NEI 08-02, DRAFT Revision 4

Corrective Action Processes for New Nuclear Power Plants During Construction

October 2015

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Nuclear Energy Institute

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This guidance document, *Corrective Action Processes for New Nuclear Power Plants During Construction*, NEI 08-02, was developed by 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

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 (CCAP) 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. Additional lessons learned to-date during the construction of the first new nuclear plants licensed under 10 CFR Part 52 were considered in the development of Revision 4 of this document. The purpose of this document is to establish guidance for roles, responsibilities, and implementation of the CCAP that will be used during the on-site construction of new nuclear power plants.

This guidance provides for identification and resolution of conditions adverse to quality (CAQ) 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 corrective action program or implement the suppliers' processes. This document identifies the basic elements that are necessary to identify and resolve CAQ in a fast-paced construction environment.

The process described herein allows any licensee/supplier employee to identify a condition that may need to be resolved. The condition is screened to determine if it is a CAQ. The 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 identification, cause, and corrective action for significant conditions adverse to quality are reported to responsible management. The actions focus on correcting CAQ and precluding repetition of significant CAQ.

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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, Corrective Action, 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, Regulatory Guide (RG) 1.28, or other Nuclear Regulatory Commission (NRC) endorsed QA standard. These requirements relate to the processes necessary to develop effective construction corrective action processes (CCAP) for new nuclear power plants up to the point in time determined by the licensee that the operations phase Corrective Action Program (CAP) is to be implemented. This document also provides guidance for implementation of an interface management process for CCAP for projects that use multiple interfacing CAPs rather than a single CAP. The CCAP interface process involves joint screening between licensee and contractor(s), identification and classification of significant/conditions adverse to quality (SCAQs/CAQs), and disposition of the conditions in a timely manner. NEI 08-02, Revision 4 provides information related to a tiered oversight approach by the licensee and contractor(s) for issues entered into CCAP. NEI 08-02 will also be applied to the activities related to Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) compliance in accordance with 10 CFR Part 52, regardless of the quality classification of the equipment associated with the ITAAC. 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.

Current operating plants have established effective corrective action processes for the operating environment, and many suppliers have established 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.

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. This CCAP guideline accounts 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 ITAAC are used to

provide reasonable assurance that the facility has been constructed and will operate in conformity with the license.

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 corrective action requirements. CAQ are identified through implementation of elements of the QA program. CCAP implements 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 or NQA-1-2008/1a-2009, as applicable, through defined processes that address failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances that are documented as specified in NQA-1-1994 and NQA-1-2008/1a-2009. The licensee will need to determine the extent to which this document is delegated to their contractors. Attachment 1 provides an illustration of CCAP.

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 CCAP 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.

Adverse Trend – a negative change in performance data that knowledge, experience and judgment indicate is unacceptable because of the adverse impact on safety or reliability or because of the large (relative) number of similar grouped performance problems that point to more significant future problems if not addressed. (Defined specific to usage in this document.)

Cognitive Trending – a process of maintaining a mental awareness of recent events and identifying trends via association of like items. Cognitive trending can be accomplished with use of constructive dialogue and consensus decisions for early action on perceived trends. (Defined specific to usage in this document.)

Combined License (COL) – 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 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 and NQA-1-2008/1a-2009, Part 1, Section 1, Introduction; and, 10 CFR 50, App. B, Criterion XVI.)

Construction Corrective Action Processes (CCAP) – An umbrella concept used to collectively describe those systems 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 integral to specific 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 and NQA-1-2008/1a-2009, Part 1, Section 1, Introduction.)

Corrective Action Program (CAP) – the process used to identify, document, and correct any Conditions Adverse to Quality related to onsite construction and further ensure that, for Significant Conditions Adverse to Quality, reporting is made to appropriate levels of management and the cause and actions to preclude repetition are identified, implemented, effective, and timely. (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 and NQA-1-2008/1a-2009, Part 1, Section 1, Introduction.)

Extent of Condition – the degree to which the situation adversely affects other work activities, processes, programs, systems, structures, or components, with consideration given to the cause(s) identified. (Defined specific to usage in this document.)

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

ITAAC Finding – a technical finding that is associated with a specific ITAAC and is material to the ITAAC acceptance criteria. (From IMC-2506.)

