NRC INSPECTION MANUAL

INSPECTION MANUAL CHAPTER 2550

NON-POWER PRODUCTION AND UTILIZATION FACILITIES (NPUFs) LICENSED UNDER 10 CFR PART 50: CONSTRUCTION INSPECTION PROGRAM (CIP)

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2550-01 PURPOSE

The purpose of this Inspection Manual Chapter (IMC) is to define the Construction Inspection Program (CIP) for non-power production and utilization facilities (NPUFs) holding a construction permit and pursuing an operating license under 10 CFR Part 50. This CIP will provide reasonable assurance that the design and construction of NPUFs have been completed in accordance with applicable regulations, license requirements, and commitments.

Note: Throughout this IMC, the terms "applicant," "permit holder," and "licensee" are used to refer to an operating license applicant and construction permit holder. As used in this IMC, these terms are interchangeable.

2550-02 OBJECTIVES

The primary objective of this manual chapter is to establish a CIP for inspecting construction at a NPUF under construction.

- 02.01 Provide reasonable assurance that regulatory requirements and licensee commitments for quality assurance (QA) are adequately included in the design, procurement, and construction of the NPUF.
- 02.02 Provide reasonable assurance that NPUFs are constructed in accordance with the applicable regulations, quality assurance program, and the NPUF's licensing basis (Safety Analysis Report (SAR), Construction Permit (CP), etc.).
- 02.03 Verify the effective implementation of the licensee's QA program. Verify that this includes timely implementation of organizational staffing, procedures, instructions, QA activities, and administrative controls necessary to achieve quality objectives.
- 02.04 Verify that the licensee identifies conditions that may adversely affect public health and safety, the environment, and worker protection so that appropriate corrective actions can be taken.
- 02.05 Conduct performance-based inspections of key Structures, Systems, and Components (SSCs), construction and pre-operational testing, and operational readiness activities to support the issuance of an operating license.

2550-03 APPLICABILITY

- 03.01 This IMC provides inspection program guidance for the NPUF CIP. The NPUF CIP applies to all construction activities including design, procurement, fabrication, construction, pre-operational testing, and operational readiness activities. Implementation of this IMC will begin at the NRC issuance of the CP and will continue through completion of construction.
- 03.02 As necessary, archived IMCs, inspection procedures (IP), and temporary instructions (TI) may be re-issued and used to perform the required inspections or reviews of outstanding design, licensing, and regulatory issues for the NPUF CIP.
- 03.03 NPUFs will remain within the scope of the Commission's current Enforcement Policy for facilities in the construction phase.

2550-04 DEFINITIONS

Additional definitions can be found in Manual Chapter 2506, "Construction Reactor Oversight Process General Guidance and Basis Document."

- 04.01 Items Relied on for Safety (IROFS). IROFS are structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in 10 CFR 70.61 or to mitigate their potential consequences.
- 04.02 Safety-related. Those physical structures, systems, components and activities that are relied on to prevent potential accidents at a facility that could exceed the applicable performance requirements, or to mitigate their potential consequences. This does not limit the licensee from identifying additional SSCs, equipment, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as IROFS.

2550-05 RESPONSIBILITIES AND AUTHORITIES

- 05.01 Office of Nuclear Reactor Regulation (NRR)
 - a. Responsible for coordinating NPUF CIP interfaces with state and local government.
 - b. Responsible for providing technical support for NPUF construction inspections (e.g., providing personnel with specific expertise to support inspections of NPUFs, providing responses to technical questions posed by NPUF construction inspectors, providing insight into the safety significance of SSCs for inspection planning purposes).
 - c. Responsible for providing technical assistance, if required, to Region II to develop site specific construction inspection plans.
 - d. Responsible for oversight of the development of the operational programs as needed to support issuance of the operating license.
 - e. Responsible for making the determination to authorize the commencement of operations.
 - f. Responsible for the approval of this IMC.
 - g. Responsible for the development and maintenance of the construction inspection program for NPUFs.

05.02 Region II

- a. Responsible for ensuring that adequate resources, as necessary to carry out the inspection process described in this IMC, are provided to the staff.
- b. Responsible for the planning, performance, and documentation of inspection and enforcement activities associated with the portions of the NPUF CIP that are performed by Region II.
- c. Responsible for notifying NRR when all construction inspection activities are complete.
- d. Responsible for developing site specific construction inspection plans.
- e. Responsible for making a recommendation to NRR as to whether the licensee is ready to transition to operations.

05.03 Office of Nuclear Security and Incident Response (NSIR)

• Except for research and test reactors, responsible for overall policy, guidance, and oversight of NPUF security and emergency planning.

05.04 Office of Nuclear Material Safety and Safeguards (NMSS)

- Responsible for providing technical support for NPUF construction inspections (e.g., providing personnel with specific expertise to support inspections of NPUFs, providing responses to technical questions posed by NPUF construction inspectors, providing insight into the safety significance of SSCs for inspection planning purposes).
- b. Responsible for providing technical assistance, if required, to Region II to develop site specific construction inspection plans.
- c. Responsible for providing support to NRR, if required, for the determination to authorize the commencement of operations.

05.05 Director, Office of Enforcement (OE).

- a. Responsible for ensuring consistent application of the enforcement process to violations of NRC regulations with the appropriate focus on the severity level of findings.
- b. Responsible for providing representatives, as necessary, to support the escalated enforcement process to ensure consistent application of the enforcement process.

2550-06 REQUIREMENTS

06.01 <u>General</u>. The NPUF CIP provides the inspection requirements for selectively assessing the adequacy of NPUF construction activities. This includes the implementation of the licensee's QA program, performance of pre-operational tests, and development of operational programs that will be needed for operation of the NPUF. Emphasis is to be placed on the inspection of SSCs that are important to safety.

Emphasis is also to be placed on the licensee oversight of principal contractors who are performing IROFS (if applicable) or safety related activities. Inspections will evaluate if contractors are implementing an acceptable QA program in accordance with the licensee's QA program. The inspection program should include direct inspections as necessary to determine whether the elements of the license's QA program are being effectively implemented throughout all stages of construction, including equipment fabrication, assembly and installation, and structural construction activities.

06.02 <u>NPUF Facility Specific Assessment and Review Group (FSARG)</u>. For NPUFs that are designed to process irradiated material or fuel (e.g., a radioisotope production facility), an FSARG may be assigned to assist Region II with the inspection program. An FSARG is an advisory group comprised of representatives from NRR, NMSS, and Region II. The purpose of the FSARG is to assist Region II in development and implementation of the inspection program to verify that the construction of the NPUF is completed in accordance with applicable regulatory requirements. The FSARG may also assist Region II in determining if sufficient inspection has been performed to determine if the construction inspection program is complete for the facility. The NRR representative will be responsible for coordinating group activities.

The FSARG may also assist Region II in developing a performance-based construction inspection plan. The plan should be based on safety significance and consider safety-related items, SAR commitments, and license conditions.

06.03 <u>Inspection Planning and Scheduling Considerations</u>. The NPUF construction inspection schedule should be based on the licensee's construction schedule and should be modified and updated periodically during the entire construction period.

Inspections should normally be announced, coordinated, and scheduled with the licensee such that the efficiency and effectiveness of the inspection effort are enhanced and unnecessary burden to the licensee is minimized. To the extent practicable, the construction and pre-operational inspections should be coordinated with the licensee to ensure that key construction activities are in accordance with the site construction project schedule. However, as appropriate, inspections of various construction activities may be scheduled as unannounced inspections.

Emphasis should be placed on early identification of problems. Inspections will be conducted periodically throughout construction. Inspections will be scheduled early in the process during implementation of individual construction activities to develop confidence that the specific construction activities have been adequately accomplished at all stages of construction. Comprehensive construction program reviews aimed at determining underlying causes and extent of problem areas should be conducted if NRC management concludes that significant deficiencies are occurring. Inspection depth and frequencies may be expanded to assure problem areas have been corrected. Corrective action programs are essential to effective resolution of individual deficiencies and

programmatic issues. Inspection effort should be planned to specifically evaluate corrective action program effectiveness. Refer to Appendix C of this IMC for further guidance on evaluating the effectiveness of corrective action programs.

NRC Region II will develop, maintain, and implement an inspection schedule for NPUF projects. The schedule will include the scope and the inspection procedures that will be used for the inspections. The list of procedures used for conducting inspections is provided in Appendix A of this IMC. The schedule will provide flexibility to address emerging issues that require additional inspection efforts, receipt of allegations, or changes in scheduled activities by the licensee.

06.04 <u>Inspection and Technical Personnel Considerations</u>. Inspectors will be assigned responsibility for the conduct of applicable inspection requirements consistent with their experience. Inspectors should be trained and/or experienced in the areas of QA, engineering, procurement, and construction activities applicable to the activities they are to inspect. Specialists may accompany or assist inspectors to provide expertise in specific areas to enhance or expand the inspection effort. The inspectors and specialists may be from the region or headquarters.

