

**NEI 08-02 Revision 0**

**Problem Identification  
and Resolution for New  
Nuclear Power Plants  
During Construction**

**December 2008**



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**Nuclear Energy Institute**

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## **ACKNOWLEDGEMENTS**

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## **EXECUTIVE SUMMARY**

NEI 08-02, “Problem Identification and Resolution for New Nuclear Power Plants During Construction,” provides generic guidance on how the licensee of a combined license (COL) issued under 10 CFR Part 52 should implement a Problem Identification and Resolution (PI&R) process during engineering, procurement and construction activities and prior to commercial operation. 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 PI&R process that will be used during the construction of new nuclear power plants. Additionally, this document will serve as the vehicle for regulatory discussion, resolution, and endorsement of the PI&R process to be used during construction of new nuclear power plants.

This guidance provides for problem identification and resolution 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 must establish the extent that suppliers and sub tier suppliers participate in the licensee’s PI&R process or implement the supplier’s process. This document identifies the basic elements that are necessary to identify and resolve problems 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 classified with respect to significance and complexity. If classified as significant, the condition is analyzed for cause commensurate with its importance to safety. The actions focus on correcting the condition and preventing recurrence when appropriate.



## **TABLE OF CONTENTS**

<b>EXECUTIVE SUMMARY.....</b>	<b>i</b>
<b>1 INTRODUCTION AND BACKGROUND .....</b>	<b>1</b>
1.1 DEFINITIONS .....	2
1.2 REFERENCES.....	4
<b>2 PURPOSE AND APPLICABILITY .....</b>	<b>5</b>
2.1 PURPOSE .....	5
2.2 APPLICABILITY .....	5
<b>3 RESPONSIBILITY .....</b>	<b>5</b>
3.1 LICENSEE .....	5
3.2 MANAGEMENT .....	6
3.3 INDIVIDUAL .....	6
3.4 SUPPLIER.....	6
<b>4 PROBLEM IDENTIFICATION AND RESOLUTION .....</b>	<b>7</b>
4.1 IDENTIFICATION AND DOCUMENTATION .....	7
4.2 CLASSIFICATION.....	8
4.2.1 Review for Significance .....	8
4.3 CAUSE ANALYSIS .....	9
4.4 CORRECTIVE ACTIONS.....	9
4.5 FOLLOW-UP AND CLOSURE.....	9
4.6 ANALYZING FOR ADVERSE TRENDS.....	10

<b>5 IDENTIFICATION AND CORRECTION OF CONDITIONS THROUGH IN-PROCESS WORK .....</b>	<b>10</b>
<b>6 RECORDS .....</b>	<b>11</b>
<b>ATTACHMENT 1 .....</b>	<b>A1-1</b>
<b>ATTACHMENT 2 .....</b>	<b>A2-1</b>



# **PROBLEM IDENTIFICATION AND RESOLUTION 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 Appendix B to 10 CFR Part 50, *Quality Assurance for Nuclear Power Plants and Fuel Reprocessing Plants*, as it relates to problem identification and resolution (PI&R) for construction of nuclear power plants up to the point in time determined by the licensee that the operations phase PI&R Process is implemented. This document establishes the elements necessary for an effective PI&R process for new nuclear plant construction. Implementation of this guidance document provides the basis for Nuclear Regulatory Commission (NRC) endorsement of the construction project PI&R process.

Current operating plants have established effective PI&R processes for the operating environment. New nuclear plant construction projects use similar PI&R elements during the construction-related activities of engineering, procurement, and construction.

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 PI&R process guideline accounts for the two key differences in the licensing processes between Part 50 and Part 52: the bulk of construction is conducted after the license 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 are identified, corrected, and managed in accordance with the requirements and commitments of the facility Quality Assurance Program Description (QAPD) and the processes defined in this guidance document. Conditions adverse to quality are identified through implementation of elements of the QA program. The PI&R process implements Criterion XVI of 10 CFR Part 50, Appendix B, through a defined corrective action process and may include separate work processes that provide for documentation and correction of conditions within the work process. The licensee/supplier will have to define the interface, if any, of these work processes with the PI&R process, including determining the need for cause evaluation, actions to prevent recurrence, and potential reporting to governing agencies; however, this document does not specifically address the evaluation and correction of these conditions. Attachment 1 provides an illustration of the PI&R process.

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 PI&R process is 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 (Defined specific to the usage in this document.)

Condition Adverse to Quality – an all inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and non-conformances (Based on ASME NQA-1-1994, Part 1, Section 1, Introduction.)

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 management process or tool, as part of the PI&R process, for collecting information concerning adverse conditions, and tracking assignments for causal determination and corrective action (Defined specific to usage in this document.)

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 the 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).)

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 supervision through senior management positions

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 or cannot be reworked to satisfy the original design requirements, a technical justification for the acceptability of the nonconforming item 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.)

