NRC INSPECTION MANUAL

IQVB

INSPECTION MANUAL CHAPTER 0617

VENDOR AND QUALITY ASSURANCE IMPLEMENTATION INSPECTION REPORTS

Effective Date: 02/25/2020

VENDOR AND QUALITY ASSURANCE IMPLEMENTATION INSPECTION REPORTS

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0617-01 PURPOSE

This inspection manual chapter (IMC) provides guidance on documenting vendor and quality assurance (QA) implementation inspections performed by the Quality Assurance and Vendor Inspection Branch (IQVB). The purpose is to ensure clear and consistent content, format, and style for all vendor and QA implementation inspection reports.

0617-02 OBJECTIVES

02.01 To ensure that vendor and QA implementation inspection reports:

a. Clearly communicate significant inspection results to applicants, vendors, licensees, Nuclear Regulatory Commission (NRC) staff, and the public.

b. Provide conclusions about the effectiveness of the programs or activities inspected. The depth and scope of the conclusions should be commensurate with the depth and scope of the inspection.

c. Provide a basis for enforcement action.

NOTE: Enforcement guidance is given in the NRC Enforcement Policy, available on the NRC website. The NRC Enforcement Manual gives specific guidance on addressing noncompliance in inspection reports.

d. Provide a focused assessment of vendor or applicant compliance.

e. Address technical concerns that are inspected at the recommendation of an Allegation Review Board, without acknowledging that the issue was raised in the context of an allegation.

02.02 This manual chapter may also be used to document inspections conducted at a licensee's facility by IQVB.

0617-03 DEFINITIONS

Applicable definitions are found in IMC 2507, "Vendor Inspections."

0617-04 RESPONSIBILITIES AND AUTHORITIES

All NRC inspectors are required to prepare vendor and QA implementation inspection reports in accordance with the guidance provided in this IMC.

General Responsibilities. Each inspection of a vendor or applicant shall be documented with a narrative inspection report consisting of a Cover Letter, a Cover Page, an Executive Summary, and inspection details, as appropriate. The inspection team leader prepares an inspection plan in accordance with the appropriate IMC prior to the inspection.

04.01 Office Directors

The Director of the Office of Nuclear Reactor Regulation (NRR) should provide overall direction for the development and implementation of the vendor and QA implementation inspection programs.

04.02 Division Directors and Branch Chief

a. A manager familiar with NRC requirements in the inspected area shall review each inspection report to ensure that the report follows the format given in this chapter.

b. The management reviewer shall ensure that inspection findings are consistent with NRC policies and technical requirements and do not represent any personal views of the individual inspectors.

c. The management reviewer shall ensure that enforcement-related findings are addressed in accordance with the NRC Enforcement Policy and the NRC Enforcement Manual.

d. The management reviewer shall ensure that conclusions are logically drawn and sufficiently supported by observations and findings.

e. The management reviewer is responsible for the report content, tone, overall regulatory focus, and timeliness of vendor and QA implementation inspection reports.

f. The management reviewer shall ensure that the inspection report does not include information that could lead to the identification of an alleger or confidential source.

04.03 Inspectors

a. NRC inspectors shall prepare vendor and QA implementation inspection reports in accordance with the guidance provided in this manual chapter.

b. Inspectors will accurately report inspection findings and correctly characterize referenced material. Inspectors will adequately support the scope and depth of conclusions with documented observations and findings consistent with NRC policies and requirements.

c. Inspectors will not include advice and recommendations in inspection reports.

d. Inspectors will ensure that the inspection report does not conflict with the information presented at the exit meeting. If the report differs from the exit meeting, the lead inspector, with support from the management reviewer, or the report reviewer, should discuss those differences and re-exit (if necessary per Section 05.08.b below) with the vendor or applicant before the report is issued.

e. Inspectors must not include information that could lead to the identification of an alleger or confidential source if applicable.

f. Inspectors should ensure that reports are issued no later than 45 calendar days for team inspections. Extensions may be granted as necessary with approval from the responsible Division Director.

NOTE: Inspection completion is typically the day of the exit meeting.

g. Inspectors should expedite the inspection report when the report covers potential escalated enforcement actions. For specific enforcement timeliness goals, see the NRC Enforcement Manual.

h. When an inspector identifies an issue involving significant or immediate public health and safety concerns, the first priority is public safety. Based on the circumstances of the case, an expedited inspection report may be prepared that is limited in scope to the issue, or expedited enforcement action may be taken before the inspection report is issued. The NRC Enforcement Manual provides additional guidance on matters of immediate public health and safety.

i. The lead inspector shall ensure that all inspection team members provide written concurrence on the inspection report. The lead inspector should also ensure that when substantial changes are made to the inspection report as originally submitted for concurrence, these changes are discussed with the inspector or inspectors involved to ensure continued concurrence. Disagreements that cannot be adequately resolved should be documented by the lead inspector as an attachment to the inspection report. Additionally, the Agency wide non-concurrence process and differing professional opinion program are available to formally resolve differing views.

04.04 NRR Enforcement Coordinator

The NRR Enforcement Coordinator is responsible for reviewing only those inspection reports that have a Notice of Violation and/or Notice of Nonconformance before they are issued to ensure that the enforcement-related findings and the reports conform to the NRC Enforcement Policy and the NRC Enforcement Manual.

04.05 Findings Review Panel

The dual purpose of the findings review panel (FRP) is to evaluate potential findings and to ensure that the findings are consistently dispositioned across the IQVB. The FRP consists of the branch chief of IQVB, or his or her designee. The lead inspector should convene the FRP prior to the report being issued, at least a week prior to the inspection report issuance due date.

0617-05 REQUIREMENTS

The inspection report states the official Agency position on what was inspected, what the inspectors observed, and what conclusions were reached. All enforcement and other Agency actions, such as Notices of Violations (NOVs), which result from an inspection, will be documented in the inspection report. Inspection reports must be clear, accurate, consistent, and complete. Appendices A - F contain specific guidance and examples for the preparation of

vendor and QA implementation inspection reports. A complete inspection report package will contain the following parts in the order listed below:

05.01 Cover Letter. The Cover Letter transmits the inspection report results from the applicable NRC official, such as the Division Director or Branch Chief, to the designated vendor, or applicant executive. All significant information contained in the Cover Letter must also be contained in the Executive Summary and supported in the report details.

Cover letter content varies somewhat depending on whether the inspection identified findings. Guidance and sample Cover Letters for reports documenting findings can be found in the NRC Enforcement Manual, Appendix B, and "Standard Formats for Enforcement Packages." A template for the cover letter is included in Appendix A to this manual chapter.

In general, every cover letter has the same basic structure, as follows:

a. Date, Enforcement Action (EA) Numbers, Addresses. At the top of the first page, the cover letter begins with the NRC seal, followed by the date on which the report cover letter is signed and the report issued.

   When findings are assigned EA numbers for escalated enforcement, they should be placed in the upper left-hand corner above the principal addressee's name.

   The name and title of the principal addressee are placed at least four lines below the letterhead, followed by the company name and address.

b. Subject Line and Salutation. The subject line of the letter should state the facility name, and inspection subject. The subject line should also contain the inspection report number and notice of violation or nonconformance, if applicable. The words "NOTICE OF VIOLATION" and/or "NOTICE OF NONCONFORMANCE" should be included if such notices accompany the inspection report. The entire subject line should be capitalized. The salutation is placed after the subject line.

c. Introductory Paragraphs. The first two paragraphs of the cover letter should give a brief introduction, including the dates of inspection, purpose of the inspection, scope of the inspection, and whether any inspection activities were related to inspections, tests, analyses and acceptance criteria (ITAAC).

d. Body. The body of the letter should discuss the most important topics first. The cover letter should communicate the overall inspection results to a vendor's or applicant's management. Inspection findings, unresolved items (URIs), or pertinent information that could affect ITAAC closure should be included in the cover letter. Specific guidance on the inclusion of inspection information related to ITAAC is included in Appendices D and F of this manual chapter.

   In addition, the body should include an explanation of why a Non-Cited Violation is being issued in terms of the criteria in Section 2.3.2, "Non-Cited Violation (NCV)," of the NRC Enforcement Policy. The cover letter is the highest-level document and does not need to include all the items inspected nor the inspection procedures used. It will note the areas covered by the inspection.

The cover letter must be consistent with the information conveyed in the inspection report and during the exit meeting. The cover letter will not contain recommendations or guidance such as "The vendor should…"

e. Closing. The final paragraph varies depending on whether enforcement action is involved. [Appendices A-D refer to sample letters in the NRC's Agencywide Documents Access and Management System (ADAMS).] The signature of the appropriate NRC official is followed by the docket and EPID number(s), enclosures, and distribution list.

f. Concurrence. The cover letter should include concurrence from all contributing inspectors, the NRR Enforcement coordinator (required only for an inspection report with violation(s) and/or nonconformance(s)), and the responsible IQVB Branch Chief. The signature of the appropriate NRC official is followed by the docket, and EPID number(s), enclosures, and distribution list.

05.02 Notice of Violation (NOV). An NOV is the official notification of a failure to meet regulatory requirements. The NOV should be an enclosure to the cover letter. NOVs are typically issued to vendors, applicants, or licensees with the associated inspection report. For applicants or licensees, NOVs are issued for violating requirements of 10 CFR Part 21 and/or Appendix B to 10 CFR Part 50, and for vendors, NOVs are issued for violating requirements of 10 CFR Part 21 regulation. However, in cases such as escalated enforcement, NOVs may be sent after the report with a separate cover letter.

NOVs should include:

- A concise, clear statement of the requirement or requirements that were violated, appropriately referenced, paraphrased, or quoted. When applicable, a concise, clear statement of the vendor or applicant's policy or procedure that was violated, appropriately referenced, paraphrased, or quoted.

- A brief statement of the circumstances of the violation, including the date(s) of the violation and the facts necessary to demonstrate that the requirement was not met ("contrary to" paragraph). The first sentence should be parallel to the requirement that was violated. The subsequent sentences should include the specifics of the violation.

A template for NOVs is included in Appendix B of this manual chapter. Significance of findings is discussed in Section 06 of this document. For additional guidance on documenting violations, refer to the NRC Enforcement Manual.

The NOV should present the most significant violations first.

05.03 Notice of Nonconformance (NON). A NON is the official notification to a vendor of a failure to meet commitments related to NRC-regulated activities, such as Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," of Title 10 of the Code of Federal Regulations (10 CFR) contractual commitments to a licensee. NONs are issued to vendors with the associated inspection report as an enclosure to the cover letter.

NONs should include:

- A concise, clear statement of the requirement or requirements that were not met, appropriately referenced, paraphrased, or quoted.

- A brief statement of the circumstances of the nonconformance, including the date(s) of the nonconformance and the facts necessary to demonstrate that the requirement was not met ("contrary to" paragraph).

For ITAAC-related NONs, refer to Appendices D and F of this manual chapter for more specific guidance on what information to include in the inspection report.

A template for NONs issued to a vendor is included in Appendix C. For additional guidance on documenting nonconformance, refer to the NRC Enforcement Manual.

The NON should present the most significant nonconformances first.

05.04 Cover Page. The report cover page gives a short summary of information about the inspection. It contains the docket/certificate number, report number, facility name and address, the vendor or applicant's contact information, a high-level description of the vendor or applicant's nuclear industry activity, dates of inspection, names and titles of participating inspectors, and name and title of the approving NRC manager. Appendix D to this inspection manual chapter includes a template for the cover page.

05.05 Executive Summary. The Executive Summary should include the following:

- The purpose, scope, and bases for the inspection.
- A description of the safety-related activities observed during the inspection.
- When including inspection information related to the assessment of a vendor's/applicant's safety conscious work environment (SCWE) program, a qualified safety culture assessor will use the guidance described in the "Executive Summary," section of Appendix D of this manual chapter.
- The date of the inspection and a summary of any violations, nonconformances, or minor violations/nonconformances [as defined in section E.2 of Appendix E], or unresolved items (identified).
- The important conclusions reached by NRC as a result of the inspection. The statements should include a high-level description of the activities observed to reach the conclusions. Conclusions stated in the cover letter should be included, as well as any corrective actions taken by the applicant/vendor (e.g. that they entered the issue into their corrective action program) for violations and NONs. There should never be anything in the Executive Summary that is new or different from the information provided in the report details.

05.06 Table of Contents. For long or complicated reports (i.e., the report details section is more than 10 pages long), the report may include a table of contents.

05.07 Report Details. The report details describe the objective evidence that provides the basis for the inspectors' conclusions. Reports should be written in the past tense. Reports should be written consistent with the guidance in NRC Editorial Style Guide (NUREG 1379).

The report details should be organized into sections addressing one area of inspection (e.g., 10 CFR Part 21, “Reporting Defects and Noncompliance” Program, Corrective Action Program, Audits of Suppliers, etc.). Any review of follow-up items should be included in the applicable section. Each section will be divided into scope, observations and findings, and conclusions, as described below.

a. Inspection Scope. The Scope describes what was inspected, consistent with the Inspection Procedure (IP). The inspectors can extract the narrative from the Objectives or Requirements section of the applicable IP. It is acceptable to state either what the inspectors did, or what the inspection accomplished. For example, a Scope section could be phrased, “The inspectors reviewed (observed, sampled, evaluated, etc.)...” The Scope statements might also describe why certain items were inspected, for example, “...to determine compliance with...”

When the inspection did not identify findings, the Scope section should, when relevant, include:

- How the inspection was conducted (i.e., the methods of inspection)
- What was inspected
- When each activity was performed approximately
- Where the inspection took place
- The criteria for determining whether the vendor or applicant was in compliance with the applicable technical and regulatory requirements.

When the inspection identified findings, much of the details listed above should only be stated in the Observations and Findings section. The Scope section should not duplicate any portion of the Observations and Findings section. Therefore, when the inspection identified findings, the Scope section should be shorter.

The Scope section should not include a detailed list of the documents reviewed for that inspection area. The attachment to the inspection report should include the list of documents reviewed. The last sentence of the Scope section should read, “The attachment to this inspection report lists the documents reviewed by the inspectors.”

b. Observations and Findings. As used in this IMC, the term "observation" refers to a fact; or any detail noted during an inspection. Observations must be objective and will not consult, praise, or criticize a vendor. The observations and findings should be consistent with the scope. For example, if the scope was to review corrective action records, the observations and findings should not discuss problems with receipt inspection records.–

The Observations and Findings section should not duplicate any portion of the Scope section. Therefore, when the inspection did not identify findings, then the Observations and Findings section should state, “No findings of significance were identified.” Document issues that are screened as minor violations/nonconformances and provide an explanation as to why the issue is being considered minor using examples for specific criteria listed in Appendix E as guidance and reference the corrective action report (CAR) initiated by the applicant/vendor.