2550-07 GUIDANCE

07.01 <u>General</u>. The licensee is ultimately responsible for the safety of the facility. The NRC ensures, through inspection sampling, that this responsibility is carried out in an effective manner during facility construction. The CIP presented in this IMC is considered the minimum necessary to achieve an acceptable level of confidence as to the adequacy of construction at the facility.

This IMC emphasizes a systematic evaluation of the adequacy and effectiveness of the licensee's QA and construction programs and their implementation. NRC will perform inspections of selected activities at the licensee site. Inspections may also be performed, as necessary, at the facilities of the licensee's consultants, contractors, and suppliers. This IMC establishes priorities for inspection by planned inspection sampling of SSCs and activities important to safety and should consider the performance of the licensee in the areas inspected.

07.02 <u>Inspection Areas</u>. The specific areas to be inspected will include a sampling of SSCs and regulatory and safety commitments as identified in licensing documents. SSCs for inspection will be chosen based on safety significance and they will be evaluated with respect to multiple safety and engineering disciplines (civil, mechanical, and electrical). Construction and pre-operational testing inspections will be performed as a part of QA implementation inspections covering test control. If necessary, operational program inspection will be performed in accordance with Inspection Procedure 69022, "Inspection of Operational Readiness during Construction of Non-Power Production and Utilization Facilities."

The NRC will periodically inspect the licensee's programs for adequate assurance that SSCs are designed, procured, fabricated, and installed in accordance with applicable requirements. The inspections will also verify that as-built construction meets the approved design. In addition, the licensee's design change and design control process will be reviewed to verify that the design process effectively implements NRC requirements and other licensing design commitments made by the licensee. These

reviews may be accomplished by multi-disciplinary technical review and/or inspection teams to verify the quality of design products and, inferentially, the entire facility design.

- 07.03 <u>Inspection Procedures (IPs)</u>. IPs are listed in Appendix A. Some IPs may cover more than one program area and additional IPs may be used as necessary.
- 07.04 <u>Implementation</u>. Region II is responsible for implementing the inspection program described in this IMC.

This IMC is intended to provide the framework for managing the inspection effort. Where needed, sample sizes, frequencies of periodic inspections, and the time frame when certain inspection activities are to be performed, are provided in the appropriate IP.

The inspection staff is expected to plan and conduct inspections based on safety considerations, current construction activities, and overall performance. Region II staff should develop a schedule of inspections to be conducted based on the anticipated site activities that are to be performed. Region II staff should review and revise the schedule as needed to account for changes in site activities. The activities for conducting inspections should include the following:

- a. Developing and documenting detailed inspection plans.
- b. Scheduling and coordinating inspection activities in accordance with this IMC.
- c. Communicating inspection results, findings, and open items to appropriate NRC and licensee management.
- d. Documenting completed inspections, findings, and open items.
- 07.05 <u>Inspection Requirements</u>. Inspections will be based on 10 CFR Part 50 and other applicable regulations, commitments, and license conditions, including the documents included as part of the licensing basis. Inspections will confirm that applicable regulations, requirements, and commitments have been met. Selection of inspection attributes will be based on safety considerations, status of work activities, and past performance.
- 07.06 <u>Focus of Inspections</u>. In order to effectively and efficiently allocate inspection resources, the NRC will perform sampling-type inspections to verify that the licensee is in compliance with NRC regulations.

Region II will use applicable information from licensing basis documents to identify those SSCs whose failure would most greatly impact safety. This approach will allow safety-significant SSCs to be identified so that the construction and pre-operational inspection samples can be focused on those SSCs. The amount of inspection and activities selected for inspection should be consistent with the importance to safety of the SSCs, and the performance of the licensee in those areas.

Inspection activities should emphasize the early identification of problem areas. It is important that inspectors evaluate whether noted problems represent isolated cases or are symptomatic of more systemic problems. To provide the perspective for performing this evaluation, inspectors should consider:

- a. The extent and the effectiveness of licensee oversight of quality related activities.
- b. Resolution of previously identified problem areas and/or recurring problems.
- c. Problems that indicate programmatic weaknesses.
- d. The adequacy of the licensee's corrective action program to identify, track, trend, resolve, and prevent problem recurrence.
- e. Deficiencies, assessment findings, and problems identified by the licensee or by its consultants, contractors, or suppliers identifying trends and/or problem areas.
- f. Whether additional NRC inspection efforts are merited in areas of concern.

The inspection plan should be considered a living document and can be modified based on inspection findings and licensee performance.

- 07.07 <u>Management Entrance and Exit Meetings</u>. Inspectors are required to meet with licensee management as part of every inspection. Inspectors should conduct an entrance meeting with the senior licensee representative who has responsibility for the areas to be inspected. Each inspection must include the discussion of inspection results with licensee management at a scheduled exit meeting. Entrance and exit meetings with licensee personnel should be scheduled to minimize the impact on other licensee activities that are necessary to assure the safe and proper construction of the facility.
- 07.08 <u>Inspection Reports (IR)</u>. Inspection findings shall be documented in inspection reports in accordance with Appendix B, "NPUF Construction Inspection Reports." When possible, inspection findings should be integrated into a single inspection report to encompass findings from in-office inspections, and/or one or more visits by regional or headquarters inspectors. Special inspections may be documented in a separate inspection report. Inspection issues that cannot be resolved at the time of the inspection will be documented as open items (i.e., partial inspections), inspection follow-up items, or unresolved items, in accordance with Appendix B. Region II will track open items and subsequent inspections will include resolution of these issues.
- 07.09 <u>Communication with State and Local Government</u>. NRR personnel are responsible for coordinating the interface with state and local government and other Federal agencies. NRR will coordinate with the regional State Liaison Officer for communications with state government. Inspectors should be aware of NRR's role and Region II should establish internal protocols to ensure that NRR is notified of, and consulted on, issues that might involve communications with state and local governments and other Federal agencies.
- 07.10 <u>Inspection Findings and Enforcement</u>. All inspection findings identified during the construction and pre-operational periods will be documented in accordance with the guidance in Appendix B "NPUF Construction Inspection Reports" after they have been placed in context and assessed for safety significance. Potential violations from inspection activities will be processed in accordance with the NRC Enforcement Policy (available on the NRC public web site at <u>http://www.nrc.gov</u>). Inspection findings will be categorized as violations, non-cited violations, apparent violations, deviations, non-conformances, unresolved items, or inspector follow-up items. This includes the use of notices of violations for violations of severity level IV and above and civil penalties, as appropriate.

It is important to note that if the NRC determines that the construction is not in accordance with the licensee's commitments, then issuance of an operating license (OL) may be denied. The failure of the licensee to meet commitments specified in the license application (including the Safety Analysis Report (SAR) and Quality Assurance Program Description) or other licensing basis documents shall be documented in the inspection report(s) as noted above. It is imperative that findings are appropriately documented in the inspection reports so that subsequent inspections can verify that the licensee implemented the appropriate corrective actions. The failure of the licensee to take the appropriate corrective actions to address the open items by the end of the construction phase could result in a denial of an OL.

07.11 <u>Assessment.</u> Different types of construction activities may require differing levels of inspection effort to provide the same degree of assurance of quality work. Increases or decreases in inspection oversight will be based on an assessment of licensee performance. Performance is assessed on a continuous basis as inspection results are evaluated for significance (trends, programmatic weaknesses, etc.) and inspection scope, depth, and frequency are adjusted as necessary. In addition, periodic reviews of the licensee's performance of construction and pre-operational activities may be warranted to provide NRC management with an overview of the licensee's performance. An objective of the program is to provide a body of information that will be used as guidance to NRC management on changes that may be required in implementation of the NPUF construction inspection program.

Appendix C, "Periodic Assessment of NPUF Licensee Performance," describes the program for conducting and documenting periodic reviews of licensee performance for NPUFs. Region II is responsible for adjusting the scope and frequency of the review during the construction and pre-operational phases, as needed, based on construction schedules and inspection findings.

07.12 <u>Operational Readiness Inspection</u>. An operating license will not be issued until the Commission verifies through inspection that construction of the facility has been substantially completed in conformity with the requirements of the CP. An operational readiness inspection is a tool to provide input for NRC decisions regarding the operational readiness of licensee programs or processes that might not have been implemented during construction, but that will be needed for safe operation of the NPUF. In making a decision on whether to allow operations, NRC senior management considers the state of readiness of facility operation based on the results of the operational readiness inspection. Specific programs and processes to be inspected will vary depending on the commitments in the specific NPUF licensing documents. Existing IPs for operating facilities may be used to inform operational readiness inspections.

Previously identified inspection findings and applicable licensee corrective actions are also considered during the decision-making process, so operational readiness inspections should include an evaluation of outstanding inspection items and significant licensee identified items requiring corrective action.

