that there is an interface between the corrective action processes and their NRC reporting process to comply with the NRC regulations.~~

The applicability of these corrective action processes ~~can~~ may be extended to incorporate security-related matters, environmental permit requirements, and industrial safety concerns (e.g., OSHA recordable injuries to workers, worker fatalities, control of access that could result in or has resulted in an unintended exposure from radiography) ~~at the discretion of the responsible organization~~. ~~, and security-related matters.~~ In areas such as these that are not subject to 10 CFR Part 50, Appendix B, processes similar to those described in this guideline for ~~conditions adverse to quality~~CAQ may be established. Licensee program documents should specify the scope of applicability of the construction corrective action processes.

In addition to the construction corrective action processes, other means are available for persons to identify construction-related concerns (e.g., Employee Concerns Program, and raising concerns to the NRC).

This guidance document is applicable to activities that are performed during quality-related construction through the point in time determined by the licensee for implementing the operations ~~construction~~ corrective action processes, except that aspects related to identifying issues with closed ITAAC may continue to be used until the Commission's finding under 10 CFR 52.103(g). Transition to the operations ~~construction~~ corrective action processes may occur based on subsystem, system, or building turnover, but must not occur later than 30 days prior to the scheduled loading of fuel (Ref. 10 CFR 50.54(a)). An interface should be established to address any corrective actions remaining from the construction program during the transition to the operations program. The applicant/licensee is responsible for determining when this guidance on construction corrective action processes will be implemented.

This document does **not** address requirements for reporting to the NRC of deviations, failures to comply, or other reportable occurrences under 10 CFR 50.55, 10 CFR Part 21, or 10 CFR Part 52; however, the licensee and suppliers of quality-related materials and services must ensure that there is an interface between the corrective action processes and their NRC reporting process to comply with the NRC regulations.

This document does not supersede any corrective action program already defined in an NRC-approved quality assurance program description. An organization with an NRC-

approved QA program that intends to make changes to their corrective action processes to implement this guidance must make their changes in accordance with the applicable NRC regulations.

3 RESPONSIBILITY

3.1 LICENSEE

The Licensee is responsible for establishing written procedures for implementing the construction corrective action processes, assuring consistency with NEI 08-02, and assuring that conditions adverse to quality are identified, corrected, and escalated in accordance with the requirements and commitments of the facility Quality Assurance Program Description (QAPD). The Licensee may delegate activities of planning, establishing, and implementing the construction corrective action processes to others. The interfaces ~~between organizations~~with suppliers and other organizations should be defined in ~~licensee program~~ QA program documents so that the potential impacts of identified conditions are appropriately evaluated across organizational boundaries.

The licensee is responsible for oversight of corrective action programs that are delegated to suppliers. The Licensee should ensure that construction corrective action processes delegated to others are implemented consistent with NEI 08-02. This oversight is typically performed through a combination of supplier audits, surveillances, and/or periodic reviews of the program development and implementation in accordance with the QAPD.

3.2 MANAGEMENT

Management plays a significant role in the construction corrective action processes. Management has the responsibility for assuring that the construction corrective action processes are understood and implemented across all segments of the project.

Management is responsible for:

- Defining and communicating standards of excellence in the quality of work at every level of project management.
- Establishing an environment that fosters participation in the construction corrective action processes.
- Defining condition reporting criteria, the condition reporting system(s) to be used, desired level(s) of condition evaluation, the timeliness of reporting conditions and corrective actions; the requirements for reporting ~~the~~ significant ~~conditions adverse to quality~~CAQ to the appropriate levels of management (including senior management responsible for the corrective action), and requirements and expectations for the implementation of the construction corrective action processes when being implemented by a contractor or subcontractor.

- Assuring that corrective actions are approved, prioritized, and completed as soon as practical, in a manner consistent with their significance.
- Assuring sufficient resources are available to investigate, prioritize, and promptly resolve ~~conditions adverse to quality~~CAQ when identified.
- Actively supporting and participating in the construction corrective action processes.
- Assuring training related to the construction corrective action processes is provided to personnel who are performing quality-related construction activities. Based on job function and responsibility, training is provided for specific duties and responsibilities of each individual.
- Providing oversight of the process to ensure effective implementation.

3.3 INDIVIDUAL

Each individual is responsible for promptly identifying and reporting the existence, occurrence, or observation of a situation that requires further review, evaluation, or action for resolution in the construction corrective action processes.

3.4 SUPPLIER

Each licensee's suppliers of quality-related materials and services are responsible for implementing the corrective action requirements of 10 CFR Part 50, Appendix B. The suppliers of the quality-related services ~~are responsible to~~ should develop construction corrective action processes and program documents to~~that~~ implement the requirements specified by the ~~purchasing organization~~licensee, unless the supplier is working under the licensee's QA program and procedures.

~~If the program has been contracted to others, then the purchaser is responsible for the overall delegated program and is required to provide the appropriate interfacing document to ensure that the requirements of 10 CFR Part 50, Appendix B, are being implemented and contains sufficient requirements to ensure conditions are identified and corrected as specified by Section 4 of this document.~~

4 CONSTRUCTION CORRECTIVE ACTION PROCESS ELEMENTS

Construction corrective action processes are an integral part of any Quality Assurance Program. Guidance is provided in the subsections below for implementing QA Program requirements to identify, evaluate, document, and develop effective corrective/preventive actions for conditions that are not in accordance with established quality requirements. The construction corrective action processes include a method by which anyone on the construction project may easily identify a condition they believe needs to be corrected.

The elements of construction corrective action processes are as follows:

(a) Identification, documentation, and reporting

(b) Screening, evaluation, and classification

(c) Cause analysis

(d) Corrective actions

(e) Verification and follow-up

(f) Analyzing for adverse trends

For each condition, responsible organizations should implement construction corrective action process elements in accordance with their significance as discussed in the following subsections.

Implementation of construction corrective action process elements should be governed by procedures with appropriate criteria to make consistent and timely significance determinations, cause analysis, and corrective actions to preclude repetition.

Attachment 1 provides an illustration of the construction corrective action processes.

4.1 IDENTIFICATION, DOCUMENTATION, AND REPORTING

Identification and documentation is an essential element of construction corrective action processes. The expectations for prompt identification and documentation should be clearly established in written procedures. Where ~~adverse~~ conditions are identified, the need to take immediate corrective action is assessed and the extent to which other items and activities may be affected should be considered so that appropriate action is taken, including measures to control any affected work in process, if necessary. Documentation of the ~~adverse~~ condition may be accomplished in various forms, including QC inspection reports, nonconformance reports, independent design reviews, procedures (work place, implementation, etc.), audit reports, or other similar documents.

There are multiple sources of information that could indicate conditions adverse to quality. The program established should ensure these sources are reviewed and evaluated to assure conditions adverse to quality are appropriately documented and resolved, including the evaluation of significance. Many ~~of the~~ conditions ~~identified~~ will be identified through the work processes controlling ~~the~~ design and construction activities, and ~~these~~ conditions that are not determined to be a significant condition adverse to quality (SCAQ) or not significant to ITAAC conclusion may ~~need to be~~ be documented and corrected within the work process as described in the following sections.~~.~~ Information sources for identifying conditions include, but are not limited to licensee audit and inspection reports, tests, design reviews, individual observations, adverse trends, and maintenance activities.

