INSPECTION PROCEDURE 90001

CONSTRUCTION REGULATORY RESPONSE COLUMN INSPECTIONS

PROGRAM APPLICABILITY: 2505

90001-01 INSPECTION OBJECTIVES

01.01 To verify that significant violations are fully documented and that the documentation includes details of prior opportunities for the licensee to have identified the findings.

01.02 To verify that the root causes and contributing causes of significant violations are understood.

01.03 To verify that the extent of condition and extent of cause of significant violations are identified.

01.04 To verify that licensee corrective actions are sufficient to address the root causes and contributing causes, and to preclude repetition.

90001-02 INSPECTION REQUIREMENTS AND GUIDANCE

02.01 Background. The U.S. Nuclear Regulatory Commission's (NRC's) construction inspection program includes three parts: construction inspections, special inspections, and construction supplemental inspections performed as a result of significant performance issues. The construction supplemental inspection program is designed to apply NRC inspection assets in an increasing manner when significant violations are identified. The NRC Center for Construction Inspection (CCI) will perform this construction supplemental inspection for those significant violations that result in licensee performance in the Regulatory Response column of the Construction Action Matrix (CAM). The scope and breadth of these inspections will be based on the guidance provided in Inspection Manual Chapter (IMC) 2505, "Periodic Assessment of Construction Inspection Program Results." The construction supplemental inspection program is designed to support the NRC's goals of ensuring safety and security.

The guidance provided in this inspection procedure (IP) was developed with consideration of the following boundary conditions:

- Performance of periodic inspections of the licensee's corrective action program (CAP) in accordance with IP 35007, "Quality Assurance Program Implementation During Construction," is independent of the construction supplemental inspection program;

- The construction supplemental inspection requirements contained in this IP will be completed for each significant violation that results in licensee performance in the "Regulatory Response" column in the CAM; and

- New examples of issues identified as a result of construction supplemental inspections will be evaluated and categorized in accordance with IMC 0613.

02.02 General Requirements. In order to adequately protect the health and safety of the public, once a significant violation is identified, the NRC staff must ensure that a licensee identifies the causes and implements actions to preclude repetition of the significant violation. The most effective and efficient way for the NRC to accomplish this objective is to allow the licensee the opportunity to perform its own evaluation of the significant violation, and then for the NRC to review the licensee's evaluation. These reviews by the NRC are expected to be sufficient, provided the licensee has demonstrated an effective CAP or other documented process.

Licensee evaluations of significant violations reviewed by the NRC during the implementation of this IP may be related to significant violations of 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Processing Plants." These significant violations will be significant conditions adverse to quality (SCAQs) and will be entered into the licensee CAP. Other evaluations of significant violations reviewed by the NRC may include those not related to Appendix B, such as an order or technical specification. The licensee may choose to include non-Appendix B significant violations in the CAP or to document these other significant violations in accordance with separate processes.

These construction supplemental inspection requirements represent a comprehensive set of attributes related to identification of the significant violation, root cause analysis, and establishment of corrective actions. The licensee's evaluation generally will need to address each of the inspection requirements in order to ensure that the causes of the significant violations are identified and effective corrective actions are taken to preclude repetition. However, the depth of the NRC's review may vary, depending upon the significance and complexity of the significant violation. In some cases, the answers to specific inspection requirements will be self-evident with little additional review or analysis required.

It is not the intent for NRC inspectors to perform an independent evaluation of the significant violation, nor to merely verify that an evaluation has been performed without assessing its adequacy. Rather, inspectors should sufficiently challenge aspects of the licensee's evaluation, as necessary, to ensure that the cause(s) of the significant violation has been identified and appropriate corrective actions have been planned or

taken to preclude repetition. Inspectors may use information previously obtained from other inspections to develop the construction supplemental inspection conclusions. However, the inspection report associated with this inspection should contain the NRC's assessment of the licensee's evaluation for each inspection requirement described in subsection 02.05 of this IP. The results of this inspection will be documented in accordance with the specific guidance contained in IMC 0613, "Documenting 10 CFR Part 52 Construction and Test Inspections."

Significant weaknesses in the licensee's actions to address the significant violation, including weaknesses associated with the failure to identify the safety culture components described in IMC 2505, or to perform an adequate evaluation of the significant violation, may be subject to additional agency actions, including: (1) those specified in IMC 2505; (2) additional enforcement actions; or (3) expansion of the implementation of this IP, as necessary, to independently acquire the information necessary to satisfy the inspection requirements. Expansion of the implementation may be necessary if inspectors need to independently evaluate the significant violation or safety culture aspects as a result of the licensee not performing its own analysis. It is not expected that inspectors would perform this safety culture evaluation as a separate construction supplemental inspection.