Operational readiness inspections should also include a status of planned SSC, QA, and pre-operational inspections. The operational readiness inspection should identify if all planned inspections have been completed or if additional inspections need to be performed in order to complete the NPUF CIP. If all planned inspections have been completed, the operational readiness inspection report will serve as notification from

Region II to NRR that the CIP has been completed. If additional planned inspections need to be performed, the IR will note this situation, and a separate notification of CIP completion will be documented by Region II once all planned inspections have been completed. Completion of the CIP does not mean that Region II will stop inspecting NPUF activities. It means that all <u>required</u> inspections to meet the <u>minimum</u> requirements of this IMC have been completed. Additional inspections may be performed to ensure continued compliance to programmatic and SSC related requirements.

07.13 <u>Transition to Operations</u>. NRR will continue to provide oversight when an NPUF OL is issued, and operations inspections will be conducted by, or coordinated through, NRR.

2550-08 REFERENCES

- IMC 0613, "Power Reactor Construction Inspection Reports"
- IMC 0620, "Inspection Documents and Records"
- IMC 2506, "Construction Reactor Oversight Process General Guidance and Basis Document"
- MD 8.8, "Management of Allegations"

Management Directive Volume 12, "Security"

NUREG 1600, "NRC Enforcement Policy"

NEI 99-04, "Guidelines for Managing NRC Commitment Changes"

NRC Enforcement Manual

SECY-99-070, "Implementation Plan for the Public Communications Initiative (DSI-14)"

SECY-00-0045, "Acceptance of NEI 99-04, 'Guidelines for Managing NRC Commitments"

END

APPENDIX A

INSPECTION PROCEDURES

Inspection procedures may be added or deleted as required. Portions of these inspection procedures may not apply to all types of NPUFs.

Construction Inspection Procedures						
IP 69020	Inspections of Safety-Related Items (and Services) During Construction of Non-Power Production And Utilization Facilities					
IP 69021	59021 Inspections of Quality Assurance Program Implementation During Construction of Non-Power Production and Utilization Facilities					
IP 81810	Protection of Safeguards Information (As Implemented by IMC 2681)					
Operational Readiness Inspections						
IP 69022	P 69022 Inspections of Operational Readiness During Construction of Non-Power Production and Utilization Facilities					

END

APPENDIX B

NON-POWER PRODUCTION AND UTILIZATION FACILITY (NPUF) CONSTRUCTION INSPECTION REPORTS

1.0 PURPOSE

To provide guidance on inspection report content, format, and style for NPUF inspection reports.

2.0 OBJECTIVES

To ensure that inspection reports:

- 2.1 Clearly communicate significant inspection results to licensees, NRC staff, and the public.
- 2.2 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.
- 2.3 Provide a basis for enforcement action.

NOTE: The NRC Enforcement Policy can be found at: <u>http://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html#manual</u>.

NOTE: The <u>NRC Enforcement Manual</u> gives specific guidance on addressing noncompliance in inspection reports and can be found at: <u>http://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html#manual</u>

2.4 Assess licensee performance in a periodic, short-term context, and present information in a manner that will be useful to NRC management in developing longer-term, broad assessments of licensee performance.

3.0 **RESPONSIBILITIES**

All NRC inspectors are required to prepare NPUF construction inspection reports in accordance with the guidance provided in this Appendix. General and specific responsibilities are listed below.

3.1 General Responsibilities. Each inspection of an NPUF licensee shall be documented. A narrative inspection report consisting of a cover letter, a cover page, an executive summary, and inspection details as appropriate is required for escalated enforcement actions.

- 3.2 Report Writing.
 - a. Inspectors have the primary responsibility for ensuring that observations and findings are accurately reported, that referenced material is correctly characterized, and that the scope and depth of conclusions are adequately supported by documented observations and findings. Advice and recommendations are not to be included in inspection reports.
 - Inspectors are responsible for ensuring that the content and tone of the report, as issued, are consistent with the content and tone of the exit meeting presentation.
 When the report differs significantly from the exit meeting, the inspector (or the report reviewer) should discuss those differences with the licensee before the report is issued.
 - c. Report writers and reviewers should ensure that inspection reports follow the general format given in this chapter.
 - d. Report numbers should be issued per regional instructions and should be consistent with ADAMS templates.
- 3.3 Report Review and Concurrence.
 - a. Before issuance, each inspection report should, as a minimum, be reviewed by a member of NRC management familiar with NRC requirements in the area inspected.
 - b. The report reviewer (i.e., the member of management referred to above) should establish that conclusions are logically drawn and sufficiently supported by observations and findings, and that the observations, findings, and conclusions are consistent with NRC policies and requirements.
 - c. The report reviewer should ensure that assessments made in the inspection report represent the judgment of the issuing organization and established NRC policy rather than solely the personal views of an individual inspector or group of inspectors.
- 3.4 The Region II Regional Administrator 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.
- 3.5 Report Issuance.

The applicable regional division director or designated branch chief is responsible for the report content, tone, conclusions, and overall regulatory focus.

3.6 Report Timeliness.

Typically, reports are issued no later than 45 calendar days after inspection completion. More than one inspection may be integrated into one periodic report. If this is done, the integrated report should be issued no later than 45 calendar days after the final calendar day of the reporting period. For example, if a periodic report includes inspection activity for a quarter, then the report should be issued no later than 45 calendar days after the end of the quarter.

3.7 Reports Preceding Escalated Enforcement Actions.

Timeliness goals should be accelerated for inspection reports that include potential escalated enforcement actions. For specific enforcement timeliness goals, see the NRC Enforcement Manual.

3.8 Expedited Reports for Significant Safety Issues.

If an issue involving significant or immediate public health and safety concerns is identified, the NRC's first priority is public health and safety. Inspection report documentation or enforcement action is secondary. Based on the circumstances of the issue, 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 concern.

4.0 GUIDANCE FOR INSPECTION REPORT CONTENT

- 4.1 General Guidance
 - a. This section provides general guidance on the contents of an inspection report for NPUF construction inspections. Region II may prepare additional instructions or guidance on inspection reports based on the specific needs of the programs that they manage.
 - b. The NRC inspection report shall state what was inspected, what the inspectors observed, and what conclusions were reached relating to the inspection. Inspectors should avoid making statements that imply more general conclusions about licensee performance in areas that weren't inspected.
 - c. All enforcement actions, and other agency actions which may be derived from an inspection (such as orders) will be based upon the associated inspection report. Inspection reports must be clear, accurate, consistent, and complete.
 - d. The inspection report will normally contain a cover page, an executive summary, and a set of report details. The report details will typically describe each specific area of inspection activity in two parts: the scope and the findings.
 - e. A cover letter is used to transmit the inspection report results. The cover letter must never contain any significant information that is not also contained in the executive summary and supported in the report details.

- f. The executive summary section of the inspection report highlights the most significant conclusions. These are usually organized into sections by inspection area, corresponding to the sections of the report. There may be conclusions in the body of the inspection report which are of minor significance, so it is not necessary that every conclusion in the report details be repeated in the Executive Summary. There should never be any conclusions in the summary, however, which are not clearly and directly derived from the detailed discussion.
- g. Guidance and letter formats for escalated enforcement actions vary. Guidance and sample cover letters are found in the <u>NRC Enforcement Manual</u>.
- 4.2 <u>Cover Letter</u>. The purpose of the cover letter is to transmit the inspection report results. Inspection reports are transmitted using a cover letter from the applicable NRC official as delegated by Region II to the designated licensee executive.
 - a. <u>Cover Letter Content</u>. Cover letter content varies somewhat depending on whether the inspection identified findings. In general, however, every cover letter has the same basic structure, as follows:
 - Addresses, Date, and Salutation. At the top of the first page, the cover letter begins with the NRC seal and address, followed by the date on which the report cover letter is signed and the report issued.
 - For cover letters transmitting reports with findings assigned an enforcement action (EA) number, the EA number 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. Note that the salutation is placed after the subject line.
 - b. <u>Subject Line</u>. The subject line of the letter should state the facility name (if it is not apparent from the Addressee line) and inspection subject. The words "NOTICE OF VIOLATION" (or "NOTICE OF DEVIATION," etc.) should be included if such a notice accompanies the inspection report. The entire subject line should be capitalized.
 - c. <u>Introductory Paragraphs</u>. The first two paragraphs of the cover letter should give a brief introduction, including the type of inspection report.
 - d. <u>Body</u>. In keeping with the "Plain English Initiative", which implements the requirements of SECY-99-070, "Implementation Plan for the Public Communications Initiative (DSI-14)," the body of the letter should discuss the most important topics first."
 - e. The cover letter is written to transmit the inspection report to the licensee's management, and to deliver the "big picture" message regarding the inspection. Because it is the highest-level document, it does not need to (and normally won't) detail all the <u>items</u> inspected or the inspection procedures used. It <u>will</u> note the <u>areas</u> covered by the inspection.