Conditions may also be identified external to the work processes such as through NRC inspections; construction experience~~ noted with other contractors, or at other sites~~; ~~individuals who may not feel comfortable reporting a condition through their~~

~~supervision~~Employee Concerns Program; 10 CFR Part 21 notifications, or 10 CFR 50.55(e) notifications. As shown in Attachment 1, conditions identified external to a work process are entered into the Corrective Action Program, evaluated, and resolved in ~~accordance with~~accordance with the significance of the condition. ~~The information reviewed may be generated by internal or external organizations and includes, but is not limited to, audit reports, inspection reports, tests, design reviews, individual observations, adverse trends, 10 CFR Part 21/10 CFR 50.55(e) notifications, and maintenance activities.~~

Construction or operating experience and NRC generic communications should be reviewed for applicability to conditions that exist at the facility and to assist in the identification of adverse trends.

4.2 SCREENING, EVALUATION AND CLASSIFICATION

4.2.1 Screening to Identify Conditions ~~that are Adverse to Quality or Otherwise~~that ~~Warrant~~ Require Further Review

~~Conditions identified via Design Control, Inspection, or other quality work process should be screened for significance.~~

The first step in the screening ~~classification~~ process is a ~~screening~~ review of the identified condition, regardless of the source of the identification (i.e., work process or externally identified), to determine whether the condition or activity is quality-related and if the condition is deemed a CAQ ~~condition adverse to quality~~. The screening process procedures should identify the persons responsible to determine when a condition requires further review for significance. For a CAQ~~conditions determined to be adverse to quality~~, an ~~additional review~~ evaluation is performed (as described in 4.2.2) to determine if a SCAQ exists.~~assess the significance of the condition.~~

The screening process established should include the following criteria for determining which conditions are adverse to quality or otherwise should receive further review for significance:

a) Impact on the health and safety of the public or environment

b) Impact on reliability, availability, or maintainability of the equipment or facility

c) Importance of meeting regulatory commitments

d) Consequence of repetition

e) The extent to which the adverse condition may apply to other equipment or activities beyond the specific occurrence where it may have greater impact

f) Impact on ITAAC conclusions, including closed ITAAC (see subsection 4.2.3 below and NEI 08-01)

Attachment 2 lists examples that are intended as guidance for each organization to use with respect to developing company- or facility-specific screening criteria. The middle column of the Attachment 2 tables depicts the type of conditions that require further evaluation of significance by knowledgeable individuals (e.g. first line supervision) ascertain the broader aspects beyond the specific ~~work~~ process where the condition was identified. CAQ~~onditions~~ identified through a work process that are determined not to require further significance evaluation may be corrected in the work process, provided the work process contains the proper controls and documentation to support trending~~low significance conditions~~, as discussed in Section 5. Conditions not adverse to quality that are identified within the work processes should be dispositioned ~~as directed by IAW~~in accordance with applicable work process procedures~~management~~. Examples of conditions that typically may be corrected within the work processes are identified in the left column of the table in Attachment 2.

Certain conditions also require reporting to regulatory agencies. The construction corrective action processes should interface with the reporting program of the licensee or supplier to ensure conditions adverse to quality are evaluated under the appropriate 10 CFR Part 21, 10 CFR 50.55(e), 10 CFR 52.6, or other regulatory requirements.

~~The screening process procedures should identify the persons responsible to determine when conditions require further evaluation.~~

There should be uniform screening criteria used for the construction site. To ensure consistent screening, the Licensee will provide oversight of implementation of the corrective action processes using the quality assurance program.

4.2.2 Evaluation to Identify Significant Conditions

For CAQ~~conditions adverse to quality~~ or otherwise requiring further review for significance, an evaluation should be performed by the organization implementing the construction corrective action processes to determine which conditions are classified as SCAQ ~~significant conditions adverse to quality~~ and therefore require cause analysis and actions to preclude repetition. Individuals performing significance evaluations should ~~and~~ have the training and knowledge needed to be able to recognize the broader implications beyond the specific ~~work~~ process where the condition was identified ~~and identify~~ to determine when a SCAQ ~~significant conditions adverse to quality~~exists. The significance of a condition may be dependent on specific circumstances related to the design or end use of the equipment including the potential effect of the condition on ITAAC conclusions or reliability assumptions used in the plant-specific Design Reliability Assurance Program (DRAP).

If the further evaluation determines that the condition is a CAQ ~~of low significance~~, the ~~condition~~ CAQ may be assigned to be corrected in the work process, provided the work process contains the proper controls for appropriate documentation to support trending ~~low significance conditions~~, as discussed in Section 5. If the further evaluation determines that the condition is a ~~significant condition adverse to quality (~~SCAQ~~)~~ or is significant to ITAAC conclusion, it should be entered into the Corrective Action Program

(CAP). ~~At the discretion of management, significant industrial safety, security or other non-quality related conditions may also be entered into the CAP.~~

Attachment 2 lists examples that are intended as guidance for each organization to use with respect to developing company- or facility-specific evaluation criteria. The right-hand column of the tables in Attachment 2 ~~is~~ contains examples of CAQ ~~conditions~~ typically considered significant, i.e., ~~including~~ SCAQ.

The evaluation must be completed promptly to ensure that appropriate actions are assigned and completed in a timely fashion. Each organization should establish criteria for prompt evaluation and timely correction. If the condition is specific to a supplier and the supplier cannot determine significance, the condition should be promptly reported to the licensee. Since it is impossible to anticipate every circumstance, management discretion is a necessary part of significance classification.

The information considered in significance evaluations may be generated by internal or external organizations and includes, but is not limited to, audit reports, inspection reports, tests, design reviews, individual observations, adverse trends, 10 CFR Part 21/10 CFR 50.55(e) notifications, and maintenance activities.

For SCAQ~~conditions determined to be significant~~, entry into CAP is required, and additional construction corrective action process elements are implemented as discussed in Sections 4.3 through 4.6.

Management (contractor and licensee) notification, including senior management responsible for the corrective action, is required when a SCAQ ~~significant conditions adverse to quality are~~ is identified.

4.2.3 Evaluating Conditions for Significance to ITAAC Conclusions

Conditions identified as needing further evaluation for significance should be evaluated to determine if the conditions are material to an ITAAC conclusion. The next step is to determine whether a condition material to an ITAAC conclusion should be placed into the CAP or may be addressed in the applicable work process. ~~conclusion in an ITAAC Closure Letter submitted to the NRC in accordance with 10 CFR 52.99(c).~~

- If the condition is determined to *not* be material to an ~~a prior~~ ITAAC conclusion ~~conclusion~~ and is not otherwise determined to be a SCAQ~~or otherwise significant~~, it may be corrected and documented in the applicable work process. ~~If the condition is determined to be material to a prior ITAAC conclusion, it should be entered into the CAP.~~
- If the condition is determined to be material to an ITAAC conclusion but an ITAAC Closure Letter has not yet been submitted to the NRC, the condition may be addressed in the applicable work process provided it was not otherwise determined to be a SCAQ. Exception: Conditions identified by the NRC as ITAAC-Related Construction Findings should be entered into the CAP.