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 and NQA-1-2008/1a-2009, 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 and NQA-1-2008/1a-2009, Part 1, Section 1, Introduction.)

Nonconforming Item – an appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit that does not conform to specified requirements. (Based on usage in ASME NQA-1-1994, Supplement 15S-1 and NQA-1-2008/1a-2009, Requirement 15.)

Program Deficiency – failure to develop, document or implement effectively any applicable element of the quality assurance program or other programs required by regulation or license related to nuclear safety. (Based on ANSI N45.2.12)

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 and NQA-1-2008/1a-2009, 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 and NQA-1-2008/1a-2009, 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 and NQA-1-2008/1a-2009, Part 1, Section 1, Introduction.)

Standard Design Certification or Design Certification – 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 and NQA-1-2008/1a-2009, Part 1, Section 1, Introduction.)

Trending – the performance of 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 originated from a common cause or 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 and NQA-1-2008/1a-2009, Part 1, Section 1, Introduction.)

Work Processes – programmatically-controlled activities affecting quality activities such as Design Control, Inspection, Test Control, Control of Nonconforming Items, etc., that are performed in accordance with 10 CFR Part 50, Appendix B, and the licensee's Quality Assurance Program. (Defined specific to the usage in this document).

1.2 REFERENCES

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

- 10 CFR Part 21, *Reporting of Defects and Noncompliance*
- 10 CFR Part 50, *Domestic Licensing of Production and Utilization Facilities*; 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 52.6, *Completeness and Accuracy of Information*
- 10 CFR Part 52, *Licenses, Certifications, and Approvals for Nuclear Power Plants*
- ASME NQA-1-1994, *Quality Assurance Requirements for Nuclear Facility Applications* (endorsed in various NRC safety evaluation reports)
- ASME NQA-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications*
- ASME NQA-1a-2009, *Addenda to ASME NQA-1-2008, Quality Assurance Requirements for Nuclear Facility Applications*

- ANSI/ASME N45.2.12-1977, *Requirements for Auditing Quality Assurance Programs for Nuclear Power Plants*
- 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
- RG 1.28*, Quality Assurance Program Criteria (Design and Construction)*
- 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"*

2 PURPOSE AND APPLICABILITY

2.1 PURPOSE

The purpose of this document is to establish guidance for roles, responsibilities, and implementation of CCAP used during the on-site construction of new nuclear power plants. This document outlines the important elements of CCAP to guide the development of administrative processes, procedures, and instructions that the licensees and/or suppliers utilize to implement corrective actions. This document also provides guidance for implementation of an interface management process for CCAP. As defined in Section 1.1, CCAP refers to the Corrective Action Program as well as corrective action elements within the work processes.

2.2 APPLICABILITY

This document is applicable to the identification and correction of CAQs. Corrective action may be implemented by using either a single corrective action process or multiple processes performed in accordance with 10 CFR Part 50, Appendix B as described in the QAP. 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 CAQs are addressed in accordance with 10 CFR Part 50, Appendix B, Criterion XVI.

Each organization participating in the interface process shall maintain a CAP that complies with 10 CFR Part 50 Appendix B requirements. The licensee shall be provided ready access to documentation of project-related CAQs affording the ability to ensure

prompt significance review, investigation, reporting, and dispositioning in a timely manner.

The applicability of these corrective action processes 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). 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 CAQ may be established. Licensee program documents should specify the scope of applicability of CCAP.

In addition to CCAP, 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 corrective action processes, except that aspects of CCAP related to identifying issues with closed ITAAC may continue to be used until the 10 CFR 52.103(g) finding is made. 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)). 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 CCAP 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 CAP already defined in an NRC-approved Quality Assurance Program Description (QAPD). An organization with an NRC-approved QAP 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 CCAP and assuring that CAQs are identified, corrected, and escalated in accordance with the requirements and commitments of the facility QAPD. The licensee may delegate activities of planning, establishing, and implementing CCAP to others. The interfaces with suppliers and other organizations should be defined in QAP documents so that the

potential impacts of identified conditions are appropriately evaluated across organizational boundaries.