In general, licensees should be given an opportunity to correct any significant violation prior to re-inspection. For significant weaknesses in the licensee's actions to address an issue associated with a significant violation, including a substantial inadequacy in the licensee's evaluation of the extent of the condition, root causes, or corrective actions, the notice of violation will remain open and will not be removed from the CAM until the weaknesses are addressed and corrected. Programmatic weaknesses associated with the licensee's evaluation of the significant violations also will be documented by briefly describing the weaknesses in the transmittal letter and the Summary of Findings section in the inspection report. An amplified discussion of the weaknesses should be provided in the inspection report details. Additional focus will be given to those areas during follow-up inspections of the implementation of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50, performed in accordance with IP 35007.

If new or additional examples of findings are identified during this inspection or by the licensee during its evaluation, then the significance of the new findings will be determined, and the corresponding construction supplemental inspection procedure (i.e., IP 90001; IP 90002, "Degraded Performance Inspection;" or IP 90003, "Unacceptable Performance Inspection") will be implemented in accordance with IMC 2505 and the CAM.

02.03 General Guidance. This IP is used to assess the adequacy of the licensee's evaluation of significant violations that result in licensee performance in the Regulatory Response column of the CAM. As such, a reasonable time (generally within 30-60 days) should be allowed for the licensee to enter the significant violation into its CAP or other documented process and to complete its evaluation; however, all corrective actions may not be fully completed upon commencement of this construction

supplemental inspection. The inspection should not be scheduled until the licensee has identified and entered the significant violation into the CAP or other documented process, evaluated the significant violation, and developed the corrective action plan. In the event that the licensee has not defined its corrective action plan within a reasonable time, NRC management should request that the licensee provide the basis for the delay. Implementation of the licensee's corrective actions may be verified during follow-up inspections, such as Criterion XVI of Appendix B to 10 CFR Part 50, performed in accordance with IP 35007.

It is not intended for the inspector to verify that the licensee's evaluation of the significant violation contains every attribute contained in the inspection guidance sections of this IP. The intent is that inspectors use the guidance sections of this IP to look for weaknesses in the licensee's evaluation that might indicate an issue associated with one of the inspection requirements. To the extent that additional independent follow-up is accomplished by looking for similar issues, the inspector should make the selection of other structures, systems, and components (SSCs) from those with Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) associated with them whenever possible.

02.04 Definitions.

a. Condition Adverse to Quality (CAQ). Failure, malfunction, deficiency, deviation, defective material and equipment, or nonconformance that requires prompt identification and correction.

b. Consequences. Actual or potential outcome of an identified issue or condition.

c. Contributing Cause. Cause that, by itself, would not create the finding, but is important enough to be recognized as needing corrective action. Contributing causes are sometimes referred to as causal factors. Causal factors are those actions, conditions, or events that directly or indirectly influence the outcome of a situation or issue.

d. Extent of Cause. Extent to which the root cause(s) of a finding has impacted other plant processes, equipment, or human performance.

e. Extent of Condition. Extent to which the actual condition exists within other plants, processes, equipment, or human performance.

f. Finding. Violation of regulatory requirements that has greater-than-minor significance. Examples of findings include a Construction Finding, an ITAAC-Related Construction Finding, or an ITAAC Finding (see definitions and guidance in Inspection Manual Chapter 0613).

g. Repeat Occurrence. Two or more independent conditions that are the result of the same basic causes.

h. Root Cause. Basic reason (e.g., hardware, process, human performance) for a finding which, if corrected, will preclude repetition of that finding.

i. Significant Condition Adverse to Quality (SCAQ). CAQ of such significance that adequate corrective actions shall be taken to assure that the cause of the condition is determined and the condition is prevented from recurring.

j. Significant violation. Inspection finding resulting in a greater-than-minor violation with escalated enforcement.

02.05 Specific Requirements and Guidance.

a. Identification of Significant Violation.

1. Requirements.

(a) Determine that the evaluation documents how the finding was identified (e.g., licensee-identified, self-revealing, NRC-identified) and under what conditions the finding was identified.

(b) Determine that the evaluation documents how long the significant violation existed and prior opportunities for identification.

(c) Determine that the evaluation documents the plant-specific (including ITAAC-related) consequences (as applicable) and compliance concerns associated with the significant violation.