- If the condition is determined to be material to a conclusion in an ITAAC Closure Letter previously submitted to the NRC in accordance with 10 CFR 52.99(c)(1), it should be entered into the CAP.
- Prior to submittal of ITAAC Closure Letters, conditions identified by the NRC as ITAAC-Related Construction Findings should be entered into the CAP.

For conditions identified as needing further evaluation for significance, vendors and sub-vendorssuppliers should coordinate with the licensee to determine the submittal status of ITAAC Closure lLetters and whether conditions are material to a prior ITAAC conclusion and thus should be entered into the CAP.

4.2.4 Classification

Conditions identified via a work process and determined to be SCAQ or material to an ITAAC conclusion (as discussed 4.2.3 above) significant are classified as such and processed within the CAP and are classified as SCAQ or otherwise significant (e.g., material to an FEIS determination, material to a prior ITAAC conclusion, or other significant issue). Conditions identified external to a work process are evaluated to determine if they are a SCAQ or material to an ITAAC conclusion and entered interesolved via the CAP as appropriate. Based on the significance classification and the nature of the specific condition, requirements for determining the cause, taking action to preclude repetition, and reporting to appropriate management are identified and implemented as discussed in Section 4.3, 4.4 and 4.5, below.

Formatted: Right: 0"

Conditions not classified as SCAQentered into CAPthat are not SCAQ or material to an ITAAC conclusion The classification evaluation provides another opportunity to determine that a condition is of low significance and may be assigned to be corrected in the a work process, as discussed in Section 5.

4.3 CAUSE ANALYSIS

Cause analysis is required for a SCAQsignificant conditions adverse to quality. Action will be taken for a SCAQ significant condition adverse to quality to preclude repetition of the condition. For some conditions, the cause may be obvious and does not need rigorous analysis to determine corrective actions to preclude repetition. For more complex conditions, an individual or a team trained in causal analysis techniques should evaluate significant problems using a structured causal analysis methodology to identify causes and corrective actions to preclude repetition. Management should be informed of the cause analysis determination and the identified actions to preclude repetition.

The documentation of the analysis includes:

(a) determination of cause;

(b) extent of condition (including review of applicable construction experience); and

(c) identification of corrective actions, including those to preclude repetition.

Management may also require causal analysis for other significant conditions even though they are not SCAQ~~adverse to quality~~.

4.4 CORRECTIVE ACTIONS

~~Corrective actions to prevent recurrence are applied commensurate with the significance of the condition. Additionally, e~~Each CAQ~~condition adverse to quality~~ requires action to correct the condition. Additionally, for SCAQ, corrective actions to preclude repetition are applied commensurate with the significance of the condition. Corrective actions should be completed in a timely manner commensurate with the condition's safety significance and complexity. In determining the actions to take, the following should be considered: (1) the consequence of malfunction or failure of the equipment; (2) the design and fabrication complexity or uniqueness of the equipment; (3) the need to apply special controls and/or surveillance over the processes and equipment; (4) the degree to which functional performance can be demonstrated by inspection or test of the equipment; (5) the quality history and degree of standardization of the equipment; (6) the difficulty of repair or replacement, especially after installation; and (7) the effect on ITAAC conclusions (refer to NEI 08-01). The actions taken to correct a condition should be documented to allow further review and evaluation.

Corrective actions implemented for SCAQ ~~significant conditions adverse to quality~~ are to be promptly reported to appropriate levels of management. The appropriate management to be notified should be established within the implementing procedures. If the construction corrective action processes ~~program is~~ are delegated to a ~~contracted organization~~supplier, the interface and requirements for reporting should be clearly documented.

4.5 VERIFICATION AND FOLLOW-UP

Corrective actions for CAQ and SCAQ will be implemented and verified as required. Monitoring of corrective action status is necessary to assure completion in a timely manner.

Corrective actions for SCAQ~~significant conditions adverse to quality~~ are verified after the actions are completed, and results are indicated in the CAP. Additionally, for SCAQ~~significant conditions adverse to quality~~, an effectiveness review of the corrective actions taken to preclude repetition is performed and documented in the CAP.

When corrective actions are found not to be effective or timely, management will be notified. Management will then determine what additional actions, if any, are necessary to be taken.

4.6 ANALYZING FOR ADVERSE TRENDS

Periodically, CAQ ~~conditions adverse to quality~~ should be analyzed for adverse trends within and across the various work processes and the CAP. A trending process should be implemented that can identify adverse trends that are QA program deficiencies or significant to safety (such as repetitive failures or process weaknesses). This review is conducted to identify generic issues and vulnerabilities early in the work process before significant problems result. Management personnel responsible for the work activities are responsible for identification of thresholds for trending to determine the presence of adverse trends, repetitive failures, process weaknesses, or other indicators of extent of cause or condition beyond the immediate problem identified.

Construction or operating experience and NRC generic communications should be reviewed for applicability to conditions that exist at the facility and to assist in the identification of adverse trends.

If this analysis indicates an adverse trend, that trend should be evaluated consistent with Section 4.2 to determine whether further action is necessary. Determination of adverse trends is dependent on the nature of conditions being trended. Procedures for individual work processes should include guidance and criteria for identifying adverse trends.

To identify patterns that warrant broad corrective actions, trending can also be accomplished using detailed codes and data analysis techniques for certain work processes. One type of trending level or technique is not practical for all conditions; therefore, a thoughtful approach to trending should be implemented by licensees and suppliers during nuclear construction.

Adverse trends should be reported to management responsible for the work activity. Management should provide oversight of the trending process to assure the process is properly implemented.

An adverse trend may exist if:

- Deficiencies identified are of a repetitive nature and the number appears excessive or exceeds an established criteria or threshold, taking into consideration time frames and levels of associated line organization and QA/QC activities.
- Recurring deficiencies that are of a significant or severe nature.
- Increases in the number of deficiencies that cannot be easily attributed to new or special work programs, or increased quality verification activities.
- Deficiencies are of a programmatic nature, apparently not limited to a specific organization.
- Previously identified corrective actions are apparently ineffective in reducing the number or severity of deficiencies.
- Recurring deficiencies appear to be related to a possible single root cause.
- Deficiencies of a like nature are being identified in multiple work activities.

The goal of the trending program is early recognition of trends so underlying causes can be investigated and actions taken before major issues/conditions occur, thus allowing for continual improvement.

5 IDENTIFICATION AND CORRECTION OF CONDITIONS THROUGH WORK PROCESSES

As stated previously, ~~some degree of corrective action is an inherent part of the work processes that implement the QAP requirements for the nuclear facility. The work processes include approriate10 CFR Part 50, Appendix B, Criterion XVI, corrective action process elements~~work processes are quality processes subject to the applicable requirements of 10 CFR Part 50, Appendix B Criterion XVI and the QAP. These quality processes include appropriate corrective action process elements as described in Section 4 (e.g., identification, documentation, correction of conditions within the scope of the work processes). Entry into the CAP is performed per 4.2.4.

Corrective actions for nonconformances, failures, malfunctions, deficiencies, and defective equipment may occur within the work processes. In general, conditions that are still within control of the work process, where the work has not been declared complete, are not conditions adverse to quality requiring further evaluation and are not required to be entered in the CAP. Examples would be: design errors identified before all approvals are complete for a calculation; installation errors identified before the final QA/QC verification is complete and where correction is within the scope of the work process; certain non-conforming material where the work process contains guidelines for repairing the material; etc.