The identified observations and findings will be described in a clear manner and be sufficiently detailed to describe what the inspectors found. The observations will describe the inspectors' conclusions and not repeat the activities identified in the scope. "The inspectors reviewed …" is a Scope statement. "The inspectors noted (verified, identified, observed, etc.) …" is an observation.

The inspector should explicitly say what was observed or found. The inspector should not make uncertain statements such as "The vendor's QA records control program did not appear to meet the requirements."

When including inspection information related to the assessment of a vendor's/applicant's SCWE program, a qualified safety culture assessor will use the guidance described in the "Report Summary," section of Appendix D of this manual chapter.

For violations, apparent violations, and nonconformance's, the inspection report will include sufficient detail to describe the deficiency that constitutes the basis for the finding. The level of detail must include the applicable traditional enforcement attributes such as regulatory process and must also describe the logic used to determine the significance of the finding (i.e., describe why the finding meets greater than minor criteria). The level of detail must allow a reader to arrive at the final conclusion. The inspection report will describe the requirement and how it was not met. This should include at least two statements. The first one should define the enforcement requirement, including the regulation. The second should describe the circumstances of the violation or nonconformance, including the date(s) of the finding and the facts necessary to demonstrate that the requirement was not met. Describe the actual or potential safety consequences to support the significance of the finding. The inspection report should describe if the item was shipped, if there is any impact to the operating or new reactor fleet. Significant or potentially significant findings may merit more discussion. When describing the violation or nonconformance, include corrective action taken or planned, response by the vendor, root cause, management involvement, and whether the finding was isolated or programmatic.

Findings that may have generic implications should include details such as the supplier's name, manufacturer's name, model number, specifications, and other pertinent technical data.

The inspection report must not lead a reader to conclude that the inspection was the result of an allegation or that an Office of Investigations (OI) investigation is possible. Observations and findings in response to an allegation must contain enough information to adequately address the allegation concerns. For findings referred to OI, the inspection report should contain only relevant factual information collected during the inspection. Any inspection reports containing material related to an ongoing investigation shall be provided to OI for review before being issued.

Findings of minor significance do not usually warrant enforcement action but must be corrected. This documentation should include an explanation as to why the issue is considered minor using the examples for specific criteria listed in Appendix E as guidance, as well as, what corrective actions were taken by the vendor/applicant (e.g., that the vendor/applicant entered the issue into its corrective action program). Minor violations/nonconformances will not be listed in the back of the report with the "List of

Items Opened, Closed and Discussed." Any corrective action reports (CARs) initiated by the vendor/applicant to address the minor violations/nonconformances will be listed under the list of documents reviewed.

c. Conclusions. Conclusions summarize the vendor or applicant's compliance in the area inspected. All conclusions must be supported by the observations and findings. If the inspection identified findings, a short summary of each violation, apparent violation, or nonconformance shall be included with its associated tracking number. If the inspection did not identify any findings, the report should state "No findings of significance were identified."

NOTE: Names of suppliers are considered to be proprietary information and should not be included in the inspection report nor in the attachments except when needed to support an NOV or a NON.

05.08 Entrance and Exit Meeting Summary. The final section of the inspection report shall briefly summarize the entrance and exit meetings and shall include the date of the meetings and the name and title of the most senior vendor manager in attendance, and a sentence on the inspection results and observations [SCWE] discussed during the exit meeting. If the inspectors conduct subsequent exit meetings, the summary should include the relevant information for each exit meeting.

a. Absence of Proprietary Information. At the exit meeting, the inspectors will verify whether the vendor or applicant considers any materials provided to or reviewed by the inspectors to be proprietary. If the vendor did not identify any material as proprietary, include a sentence to that effect. If the report includes proprietary information, refer to IMC 0620, "Inspection Documents and Records."

NOTE: When an inspection report is likely to involve proprietary information (i.e., given the technical area or other considerations of inspection scope), handling of proprietary information should be discussed at both the entrance and exit meetings.

b. Subsequent Contacts or Changes in NRC Position. If the NRC's position on an inspection changes after the exit meeting (i.e., an additional finding is identified that was not discussed at the exit meeting), the NRC will conduct an additional exit meeting to discuss that change with the vendor or applicant. This additional exit meeting may be satisfied via a phone call with management personnel at the vendor or applicant. Inspectors will document additional exit meetings in the inspection report.

c. Characterization of Vendor or Applicant Response. Inspectors will not characterize a vendor's or applicant's exit meeting response. If the entity inspected disagrees with an inspection finding, this position may be characterized by the entity in its formal response.

d. Oral Statements and Regulatory Commitments. Inspectors will not attempt to characterize or interpret any oral statements the vendor or applicant makes at any time during the inspection as a commitment.

Because regulatory commitments are sensitive, the inspector should ensure that any reporting of vendor or applicant statements are paraphrased accurately and contain appropriate reference to any applicable vendor or applicant document.

05.09 Report Attachments. The attachments discussed below are included at the end of the inspection report, if applicable. The attachments may be combined into a single attachment entitled "Attachment."

a. Entrance/Exit Meeting Attendees and Key Points of Contact. A list of personnel who attended the entrance and exit meetings shall be included in the report attachments. This list should include the name and title/affiliation of persons attending the meetings and an indication of whether they attended the entrance and/or exit meetings. It will also list, by name and title, those individuals who provided relevant information during interviews or were key points of contact during the inspection (NOTE: Except in cases: (1) where there is a need to protect the identity of an individual, or (2) where a vendor requests the names of its employees to not be made public (in which case, titles of employees can be provided instead).

   The list does not need to be exhaustive but should identify those individuals who provided information related to developing and understanding findings. The list should include the most senior manager present at the exit meeting and NRC technical personnel who were involved in the inspection.

b. List of Items Opened, Closed, and Discussed. The report shall include a quick-reference list of items opened and closed along with the status of the items. The list shall include the type of item (NOV, NON, URI, etc.) and a reference to the requirement associated with the item, such as the 10 CFR Part 21 reference, or appropriate Appendix B to 10 CFR Part 50 criterion. This list should also include whether any of the items were related to specific ITAAC. If the item was related to ITAAC and could affect the closure of the ITAAC, the affected design commitment, inspection, test, or analysis should be identified. The list should be formatted in accordance with the template provided in Section 05.11 and Appendix D of this inspection manual chapter.

c. Inspections, Tests, Analyses, and Acceptance Criteria. Provide a description of the ITAAC related to the basic component or service provided by the vendor. Include which design the ITAAC relates to and the specific Appendix B to 10 CFR Part 50, controls that were inspected with respect to the ITAAC. Include a table that identifies the location in the combined license (COL) where the ITAAC are addressed for a specific COL holder and the ITAAC number. Appendices D and F to this inspection manual chapter provides a template and additional detailed guidance.

d. List of Documents Reviewed. A list of the appropriate key documents and records reviewed during an inspection that are significant to any finding should be publicly available if possible. Therefore, if a list is not otherwise made public, the report should list the key documents and records reviewed during the inspection. As stated in Section 05.07 above, names of suppliers are considered to be proprietary and should not be included in the list of documents reviewed except when needed to support an NOV or an NON. See Inspection Manual Chapter 0620, "Inspection Documents and Records" for additional guidance on records requirements. The list of documents reviewed should be included as an attachment to facilitate reading. CARs initiated by the vendor/applicant to address issues identified during the inspection should be included in the list of documents reviewed.

e. List of Acronyms (Optional). Reports whose details section exceeds 20 pages should include a list of acronyms. For reports in which a relatively small number of acronyms have been used, the list is optional. In all cases, however, acronyms should be spelled out when first used in inspection report text.

05.10 Documenting Unresolved Items (URIs)

a. Opening. An inspector should open an URI when an issue of concern is identified during the inspection, but more information is required but is not available to the inspector prior to inspection exit meeting to make a determination if there is a performance deficiency, or if the performance deficiency is greater-than-minor or if the issue of concern constitutes a violation. URIs should be closeable; that is, there is a way to bring the URI to closure at a future point. URIs cannot be used to determine the significance of a finding but are identified for tracking purposes and are documented only in the body of the inspection report.

b. An inspector should document a URI when vendor or applicant action is pending or when information is required to determine if an issue is acceptable, a nonconformance, or a violation. An inspector should open a URI if the resolution is likely to result in a finding that is greater than minor or is material to the ITAAC acceptance criteria. An URI should document the issue with sufficient detail to allow another inspector to complete the inspection effort. The inspection report should document the additional information needed to resolve the issue. URIs should be listed in the "List of Items Opened, Closed, and Discussed" section.

c. Follow-up and Closure. IQVB will be responsible for closing out the URI once enough information has been gathered to determine whether a finding exists. The resolution of a URI should: summarize the issue; summarize the NRC's follow-up actions; evaluate the adequacy of any vendor actions; determine if a violation or nonconformance has occurred, and; provide enough detail to justify closing the URI.

Sufficient detailed information must be provided to justify closing the item. Document when assistance from NRC technical staff and regional inspectors aided in resolution of an URI.

Branch chief, inspectors, and technical staff involved in resolution should concur on the inspection report, where documentation of the closure is placed in the applicable report details section. The inspection report shall include affected licensees on the distribution for all vendor inspection reports with URIs that have the potential to affect the ITAAC acceptance criteria.

If closure of an URI is significantly delayed due to vendor delays in providing complete information, NRC management should engage vendor management to expedite resolution of the issue. URIs should not be left open to characterize significance of the finding if it is clear that a violation has occurred.

05.11 Tracking. The lead inspector will assign all apparent violations, violations, nonconformances, NCVs, and URIs a sequential tracking number. If there are multiple types of findings, do not repeat tracking numbers. For example:

LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description	Applicable ITAAC
99912345/2008-201-01	Opened	NOV	10 CFR 21.21(a)	N/A
99912345/2008-201-02	Opened	NOV	10 CFR 21.21(b)	N/A
99912345/2008-201-03	Opened	NON	Criterion I	N/A
99912345/2008-201-04	Opened	NON	Criterion II	N/A
99912345/2008-201-05	Opened	NON	Criterion III	2.2.03.05a.iii
99912345/2008-201-06	Opened	URI	Criterion III	2.2.03.05a.iii

0617-06 SIGNIFICANCE OF FINDINGS

Enforcement guidance is given in the NRC Enforcement Policy, and the NRC Enforcement Manual. In assessing the significance of a noncompliance, the NRC considers four specific issues: (1) actual safety consequences: (2) potential safety consequences, including the consideration of risk information; (3) potential for impacting the NRC's ability to perform its regulatory function: and (4) any willful aspects of the violation or nonconformance.

The following summarizes the guidance as it relates to vendor and QA implementation inspection reports.

06.01 Types of Noncompliance. An inspector may address a noncompliance as a minor violation or nonconformance, an NCV, a non-escalated enforcement action (i.e., a Severity Level (SL) IV violation or a nonconformance), or an escalated enforcement action (i.e., an apparent SL I, II, or III violation). The NRC issues violations to applicants or licensees for failures to comply with the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21. Violations are issued to vendors for failures to comply with the requirements of 10 CFR Part 21 since vendors are within the scope of that regulation. The NRC issues nonconformances to vendors for noncompliance with the requirements of Appendix B to 10 CFR Part 50 because the requirements of Appendix B are imposed on vendors contractually through procurement documents. The documentation of a noncompliance depends on the disposition of that noncompliance.

An inspection report may not document a noncompliance informally (i.e., a report may not describe a weakness, or a vendor or applicant failure, without an associated finding). An observation that suggests that a violation may have occurred must be clearly dispositioned as a nonconformance, a violation, an apparent violation, or an NCV. If a violation or nonconformance does not exist (e.g., no requirement exists in this area), it may be appropriate to clarify an observation by stating that "this condition [or event] does not constitute a violation of NRC requirements," or “this condition [or event] does not constitute a nonconformance of contractually imposed requirements.”

a. Minor Violations/Nonconformances. There is no set rule as to what is minor and what is not, i.e., the determination that an issue is minor will depend on the circumstances of the particular issue. Minor violations/nonconformances do not usually warrant enforcement action but must be corrected. The report details may describe minor violations/nonconformances, but these minor violations/nonconformances do not receive a tracking number.

The inspection report may identify minor violations/nonconformances for non-repetitive noncompliance with little or no safety significance or regulatory impact. Documentation of minor violation/nonconformances will be at the discretion of the inspection team leader and the appropriate management personnel. Minor violations/nonconformances may include applicant or vendor-identified issues such as:

- isolated failures to implement a requirement that do not result in significant safety or regulatory consequences;
- record keeping issues that do not preclude the applicant or vendor from taking appropriate action on safety-related issues;
- insignificant dimensional, time, calculation, or drawing discrepancies or procedural errors, and;
- typographical or clerical errors in quality documents that do not affect QA program functionality or the validity of QA records.

Inspectors should treat minor nonconformance's in the same manner as minor violations with respect to documentation and screening for significance.

Appendix E contains the definition, screening criteria for minor violations/nonconformances and examples of violations/nonconformances that have been categorized as minor. Inspectors may use these examples to help understand the threshold for classification of findings. The inspectors will review the corrective action to ensure the minor violation/nonconformance is documented in the vendor's corrective action program and that the problem statement adequately captures the violation/nonconformance. It is not expected for the vendor to correct the minor violation/noncompliance before the end of the inspection.

For screening a potential finding for minor violations/nonconformances, the inspectors should consider whether the potential finding has very minimal or no safety regulatory impact of any kind; or whether there isn't an adequate regulatory basis to support it. Minor issues that are isolated or programmatic and non-repetitive should be entered into the vendor's/applicant's corrective action program and documented in the inspection report at the discretion of the inspection team leader. Similarly, those CARs opened in response to minor violations/nonconformances should be listed in the list of documents reviewed.

b. Non-Cited Violations (NCVs). Guidance in Section 2.3.2 of the NRC Enforcement Policy describes the circumstances for consideration of issuing an NCV for SL IV violations. When the NRC applies this enforcement discretion, the report shall briefly describe the circumstances of the violation, the vendor's corrective actions, and the following statement: "This non-repetitive, vendor/licensee-identified and corrected violation is being treated as an NCV, consistent with Section 2.3.2 of the NRC Enforcement Policy."