2. Guidance.

(a) The evaluation should state how and by whom the finding was identified. When appropriate, the licensee's failure to identify the finding at a precursor level should be evaluated. Specifically, the licensee's failure to identify a finding before it becomes significant may indicate a more substantial issue. Examples include the licensee's failure to:

(1) enter a recognized finding into its CAP or other documented process

(2) raise quality concerns to management; or

(3) complete corrective actions for a previously identified finding that resulted in additional findings.

If the NRC identified the finding, the licensee's evaluation should address why licensee processes, such as peer review, supervisory oversight, inspection, testing, self assessments, or quality activities, did not identify the finding.

(b) The evaluation should state when the significant violation was identified, how long the significant violation existed, and whether there were prior opportunities for correction. For example, a construction activity may have resulted in a component not functioning correctly and that failure to function correctly was not detected by testing or by quality assurance oversight. The reasons that the testing and quality assurance oversight did not detect the error should be included in the significance identification statement and addressed in the root cause evaluation.

(c) The evaluation should state how the licensee determined the significance of the finding (e.g., based upon potential consequences), the priority for resolving the significant violation, the schedule for timely resolution of the significant violation, and the individuals or organizations responsible for implementing the corrective actions.

b. Root Cause, Extent of Condition, and Extent of Cause Evaluation of Significant Violation.

1. Requirements.

(a) Determine that the significant violation was evaluated using a systematic methodology to identify the root and contributing causes.

(b) Determine that the root cause evaluation was conducted to a level of detail commensurate with the significance of the finding.

(c) Determine that the root cause evaluation included a consideration of prior occurrences of the finding and knowledge of any prior construction experience (at the facility or other facilities).

(d) Determine that the root cause evaluation addresses the extent of condition and the extent of cause of the significant violation.

(e) Determine that the root cause, extent of condition, and extent of cause evaluations appropriately considered the safety culture components as described in IMC 2505.

2. Guidance.

(a) The licensee's evaluation should generally make use of systematic methods to identify root and contributing causes. Some root cause evaluation methods that are commonly used in nuclear facilities include:

(1) Events and causal factors analysis - to identify the events and conditions that led up to the finding;

(2) Fault tree analysis - to identify relationships among events and the probability of event occurrence;

(3) Barrier analysis - to identify the barriers that, if present or strengthened, would have prevented the event from occurring;

(4) Change analysis - to identify changes in the work environment since the activity was last performed successfully that may have caused or contributed to the event;

(5) Management Oversight and Risk Tree (MORT) analysis - to systematically check that all possible causes of findings have been considered;

(6) Critical incident techniques - to identify critical actions that, if performed correctly, would have prevented the event from occurring or would have significantly reduced its consequences;

(7) Why Staircase - to produce a linear set of causal relationships and use the experience of the finding owner to determine the root cause and corresponding solutions; and

(8) Pareto Analysis - to use a statistical approach to problem solving to determine where to start an analysis.

(b) The licensee may use other methods to conduct the root cause evaluations. A systematic evaluation of a significant violation using one of the above methods should normally include:

(1) Clear identification of the significant violation and the assumptions made as a part of the root cause evaluation.

For example, the evaluation should describe the initial conditions of the system or component identified, staffing levels, and training requirements as applicable.

(2) Timely collection of data, verification of data, and preservation of evidence to ensure that the information and circumstances surrounding the finding are fully understood. The analysis should be documented such that the progression of the finding is clearly understood, any missing information or inconsistencies are identified, and the finding can be easily explained and/or understood by others.

(3) Determination of cause and effect relationships resulting in an identification of root and contributing causes that consider potential hardware, process, and human performance issues. For example:

- Hardware issues could include design, materials, damage during installation, and environmental conditions;

- Process issues could include procedures, work practices, construction policies, supervision and oversight, preventive and corrective maintenance programs, and quality control methods; and

- Human performance issues could include training, communications, human system interface, and fitness for duty (if applicable).

(c) The root cause evaluation should be conducted to a level of detail that is adequate for the complexity of the significant violation. Different root cause evaluation methods provide different perspectives on the finding. In some instances, using a combination of methods helps ensure that the analysis is thorough. Therefore, the root cause evaluation should consider evaluating complex significant violations, which could result in significant consequences, using multi-disciplinary teams and/or different and complementary methods appropriate to the circumstances. For example, significant violations that involve hardware issues could be evaluated using barrier analysis, change analysis, or fault trees.

The depth of a root cause evaluation is normally achieved by completely and systematically applying the methods of analysis described in subsection 02.05.b.2 of this IP and by repeatedly asking the question “Why?” about the occurrences and

circumstances that caused or contributed to the significant violation. Once the analysis has developed all of the causes for the finding (i.e., root, contributing, and programmatic), the evaluation should also look for any relationships among the different causes. The depth of the root cause evaluation may be assessed by:

(1) Determining that the questioning process appeared to have been conducted until the causes were beyond the licensee's control.