The licensee is responsible for oversight, in accordance with the QAP, of CCAP that are delegated to suppliers. The licensee should ensure that CCAP 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.

Licensee responsibilities, directly or through delegation, include, but are not limited to:

- Maintaining a CAP that complies with 10 CFR Part 50, Appendix B
- Maintaining overall responsibility for the CCAP interfacing procedure(s)
- Developing and enforcing thresholds for levels of CAP issues identified by interfacing organizations
- Developing a threshold for when to share construction experience (CE) and ensuring that it is shared, including CE from the consortium, based on the threshold
- Developing/maintaining training qualifications, for members of the CCAP interfacing management review and screening teams, as appropriate
- Providing oversight of project-related CCAP items pertaining to structures, systems, and components defined as SCAQ/CAQ or ITAAC applicable
- Ensuring periodic generation of project-related aggregate CCAP trend reports including trending across multiple CAPs, i.e., licensee (construction and operational readiness), contractor(s), and common
- Maintaining a cross reference list of CCAP items between the licensee and contractor(s), if using multiple CAP systems
- Verifying quorums prior to initiation of CCAP management oversight meetings

3.2 MANAGEMENT

Management plays a significant role in CCAP. Management has the responsibility for assuring that CCAP 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 CCAP.
- 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 significant CAQs (SCAQs) to the appropriate levels of management (including senior management responsible for the corrective action), and requirements and expectations for the implementation of CCAP 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 CAQ when identified.
- Actively supporting and participating in CCAP.
- Assuring training related to CCAP 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.
- Providing oversight of CCAP interface process and SCAQ/CAQ dispositions.
- Providing CCAP oversight through review of licensee and contractor(s) trend reports.

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 CCAP.

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 should develop CCAP and program documents to implement the requirements specified by the licensee, including CCAP interface requirements, unless the supplier is working under the licensee's QAP and procedures.

When an onsite safety-related supplier demobilizes and leaves the site, the licensee and supplier will review all open CAQ related to that specific supplier for correct disposition and ensure that responsibility is appropriately transferred.

4 CONSTRUCTION CORRECTIVE ACTION PROCESS ELEMENTS

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

The elements of CCAP are as follows:

(a) Identification, documentation, and reporting

(b) Screening, evaluation, and classification

(c) Cause analysis

(d) Corrective actions

(e) Verification and follow-up, e.g., measuring effectiveness

(f) Analyzing for adverse trends

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

Implementation of CCAP elements should be governed by procedures with appropriate criteria to make consistent and timely significance determinations, cause analyses, and corrective actions including actions to preclude repetition when significant.

Attachment 1 provides an illustration of CCAP.

4.1 IDENTIFICATION, DOCUMENTATION AND REPORTING

Identification and documentation is an essential element of CCAP. The expectations for prompt identification and documentation should be clearly established in written procedures. Where 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 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 that are considered part of the work process. In general, conditions that are still within control of the work process, where the work has not been declared complete, are not required to be entered in the CAP if they can be corrected within the work process. Examples would be: design errors identified before all approvals are complete for a calculation, installation errors identified before the QA/QC verification is complete and where correction is within the scope of the work process, and certain non-conforming material where the work process contains guidelines for repairing the material.

There are multiple sources of information that could indicate CAQ. The established CCAP 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 conditions will be identified through the work processes controlling design and construction activities, and conditions that are not determined to be a CAQ or a SCAQ or not significant to ITAAC conclusions may 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; 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 CAP, evaluated, and resolved in accordance with the significance of the condition.

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.

Certain conditions also require reporting to regulatory agencies. CCAP 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.

4.2 SCREENING, EVALUATION AND CLASSIFICATION

4.2.1 Screening to Identify Conditions that Require Further Review

The first step in the screening process is a 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. The screening process procedures should identify the persons responsible to determine when a condition requires further review for significance. For a CAQ requiring further review, an evaluation is performed (as described in 4.2.2) to determine if a SCAQ exists.

The screening process established should include the following criteria for determining which conditions are adverse to quality and which CAQ 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 or condition being left uncorrected

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 completed 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 left column of Attachment 2 depicts the type of conditions that require further evaluation of significance by knowledgeable individuals (e.g., subject matter experts, or individuals within the CAP screening process) to ascertain the broader aspects beyond the specific

process where the condition was identified. CAQ 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, as discussed in Section 5.