The approval of the OE Director is required to disposition willful violations as NCVs. When the NRC dispositions a willful SL IV violation as an NCV per Section 2.3.2 of the

NRC Enforcement Policy, the inspection report shall also address the use of this enforcement discretion. For example:

> "Although this violation is willful, it was brought to the NRC's attention by the vendor, it involved isolated acts of a low-level individual without management involvement, and the violation was not caused by a lack of management oversight, and it was addressed by appropriate remedial action.
>
> Therefore, this non-repetitive, vendor/licensee-identified and corrected violation is being treated as a Non-Cited Violation, consistent with Section 2.3.2 of the NRC Enforcement Policy."

c. Non-Escalated Enforcement Actions. Most violations of low significance, but greater than minor, fall into the SL IV category. SL IV Violations involve failures to meet regulatory requirements, such as failures to meet one or more QA criteria of Appendix B to 10 CFR Part 50 (for applicants) or 10 CFR Part 21 (for applicants, and vendors) not amounting to Severity Level I, II, or III violations that have greater than minor safety or environmental significance. Nonconformance's are also considered non-escalated enforcement actions. Non-escalated enforcement actions follow a similar format and require a similar level of report detail.

The NRC sends an NOV or NON that it dispositions as non-escalated with the inspection report. The cover letter for reports that include non-escalated enforcement actions should follow the appropriate NRC Enforcement Manual guidance and Appendix A of this manual chapter.

d. Potential Escalated Enforcement Actions. When the NRC is considering an issue for escalated enforcement action, the inspection report narrative should refer to the potential noncompliance as an "apparent violation." The report details should not include any speculation on the severity level of such violations nor on expected NRC enforcement sanctions. Potential escalated actions require further agency deliberation, and usually additional vendor or applicant input, to determine the appropriate severity level and NRC action.

Report details that discuss apparent violations should avoid making explicit conclusions about the safety significance of the issue. The report should include details that demonstrate safety significance and describe any corrective actions taken or planned by the vendor.

Inspectors should consider the guidance provided in IMC 0613, "Power Reactor Construction Inspection Reports," when evaluating findings associated with construction activities versus QA program and 10 CFR Part 21 findings.

06.02 Enforcement Discretion. Where the NRC is using discretion for a violation that meets the criteria of Section 3 of the NRC Enforcement Policy, the report shall state: "Discretion is being exercised after consultation with the Office of Enforcement pursuant to Section 3 of the NRC Enforcement Policy and a violation is not being issued."

06.03 Noncompliance Involving Willfulness. Conclusions about the willfulness of a violation or nonconformance are agency decisions and are normally not made until after OI has completed an investigation. Inspection reports that include potentially willful violations or nonconformances

are to be coordinated with OI and OE.

0617-07 RELEASE AND DISCLOSURE OF INSPECTION REPORTS AND ASSOCIATED DOCUMENTS

07.01 General Public Disclosure and Exemptions. Except for report enclosures containing exempt information, all final inspection reports will be routinely disclosed to the public. Information that should not appear in an inspection report is described in 10 CFR 2.390, “Public inspections, exemptions, requests for withholding,” and 10 CFR 9.17, “Agency records exempt from public disclosure.” Management Directive 8.8, Management of Allegations, addresses the manner in which an inspection report may be used to document allegation follow up activities. Inspection Manual Chapter 0620, "Inspection Documents and Records," provides guidance on acquisition and control of NRC records, including inspection-related documents. The NRC only releases sensitive–unclassified information such as safeguards information, official use only, and proprietary information in accordance with instructions from the Office of Administration, Division of Facilities Security.

07.02 Release of Investigation-Related Information

a. When an inspector accompanies an investigator on an investigation, the inspector shall not release the investigation report or their individual input on the investigation report. This information is exempt from disclosure as provided by 10 CFR 9.17, subject to determination by OI. The NRC will not circulate investigation reports outside the NRC without specific approval of the OI approving official.

b. The NRC can communicate technical and safety concerns to a vendor without revealing that an investigation may occur or is underway. When safety concerns require the release of investigation-related information, the appropriate Office Director or Regional Administrator (RA) will inform the OI Field Office Director in advance. The OI Field Office Director will review the information to be released and advise the Office Director or RA of the anticipated effect on the course of the investigation. The Office Director or RA will release the information only after determining that the safety concerns are significant enough to justify the risk of compromising the pending investigation and any potential subsequent regulatory action.

   After consulting with the OI Field Office, the Office Director or RA may decide to delay informing the vendor of an issue. In this case, the Office Director or RA should document why the delay is consistent with public health and safety considerations. Any such decision should be re-examined every three months to assure validity of the delay until the investigation is closed.

   For findings referred to OI, the report should contain only relevant factual information collected during the inspection. OI should review any reports containing material that may be related to an ongoing investigation before being issued.

c. When a significant issue requires immediate action, NRC employees may provide any relevant material to the vendor. When possible, the staff should consult management first.

END

Appendices:

A. Guidance for Vendor and QA Implementation Inspection Cover Letters
B. Guidance for Vendor and QA Implementation Inspection Notice of Violation (Non-Licensees)
C. Guidance for Vendor Inspection Notice of Nonconformance (Non-Licensees)
D. Guidance for Vendor and QA Implementation Inspection Report Details
E. Minor Examples of Vendor and QA Implementation Findings
F Guidance for Handling ITAAC Before, During, and After Vendor Inspections

Attachment:

Revision History for IMC 0617

APPENDIX A

GUIDANCE FOR VENDOR AND QA IMPLEMENTATION INSPECTION
COVER LETTERS

This guidance is based on the NRC Enforcement Manual, Appendix B, Form 10: Cover Letter Transmitting Inspection Report and Notice of Violation (Includes Optional Paragraphs for Inclusion of a Notice of Nonconformance and/or "Apparent" Violations) (Non-licensees).

EXAMPLES

Examples of Cover Letters, Notices of Violation, Notices of Nonconformance, and Inspection Reports can be found on the Vendor Quality Assurance Inspections Website.

The following is a key to the notation used in the standard formats:

Symbol	Meaning
(____) or _____	Fill in the blank with the appropriate information
( )	Text within parentheses indicates the optional use of an alternative word or an optional choice or the plural form of the word preceding the parentheses.
[ ]	Text within brackets indicates narrative guidance that should be followed in terms of addressing specific elements that should be included in the particular document.
" "	Text within quotes indicates a suggested sentence or language.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

(Date)

EA-YY-XXX (If applicable)

(Vendor/Applicant executive name, Position Title)
(Name of company)
(Address)

SUBJECT: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT OF (VENDOR/APPLICANT NAME) NO(S). (XXXXXXXX/YYYY-NNN), [If applicable, add "AND (INVESTIGATION REPORT NO(S). (X-XXXX-XXX)), (NOTICE OF VIOLATION AND NOTICE OF NONCONFORMANCE)

Dear (Vendor/Applicant executive):

On (dates), the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at (facility name) [if applicable (hereafter referred to as (Acronym)] facility in (City, State/Country) (or, on [date of exit meeting if different], the NRC staff) discussed the results of this inspection with [name of principal manager who attended exit] and other members of your staff. [Include one of the following three descriptions of the inspection: "The inspection was conducted as a result of the ..." or "The inspection was conducted to ..." or "The purpose of this limited-scope (routine/reactive) inspection was to assess (Vendor/Applicant name) compliance with provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

This technically-focused inspection (was to follow-up inspection to the date NRC inspection) specifically evaluated (Vendor/Applicant name) implementation of the quality activities associated with the supply of (provide a brief description of activity or activities) for U.S nuclear power plants.] The enclosed report presents the results of this inspection.

[For vendor inspections that looked at activities associated with ITAAC, include the following statement: "During this inspection, the NRC staff inspected (describe the activity or activities) associated with inspections, tests, analyses, and acceptance criteria (ITAAC) from Revision (No.) of the approved (design) design certification document or Combined License for [include COL Holder]. Specifically, these activities were associated with ITAAC (No.)." Include one of the following three statements: "This report contains (one) ITAAC finding(s) associated with ITAAC (No.)" or, "This report contains (one) URI associated with ITAAC (No.). More information on how this [NON] or [URI] affects the ITAAC is included in Section (4) of the attachment to this report, or "The NRC inspection team did not identify any findings associated with the ITAAC contained in Section (4) of the attachment to this report."] [Any subsequent

meetings and/or telephone discussions should be documented.] This NRC inspection report does not constitute NRC endorsement of your overall quality assurance or Part 21 programs.

Within the scope of this inspection, no violations or nonconformance's were identified. [If applicable]

[Include the following paragraphs if issuing Notice of Violation:

"Based on the results of this inspection, the NRC staff determined that (a) Severity Level IV violation(s) of NRC requirements occurred. The(se) violation(s) is (are) cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it (them) are described in detail in the subject inspection report. The violation(s) is (are) being cited in the NOV because [An explanation MUST be included that clearly articulates why a NOV is being issued in terms of the criteria in Section 2.3.2, "Non-Cited Violation (NCV)," of the NRC Enforcement Policy. This explanation may be expanded to convey the appropriate message to the vendor in terms of those actions that require additional attention and must include the basis for issuing the citation, notwithstanding the normal policies.]

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. [If other responses are required, remind addressee that, as appropriate, these responses should be addressed separately, in addition to this response]. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements."

[For Severity Level IV violations where the staff determined that no response is required, the following paragraph may be substituted:

"The NRC has concluded that information regarding: (1) the reason for the violation(s); (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance will be (was) achieved is already adequately addressed on the docket in [Indicate the correspondence, e.g., Inspection Report No. (XXXXXXXX/YYYY-NNN), (LER YY-NNN), or letter from your company dated (date). Therefore, you are not required to respond to this letter unless the description does not accurately reflect your corrective actions or your position. If you choose to provide additional information, please follow the instructions specified in the enclosed Notice."]

[For inspection reports with NCVs, include the following paragraph:

Based on the results of this inspection, the NRC has (also) determined that (number) (additional) Severity Level IV violation(s) of NRC requirements occurred. These violations are being treated as Non-Cited Violations (NCVs), consistent with Section 2.3.2 of the Enforcement Policy. The(se) NCVs are described in the subject inspection report. If you contest the violation(s), you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Director, Office of _____; and (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

[Include the following two paragraphs if a Notice of Nonconformance is to be issued:

"During this inspection, NRC inspectors (also) found that the implementation of your Quality Assurance (QA) program failed to meet certain NRC requirements imposed on you by NRC licensees. [Add a sentence or two that summarizes the most important findings.] The specific findings and references to the pertinent requirements are identified in the enclosures to this letter. In response to the enclosed notice of nonconformance (NON), (Vendor name) should document the results of the extent of condition review for the finding and determine if there are any effects on other safety-related components.

Please provide a written statement or explanation within 30 days from the date of this letter in accordance with the instructions specified in the enclosed Notice of Nonconformance. We will consider extending the response time if you show good cause for us to do so."]

[If apparent violations are being considered for escalated enforcement, include the following paragraphs:

"Finally, (number) apparent violation(s) was (were) identified and is (are) being considered for escalated enforcement action in accordance with the NRC Enforcement Policy (Enforcement Policy). The current Enforcement Policy is included on the NRC's Web site at (http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html). [The narrative that follows should briefly discuss the nature of the apparent violation(s).] Accordingly, no Notice of Violation is presently being issued for these inspection findings. Please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review.]

An open (A closed) predecisional enforcement conference to discuss this (these) apparent violation(s) has been scheduled for (date). The decision to hold a predecisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information to enable the NRC to make an enforcement decision, such as a common understanding of the facts, root causes, missed opportunities to identify the apparent violation(s) sooner, corrective actions, significance of the issue(s) and the need for lasting and effective corrective action. [If appropriate, add: "In particular, we expect you to address _____".] In addition, this is an opportunity for you to point out any information in our inspection report that you believe to be in error and for you to provide any information concerning your perspectives on: (1) the severity of the violation(s); (2) the application of the factors that the NRC considers when it determines the amount of a civil penalty that may be assessed in accordance with Section 2.3.4 of the Enforcement Policy; and (3) any other application of the Enforcement Policy to this case, including the exercise of discretion in accordance with Section 3.0.

You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding the(se) apparent violation(s) is required at this time.

[For inspection report with no findings, use the statement below]

In accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding, "of the NRC's "Rule of Practice," a copy of this letter, its enclosure(s), and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible at http://www.nrc.gov/reading-rm/adams.html.

[For inspection report with findings use the statement below]

In accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response, (if applicable), should not include any personal privacy, proprietary, or safeguards information (SGI) so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of safeguards information: performance requirements."

[For those packages containing Safeguards Information, replace the previous paragraph with:

"The material enclosed herewith contains Safeguards Information as defined by 10 CFR Part 73.21, and its disclosure to unauthorized individuals is prohibited by Section 147 of the Atomic Energy Act of 1954, as amended. Therefore, the material will not be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html."]

Sincerely,
(Name of Branch Chief), Chief
(Branch)
(Division)
(Office)

Docket No. (XXXXXXXX)

EPID No.: (1-XXXX-XXX-XXXX)

Enclosure(s): [as applicable: Notice(s) of Violation, Notice(s) of Nonconformance, Inspection Report (XXXXXXXX/YYYY-NNN) (…), Attachments]

DISTRIBUTION:
(Vendor/Applicant management e-mail)
(NRR Vendor Program Analyst)
(NRR Enforcement Coordinator)
(ConE Resource)
(NRR Division Deputy Director)
(NRR Division Director)

APPENDIX B

GUIDANCE FOR VENDOR AND QA IMPLEMENTATION INSPECTION
NOTICE OF VIOLATION (NON-LICENSEES)

This guidance is based on the NRC Office of Enforcement Manual, Appendix B, and Form 4-III: Notice of Violation (For All Violations Without a Civil Penalty) (Non-Licensees).

EXAMPLES

Examples of Cover Letters, Notices of Violation, Notices of Nonconformance, and Inspection Reports can be found on the Vendor Quality Assurance Inspections Website.