For example, findings that were initiated by an act of nature, such as a lightning strike or tornado, could have the act of nature as one of the causes of the significant violation. The act of nature would not be a candidate root cause, in part, because the licensee could not prevent it from happening again. However, a licensee's failure to plan for, or respond properly to, acts of nature would be under management control and could be root causes for the significant violation.

(2) Determining that the significant violation was evaluated to ensure that other root and contributing causes were not inappropriately ruled out because of assumptions made as a part of the analysis.

For example, a root cause evaluation may not consider the adequacy of the design or process controls for a system if the significant violation appears to be primarily human-performance focused. Consideration of the technical appropriateness of the evaluation assumptions used in the root cause evaluation and their impact on the root causes also would be appropriate.

(3) Determining that the evaluation collectively reviewed all root and contributory causes for indications of more fundamental issues with a process or system.

For example, a significant violation that involved a number of procedural inadequacies or errors may indicate a more fundamental or higher level inadequacy in the processes for procedural development, control, review, and approval. Significant violations associated with personnel failing to follow procedures may also be indicative of inadequate supervisory oversight and communication of standards.

(4) Determining that the root cause evaluation properly ensured that correcting the causes would preclude repetition of the

same or similar significant violation. Complex significant violations may have more than one root cause, as well as several contributing causes. The evaluation should include a process to verify that corrective actions for the identified root causes do not rely on unstated assumptions or conditions that are not controlled or ensured.

For example, root causes based on the work practices of a contractor or vendor may not apply to other contractors and vendors, even though they provide a similar service or item.

(5) Determining that the evaluation appropriately considered other possible root causes. Providing a rationale for ruling out alternative possible root causes helps to ensure the validity of the specific root causes that are identified.

(d) The root cause evaluation should include appropriate consideration of repeat occurrences of the same or similar significant finding at the facility and knowledge of prior construction experience. Prior construction experience includes experience at other facilities that the licensee should reasonably have been aware of through NRC generic communications and through information from other industry sources. This review is necessary to help in developing the specific root and contributing causes and also to provide indication as to whether the significant violation is a result of a more fundamental concern involving weaknesses in the licensee's CAP or other documented process.

The licensee's root cause evaluation should:

(1) Broadly question the applicability of other similar events or issues with related root or contributing causes.

For example, root cause evaluations associated with work activities by one contractor at the site (including remote fabrication sites) or by one vendor may be applicable to other contractors or vendors.

(2) Determine if previous root cause evaluations and/or corrective actions missed or inappropriately characterized the issues. Determine those aspects of the corrective actions that did not preclude repetition of the significant violation.

For example, the evaluation should review the implementation of the previously specified corrective actions and reassess the

identified root causes to determine process or performance errors that may have contributed to the repeat occurrence.

(3) Determine if the root cause evaluation for the current significant violation specifically addresses those aspects of the prior root cause evaluations or corrective actions that were not successfully addressed.

For example, if during the review of a tagging error that resulted in a misaligned valve during pre-operational testing the licensee determines that a previous similar significant violation occurred and the corrective actions only focused on individual training, then the root cause evaluation for the repeat occurrence should document why the previous corrective actions were inadequate.

(4) Include a review of prior documentation of findings and their associated corrective actions to determine if similar incidents have occurred previously.

For example, the licensee staff should consider the following during its review of prior construction experience: internal self-assessments, maintenance history, condition reports, and external databases developed to identify and track construction experience issues. Examples of external databases may include NRC Information Notices, NRC Generic Letters, Part 21 Reports, and vendor/industry generic communications.

The inspectors should discuss the significant violation and associated root causes with other resident, regional, or headquarters personnel to assess whether other similar findings or root causes should have been considered.

(e) The root cause evaluation should include a proper consideration of the extent of condition and the extent of cause of the significant violation and whether other systems, equipment, programs, or conditions could be affected.

The extent of condition review differs from the extent of cause review. The extent of condition review focuses on the actual condition and its existence in other places. The extent of cause review focuses more on the actual root causes of the condition and on the degree that these root causes have resulted in additional weaknesses.

(1) The extent of condition review should assess the degree that the actual finding (e.g., failed valve, inadequate procedure, improper human action) may exist in other plant equipment, processes, or human performance.

(2) The extent of cause review should assess the applicability of the root causes across disciplines or departments, contractors, or vendors for different programmatic activities, human performance, or different types of equipment.