Conditions and corrective actions should be documented in a format that permits reviewing, trending, and verifying the results of the activities. Management responsible for the work processes~~ activities is responsible for~~ should establish~~ing~~ a process and procedures to identify ~~adverse conditions~~ CAQ that require further evaluation of their significance including the identification of adverse trends. CAQ ~~onditions~~ that receive further evaluation for significance, but ultimately are determined not to be SCAQ~~significant~~, may nonetheless be entered into the CAP, at the discretion of the licensee/supplier to allow for the consolidation of documentation and trending.

NQA-1-1994 Basic and Supplemental Requirements discuss the resolution of nonconformances, failures, malfunctions, deficiencies, and defective equipment. The following are examples where work processes may be implemented.~~for~~in ~~areas where work processes may be implemented: that discuss documentation and resolution of certain CAQ. As the work processes are developed the NQA-1 requirements are factored into the processes, including any specified correction of CAQ..conditions adverse to quality.~~

1. NQA-1-1994 Basic Requirement 3 and Supplement 3S-1 for Design, states that changes to final designs, field changes, and nonconforming items dispositioned

use-as-is or repair shall be justified and are subject to design control measures commensurate with those applied to the original design.

If a significant design change is necessary because of an incorrect design, this supplement requires modification of the design process and verification procedure, if necessary. In this case the identified condition that resulted in the need for the design change should be treated as a significant condition adverse to quality.

2. NQA-1-1994 Basic Requirement 4 and Supplement 4S-1 for Procurement Document Control. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. Any missing or incorrect provisions in the procurement documents which assure items or services will meet the specified requirements discovered during review shall be corrected.

3. NQA-1-1994, Supplement 7S-1, Supplementary Requirements for Control of Purchased Equipment and Services, paragraph 9, addresses actions for disposition of equipment and services that do not meet procurement documentation requirements including the evaluation, submittal and disposition approval of supplier generated nonconformances and nonconforming items.

4. NQA-1-1994 Basic Requirement 10 and Supplement 10S-1for Inspection paragraph 2 requires the inspection activities to be documented and controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. Paragraph 4 addresses the identification of hold points. Paragraph 5 requires the planning documentation to include characteristics, methods, and acceptance criteria and to provide for recording of objective evidence of the inspection results. Paragraph 6 provides for in-process inspection. Paragraph 7 addresses final inspections, including the resolution of nonconforming items identified by prior inspections. Paragraph 7.4 requires re-inspection or retest if a piece of equipment or system is modified, repaired, or replaced subsequent to the final inspection. Paragraph 9 identifies inspection records, which include reference to information on action taken in connection with nonconforming items.

5. NQA-1-1994 Basic Requirement 11 and Supplements 11S-1for Test Control and 11S-2 for Computer Program Testing NQA-1-1994, require identification of Test Requirements and Acceptance Criteria and use of written test procedures that identify required monitoring, environmental conditions, and prerequisites for the tests. Paragraph 4 and 5 require review of results for acceptability and documentation of actions taken in connection with any deviations noted.

   As identified in Part II, Section11 of NEI-06-14A, *Quality Assurance Program Description,* Supplement 11S-2, Supplementary Requirements for Computer Program Testing, is used in conjunction with Subpart 2.7, Quality Assurance

Requirements of Computer Software for Nuclear Facility Applications. Subpart 2.7 requires documentation and review of test results. Required verification documentation includes results and acceptability and actions taken in connection with any deviations noted.

6. NQA-1-1994 Basic Requirement 12 and Supplement 12S-1 for Control of Measuring and Test Equipment NQA-1-1994, addresses actions to be taken when measuring and test equipment (M&TE) is found to be out of calibration, including a documented evaluation of the validity of previous inspection or test results and of the acceptability of equipment previously inspected or tested.

7. NQA-1-1994 Basic Requirement 15 and Supplement 15S-1 for Control of Nonconforming Items NEI 06-14A, *Quality Assurance Program Description (QAPD) Template*, describes the quality assurance program requirements. The controls include identification, documentation, evaluation, and correction. In addition, nonconforming item dispositions are reviewed for adequacy, analyzed for quality trends, and reported to designated management.

   NQA-1-1994, Basic Requirement 15 further amplifies these requirements by requiring that controls shall be provided for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification of affected organizations. Supplement 15S-1, Supplementary Requirements for the Control of Nonconforming Items, requires identification and disposition of nonconforming items.

8. NQA-1-1994 Basic Requirement 18 and Supplement 18S-1 for Audits, includes requirements for establishing audit programs. The requirements include documentation of the audit results. If audit findings are identified, corrective actions shall be initiated and documented. Documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means are required to verify implementation of the assigned corrective action.

   Consistent with the requirements stated above, NQA-1-1994, Supplement 18S-1, Supplementary Requirements for Audits, requires the documentation audit findings for corrective action and addresses follow-up verification of corrective action completion.

Procedural guidance for documenting and resolving CAQ ~~conditions adverse to quality~~ must include specific steps to ensure these NQA-1 requirements ~~sources~~ are reviewed and evaluated to assure CAQ ~~conditions adverse to quality~~ are appropriately documented and resolved, including the appropriate significance evaluation.

Management responsible for the work processes ~~activities~~ ~~is responsible for~~ should ensure~~ing~~ a program is developed for identification of adverse trends, such as repetitive failures or process weaknesses. These programs should establish procedures for

documentation, actions necessary to resolve the conditions that caused the trend, and notification to the appropriate levels of management (refer to Section 4.6).

Work processes should be periodically reviewed (sample, self assessment, etc) to ensure that CAQ requiring further evaluation or SCAQ have been correctly characterized.

Each document generated within a work process must meet the requirements established within the QA Program for defining, controlling and verifying the quality of the activity or equipment. The process must include the provisions for documenting identification of CAQ and corrective actions to a level of detail necessary to allow the process to be carried out in a correct manner, and permit verification that the specified requirements are met. Documentation of the ~~adverse condition~~ CAQ may be accomplished in various forms, including QC inspection reports, nonconformance reports, independent design reviews, procedures (work place, implementation, etc.), audit reports, or other similar documents.

Work Process managers will screen (4.2.1) concerns to determine if the concern needs further evaluation for significance (Attachment 2) as stated in the work process procedure). Where ~~conditions~~ CAQ are of the nature of those identified in Attachment 2, initial corrective actions may be implemented, but they ~~adverse conditions~~ are documented and processed for ~~further~~ evaluation of their significance as described in Section 4.2.2. Any condition, nonconformance, or CAQ ~~condition adverse to quality~~ that adversely impacts an ITAAC conclusion, including closed ITAAC, should be processed for further evaluation of significance as previously described in Section 4.2.3.

~~If conditions adverse to quality identify Nonconforming Items as defined in NQA-1, then Requirement 15 of that standard on Control of Nonconforming Items must be applied per the QAPD.~~

The work process manager will ensure that if workers find problems outside their work process they are appropriately documented in accordance with this document.

6 RECORDS

Records of corrective actions and nonconforming item resolution are retained in accordance with the applicable ~~licensee's~~ QAPD.