The following is a key to the notation used in the standard formats:

Symbol	Meaning
(____) or _____	Fill in the blank with the appropriate information
( )	Text within parentheses indicates the optional use of an alternative word or an optional choice or the plural form of the word preceding the parentheses.
[ ]	Text within brackets indicates narrative guidance that should be followed in terms of addressing specific elements that should be included in the particular document.
" "	Text within quotes indicates a suggested sentence or language.

NOTICE OF VIOLATION

(Name of Vendor/Applicant)
(Vendor/Applicant Street Address)
(Vendor/Applicant City, State, Zip)
(Vendor/Applicant Country if outside of the U.S)

Docket No. (No.)
Report No. (No.)
EA-(YY-XXXX) (if applicable)

During a U.S. Nuclear Regulatory Commission (NRC) inspection (investigation) conducted at the (Vendor/Applicant name) (hereafter referred to as name) facility in (City, State or Country) on (dates), a violation(s) of NRC requirements was (were) identified. In accordance with the NRC Enforcement Policy, the violation(s) is (are) listed below [list violations in order of significance]:

[State the requirement that was violated, e.g., 10 CFR Part 21]

[SAMPLE:

Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, Reporting of Defects and Noncompliance, Paragraph 21.21(c)(1), states, in part, that, "A dedicating entity is responsible for identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items."]

Contrary to the above, (date and description of precisely how the requirement was violated).

[SAMPLE:

Contrary to the above, as of September 22, 2016, VendorX failed to adequately evaluate deviations associated with a substantial safety hazard for a dedicated item. Specifically, VendorX failed to adequately evaluate spurious tripping of XFY circuit breakers supplied to CustomerXYZ- PlantX, as required by 10 CFR 21.21(c)(1). VendorX's evaluation for this issue inadequately concluded that this issue was not reportable based upon the assumption that the only safety function of these breakers was to open, and that spurious tripping would not affect the safety function of these breakers.

This issue has been identified as Violation (No.).

This is a Severity Level IV violation (Section (No.) of the NRC Enforcement Policy). [Violations identified in vendor and QA implementation inspections are typically Severity Level IV violations and the appropriate reference is Section 6.9.d of the NRC Enforcement Policy.]

Pursuant to the provisions of 10 CFR 2.201, (name of Vendor/Applicant) is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-001 with a copy to the Chief, [Insert applicable branch, Division, and Office] within 30 days of the date of the letter transmitting this Notice of Violation. This reply should be clearly marked as a "Reply to a Notice of Violation; [add "EA-(YY-XXXX)", if applicable]" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, consideration will

be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information.

If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

[For violations where the responsible program office has determined that no response is required, the following paragraphs may be substituted:

"The NRC has concluded that information regarding the reason for the violation, [if more than one violation, specify which violation or violations] the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be (was) achieved is already adequately addressed in [indicate the correspondence, the date, and the ADAMS accession number]. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation; (EA-YY-XXXX)" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Director (Chief), [Insert applicable branch, division, and program office] within 30 days of the date of the letter transmitting this Notice of Violation.

NOTE: If this option is used, substitute the following for the last paragraph of this NOV:

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or Safeguards Information so that it can be made available to the Public without redaction."

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt. [This statement does not apply to vendors. This statement is only applicable to licensees when a notice of violation involving radiological working conditions, a proposed imposition of civil penalty, or an order is issued under Subpart B of 10 CFR Part 2. It is only applicable to applicants and holders of standard design approvals, applicants for an early site

permit, applicants for standard design certifications, and applicants for manufacturing licenses when a notice of violation, proposed imposition of civil penalty, or order is issued under Subpart B of 10 CFR Part 2.]

Dated this (day) day of (Month Year)

APPENDIX C

GUIDANCE FOR VENDOR INSPECTION NOTICE OF NONCONFORMANCE
(NON-LICENSEES)

This guidance is based on NRC Office of Enforcement Manual, Appendix B, and Form 11: Notice of Nonconformance (Non-Licensees).

EXAMPLES

Examples of Cover Letters, Notices of Violation, Notices of Nonconformance, and Inspection Reports can be found on the Vendor Quality Assurance Inspections Website.

The following is a key to the notation used in the standard formats:

Symbol	Meaning
(____) or _____	Fill in the blank with the appropriate information
( )	Text within parentheses indicates the optional use of an alternative word or an optional choice or the plural form of the word preceding the parentheses.
[ ]	Text within brackets indicates narrative guidance that should be followed in terms of addressing specific elements that should be included in the particular document.
" "	Text within quotes indicates a suggested sentence or language.

NOTICE OF NONCONFORMANCE

(Name of Vendor Name)
(Vendor Street Address)
(Vendor City, State, Zip)
(Vendor Country if outside of the US)

Docket No. 999XXXXX
Report No. XXXX-XXX

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the (Vendor name) from (dates), (Vendor name) did not conduct certain activities in accordance with NRC requirements which were contractually imposed on (Vendor name) by its customers or NRC licensees. [List nonconformance's in order of significance.]

A. [Provide statement of requirement(s) that were violated,
Criterion (roman numeral) "Title," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states in part that, "(specify the requirements)."

QA Procedure (No.) states [Provide a statement from QA Procedure.]

[SAMPLE:

Criterion III "Design Control," of Appendix B to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, states in part that, "Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions for the structures, systems and components."]

Contrary to the above, as of (date of nonconformance), (Vendor name) failed to [Provide a description of precisely how the criteria was not met.]

[SAMPLE:

Contrary to the above, as of June 26, 2018, VendorX failed to ensure the suitability of materials, parts, equipment, and processes that are essential to the safety-related functions of the inverters being supplied to the Vogtle Units 3 and 4 nuclear power plants. Specifically, as part of its commercial grade dedication process, VendorX failed to verify the functionality of the surge suppressors installed on the direct current (DC) input to the safety-related inverters being supplied to the Vogtle Units 3 and 4 nuclear power plants. These surge suppressors are installed to ensure the inverters can withstand voltage spikes of up to 4000 volts as required by VendorX customer design specification APP-XXXX, Revision 10. Although VendorX tested the surge suppressors to ensure that they would not spuriously conduct at lower voltages, the components were not tested to ensure they would be capable of clamping voltage spikes of up to 4000 VDC to the required level of 2500 VDC, as per the design specification.]

This issue has been identified as Nonconformance (No.). [All violations and nonconformances must be assigned a sequential tracking number. If there are multiple types of findings, do not repeat tracking numbers. For example, if the last violation in the NOV was numbered 99900000/2013-201-02, the first nonconformance will be numbered 99900000/2013-201-03.]

B. Continue with findings as applicable using the above-identified format.

This issue has been identified as Nonconformance 999XXXXX/XXXX-XXX-XX.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Chief, [Insert name of applicable branch, division, and office] within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each noncompliance: (1) the reason for the noncompliance, or if contested, the basis for disputing the noncompliance; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid noncompliance's; and (4) the date when your corrective action will be completed. Where good cause is shown, consideration will be given to extending the response time.

In accordance with the requirements of 10 CFR 2.390, "Public inspections, exemptions, requests for withholding," of the NRC's "Rule of Practice," your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information.

If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of safeguards information: performance requirements."

[For nonconformance's where the responsible program office has determined that no response is needed, the following paragraphs may be substituted:

"The NRC has concluded that information regarding the reason for the nonconformance, [if more than one nonconformance, specify which nonconformance or nonconformance's] the corrective actions taken and planned to correct the nonconformance and prevent recurrence, and the date when full compliance will be (was) achieved is already adequately addressed in [indicate the correspondence, the date, and the ADAMS accession number]. Submit a written statement or explanation if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Nonconformance" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Director (Chief), [Insert applicable program office division director or branch chief] within 30 days of the date of the letter transmitting this Notice of Nonconformance.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent

possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21."]

Dated this (day) day of (Month/Year)

APPENDIX D

GUIDANCE FOR VENDOR AND QA IMPLEMENTATION INSPECTION REPORT DETAILS

EXAMPLES

Examples of Cover Letters, Notices of Violation, Notices of Nonconformance, and Inspection Reports can be found on the Quality Assurance for New Reactors website and the Vendor Quality Assurance Inspections Website.

The following is a key to the notation used in the standard formats:

Symbol	Meaning
(____) or _____	Fill in the blank with the appropriate information
( )	Text within parentheses indicates the optional use of an alternative word or an optional choice or the plural form of the word preceding the parentheses.
[ ]	Text within brackets indicates narrative guidance that should be followed in terms of addressing specific elements that should be included in the particular document.
" "	Text within quotes indicates a suggested sentence or language.

Included in this Appendix is a blank template.

These exhibits may be used as a sample report for format and style. They illustrate how to use the standardized inspection report outline and adhere to the expected internal organization for each report section.

Pages are numbered continuously through this appendix. Inspection reports should use separate page numbering for the cover letter, report (beginning with report cover page), and supplemental information.

The font face and size should be Arial 11 for inspection reports.

U.S. NUCLEAR REGULATORY COMMISSION
(OFFICE)
(DIVISION)
VENDOR/QA IMPLEMENTATION INSPECTION REPORT

Docket No.:	(XXXXXXXX)
Report No.:	(XXXXXXXX/YYYY-NNN)
Vendor/Applicant:	(Vendor/Applicant Name) (Vendor/Applicant Address)
Vendor/Applicant Contact:	(Vendor/Applicant Contact Name and Contact Information)
Nuclear Industry Activity:	(Description of basic components or services supplied to the nuclear industry or, if applicant, brief summary of planned facility)
Inspection Dates:	(Month XX – Month XX, YYYY)
Inspectors:	(Name of Inspector, OFFICE/DIVISION/BRANCH), Team Leader (if applicable) (Name of Inspector, OFFICE/DIVISION/BRANCH) (Name of Inspector, OFFICE/DIVISION/BRANCH)
Approved by:	(Name of Branch Chief), Chief (Branch) (Division) (Office)

Enclosure

EXECUTIVE SUMMARY

(Vendor/Applicant Name)
(REPORT NO. XXXXXXXX/YYYY-NNN)

[Describe the purpose, scope, and bases of the inspection.

Describe the safety-related activities observed on the inspection.

Describe previous inspections at the vendor or applicant facility.

If applicable, describe any additional information, such as observation of a NUPIC Audit.]

The results of the inspection are summarized below. Only Sections with findings should be listed individually here. If there aren't any findings, then just include the paragraph under "Other Inspection Areas" with the heading "Inspection Areas."

(Section Title, e.g., 10 CFR Part 21 Program)

[Reiterate the Conclusion from the Report Details Section.]

(Section Title, e.g., Corrective Action Program)

(Section Title, e.g., Safety Conscious Work Environment (SCWE))

[For assessment of a vendor's/applicant's SCWE program, the qualified safety culture assessor will include a brief description of the status of the vendor's/applicant's SCWE based on the outcome of random interviews conducted on a selected sample of individuals within the vendor/applicant organization in order to identify any reluctance to report safety issues by vendor/applicant personnel.

For an inspection report with no SCWE issues, then include this statement: "The NRC inspection team concluded that (Vendor/Applicant name) SCWE program and implementation were consistent with the NRC's guidance in inspection procedure (IP) 71152, "Problem Identification and Resolution," Appendix 1, "Guidance for Gathering SCWE and PI&R Insights." Based on the outcome of limited number of interviews conducted of selected individuals within the (Vendor/Applicant name) organization, the NRC inspection team determined that the (Vendor/Applicant name) staff are willing to raise nuclear safety concerns and the individual's perception of their management's responsiveness to these concerns was positive. The (Vendor/Applicant name) staff also indicated that they felt comfortable raising concerns to their supervisor and management, and elevating issues up through supervision or management if not appropriately addressed. The (Vendor/Applicant name) staff can enter issues directly into the corrective action program or nonconformance program."]

[Reiterate the Conclusion from the Report Details Section. If the inspectors closed findings from a previous inspection, then include the following:

The NRC inspection team reviewed the corrective actions that [applicant or vendor name] took to address Nonconformance No. 9990XXXX/20XX-XX-XX, documented in inspection report No. 9990XXXX/20XX-XXX, dated XXXX XX, XXXX. The NRC inspection team reviewed the

documentation that provided the objective evidence that all of the corrective actions were completed and adequately implemented. Based on this review, the NRC inspection team closed Nonconformance No. 9990XXXX/20XX-XXX-XX.]

(Other Inspection Areas)

The NRC inspection team determined that [applicant or vendor name] established its programs for [list the Appendix B criteria evaluated] in accordance with the applicable regulatory requirements of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed and activities observed, the NRC inspection team also determined that [applicant or vendor name] is implementing its policies and procedures associated with these programs. No findings of significance were identified in these areas.

REPORT DETAILS

1. (Section Title, e.g., 10 CFR Part 21 Program)

   a. Inspection Scope

      [Describe what was inspected, consistent with the Inspection Procedure (IP) if one was used. The narrative can be extracted from the Objectives or Requirements section of the applicable IP. State either what the inspectors did or what the inspection accomplished: "The inspectors reviewed (observed, sampled, evaluated, etc.)..." The Scope statements might also describe why certain items were inspected. For example, "...to determine compliance with..." A list of the documents reviewed should be included in the attachment and not in the Scope statement. The last sentence of the Scope statement should be, "The documents reviewed by the inspectors are included in the attachment to this inspection report."]

   b. Observations and Findings

      [Describe the inspectors' conclusions, and do not repeat the activities identified in the scope. "The inspectors reviewed…" is a Scope statement. "The inspectors noted (verified, observed, identified, etc.) …" is the inspector's observation. When no findings were identified, the Observations and Findings section should state, "No findings of significance were identified."

      Only include detailed descriptions of the vendor or applicant's procedures or inspection activities if findings were identified with those documents or activities, or it is needed to support an allegation or licensing action.

      For violations, apparent violations, and nonconformance's, include sufficient detail to describe the requirement and how it was not met. This should include the circumstances of the noncompliance, including the date(s) of the noncompliance and the facts necessary to demonstrate that the requirement was not met. Actual or potential safety consequences should be described to support the significance of the noncompliance. This discussion should include whether the item was shipped, if there is an impact to the operating or new reactor fleet. Corrective action taken or planned, response by the vendor, root cause, management involvement, whether the no noncompliance appears isolated or programmatic may also be included to fully describe the violation or nonconformance. The level of detail must include the applicable traditional enforcement attributes such as regulatory process, or actual consequences and must also describe the logic used to determine the significance of the finding, i.e., describe why the finding meets greater than minor criteria. The level of detail must allow a knowledgeable reader to reconstruct the logic used to arrive at the final conclusion.

