

VENDOR INSPECTION REPORTS

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VENDOR INSPECTION REPORTS

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Attachment 1 Revision History for IMC 0617

VENDOR INSPECTION REPORTS

0617-01 PURPOSE

This inspection manual chapter provides guidance on documenting the Office of Nuclear Reactor Regulation (NRR) and the Office of New Reactors (NRO) vendor inspections. The purpose is to ensure clear and consistent content, format, and style for all vendor inspection reports.

0617-02 OBJECTIVES

To ensure that vendor inspection reports:

02.01 Clearly communicate significant inspection results to vendors, licensees, NRC staff, and the public.

02.02 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.

02.03 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.

02.04 Provide a focused assessment of vendor compliance.

02.05 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.

02.06 This manual chapter may also be used to document inspections conducted at a licensee's facility by vendor inspection staff.

0617-03 DEFINITIONS

03.1 Allegation. See Definition in Management Directive 8.8.

03.2 Apparent violation. A potential noncompliance with a regulatory requirement that has not yet been cited as a violation in a Notice of Violation or Order.

03.3 Conclusion. As used in this chapter, an assessment of a vendor program or process based on observations or findings.

03.4 Defect. See Definition in 10 CFR Part 21.

03.5 Deviation. See Definition in 10 CFR Part 21.

03.6 Draft Inspection Report. Any version of the inspection report before its official issuance.

03.7 Escalated Enforcement Action. A Notice of Violation for any Severity Level I, II, or III violation (or problem), or a civil penalty or order based on a violation.

03.8 Finding. As used in this chapter, an observation of a vendor not meeting a requirement that has been described with objective evidence and assessed for significance.

03.9 Inspection. The examination and assessment of any vendor activity to determine its effectiveness, to ensure safety, and/or to determine compliance.

03.10 Inspection Document. Any material obtained or developed during an inspection that is considered to be an NRC record (see below).

03.11 Licensee. The holder of an NRC license, construction permit, or combined license. The provisions listed as applicable to "licensees" in this chapter are also applicable to vendors and applicants for an NRC license.

03.12 Minor Violation. A violation that is less significant than a Severity Level IV violation, not the subject of formal enforcement action, and not usually described in inspection reports or inspection records.

03.13 Non-Cited Violation (NCV). A violation which satisfies the criteria in the NRC Enforcement Policy that requires the staff to exercise discretion and refrain from issuing a 10 CFR Part 2.201 Notice of Violation.

03.14 Noncompliance. A violation, non-cited violation, or nonconformance.

03.15 Nonconformance. A vendor's failure to meet a contract requirement related to NRC activities, where the NRC has not placed the requirement directly on the vendor.

03.16 Notice of Nonconformance (NON). A formal written notice that sets forth one or more nonconformances.

03.17 Notice of Violation (NOV). A formal written citation in accordance with 10 CFR 2.201 that sets forth one or more violations of a legally binding regulatory requirement.

03.18 Record. Any written, electronic, or photographic record under legal NRC control that documents the policy or activities of the NRC or an NRC licensee (see also the definition of Record in 10 CFR Part 9).

03.19 Observation. A fact; any detail noted during an inspection.

03.20 Regulatory Commitment. An explicit statement to take a specific action agreed to or volunteered by a licensee, where the statement has been submitted in writing on the docket to the NRC. This may include a commitment in the licensee's application, a response to a Notice of Violation, etc.

03.21 Requirement. A legally binding obligation such as a statute, regulation, license condition, technical specification, or order.

03.22 Team inspection. An inspection with two or more inspectors.

03.23 Unresolved Item (URI). An issue about which more information is required to determine if it acceptable, if it is a finding, or if it constitutes a deviation or violation. Such a matter may require additional information from the vendor or cannot be resolved without additional guidance, or clarification or interpretation of the existing guidance.

03.24 Vendor. A supplier of products or services to be used in an NRC-licensed facility or activity.

03.25 Violation. The failure to comply with a legally binding regulatory requirement, such as a statute, regulation, order, license condition, or technical specification.

03.26 Willfulness. An attitude towards noncompliance with requirements that ranges from careless disregard to a deliberate intent to violate or falsify.

0617-04 RESPONSIBILITIES AND AUTHORITIES

All NRR and NRO vendor inspectors are required to prepare vendor inspection reports in accordance with the guidance provided in this Inspection Manual chapter.

04.01 General Responsibilities: Each inspection of a vendor 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 Inspection Manual Chapter prior to the inspection.

04.02 Office Directors Office Directors should establish internal procedures to provide a record of inspectors' and reviewers' concurrences. The procedures should address how to ensure continued inspector concurrence when substantive changes are made to the report as originally submitted, and how to treat disagreements that occur during the

review process. As a minimum, substantial changes should be discussed with the inspector or inspectors involved to ensure continued concurrence, and disagreements that cannot be adequately resolved should be documented.

04.03 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 alleged or confidential source.

04.04 Inspectors

- a. NRC vendor inspectors shall prepare 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 before the report is issued.