7 TRANSITIONING TO THE OPERATIONS CORRECTIVE ACTION PROGRAM

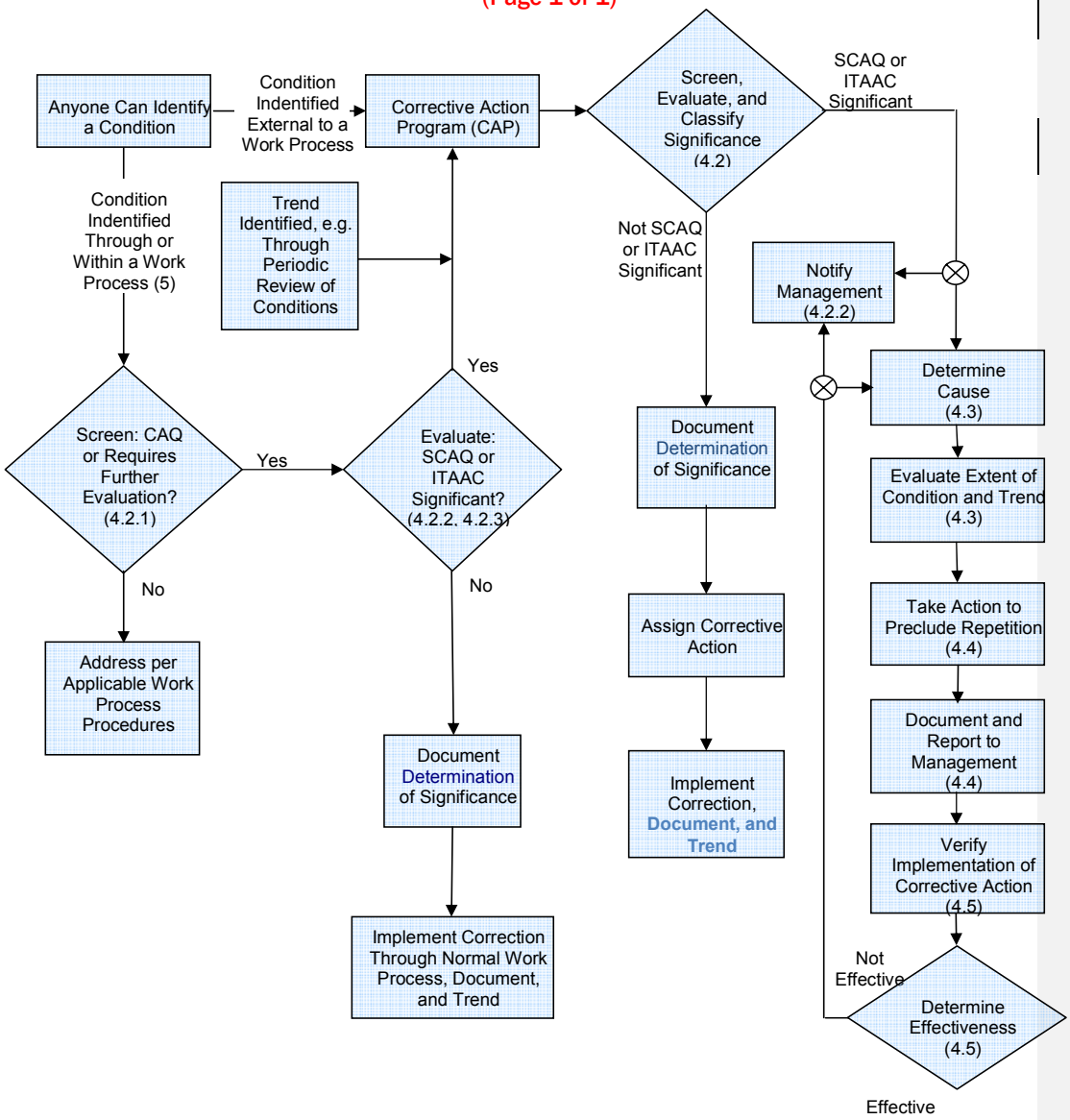
The licensee will determine the appropriate time to transition from the construction corrective action processes to the operations phase processes. Transition to the operations corrective action processes may occur based on subsystem, system, or building turnover, but must not occur later than 30 days prior to the scheduled loading of fuel (Ref. 10 CFR 50.54(a)). CCAP aspects related to identifying issues with closed ITAAC may continue to be used until the Commission's finding under 10 CFR

52.103(g).~~This transition should be no later than 30 days prior to being ready to load nuclear fuel.~~ As a part of this transition, the licensee will verify that all open conditions are evaluated to determine if they should be placed into the operations corrective action processes with a date for their resolution. Construction-phase corrective action processes related to identifying, correcting, and notifying management of conditions that affect a closed ITAAC should continue until the Commission makes its Section 52.103(g) ITAAC finding. If systems or subsystems have been transferred to the licensee prior to the 52.103(g) finding and a condition is identified related to an ITAAC conclusion the condition will be resolved within the licensee corrective action process.

ATTACHMENT 1

Construction Corrective Action Processes Flow

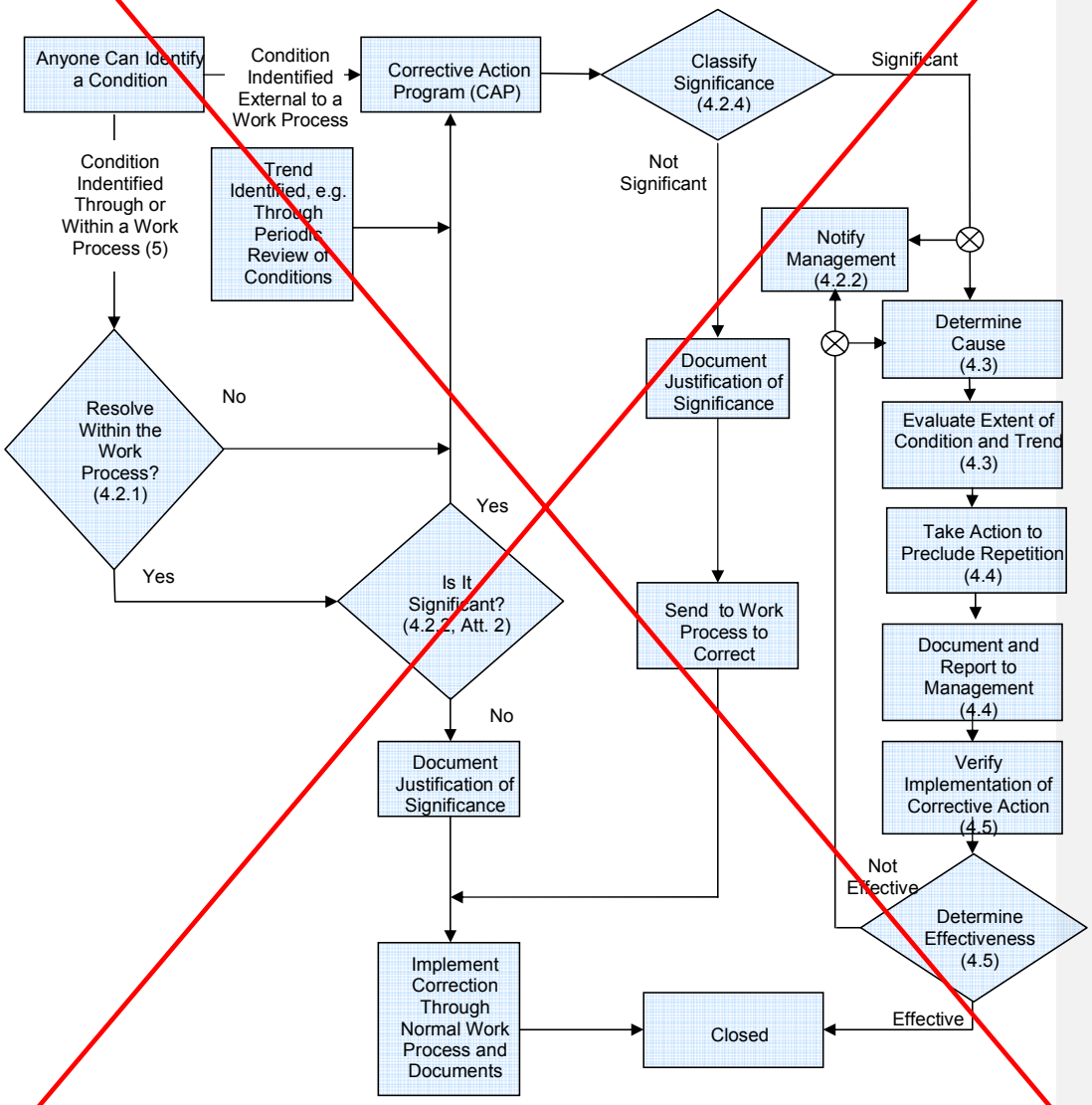
(Page 1 of 1)