      This issue has been identified as Nonconformance XXXXXXX/20XX-20X-0X.

      For potential findings that are screened as minor violations/nonconformances the inspector will include a detail description of the minor violation/nonconformance and include an explanation as to why the issue is being considered minor using the examples for specific criteria listed in Appendix E as guidance. The inspector will reference the corrective action report initiated by the vendor/applicant (e.g. that they entered the issue into their corrective action program).

c. Conclusions

[Summarize the vendor performance in the area inspected. If findings were identified, a short summary of each violation, apparent violation, or nonconformance should be included with its associated tracking number. If no findings were identified, include the statement, "No findings of significance were identified."]

2. (Section Title, e.g., Corrective Action Program)

a. Inspection Scope

(…)

b. Observations and Findings

(…)

c. Conclusions

(…)

3. (Section Title, e.g., Commercial-Grade Item Dedication) (If applicable, include ITAAC No.)

a. Inspection Scope

(…)

b. Observations and Findings

(…)

c. Conclusions

(…)

4. (Section Title, e.g., Safety Conscious Work Environment)

a. Inspection Scope

[Describe what was inspected, consistent with the Inspection Procedure (IP) if one was used. State either what the inspectors did or what the inspection accomplished.

A qualified safety culture assessor may use the following statement: "The NRC inspection team reviewed the processes and procedures that implements the (Vendor/Applicant name)'s nuclear safety culture. The NRC inspection team selected and interviewed a sample of the technical staff, supervisors, and managers to gain insight on the willingness of (Vendor/Applicant name) staff to raise nuclear safety issues. The NRC inspection team discussed the implementation of the various processes and procedures that support the Vendor/Applicant safety culture with Vendor/Applicant management and staff. The NRC inspection team determined that the

(Vendor/Applicant name) staff are willing to raise nuclear safety concerns. (Vendor/Applicant name) staff also indicated that they felt comfortable raising concerns to their supervisor and management, and elevating issues up through supervision or management if not appropriately addressed. The (Vendor/Applicant name) staff can enter issues directly into the corrective action program or nonconformance program. The attachment to this inspection report lists the individuals and documents reviewed by the NRC inspection team."]

b. Observation and Findings

[A qualified safety culture assessor will include sufficient detail information to describe the status of the vendor's/applicant's SCWE. This will be based on interviews conducted of selected individuals within the vendor/applicant organization to identify any reluctance to report safety issues by vendor/applicant personnel to their management. If the qualified safety culture assessor identifies SCWE issues such as a chilling environment among individuals to raise nuclear safety issues to their management, then, the inspector will document and communicate the SCWE issues to the team lead, his/her branch chief and the NRC Senior SCWE specialist for further guidance.

For an inspection report with SCWE-related issues, then use the statement below:

"The NRC inspection team and (Vendor/Applicant name) management discussed (Vendor/Applicant name)'s SCWE assessment and potential improvement recommendations."

For an inspection report with no SCWE issues, then use this statement:

"No findings of significance were identified."]

c. Conclusion

[Summarize the vendor/applicant performance in the area inspected. If no SCWE issues were identified, then use this statement: "The NRC inspection team concluded that the (Vendor/Applicant name) safety culture is adequate. No findings of significance were identified."]

5. Entrance and Exit Meeting

On (Date) the NRC inspectors discussed the scope of the inspection during the entrance meeting with (Name of senior vendor or applicant management in attendance) and other members of the (vendor or applicant) management and technical staff. On (Date), the NRC inspectors presented the inspection results and findings during an exit meeting with (Name of senior vendor or applicant management in attendance) and other members of the (vendor or applicant) management and technical staff (or On [date of exit meeting if different], the NRC inspectors discussed the results of this inspection with [name of principal manager who attended the exit] and other members of (vendor or applicant) management and technical staff.)

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES AND INDIVIDUALS INTERVIEWED

Name	Title	Affiliation	Entrance	Exit	Interviewed
First, Last Name	Inspection Team Leader	NRC/(Office)	X	X	
First, Last Name	Inspector	NRC/(Office)	X	X	
First, Last Name	Technical Specialist	NRC/(Office)	X	X	
First, Last Name	President/CEO	Vendor ABC		X	
First, Last Name	QA Manager	Vendor ABC	X	X	X
First, Last Name	NDE Technician	Vendor ABC	X	X*	X

NOTE: Redact the name(s) of individual(s) from the list when: (1) there is a need to protect the identity of an individual, or (2) a vendor requests the name of its employees not be made public.

2. INSPECTION PROCEDURES USED

Inspection Procedure (IP) 36100, “Inspection of 10 CFR Parts 21 Programs for Reporting Defects and Noncompliance”

(…)

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description	Applicable ITAAC
99912345/2008-201-01	Opened	NOV	10 CFR 21.21(a)	N/A
99912345/2008-201-02	Opened	NOV	10 CFR 21.21(b)	N/A
99912345/2008-201-03	Opened	NON	Criterion I	N/A
99912345/2008-201-04	Opened	NON	Criterion II	N/A
99912345/2008-201-05	Opened	NON	Criterion III	2.2.03.05a.iii
99912345/2008-201-06	Opened	URI	Criterion XI	2.2.03.06a.i

(…)

4. INSPECTIONS, TESTS, ANALYSES, AND ACCEPTANCE CRITERIA [if applicable]

If there are ITAAC related to components being manufactured, designed, or tested; include the following text:

As required by 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” ITAAC identified in a licensee’s combined license are necessary and sufficient, when successfully completed, to provide reasonable assurance that the facility has been constructed and will operate in conformity with the combined license, the provisions of the Atomic Energy Act, as amended, and the Commission's rules and regulations.

During construction, the licensee is responsible for performing all inspections, tests, and analyses and ensuring that the specified acceptance criteria are met. However, work performed by vendors to supply components, parts, materials, or services to the facility may impact the ability of the licensee to meet its ITAAC.

The NRC inspectors identified the following inspections, tests, analyses, and acceptance criteria (ITAAC) related to components being (manufactured, designed, and tested) by (vendor name). At the time of the inspection, (vendor name) was involved in (manufacturing/designing/testing) (basic component) for the (design type) reactor design being constructed by (licensee's name). For the ITAAC listed below, the NRC inspection team reviewed (Vendor)'s quality assurance controls in the areas of [insert applicable Appendix B criteria]. The ITAAC(s) design commitment referenced below are for reference by the NRC staff during reviews of ITAAC notifications submitted by licensee; the listing of these ITAAC does not constitute closure or verification. The NRC inspection team (did not identify any) identified findings associated with the ITAAC identified below.

ITAAC Index No	ITAAC Section No.	Design Commitment	Inspection, Tests, Analyses	Acceptance Criteria
253	2.2.05.02a	2.a) The components identified in Table 2.2.5-1 as ASME Code Section III are designed and constructed in accordance with ASME Code Section III requirements.	Inspection will be conducted of the as-built components as documented in the ASME design reports.	The ASME Code Section III design reports exist for the as-built components identified in Table 2.2.5-1 as ASME Code Section III.
256	2.2.05.03b	3.b) Pressure boundary welds in piping identified in Table 2.2.5-2 as ASME Code Section III meet ASME Code Section III requirements.	Inspection of the as-built pressure boundary welds will be performed in accordance with the ASME Code Section III.	A report exists and concludes that the ASME Code Section III requirements are met for nondestructive examination of pressure boundary welds.

Please refer to Appendix F of this manual chapter for more specific guidance on what information to include in this section.

5. LIST OF ACRONYMS USED (optional)

IP Inspection Procedure
NRC Nuclear Regulatory Commission
QA Quality Assurance
(…)

6. DOCUMENTS REVIEWED

Procedures

[Procedure Number], “[Title],” [Revision number], date [Date]

Corrective Action Reports:

[Number], [Title (if given) or paraphrase the main reason for the CAR], dated [Date]

Corrective Action Reports Opened During This Inspection:

[Do no list minor violations/nonconformances unless documented in the Report Details per Section 06.01.a above]

[Number], [Title (if given) or paraphrase the main reason for the CAR], dated [Date]

APPENDIX E

MINOR EXAMPLES OF VENDOR AND QA IMPLEMENTATION FINDINGS

E.1 PURPOSE

The purpose of this appendix is to provide additional guidance to the Nuclear Regulatory Commission (NRC) staff regarding the difference between minor and greater than minor vendor and QA implementation findings. The information contained in this section provides clarification and examples that may help the inspector determine if an inspection finding is greater than minor. In all cases, the final decision in determining if a finding is greater than minor should be based on the specifics of the inspection finding.

E.2 DEFINITION OF MINOR VIOLATIONS AND NONCONFORMANCES

Minor violations are below the significance of that associated with Severity Level IV violations and are not the subject of formal enforcement action or documentation. Failures to implement requirements that have insignificant safety or regulatory impact or findings that have no more than minimal risk should normally be categorized as minor. While vendors or applicants must correct minor violations, minor violations do not normally warrant enforcement action. However, minor violations may be documented if they are needed to support a licensing action.

Minor nonconformances to the technical and quality requirements imposed on a vendor through a purchase order and should be screened in the same manner as minor violations.

As used in this appendix, the term “insignificant” relates to a condition adverse to quality that has a minimal safety or regulatory impact.

E.3 WORK IN PROGRESS FINDINGS

All examples in this appendix assume (unless otherwise stated) that the document or activity had been released for use. This does not imply that “actual” work had to have been performed for an issue to be greater-than-minor. For example, if a design drawing had been released for use (i.e., the vendor, or applicant had reviewed and approved the drawing), and it contained significant errors, the issue may be greater-than-minor even if the incorrect drawing had not been used.

All examples in this appendix assume that the vendor or applicant had an opportunity to identify and correct the issue (i.e., the document or activity had been reviewed by at least one level of quality assurance, quality control, or other designated / authorized personnel.)

This does not imply that the vendor or applicant must have “signed-off” the activity as complete. If the vendor or applicant had performed a quality control acceptance inspection, check, or review, which would reasonably be expected to identify and correct the issue, then the specific activity may not be a “work-in-progress.”

E.4 ISOLATED ISSUES

Issues that represent isolated (i.e., “isolated” in that based on a reasonable effort, the staff determines that the issue is not recurring nor is it indicative of a programmatic issue such as inadequate supervision, resources, etc.) failures to implement a requirement and have insignificant safety or regulatory impact should normally be categorized as minor violations or nonconformance’s.

If possible, the inspector should determine whether the issue represented an isolated failure to implement a requirement that had an insignificant safety or regulatory impact. For an issue to be considered isolated, the inspector has determined that the issue is not indicative of a programmatic issue. If the inspector did not sample enough to make this determination, the issue should not be considered isolated. The determination that an issue is isolated should imply that the vendor or applicant had established adequate measure to control the activity.

EXAMPLE OF AN ISOLATED ISSUE:

Example a.:	The NRC inspectors identified that the vendor failed to implement a requirement.
Minor because:	Based on the number of similar samples inspected, independent review and/or observation of quality activities, and discussion with appropriate vendor personnel, the inspectors determined that the issue was not recurring, and not indicative of a programmatic issue, and that the issue had an insignificant safety or regulatory impact.
Greater-than- minor if:	Based on the number of similar samples inspected, independent review and/or observation of quality activities, and discussion with appropriate vendor personnel, the inspectors determined that the issue was recurring, indicative of a programmatic issue, or that the issue had a significant safety or regulatory impact.

E.5 ISSUES RELATED TO THE QUALITY OF A SSC OR ACTIVITY

Issues that could render the quality of a SSC or activity unacceptable or indeterminate would generally be associated with findings and be greater-than-minor.

An issue that could adversely affect an SSC’s ability to perform its intended safety function or could impair the accomplishment of another SSC’s safety function, should generally be considered greater-than-minor. In addition, issues that represent a reduction in safety margin compared to the latest safety analysis under review or approved by the NRC should also be considered greater-than-minor.

"Could" does NOT imply that the issue would absolutely adversely affect the SSC. It implies a probability that the ability of the SSC to perform its intended safety function may be adversely affected if the proper conditions existed.

A finding should not be screened as minor solely based on the fact that it did not require detailed engineering justification; the inspector should consider that the lack of a more detailed

evaluation may indicate that the vendor or applicant failed to adequately consider the scope of the issue or fully understand the technical and quality requirements. In some cases, re-design may appear to be a simple corrective action, and minor on the surface; however, the staff should verify that all interactions and interfaces have been considered and that sufficient design margin is available.

E.6 ISSUES RELATED TO THE FAILURE TO ESTABLISH, A PROCESS, PROGRAM, PROCEDURE OR QUALITY OVERSIGHT FUNCTION

Failures to establish programs, processes, instructions, procedures, or drawings are typically precursors to more significant noncompliances. If inspectors identify the lack of a program, process, instruction, procedure, or drawing, they should continue the inspection to assess the impact of the issue. If the inspectors are unable to establish an impact, the finding is potentially a minor finding. Factors specific to the issue, including the vendor's response to the issue, should be considered.

E.7 ISSUES THAT COULD ADVERSELY AFFECT THE CLOSURE OF AN INSPECTION, TEST, ANALYSIS, AND ACCEPTANCE CRITERIA (ITAAC)

An issue, that if left uncorrected, could potentially prevent a licensee from closing an ITAAC, should be considered greater-than-minor. The issue must be material to the acceptance criteria of the ITAAC.

E.8 SCREEN FOR GREATER-THAN-MINOR

Determine whether the violation or nonconformance is greater-than-minor. If the answer to any of the following questions is "YES," the violation or nonconformance is greater-than-minor. If the answer to all four questions is "NO," the violation or nonconformance is not greater-than-minor.

The violation/nonconformance:

1. Is the issue similar to the "greater-than-minor if" statement of an example in Section E.9?

2. Does the issue, if left uncorrected, represent a condition adverse to quality that renders the quality of a structure, system, or component (SSC) or activity, unacceptable or indeterminate, AND the issue is associated with any one or more of the following?