Problem Identification and Resolution (PI&R) – an overarching process used to identify, document, and correct adverse conditions as identified in this document (Defined specific to usage in this document)

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 recurrence 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.)

## 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*
- 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"*

## **2 PURPOSE AND APPLICABILITY**

### **2.1 PURPOSE**

The purpose of this document is to establish guidance for roles, responsibilities, and implementation of the PI&R process used during the construction of new nuclear power plants. This document outlines the important elements of the PI&R process to guide the development of administrative processes, procedures and instructions that the licensees and/or suppliers utilize to implement the PI&R process.

### **2.2 APPLICABILITY**

This document is applicable to the identification and correction of conditions adverse to quality and environmental issues related to the information submitted in the Environmental Report affecting Final Environmental Impact Statement determinations (e.g., water use assumptions, population predictions, discharge water temperature limits). The applicability can be extended to incorporate 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), and security-related matters. Licensee program documents should specify the scope of applicability of the PI&R process.

In addition to the PI&R process, 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 PI&R process, such as subsystem, system, or building turnover, but no later than when the NRC issues the 10 CFR 52.103(g) finding. An interface must 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 phase PI&R will be implemented.

## **3 RESPONSIBILITY**

### **3.1 LICENSEE**

The Licensee is responsible for establishing written procedures for implementing the PI&R process, 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 part or all of the activities of planning, establishing, and

implementing the PI&R process to others. The interfaces between organizations must be defined 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. This oversight is typically performed through a combination of supplier audits, surveillances, and/or periodic reviews of the program development and implementation.

### **3.2 MANAGEMENT**

Management plays a significant role in the PI&R process. Management has the responsibility for assuring that the PI&R process is 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 PI&R process.
- Defining condition reporting criteria, the condition reporting system(s) to be used, desired level(s) of condition evaluation, and the timeliness of corrective actions.
- Assuring that corrective actions are approved, prioritized, and completed in a timely manner consistent with their significance.
- Assuring sufficient resources are available to investigate, prioritize, and promptly resolve conditions when identified.
- Actively supporting and participating in the PI&R process.
- Assuring training related to the PI&R process 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 identifying and reporting the existence, occurrence, or observation of a situation that requires further review, evaluation, or action for resolution in the PI&R process.

### **3.4 SUPPLIER**

Each licensee's suppliers of quality related materials and services are responsible for implementing the PI&R process as specified by the licensee. Where the licensee has delegated responsibility for the development and implementation of the PI&R process to

a supplier, the use of the term “licensee” within this document includes the delegated supplier.

## **4 PROBLEM IDENTIFICATION AND RESOLUTION**

The PI&R process is an integral part of any Quality Assurance Program and is used for evaluating, documenting, and developing effective corrective/preventive actions for identified conditions that are not in accordance with established requirements. The PI&R process includes a method by which anyone on the construction project may easily identify a condition they believe needs to be corrected.

The elements of a Problem Identification and Resolution Process are as follows:

- (a) Identification and documentation
- (b) Classification
- (c) Cause analysis
- (d) Corrective actions
- (e) Follow-up and closure
- (f) Analyzing for adverse trends

For each condition, responsible organizations should implement PI&R elements in accordance with their significance as discussed in the following subsections. Correction and documentation of nonsignificant conditions may be accomplished within applicable work processes. Conditions determined to be significant should be entered into a Corrective Action Program (CAP) for implementation of additional PI&R elements, as appropriate.

PI&R process elements are discussed further in the following Sections. Attachment 1 provides an illustration of the PI&R process flow.

### **4.1 IDENTIFICATION AND DOCUMENTATION**

Identification and documentation is an essential element of any PI&R process. The expectations for identification and documentation must be clearly established in written procedures. Where conditions are identified, 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.

There are multiple sources of problem identification that are reviewed and evaluated to assure conditions adverse to quality are included in the corrective action process. The information reviewed may be generated by internal or external organizations and

includes, but is not limited to, the processes described in Section 6, audit reports, inspection reports, tests, design reviews, individual observations, adverse trends, construction or operating experience, 10 CFR Part 21/10 CFR 50.55(e) notifications, NRC generic communications, and maintenance activities.

## **4.2 CLASSIFICATION**

The first step in the classification process is a review of the identified condition to determine whether the item or activity is quality-related and if the condition is deemed a condition adverse to quality. An additional review is then performed to assess the significance of the condition. The significance of a condition may be dependent on specific circumstances related to the design or end use of the item 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 supplier cannot determine significance, the condition should be reported to the licensee. Since it is impossible to list every circumstance, management discretion is a necessary part of significance determination. Management notification is required when significant conditions adverse to quality are identified.

Certain conditions also require reporting to regulatory agencies. The PI&R process 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.

### **4.2.1 Review for Significance**

A process is required to be established by the organizations implementing a PI&R process to identify which conditions should receive further review. This is critical to the PI&R process, particularly as it relates to the individual work process controls to assure that a condition adverse to quality is appropriately reviewed for processing when determined to be potentially significant.