ATTACHMENT 1

Construction Corrective Action Processes Flow

(Page 1 of 1)



ATTACHMENT 2

Examples for Screening, Evaluating and Classifying Conditions in the Construction Corrective Action Processes

NOTE: The following tables contain~~s~~ examples of conditions adverse to quality (CAQ) ~~conditions~~ that may be identified during the construction phase. The table illustrates the differences between CAQ ~~conditions~~ of generally lesser significance that may typically be addressed within the work processes, ~~conditions~~ those that require further evaluation for significance, and those ~~conditions~~ that would typically be considered ~~S~~significant CAQ ~~significant~~ and thus entered in the Corrective Action Program. A table is also included that addresses conditions affecting an ITAAC conclusion. These examples are not all-inclusive, but are intended to guide the user of this document in developing and implementing criteria for screening, evaluating and classifying conditions as discussed in Section 4.2 of this guideline.

ATTACHMENT 2

Design Control		
~~Conditions/Nonconformances/~~Conditions within the scope of the Work Processes	Conditions adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• Design errors identified and documented during (independent) Design Verification – e.g., wrong input specified or incorrectly incorporated into the design, improper assumption utilized, improper design method, calculation error, insufficient design margin, inappropriate material specified • Configuration management discrepancies (e.g. minor interferences due to tolerance stack-up) • Drafting errors that do result in incorrect or deficient design • Computer software deficiencies identified during or after verification testing that are determined to be isolated to software that has not been utilized in any application	• Design errors or deficiencies found in design documents, (e.g. drawings, specifications, calculations, etc.) after release for use, procurement, or construction • A deviation, nonconformance, or failure to comply with regulations that could result in a substantial safety hazard as defined in 10 CFR Part 21 or 10 CFR 50.55(e) • A design deficiency that results in deviation from performance specifications that could: (1) require extensive evaluation or redesign to establish the adequacy of the structure, system, or component to perform its intended function or (2) fail to meet Design Reliability Assurance or ITAAC requirements • A design condition identified after an piece of equipment, activity, or service is released for use that would prevent the piece of equipment, activity, or service from meeting or performing its intended function or output • An adverse trend related to the design control program • Operating/construction experience or reviews that identify a failure to meet design requirements • Completed construction activities are not within the tolerances allowed by design documents or process controls	• Design documents or drawings released for construction do not meet applicable codes or deviates from design criteria and bases (including unapproved deviations or departures from the Certified Design or Combined License) or uses a code that is not qualified/accepted for use • A deviation, nonconformance, or failure to comply with regulations found to be reportable under 10 CFR Part 21 or 10 CFR 50.55(e) • A design deviation from performance specifications that: (1) requires extensive evaluation or redesign to establish the adequacy of the structure, system, or component to perform its intended function or (2) fails to meet Design Reliability Assurance or ITAAC requirements • An adverse trend related to the design control program indicating a significant program or process breakdown • A design deficiency by which the capability to withstand a single failure is compromised, where required • A significant error in a computer program used to support activities affecting quality after it has been released for use (e.g. the error results in significant non-conservative analytical results relied upon in a safety-related design)

ATTACHMENT 2

Control of Purchased Items		
~~Conditions/Nonconformances/~~ Conditions within the scope of the Work Processes	Conditions adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• Conditions identified with equipment or materials identified during receipt inspection that deviate from technical or quality requirements specified in the purchase documents • Errors in procurement document (inadequate procurement requirements that affect the quality of the item or service) identified prior to issuance • Inadequate storage conditions that have not impacted stored items	• Deviations from procurement documents or other quality-related conditions identified by the buyer in the supplier's shop prior to the delivery of the product to the purchaser • Procurement document errors (inadequate procurement requirements that affect the quality of the item or service) identified after issuance but prior to authorization of the supplier to perform work • Procurement document errors (inadequate procurement requirements that affect the quality of the item or service) identified after the supplier has been given a notice to proceed with the affected activities • A deviation, nonconformance, or failure to comply with regulations that could result in a substantial safety hazard as defined in 10 CFR Part 21 or 10 CFR 50.55(e) • Inadequate environmental storage conditions that have potentially degraded stored items • Programmatic procurement-related conditions • An adverse trend in the procurement of items or services • The loss of essential data required for activities or items subject to the QA program (QA Records) Conditions/Nonconformances/Conditions Adverse to Quality • Conditions identified with equipment or materials identified after receipt inspection that deviate from technical or quality requirements specified in the purchase documents	• Evidence of fraudulent activities by the supplier • Procurement document errors (inadequate procurement requirements) that result in an item delivered by the supplier to be of insufficient quality for its intended purpose and it has been installed • A deviation, nonconformance, or failure to comply with regulations found to be reportable under 10 CFR Part 21 or 10 CFR 50.55(e) • An adverse trend in the procurement of items or services that indicates a significant program or process breakdown • Inadequate environmental storage conditions that degrades a stored item that has been released for use and if installed couldn't perform its intended safety function