- f. The tone of the cover letter must have a correct balance. The NRC focuses on performance issues. If a licensee performed some activity 100 times, and succeeded 99 times, we will be most interested in the single failure. That does not mean that the cover letter will make it appear that the licensee rarely succeeded. The safety and regulatory significance of any licensee failure will be a primary consideration, above and beyond the numerical frequency of failure compared to success.
- g. The cover letter must always be consistent with the inspection report. In addition, it must be consistent with the information, which the inspector conveyed to licensee managers at the exit meeting. If the inspector's understanding of the facts, or the perspective on the nature or significance of our findings changes after the exit meeting, the NRC shall contact the licensee and re-exit. There should never be any surprises in a cover letter to anyone who was present at the exit meeting.
- h. Lastly, the cover letter usually should not contain recommendations. There shouldn't be any statements to the effect, "The licensee needs to...." or, "The licensee should...." If the licensee is not meeting safety or regulatory requirements, the statements should clearly show those facts. If the NRC believes that a licensee cannot ensure the safety of its activities, then an Order or some similar official action may be appropriate. Guiding licensee decision-making through the use a cover letter to an inspection report is not the appropriate method for accomplishing this type of action.
- i. <u>Closing</u>. The final paragraph consists of standard legal language that varies depending on whether enforcement action is involved.
- j. The signature of the appropriate NRC official is followed by the docket number(s), license number(s), enclosures, and distribution list.

4.3 <u>Notice of Violation</u>.

- a. Licensees may be notified that they have failed to meet regulatory requirements with the issuance of an NOV. NOVs may be sent to licensees as part of a package of documents which also includes a cover letter and associated inspection report. NOVs may also be sent with a cover letter which refers to an inspection report that was distributed previously. An NOV should not be sent to the licensee in advance of the inspection report.
- b. Every NOV must be clear, so that there is little doubt that the licensee (or other interested reader) can understand the basis for the violation. The licensee may not agree with the NRC's basis, but they must understand the agency's position.
- c. Every NOV must clearly state what the requirement was that was not met. That may mean that the date and revision number of the applicable document will need to be provided. Then, a clear statement of what happened (including when, if the timing is important) will be provided. The intention is that any interested reader will be able to clearly see and understand what the requirement was and how it was not met. For additional guidance on documenting violations, refer to the NRC Enforcement Manual. The NOV should be an enclosure to the cover letter. Additional guidance on enforcement actions are found in Section 5 of this Appendix.

- 4.4 <u>Cover Page</u>. The report cover page gives a quick-glance 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.
- 4.5 <u>Executive Summary</u>. The Executive Summary will contain the important conclusions reached by NRC as a result of performing the inspection. The statements provided in this section may duplicate or condense the conclusions provided in the various separate sections of the report details. There should never be anything in the Executive Summary which is new or different from the information provided in the detailed discussion. Not every conclusion contained in the inspection report needs to be repeated in the Executive Summary, but the important conclusions, which would provide the bases for the results of the inspection stated in the cover letter should be included.
- 4.6 <u>Table of Contents</u>. For reports that are considered complicated or are of significant length (i.e., the Report Details section to the Exit Interview section is more than 20 pages long), the writer should include a table of contents as an aid to clarity.
- 4.7 <u>Report Arrangement</u>. NPUF construction inspection reports should include the following elements, arranged in the order listed:
 - Cover Letter
 - Notice of Violation (if applicable)
 - Cover Page
 - Executive Summary
 - Report Details
 - Exit Meeting Summary
 - Partial List of Key Licensee Personnel Contacted
 - List of Documents Reviewed
 - List of Acronyms (if applicable)
 - List of Inspection Procedures Used
 - Summary of Items Opened, Closed and Discussed (if applicable)
- 4.8 <u>Report Details.</u> The detailed discussion in the report provides the information which forms the bases upon which the other sections of an inspection report are developed. In most cases, the detailed discussion will be organized into one or more sections, each addressing an area of inspection. Each area will in turn be divided into two parts: inspection scope and findings. These are discussed in more detail below.
 - a. <u>Inspection Scope</u>. The scope portion of each area inspected will describe what was inspected. In most cases, the approach that can be used in writing the scope should be consistent with the Inspection Procedure (IP) which was used in performing that portion. Much of the write-up can be extracted from the "Inspection Objectives" section of the applicable IP. When describing the scope, it is acceptable to state either what the inspector(s) did, or what the inspection accomplished. That is, a scope section could be phrased, "This inspection included a review (or observation, or evaluation, etc.) of...." or it could be written as, "The inspectors reviewed (observed, evaluated) the...." The scope statements might also describe why certain items were inspected. For example, "...to determine compliance with...."

The scope section should not duplicate any portion of the findings section. Therefore, when findings are identified, much of the required detail listed below should be stated only in the findings section, resulting in a much shorter scope section.

When no findings are identified, the scope section should, when germane to the inspection, include (1) <u>how</u> the inspection was conducted (i.e., <u>the methods</u> of inspection), (2) <u>what</u> was inspected, (3) <u>where</u> the inspection took place (i.e., what room(s) or buildings), as well as (4) the inspection objectives and/or criteria for determining whether the licensee is in compliance.

If a substantive portion of the inspection activity was conducted at a location other than the plant, (e.g., an in-office review or at a vendor facility), then identify where the inspection took place.

b. <u>Findings</u>. There should always be a readily identifiable connection between the stated inspection scope and the reported findings.

Findings are assessed for significance and documented using the guidance for traditional enforcement contained in the NRC Enforcement Policy and NRC Enforcement Manual. Finding documentation should include enough detailed information for an interested reader to understand what the requirement was, how it was not met, and how the significance of the finding was determined. The description of the finding should also include when the violation occurred, how long it existed, and planned or taken corrective actions. Assign each issue a tracking number starting with the finding type (NOV, NCV, AV, URI) followed by the docket number, the inspection report number and a sequential number starting with "01." For example, the second NOV in inspection report number 05000999/2021201 would be assigned the tracking number NOV 05000999/2021201-02.

Inspector follow-up issues (IFIs) are used to track issues where the inspector performed a partial inspection and wants to document an issue that requires inspection completion later. IFIs should contain enough information so that a different inspector can understand the issue and complete the inspection without further guidance. IFIs are assigned tracking numbers in the same format as violations.

If no violations of significance greater than minor are identified during the inspection, include the statement "No violations of more than minor significance were identified."

- 4.9 <u>Exit Meeting(s) Summary.</u> The final section of each inspection report briefly summarizes the exit meeting(s), which is also described in the first paragraph of the cover letter and identifies the most senior licensee manager who attended the meeting(s), and includes the following information:
 - a. <u>Absence of Proprietary Information</u>. At the exit meeting, the inspectors should verify that information which the inspector reviews during the meeting and intends to include in the report is not proprietary. If the licensee does not identify any material as proprietary, the exit meeting summary should include a sentence to that effect.

Management Directive 12, Security, addresses minimum handling requirements. For current instructions on actions to take if the report includes proprietary material, contact the regional security advisor.

NOTE: Inspectors should be aware of minimum requirements for handling classified and sensitive-unclassified information (i.e., safeguards information, official use only, and proprietary information). When an inspection is likely to involve SUNSI or proprietary information (i.e., given the technical area or other considerations of inspection scope), how to handle such information should be discussed at the entrance meeting.

b. <u>Subsequent Contacts or Changes in NRC Position</u>. The inspector should briefly discuss any contact with the licensee management after the exit meeting to discuss new information relevant to an inspection finding. In addition, if the NRC's position on an inspection finding changes after the exit meeting, that change should be discussed with the licensee before the report is issued.

The following information is normally not included in the exit meeting summary.

- c. <u>Characterization of Licensee Response</u>. Licensee responses should not be included in the summary except in cases where the licensee disagrees with the inspection findings. In that case, the summary should state that the licensee took exception to the findings.
- d. <u>Oral Statements and Regulatory Commitments</u>. If at the exit meeting or at any other time during the inspection, the licensee makes an oral statement that it will take a specific action in response to a non-compliance, the statement may be documented in the body of the report. Details of statements made at the exit meeting should not be included in the exit meeting summary. Such statements should only be characterized in the report if the statements represent licensee commitments in response to a non-compliance in order to eliminate the need for a subsequent licensee response. However, the report cover letter must include a provision for the licensee to respond if the commitment documented in the report does not accurately reflect the licensee's corrective actions or position. Otherwise, licensee commitments are documented by licensee correspondence, after which the inspector may reference the correspondence in the inspection report. For further licensee guidance on managing regulatory commitments, see ADAMS Accession Nos. ML003680088 (NEI 99-04), ML003680078 (NEI Cover Letter), and ML003679799 (SECY 00-045 endorsing NEI 99-04 guidance).