There should be uniform screening criteria used for the construction site. To ensure consistent screening, the licensee will provide oversight of implementation of corrective action processes in accordance with the QAP.

With interfacing CCAP, each organization is responsible for providing all CAP documents necessary for licensee/contractor(s) joint team screening to determine if SCAQ/CAQ conditions exist. For efficiency, the same team may also screen conditions for reportability under 10 CFR 21 and 10 CFR 50.55(e) requirements and ITAAC applicability.

For issues classified as SCAQs/CAQs or ITAAC applicable, the interface screening team should assign an organization responsible for dispositioning the condition. If the issue is assigned to a contractor(s), the licensee may elect to track closure of the issue to ensure the disposition includes adequate reasoning. Licensee tracking depends on issue significance related to:

- SCAQ/CAQ determination
- ITAAC applicability
- Potentially reportable conditions (10 CFR 21 and 10 CFR 50.55(e))
- NRC identified issues not previously entered in CCAP

It is the licensee's responsibility under Criterion XVI of Appendix B to 10 CFR Part 50 to assure, either directly or through delegation, that SCAQs/CAQs are identified, corrected and managed in accordance with the quality assurance program.

The interfacing CCAP should involve a tiered oversight approach based on risk, e.g., initial screening by joint licensee/contractor team, licensee/contractor(s) management review, and oversight by a joint executive committee. Key features of such a process are licensee oversight of the screening process and a path for differing professional opinions.

Continuing the above example, a licensee could implement tiered oversight interfacing CCAP as follows: The functionalities of the management and executive oversight committees should be provided in an established charter maintained by the licensee. The charter should include the following elements:

- Management review to approve/challenge decisions made by the joint screening team for SCAQs/CAQs, ITAAC applicability and reportability
- Resolution of disagreements by quorum members of the joint management review committee, e.g., by vote or escalation to the joint executive committee
- Conduct of executive committee meetings as specified in the CCAP procedure to approve/challenge issues including but not limited to:
    - Corrective actions for SCAQs

- Issues unresolved during the joint management review committee meetings
- Project trending results
- Effectiveness of the joint management review committee

4.2.2 Evaluation to Identify Significant Conditions

For CAQ requiring further review for significance, an evaluation should be performed by the organization implementing CCAP to determine which conditions are classified as SCAQ and therefore require actions to preclude repetition. Individuals performing significance evaluations should have the training and knowledge needed to be able to recognize the broader implications beyond the specific process where the condition was identified to determine when a SCAQ 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).

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.

If the further evaluation confirms that the condition is a CAQ (not SCAQ), the 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, as discussed in Section 5. CAQ may be entered into the CAP for correction and trending. CAQ entered into the CAP are processed in accordance with the CAP procedure utilizing the CAP elements commensurate with their safety significance.

If the further evaluation determines that the condition is a SCAQ or is an ITAAC significant condition (See Attachment 2), it should 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 Attachment 2 contains examples of CAQ typically considered significant, i.e., 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, entry into CAP is required, and additional CCAP elements are implemented as discussed in Sections 4.3 through 4.6.

Attachment 2 lists examples that are intended as guidance for each organization to use with respect to developing company- or facility-specific evaluation criteria. Attachment 2 contains examples of CAQ typically considered significant, i.e., SCAQ.

Management (contractor and licensee) notification, including senior management responsible for the corrective action, is required when a SCAQ is identified.

4.2.3 Evaluating Conditions for Relationship to ITAAC Conclusions

Conditions identified as needing further evaluation for significance should be evaluated to determine if the conditions are material to the conclusion that an ITAAC has been or will be met. 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.

- If the condition is determined to *not* be material to an ITAAC conclusion and is not otherwise determined to be a SCAQ, it may be corrected and documented in the applicable work process.
- If the condition is determined to be material to an ITAAC conclusion but an ITAAC Closure Notification 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 Findings should be entered into the CAP.
- If the condition is determined to be material to a conclusion in an ITAAC Closure Notification previously submitted to the NRC in accordance with 10 CFR 52.99(c)(1), it should be entered into the CAP.

