

NRC INSPECTION MANUAL

DCIP

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) designed to produce medical radioisotopes, such as molybdenum-99 under 10 CFR Part 50. Broader applicability of this IMC to other non-power utilization facilities, such as research and test reactors, should be considered on a case-by-case basis. 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.

The NPUF CIP applies to all safety related construction activities, including, design, procurement, fabrication, construction, pre-operational testing activities, and development of programs required for operation. Implementation of this IMC will begin at NRC issuance of the Construction Permit and will continue through completion of construction.

2550-02 OBJECTIVES

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

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 documents (Safety Analysis Report (SAR), Construction Permit (CP), etc.).

02.03 Verify the effective implementation of the quality assurance program as specified in 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 is identifying 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 decision to allow operations at the NPUF.

2550-03 APPLICABILITY

03.01 This IMC was developed to provide inspection program guidance for the NPUF CIP. The NPUF CIP applies to all construction activities, including, the design, procurement,

fabrication, construction, and pre-operational testing and operational readiness activities. Implementation of this IMC will begin at the NRC issuance of the Construction Permit, 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. Traditional enforcement, i.e. the use of Severity Levels (SL), will be used for any SL IV and above non compliances that are identified during inspections.

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 New Reactors (NRO)

- a. Responsible for the development and maintenance of the construction inspection program for NPUFs.
- b. Responsible for approval of this IMC.

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, documentation, 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 assigning a Regional Project Inspector for each NPUF under construction.
- e. Responsible for coordinating with NRR and NMSS to develop site specific construction inspection plans as a part of the Facility Specific Assessment and Review Group (FSARG).
- f. 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)

- a. Responsible for policy, guidance, and approval of emergency preparedness and security inspection programs (e.g., physical security, information security, and transportation security).
- b. Responsible for the planning, performance, documentation, and enforcement associated with the Headquarters emergency preparedness.

05.04 Office of Nuclear Reactor Regulation (NRR)

- a. Responsible for NPUF application reviews, amendment reviews, and the overall licensing process.
- b. Responsible for coordinating NPUF CIP interfaces with state and local government.
- c. 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).
- d. Responsible for coordinating with NMSS and Region II to develop site specific construction inspection plans.
- e. Responsible for the planning, performance, documentation, and enforcement associated with security inspection programs (e.g., physical security, information security, and transportation security), in coordination with NSIR.
- f. Responsible for oversight of the development of the operational programs as needed to support issuance of the operating license.
- g. Responsible for making the determination to authorize the commencement of operations, in coordination with NMSS and Region II.
- h. Responsible for concurring on the approval of this IMC.

05.05 Office of Nuclear Material Safety and Safeguards (NMSS)

- a. Responsible for providing technical support for the construction inspections of the facility.

05.06 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 the finding.
- b. Responsible for providing representatives, as necessary, to support the escalated enforcement process in order to ensure consistent application of the enforcement process.

2550-06 BASIC REQUIREMENTS

06.01 General. 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. Substantial 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 delegated authority to conduct activities related to safety. Inspections will evaluate whether 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 licensee's QA program are being effectively implemented throughout all stages of construction, including equipment fabrication, assembly and installation, and structural construction activities.

06.02 NPUF Facility Specific Assessment and Review Group (FSARG). The FSARG is an assessment group comprised of representatives from NRR, NMSS, and Region II. The FSARG will have the responsibility of overseeing the development and implementation of the program to verify that the construction of the NPUF was completed in accordance with applicable regulatory requirements. The effort is focused on ensuring that the inspection programs will collect the information necessary for the Commission to make a determination that the applicable requirements for issuing an operating license have been met. The FSARG also has the responsibility for overseeing project completion and will serve as the focal point for coordination between Region II and Headquarters. The NRR representative will be responsible for coordinating group activities.

The FSARG will also develop the performance based master construction inspection plan. The plan will be based on safety significance and will consider safety-related items, SAR commitments, and license conditions.

06.03 Inspection Planning and Scheduling Considerations. 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.

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 Inspection and Technical Personnel Considerations. Inspectors will be assigned responsibility for the conduct of applicable inspection requirements consistent with their experience. In conducting this inspection program, it is necessary that inspectors 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. To this aim, the inspectors may be from the region or headquarters.

2550-07 GUIDANCE

07.01 General. The licensee is ultimately responsible for the safety of the facility. The NRC ensures, through a sampling type of inspection program, that the responsibility is carried out in an effective manner during facility construction. The CIP presented in this manual chapter 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 will also be performed, as necessary, at the facilities of the licensee's consultants, contractors, and suppliers. This IMC establishes priorities for inspection by planned sampling of SSCs and activities important to safety and should consider the performance of the licensee in the areas inspected.

