MANUAL CHAPTER 0617

VENDOR AND QUALITY ASSURANCE IMPLEMENTATION INSPECTION REPORTS

VENDOR AND QUALITY ASSURANCE IMPLEMENTATION INSPECTION REPORTS

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0617-01 PURPOSE

This inspection manual chapter provides guidance on documenting the Vendor Inspection Center of Expertise (COE) vendor inspections and quality assurance (QA) implementation inspections. 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, 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 vendor inspection staff.

0617-03 DEFINITIONS

Applicable definitions are found in Inspection Manual Chapter 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 Inspection Manual chapter.

General Responsibilities. Each inspection of a vendor, licensee, 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 Office of New Reactors (NRO) Office Director should provide overall direction for development and implementation of the vendor and QA implementation inspection programs.

04.02 Division Directors and Branch Chiefs

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 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 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 30 calendar days after inspection completion or 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. Additionally, the agency wide non-concurrence process and differing professional opinion process are available if issues cannot be adequately resolved.

04.04 NRO Enforcement Coordinator

The NRO Enforcement Coordinator is responsible for reviewing inspection reports before they are issued to ensure that the reports conform to the NRC Enforcement Policy and the NRC Enforcement Manual.

04.05 Findings Review Panel

The objectives of the findings review panel are to evaluate potential findings and to ensure that the findings are consistently dispositioned across the Vendor Inspection COE. The findings review panel consists of one branch chief from each branch in the Vendor Inspection COE, or his or her designee. The lead inspector should convene the findings review panel within two weeks of the exit meeting.

0617-05 REQUIREMENTS

The NRC 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 Orders, which result from an inspection, will be documented in the inspection

report. Inspection reports must be clear, accurate, consistent and complete. Appendices A - D 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 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, "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, if it is not apparent from the Addressee line, and inspection subject. The subject line should 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 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, applicant's, or licensee's management. Inspection findings, unresolved items, 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 Appendix A of this manual chapter. In addition, the body should include an explanation of why a Notice 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 ADAMS.) The signature of the appropriate NRC official is followed by the docket number(s), license number(s) if any, enclosures, and distribution list.

f. Concurrence. The Cover Letter should include concurrence from all contributing inspectors, the NRO Office of Enforcement coordinator, and the responsible Vendor Inspection COE Branch Chief.

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. 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). An NON is the official notification to a vendor of a failure to meet commitments related to NRC activities, such as contractual 10 CFR Part 50, Appendix B 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).

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. A template for the cover page is included in Appendix D to this inspection manual chapter.

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

- The purpose, scope, and bases for the inspection, and whether any ITAAC were addressed during the inspection.

- A description of the safety related activities observed during the inspection.

- Recently performed inspections at the facility, including the dates of the inspection(s) (i.e., in the last five years) as applicable. The summary should briefly describe or list recent violations, nonconformances, or unresolved items at the vendor.

- The important conclusions reached by NRC as a result of the inspection. The statements may duplicate or condense the conclusions provided in the report details, and should include a high level description of the activities observed to reach the conclusions. Not every conclusion in the inspection report needs to be repeated in the Executive Summary. However, the conclusions stated in the cover letter, should be included. 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., Part 21 Program, Corrective Action Program, Audits of Commercial 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 narrative can be extracted 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 no findings are identified, 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.

When findings are identified, 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 findings are identified, the Scope section should be shorter.

A detailed list of the documents reviewed for that inspection area should not be included in the scope section; a list of the documents reviewed should be included in the attachment to the inspection report. The last sentence of the scope should read, "The attachment to this inspection report lists the documents reviewed by the inspectors."

b. Observations and Findings. As used in this Inspection Manual Chapter, 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 findings are not identified, the Observations and Findings section should state, "No findings of significance were identified."

When findings are identified, observations and findings will be described in a clear manner and be sufficiently detailed to describe what was observed or 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 the inspector's 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."

For violations, apparent violations, and nonconformances, the report will include sufficient detail to describe the requirement and how it was not met. This should

include at least two statements. The first one should define the requirement, including the regulation. The second should describe the circumstances of the violation, including the date(s) of the finding 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 finding. The inspection report should describe if the item was shipped, if there is any impact to the operating or new reactor fleet, or if there is an impact to any ITAAC. Significant or potentially significant findings may merit more discussion. Corrective action taken or planned, response by the vendor, root cause, management involvement, and whether the finding was isolated or programmatic may also be included to fully describe the violation or nonconformance.