    A. A deficiency in the design, manufacture, construction, installation, inspection, or testing of a SSC, which required one of the following to establish the adequacy of the SSC to perform its intended safety function: (i) detailed engineering justification; (ii) redesign; (iii) replacement; (iv) supplemental examination, inspection, or test; (v) substantial rework; or (vi) repair

    B. A non-conservative error in a computer program, design specification, construction specification, design report, drawing, calculation, or other design output document that defines the technical requirements for the SSC

C. An irretrievable loss of a quality assurance record; or a record-keeping issue that could preclude the vendor or applicant from being able to take appropriate action on safety-significant matters, or from objectively or properly assessing, auditing, or otherwise evaluating safety-significant activities, or

D. An unqualified process, procedure, tool, instrument or personnel used for a quality activity that either invalidated previously accepted activities, or required requalification

3. Does the issue, if left uncorrected, represent a failure to establish, implement or maintain a process, program, procedure, or quality oversight function that could render the quality of the SCC or activity unacceptable or indeterminate?

4. If left uncorrected, could the issue adversely affect the closure of an Inspection, Test, Analyses, and Acceptance Criteria (ITAAC)?

If the answer to all the preceding questions is no, the violation or nonconformance is minor. The inspectors inform the vendor or applicant of the minor violation or nonconformance and the vendor or applicant dispositions the minor violation or nonconformance in accordance with its corrective action program. If the vendor or applicant does not disposition the minor violation or nonconformance in accordance with its corrective action program, then the inspectors screen this as a new issue. Normally, minor violations or nonconformance's will not be documented.

If the answer to any of the preceding questions is yes, the violation or nonconformance is a greater-than-minor violation or nonconformance.

E.9 EXAMPLES OF MINOR VIOLATIONS AND NONCONFORMANCES

When determining whether issues can be considered minor, inspectors should compare the issue to the following examples to answer the first screening questions in section E.8. The examples are written about vendors but apply to COL and DCD applicants as well.

1.	10 CFR Part 21 Issues
Example a.	The vendor does not complete a technical evaluation for a departure from technical requirements included in a procurement document.
Minor because:	The deviation is on a component that has not shipped. Or, the vendor did not document the technical evaluation appropriately; however, engineering had reviewed the deviation to determine it did not constitute a potential defect.
Greater-than-minor if:	The vendor would have to perform additional work to determine if there is a potential defect on a shipped component.

Example b.	The vendor's 10 CFR Part 21 procedure does not address all of the requirements of 10 CFR Part 21.21(a) for evaluating deviations and failures to comply.
Minor because:	The inspectors reviewed a sample of recent Nonconformance Reports and Corrective Action Reports and did not identify any specific issues that would have warranted further evaluation under the vendor's Part 21 program.
Greater-than-minor if:	The inspectors reviewed a sample of recent Nonconformance Reports and Corrective Action Reports and identified specific issues that would have warranted further evaluation under the vendor's 10 CFR Part 21 program. Or, the vendor does not have a procedure for evaluating deviations and failures to comply in accordance with 10 CFR Part 21 and the inspectors identified a deviation that required evaluation.
Example c.	The vendor does not have the most recent version of 10 CFR Part 21 posted in a conspicuous location on the premises where safety-related activities are conducted.
Minor because:	The posting includes 10 CFR Part 21 and the revision posted does not have any major changes in processes or definitions
Greater-than-minor if:	The vendor has no postings, and personnel are not trained on 10 CFR Part 21. Or, the revision of 10 CFR Part 21 included in the posting has major changes in processes or definitions and has led to deviations and failures to comply not being evaluated or reported.
Example d.	The vendor did not specify that 10 CFR Part 21 applied to a safety-related purchase order.
Minor because:	The issue was isolated and had no safety impact, or the vendor verified the supplier has a 10 CFR Part 21 procedure and is effectively implementing it.
Greater-than-minor if:	The issue is repetitive, and the vendor did not verify the suppliers had a 10 CFR Part 21 procedure and were effectively implementing it. Or, the vendor received a part, material, or service from a supplier containing a deviation that warrants evaluation for reporting a potential defect under 10 CFR Part 21.

2.	QA Organization
Example a.	The vendor's organizational structure was set up so that the quality assurance manager was responsible for quality assurance and quality control inspections.
Minor because:	The QA manager was only responsible for the programmatic aspects of the quality control program (procedures, training, etc.) and did not have production responsibilities.
Greater-than-minor if:	The QA organization was not free from cost and schedule pressures, had production responsibilities, and was not free to report quality issues to the specified responsible officer.
3.	Quality Assurance Program
Example a.	The vendor failed to ensure personnel performing inspection and test activities for safety related components had completed required training. This same vendor also failed to maintain accurate training records in accordance with the vendor's testing procedures.
Minor because:	The testing and inspection personnel had not performed inspection on safety-related components. Or the personnel's lack of qualification was solely an administrative issue. While the training record was not signed by the employer, the ability or competence of the inspector was not in question and he had completed all other required training and qualification requirements.
Greater-than-minor if:	The inspection/testing was performed on safety-related components with personnel who were not qualified for the inspection/testing procedures, and there is evidence to question the quality of those safety-related components that were accepted by the inspection/testing activities.
Example b.	The applicant created procedures based on a different quality assurance standard (e.g., ASME NQA-1, ANSI N45.2) than approved in its quality assurance program description (QAPD).
Minor because:	The NRC has reviewed and approved the revision of the standard used to create the procedures and the applicant has verified that there is no reduction in commitment.
Greater-than-minor if:	The changes, or use of an alternate standard, reduce the commitments in the QAPD that would not be accepted by the NRC.

4.	Design Control
Example a.	The inspectors identified a design change that had not been evaluated using the design control process.
Minor because:	The design change would not negatively affect the original design requirements, assumptions, and qualifications.
Greater-than-minor if:	The design change requires evaluation to determine whether the SSC can perform its intended safety function or meet its original qualifications.
Example b.	The inspectors identified an instance where the vendor's design control measures to verify and check the adequacy of the design was performed by the same individuals or groups as those who performed the original design.
Minor because:	The issue is isolated and further verification did not yield any negative impacts to the design or prevent the SSC from meeting its intended safety function.
Greater-than-minor if:	The design requirements would not be met or cannot be readily proven that they are met. Or independent verification and validation was not performed on safety-related software (software QA).
Example c.	The inspectors identified an instance where measures were not established for the identification and control of design interfaces.
Minor because:	Not establishing the measures necessary for the identification and control of design interfaces did not negatively affect the ability of the SSC to perform its intended safety function.
Greater-than-minor if:	An insufficient or missing design interface led to not accounting for a design requirement that could potentially affect the ability of the SSC to perform its intended safety function.
Example d:	The inspectors identified that the vendor's design specification does not conform to the technical requirements in the purchase order (i.e., the vendor failed to adequately translate the approved design to appropriate drawings, instruction, procedures, etc.).

Minor because:	The failure to incorporate the technical requirements resulted in a more conservative analysis than what was required by the governing technical requirements. Or the failure to incorporate the technical requirements was insignificant, in that the ability of the as-designed SSC to perform its intended safety function was not challenged.
Greater-than-minor if:	The failure to incorporate the technical requirements resulted in a less conservative result that could adversely affect the SSC's ability to perform its intended safety function.

Example e.	The inspectors identified an instance where the vendor's software used for modeling had an error in the software output due to the use of non-cited valid data test sets in the calculation.
Minor because:	The software's output would not negatively affect the final safety-related modeling or analysis delivered to the licensee.
Greater-than-minor if:	The software's output would require evaluation to determine whether the design calculations could affect the intended safety function of the modeling or analysis that has been delivered to the licensee.

Example f.	The inspectors identified an instance where as part of a commercial grade dedication process, the vendor failed to identify and/or verify all critical characteristics necessary to support the safety function of the item.
Minor because:	Verification of the critical characteristics was performed, it was just performed outside of the commercial grade dedication process.
Greater-than-minor if:	The critical characteristic(s) in question have a direct impact on the safety-function of the item.

Example g.	The inspectors identified an instance where a vendor used unverified design information as an input into a safety-related calculation.
Minor because	Changes in the input parameters would have minimal effect on the outcome of the overall calculation or analysis.
Greater-than-minor if:	Changes in the input parameters would have a more than minimal effect on the outcome of the overall calculation or analysis.

5.	Procurement Document Control

Example a. The vendor failed to include the critical characteristics in the purchase order for commercial calibration services by domestic calibration laboratories accredited by one of the 6 ILAC domestic accrediting bodies for the calibration of measuring and test equipment (M&TE) that will be used in safety-related applications.

Minor because: The equipment affected by the commercial calibration services was not used on safety-related parts.

Or, the vendor verified that the accreditation was by one of the 6 approved ILAC domestic accrediting bodies, that the scope of accreditation covers the contracted services, and that the calibration records for the affected M&TE attest that the laboratory used its accredited ISO 17025 quality program, reported as found data, and identified the laboratory equipment and standards used.

Or, the M&TE calibration was found to be within acceptable ranges when used on safety-related applications.

Greater-than-minor if: The M&TE was used in safety-related applications for which the resulting calibration was found to exceed acceptable limits or was indeterminate.

Example b. The vendor's purchase order to a supplier did not state the proper technical standard and revision for testing.

Minor because: Documentation exists that demonstrates that testing was performed to the proper technical standard.

Or the vendor evaluated the differences between the proper technical standard and the one used, and the evaluation demonstrates the differences between the standards/revisions are minor and would not impact the testing performed.

Greater-than-minor if: Testing was not performed to the proper technical standard and the ability of the SSC to perform its safety function is in question.

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6. Instructions, Procedures, and Drawings

Example a. The vendor failed to adequately prescribe and perform activities affecting quality in accordance with documented instructions, procedures, or drawings. Specifically, the vendor failed to incorporate all the requirements from the customer's specification into its procedures for blasting structural steel surfaces in accordance with American Welding Society (AWS) Code D1.1-2000, "Structural Welding Code–Steel."

Minor because: No material was blasted using this procedure.

Or the procedure met AWS D1.1-2000 requirements and the additional requirements in the customer's specification would not affect the ability of the component to perform its safety function.

Greater-than-minor if: The material's ability to meet its safety function is in question.

Example b. The vendor placed two components in the "complete status ready for shipment." However, the tags did not contain required identification of the QC inspector who approved the completion of the final inspection as required by the vendor's procedure.

Minor because: It is an isolated incident, and the inspection status is also identified in inspection records, or a traveler, and the final inspection had been performed.

Greater-than-minor if: There are repetitive occurrences where final inspections were not adequately documented.

Or the components would not meet the acceptance criteria of the final inspection.

Example c. The inspectors identified that the vendor's procedure was not compliant with technical or quality requirements required in the purchase order.

Minor because: The issue was insignificant, in that the procedure was not unqualified due to a technical issue (i.e., the procedure did not require requalification, and the results of previous work was not suspect).

Or the procedure was not used on safety-related SSCs.

Greater-than-minor if: The procedure was required to be qualified by performance demonstration. For example, welding procedure specifications are qualified by using the welding procedure specification to create a sample weld and then performing inspection and/or testing to verify that use of the procedure will create a sound weld.

Or the results of previous work were suspect.

Example d. NRC inspectors identified that a vendor procedure had undergone major revision and contained reference to another procedure that was cancelled prior to the date of the revision.

Minor because: The issue was insignificant, in that the cancelled procedure was not required to provide information that was material to the successful completion of the specific work activity (i.e., the issue was administrative.)

Greater-than-minor if:	The issue was significant, in that the revised procedure relied on a cancelled procedure to provide information that was important to the successful completion of a work activity that affected a SSC (e.g., acceptance criteria for an inspection, guidance for technical evaluation of data, qualification criteria, etc.), and the procedure was used in a safety-related activity.

7.	Document Control

Example a.	During an inspection, the NRC inspector found a superseded copy of the work procedure beside some tools staged at the job site.
Minor because:	Work activities had not been conducted with the outdated procedure. Or work activities had been completed with the outdated procedure, but the difference between the outdated procedure and current revision did not render the quality of the activity unacceptable or indeterminate.
Greater-than-minor if:	The outdated procedure was being used and the differences were not insignificant (i.e., the quality of the activity was unacceptable or indeterminate.)

Example b:	The completed component did not match the design drawing, because the drawing was not updated with an approved engineering change request.
Minor because:	The failure to update the design drawing was isolated, and the vendor performed an evaluation and determined that the SCC is acceptable as is. Or, the vendor did not perform any work to the affected drawing. Or the vendor performed work to the affected drawing, but the change did not directly affect the work performed.
Greater-than-minor if:	The failure to update design drawings was not isolated. Or the SSC was unacceptable, in that the engineering change request was inappropriately approved. Or the design change was directly related to work performed and rendered the quality of the SSC unacceptable or indeterminate.

Example c.	An applicant's procedure for Document Control did not require the same level of review of revisions to instructions, procedures, and drawings as

required for the original issue.

Minor because: The procedural inadequacy did not result in the approval and use of any inadequate instructions, procedures, or drawings;

Or the procedural inadequacy allowed an isolated instance of the approval of an inadequate instruction, procedure, or drawing, the use of which was determined to have no safety or regulatory impact.

Greater-than-minor if: The Document Control procedural inadequacy resulted in the approval of revisions to instructions, procedures, or drawings that had not received the same level of review as the initial issue. The use of these inadequately reviewed revisions to instructions, procedures, or drawings could result in component not being able to meet its intended safety function.

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8. Control of Purchased Material, Equipment, and Services

Example a. The vendor failed to perform an adequate assessment of a third-party audit used to qualify a supplier of basic components.

Minor because: The third-party audit was applicable and provided objective evidence that the supplier's quality assurance program met the requirements of 10 CFR 50, Appendix B. The applicant identified the issue and provided adequate and prompt corrective action.

Greater-than-minor if: The third-party audit had significant open findings that call into question the supplier's ability to provide basic components in accordance with the requirements of 10 CFR 50 Appendix B.

Or the third-party audit didn't cover the basic components or services procured from the supplier.

Or the supplier's quality assurance program did not meet the requirements of 10 CFR 50, Appendix B.

Example b. A vendor failed to perform annual evaluation of a supplier.

Minor because: The vendor conducted an initial qualification audit that verified programmatic controls and implementation of the QA program and the supplier continued to demonstrate adequate controls over technical and quality requirements as evidenced by acceptable receipt inspections performed upon delivery of the SSCs to the vendor.

Or the vendor conducted an initial qualification audit that verified programmatic controls and implementation of the QA program and had not procured any basic components from the supplier since the vendor

failed to perform the annual evaluation.