07.02 Inspection Areas. 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 facility specific inspection plan will be developed by the NPUF FSARG.

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 Inspection Procedures (IPs). 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 Implementation. Region II is responsible for implementing the inspection program described in this IMC. The scheduling and conduct of inspections will be coordinated with NRR, NMSS, and NSIR, as appropriate, to ensure the effective and efficient completion of the inspection program.

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 activities, and 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. Any changes in the schedule directly impacting inspections coordinated with NRR, NMSS, or NSIR personnel should be communicated to the affected individuals in as timely a manner as possible. 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 Inspection and Technical Personnel Considerations. Inspectors and technical representatives will be assigned responsibility for performing inspections consistent with their qualifications. In addition, inspectors performing inspection activities will either be provided familiarization training on this IMC and related procedures and/or become familiar with the requirements of this IMC and applicable regulatory requirements.

07.06 Inspection Requirements. 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.

07.07 Focus of Inspections. 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. As stated in 07.02, the NPUF FSARG will develop facility specific construction inspection plans.

The NPUF FSARG will use applicable information from licensing basis documents to identify those SSCs whose failure would most greatly impact safety (in consultation with NRR and NMSS technical and licensing personnel to assist in identifying SSCs with greatest impact on safety). This approach will allow the more 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, the CIP program should take into account:

- 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 facility specific inspection plan developed by the NPUF FSARG is considered a living document and can be modified based on inspection findings and licensee performance. If the inspection staff believes that additional inspections, beyond the planned CIP, are needed, then requests and justifications for the additional inspections should be coordinated through the Regional Project Inspector (RPI). The RPI will coordinate with the NPUF FSARG and appropriate management in order to determine whether a change to the plan is warranted.

Additionally, Inspectors should coordinate the development of specific inspection plans with the RPI for the facility.

07.08 Management Entrance and Exit Meetings. 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. Management 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.

07.09 Inspection Reports. 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, 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.

07.10 Communication with State and Local Government. 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.

07.11 Inspection Findings and Enforcement. 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 <http://www.nrc.gov>), using traditional enforcement tools. Inspection findings (or open items) 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 open items are appropriately documented in the inspection reports so that subsequent inspections can verify whether or not 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.

07.12 Assessment. 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, and provide feedback for NRC management's conclusions regarding the quality of the licensee's programs for protecting the public health and safety. 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. An initial recommended frequency for this assessment is once per calendar year.

07.13 Operational Readiness Inspection. 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.

The status of previously identified inspection findings 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 whether all planned inspections have been completed or whether 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 NRO and NRR that the CIP has been completed. If additional planned inspections need to be performed, the Inspection Report (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 required inspections to meet the minimum requirements of this IMC have been completed. Additional inspections may be performed to ensure continued compliance to programmatic and SSC related requirements.

07.14 Transition to Operations. Oversight responsibilities will transition from NRO to NRR when an NPUF Operating License is issued. Additional transition information may be promulgated by NRO/NRR/NMSS/Region II based on the specific circumstances of individual NPUF licensees.

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

Additional IPs covering Emergency Preparedness and Security are developed and maintained by NSIR. See the appropriate IMCs for a list of those IPs.

Construction Inspection Procedures	
IP 69020	INSPECTIONS OF STRUCTURES, SYSTEMS AND COMPONENTS DURING CONSTRUCTION OF NON-POWER PRODUCTION AND UTILIZATION FACILITIES
IP 69021	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	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: <http://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html#manual>.

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

- 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.
- b. 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 30 calendar days after inspection completion or 45 calendar days for team inspections.

3.7 Reports Preceding Escalated Enforcement Actions.

Timeliness goals should be accelerated for inspection reports covering potential escalated enforcement actions. For specific enforcement timeliness goals, see the [NRC Enforcement Manual](#).