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 report should contain only relevant factual information collected during the inspection. Any reports containing material related to an ongoing investigation shall be provided to OI for review before being issued.

Findings of minor significance should not be documented in the report unless they are needed to support an allegation, investigation, or a licensing decision.

c. Conclusions. Conclusions summarize the vendor compliance in the area inspected. All conclusions must be supported by the observations and findings. If findings were identified, a short summary of each violation, apparent violation, or nonconformance should be included with its associated tracking number. If the inspector identifies no findings during an inspection, the report should state "No findings of significance were identified."

05.08 Exit Meeting Summary. The final section of the inspection report should briefly summarize the exit meeting and include the date of the meeting and the name and title of the most senior vendor manager in attendance. 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 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 Inspection Manual Chapter 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 the entrance meeting.

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, applicant, or licensee. This additional exit meeting may be satisfied via a phone call with management personnel at the vendor, applicant, or licensee facility. Inspectors will document additional exit meetings in the inspection report.

c. Characterization of Vendor, Applicant, or Licensee Response. Inspectors will not characterize a vendor's, applicant's, or licensee'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 makes at any time during the inspection as a commitment.

Because regulatory commitments are sensitive, the inspector should ensure that any reporting of licensee statements are paraphrased accurately and contain appropriate reference to any applicable licensee 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 or were key points of contact during the inspection (except in cases where there is a need to protect the identity of an individual).

The list should not 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, if they are not listed as inspectors on the cover page.

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 10 CFR 50, Appendix B 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 relate to and the specific 10 CFR 50, Appendix B controls that were inspected with respect to the ITAAC. Include a table that identifies the location in the COL where the ITAAC are addressed for a specific COL holder and the ITAAC number. A template and additional guidance are provided in Appendix D to this inspection manual chapter.

d. List of Documents Reviewed. A list of the appropriate key documents and records reviewed during an inspection that are significant to any finding must be publicly available. Therefore, if a list is not otherwise made public, the report should list the key documents and records reviewed during the inspection. See Inspection Manual Chapter 0620, "Inspection Documents and Records" for additional guidance on records requirements. The list of documents reviewed should not be included in the body of the report; it should be included as an attachment to facilitate reading.

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. URIs are identified for tracking purposes and are documented only in the body of the inspection report. URIs are not documented in the executive summary or in the inspection report cover letter, unless they are related to ITAAC. For vendor inspection reports with a URI involving potential ITAAC findings, the vendor inspection COE will, in the cover letter, give a brief description of how the finding is specifically material to the ITAAC acceptance and the cover letter should include the following statement, "This report contains (one) URI associated with a specific ITAAC (#). The final resolution of this URI may be material to the ITAAC acceptance criteria, specifically…"

Documenting a URI should be used when vendor or applicant action is pending or when information is required to determine if an issue is acceptable, a nonconformance, or a violation. A URI should be opened if the resolution is likely to result in a finding that is greater than minor or is material to ITAAC acceptance. 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.

b. Follow-up and Closure. 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. If resolution of a URI is based on discussions with NRC technical staff, document the decision.

Branch chiefs, inspectors, and technical staff involved in resolution should concur on the inspection report. Document the closure in the applicable report details section.

All vendor inspection reports with URIs that have the potential to affect ITAAC acceptance will be distributed to affected licensees. In addition, the URI may result in a technical assistance request (TAR) from the vendor inspection COE to Region II so the issue may be tracked to closure. Assistance and coordination with Region II and/or NRO technical staff will most likely be needed in these cases. The vendor inspection COE will be responsible for closing out the URI once enough information has been gathered to determine whether a finding exists.

05.11 Tracking. All apparent violations, violations, nonconformances, NCVs, and URIs must be assigned a sequential tracking number by the lead inspector. 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	ITAAC 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. A noncompliance may be addressed 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). Violations are issued to applicants or licensees for failures to comply with the requirements of Appendix B and Part 21. Violations are issued to vendors for failures to comply with the requirements of Part 21. Nonconformances are issued to vendors for noncompliances with the requirements of Appendix B 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.