Attachment 2 lists examples that are intended as guidance for each organization to use with respect to developing company or plant specific requirements. The left and center columns depict the difference between conditions that would be considered nonsignificant and those that are potentially significant, including conditions that represent an adverse trend. Conditions identified as nonsignificant may be corrected in the work process. Conditions identified as potentially significant should be evaluated further by qualified personnel to determine if the conditions are 1) nonsignificant and may be corrected and documented in applicable work processes, or 2) significant and should be elevated to a CAP.

Section 5 provides guidance on correcting and documenting nonsignificant conditions within the applicable work processes. For conditions determined to be significant and entered into a CAP, the additional elements of PI&R are implemented as discussed in Sections 4.3 through 4.5.



### **4.3 CAUSE ANALYSIS**

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

The documentation of the analysis includes:

- (a) determination of cause;
- (b) extent of condition; and
- (c) identification of corrective actions, including those to preclude recurrence.

Management may also require causal analysis for other significant conditions.

### **4.4 CORRECTIVE ACTIONS**

Corrective actions are applied commensurate with the significance of the condition. Additionally, each condition adverse to quality requires action to correct the condition. In determining the actions to take, the following should be considered: (1) the consequence of malfunction or failure of the item; (2) the design and fabrication complexity or uniqueness of the item; (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 item; (5) the quality history and degree of standardization of the item; (6) the difficulty of repair or replacement, especially after installation; and (7) the effect on ITAAC conclusions (refer to NEI 08-01). Completion of corrective actions should be documented.

Corrective actions implemented for significant conditions adverse to quality are to be reported to appropriate levels of management.

### **4.5 FOLLOW-UP AND CLOSURE**

Corrective actions for significant conditions adverse to quality are verified after the actions are completed. Monitoring of corrective action status is required to assure completion in a timely manner. Additionally, for significant conditions adverse to quality an effectiveness review of the corrective actions taken to preclude recurrence is performed.

#### **4.6 ANALYZING FOR ADVERSE TRENDS**

Periodically, conditions adverse to quality will be analyzed for adverse trends within and across the various work processes. A trending process will be implemented that can identify adverse trends that are QA program deficiencies or significant to safety (such as repetitive failures or process weaknesses). If this analysis indicates an adverse trend, that trend will be entered into the corrective action process. The significance of identified trends is classified in accordance 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.

Trending of conditions adverse to quality can be accomplished using cognitive skills, on a periodic basis, 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.

The documentation necessary for trending can take many forms and should be called out in the individual implementing procedures. Each of the Basic and Supplementary Requirements of NQA-1 specify the documentation and records that are necessary to provide the objective evidence of satisfactory accomplishment of the process being implemented.

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

Each project will be responsible for defining the parameters that represent an adverse trend for each work process taking into consideration the time period of the assessment, the number and duration of activities being trended and the number of identified conditions.

### **5 IDENTIFICATION AND CORRECTION OF CONDITIONS THROUGH IN-PROCESS WORK**

Some degree of corrective action is an inherent part of the work processes that implement the quality assurance program requirements for the nuclear facility. The governing procedures for these work processes must include requirements for promptly identifying, documenting, and correcting conditions. Conditions and corrective actions are documented in a format that permits reviewing, evaluating, trending, and verifying the results of the activities; thereby satisfying the requirements for corrective action identified in Section 4. Management responsible for the work activities are responsible

for establishing a process to identify potentially significant conditions. Conditions determined to be potentially significant are elevated for further review. Management responsible for the work activities is responsible for identification of adverse trends, such as repetitive failures or process weaknesses.

Each work process must meet the QA requirements for defining, controlling and verifying the quality of the activity or item. The process must include the provisions for documenting activities 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.

The left column of Attachment 2 provides examples of nonsignificant conditions that would normally be identified and corrected during the work process.

If corrective actions associated with measuring and test equipment are not addressed in a separate administrative process, the corrective action process shall address actions to be taken when measuring and test equipment is found out of calibration, including a documented evaluation of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested.

If conditions adverse to quality identifying hardware nonconformance with a technical requirement are not addressed in a separate administrative process, the corrective action process shall address identification, documentation, evaluation, segregation, and disposition of nonconforming items, and for notification of affected organizations. Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use-as-is shall be documented. Nonconformance to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design, and as-built records, if such records are required, shall reflect the accepted deviation. Definitions for nonconformance dispositions (i.e., *repair*, *rework*, and *use-as-is*) are provided in Section 1.1.