3.8 Expedited Reports for Significant Safety Issues.

Whenever an inspector identifies an issue involving significant or immediate public health and safety concerns, the first priority is facility and public safety; issues of documentation or enforcement action are secondary. Based on the circumstances of the case, an expedited inspection report may be prepared that is limited in scope to the issue, or expedited enforcement action may be taken before the inspection report is issued. The NRC Enforcement Manual provides additional guidance on matters of immediate public health and safety 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. IMC 0610 Appendix E provides inspection writing style guidance which should be used in the development of NPUF inspection reports.
- b. Region II may prepare additional instructions or guidance on inspection reports based on the specific needs of the programs that they manage.
- c. The NRC inspection report is the document that states the official agency position on what was inspected, what the inspectors observed, and what conclusions were reached relating to the inspection.
- d. All enforcement, routine and escalated, and all other agency actions which may derive out of an inspection (such as orders) will be based upon the associated inspection report. Inspection reports must be clear, accurate, consistent and complete.
- e. The package created to document an NRC inspection will usually consist of two or three separate documents, as appropriate. In essentially all cases, there will be a cover letter and the inspection report itself. When warranted by the inspection findings, there should also be a Notice of Violation (NOV).

- f. The inspection report itself 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 three parts: the scope, the observations/findings, and the conclusions.
- g. 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.
- h. 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.
- i. Guidance and letter formats for escalated enforcement actions vary. Guidance and sample cover letters are found in the NRC Enforcement Manual.

4.2 Cover Letter. 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. Cover Letter Content. 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. Subject Line. 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. Introductory Paragraphs. The first two paragraphs of the cover letter should give a brief introduction, including the type of inspection report.

- d. Body. 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 items inspected and the inspection procedures used. It will note the areas 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. Closing. 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 Notice of Violation.

- a. Licensees are officially notified that they have failed to meet regulatory requirements when NRC issues a Notice of Violation (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 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 Cover Page. 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 Executive Summary. The Executive Summary will contain the important conclusions reached by NRC as a result of performing the inspection. 000000000000 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 Table of Contents. 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 Report Arrangement. 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

4.8 Report Details. 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 three parts: scope, observations and findings, and conclusions. These are discussed in more detail below.

- a. Inspection Scope. 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 “Purpose” section(s) 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) how the inspection was conducted (i.e., the methods of inspection), (2) what was inspected, (3) where 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.

- b. Observations and Findings. The observations and findings are the foundation of every inspection report. They are derived from performing inspections according to the applicable IP. There should always be a readily-identifiable connection between the stated Scope and the reported observations and findings. Thus, if the Scope was to review personnel dosimetry records, the observations and findings will not be about packaging and shipping problems.

Observations and findings will be descriptive, and will be relatively detailed compared to the other parts of the report documentation package. The amount of detail will be as much as is needed to make clear what was found, and whether it

was significant. The inspector should say what was observed or found in an unequivocal manner. If an inspector was looking to see if contamination was well controlled - and it was - the report should state: "Contamination was well controlled" not "Contamination appeared to be well controlled." If too small a sample was examined to reach an unequivocal conclusion, the qualifier state what specifically was inspected. For example, the report should state that, "Contamination was well controlled in the areas examined by the inspectors." If the inspector identifies no findings during an inspection (other than minor findings), the report should state "No findings of significance were identified."

Findings that are likely to have generic concerns should include details such as the manufacturer's name and model number for components, specifications, and other names and technical data that identify the item of concern.

In the case of a finding of a violation, it is critical that enough detailed information be given so that the interested reader can understand what the requirement was, and how it was not met. After the details of what occurred are provided, two specific concluding statements should be constructed. The first statement will define what the requirement was, including the regulation. The second statement will describe (or refer to a preceding description) how the requirement was violated. Additional actions or responses by the licensee, if any, should be included to fully describe the violation.

If a finding is to be referred to the Office of Investigations (OI), the inspection report should not lead a reader to conclude or infer that an OI investigation is possible. For findings referred to OI, the report should contain only relevant factual information collected during the inspection. The referral to OI is made by correspondence separate from the inspection report and includes any additional information needed to support the referral. One available option is to document only the pertinent facts of the event and open an unresolved item or inspection follow-up item to track the issue until resolved. Any reports containing material that may be related to an ongoing investigation should be reviewed by OI before being issued.

- c. Conclusions. The Conclusions are statements describing the quality of licensee performance in the area inspected. The report will discuss whether the licensee succeeded or failed, whether performance was adequate (or some other descriptor), and whether violations were identified. Every statement in a Conclusion section should have a basis (proof that it is correct) written in the observations and findings. The conclusion should also discuss how the inspection activity relates to a regulatory finding or licensee commitment. This is necessary to support the final determination by the staff the CIP has been completed and that all regulatory requirements and commitments have been met.