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

- 4.10 <u>Report Attachments.</u> The attachments discussed below are included at the end of the inspection report if applicable to the inspection. The attachments may be combined into a single attachment entitled "Supplementary Information."
 - a. <u>Key Points of Contact</u>. The inspector lists, by name and title, those individuals who furnished 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; a list of 5–10 individuals is sufficient. The alphabetized list includes the most senior licensee 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. <u>List of Items Opened, Closed, and Discussed (Optional)</u>. The report should 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. <u>List of Documents Reviewed</u>. 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 include a listing of all the documents and records reviewed during the inspection that are not identified in the body of the report. (See IMC 0620, "Inspection Documents and Records.)" "Reviewed" in this context means to examine critically or deliberately. The list does not include records that were only superficially reviewed. Lists consisting of more than six condition reports, documents reviewed or procedures, etc., should normally be removed from the body of the report and included as an attachment to facilitate reading.
 - d. <u>List of Acronyms</u>. 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.
- 4.11 Release and Disclosure of Inspection Reports
 - a. <u>General Public Disclosure and Exemptions</u>. 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 2.790 and 9.17. Management Directive 8.8, "Management of Allegations," addresses how an inspection report may be used to document allegation follow up activities. IMC 0620, "Inspection Documents and Records," gives guidance on acquiring and controlling NRC records, including inspection-related documents. Sensitive–unclassified information (i.e., Safeguards Information, Official Use Only, proprietary information) should not be released as per instructions from the Office of Administration, Division of Facility Security.
 - b. <u>Release of Investigation-Related Information</u>. When an inspector accompanies an investigator on an investigation, the inspector must not release either the investigation report or his or her individual input to the investigation report. This information is exempt from disclosure by 10 CFR 9.17, and must not be circulated outside the NRC without specific approval of the OI approving official.

5.0 OTHER GUIDANCE

5.1 Minor Findings.

The NRC Enforcement Policy acknowledges that some violations of minor safety, environmental, and regulatory concern are below the level of significance of Severity Level (SL) IV violations. Because of their minor nature, these minor violations are not the subject of formal enforcement action and are not usually documented in inspection reports. Additional guidance concerning minor violations is contained in the NRC Enforcement Policy and NRC Enforcement Manual.

Appendix E of Inspection Manual Chapter 0613, "Power Reactor Construction Inspection Reports," contains examples of construction-related minor issues which are violations of requirements but have insignificant safety or regulatory impact or have no more than minimal safety significance. Appendix E of IMC 0613 may be used as an aid to inspectors when determining if construction-related issues are minor. Do not reference IMC 0613 when documenting findings that are greater than minor.

In general, minor violations should <u>not</u> be documented; however, certain exceptions apply. Documentation may be necessary as part of the resolution of an allegation. In other cases, while the violation itself is minor, the associated technical information may relate directly to an issue of agency-wide concern (e.g., the inspection was performed in response to an NRC Temporary Instruction (TI)). If, for these reasons or any other reason, the report writers and reviewers wish to document a minor violation, then it should be documented as a minor violation, with a reference to Section 2 of the <u>NRC Enforcement Policy</u>.

5.2 <u>Violations Identified as Part of Licensee Self-Assessments</u>. Under certain circumstances, even a violation that could be classified as SL IV ("more-than-minor") need not be documented. This is generally justified when the violation has been identified and corrected as part of a licensee self-assessment effort. As a matter of policy, NRC enforcement seeks to encourage licensee self-assessment efforts, and seeks to avoid the negative impact that can result from a redundant NRC emphasis on problems which the licensee's responsible action has already identified and corrected.

For example, suppose that while evaluating the licensee's quality assurance efforts in the fire protection area, an inspector reviews relevant audits and surveillances conducted over the previous year. The review reveals that the audits have been probing and thorough; the findings are well-developed and technically sound, and include six noncompliance issues, four of which might be classified at SL IV.

In such a case, the inspector should follow up on the non-compliances and other audit findings to ensure that causes have been appropriately assessed, that appropriate and comprehensive corrective actions have been taken, and that no new examples of the violations exist. Provided, however, that no new problems are revealed by this follow-up, the inspector is normally <u>not</u> expected to cite the four violations individually, nor to report the details of those violations in the inspection report. Instead, the NRC report inspection scope should include a clear reference to the name, dates, and general subject matter of the audit or self-assessment.

NOTE: This expectation only applies to SL IV violations. Even when identified through a licensee self-assessment, violations that could be categorized at SL III or above <u>must</u> be documented in the inspection report and given appropriate follow-up.

In some instances, reasons exist to document one or more of the violations found in a licensee audit or self-assessment. For example, if the inspector concludes that the licensee's self-assessment was especially negative, one or more examples should be given to support that conclusion. In addition, the inspector may decide to document one or more of the violations found in the licensee self-assessment due to the technical significance or generic implications of the item. The violation(s) may provide useful insight on equipment or system reliability, or on some aspect of human performance. In some cases, the inspector may decide to pursue additional follow-up of a particular licensee finding because of related licensee problems, previous NRC observations or violations involving the same or a related topic, or emerging agency or industry sensitivity in the given technical area.

If, for any of these reasons, the inspector decides to include in the inspection report a particular licensee self-assessment finding or audit finding, and that finding involves a violation, then the violation must be clearly dispositioned in the report. The violation may be dispositioned as a non-cited violation (NCV) unless any one of the circumstances listed in Section 2 of the NRC Enforcement Policy results in an NOV requiring a formal written response from the licensee.

Note the discussion in this subsection applies to violations identified through licensee audits and self-assessments (i.e., cases in which the NRC's inspection is focused on the licensee's quality assurance efforts) and should <u>not</u> be applied to all licensee-identified violations. When the inspector pursues an issue as part of day-to-day licensee observation or other normal inspection activities, the decision on whether to document the issue should be based on its significance. Unless the inspection is specifically focused on licensee auditing and self-assessment capability, violations of more-than-minor significance should be documented and dispositioned, regardless of whether they are NRC- or licensee-identified.

NOTE: The NRC Enforcement Manual, section 2 provides additional guidance on documenting and dispositioning violations.

- 5.3 <u>Documenting Noncompliance</u>. The primary guidance for all matters related to enforcement, including documentation, is given in the NRC Enforcement Policy and the NRC Enforcement Manual. The following discussion summarizes certain aspects of that guidance related to inspection reports.
 - a. <u>Types of Noncompliance</u>. The manner of documenting a noncompliance in the inspection report depends on how that noncompliance will be dispositioned. A noncompliance may be addressed as a non-escalated enforcement action (i.e., an SL IV violation, a deviation, or a nonconformance); as an escalated enforcement action (i.e., an apparent SL I, II, or III violation); or as an NCV.

Note that a noncompliance may <u>not</u> be documented simply as a "weakness," "licensee failure," or a similar informal characterization. If the report narrative describes a condition or event in a manner that <u>suggests</u> to the reader that a violation may have occurred, then the finding must be clearly dispositioned as a violation, an apparent violation, or an NCV. If a violation does <u>not</u> exist (e.g., no

requirement exists in this area), it may be appropriate to clarify the finding by stating that "this condition [or event] does not constitute a violation of NRC requirements."

 <u>Non-Escalated Enforcement Actions</u>. Most violations that are more than minor fall into the SL IV category. SL IV violations will be dispositioned in the inspection report as either an NOV or an NCV. See the NRC Enforcement Policy for further guidance in determining if an NOV or NCV is appropriate. If, at the time of issuing the inspection report, an SL IV violation is determined to be an NOV, then the NOV is generally sent out with the inspection report as a "non-escalated" enforcement action. If the licensee's corrective action program (CAP) has been determined to be effective by the NRC (see appendix C of this IMC for guidance on determining if a licensee's CAP is effective), then the SL-IV violation is generally categorized as an NCV in accordance with the NRC Enforcement Policy section 2.3.2.a. The cover letter for reports that include nonescalated enforcement actions should follow the appropriate NRC Enforcement Manual guidance.

Deviations and nonconformances are also considered non-escalated enforcement actions. When a licensee fails to meet a regulatory commitment or to conform to the provisions of an applicable code or industry standard, the failure may result in a Notice of Deviation. When a vendor or certificate holder fails to meet a contract requirement related to NRC activities, the failure may result in a Notice of Nonconformance. While less frequently issued than SL IV NOVs and NCVs, these non-escalated enforcement actions follow a similar format and require a similar level of report detail.

 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, by their nature, require further agency deliberation (and usually additional licensee input) to determine the appropriate severity level and NRC action.

Similarly, report narratives that discuss apparent violations should be carefully constructed to avoid making explicit conclusions (i.e., final judgments) about the safety significance of the issue. The report should include any available details that demonstrate safety significance, or that would help in making such a decision and should also describe any corrective actions taken or planned by the licensee. However, since a potential escalated enforcement action automatically entails further evaluative steps, neither the inspection report details nor the accompanying cover letter should present a final judgment on the issue.

3. <u>Non-Cited Violations</u>. Section 2 of the NRC Enforcement Policy lists circumstances that result in consideration of an NCV not requiring a formal written response from a licensee. When an NCV is issued, the report should briefly describe the circumstances of the violation, briefly describe the licensee's corrective actions, and conclude with the following boilerplate statement: "This non-repetitive, licensee-identified and corrected violation is being treated as a Non-Cited Violation, consistent with section 2 of the NRC Enforcement Policy."