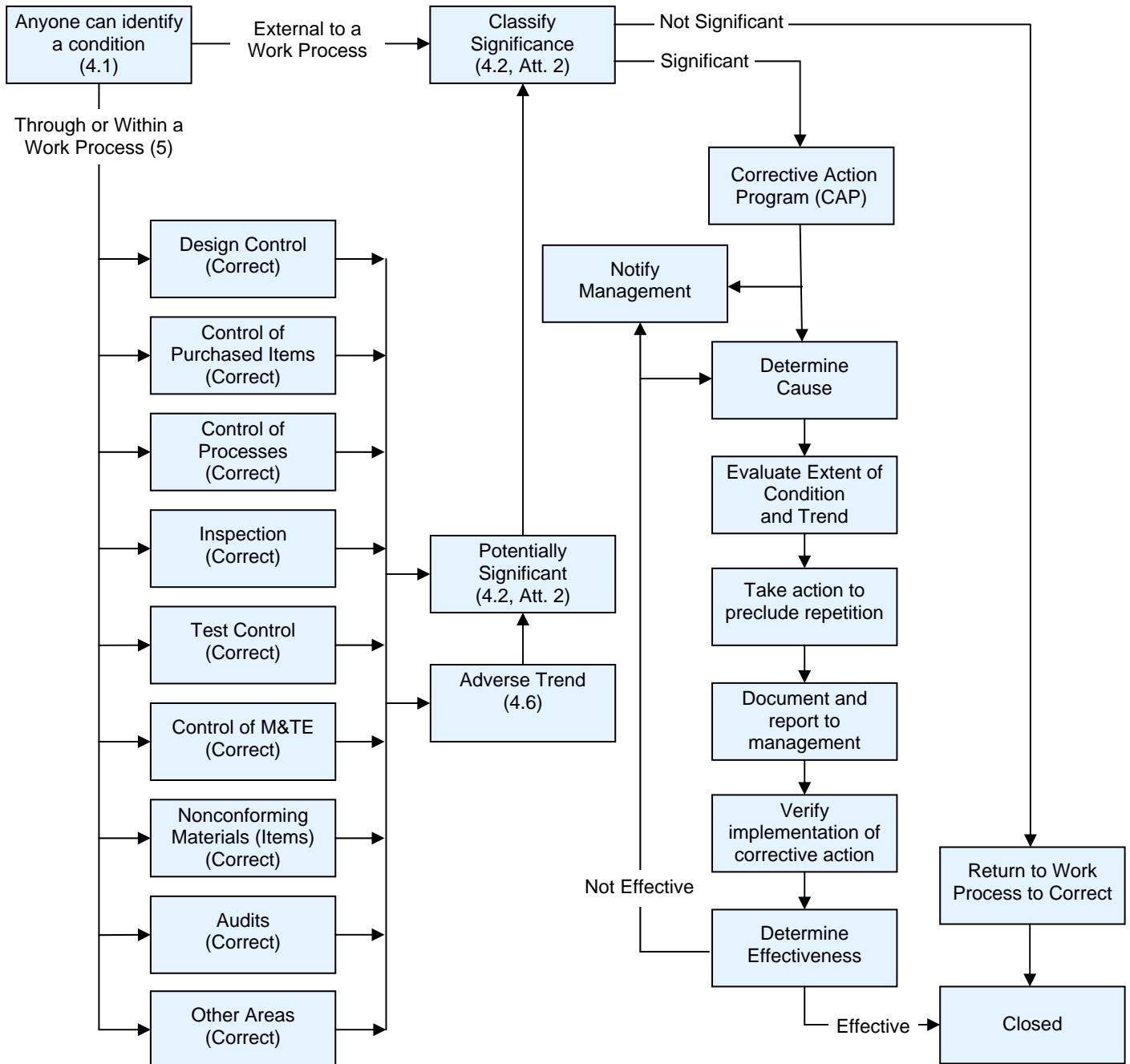
## **6 RECORDS**

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



# ATTACHMENT 1

## PI&R Process Flow (Page 1 of 2)



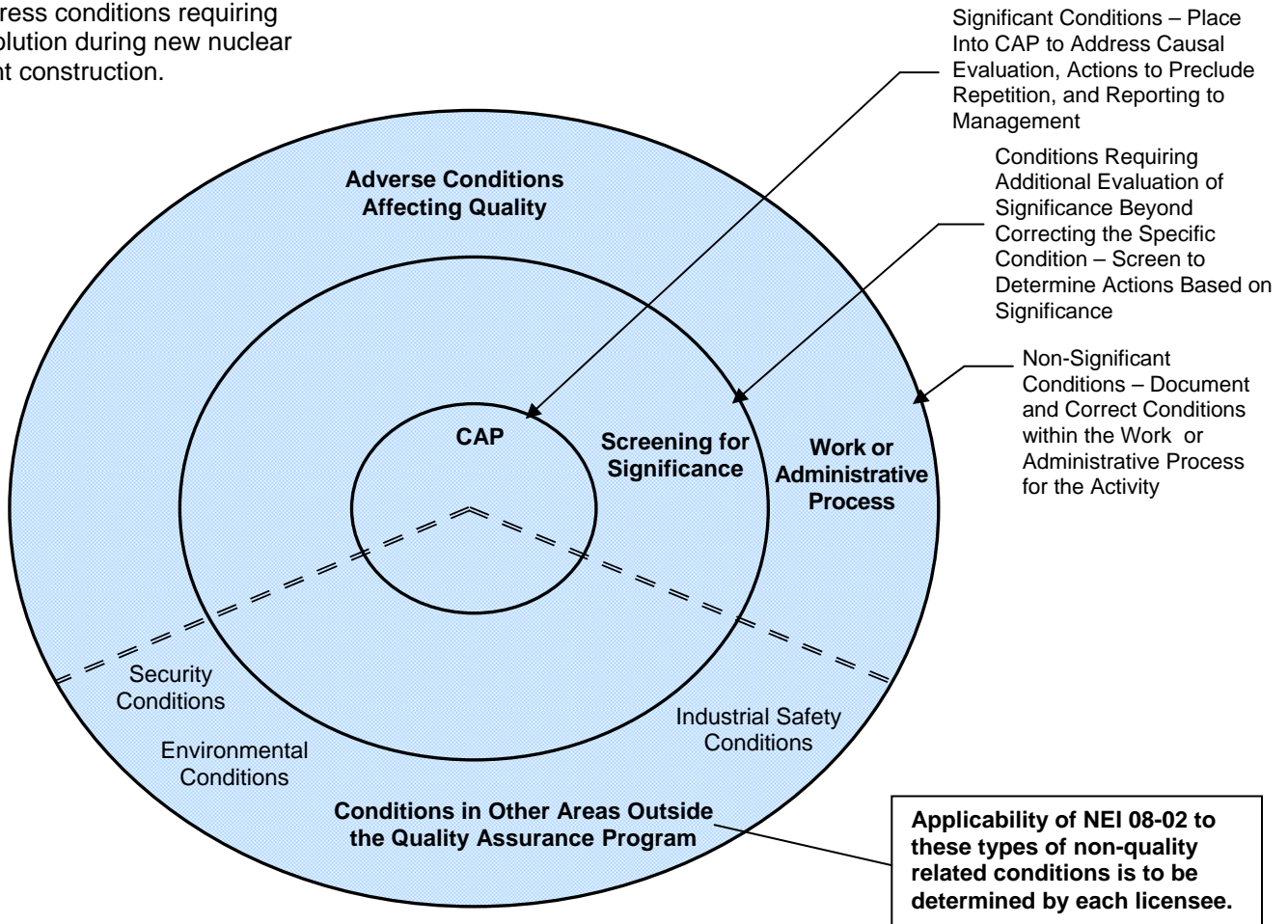
# ATTACHMENT 1

## ATTACHMENT 1

### PI&R Process Diagram

(Page 2 of 2)

The PI&R Process is used to address conditions requiring resolution during new nuclear plant construction.



## **ATTACHMENT 2**

### **Examples for Identifying and Classifying Conditions in the PI&R Process during the Construction Phase**

NOTE: The following table contains examples of conditions that would be identified during the construction phase showing the differences between those considered non-significant, those that have the potential to be significant, and those that would be considered significant. These examples are not all-inclusive, but are intended to guide the user of this document in developing and implementing their PI&R process.

The examples listed in the Non-Significant column are those that could be identified, resolved and documented within the normal implementing work procedures for the work area without entering into the CAP.

The examples listed in the Potentially Significant column are those that require additional evaluation beyond correcting the specific issue. These items may also warrant causal determination and identification of additional corrective actions, but could be determined to not require any additional actions outside of the work process.

The examples listed in the Significant column are those that require causal determination and actions to prevent recurrence of the condition. Where the condition includes process or program deficiencies, it would be necessary to identify the extent of the condition and ensure the actions correct any other occurrences, including past occurrences. In addition, the significant conditions require reporting of the condition, cause, and corrective actions taken to appropriate levels of management.