- e. Inspectors must not include information that could lead to the identification of an alleged 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 inspection.

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.

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 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 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."

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 licensee's 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.
- d. Body. The body of the letter should discuss the most important topics first. The cover letter should communicate the overall inspection results to a vendor's or licensee's management. It 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.

05.02 Notice of Violation. An NOV is the official notification of a failure to meet regulatory requirements. The NOV should be an enclosure to the cover letter. NOV's are typically issued to vendors or licensees with the associated inspection report. However, in cases such as escalated enforcement, NOV's may be sent after the report with a separate cover letter.

NOV's should include:

- A concise, clear statement of the requirement or requirements that were 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).

A template for NOV's issued to a vendor is included in Appendix B. Significance of findings is discussed in Section 06 of this document. For additional guidance on documenting violations, refer to the NRC Enforcement Manual.

05.03 Notice of Nonconformance. 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.

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, dates of inspection, names and titles of participating inspectors, and name and title of the approving NRC manager.

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

- The purpose, scope, and bases for 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. 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 which 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 should include a table of contents.

05.07 Report Details. The report details describe the objective evidence which 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 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, evaluated)...." 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 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.

- b. Observations and Findings. As used in this Inspection Manual Chapter, the term "observation" refers to a fact; 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.

Observations and findings will be sufficiently detailed to describe what was observed or found in a clear manner. The observations will describe the inspectors' conclusions and not repeat the activities identified in the scope. "The inspectors reviewed the Part 21 program" is a Scope statement. "The inspectors noted (verified, concluded, etc.) that the vendor's Part 21 program met the regulations" is the inspector's observation.

The inspector should say what was observed or found in an explicit manner. The inspector should not make uncertain statements such as “The vendor’s QA records control program appeared 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 violation 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 violation. Corrective action taken or planned, response by the vendor, root cause, management involvement, and whether the violation 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.

- 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 finding changes after the exit meeting, the inspectors will conduct an additional exit meeting to discuss that change with the vendor. Inspectors will document additional exit meetings in the inspection report.
- c. Characterization of Licensee Response. Inspectors will not characterize a vendor's or licensee's exit meeting response. If the vendor disagrees with an inspection finding, this position may be characterized by the vendor 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 "Supplementary Information."

- a. Key Points of Contact. The inspector should alphabetically 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 (Optional). The report can include a quick-reference list of items opened and closed. Open items that were discussed (but not closed) should also be included in this list, along with a reference to the sections in the report in which the items are discussed.
- c. List of Documents Reviewed (Optional). 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 that are not identified in the body of the report. See Inspection Manual Chapter 0620, "Inspection Documents and Records" for additional guidance on records requirements. Lists containing many documents can be removed from the body of the report and included as an attachment to facilitate reading.

- d. 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.

Documenting a URI should be used when vendor 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 violation that is greater than minor. 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 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.

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:

<u>LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED</u>			
<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
99912345/2008-001-01	Opened	NOV	Violation of Part 21
99912345/2008-001-02	Opened	NOV	Violation of Part 21
99912345/2008-001-03	Opened	NON	Criterion I
99912345/2008-001-04	Opened	NON	Criterion II

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

06.01 Types of Noncompliance. A noncompliance may be addressed as a minor violation, an NCV, a non-escalated enforcement action (i.e., a Severity Level (SL) IV violation or a nonconformance), or an escalated enforcement action (i.e., an apparent SL I, II, or III violation). The 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. If a violation 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."

- a. **Minor Violations.** Minor violations should not normally be documented in inspection reports. However, if documentation is necessary, such as to address an allegation, use the following statement: "This failure constitutes a violation of minor significance and is not subject to formal enforcement action."
- b. **Non-Cited Violations.** Guidance in Section VI.A.8 of the NRC Enforcement Policy describes the circumstances for consideration of issuing an NCV. 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 VI.A.8 of the NRC Enforcement Policy."

When a willful SL IV violation is dispositioned as an NCV per Section VI.A.8.d 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 VI.A.8 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. NONs 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.

- 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 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.

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

06.03 Noncompliance Involving Willfulness. Conclusions about the willfulness of a violation are agency decisions and are normally not made until after OI has completed an investigation. Inspection reports that include potentially willful violations are to be coordinated with OI and the Office of Enforcement (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 – D

Attachment 1: Revision History for IMC 0617:

APPENDIX A

GUIDANCE FOR VENDOR 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 and templates of cover letters, Notices of Violation, Notices of Nonconformance, and inspection reports can be found on the Vendor Quality Assurance Inspections Website and in the ADAMS package MLxx.

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 executive)

(Name of company)

(Address)

SUBJECT: NRC INSPECTION REPORT NO(S). (XXXXXXXX/YYY-NNN), NOTICE OF VIOLATION, AND NOTICE OF NONCONFORMANCE [as applicable]

Dear (vendor executive):

On (dates), the U.S. Nuclear Regulatory Commission (NRC) 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. [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 determined that (a) violation(s) of NRC requirements occurred. The 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 because [Include an explanation of why a Notice is being issued in terms of the criteria in Section VI.A, "Non-Cited Violation (NCV)," of the NRC Enforcement Policy. This explanation may be expanded to convey the appropriate message to the vendor in terms of those actions that require additional attention and must include the basis for issuing the citation, notwithstanding the normal policies.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. [If other responses are required,

remind addressee that, as appropriate, these responses should be addressed separately, in addition to this response]. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.”]