- 4.9 Exit Meeting(s) Summary. 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. Absence of Proprietary Information. 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. Subsequent Contacts or Changes in NRC Position. 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. Characterization of Licensee Response. 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. Oral Statements and Regulatory Commitments. 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 Report Attachments. 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. Key Points of Contact. 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. List of Items Opened, Closed, and Discussed (Optional). 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. List of Documents Reviewed. A list of the appropriate key documents and records reviewed during an inspection that are significant to any finding, must be publicly available. Therefore, if a list is not otherwise made public, the report should 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. List of Acronyms. 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. General Public Disclosure and Exemptions. Except for report enclosures containing exempt information, all final inspection reports will be routinely disclosed to the public. Information that should not appear in an inspection report is described in 10 CFR 2.790 and 9.17. Management Directive 8.8, Management of Allegations, addresses the manner in which an inspection report may be used to document allegation follow up activities. 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. Release of Investigation-Related Information. 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 SIGNIFICANCE OF OBSERVATIONS

This section discusses the significance of observations including violations, non-compliances and enforcement actions. The guidance provided in this section is for informational purposes. Final agency actions shall be reviewed against the guidance contained in the NRC Enforcement Policy (NUREG-1600) and the NRC Enforcement Manual.

5.1 **Thresholds of Significance.** When conducting inspections, the NRC inspector only reviews a small number of selected procedures, events, and operations; he or she cannot hope to monitor all the activities in progress, nor to document every minor discrepancy that occurs. As part of maintaining a focus on safety, inspectors continually use NRC requirements, inspection procedures, industry standards, regional and headquarters guidance, and their own training and insight to make judgments about which issues are worth pursuing and which are not.

To communicate effectively, inspection reports must give evidence of inspector judgment and prioritization. The report should discuss significant safety issues in appropriate detail, treating less significant issues succinctly, and avoiding excess verbiage. To maintain some consistency in how minor issues are treated, report writers must recognize certain "thresholds of significance": that is, they must use similar criteria in deciding whether an issue is important enough to document, important enough to track or follow up, etc.

- a. Thresholds of Significance for Noncompliance Issues. 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.

Note: For additional guidance in this area, see the NRC Enforcement Manual at: <http://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html#manual>. Also, Appendix E to Inspection Manual Chapter 0613, Power Reactor Construction Inspection Reports, contains examples of minor issues which are violations of requirements but have insignificant safety or regulatory impact or have no more than minimal safety significance. Although the appendix specifically addresses power reactor construction issues, the general methodology described can be applied to NPUF construction. The appendix explains how to determine whether or not the issue is minor. Depending on the circumstances of the observations and the judgments of the inspector and their supervisor an issue which is similar to an example in the appendix should be considered to be a minor violation which would not be documented in the inspection report.

1. Minor Violations-Determining Whether to Document. In general, minor violations should not 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 NRC Enforcement Policy. For example, "This failure constitutes a violation of minor significance and is not subject to formal enforcement action."

2. Violations Identified as Part of Licensee Self-Assessments. 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 root 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 not expected to cite the four violations individually, nor to report the details of those violations in the inspection report. Instead, the NRC report findings and conclusions should assess the adequacy of the licensee's quality assurance efforts, including 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 must 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 report 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 a licensee self-assessment due to the technical significance or generic implications of the particular item. Technical details

surrounding the violation 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 discuss 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. If the issue represents a minor violation, it should be documented as follows: "This failure is considered a minor violation and should not be documented in an inspection report."

Note, finally, that 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 not 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.

- b. Thresholds of Significance for Non-Enforcement-Related Issues. Inspectors must also make judgments about the relative significance of non-enforcement-related findings. As with enforcement issues, the judgment of individual inspectors will differ; questions on the relative significance of an issue should be discussed with other inspectors and with NRC managers.
 1. Determining the Significance of Negative Findings. The following questions should be used to determine whether or not a finding should be documented in the inspection report:
 - Does this finding have any actual impact (or any significant potential for impact) on safety?
 - Is this finding illustrative of a programmatic licensee problem that could have a safety or regulatory impact?
 - Does this finding provide insights on an equipment, system, or human performance problem?
 - Could this finding be viewed as the possible precursor to a significant event?

- If the licensee takes no action on this matter, will the condition worsen (i.e., will the safety significance increase)?
- If this finding recurs, will its recurrence result in more significant or additional safety concerns?
- Will this information be useful in assessing the long-term performance of this licensee program or functional area?
- Does this finding have generic significance?

If the answer to any one of these questions is "yes," the finding should be documented in the inspection report. If the answers to all questions are "no," the finding normally should not be documented.