ATTACHMENT 2

Control of Special Processes		
~~Conditions/Nonconformances/~~ Conditions within the scope of the Work Processes	Conditions adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• Unsatisfactory weld inspection or nondestructive examination results to predetermined criteria that can be reworked in accordance with an approved Welding Procedure Specification (e.g., excessive undercut, undersized weld, linear indication, lack of penetration, arc strikes, scratches) • Improper weld preparation (e.g. dimensions for an EB insert, improper land dimension, wrong face angle) identified within the process • Improper preparation for coating application identified within the process • Deficiencies related to code compliance identified during review of procedures governing special processes prior to release for use • Equipment (e.g. weld machine, NDE equipment, heat treating equipment, fire-resistant foam machine, M&TE, etc.) malfunction identified prior to or during the process • Performing special process without proper instructions/procedure (e.g. weld traveler) with no material impact	• Major weld defects after weld completion where engineering disposition is required for directing repair • Weld rod control problems that resulted in incorrect filler material in an accepted weld installed in the facility • Improper weld preparation (e.g. dimensions for an EB insert, improper land dimension, wrong face angle) identified outside the process • Improper preparation for coating application identified outside the process • A deviation, nonconformance, or failure to comply with regulations that could result in a substantial safety hazard as defined in 10 CFR Part 21 or 10 CFR 50.55(e) • Equipment malfunctions identified after completion of the process • Heat treatment outside procedure acceptance criteria (requiring engineering evaluation) • Unqualified process/procedure/person used (may be weld/welder, NDE technician, coating, concrete mix adjustment, fire barrier installation, etc.) for fabrication/installation • Expired shelf life of consumable material (e.g. NDE materials, fire barrier material, coatings, etc.) discovered after their use • An adverse trend related to an activity or item subject to process controls • Performing a special process without proper instructions/procedure.	• Major weld process control problems (programmatic) that could result in significant defects • Weld rod control problems that resulted in incorrect filler material in an accepted weld installed in the facility that results in noncompliance with the applicable code • A deviation, nonconformance, or failure to comply with regulations found to be reportable under 10 CFR Part 21 or 10 CFR 50.55(e) • Unqualified process/procedure or personnel used (may be weld/welder, NDE technician, coating, concrete mix adjustment, fire barrier installation, etc.) for fabrication/installation, and the process/procedure/person could not qualify when attempted • Programmatic process control problems that result in unacceptable defects • An adverse trend related to an activity or item subject to process controls that indicates a significant program or process breakdown

ATTACHMENT 2

Inspection		
~~Conditions/Nonconformances/~~ Conditions within the scope of the Work Processes	Conditions adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• Inspection results that indicate deviation from engineering drawings, specifications, procurement documents, or procedures identified during in process Quality Control inspection activities.	• A deviation, nonconformance, or failure to comply with regulations that could result in a substantial safety hazard as defined in 10 CFR Part 21 or 10 CFR 50.55(e) • Inspection results that indicate deviation from engineering drawings, specifications, or procedures identified after final acceptance/inspection • Conditions where an item failed to meet specified requirements during final inspection. • The inspection identifies a deviation from the controlling process (e.g., incorrect or unqualified process implemented, bypassed hold points) • The loss of essential data required for activities or items subject to the QA program (QA Records) • An adverse trend related to the inspection program • Inspector not qualified for inspection performed • Unsatisfactory inspection results where corrective action involves multiple work processes • A program or process deficiency that has the potential to affect a previously accepted inspection	• A deviation, nonconformance, or failure to comply with regulations found to be reportable under 10 CFR Part 21 or 10 CFR 50.55(e) • Evidence of fraudulent activities or material • An adverse trend related to the inspection program that indicates a significant program or process breakdown

ATTACHMENT 2

Test Control		
~~Conditions/Nonconformances/~~ Conditions within the scope of the Work Processes	Conditions adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• Conditions identified during the set-up of the test • Computer software deficiencies identified during or after verification testing that are determined to be isolated to software that has not been utilized in any application • Test equipment malfunctions • Conditions or problems identified during tests (equipment functional and pre-operational testing problems) that can be corrected within the test plan	• A deviation, nonconformance, or failure to comply with regulations that could result in a substantial safety hazard as defined in 10 CFR Part 21 or 10 CFR 50.55(e) • Control system error identified after software has been released for use • Inadequately performed test due to test procedure not adhered to or incorrectly written • An adverse trend related to the test program • Test personnel not qualified for test performance • The loss of essential data required for activities or items subject to the QA program (QA Records)	• A deviation, nonconformance, or failure to comply with regulations found to be reportable under 10 CFR Part 21 or 10 CFR 50.55(e)A significant error in a computer program used to support activities affecting quality after it has been released for use (e.g. the error results in significant non-conservative analytical results relied upon in a safety-related design) • Control system error in the safety-related control system that would result in an unintended action or disable the system that is identified after software has been released for use • An adverse trend related to the test program that indicates a significant program or process breakdown

ATTACHMENT 2

Control of M&TE		
~~Conditions/Nonconformances/~~ Conditions within the scope of the Work Processes	Conditions adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• M&TE found out of the required accuracy limits (i.e., out of tolerance) during post-use calibration that does not require reinspection or retest • Calibration activities not performed in accordance with specified procedures identified prior to issuance of M&TE • Incorrect specifications or standards utilized in calibration process identified prior to issuance/use of M&TE • Evaluation of out of tolerance, lost, or damaged M&TE indicates questionable acceptability for previous inspection or test results indicating the need to re-inspect or re-test the SSC	• Re-inspection or re-test of an SSC, as a result of out of tolerance, lost, or damaged M&TE, has an unacceptable result • Calibration activities not performed in accordance with specified procedures – • Incorrect specifications or standards utilized in calibration process identified after issuance/use of M&TE • A deviation, nonconformance, or failure to comply with regulations that could result in a substantial safety hazard as defined in 10 CFR Part 21 or 10 CFR 50.55(e) • An adverse trend related to the M&TE program	• Evidence of Fraudulent activities associated with calibration or use of M&TE • A deviation, nonconformance, or failure to comply with regulations found to be reportable under 10 CFR Part 21 or 10 CFR 50.55(e) • An adverse trend related to the M&TE program that indicates a significant program or process breakdown

ATTACHMENT 2

Nonconforming Materials (Items)		
~~Conditions/Nonconformances/~~ Conditions within the scope of the Work Processes	Conditions adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• Nonconforming item conditions from engineering technical or quality requirements dispositioned as repair, rework, or use-as-is that is within the design requirements for the item prior to installation • Expired shelf life identified prior to using the material • Nonconforming item discovered prior to final acceptance • Damaged safety-related or quality-related item received at site	• A deviation, nonconformance, or failure to comply with regulations that could result in a substantial safety hazard as defined in 10 CFR Part 21 or 10 CFR 50.55(e) • An adverse trend related to nonconforming items • Nonconforming item that renders the quality of an installed component unacceptable or indeterminate identified after final acceptance • Nonconforming item identified that potentially has broad industry implications	• A deviation, nonconformance, or failure to comply with regulations found to be reportable under 10 CFR Part 21 or 10 CFR 50.55(e) • An adverse trend related to nonconforming items that indicates a significant program or process breakdown

ATTACHMENT 2

Audits		
~~Conditions/Nonconformances/~~ Conditions within the scope of the Work Processes	Conditions adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• Audit findings for corrective action requiring response by the management of the audited organization, and follow-up verification of corrective action completion as directed in the audit report	• A deviation, nonconformance, or failure to comply with regulations that could result in a substantial safety hazard as defined in 10 CFR Part 21 or 10 CFR 50.55(e) • An adverse trend related to the audit program • Audit team member not qualified • A program or process deficiency that has the potential to affect audit performance • Audit team fails to provide objective evidence to substantiate the audit conclusion • Audit team members are not independent of the process being audited • Isolated cases of not performing audits within the required frequency • Failure to follow-up corrective action • Audit findings requiring corrective action and a response by the management of the audited organization, and follow-up verification of corrective action completion as authorized by the audit procedure	• Adverse audit findings indicative of a significant quality assurance program breakdown (Ref. 10 CFR 50.55(e)) • A deviation, nonconformance, or failure to comply with regulations found to be reportable under 10 CFR Part 21 or 10 CFR 50.55(e) • An adverse trend related to the audit program that indicates a significant program or process breakdown • Audit program is inhibited • Repeated occurrences of not performing audits within the required frequency • Audit team fails to identify pre-existing conditions such as: inadequate records retention, inadequate supplier ~~PI&R~~ CCAP process implementation, or inadequate configuration control