For conditions identified as needing further evaluation for significance, suppliers should coordinate with the licensee to determine the submittal status of ITAAC Closure Notifications 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 above) are classified as such and processed within the CAP. Conditions identified external to a work process are entered into the CAP, evaluated

to determine if they are a CAQ, SCAQ or material to an ITAAC conclusion and resolved 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, 4.5, and 4.6, below.

Conditions that are not SCAQ or material to an ITAAC conclusion may be assigned to be corrected in a work process, as discussed in Section 5.

4.3 CAUSE ANALYSIS

Cause analysis is required for a SCAQ. Action will be taken for a SCAQ to preclude repetition of the condition. Causal analysis techniques should be used to 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) the determined cause;

(b) extent of condition and cause (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.

4.4 CORRECTIVE ACTIONS

Each CAQ requires action to correct the condition. Additionally, for SCAQ, corrective actions to preclude repetition are applied. 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 are to be promptly reported to appropriate levels of management. The appropriate management to be notified should be established

within the implementing procedures. If elements of CCAP are delegated to a supplier, the interface and requirements for reporting should be clearly documented.

4.5 Verification and Follow-Up

Corrective actions for 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 are verified after the actions are completed, and results are indicated in the CAP. Additionally, for SCAQ, 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

CAQ identified through the Corrective Action Program(s) should be periodically analyzed for adverse trends. Trending should include a layered approach which includes groups, processes, programs, site wide issues, events and causes. A trending process should be developed and implemented that can identify adverse trends that are QAP 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 potential trends, adverse trends, repetitive failures, process weaknesses, or other indicators of extent of cause or condition beyond the immediate problem identified.

The trending process should include analytical and cognitive methods. Cognitive trending occurs on a routine basis through noting of issues during daily management meetings, review of newly generated CAP items, review of conditions identified within the work processes, and observation of personnel. Analytical trending should be performed by a trending analyst using a database and data analysis techniques. One type of trending level or technique is not practical for all conditions; therefore, a structured approach to trending within the work processes and CAP should be implemented by licensees and suppliers during nuclear construction. If this analysis indicates a potential or adverse trend, the 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.

Consideration should be given to developing and implementing a lower tier trending program for problems identified and corrected within the work process for performance improvement purposes. Procedures for individual work processes should include

guidance and criteria for identifying potential or adverse trends that may require further evaluation for significance as potential CAQs.

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.

Adverse trends should be reported to management responsible for the work process. 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.
- 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.
- Deficiencies of a like nature are being identified in multiple work activities.

Procedures should include guidance for monitoring trends, evaluation for significance, and closure of adverse trends.

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.

4.7 Construction Experience, Operating Experience, and Lessons Learned

Using construction experience (CE), operating experience (OE), and internally generated lessons learned (LL) are important to constructing nuclear plants in a quality, safe, and efficient manner. A CE/OE/LL program shares and uses knowledge derived from internal and external sources to both promote the recurrence of desirable outcomes, and preclude the recurrence of undesirable outcomes.

All stakeholder management (licensee, constructor, designer, etc.) is responsible for ensuring that applicable CE/OE/LL are included in the CAP. CE/OE/LL may be entered and tracked in a system that is separate from the CAP, as long as the CE/OE/LL process is defined and the collection, screening, evaluation, and communication (internal and external) process is systematic and auditable. For simplicity, this guidance assumes use of the CAP.

The CAP should include a process to gather and evaluate the CE/OE/LL information. Specifically, relevant CE/OE/LL should be thoroughly collected, screened, evaluated, and communicated to affected internal and external stakeholders.

Issues identified through INPO (findings, recommendations and OE), NRC CE/OE/LL, and industry CE/OE/LL should all be considered in the CAP. In addition, externally identified problems such as 10 CFR Part 21 notifications, NRC generic communications, reports issued by the Nuclear Steam Supply System vendor (and the applicant for applicable Design Certification), other facilities under licensee's control, similarly designed facilities under construction, the Architect/Engineer corporate office, the Electric Power Research Institute, major contractor corporate offices, and equipment suppliers and manufacturers should be taken into consideration.

