

NRC INSPECTION MANUAL

NMSS

INSPECTION MANUAL CHAPTER 2800

MATERIALS INSPECTION PROGRAM

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2800-01 PURPOSE

To establish the inspection program for U.S. Nuclear Regulatory Commission (NRC) licensees authorized to possess, use, store, transfer, and dispose of radioactive material associated with various types of use (e.g., industrial, academic, research and development, manufacturing, distribution, irradiators, well logging, industrial radiography, medical programs, various types of service (e.g., leak testing of sealed sources, calibration of instruments, servicing of devices, collection and repackaging of radioactive waste for final disposal)) and transportation related thereto.

2800-02 OBJECTIVES

- 02.01 To describe the types of materials inspections and establish the general policy for the materials inspection program.
- 02.02 To describe a performance-based, risk-informed inspection approach.
- 02.03 To place the major emphasis of the materials inspection program on timely and thorough follow-up of incidents, events, and allegations.
- 02.04 To establish relative, risk-informed priorities for routine inspections of licensees and the criteria for extending or reducing inspection intervals based on licensee performance.
- 02.05 To establish a consistent process of inspection for materials licensees to ensure the health and safety of workers and the public, protect the environment, and promote common defense and security.

2800-03 DEFINITIONS

- 03.01 Hybrid Inspection. A hybrid inspection is an inspection technique that allows for flexibility in planning and executing the inspection activities where some inspection activities are performed by direct observation and/or face-to-face licensee interaction and some inspection activities are performed from remote locations. Entrance meetings for hybrid inspections may be performed virtually and the exit meeting may be performed on-site or remotely upon the completion of all inspection activities. On-site verification, observation, or walkdown by an inspector or the inspection team is required to consider a hybrid inspection complete.

The inspector should identify the inspection activities that will necessitate on-site verification or face-to-face interaction with license personnel during inspection planning and discuss with their peers if it will be team inspection.

- 03.02 Initial Inspection. The first inspection conducted after a new license is issued.
- 03.03 Inspection. The act of assessing licensee performance to determine whether the licensee is using radioactive material safely and whether an individual or organization is in compliance with established standards, such as orders, regulations, license conditions, and the licensee commitments submitted in support of an application and incorporated into the license. Inspections typically involve a visit to a licensee's facility or temporary job site or both by inspector(s), observations of licensed activities, interaction

with licensee personnel, independent radiological measurements, and communication of the inspection results. Pre-licensing visits and onsite security reviews are not inspections.

- 03.04 Inspection Plan. An inspection plan is a written outline listing the licensee's activities and programs that will be covered during an inspection.
- 03.05 Inspection Priority. The inspection priority is assigned to each radioactive material license during the licensing process based on program code(s). The priority (i.e., 1, 2, 3, 4, 5, or 5R) is the interval between routine inspections, expressed in years. The list of the program codes (types of use) along with the assigned priority codes can be found at <https://www.nrc.gov/materials/miau/mat-toolkits.html>. The inspection priority is based on the relative risk of radiation hazard. Priority 1 represents the greatest risk to the health and safety of workers, members of the public, and the environment, while Priority 5R represents the lowest risk. Because a license may authorize multiple types of use (i.e., multiple program codes), the inspection priority for the license is based on the program code with the shortest routine inspection interval. For more information on inspections of Priority 5R licensees, please see section 05.04.
- 03.06 Limited Scope Inspections. Inspections that do not cover the full scope of licensed activities or the inspection procedure or both.
- 03.07 National Materials Program (NMP). The broad and collective effort within which the NRC and the Agreement States function in carrying out their respective regulatory programs for radioactive material. The goal of the NMP is the protection of public health, safety, security, and the environment associated with the hazards of radioactive material while effectively using regulatory resources.
- 03.08 Non-Routine Inspection. Those inspections specified in section 2800-07 that require additional guidance. Non-routine inspections include: 1) reactive inspections; 2) inspections of bankrupt, expired, abandoned, or revoked licenses; 3) follow-up inspections to escalated enforcement; 4) reciprocity inspections; 5) inspections of significantly expanded licensee programs; 6) general licensee inspections; and 7) inspections of licensees undergoing decommissioning.
- 03.09 Onsite Inspection. An inspection technique where most inspection activities are performed through direct observation of licensed activities, including walkdowns of the facility, interviews, and review of licensee documents and records. If a licensee needs to provide any records/documents after the on-site inspection that could not be located while the inspector was on-site, this inspection would still be considered an on-site inspection.
- 03.10 Onsite Security Review. A site visit conducted before the issuance of a new license or amendment authorizing the possession of an aggregated Category 1 or Category 2 quantity of radioactive material to ensure that the applicant or licensee is prepared to meet the additional security requirements of Title 10 of the *Code of Federal Regulations* (CFR) Part 37.
- 03.11 Open Items. A generic term that can encompass any previous violations that have not been closed, any incidents or events reported since the last inspection requiring review, or any other issues requiring additional review.