If the licensee's CAP has been determined to be effective per Appendix C of this IMC, then SL IV violations may be dispositioned as NCVs if the criteria of section 2.3.2.a of the NRC Enforcement Policy are met. When this is the case, briefly describe the licensee's corrective actions, and conclude with the following boilerplate statement: "This violation is being treated as an NCV, consistent with section 2.3.2 of the Enforcement Policy. The violation was entered into the licensee's corrective action program as [###] to ensure actions are taken to correct the condition."

The NRC Enforcement Policy also provides that willful SL IV violations may be dispositioned as NCVs provided that they meet the four criteria outlined in section 2 of the Policy. In these cases, the inspection report should include additional discussion to address this before providing the standard conclusive language. For example: "Although this violation is willful, it was brought to the NRC's attention by the licensee, 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, licensee-identified and corrected violation is being treated as a Non-Cited Violation, consistent with section 2 of the NRC Enforcement Policy."

- 4. <u>Minor Violations</u>. Minor violations should not normally be documented in inspection reports. However, to the extent that documentation is necessary, the standard language should be used: "This failure constitutes a violation of minor significance and is not subject to formal enforcement action."
- 5. Enforcement Discretion. There are various subsections in the NRC Enforcement Policy in section 3 where discretion is exercised, and formal citations are not issued. The approval of the Director, Office of Enforcement, in consultation with the Deputy Executive Director as warranted, is required for exercising discretion of the type described in section 3. Where discretion is being reviewed 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."
- b. <u>Supporting Details and Discussions of Safety Significance</u>. The discussion of noncompliance issues must be sufficiently detailed to substantiate any NRC safety and regulatory concerns and to support any enforcement sanction the NRC may choose to issue. At a minimum, for a violation, the report should state:
 - a) What requirement was violated;
 - b) How the violation occurred;
 - c) When the violation occurred, and how long it existed;
 - d) Who identified it, and when; Any actual or potential safety consequence;
 - e) The root cause (if identified), and;
 - f) What corrective actions have been taken or planned.

The degree of detail necessary to support an enforcement action is a function of the significance and complexity of the noncompliance.

Although supporting details clearly assist in determining the safety significance of the noncompliance, inspectors should be cautious in making direct statements regarding safety significance in the inspection report details. Violation severity levels, as described in the NRC Enforcement Policy, are based on the degree of safety significance involved. In assessing the significance of a noncompliance, the NRC considers four specific issues: (1) actual safety consequences: (2) potential safety consequences, (3) potential for impacting the NRC's ability to perform its regulatory function, and (4) any willful aspects of the violation. As a result, if an inspection report refers to a noncompliance as being "of low safety significance" (meaning, in a general sense, that the noncompliance did not result in any actual adverse impact on equipment or personnel), the writer may have inadvertently made it difficult for the NRC to subsequently decide that the potential for an adverse impact or the regulatory significance of the noncompliance warrants issuance of a SL III violation. Therefore, before characterizing a violation as being of "low safety significance," the inspector should also address the potential consequences and regulatory consequences of the violation in addition to the absence of an actual adverse consequence.

- c. <u>Noncompliance Involving Willfulness</u>. Inspection reports should neither speculate nor reach conclusions about the intent behind a violation, such as whether it was deliberate, willful, or due to careless disregard. As with any observation, the report discussion should include relevant details on the circumstances of the violation without making a conclusion about the intent of the violator:
 - EXAMPLE: "The radiographer failed to activate his alarming rate meter, although he had informed the inspectors earlier that he had been properly trained on the use of the device;" <u>not</u>, "The radiographer deliberately failed to activate his alarming rate meter."

Conclusions about the willfulness of a violation are agency decisions and are normally not made until after the OI has completed an investigation. A premature or inaccurate discussion of the willfulness of an apparent violation in the inspection report could result in later conflicts based on additional input and review. Inspection reports that include potentially willful violations are to be coordinated with OI and the Office of Enforcement (OE).

6.0 Release and disclosure of inspection reports and associated documents

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 how an inspection report may be used to document allegation follow up activities. IMC 0620, "Inspection Documents and Records," provides guidance on acquisition and control of NRC records, including inspection-related documents.

Information in inspection reports concerning a licensee's physical protection, classified matter protection, or material control and accounting program, which is not otherwise designated as Safeguards Information or classified as National Security Information or Restricted Data, is withheld from public disclosure under 10 CFR 2.390. The cover letters are public, but the reports are not.

- 6.1 Release of Investigation-Related Information
 - a. When an inspector accompanies an investigator on an investigation, the inspector shall not release either 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. OI reports of investigations will not be circulated outside NRC without specific approval of the OI approving official.
 - b. Generally, NRC technical and safety concerns can be communicated to a licensee without revealing that an investigation is contemplated or underway. However, when information cannot be released without risk of compromising an investigation, the regional administrator (RA) will inform the OI Field Office Director, in advance, that safety concerns require releasing to the licensee information related to an open investigation.
 - c. The OI Field Office Director will review the information to be released and advise the RA of the anticipated effect on the course of the investigation. The 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.
 - d. Conversely, when the RA decides, after consultation with the OI Field Office Director, to delay informing the licensee of an issue, the RA should document this decision, including the basis of determining that the delay is consistent with public health and safety considerations. Any such decision should be reexamined every three months to assure validity of the delay to inform the licensee about the technical and safety concerns until the investigation is closed.
 - e. When an emergency or significant safety or security issue appears to require immediate action, NRC employees, at their discretion, may discuss with, show to, or provide the licensee any pertinent material they believe the circumstances warrant. If time permits, regional management should be consulted first. An emergency situation meeting this criteria is one in which, in the opinion of the senior NRC employee cognizant of the situation, presents a danger to public health or safety, or to the common defense and security, and requires the release of investigative information to a licensee without the delay necessary to consult with appropriate OI personnel. If an issue disclosed during an inspection is to be referred to OI for possible investigative action, the inspection report should not contain information that would lead a reader to conclude or infer that an investigation may be opened. In this case, the report should contain only relevant factual information collected during the inspection. The referral to OI should be made by separate correspondence, with any additional information needed to support the referral.

END

APPENDIX C

NPUF ASSESSMENT PROCESS

1.0 PURPOSE

This appendix provides guidance for assessing the licensee's performance in the construction and pre-operational phases of NPUFs and to provide feedback for NRC management's conclusions regarding the quality of the licensee's construction and pre-operational programs. The results of such a review should:

- 1.1 Provide an assessment of licensee performance to NRC management.
- 1.2 Inform the licensee and the public how the NRC assesses facility performance.
- 1.3 Provide a basis for adjusting the construction and pre-operational inspection program, including such areas as focus, frequency, and resources.

2.0 OBJECTIVES

- 2.1. To describe the processes for assessing an NPUF's performance during construction.
- 2.2. To ensure that the assessments are performed in a timely, effective, and efficient manner.
- 2.3. To ensure that the assessments are focused on determining if construction of the facility is performed in accordance with the facility licensing basis.

3.0 EVALUATION FACTORS

The assessment should review the licensee's performance. NRR, NMSS, the FSARG, and the Region II Branch Chiefs may confer to consider the specific evaluation factors to be used to assess licensee performance.

4.0 IMPLEMENTATION

4.1 <u>Overall Assessment Process</u>. Typically, Region II (in coordination with the FSARG if applicable) will conduct an end of cycle performance assessment using the inspection findings compiled over the previous 12 months (four quarters). If licensee performance results in the licensee changing columns of the NPUF Construction Action Matrix (Exhibit 1), or if the licensee is not in column one of the NPUF Construction Action Matrix, then the output of this review is an end of cycle assessment letter to the licensee. If the licensee has not changed columns and is in column one of the NPUF Construction Action Action Matrix, then an end of cycle letter is optional.

The 12-month assessment cycle will be from January 1 through December 31 of each year. The assessments will be based on the findings and conclusions documented in NRC inspection reports and any feedback on licensing performance received from the applicable NRC licensing organization and the NRR program office. Overall licensee

performance assessment will be based on the severity level and number of violations. The Agency's response and communication of applicant/licensee performance will generally follow the guidance in the NPUF Construction Action Matrix. Any deviations from the CAM require approval of the Region II Regional Administrator and the NRR Office Director.

- 4.2 <u>Performance Reviews</u>. The assessment process consists of a series of reviews which are described below.
 - a. <u>Periodic Review</u>. Region II staff, regional inspectors, and the Branch Chiefs who participated in inspection activities during the quarter may optionally conduct a periodic review (in coordination with the FSARG) using the inspection findings compiled over the previous quarter. An assessment follow-up internal memo should be issued by Region II to the NRR program office if the periodic review identified significant performance issues that resulted in changes to planned inspections. If applicant/licensee performance has declined resulting in changes to the planned inspections, this should be communicated to the applicant/licensee.
 - b. <u>End-of-Cycle Review</u>. Region II will conduct (in coordination with the FSARG, if applicable) an end-of-cycle review using documented inspection findings compiled over the assessment period (typically a calendar year). This review incorporates activities from the periodic reviews (if performed).