CE/OE should be shared via industry databases. This may be accomplished without mentioning company names, etc. to avoid disclosure of proprietary information. Internal CE/OE/LL databases and/or processes should share information amongst projects with the same consortium members to the maximum extent possible. Licensees should establish thresholds and expectations to ensure reporting of CE/OE/LL.

In addition to communicating the CE/OE/LL to affected internal stakeholders, and via industry CE/OE databases, a process should be established for employees at every level of the organization to proactively review the CE/OE/LL in the CAP before performing relevant tasks. For example, design engineers should review the CAP to determine if CE/OE/LL needs to be considered in their design. Construction managers should review the CAP to determine if CE/OE/LL needs to be considered in their construction process.

5 IDENTIFICATION AND CORRECTION OF CONDITIONS THROUGH WORK PROCESSES

As defined in Section 1.1, work processes are quality processes subject to the applicable requirements of 10 CFR Part 50, Appendix B, Criterion XVI and the QAP. Work processes include appropriate corrective action process elements as described in Section 4 (e.g., identification, documentation, correction, and trending of conditions within the scope of the work processes). CAQ may be entered into the CAP as an alternative to addressing them within the work process. SCAQ are entered into the CAP as described in Section 4.2.4.

Corrective actions for nonconformances, failures, malfunctions, deficiencies, and defective equipment may occur within the work processes. As noted in Section 4.1, conditions that are still within control of the work process, where the work has not been declared complete, are not required to be entered in the CAP.

CAQ, SCAQ, 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 should establish the process and procedures to identify CAQ that require further evaluation of their significance including the identification of adverse

trends. CAQ that receive further evaluation for significance, but ultimately are determined not to be SCAQ, 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 and NQA-1-2008/1a-2009 Requirements discuss the resolution of nonconformances, failures, malfunctions, deficiencies, and defective equipment. The following table provides examples where work processes may be implemented.

Issue area	NQA-1 Requirement	NQA-1-1994 Part I	NQA-1-2008/1a-2009 Part I
Design	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.	Basic Requirement 3 and Supplement 3S-1	Requirement 3
	If a significant design change is necessary because of an incorrect design, modification of the design process and verification procedure, if necessary, is required. 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.	Supplement 3S-1	Requirement 3, Section 600
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 prior to issuance are not CAQ and may be corrected within the work process; those discovered after issuance shall be considered CAQ and corrected.	Basic Requirement 4 and Supplement 4S-1	Requirement 4
Control of Purchased Equipment and Services	Required 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 prior to	Supplement 7S-1, Supplementary Requirements, paragraph 9	Requirement 7, Section 600

Issue area	NQA-1 Requirement	NQA-1-1994 Part I	NQA-1-2008/1a-2009 Part I
	release of the material for use or installation.		
Inspection	Inspection activities shall be documented and controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. (Similarly, NQA-1-2008/1a-2009 requires inspections to be planned, executed, and documented.)	Basic Requirement 10, and Supplement 10S-1, paragraph 2	Requirement 10, Section 100
	Identification of hold points.	Paragraph 4	Section 300
	Planning documentation shall include characteristics, methods, and acceptance criteria and recording of objective evidence of the inspection results.	Paragraph 5	Section 400
	In-process inspection	Paragraph 6	Section 500
	Final inspections, including the resolution of nonconforming items identified by prior inspections.	Paragraph 7	Section 600
	Re-inspection or retest if a piece of equipment or system is modified, repaired, or replaced subsequent to the final inspection.	Paragraph 7.4	Section 603
	Inspection records, which include reference to information on action taken in connection with nonconforming items.	Paragraph 9	Section 800

Issue area	NQA-1 Requirement	NQA-1-1994 Part I	NQA-1-2008/1a-2009 Part I
Test Control and Computer Program Testing	Identification of test requirements and acceptance criteria and use of written test procedures that identify required monitoring, environmental conditions, and prerequisites for the tests.	Basic Requirement 11 and Supplements 11S-1 and 11S-2 in conjunction with Part II, Subpart 2.7*	Requirement 11 in conjunction with Part II, Subpart 2.7*
	Document and review results, their acceptability, and document actions taken in connection with any deviations noted.	Paragraphs 4 and 5, and Part II, Subpart 2.7*	Sections 500 and 600, and Part II, Subpart 2.7*
Control of Measuring and Test Equipment	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.	Basic Requirement 12, and Supplement 12S-1	Requirement 12

* The NRC is in the process of endorsing industry guidance on the commercial grade dedication of design and analysis software for use in safety-related applications. NRC Draft Regulatory Guide DG-1305 approves EPRI-3002002289, *Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications*, Revision 1 of 1025243, December 2013, by the Electric Power Research Institute.