Greater-than-minor if: The vendor made purchases from the supplier during the timeframe that the annual evaluation was not performed and the nonconformance's to technical or quality requirements were identified.

Or the vendor had not established measures to ensure that purchased materials, equipment, and services conformed to applicable technical and quality requirements.

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9. Identification and Control of Materials, Parts, and Components (Traceability)

Example a. The vendor failed to maintain lot traceability of safety-related items. Specifically, the inspectors found a lay down area of safety-related items at the vendor facility with missing tags.

Minor because: The tags were an administrative control, in that the items did not rely on the tags to maintain material traceability. Instead stamps and receipt inspection logs were used on the safety related item to maintain material traceability.

Greater-than-minor if: The tags were required to maintain traceability, and the vendor shipped the items.

Or traceability could not be reestablished.

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10. Special Processes

Example a. The inspectors identified that the vendor was welding with a different size and type of tungsten electrode than that allowed by the welding procedure specification.

Minor because: For the specific welding process, a change in the electrode size or type is a nonessential variable; therefore, the welding procedure specification does not need to be re-qualified.

Greater-than-minor if: For the specific welding process, a change in electrode size or type is an essential variable and the procedure was required to be re-qualified.

Example b. During visual examination of a weld, the inspectors identified that the vendor's QC inspector failed to verify that he had the minimum required light intensity

Minor because: Although the QC inspector did not measure the light intensity, the ambient lighting was more than the minimum and a visual indication could have been seen by the inspector.

Greater-than-minor if: The ambient lighting was less than the minimum, the welds were required to be re-inspected, and a previously unidentified indication was found.

Or the lighting could have been less than the required minimum and the welds were not accessible for re-inspection.

Example c. The vendor's welding procedure allowed higher limits on amperage than that allowed by the welding code.

Minor because: No welding had been performed in the unacceptable range.

Or welding at the higher amperage would not adversely affect the weld.

Greater-than-minor if: Welding had been performed at an amperage higher than what the code allowed, and the welding procedure had not been re-qualified at the higher amperage.

Example d. During pre-production testing for stud welding qualification at the start of the shift, the NRC inspectors identified that one of the first two studs welded did not exhibit a full 360-degree flash as required by AWS D1.1.

Minor because: The vendor corrected the welding procedure and performed two more stud welds that passed the examination as required by AWS D1.1.

Greater-than-minor if: The vendor proceeded with production welding without correcting and qualifying the procedure.

Example e. A Level II inspector failed to identify and document an indication on a radiograph of a weld.

Minor because: The indication was not relevant and did not affect the acceptability of the radiograph.

Or the indication was relevant but within acceptable limits.

Greater-than-minor if: The indication was not relevant but required the weld to be reshot.

Or the indication was relevant and would have required evaluation or rejection.

11.	Inspection
Example a.	The vendor failed to meet the acceptance limit for a completed inspection and documented the inspection as acceptable.
Minor because:	The acceptance limit was more conservative than the technical requirement or governing regulatory requirement.
Greater-than-minor if:	The acceptance limit was a technical requirement or a regulatory limit, and the failed test rendered the quality of the SSC unacceptable or indeterminate.
Example b.	The inspectors identified an error on an inspection record for a code required examination.
Minor because:	The error was insignificant, as determined by a technical evaluation. Or the error was administrative.
Greater-than-minor if:	The error could affect the ability of the component to perform its intended safety function and the person responsible for the completeness and accuracy of the information on the report had signed it.
12.	Test Control
Example a.	The inspectors identified an instance where test results were not documented or evaluated.
Minor because:	It was verified that the SSC could perform its safety function through additional test results, calculations, or evaluations.
Greater-than-minor if:	A test configuration or test setup was changed to successfully pass the test but did not envelop the original design requirements. Or an engineering evaluation was not performed to prove that the original design requirements were still met.
Example b.	The inspectors identified an instance where a test program was missing test parameters.
Minor because:	Failing the missing test parameters would not negatively affect the SSC from being able to perform its intended safety function.

Greater-than-minor if:	Passing the missing test parameters are necessary to show that the SSC could perform under its intended safety function.

Example c.	The inspectors identified an instance where testing or instrumentation used was not done according to the requirements.
Minor because:	The test performed, or instrumentation used was equal to or more conservative than the original requirements and the SSC would be able to perform its intended safety function.
Greater-than-minor if:	No reasonable assurance could be provided that the testing or instrumentation used was equal to or more conservative than the original requirements and leaves in question the ability of the SSC to perform its intended safety function.

13.	Control of Measuring and Test Equipment

Example a.	Inspectors identified that the calibration records for M&TE being used were out of date or in error.
Minor because:	When tested, the M&TE was found to be within calibration limits.
Greater-than-minor if:	The error would not have been discovered during routine tests or calibration. Or the material that the M&TE was used for could not be re-inspected or repaired.

Example b.	Inspectors identified that measuring and testing devices used in activities affecting quality were not properly calibrated for the full range of intended use.
Minor because:	The M&TE has been retested (performed during the week of inspection as part of corrective actions) and the results are clearly within the prescribed acceptance standards.
Greater-than-minor if:	If the M&TE has not been, or cannot be retested, and the issue calls into question the results of previous measurements or tests. Or, the M&TE was not calibrated to its full range of operation and was used for testing of safety-related components resulting in the test being unacceptable or results of indeterminate quality.

Example c.	Inspectors identified that no evaluation had been performed for previous

inspection or test results affected by M&TE found to be out of calibration.

Minor because: The M&TE had gone beyond its calibration date but was found to be within acceptable limits.

Or an isolated incident where the M&TE was found to be marginally beyond acceptable limits and the inspection or test results item was evaluated to be acceptable.

Greater-than-minor if: If the issue requires an evaluation of out of tolerance, lost, or damaged M&TE that indicates questionable acceptability for previous inspection or test results indicating the need to re-inspect or re-test.

Or the issue is repetitive.

Example d. A vendor failed to indicate the calibration status of M&TE, as required by procedure.

Minor because: The M&TE was traceable to the calibration record and was within its calibration date.

Or the as-found condition of the M&TE was verified to be within the calibrated range.

Greater-than-minor if: The vendor was using M&TE that was out of calibration on safety-related components.

Example e. A vendor procedure failed to provide guidance on how to control out-of-tolerance M&TE.

Minor because: The vendor could provide objective evidence that the as-found condition on the calibration records for all its M&TE were within the acceptable calibration range.

Greater-than-minor if: The inspectors identified M&TE that was out of calibration and the vendor had not performed the required evaluations for all measurements or tests in which the out-of-tolerance instrumentation was used since it was last known to be within tolerance.

14.	Handling, Shipping, and Storage
Example a.	The vendor failed to meet the specified storage requirements for structural steel, including storing the material off the ground to prevent corrosion.
Minor because:	The inspectors found that the structural steel was not damaged and there was no active corrosion that would require a detailed engineering evaluation or repair of the steel.
Greater-than-minor if:	The structural steel was damaged such that a detailed engineering evaluation, re-design, or repair was necessary to establish the adequacy of the structural steel to perform its intended safety function.
Example b.	The NRC inspectors identified that the environmental storage conditions (e.g., humidity and temperature control) of safety-related SSCs did not meet the vendor's QA environmental storage program requirements.
Minor because:	Storage conditions had no significant impact on the safety related SSCs.
Greater-than-minor if:	Inadequate environmental storage conditions adversely affected stored safety related SSCs.
Example c.	The inspectors found that the vendor failed to establish procedures for cleaning and preservation of equipment and materials. Specifically, the vendor used a potential contaminant within the safety-related components assembly areas without procedural controls or evaluation of potential detrimental effect on safety-related components.
Minor Because:	The NRC inspectors and the vendor found no degradation related to use of the potential contaminant being used in the safety-related assembly areas.
Greater-than-minor if:	The NRC inspectors found safety-related component damage as a result of using the potential contaminant.

15.	Nonconforming Material, Parts, or Components
Example a.	A lot of printed circuit boards that did not meet the specification was screened through receipt inspection and placed in stock. When a printed circuit board was withdrawn to be installed in a module, an electrician noted that it was not the correct board.
Minor because:	It was work in progress and no adverse consequences resulted.
Greater-than-minor if:	The wrong circuit boards were installed in a module and completed modules were shipped.
Example b.	The vendor failed to review and accept nonconformance reports which were dispositioned as “repair” in accordance with documented procedures.
Minor because:	The repairs were accepted by engineering and not documented appropriately on the nonconformance report.
Greater-than-minor if:	The repair resulted in the component not being in tolerance with the applicable technical specification.
Example c.	The vendor did not establish adequate measures to control parts or components which do not conform to requirements. Specifically, the vendor failed to provide an adequate technical justification for the acceptance of components with an identified material discrepancy.
Minor because:	The vendor performs a technical justification that determines the component is acceptable with material discrepancy.
Greater-than-minor if:	The vendor performs a technical justification that determines the component is not acceptable with material discrepancy.
16.	Corrective Action
Example a.	An applicant’s corrective action report, which was issued to address a significant condition adverse to quality, did not adequately identify the cause of the condition.
Minor because:	The corrective actions were comprehensive enough to prevent recurrence of the condition, so there was no safety significance.

Greater-than-minor if: The adverse condition recurred or could reasonably be expected to reoccur,

Or there were multiple instances of failures to properly identify the root causes of significant conditions adverse to quality.

Example b. The vendor identified a lack of dedication requirements for mechanical testing of seismically-sensitive components such as relays, but their corrective actions failed to address if design changes for relays that have already been supplied to the industry invalidate their seismic qualification.

Minor because: The vendor provided adequate documentation to demonstrate previously shipped components are seismically qualified.

Greater-than-minor if: The vendor's failure to do an appropriate extent of condition for the condition adverse to quality could result in an unanalyzed design change that may invalidate the qualification of components currently used by nuclear power plants. This could include the failure to address design changes that could affect seismic or environmental qualification.

Example c. The vendor's corrective action procedure failed to provide sufficient guidance as to when to initiate a corrective action report.

Minor because: Despite the inadequate guidance, the vendor was still generating corrective action and nonconformance reports to address deficiencies.

Greater-than-minor if: The vendor failed to enter deficiencies into their process and disposition those deficiencies to correct conditions adverse to quality.

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17. QA Records

Example a. Adequate controls were not established to ensure that quality records were stored in a controlled area to prevent access by unauthorized personnel and to protect documents against loss. Specifically, the calibration quality records were stored in an unlocked filing cabinet that was located in a room that was not access controlled.

Minor because: The records were not damaged or lost, and adequate procedures for the retention (storage) of records were established.

Or an insignificant portion of a record was damaged or lost, such as a cover page, index, etc., which did not provide the documentary evidence that the SSC would perform its intended safety function.

Greater-than-minor if: Actual required records were lost or damaged, and the vendor could not easily recreate the records with reasonable assurance of their accuracy (i.e., supplemental inspections were required to recreate the missing information.) [Note: If actual records were lost, the issue may be indicative of a programmatic deficiency, even if the records were able to be recreated]

Or the vendor had not established adequate procedures for the retention of QA records (e.g., the licensee had not purchased adequate storage cabinets for permanent or temporary storage of QA records.)

Example b. The inspectors identified that the vendor failed to authenticate QA records as required by the QA program.

Minor because: The failure to authenticate QA records was isolated to one work activity, and the vendor had established measures to ensure that records were complete and accurate, and the actual records were complete and accurate (i.e., the failure to formally validate the QA records did not adversely affect the quality of the work activity).

Greater-than-minor if: The vendor had failed to establish a process or program to ensure that QA records were complete and accurate, and examples were identified that were incomplete or inaccurate.

Or the failure to authenticate QA records was not isolated, in that records for multiple work activities were not authenticated.

Or the record issue was significant, in that the records were found to be incomplete or inaccurate such that the quality of the activity was indeterminate (i.e., the QA records did not contain information needed to provide reasonable evidence that the SSC could perform its intended safety function).

Example c. Inspectors identified an error on the calibration records for M&TE.

Minor because: The M&TE can be retested and the results are clearly within the prescribed acceptance standards (i.e., the error was a documentation error and not evidence of an M&TE that was out of calibration.)

Greater-than-minor if: If the issue requires an evaluation of out of tolerance, lost, or damaged M&TE that indicates questionable acceptability for previous inspection or test results indicating the need to re-inspect or re-test.

18.	Audits
Example a.	Vendor failed to verify that audits were performed by personnel not having direct responsibilities in the areas being audited. Specifically, an internal audit in which the QA Manager, who has direct responsibility for the implementation of the vendor/applicants' QA program, participated in an internal audit as a member of the audit team.
Minor if:	The QA manager did not audit an area for which he had direct responsibility
Greater-than-minor if:	The QA manager did audit an area for which he had direct responsibility and the satisfactory implementation of that area was in question.
19.	Commercial Grade Dedication
Example a.	The inspectors identified qualification testing from a commercial third-party that was dedicated by performing a commercial grade survey.
Minor because:	The commercial grade survey identifies and verifies all the applicable critical characteristics needed for the testing and the vendor verified through receipt inspection that the critical characteristics were met.
Greater-than-minor if:	The commercial grade survey does not identify or verify applicable critical characteristics needed to perform the test or the survey relies on a third--party accreditation such as NVLAP or A2LA for testing capabilities. The NRC currently has not accepted such accreditation for laboratory services other than specific instances for calibration as part of the commercial grade dedication process.
Example b.	A vendor's dedication package did not include documented engineering evaluation of the critical characteristics.
Minor because:	The identified critical characteristics provide reasonable assurance that the item will be able to perform its safety function.
Greater-than-minor if:	The critical characteristics do not provide reasonable assurance that the item will perform its intended safety function.

Example c.	A vendor places a calibration or testing laboratory on their safety-related approved suppliers list based on NVLAP (ILAC) certification only.
Minor because:	It is found the vendor verifies the following before contracting calibration or testing services: (1) the accreditation is to ANSI/ISO/IEC 17025; (2) the accrediting body is one of the 6 NRC approved domestic ILAC accrediting bodies; (3) the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties; (4) the purchase documents impose additional technical and administrative requirements, as necessary, to satisfy the vendor's QA Program and technical requirements; (5) the purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance; and (6) the laboratory reports the standards and measuring equipment used for all calibrations.
Greater-than-minor if:	All the above are not met, the M&TE was not in calibration, and the M&TE was used on safety related SSCs.