The end-of-cycle review is normally chaired by the appropriate Branch Chief or his/her designee. If applicant/licensee performance has degraded to Column 2 or higher of the Construction Action Matrix, then the end-of-cycle review should be chaired by the applicable Division Director or, if appropriate, the Region II Deputy Regional Administrator or his/her designee. Other routine participants should include representatives from the FSARG if applicable, the NRR program office, applicable regional inspectors, and any other additional participants deemed necessary by the regional office. The following representatives should also participate if there are pertinent performance issues that should be factored into the performance assessment: the regional Allegations Coordinator or the Agency Allegations Advisor, OI, and OE.

If an assessment letter is required, then it should be issued within nine weeks of the end of the assessment cycle.

If an assessment letter is not required and there has been insignificant construction and inspection activity at the facility, then the end-of-cycle meeting is not required. In this case, the Region 2 should notify the NRR project office that no end-of-cycle meeting was conducted.

c. <u>Corrective Action Program (CAP) Effectiveness Reviews</u>. A fundamental goal of the NRC's oversight of new construction activities is to establish confidence that licensees and their contractors are detecting and correcting problems in a manner that ensures quality and safety. To this end, the licensee must conduct construction activities in a manner that ensures each facility is constructed in accordance with the licensing basis and will operate safely. The NRC construction inspection program for NPUFs provides for review of CAP issues through the conduct of inspection procedures 69020, "Inspections of Safety-Related Items (and Services) during Construction of Non-Power Production and Utilization Facilities;" 69021, "Inspections

of Quality Assurance Program Implementation During Construction of Non-Power Production and Utilization Facilities;" and 69022, "Inspection of Operational Readiness During Construction of Non-Power Production and Utilization Facilities." Results of completed inspections using these IPs shall be used when assessing the effectiveness of licensee corrective action programs.

It is important that sufficient licensee CAP activity has occurred prior to designating a licensee's CAP as effective. This CAP activity should be representative of all areas of construction (e.g., design, work management, change processes, and physical construction). It is also important that sufficient NRC inspection has been conducted to provide adequate information for the CAP assessment. As a minimum, the initial CAP document inspection and one annual CAP implementation inspection as described in IP 69021, Appendix P, "Inspection of Requirement 2.16 – Corrective Actions," shall be complete prior to a CAP effectiveness assessment. Additionally, results of completed IP 69020 and IP 69022 inspections involving nonconformance and deviation reports or other documents describing the status and resolution of corrective actions shall be used for the CAP effectiveness assessment. The CAP effectiveness assessment should cover diverse areas of construction (i.e., civil, mechanical, and electrical).

The CAP effectiveness assessment will consider the results of all inspections that have been performed at the facility up until the time of the assessment. The NRC will use inspection results from the inspections described above and the following criteria to assess the adequacy of the licensee's development and implementation of the CAP:

- CAP Development: the licensee has adequately developed a CAP if there were no findings associated with the IP 69021 CAP document inspection or the NRC has determined that any findings associated with the inspection have been corrected, and
- CAP Implementation: the licensee has corrected any weakness in the CAP (as confirmed by NRC follow-up inspection) that was, or contributed to, the cause of any findings documented prior to the effectiveness assessment.

The CAP effectiveness assessment will normally be conducted during end-of-cycle reviews. If insufficient licensee CAP activity has occurred to perform an adequate CAP effectiveness assessment at the time of the end-of-cycle review, or if the CAP has been determined to be ineffective, then this will be stated in the applicable assessment letter. Once it is determined that the licensee's CAP meets the above criteria, the NRC will notify the licensee in the applicable end-of-cycle assessment letter that its CAP has been adequately developed and implemented. The NRC will continue to assess the adequacy of the licensee's CAP throughout construction of the facility, even if the CAP has been determined to be effective.

The NRC will notify the licensee in the applicable assessment letter if a substantive change in the effectiveness of the CAP has occurred. If the CAP is subsequently determined to be ineffective, then the NRC will not issue NCVs in accordance with Section 2.3.2.a of the NRC Enforcement Policy until the CAP is reassessed. If the CAP is not determined to be effective during construction, the NRC may continue to

evaluate the effectiveness of the licensee's CAP as part of the NRC operations inspection program.

Additionally, if adequate CAP activity and NRC inspection of the CAP have occurred (as described above), the NRC may perform an assessment of the CAP separately from the end-of-cycle assessment. This would typically be done if sufficient CAP activity occurs early in the yearly assessment period (i.e. early in the calendar year). If the CAP is determined to be effective, then a stand-alone assessment letter may be issued to inform the licensee that their CAP has been adequately developed and implemented.

4.3 <u>Public Meeting with Applicant/Licensee</u>. Region II may conduct an end-of-cycle public meeting in the vicinity of the NPUF site to communicate the results to the applicant/licensee and members of the public. Region II will coordinate with the FSARG if applicable, and the NRR program office for their participation in the meeting. If conducted, the meeting should be scheduled within 16 weeks of the end of the cycle.

The involvement of the public in the results of the NRC's assessment of applicant/licensee performance is intended to provide an opportunity for the NRC to engage interested stakeholders on the performance of the facility and the role of the NRC in ensuring safe and quality conduct of construction activities. The assessment letter provides the minimum performance information that should be conveyed to the applicant/licensee in a public meeting, if conducted. However, this does not preclude the presentation of additional facility performance information when placed in the proper context. The applicant/licensee should be given the opportunity to respond at the meeting to any information contained in the assessment letter. The applicant/licensee should also be given the opportunity to present to the NRC any new or existing programs that are designed to maintain or improve their current performance.

If a meeting is conducted with the applicant/licensee, it will be a Category 1 public meeting in accordance with the Commission's policy on public meetings, with the exception that the meeting must be closed for such portions which may involve matters that should not be publicly disclosed under Section 2.390 of Title 10 of the *Code of Federal Regulations* (10 CFR 2.390). Members of the public, the press, and government officials from other agencies are considered as observers during the conduct of the meeting. However, attendees should be given the opportunity to ask questions of the NRC representatives after the conclusion of the meeting.

Public involvement in the results of the NRC's assessment of applicant/licensee performance should focus on topics of interest to the public. In lieu of a public meeting, the format for the public involvement could include an open house, round table discussion, or poster board session. For higher-profile interactions, consideration should include NRC or non-NRC facilitators.

- 4.4 <u>Assessment Areas</u>. The following assessment areas and associated attributes should be used to assess NPUF construction performance. Depending on the stage of the construction project, not all assessment areas would be applicable during a given assessment period.
 - a. <u>Quality Assurance Program</u>. The requirements of the QA program are effectively implemented, including design control. Design control activities are conducted in accordance with facility procedures and the QA plan. Engineering activities are

effective in ensuring the facility is constructed in accordance with the approved design and authorized design changes.

- b. <u>Construction Oversight</u>. Construction Activities. Construction activities are conducted in accordance with the CP and QA program. The applicant/licensee recognizes non-routine events affecting safety and effectively implements the corrective action program.
- c. <u>Operational Readiness Activities</u>. Activities completed during the operational preparedness phase to support the transition from construction to operation. The following performance areas should be coordinated with the FSARG if applicable, and the NRR program office to assess applicant/licensee performance:
 - 1. Safeguards. Safeguards includes areas pertaining to material control and accounting (e.g., physical protection of special nuclear material and information security).
 - 2. Radiological Controls. Radiological controls includes areas pertaining to radiation protection, environmental protection, waste management, and transportation.
 - 3. Facility Support. Facility support includes areas pertaining to safety controls, management organization and controls, operator training, and facility modifications.
- d. <u>Other Areas</u>. Other areas may include special issues that arise, but are not included in the review on a routine basis unless the significance of the issue rises to a level that is perceived to affect the quality of applicant/licensee performance. Examples include quality of licensing submittals, deviations from commitments in Confirmatory Action Letters or Confirmatory Orders, and labor difficulties.
- 4.5 <u>NRC Actions in Response to Applicant/licensee Performance Issues</u>. Periodic assessments will determine the NRC response to significant performance issues. Significant performance issues are defined as Severity Level I, II, and III violations.
 - a. <u>Description of the CAM</u>. The CAM (Exhibit 1) was developed with the philosophy that, within a certain level of performance (i.e., Column I), applicant/licensees would address their performance issues without additional NRC engagement beyond the routine inspection program. Agency action beyond the routine inspection program will normally occur only if assessment input thresholds are exceeded. The CAM identifies the range of NRC and applicant/licensee actions and the appropriate level of communication for varying levels of applicant/licensee performance.

Overall response to applicant/licensee performance will be determined by the number and severity of violations. The CAM uses a graded approach in determining the response to the identified issues. This graded approach will result in an increase in sampling in the area(s) of concern, an increase in the SSCs being inspected, and/or the issuance of a Confirmatory Action Letter (CAL), Demand for Information, and/or the issuance of an Order. Increased inspection will be conducted using supplemental construction inspections.