Issue area	NQA-1 Requirement	NQA-1-1994 Part I	NQA-1-2008/1a-2009 Part I
Control of Nonconforming Items	Quality assurance program requirements include identification, documentation, and correction . In addition, nonconforming item dispositions are reviewed for adequacy and reported to designated management.	Basic Requirement 15 and Supplement 15S-1	Requirement 15
	Controls shall be provided for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification of affected organizations.	Basic Requirement 15 and Supplement 15S-1	Requirement 15, Sections 200 and 400
Audits	Documentation of audit results. If adverse findings are identified by the audit, corrective actions shall be initiated and documented.	Basic Requirement 18 and Supplement 18S-1	Requirement 18

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

Management responsible for the work processes should ensure a program is developed for identification of adverse trends, such as repetitive failures or process weaknesses. This program should address the individual work processes as well as trending across the various work processes and the CAP. 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).

Procedures should be established that ensure work processes are periodically reviewed (sample, self assessment, etc) to ensure that CAQ requiring further evaluation and SCAQ are being correctly characterized.

Each document generated within a work process must meet the requirements established within the QAP 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 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. Documentation of CAQ within the CAP is also a recommended method to ensure consistent documentation, evaluation for significance, correction and trending.

Work process managers, or the CAP screener for CAQ entered into the CAP, will screen conditions as described in Section 4.2.1 to determine if the condition needs further evaluation for significance as stated in the work process procedure or the CAP procedure. Where CAQ are of the nature of those identified in the first column of Attachment 2, initial corrective actions may be implemented, but they are documented and processed for evaluation of their significance as described in Section 4.2.2. Any condition, nonconformance, or CAQ 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.