**ATTACHMENT 2**

<b>Design Control</b>		
Non-significant	Potentially Significant	Significant Conditions
<ul style="list-style-type: none"> <li>• 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,</li> <li>• Configuration management discrepancies (e.g. minor interferences due to tolerance stack-up)</li> <li>• Drafting errors that do result in incorrect or deficient design</li> <li>• 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</li> </ul>	<ul style="list-style-type: none"> <li>• Design errors or deficiencies found in design documents, (e.g. drawings, specifications, calculations, etc.) after release for procurement or construction</li> <li>• 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)</li> <li>• 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) fails to meet Design Reliability Assurance or ITAAC requirements</li> <li>• A design condition identified after an item, activity, or service is released for use that would prevent the item, activity, or service from meeting or performing its intended function or output</li> <li>• An adverse trend related to the design control program</li> <li>• Operating/construction experience or reviews that identify a failure to meet design requirements</li> </ul>	<ul style="list-style-type: none"> <li>• 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</li> <li>• A deviation, nonconformance, or failure to comply with regulations found to be reportable under 10 CFR Part 21 or 10 CFR 50.55(e)</li> <li>• 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</li> <li>• An adverse trend related to the design control program indicating a significant program or process breakdown</li> <li>• A design deficiency by which the capability to withstand a single failure is compromised, where required</li> <li>• 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)</li> </ul>