- b. <u>Expected Responses for Performance in Each CAM Column</u>. The CAM lists expected NRC and applicant/licensee actions based on the inputs to the assessment process. Actions are graded such that the agency becomes more engaged as applicant/licensee performance declines. Listed below are the ranges of expected NRC and applicant/licensee actions for each column of the CAM:
 - 1. CAM Column I. Violations that are not greater than SL IV. The applicant/licensee will receive only the routine inspection program and identified deficiencies will be addressed through the applicant/licensee's CAP.
 - 2. CAM Column II. There are no more than two SL III violations. The applicant/licensee is expected to place the identified deficiencies in its CAP and perform an evaluation of the root and contributing causes. The applicant/licensee's evaluation will be reviewed during subsequent inspections. Following completion of the inspections, the branch chief or division director should discuss the performance deficiencies and the applicant/licensee's proposed corrective actions with the applicant/licensee, typically during an inspection exit meeting, at a periodic NRC management visit, or during a conference call with the applicant/licensee.
 - 3. CAM Column III. A combination of three SL III violations or one SL II violation. The applicant/licensee is expected to place the identified deficiencies in its CAP and perform an evaluation of the root and contributing causes for both the individual and the collective issues.

The applicant/licensee's evaluation will be reviewed during subsequent inspections. Also, an independent assessment of the extent of condition will be performed by Region II. Following completion of the inspections, the Deputy Regional Administrator (DRA), or designee, should discuss the performance deficiencies and the applicant/licensee's proposed corrective actions with the applicant/licensee, typically during a public meeting with the applicant/licensee.

4. CAM Column IV. One SL I violation, multiple SL II violations, or a combination of the following: one SL II and a total of four SL III violations; or a total of seven or more SL III violations. The applicant/licensee is expected to place the identified deficiencies in its CAP and perform an evaluation of the root and contributing causes for both the individual and the collective issues. This evaluation may consist of a third-party assessment.

Inspection(s) will be performed to review the breadth and depth of the performance deficiencies. The construction supplemental inspection plan must be approved by the appropriate Region II division director.

Following the completion of the inspection, the Region II Regional Administrator (or designee), and the Director, NRR/DANU will decide whether additional agency actions are warranted. These actions could include additional construction supplemental inspection, a Demand for Information, a CAL, or issuance of an Order, up to and including a stop work order. At a minimum, the Region II will issue a CAL to document the applicant/licensee's commitments as discussed in their performance improvement plan, as well as any other written or verbal commitments. The Region II Regional Administrator should document the results of their decision in a letter to the applicant/licensee. Typically, these

results will be discussed during a public meeting between the applicant/licensee and the Region II Regional Administrator (or designee).

Note: Other than the CAL, the regulatory actions listed in this column of the CAM are not mandatory. However, the regional office should consider each of these regulatory actions when significant new information regarding applicant performance becomes available.

Due to the depth and/or breadth of performance issues reflected by a facility being in Column IV of the CAM, it is prudent to ensure that actual performance improvements have been made prior to closing out the violations and exiting Column IV of the CAM. In making this determination, the regional office should consider whether:

- New site issues or violations do not reveal similar significant performance weaknesses;
- The applicant/licensee's performance improvement program has demonstrated sustained improvement;
- NRC supplemental construction inspections show applicant/licensee progress in the principal areas of weakness;
- There were no issues that led the NRC to take additional regulatory actions beyond those already taken due to the applicant/licensee being in Column IV of the CAM. Additionally, the applicant/licensee has made significant progress on any regulatory actions that were imposed (e.g., CALs, orders) because of the performance deficiencies that led to the Column IV designation.

After the original violations have been closed out, the applicant/licensee will return to the CAM column that is represented by the other outstanding inputs to the CAM. Additionally, for a period of up to one year after the initial violations have been closed out, the regional office may use some actions that are consistent with Column III or Column IV of the CAM in order to ensure the appropriate level of agency oversight of applicant/licensee improvement initiatives. These actions, which do not constitute a deviation from the CAM, include senior management participation at periodic meetings/site visits focused on reviewing the results of improvement initiatives (such as efforts to reduce corrective action backlogs and progress in completing the applicant/licensee Performance Improvement Plan) and CAL follow-up inspections. The actions taken beyond those required by the CAM shall be discussed at the next end of cycle assessment meeting to ensure an appropriate basis for needing the additional actions to oversee the applicant/licensee improvement initiatives. These actions will also be described in subsequent performance review assessment letters until the NRC determines the actions have been completed in a satisfactory manner.

The regional office must convey the specific actions that the applicant/licensee needs to address to resolve the violations that caused the applicant/licensee to enter Column IV. Until the violations are addressed, the applicant/licensee will remain in Column IV.

- c. <u>CAM Deviations</u>. The regulatory actions dictated by the CAM may not be appropriate in rare instances. In these instances, the NRC may deviate from the CAM to either increase or decrease NRC action. The use of additional resources to evaluate issues not related to licensee performance is not considered a deviation from the CAM.
 - 1. A CAM deviation is defined as any regulatory action taken that is outside of the range of actions described in the CAM. A CAM deviation may be considered for a situation that results in an inappropriate level of regulatory attention when entered into the CAM.
 - 2. Deviations from the CAM shall be approved by the Region II Regional Administrator and the NRR Office Director.
 - Deviations from the CAM shall be communicated to the licensee in an assessment follow-up letter or end-of-cycle assessment letter. The letter shall be made publicly available after the licensee is notified of the deviation.
 - 4. Ensure that deviation documents containing Sensitive Unclassified Non-Safeguards Information (SUNSI) security-related information are marked and handled in accordance with Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program." The NRC policy for handling, marking, and protecting SUNSI is publicly available on the NRC Public Web site at <u>http://www.nrc.gov/reading-rm/doc-collections/commission/commsecy/2005/2005-0054comscy-attachment2.pdf</u>

END

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		Column I	Column II	Column III	Column IV			
RESULTS		Only Severity Level (SL) IV violations or non-cited violations NRC requirements	One or two SLIII violations NRC requirements met with some challenges to applicant/licensee	Three SL III violations or one SL II violation, or a combination of the above. NRC requirements met with some significant challenges to	One SL I violation, multiple SL II violations, or a combination of the following: one SL II and four or more SL III violations; or seven or more SL III violations			
		fully met		applicant/licensee (Degraded Performance)	Loss of confidence to construct within NRC requirements (Unacceptable Performance)			
RESPONSE	Regulatory Performance Meeting	None	Branch Chief or Division Director meets with applicant/licensee	Deputy Regional Administrator or designee meets with senior applicant/licensee management	Regional Administrator (RA) or designee meet with senior applicant/licensee management			
	Applicant/licensee Action	Applicant/licensee corrective actions	Applicant/licensee root cause evaluation and corrective action with NRC oversight	Applicant/licensee cumulative root cause evaluation with NRC oversight	Applicant/licensee Performance Improvement Plan and independent inspection with NRC oversight			
	NRC Inspection	Routine inspection program	Limited increase in NRC oversight of area(s) of concern.	Expanded NRC oversight in area(s) of concern. Inspection sample increased as appropriate	Reactive team inspection in area(s) of concern.			
	Regulatory Actions	None Additional actions considered for sites exiting Column III or Column IV.	Additional inspection only. Additional actions considered for sites exiting Column III or Column IV.	Additional inspection only. (Additional actions considered for sites exiting Column IV).	At minimum, issue confirmatory action letter. Evaluate need for Demand for Information and/or Order.			
COMMUNICATION	Assessment Letters	If needed, Branch Chief or Division Director reviews/signs assessment report	Division Director reviews/signs assessment report	Deputy Regional Administrator or designee reviews/signs assessment report	Regional Administrator reviews/signs assessment report			
	Annual Public Meeting	Project Inspector or Branch Chief meets with applicant/licensee	Branch Chief or Division Director discusses performance with applicant/licensee	Deputy Regional Administrator or designee discusses performance with applicant/licensee	Regional Administrator or designee discusses performance with applicant/licensee			
COM	Commission Involvement	None	None	None	Consider Commission meeting with senior management			

Exhibit 1: NPUF Construction Action Matrix

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non- Public Information)
N/A ML15083A166 12/14/15 CN 15-029		Initial issuance to document Construction Inspection Program for Non-Power Production and Utilization Facilities Licensed under 10 CFR Part 50.	Inspectors should be trained or briefed on the NPUF Inspection Program before they perform NPUF related inspections.	ML15182A159
N/A	ML17205A247 05/01/18 CN 18-009	Routine update, also added language discussing assessing the effectiveness of a licensee's CAP and CAM deviations.	N/A	ML17226A345
N/A	ML21208A134 12/07/21 CN 21-039	Routine update including organizational changes, changes to inspection report documentation guidance, and changes to IMC wording for applying the IMC to construction of non-radioisotope NPUFs.	Construction inspectors should be briefed of changes to inspection report guidance.	ML21208A112

Attachment 1: Revision History for IMC 2550