- 03.12 Performance-Based Approach. A regulatory approach that establishes measurable outcomes as the primary bases for regulatory decision making. Elements of a performance-based approach to an inspection include observations of activities, interviews with licensee personnel, conduct of independent and confirmatory surveys, and review of records.
- 03.13 Pre-Licensing Visit. A face-to-face meeting with an applicant, usually at the proposed site of use/storage, conducted to provide a basis for confidence that radioactive material will be used as specified in the application. Staff should use the Pre-licensing Checklist to determine which applicants require visits.
- 03.14 Reactive Inspection. A non-routine inspection conducted in response to an incident, allegation, or information obtained by NRC (e.g., report of a medical event, information shared by an Agreement State, information obtained as a result of the issuance of a generic letter or bulletin, or other Federal agency interests). Reactive inspections may focus on one or several issues and need not examine the rest of a licensee's program. If the reactive inspection does not cover all the activities normally reviewed during a routine inspection, then it does not satisfy the requirement to inspect the licensee at the routine, established interval.
- 03.15 Regional Management. In the context of this IMC, regional division directors and/or supervisors. Each region should determine the appropriate level of management involvement based on the circumstances. It normally involves division level oversight; however, it could be delegated to the supervisor, if needed.
- 03.16 Remote Inspections. A remote inspection is an inspection technique where all inspection activities are performed from a remote location. Licensee documents and records are provided directly to the inspector electronically or through an agreed-upon third-party file sharing method. Remote communications resources can be utilized so that no on-site presence is required to complete the inspection and any requests for additional information from licensee personnel are expected to be adequate to resolve any issues or concerns identified during the remote inspection. If extensive interaction with licensee personnel is anticipated during the course of a remote inspection, or substantial issues are identified which cannot be adequately resolved remotely, or inspector cannot adequately verify compliance via remote inspection, the inspection should transition to a hybrid or on-site inspection.
- 03.17 Risk-Informed Approach. A philosophy in which risk insights are considered together with other factors to determine a course of action that focuses inspection activities commensurate with the licensee's authorized program. Risk can be determined by evaluating the combined answer to three questions (i.e., the risk triplet): (1) what can go wrong, (2) how likely it is, and (3) what its consequences might be.
- 03.18 Risk-Module. A component in the Inspection Procedures used to focus the inspection effort on licensed activities that present higher risk for a particular licensee type, or radiation safety program areas that are expected to effectively reduce the risk associated with the use of radioactive material.
- 03.19 Risk-Significant Radioactive Material (RSRM). RSRM refers to the values of Category 1 and 2 material as identified in 10 CFR Part 37, Appendix A.

- 03.20 Routine Inspection. Periodic, comprehensive inspection performed at a specified interval based on the activities authorized under the license. Routine inspections include inspections of authorized locations of use, including permanent and temporary job sites; interviews with key personnel; and review of selected documentation and records.
- 03.21 Team Inspection. For the purposes of this Inspection Manual Chapter (IMC) only, team inspections are defined as those inspections conducted by more than three qualified inspectors, or any materials inspection that includes a representative from outside NRC (other than members from a State's radiation control program). Often, at least one of the inspectors is included on the team because of a specialty in a particular field and may come from a different region or office. Individuals that are observing the inspection for training purposes do not count toward the total number of inspectors. Team inspections can be routine inspections of a large or complex licensee, or reactive inspections in response to a complex or unusual incident or event. Team inspections do not include those where a supervisor or program office staff member accompanies an inspector to evaluate the inspector's performance. In this context, team inspections are not meant to cover Augmented Inspection Teams (AITs) or Incident Investigation Teams (IITs), described in Management Directive (MD) 8.3, "NRC Incident Investigation Program," or Special Inspection Teams (SITs), described in Inspection Procedure (IP) 93812, "Special Inspection."
- 03.22 Very low safety significance issue resolution process. A process used to discontinue evaluation of an issue involving an unresolved licensing basis¹ question in which: (1) the resolution of the issue would require considerable staff effort; and (2) the agency has chosen to not expend further effort to resolve the question because the issue would be no greater than very low safety significance.