ATTACHMENT 2

Other Areas Affecting Quality Assurance		
~~Conditions/Nonconformances/~~ Conditions within the scope of the Work Processes	Conditions adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• Corrections of obvious editorial or typographical errors on a QA Record • Surveillance findings for corrective action requiring response by the management of the organization, and follow-up verification of corrective action completion as directed in the surveillance report • Foreign Material Exclusion concerns such as near miss events in systems/components important to Nuclear Safety prior to turnover • Work packages or Travelers found to have incorrect instructions before being issued for use. • Incorrect supplier manuals/instructions identified during work execution prior to SSC turnover • Isolated examples of failure to follow procedures • Isolated examples of inadequate management oversight of individual processes • Construction experience/operating experience determined to be applicable to the facility.	• A deviation, nonconformance, or failure to comply with regulations that could result in a substantial safety hazard as defined in 10 CFR Part 21 or 10 CFR 50.55(e) • Adverse surveillance findings indicating a programmatic breakdown • Significant procedural or administrative control non-compliance that affects plant safety • A nonconformance that indicates a problem exists within the controlling process as opposed to a hardware condition • Work packages or Travelers found to have incorrect instructions after being issued for use and implementation ~~• Completed construction activities are not within the tolerances allowed by design documents or process controls~~ • Procedural adherence issue • Loss of essential data required for activities or items subject to the QA Program (QA Records) • Missing, incomplete or otherwise deficient QA Records • Documentation required by NRC requirements such as 10 CFR 50.49 is unavailable or deficient • Any adverse trend related to an activity or item subject to the QA program • Individual performing activities does not have a valid qualification	• A deviation, nonconformance, or failure to comply with regulations found to be reportable under 10 CFR Part 21 or 10 CFR 50.55(e) • Adverse surveillance findings indicative of a significant quality assurance program breakdown (Ref. 10 CFR 50.55(e)) • Deficiencies in the fabrication or construction of, or significant damage to, structures, systems or components that require extensive evaluation, re-design or repair in order to establish the adequacy of the structure, system or component to perform its intended function of assuring public health and safety • Repetitive problems indicating programmatic failures or precursor of significant technical deficiencies • Falsification of QA Records • A significant adverse trend related to an activity or item subject to the QA program • Apparent sabotage or tampering • Incorrect supplier instructions identified after SSC turnover that significantly affects SSC safety function • Significant Loss of Foreign Material Exclusion controls impacting safety-related systems ~~•~~ Significant human performance event causing damage to safety-related equipment

ATTACHMENT 2

Other Areas Affecting Quality Assurance		
~~Conditions/Nonconformances/~~ Conditions within the scope of the Work Processes	Conditions adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
	• Surveillance findings for corrective action requiring response by the management of the organization, and follow-up verification of corrective action completion as directed in the surveillance report • Adverse condition found after licensee acceptance of the SSC for service, such as an SSC that fails to conform to one or more applicable codes or standards (e.g., the CFR, Combined License, Tech Specs, FSAR, and/or licensee commitments) • Any condition or nonconformance that results in a Stop Work Order being imposed • Repetitive issues identified in human performance, procedure use and adherence, supervisor oversight, corrective action, or SCWE • Adverse audit findings indicating a programmatic breakdown • Ineffective corrective action for an adverse audit finding • NRC identified issues (Cited or non-cited violations) • Foreign Material in any system/component important to plant generation with a high potential to affect system functionality or operations	

ATTACHMENT 2

ITAAC		
Adverse Conditions	Conditions Requiring Further Evaluation for Significance	Significant Conditions
• Deficiency related to an SSC covered by ITAAC that is not material to an ITAAC conclusion	• A design deficiency that results in deviation from performance specifications that could fail to meet ITAAC requirements • Error or deficiency material to an ITAAC acceptance criterion • A programmatic QA/QC deficiency that is not related to one or more aspects of a given ITAAC under review • Errors found in the licensee's ITAAC closure package before the closure letter is sent • Error or deficiency related to an ITACC inspection or test performed prior to installation in the plant or associated ITAAC closure documentation (e.g. test or inspection record) that was generated at the supplier site and provided to the licensee.	• A design deviation from performance specifications that fails to meet ITAAC requirements • A test result that indicates an SSC that is the subject of a completed ITAAC no longer meets its ITAAC acceptance criterion (e.g., requires corrective maintenance) • Reinspection or retest of an SSC, as a result of out of tolerance, lost, or damaged M&TE, has an unacceptable result that adversely affects a completed ITAAC • A condition that is material to a prior ITAAC conclusion in an ITAAC Closure Letter submitted in accordance with Section 52.99(c)(1) • A condition that is subject of an ITAAC Finding, i.e., a regulatory violation that is greater than minor, and is associated with a specific ITAAC for which the licensee has issued the ITAAC closure letter • An error or deficiency that is determined to be material to the ITAAC acceptance criteria, and is documented by the NRC as an ITAAC-Related Construction Finding (IRCF) • Error or deficiency related to an ITAAC inspection or test performed prior to installation in the plant or associated ITAAC closure documentation (e.g., test or inspection record) that was generated at the supplier site and provided to the licensee that invalidates a prior ITAAC Closure letter. • Errors found during inspection of the licensee's ITAAC closure package after the closure letter is sent

~~ATTACHMENT 2~~

~~Other Areas Outside the Quality Assurance Program~~		
~~Adverse Conditions~~	~~Conditions Requiring Further Evaluation for Significance~~	~~Significant Conditions~~
• ~~Injury requiring first aid only~~ • ~~Potential fire or safety concern~~ • ~~OSHA recordable incident~~	• ~~Any occurrence that results in the potential radiation exposure in excess of regulatory limits (e.g., failure to control a source during radiography, or failure to adequately control access to an area undergoing radiography)~~ • ~~Unattended Safeguards Information or loss of Safeguards Information~~ • ~~NRC identified issues (Cited or non-cited violations)~~ • ~~A Physical Protection Program, Access Authorization/Control, Fitness for Duty breakdown~~ • ~~Foreign Material in any system/component important to plant generation with a high potential to affect system functionality or operations~~ • ~~An individual who met denial criteria was granted access~~ • ~~Fire incident inside the plant boundary with potential impact on personnel safety or SSCs~~	• ~~Any occurrence that results in radiation exposure in excess of regulatory limits (as in failure to control a source during radiography, or failure to adequately control access to an area undergoing radiography)~~ • ~~Fire in the plant with significant impact on corporate assets~~ • ~~Significant security issues as defined by security procedures or reportability requirements~~ • ~~Fatality, severe personal injury, or significant industrial hazard~~ • ~~An event that results in a violation of non-radiological environmental release limits~~ • ~~Information in the Environmental Report is found to be inaccurate or incomplete such that the safety evaluation for the Final Environmental Impact Statement (FEIS) conclusions are not characterized correctly~~

Formatted: Left