For example, if a root cause for the misalignment of a valve during a test was determined to be a lack of quality control verification, then the adequacy of the verification should be assessed in other processes beyond valve alignments.

(f) The root cause evaluation should include a proper consideration of whether a weakness in any safety culture component was a root cause or significant contributing cause of the significant violation, and, if so, that weakness should be addressed through adequate corrective actions. Therefore, for each significant violation that prompted this inspection, consider whether the significant violation, the licensee's evaluation methodology, the set of results obtained using that methodology, or any related circumstance indicates that a weakness in any safety culture component could reasonably have been a root cause or significant contributing cause of the significant violation. If so, then for each such weakness, determine if the licensee considered in its evaluation if the weakness was a root cause or significant contributing cause of the significant violation and documented that consideration in its evaluation.

c. Corrective Actions for Significant Violations.

1. Requirements.

(a) Determine that appropriate corrective actions are specified for each root and contributing cause or that the licensee has an adequate evaluation for why no corrective actions are necessary.

(b) Determine that the corrective actions have been prioritized with consideration of the significance and regulatory compliance.

(c) Determine that a schedule has been established for implementing and completing the corrective actions and that the corrective actions are planned to be taken or have been taken in a reasonable amount of time, considering the complexity and significance of the finding.

(d) Determine that quantitative or qualitative measures of success have been developed for determining the effectiveness of the corrective actions to preclude repetition.

(e) Determine that the corrective actions planned or taken adequately address the significant violation that was the basis for the construction supplemental inspection.

2. Guidance.

The proposed corrective actions to the root and contributing causes should:

(a) Address each of the root and contributing causes and any weakness associated with the extent of condition and extent of cause of the significant violation. The corrective actions should be clearly defined and should have been taken or planned to be taken in a timely manner commensurate with the complexity and significance of the finding. Examples of corrective actions may include, but are not limited to: modifications, inspections, tests, process or procedure changes, and training. The proposed corrective actions should not create new or different issues as a result of the corrective actions. If the licensee determines that no corrective actions are necessary, then the basis for this decision should be documented in the evaluation.

(b) Include consideration of the results of the licensee's significance determination of the finding in prioritizing the type of corrective action(s) chosen. Attention should be given to solutions that involve only changing procedures or providing training, because these solutions are sometimes overused and may be inadequate. In such cases, consideration should be given to more comprehensive corrective actions, such as design modifications. The corrective action plan should also include a review of the regulations to ensure that the corrective actions result in compliance.

(c) Be assigned to the appropriate individuals or organizations to ensure that the actions are planned and taken in a timely manner. The licensee should also establish a formal tracking mechanism for each of the specific corrective actions.

(d) Establish a method to validate the effectiveness of the overall corrective action plan. Specifically, a method should be established to quantitatively or qualitatively measure the effectiveness of the corrective actions. Effective methods would include, but are not

limited to: assessments, audits, inspections, tests, trending of data, and/or follow-up discussions with plant staff.

The licensee's response to a significant violation that was the basis for the construction supplemental inspection should address:

(e) The reason for the significant violation

(f) Corrective actions that have been taken and the achieved results

(g) Corrective actions that will be taken (if applicable), and

(h) The date when full compliance was or will be achieved. The adequacy of the corrective actions should be reviewed in accordance with the guidance above to determine if they address the significant finding.

90001-03 RESOURCE ESTIMATE

It is estimated that a construction supplemental inspection in accordance with this IP will take between 16 and 80 inspection hours to complete for each finding. The inspector(s) assigned should be familiar with the discipline associated with the subject of the licensee's evaluation. For planning purposes, a resource estimate near the lower end of the scale should be used for licensees with CAPs that have been determined to be effective during Criterion XVI inspections conducted in accordance with IP 35007. This lower resource estimate also applies to licensees with separate processes for documenting non-Appendix B significant violation and that have been inspected in accordance with other IPs. For licensees with CAPs or other separate processes that have been previously determined to be ineffective, a resource estimate near the higher end of the scale should be used.

90001-04 PROCEDURE COMPLETION

Implementation of this IP is considered complete for a specific site when an affirmative 10 CFR 52.103 (g) finding occurs, at which time regulatory oversight transitions to the Reactor Oversight Process.

END

Attachment:
1. Revision History for IP 90001

Attachment 1: Revision History Sheet for IP 90001

Construction Regulatory Response Column Inspections

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number
N/A	10/27/10 CN 10-022	Original issue to support new reactor construction assessment programs described in IMC 2505. This is the initial issue of this document; therefore, a 4-year search of Historical Changes Notices is not applicable	No	N/A	ML100620079