20.	Safeguards Information (SGI)
Example a.	Adequate controls were not established to ensure that Safeguards Information (SGI) was stored in a controlled manner. Specifically, a hard drive or bootable partition was not stored within an approved lockable container.
Minor because:	There was no actual spillage of SGI, because the unlocked information still remained within a locked room that was access-controlled.
Greater-than-minor if:	There was an actual spillage of SGI beyond an authorized person or controlled-access location, or for example spillage to a publicly-accessible website.

21.	Critical Digital Assets (CDA) (NEI 08-09 Appendix A, Section 3.1.3)
Example a.	A critical digital asset (CDA) was classified by the licensee as a direct CDA and the inspectors discovered that the licensee had inadequately implemented some of the NEI 08-09, "Cyber Security Plan for Nuclear Reactors," Appendix D technical controls. However, when re-reviewed it was determined that the CDA met the criteria for an indirect CDA and the required baseline controls, in accordance with NEI 13-10, "Cyber Security Control Assessments," Section 5 were in place.
Minor because:	Upon assessment, the CDA met the criteria for an indirect CDA in accordance with NEI 13-10 and all the required baseline controls were in

place for an indirect CDA.

Greater-than-minor if: The baseline controls for an indirect CDA were not in place. In addition, the performance deficiency would be more than minor if the CDA was categorized as an indirect CDA, and inspector assessment showed that the CDA was a direct CDA, and the CDA was not adequately protected because the required controls were not in place.

APPENDIX F

GUIDANCE FOR HANDLING ITAAC BEFORE, DURING, AND AFTER VENDOR INSPECTIONS

F.1 PURPOSE

The purpose of this appendix is to provide guidance to the inspectors on what actions should be taken when doing inspections that involve inspections, tests, analyses, and acceptance criteria (ITAAC). In addition, this appendix provides guidance on how to document an ITAAC finding, criteria, and examples to help the inspectors determine when an inspection finding should be considered an ITAAC finding. The information contained in this appendix provides guidance for activities that should be taken before, during, and after the inspection is completed.

F.2 BACKGROUND

The Atomic Energy Act (AEA) of 1954, as amended, requires the Commission verify all acceptance criteria in the combined license are met prior to operation. 10 CFR 52.103(g) codifies this requirement. To allow a determination to be made by the Commission a three-prong approach was developed consisting of: 1) inspections of ITAAC SSCs at vendor facilities, 2) ITAAC inspections on-site, and 3) review and acceptance of all ITAAC completion notifications (ICNs). Licensees must submit to the NRC an ICN for each ITAAC pursuant to 52.99(c).

Identifying findings material to the ITAAC is critical to ensure the requirements of the AEA and 52.103(g) are met. All ITAAC findings must be verified as having been corrected prior to the NRC making an affirmative 52.103(g) finding.

Designating findings as “ITAAC findings” ensures that issues that prevent or may prevent the acceptance criteria of an ITAAC from being met are identified, tracked, and properly closed in the Construction Inspection Program Information Management System (CIPIMS). The NRC cannot verify closure of an ITAAC if an ITAAC finding is still open. This is discussed in the NRC Enforcement Manual Section 2.2.1.D, which states: “Unlike other NCVs, the NRC will only close NCVs that are material to the acceptance criteria of an inspection, test, analyses, and acceptance criteria (ITAAC) after a review is conducted by the NRC to ensure adequate corrective actions have been developed and implemented such that the deficiency can no longer prevent the ITAAC from being closed.”

ITAAC findings are closed when the deficiency has been corrected so that the acceptance criteria can be met. The NRC can verify adequate corrective action through re-inspection, or through an in-office review of relevant documentation (i.e., vendor’s response to the Notice of Nonconformance (NON)). To support the NRC’s 10 CFR 52.103(g) finding, closure of all ITAAC findings are documented in CIPIMS (documentation in CIPIMS is performed by the Region II staff) and published in an official agency record.

Although the NRC Enforcement Manual discusses NCVs at reactor sites under construction and does not discuss other forms of enforcement (e.g., NONs at vendor sites), any finding that would prevent an ITAAC from being closed must be tracked as an ITAAC finding.

F.3 PRIOR TO THE INSPECTION

1. Once a vendor providing components or services for the licensee has been identified for inspection, the team leader should engage NRR technical staff, Region II construction inspection staff, or staff from the Construction Inspection Program Branch, to help identify any ITAACs associated with the components or services the vendor is supplying.

2. The ITAACs should be listed in the inspection plan. For example:

[Some of the fabrication activities are associated with inspections, tests, analyses, and acceptance criteria (ITAAC). Several ITAAC have been identified from the Combined License (COL) for [include COL Holder] that apply to the [list the component(s)]. The design, fabrication, and testing activities related to these ITAACs shall be documented in the vendor inspection report to support future ITAAC closure upon plant construction. The applicable ITAAC design commitments are from the Combined License for [include COL Holder]. The table listing the ITAAC is included as Attachment 1. All team members should be familiar with all associated ITAAC for the items that will be sampled during this inspection.]

NOTE: For inspections where the scope of the inspection is related to components or services being supplied for operating reactors, the team leader should be aware if the vendor is actively supplying or already supplied components or services that have associated ITAACs for new reactor designs. This is important to know in case the inspection results in findings that may have the potential of being considered ITAAC findings.

F.4 DURING THE INSPECTION

1. When performing inspection activities (e.g., reviewing records, observing welding and non-destructive examination, etc.), the inspectors should be cognizant of the applicable ITAAC associated with the components or services being inspected in case there are potential issues identified that may result in a finding.

2. If the inspectors identify a potential finding, to the extent possible, the inspectors should gather sufficient information to help with the determination on whether the finding could be material to the ITAAC acceptance criteria and therefore considered an ITAAC finding.

F.5 AFTER THE INSPECTION

F.5.1 Documenting Information Related to ITAAC In the Inspection Report

As shown in Appendix D of this manual chapter, inspection information related to ITAAC is documented in Section 4 of the attachment to the inspection report. The inspectors should:

1. Provide a brief description of documentation reviewed and activities observed about the ITAAC related to the basic component or service provided by the vendor. Include which design the ITAAC relates to and the specific 10 CFR Part 50, Appendix B, criteria that were inspected with respect to the ITAAC.

2. Include a table that identifies the location in the COL where the ITAAC are addressed for a specific COL holder, and the ITAAC number. Appendix D of this manual chapter provides a template and additional guidance.

3. Once the inspectors make a determination that the finding or unresolved item (URI) is material to the acceptance criteria of the ITAAC, and therefore an ITAAC finding, the inspectors should provide a concise, clear statement explaining why the nonconformance or URI is material to the ITAAC acceptance criteria, provide the acceptance criteria and a statement explaining why the ITAAC acceptance criteria is impacted by the performance deficiency. The inspectors must clearly list the component(s) affected by the ITAAC finding.

F.6 ITAAC FINDING CRITERIA

An inspection finding is an ITAAC finding if the finding is material to the ITAAC acceptance criteria. A finding is material to the acceptance criteria of the ITAAC if it would prevent the ITAAC acceptance criteria from being met.

The inspection team should make an initial determination of whether the finding is material to the acceptance criteria of the ITAAC. If the finding is material to the ITAAC acceptance criteria, then the finding is an ITAAC finding. This determination is documented in Section 4 of the Attachment to the inspection report. Since not all deficiencies would prevent meeting the ITAAC acceptance criteria, it is necessary to understand the impact on the SSC. If sufficient information is not available to determine if the finding has an impact on meeting the ITAAC acceptance criteria at the conclusion of the on-site portion of the inspection, then the inspectors should continue to evaluate the issue by engaging the Regional and technical staff for assistance.

The inspectors should determine if the finding caused an actual failure to meet the ITAAC acceptance criteria prior to issuing the inspection report. If information is not available to make a final determination of whether the finding had an actual impact on meeting the ITAAC acceptance criteria, and the finding reasonably would affect an ITAAC, then the finding shall be issued as an ITAAC finding.

F.7 EXAMPLES OF ITAAC FINDINGS

Example 1:	The ITAAC acceptance criteria requires that a report exists that demonstrates the structures, systems, and components (SSCs) in Table X are seismically qualified for the design basis accident.
Finding:	The inspectors identified an equation in the vendor's seismic qualification analysis was incorrect.
ITAAC finding if:	The analysis was for an ITAAC component and the error resulted or may result in the component not being seismically qualified.

Not an ITAAC finding:	The analysis was not used to qualify components within the scope of the ITAAC or upon correction of the error the component(s) were determined to still be seismically qualified.
Example 2:	The ITAAC acceptance criteria requires that a report exists for SSCs identified in Table X that demonstrates the SSCs are constructed in accordance with ASME Section III.
Finding:	The inspectors determined that a welding procedure failed to meet ASME Section III requirements by not providing adequate instructions for monitoring and controlling a critical variable during welding.
ITAAC finding if:	The welders used the deficient procedure to perform the ASME Section III welds, and the welds were determined to be unacceptable.
Not an ITAAC finding if:	The procedure was not used to perform the ASME Section III welds, or the NDE of the welds performed by the welders using the deficient procedure found no deficiencies.
Example 3:	The ITAAC that requires an SSC to pass a test such as seismic testing, environmental qualification testing, or functional testing.
Finding:	The inspectors determined that a part used to fabricate an SSC was not dedicated properly because a critical characteristic of the part was not identified.
ITAAC finding if:	The finding affects the ITAAC SSC in a way that would invalidate the conclusion of the test used to satisfy the ITAAC acceptance criteria. For example, the part that was not dedicated correctly makes the component less capable of meeting the test requirements; or if the ITAAC is satisfied using an analysis with certain assumptions about the component in question, and the analysis is affected if the finding invalidated those assumptions.
Not an ITAAC finding if:	The part that was not dedicated properly has no effect on the test used to satisfy the ITAAC acceptance criteria and the component passed the test.
Example 4:	The ITAAC acceptance criteria requires the decay heat removal pump to provide 5000+/- 100 gpm flow to the reactor vessel.
Finding:	The inspectors identified that a test gauge used during testing is not within the required calibration period.
ITAAC finding if:	The gauge was used to record official test data necessary to demonstrate the acceptance criterion was met, and the gauge was subsequently found to be out of calibration such that the measured flowrate did not meet the ITAAC acceptance criteria, or the gauge was no longer available to check the calibration.

Not an ITAAC finding if: The gauge was not used to record official test data necessary to demonstrate the flow requirement was met or subsequent calibration verifies the gauge was in calibration during the test.

F.7 ITAAC CLOSURE

ITAAC findings are be closed when the deficiency has been corrected so that the acceptance criteria can be met. The NRC can verify adequate corrective action through re-inspection, or through an in-office review of relevant documentation (i.e., vendor's response to the NON. The decision to re-inspect a vendor to verify closure of an ITAAC finding will be made on a case-by-case basis.

Attachment 1 – Revision History for IMC 0617

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
N/A	ML082770025 03/06/09 CN 09-008	New Manual Chapter to describe Vendor Inspection Reports.	None- Based on other Manual Chapters for Inspection Report Documentation	ML082770035
N/A	ML092660012 10/29/09 CN 09-025	Revised Manual Chapter to expand scope to include QA Implementation inspections. Also, added clarifying text to 06.01for types of violations and added Appendix E to give examples of minor violations.	None.	ML092660020
N/A	ML13246A450 10/03/13 CN 13-024	Revised Manual Chapter to provide changes to the documentation of inspection observations and findings to ensure that inspection reports highlight the most significant findings, clearly describe the technically-focused activities conducted during the inspection, document ITAACs that were inspected, and clearly articulate the inspection scope, observations, and findings. Appendix E was revised to add additional guidance on screening minor violations and non-conformances. Definitions were moved to IMC 2507, Vendor Inspections.	None	ML13246A451

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
N/A	ML17090A543 08/25/17 CN 17-016	Revised Manual Chapter to be consistent with Enforcement Manual/Policy by deleting the words allegation and investigation from sentences related to minor violations in subsections 05.07b, 06.01a and in Appendix E to prevent fingerprinting an alleger and in Appendices A & E; Added guidance for documenting inspection of ITAAC-related activity in Sections 05.07a, 05.07b Appendix D – Executive Summary, Scope and Observation and Findings; Added guidance for documenting finding(s) related to ITAAC in Sections 05.03, 05.05, 05.07b, and Appendices A, C & D; Revised 05.07b and Appendix D "Observation and Finding," section for documenting a finding to include a logical statement that describes why the finding meets greater than minor criteria; In Section 05.10 added guidance on URI related to opening, closure and follow-up; Added guidance on re-exiting an inspection; Revised inspection report letter template to current practice; In Appendix D, revised ITAAC table to include Nuclear Power Unit Name, ITAAC sequence No, ITAAC No, Design Commitment, Inspection, Tests and Analyses, and Acceptance Criteria; Under list of Entrance/Exit Attendees and Individuals Interviewed, Added a Note: "Redact names where to protect the identity of concerned individual, and when the vendor requests the names of their employees to not be made public." Added new Appendix F that provides examples of vendor related ITAAC findings.	None	ML17090A541

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
N/A	ML18220B113 09/06/18 CN 18-030	The revision is being made to remove information related to including ITAAC information in the Notice of Nonconformance; include a Note related to not including names of suppliers in the inspection reports with one exception; remove Appendix F, “Examples of Vendor Related ITAAC Findings,” in its entirety and replace it with a new Appendix F titled “Guidance for Handling ITAAC Before, During, and After Vendor Inspections;” make minor changes to the examples of minor violations and non-conformances in Appendix E; and other minor editorial and clarification changes.	N/A	ML18220B117
N/A	ML19192A189 02/25/20 CN 20-011	The revision is made to reflect current practice, meet Enforcement Manual and Enforcement Policy; included guidance for inspection of safety conscious work environment in Executive Summary and Report Details. Included are changes to reflect reorganization from QVIB vendor branch(es) in NRO to IQVB in NRR. Deleted COE; Added guidance for documenting minor nonconformances in Report details, list of documents reviewed as well as in Appendix D; changed the title Minor Violations to Minor Violations/Nonconformances and revised guidance for documenting minor violations/nonconformances in Section 06.01.a; updated Appendices A through C to current practice; clarified definition of minor nonconformances in Appendix E, added two examples to Appendix E for SGI and CDA and additional sub-examples for software modeling and M&TE; and other minor editorial and clarification changes throughout.	N/A	ML19192A221