2. Determining the Significance of Neutral or Positive Findings. For neutral or positive findings or for licensee improvements, similar thresholds of significance should apply. The inspector should ask questions similar to those below:

- Does this licensee improvement have an actual positive impact (or a significant potential for positive impact) on safety?
- Will the licensee's efforts to effect change in this area be likely to result in programmatic improvements to safety or regulatory performance?
- Will this upgrade be likely to result in improved equipment or system reliability or improved human performance? Does this information provide useful equipment, system, or human performance insights?
- Does this licensee action significantly reduce the probability of a particular event?
- Will this information be useful in assessing the long-term performance of this licensee program or functional area?
- Does this finding have generic significance?

If the answer to any one of these questions is "yes," the finding should be documented in the inspection report. If the answers to all questions are "no," the finding normally should not be documented.

NOTE: Inspectors should use care in giving credit or making strong positive statements for a proposed licensee action that has not yet been implemented, is in early stages of implementation, or has not been verified by the NRC.

3. Findings Previously Covered in Licensee Self-Assessments. This decision should be treated similarly to the corresponding decision for enforcement issues. In general, little benefit exists in NRC's re-emphasis of issues already covered in licensee self-assessments, unless there is some problem with the licensee's actions.

In some instances, however, the technical significance or generic implications of an issue merit ensuring that it is discussed on the docket and preserved as a matter of public record. If the licensee self-assessment that initially discussed the issue is already on the docket, the inspection report may simply refer to the discussion in the licensee self-assessment. If more

detail is needed, or if the licensee self-assessment is not on the docket, the inspector may wish to discuss the issue in the inspection report narrative.

5.2 Documenting Noncompliance. 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. Types of Noncompliance. 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 not 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 suggests 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 not 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."

1. Non-Escalated Enforcement Actions. Most violations of moderate significance (i.e., more than minor concerns) fall into the SL IV category. If at the time of issuing the inspection report a violation has been categorized at SL IV, then an NOV is generally sent out with the inspection report, as a "non-escalated" enforcement action. The cover letter for reports that include non-escalated enforcement actions should follow the appropriate NRC Enforcement Manual guidance.

NOTE: A violation's severity level should not be discussed in the report details. Whether an NOV accompanies the report or is issued later, the designation of severity level is made in the NOV itself.

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, these non-escalated enforcement actions follow a similar format and require a similar level of report detail.

2. 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. Non-Cited Violations. Section 2 of the NRC Enforcement Policy lists circumstances that result in consideration of an NOV requiring a formal written response from a licensee. When this enforcement discretion is applied, 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."

In addition, the 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. Minor Violations. 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 under the 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 Enforcement Policy, the subject report should state: "Discretion is being exercised after consultation with the Office of Enforcement pursuant to Section 3 of the Enforcement Policy and a violation is not being issued."

- b. Supporting Details and Discussions of Safety Significance. 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);
 - (f) Whether the violation appears isolated or programmatic;
 - (g) What corrective actions have been taken or planned, and
 - (h) Who was involved with the violation (i.e., management involvement)?

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. Noncompliance Involving Willfulness. 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;" not, "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 Office of Investigation (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

6.1 General Public Disclosure and Exemptions. Except for report enclosures containing exempt information, all final inspection reports will be routinely disclosed to the public. Information that should not appear in an inspection report is described in 10 CFR 2.390 and 9.17. Management Directive 8.8, Management of Allegations, addresses the manner in which an inspection report may be used to document allegation follow up activities. 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.

6.2 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, a present danger to public health or safety or to the common defense and security 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.
- 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 whether safety has been adequately and effectively maintained.

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 Overall Assessment Process. Typically, the regional office (in coordination with the FSARG as appropriate) will conduct an applicant/licensee performance review (APR) using the inspection findings compiled over the previous 12 months (four quarters). This review should consider activities identified in the previous APR. The output of this review is an APR assessment letter to the applicant/licensee. 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 IRs and any feedback on licensing performance received from the FSARG, as well as the NMSS and NRR program offices. Overall applicant/licensee performance will be based on the severity level and number of violations. The Agency's response and communication of applicant/licensee performance will follow the guidance in the Construction Action Matrix (CAM) (Exhibit 1 of this IMC).

4.2 Performance Reviews. The assessment process consists of a series of reviews which are described below.

- a. **Periodic Review.** 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 as appropriate) using the inspection findings and IRs conclusions compiled over the previous quarter. An assessment follow-up internal memo should be issued 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, an assessment follow-up letter to the applicant/licensee should be considered.
- b. **End-of-Cycle Review.** Region II will conduct (in coordination with the FSARG) an end-of-cycle review using documented inspection findings and inspection report conclusions compiled over the assessment period (typically a calendar year). This review incorporates activities from the periodic reviews (if performed).