**ATTACHMENT 2**

<b>Control of Purchased Items</b>		
<b>Non-significant</b>	<b>Potentially Significant</b>	<b>Significant Conditions</b>
<ul style="list-style-type: none"> <li>• Conditions identified with equipment or materials identified during receipt inspection that deviate from technical or quality requirements specified in the purchase documents</li> <li>• Errors in procurement document (inadequate procurement requirements that affect the quality of the item or service) identified prior to issuance</li> <li>• Inadequate storage conditions that have not impacted stored items</li> </ul>	<ul style="list-style-type: none"> <li>• 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</li> <li>• 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</li> <li>• 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</li> <li>• 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)</li> <li>• Inadequate environmental storage conditions that have potentially degraded stored items</li> <li>• Programmatic procurement-related conditions</li> <li>• An adverse trend in the procurement of items or services</li> <li>• The loss of essential data required for activities or items subject to the QA program (QA Records)</li> </ul>	<ul style="list-style-type: none"> <li>• Evidence of fraudulent activities by the supplier</li> <li>• 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</li> <li>• A deviation, nonconformance, or failure to comply with regulations found to be reportable under 10 CFR Part 21 or 10 CFR 50.55(e)</li> <li>• An adverse trend in the procurement of items or services that indicates a significant program or process breakdown</li> <li>• 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</li> </ul>

**ATTACHMENT 2**

<b>Control of Special Processes</b>		
<b>Non-significant</b>	<b>Potentially Significant</b>	<b>Significant Conditions</b>
<ul style="list-style-type: none"> <li>• 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)</li> <li>• Improper weld preparation (e.g. dimensions for an EB insert, improper land dimension, wrong face angle) identified within the process</li> <li>• Improper preparation for coating application identified within the process</li> <li>• Deficiencies related to code compliance identified during review of procedures governing special processes prior to release for use</li> <li>• Equipment (e.g. weld machine, NDE equipment, heat treating equipment, fire-resistant foam machine, M&amp;TE, etc.) malfunction identified prior to or during the process</li> <li>• Performing special process without proper instructions/procedure (e.g. weld traveler) with no material impact</li> </ul>	<ul style="list-style-type: none"> <li>• Major weld defects after weld completion where engineering disposition is required for directing repair</li> <li>• Weld rod control problems that resulted in incorrect filler material in an accepted weld installed in the facility</li> <li>• Improper weld preparation (e.g. dimensions for an EB insert, improper land dimension, wrong face angle) identified outside the process</li> <li>• Improper preparation for coating application identified outside the process</li> <li>• 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)</li> <li>• Equipment malfunctions identified after completion of the process</li> <li>• Heat treatment outside procedure acceptance criteria (requiring engineering evaluation)</li> <li>• Unqualified process/procedure/person used (may be weld/welder, NDE technician, coating, concrete mix adjustment, fire barrier installation, etc.) for fabrication/installation</li> <li>• Expired shelf life of consumable material (e.g. NDE materials, fire barrier material, coatings, etc.) discovered after their use</li> <li>• An adverse trend related to an activity or item subject to process controls</li> </ul>	<ul style="list-style-type: none"> <li>• Major weld process control problems (programmatic) that could result in significant defects</li> <li>• 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</li> <li>• A deviation, nonconformance, or failure to comply with regulations found to be reportable under 10 CFR Part 21 or 10 CFR 50.55(e)</li> <li>• 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</li> <li>• Programmatic process control problems that result in unacceptable defects</li> <li>• An adverse trend related to an activity or item subject to process controls that indicates a significant program or process breakdown</li> </ul>

**ATTACHMENT 2**

<b>Inspection</b>		
Non-significant	Potentially Significant	Significant Conditions
<ul style="list-style-type: none"> <li>• Inspection results that indicate deviation from engineering drawings, specifications, procurement documents, or procedures identified during routine Quality Control inspection activities that can be corrected within the work process .</li> </ul>	<ul style="list-style-type: none"> <li>• 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)</li> <li>• Inspection results that indicate deviation from engineering drawings, specifications, or procedures identified after final acceptance</li> <li>• The inspection identifies a deviation from the controlling process (e.g., incorrect or unqualified process implemented, bypassed hold points)</li> <li>• The loss of essential data required for activities or items subject to the QA program (QA Records)</li> <li>• An adverse trend related to the inspection program</li> <li>• Inspector not qualified for inspection performed</li> <li>• Unsatisfactory inspection results where corrective action involves multiple work processes</li> <li>• A program or process deficiency that has the potential to affect a previously accepted inspection</li> </ul>	<ul style="list-style-type: none"> <li>• A deviation, nonconformance, or failure to comply with regulations found to be reportable under 10 CFR Part 21 or 10 CFR 50.55(e)</li> <li>• Evidence of fraudulent activities or material</li> <li>• An adverse trend related to the inspection program that indicates a significant program or process breakdown</li> </ul>