A noncompliance may not be documented informally, such as a weakness, or licensee failure. An observation that suggests that a violation may have occurred must be clearly dispositioned as a violation, an apparent violation, or an NCV. Likewise, an observation that suggests that a nonconformance exists must be clearly dispositioned as a nonconformance. 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. Minor violations do not usually warrant enforcement action or documentation in inspection reports but must be corrected. However, if documentation is necessary, such as to address an allegation or to support a licensing decision, use the following statement: "This failure constitutes a violation of minor significance and is not subject to formal enforcement action." Minor violations may be described in the report details and Executive Summary but do not receive a tracking number.

   Minor violations may be identified at the discretion of the inspection team leader and the appropriate management personnel for non-repetitive noncompliances with little or no safety significance or regulatory impact. Minor violations 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.

   Minor nonconformances should be treated in the same manner as minor violations with respect to documentation and screening for significance.

   Appendix E contains the screening criteria for minor noncompliances and examples of noncompliances that have been categorized as minor. Inspectors may use these examples to help understand the threshold for classification of findings.

b. Non-Cited Violations. 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 this enforcement discretion is applied, the report should 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 a Non-Cited Violation, consistent with Section 2.3.2 of the NRC Enforcement Policy."

   The approval of the Director, Office of Enforcement (OE), is required to disposition willful violations as NCVs. When a willful SL IV violation is dispositioned as an NCV per Section 2.3.2 of the NRC Enforcement Policy, the inspection report should 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 (i.e., more than minor concerns) fall into the SL IV category. SL IV Violations involve failures to meet regulatory requirements (such as the failure to meet one or more Quality Assurance Criterion of Appendix B (for applicants) or Part 21 (for applicants and vendors) not amounting to Severity Level I, II, or III violations that have more than minor safety or environmental significance. Nonconformances are also considered non-escalated enforcement actions. Non-escalated enforcement actions follow a similar format and require a similar level of report detail.

An NOV or NON is generally sent out with the inspection report if it has been dispositioned as non-escalated at the time of issuing 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 an issue is being considered 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, “Documenting 10 CFR Part 52 Construction and test Inspections,” when evaluating findings associated with actual construction activities versus QA program and Part 21 findings.

06.02 Enforcement Discretion. Where discretion is being used for a violation that meets the criteria of Section 3 of the NRC Enforcement Policy, the subject report should 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 noncomformance 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 and 9.17. 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. Sensitive–unclassified information such as safeguards information, official use only, and proprietary information shall only be released 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 his or her individual input on the investigation report. This information is exempt from disclosure as provided by 10 CFR 9.17, subject to determination by OI. Investigation reports will not be circulated outside the NRC without specific approval of the OI approving official.

b. NRC technical and safety concerns can be communicated 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.

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

d. When a significant issue requires immediate action, NRC employees may provide any relevant material to the vendor. When possible, management should be consulted 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

Attachment:

Revision History for IMC 0617

APPENDIX A

GUIDANCE FOR VENDOR AND QA IMPLEMENTATION INSPECTION
COVER LETTERS

This guidance is based on 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: NRC VENDOR INSPECTION REPORT 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) facility in (City, State). [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 the inspection was ..."] 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 looked at [describe the activity] associated with inspections, tests, analyses, and acceptance criteria (ITAAC) from revision (#) of the approved [design] design certification document. Specifically, these activities were associated with ITAAC (#)." Include one of the following three statements: "This report contains (one) ITAAC finding(s) associated with a specific ITAAC (#). The(se) finding(s) is (are) material to the ITAAC acceptance criteria, specifically…" or "This report contains (one) URI associated with a specific ITAAC (#). The final resolution of this URI may be material to the ITAAC acceptance criteria, specifically…" 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 nonconformances 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) 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 of Violation 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 review of your response to the Notice will also 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 (other correspondence) 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 paragraphs if issuing Notice of Nonconformance:

"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 your customers. [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.

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.

In accordance with 10 CFR 2.390 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 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.

[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)
(Branch)
(Division)
(Office)

Docket No. (Docket No.)