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

6 RECORDS

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

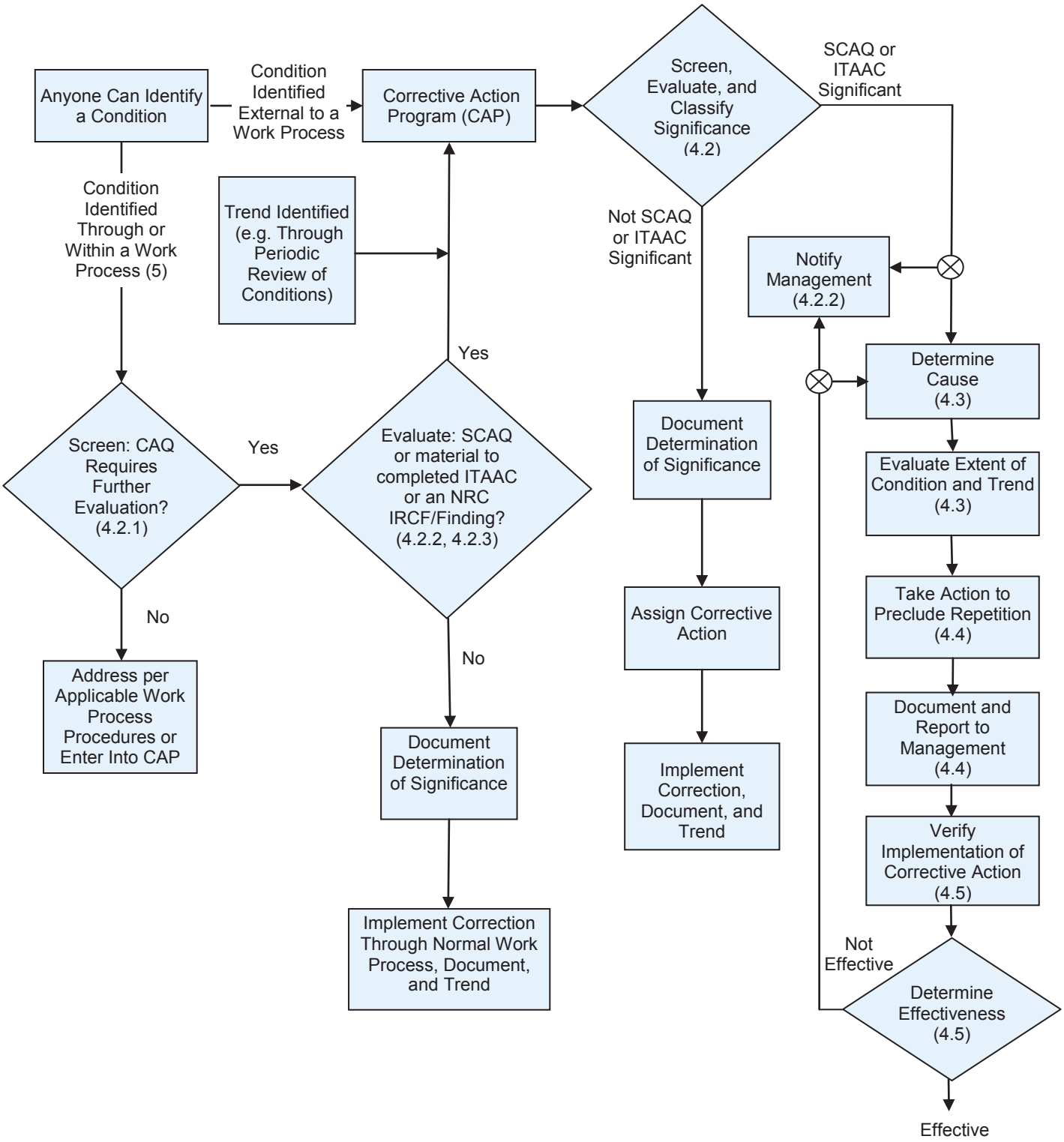
7 TRANSITIONING TO THE OPERATIONS CORRECTIVE ACTION PROGRAM

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 10 CFR 52.103(g) finding is made. 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 consistent with the guidance in Section 4.2.3.

Any CE documented in CCAP and pertaining to impact on ITAAC acceptance criteria or any aspect of startup or operations should be carried forward in the transition to operations. This information should be coded as CE in the (operations) CAP to ensure the history of the CE is maintained. Not all CE would fall into categories that would necessarily apply to operations.

ATTACHMENT 1

Construction Corrective Action Processes Flow



ATTACHMENT 2

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

The following table identifies examples of conditions adverse to quality (CAQs) that typically require further evaluation for significance and those that would generally be considered significant CAQ (SCAQs) and therefore entered into CAP. 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 document.

ATTACHMENT 2

Design Control	
Conditions adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• 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 • Drafting errors in 'approved design' that do result in incorrect or deficient design • Computer software deficiencies identified after verification testing that are determined to be isolated to software that has not been utilized in any application	• 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 adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• 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 • Conditions identified with equipment or materials identified during receipt inspection that deviate from technical or quality requirements specified in the purchase documents • Inadequate maintenance and storage conditions that do not meet specific requirements have not impacted stored items	• 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 adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• 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 (e.g. welding traveler not approved)	• 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 adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• 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 adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• 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) • 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 after testing completion	• 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 adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• 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 adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• 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 • Damaged safety-related or quality-related item after being received and accepted at site	• 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 adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• 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

ATTACHMENT 2

Other Areas Affecting Quality Assurance	
Conditions adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
• 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 • 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 • 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	• 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 adverse to quality Requiring Further Evaluation for Significance	Significant Conditions Adverse to Quality
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	
Conditions Requiring Further Evaluation for Significance	Significant Conditions
• 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 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 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.	• 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) • Re-inspection 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 Notification submitted in accordance with Section 52.99(c)(1) • A condition that is subject of an ITAAC Finding, i.e., a technical finding that is associated with a specific ITAAC and is material to the ITAAC acceptance criteria • An error or deficiency that is determined to be material to the ITAAC acceptance criteria, and is documented by the NRC as an ITAAC Finding • 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 Notification. • Errors found during inspection of the licensee's ITAAC Completion Package after the closure notification is sent