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

“The NRC has concluded that the reason for the violation, and the corrective actions to correct the violation and prevent recurrence are already adequately addressed on the docket in [Indicate the correspondence, e.g., Inspection Report No. (XXXXXXXXX/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.”]

[Include the following paragraphs if issuing Notice of Nonconformance:

“During this inspection, NRC inspectors found that the implementation of your Quality Assurance (QA) program failed to meet certain NRC requirements. [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:

“Based on the results of the inspection, (number) apparent violation(s) was (were) identified and is (are) being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC’s Web site at www.nrc.gov. [The narrative that follows should briefly discuss the nature of the apparent violation(s).] Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued for these inspection findings at this time. In addition, 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) pre-decisional enforcement conference to discuss this (these) apparent violation(s) has been scheduled for (date). [If an open conference, add: “This Conference will be open to public observation in accordance with Section V of the NRC Enforcement Policy.

The decision to hold a pre-decisional 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 assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. The conference will provide an opportunity for you to provide your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision.

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 Director or Branch Chief)
Division Director(Branch)
(Division)
(Office)

Docket No. (Docket No.)

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

APPENDIX B

GUIDANCE FOR VENDOR 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 and templates of cover letters, Notices of Violation, Notices of Nonconformance, and inspection reports can be found on the Vendor Quality Assurance Inspections Website and in the ADAMS package MLxx.

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 company)
(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:

[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 is a Severity Level (No.) violation (Supplement (No.)).

Pursuant to the provisions of 10 CFR 2.201, (name of company) 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 Director (Chief), [Insert applicable program office division director or branch chief] 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; EA-(YY-XXXX)" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous 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 program office division director or branch chief] 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.”]

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 and templates of cover letters, Notices of Violation, Notices of Nonconformance, and inspection reports can be found on the Vendor Quality Assurance Inspections Website and in the ADAMS package MLxx.

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 company)

(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.

[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 violation occurred, e.g., no record inspection, etc.].

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 Director (Chief), [Insert name of applicable program office division director or branch chief] 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 non-compliances; 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 INSPECTION REPORT DETAILS

EXAMPLES

Examples and templates of cover letters, Notices of Violation, Notices of Nonconformance, and inspection reports can be found on the Vendor Quality Assurance Inspections Website and in the ADAMS package MLxx.

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.

A sample inspection report can be found in ADAMS with the following Accession Number: MLxxxx. The inspection report is a representative sample inspection report and not an all inclusive guide. It is based on a fictional vendor. The report contains realistic findings; however, any resemblance to an existing facility or actual events is coincidental.

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 INSPECTION REPORT

Docket No.: (XXXXXXXX)

Report No.: (XXXXXXXX/YYY-NN)

Vendor: (Vendor Name)
(Vendor Address)

Vendor Contact: (Vendor Contact Name and Contact Information)

Nuclear Industry Activity: (Description of basic components or services supplied to the nuclear industry)

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 Name)
(XXXXXXXXXX/YYYYY-NNN)

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

Describe previous inspections at the vendor.

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 Conclusions from Report Details Section.]

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

[Reiterate Conclusions from Report Details Section.]

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

[Reiterate Conclusions from Report Details Section.]

(...)

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, evaluated)..." The Scope statements might also describe why certain items were inspected. For example, "...to determine compliance with...."]

b. Observations and Findings

[Describe the inspectors' conclusions, and do not repeat the activities identified in the scope. "The inspectors reviewed the Part 21 program" is a Scope statement. "The inspectors noted (verified, concluded, etc.) that the vendor's Part 21 program met the regulations" is the inspector's observation.

For violations, apparent violations, and nonconformances, 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 violation and the facts necessary to demonstrate that the requirement was not met ("Contrary to..."). Actual or potential safety consequences should be described to support the significance of the violation. Corrective action taken or planned, response by the vendor, root cause, management involvement, whether the violation 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.]

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 management in attendance) and (vendor) personnel.

ATTACHMENT

1. PERSONS CONTACTED

(First Initial, Last Name, Title, Organization)
(First Initial, Last Name, Title, Organization)
(First Initial, Last Name, Title, Organization)
(...)

2. INSPECTION PROCEDURES USED

IP 36100, "Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance"
(...)

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
<u>(XXXXXXXXXX/YYYY-NNN-01)</u>	Opened	NOV	Violation of Part 21
<u>(XXXXXXXXXX/YYYY-NNN-02)</u>	Opened	NON	Criterion <u>(XX)</u>
(...)			

4. LIST OF ACRONYMS USED(optional)

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

Attachment 1 – Revision History for IMC 0617

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment 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	-N/A	ML082770035