**ATTACHMENT 2**

<b>Test Control</b>		
Non-significant	Potentially Significant	Significant Conditions
<ul style="list-style-type: none"> <li>• Conditions identified during the set-up of the test</li> <li>• 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</li> <li>• Test equipment malfunctions</li> <li>• Conditions or problems identified during tests (equipment functional and pre-operational testing problems) that can be corrected within the test plan</li> </ul>	<ul style="list-style-type: none"> <li>• 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)</li> <li>• Control system error identified after software has been released for use</li> <li>• Inadequately performed test due to test procedure not adhered to or incorrectly written</li> <li>• An adverse trend related to the test program</li> <li>• Test personnel not qualified for test performance</li> <li>• The loss of essential data required for activities or items subject to the QA program (QA Records)</li> </ul>	<ul style="list-style-type: none"> <li>• 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)</li> <li>• 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</li> <li>• 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)An adverse trend related to the test program that indicates a significant program or process breakdown</li> </ul>

**ATTACHMENT 2**

<b>Control of M&amp;TE</b>		
<b>Non-significant</b>	<b>Potentially Significant</b>	<b>Significant Conditions</b>
<ul style="list-style-type: none"> <li>• M&amp;TE found out of the required accuracy limits (i.e., out of tolerance) during post-use calibration that does not require reinspection or retest</li> <li>• Calibration activities not performed in accordance with specified procedures identified prior to issuance of M&amp;TE</li> <li>• Incorrect specifications or standards utilized in calibration process identified prior to issuance/use of M&amp;TE</li> <li>• Evaluation of out of tolerance, lost, or damaged M&amp;TE indicates questionable acceptability for previous inspection or test results indicating the need to re-inspect or re-test the SSC</li> </ul>	<ul style="list-style-type: none"> <li>• Re-inspection or re-test of an SSC, as a result of out of tolerance, lost, or damaged M&amp;TE, has an unacceptable result</li> <li>• Calibration activities not performed in accordance with specified procedures – identified after issuance of M&amp;TE</li> <li>• Incorrect specifications or standards utilized in calibration process identified after issuance/use of M&amp;TE</li> <li>• 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)</li> <li>• An adverse trend related to the M&amp;TE program</li> </ul>	<ul style="list-style-type: none"> <li>• Re-inspection or re-test of an SSC, as a result of out of tolerance, lost, or damaged M&amp;TE, has an unacceptable result that adversely affects a completed ITAAC</li> <li>• Evidence of Fraudulent activities associated with calibration or use of M&amp;TE</li> <li>• A deviation, nonconformance, or failure to comply with regulations found to be reportable under 10 CFR Part 21 or 10 CFR 50.55(e)</li> <li>• An adverse trend related to the M&amp;TE program that indicates a significant program or process breakdown</li> </ul>

**ATTACHMENT 2**

<b>Nonconforming Materials (Items)</b>		
<b>Non-significant</b>	<b>Potentially Significant</b>	<b>Significant Conditions</b>
<ul style="list-style-type: none"> <li>• 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</li> <li>• Expired shelf life identified prior to using the material</li> <li>• Nonconforming item discovered prior to final acceptance</li> <li>• Damaged safety-related or quality-related item received at site</li> </ul>	<ul style="list-style-type: none"> <li>• 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)</li> <li>• An adverse trend related to nonconforming items</li> <li>• Nonconforming item that renders the quality of an installed component unacceptable or indeterminate identified after final acceptance</li> <li>• Nonconforming item identified that potentially has broad industry implications</li> </ul>	<ul style="list-style-type: none"> <li>• A deviation, nonconformance, or failure to comply with regulations found to be reportable under 10 CFR Part 21 or 10 CFR 50.55(e)</li> <li>• An adverse trend related to nonconforming items that indicates a significant program or process breakdown</li> </ul>

## ATTACHMENT 2

<b>Audits</b>		
Non-significant	Potentially Significant	Significant Conditions
<ul style="list-style-type: none"> <li>• 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</li> </ul>	<ul style="list-style-type: none"> <li>• 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)</li> <li>• An adverse trend related to the audit program</li> <li>• Audit team member not qualified</li> <li>• A program or process deficiency that has the potential to affect audit performance</li> <li>• Audit team fails to provide objective evidence to substantiate the audit conclusion</li> <li>• Audit team members are not independent of the process being audited</li> <li>• Isolated cases of not performing audits within the required frequency</li> <li>• Failure to follow-up corrective action</li> </ul>	<ul style="list-style-type: none"> <li>• Adverse audit findings indicative of a significant quality assurance program breakdown (Ref. 10 CFR 50.55(e))</li> <li>• A deviation, nonconformance, or failure to comply with regulations found to be reportable under 10 CFR Part 21 or 10 CFR 50.55(e)</li> <li>• An adverse trend related to the audit program that indicates a significant program or process breakdown</li> <li>• Audit program is inhibited</li> <li>• Repeated occurrences of not performing audits within the required frequency</li> <li>• Audit team fails to identify pre-existing conditions such as: inadequate records retention, inadequate vendor PI&amp;R process implementation, or inadequate configuration control</li> </ul>