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

APPENDIX B

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

This guidance is based on NRC Office of Enforcement Manual, Appendix B, 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)
(City, State)

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

During an NRC inspection (investigation) conducted at (location) 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]
>
> Contrary to the above, (date and description of precisely how the requirement was violated).

This issue has been identified as Violation [#].

This is a Severity Level (No.) 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, 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.

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, 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)
(City, State)
Docket No. (No.)

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted at (location) on (dates), certain activities were not conducted in accordance with NRC requirements which were contractually imposed on (vendor) by NRC licensees. [List nonconformances in order of significance.]

[Provide statement of requirement(s) that were violated, e.g., for example, Criterion V of Appendix B to 10 CFR Part 50 states: "Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, and or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished."

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

Contrary to the above, [Provide a statement explaining why the nonconformance occurred, e.g., no record inspection, etc.].

This issue has been identified as Nonconformance [#]. [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.]

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 noncompliances; 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.

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 nonconformances 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 nonconformances] 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, BRANCH/DIVISION/OFFICE), Team Leader (if applicable) (Name of Inspector, BRANCH/DIVISION/OFFICE) (Name of Inspector, BRANCH/DIVISION/OFFICE)
Approved by:	(Name of Branch Chief), Branch Chief (Branch) (Division) (Office)

EXECUTIVE SUMMARY

(Vendor/Applicant Name)
(XXXXXXXX/YYYY-NNN)

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

Describe any inspection activities related to ITAAC.

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.

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

[Reiterate the safety-related activities observed and Conclusions from Report Details Section. Expand on any findings identified in the conclusions.]

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

[Reiterate the safety-related activities observed and Conclusions from Report Details Section. Expand on any findings identified in the conclusions.]

(Section Title, e.g., Commercial-Grade Item Dedication)

[Reiterate the safety-related activities observed and Conclusions from Report Details Section. Expand on any findings identified in the conclusions.]

(…)

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 nonconformances, 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, or if the finding is material to ITAAC acceptance criteria. Corrective action taken or planned, response by the vendor, root cause, management involvement, whether the nononcompliance appears isolated or programmatic may also be included to fully describe the violation or nonconformance.]

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)

   a. Inspection Scope

      (…)

   b. Observations and Findings

      (…)

   c. Conclusions

      (…)

4. Exit Meeting

   On (Date) the inspectors presented the inspection scope and findings during an exit meeting with (Name of senior vendor or applicant management in attendance) and (vendor or applicant) personnel.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES

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

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	ITAAC 2.2.03.05a.iii

(…)

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

[If ITAAC were looked at during the inspection, include the following text:]

"The U.S. Nuclear Regulatory Commission (NRC) inspectors identified the following inspections, tests, analyses, and acceptance criteria (ITAAC) related to components being (manufactured, designed, tested) by (vendor name). At the time of the inspection, (vendor vendor name) was involved in (manufacturing/designing/testing) (basic component) for the (design type) reactor design. 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 future use by the NRC staff during the ITAAC closure process; the listing of these ITAAC design commitments does not constitute that they have been met and closed. The NRC inspection team (did not identify any) identified findings associated with the ITAAC identified below.

Appendix C from the Combined License for (Plant) Unit (#)	No. 355	ITAAC 2.3.06.02a
Appendix C from the Combined License for (Plant) Unit (#)	No. 357	ITAAC 2.3.06.03a

5. LIST OF ACRONYMS USED(optional)

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

6. DOCUMENTS REVIEWED

Quality Procedure (QP) 10, “Document Control,” Revision 0, dated March 1, 2010
(…)

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 more 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 documentation in inspection reports or inspection records and do not warrant enforcement action. However, minor violations may be documented if they are needed to support an allegation or licensing action.

Minor nonconformances to the technical and quality requirements imposed on a vendor through a purchase order 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 nonconformances.

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.
Not 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 a 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 and discussed during the findings review panel to make the final significance determination. In some instances, this could be an example of when the NRC would choose to document a minor inspection finding.

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 "not 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 of 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 nonconformances 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 and is considered a finding.