In preparation for the end-of-cycle review, Region II will prepare a summary of inspection findings and documented conclusions related to applicant/licensee performance and a summary of allegations received and/or closed, and proposed inspections.

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 (see Exhibit 2 of this IMC), then the end-of-cycle review should be chaired by the Division Director, Division of Construction Projects or, if appropriate, the Region II Deputy Regional Administrator for Construction or his/her designee. Other routine participants should include representatives from the FSARG, NRO and NRR program offices, 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, Office of Investigations, Office of Enforcement, and Office of Nuclear Security and Incident Response.

The assessment letter should be issued within nine weeks of the end of the assessment cycle.

4.3 Public Meeting with Applicant/licensee. 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, NRR, NMSS and NSIR 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 Assessment Areas. The following assessment areas and associated attributes should be used to assess NPUF performance. Depending on the stage of the construction project, not all assessment areas would be applicable during a given assessment period.
- a. Quality Assurance Program. 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. Construction Oversight. 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. Pre-operational Oversight.
 1. Pre-Operational Activities. Pre-operational activities (when applicable) are effective and ensure systems and components important to the safety of the facility are fully tested to demonstrate that they satisfy design requirements. Management controls and procedures necessary for operation of the facility are effectively implemented.
 2. Training and Qualification of Facility Personnel. The training and qualification program (when applicable) is effective in training of personnel including managers, designers, technical staff, construction personnel, technicians, inspectors and other personnel whose level of knowledge is relied on for safety.

- d. Operational Readiness Activities. Activities completed during the operational preparedness phase to support the transition from construction to operation. The following performance areas should be coordinated with NRO, NRR, NMSS, and NSIR to assess applicant/licensee performance:
 - 1. Safety Operations. The safety operations performance area includes areas pertaining to facility operations
 - 2. Safeguards. The safeguards performance area includes areas pertaining to material control and accounting (e.g., physical protection of special nuclear material, and information security).
 - 3. Radiological Controls. The radiological controls performance area includes areas pertaining to radiation protection, environmental protection, waste management, and transportation.
 - 4. Facility Support. The facility support performance area includes areas pertaining to safety controls, management organization and controls, operator training, and facility modifications.
- e. Other Areas. This performance area is intended to include special issues that may arise on an occasional basis, 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 NRC Actions in Response to Applicant/licensee Performance Issues. The optional quarterly or the end-of-cycle assessment panels will determine the NRC response to significant performance issues. The staff may consider performance issues that extend across two or more performance areas and/or across two or more areas within a single performance area. Significant performance issues are defined as Severity Level I, II, and III violations.

- a. Description of the CAM. 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 through the use of supplemental construction inspections.

- b. Expected Responses for Performance in Each CAM Column. 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 the region. Following completion of the inspections, the Deputy Regional Administrator for Construction (DRAC), 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 regional division director with concurrence of the Director, DCIP.

Following the completion of the inspection, the Regional Administrator (or designee), the Director, NRO/DCIP and the Director, NRR/DPR 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 regional office 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 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 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 above those required by the CAM shall be discussed at the next APR 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.

END

Exhibit I NPUF Construction Action Matrix

		Column I	Column II	Column III	Column IV
RESULTS		Only Severity Level (SL) IV violations or non-cited violations NRC requirements fully met	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 applicant/licensee (Degraded Performance)	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 Loss of confidence to construct within NRC requirements (Unacceptable Performance)
	Regulatory Performance Meeting	None	Branch Chief or Division Director meets with applicant/licensee	Deputy Regional Administrator for Construction (DRAC) or designee meets with senior applicant/licensee management	Regional Administrator (RA) or designee meet with senior applicant/licensee management
RESPONSE	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	DRAC or designee reviews/signs assessment report	Regional Administrator reviews/signs assessment report
	Annual Public Meeting	Senior Project Inspector or Branch Chief meets with applicant/licensee	Branch Chief or Division Director discusses performance with applicant/licensee	DRAC or designee discusses performance with applicant/licensee	Regional Administrator or designee discusses performance with applicant/licensee
	Commission Involvement	None	None	None	Consider Commission meeting with senior management

Attachment 1 - Revision History for IMC 2550

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required And Completion Date	Comment and Feedback Resolution Accession Number (Pre-Decisional, Non-Public)
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