## ATTACHMENT 2

<b>Other Areas Affecting Quality Assurance</b>		
Non-significant	Potentially Significant	Significant Conditions
<ul style="list-style-type: none"> <li>• Corrections of obvious editorial or typographical errors on a QA Record</li> <li>• 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</li> <li>• Foreign Material Exclusion concerns such as near miss events in systems/components important to Nuclear Safety prior to turnover</li> <li>• Work packages or Travelers found to have incorrect instructions before being issued for use.</li> <li>• Incorrect vendor manuals/instructions identified during work execution prior to SSC turnover</li> <li>• Isolated examples of failure to follow procedures</li> <li>• Isolated examples of inadequate management oversight of individual processes</li> </ul>	<ul style="list-style-type: none"> <li>• 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)</li> <li>• Adverse surveillance findings indicating a programmatic breakdown</li> <li>• Significant procedural or administrative control non-compliance that affects plant safety</li> <li>• A nonconformance that indicates a problem exists within the controlling process as opposed to a hardware condition</li> <li>• Work packages or Travelers found to have incorrect instructions after being issued for use and implementation</li> <li>• Completed construction activities are not within the tolerances allowed by design documents or process controls</li> <li>• Procedural adherence issue</li> <li>• Loss of essential data required for activities or items subject to the QA Program (QA Records)</li> <li>• Missing, incomplete or otherwise deficient QA Records</li> <li>• Documentation required by NRC requirements such as 10 CFR 50.49 is unavailable or deficient</li> <li>• Any adverse trend related to an activity or item subject to the QA program</li> <li>• Individual performing activities does not have a valid qualification</li> <li>• Adverse condition found after licensee</li> </ul>	<ul style="list-style-type: none"> <li>• A deviation, nonconformance, or failure to comply with regulations found to be reportable under 10 CFR Part 21 or 10 CFR 50.55(e)</li> <li>• Adverse surveillance findings indicative of a significant quality assurance program breakdown (Ref. 10 CFR 50.55(e))</li> <li>• 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</li> <li>• Repetitive problems indicating programmatic failures or precursor of significant technical deficiencies</li> <li>• Falsification of QA Records</li> <li>• A significant adverse trend related to an activity or item subject to the QA program</li> <li>• Apparent sabotage or tampering</li> <li>• Incorrect vendor instructions identified after SSC turnover that significantly affects SSC safety function</li> <li>• Significant Loss of Foreign Material Exclusion controls impacting safety-related systems</li> <li>• Significant human performance event causing damage to safety-related equipment</li> </ul>



**ATTACHMENT 2**

<b>Other Areas Affecting Quality Assurance</b>		
<b>Non-significant</b>	<b>Potentially Significant</b>	<b>Significant Conditions</b>
	<p>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)</p> <ul style="list-style-type: none"> <li>• Any condition or nonconformance that results in a Stop Work Order being imposed</li> <li>• Repetitive issues identified in human performance, procedure use and adherence, supervisor oversight, corrective action, or SCWE</li> <li>• Adverse audit findings indicating a programmatic breakdown</li> <li>• Ineffective corrective action for an adverse audit finding</li> </ul>	

<b>Other Areas Outside the Quality Assurance Program</b>		
Non-significant	Potentially Significant	Significant Conditions
<ul style="list-style-type: none"> <li>• Injury requiring first aid only</li> <li>• Potential fire or safety concern</li> <li>• OSHA recordable incident</li> </ul>	<ul style="list-style-type: none"> <li>• 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)</li> <li>• Unattended Safeguards Information or loss of Safeguards Information</li> <li>• NRC identified issues (Cited or non-cited violations)</li> <li>• A Physical Protection Program, Access Authorization/Control, Fitness for Duty breakdown</li> <li>• Foreign Material in any system/component important to plant generation with a high potential to affect system functionality or operations</li> <li>• An individual who met denial criteria was granted access</li> <li>• Fire incident inside the plant boundary with potential impact on personnel safety or SSCs</li> </ul>	<ul style="list-style-type: none"> <li>• 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)</li> <li>• Fire in the plant with significant impact on corporate assets</li> <li>• Significant security issues as defined by security procedures or reportability requirements</li> <li>• Fatality, severe personal injury, or significant industrial hazard</li> <li>• An event that results in a violation of non-radiological environmental release limits</li> <li>• 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</li> </ul>