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.
Not 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.
Not minor if:	The inspectors reviewed a sample of recent Nonconformance Reports and Corrective Action Reports, and did identify specific issues that would have warranted further evaluation under the vendor's 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
Not 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 21 applied to a safety-related purchase order.
Minor because:	The issue was isolated and the vendor invoked a 10 CFR 50, Appendix B, quality assurance program, and verified that the supplier has a 10 CFR Part 21 procedure and is effectively implementing it.
Not minor if:	The issue is repetitive or it is not clear from the procurement documents that it is a safety-related purchase order. Or the vendor did not verify that the supplier had a 10 CFR Part 21 procedure and is effectively implementing it.
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.
Not 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.
Not minor if:	The testing was performed on safety-related components with personnel who were not qualified for the inspection/testing procedures and whose competence was suspect.
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.
Not minor if:	The applicant did not use a version of a standard that was reviewed and approved by the NRC and the changes or use of an alternate standard reduce the commitments in the QAPD that was 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 could not negatively affect the original design requirements, assumptions, and qualifications.
Not 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 not implemented or not performed by individuals or groups other than those who performed the original design, but may be from the same organization.
Minor because:	The verification would not yield any negative impacts to the design or the SSC would still meet its intended safety function as per the design requirements.
Not minor if:	The design requirements would not be met or cannot be proven that they are met, Or independent verification and validation was not performed on design analysis code (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.
Not minor if:	An insufficient or missing design interface led to not accounting for a design basis specification that could affect the ability of the SSC to perform its intended safety function or the design control process was bypassed and proper approval of modifications and deletions of design documents was not controlled.

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.
Not minor if:	The failure to incorporate the technical requirements resulted in a less conservative analysis that could have adversely affected the SSC's ability to perform its intended safety function.

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 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.
More than minor if:	The vendor did not verify 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, and the M&TE was used in safety-related applications.
Example b.	The vendor's purchase order to a supplier did not state the proper technical standard and revision for testing.
Minor because:	The vendor/applicant identified the error and implemented adequate and timely corrective action. Or documentation exists that demonstrates that testing was performed to the proper technical standard
More 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
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 of 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.
Not 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:	The inspection status is also identified in inspection records or a traveler and the final inspection had been performed.
More than minor if:	Or there is no documentary evidence that the final inspection was performed.
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 hadn't been used on safety related SSCs.
Not 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.)
Not 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.
Not 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.
Not 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.

Not 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.
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.
More 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.
More than minor if:	The vendor made purchases from the supplier during the timeframe that the annual evaluation was not performed and the nonconformances 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.

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.
Not minor if:	The tags were required to maintain traceability, and the vendor shipped the items. Or traceability could not be reestablished.
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.
Not 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 greater than the minimum, and a visual indication could have been seen by the inspector.
Not minor if:	If the ambient lighting was less than the minimum, and 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.
Not minor if:	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.
More 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 nonrelevant and did not affect the acceptability of the radiograph Or the indication was relevant but within acceptable limits.
More than minor if:	The indication was nonrelevant 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.
Not 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.
Not 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.
Not 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.
Not 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.
Not 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 the SSC would not be able to perform its intended safety function.
13.	Control of Measuring and Test Equipment
Example a.	Inspectors identified that the calibration records for measuring and test equipment (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.

Not 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 and the results are clearly within the prescribed acceptance standards.
Not 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.
Example c.	Inspectors identified that no evaluation had been performed for previous inspection or test results affected by measuring & test equipment (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.
Not 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.
Not 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 of its M&TE were within the acceptable calibration range.
Not 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 know 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.
Not 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.
Not 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.
Not 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.
Not 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.
Not 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.
Not 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 (CAR), 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.
Not 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.
Not 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.
Not minor if:	The vendor failed to enter deficiencies into their process and disposition those deficiencies to correct conditions adverse to quality
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.
More 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).
More 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 measuring & test equipment (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.)
More 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
More 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.
More 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.
More 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 laboratory on their safety-related approved suppliers list based on NVLAP (ILAAC) certification only.
Minor because:	It is found the vendor verifies the following before contracting calibrations 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.
Not minor if:	All of the above are not met, the M&TE was not in calibration, and the M&TE was used on safety related SSCs.

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 and Feedback Resolution Accession Number
N/A	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	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