2800-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Director, Office Nuclear Material Safety and Safeguards (NMSS)

Provides overall program direction for the NRC materials inspection program.

04.02 Regional Administrator(s)

Oversees implementation of the materials inspection program within their respective region.

04.03 Director, Division of Materials Safety, Security, State, and Tribal Programs (MSST)

- a. Develops and directs the implementation of policies, programs, and procedures for inspecting applicants, licensees, and other entities subject to NRC jurisdiction.

1. In the context of VLSSIR, the term "licensing basis" refers to all regulations, license conditions, and requirements applicable to a facility or licensee, including, but not limited to, the licensee's written commitments for ensuring compliance.

- b. Assesses the effectiveness, uniformity, and completeness of implementation of the materials inspection program.
- c. Approves changes to the materials inspection program.
- d. Ensures that operating plans are consistent among the regional offices responsible for materials inspections.
- e. Uses the agency's Enterprise Risk Management System to characterize, assess, and mitigate risks associated with the implementation of the materials inspection program.
- f. Coordinates with the regional offices to obtain technical assistance, as necessary.

04.04 Director(s), Regional Division of Radiological Safety and Security (DRSS)

- a. Manages the implementation of the inspection program elements performed by their respective region.
- b. Ensures, within budget limitations, that the regional office staff includes adequate numbers of inspectors to carry out the inspection program described in this chapter, including reactive inspections.
- c. Applies inspection resources, as necessary, to deal with significant issues and problems at specific facilities.
- d. Coordinates with MSST to obtain technical assistance, as necessary.
- e. Recommends changes to the materials inspection program to the Director, MSST.

04.05 Supervisor(s), Regional Materials Inspection Program

- a. Implements the regional materials inspection program.
- b. Reviews and approves inspection schedules.
- c. Reviews enforcement actions in accordance with NRC enforcement guidance.
- d. Ensures that regional materials inspectors achieve and maintain qualifications, in accordance with IMC 1248.
- e. Ensures that the performance of each inspector who routinely performs inspections is evaluated during actual inspections at least once annually. For qualified inspectors who no longer routinely perform inspections, the individual should be evaluated at an appropriate frequency, as established by regional management, relative to their other assigned duties.
- f. Proposes changes to the materials inspection program and encourages inspectors to propose changes to the materials inspection program in accordance with section 2800-14 of the document.

2800-05 BASIC REQUIREMENTS

The NRC employs a performance-based, risk-informed approach in its materials inspection program. Non-routine inspections [See section 2800-07] are of the highest importance and are scheduled commensurate with the health, safety, or security significance of the issue(s); followed by initial inspections [See section 05.02]; and then routine inspections [See section 05.03] based on inspection priority.

Most inspections are performed by a single inspector. There may be instances, based on the scope or complexity of the license, where multiple inspectors are assigned to perform the inspection. When more than three inspectors participate, it is considered a team inspection.

The physical presence of the Radiation Safety Officer (RSO) is not required to perform an inspection; however, an inspection will not be considered to have been performed if the licensee or licensee's representative(s) is not available to assist with the inspection. The inspector may document any attempted inspections by placing a signed note on the docket. Additional attempts will be made until the inspection can be performed. The inspector may consider announcing the inspection in accordance with section 05.03.

05.01 General Inspection Process

For each inspection, the inspector should implement the process described below for pre-inspection activities, onsite inspection activities, and post-inspection activities. Inspection activities must also be conducted in accordance with applicable Management Directives (MDs), Inspection Manual Chapters (IMCs), and Inspection Procedures (IPs) for the type of inspection or type of license being inspected. The pertinent MDs, IMCs, and IPs listed in Enclosure 1 provide additional specific guidance for onsite inspection activities. Section 2800-09 provides guidance for documenting inspection results.

Regional offices are expected to utilize the tools and capabilities of the Inspection Module of the Web-Based Licensing System (WBL) to track and capture inspection related information. Although most inspections are normally conducted onsite, the supervisor may approve, upon inspector(s) request, performing an inspection remotely (other than priority 5R) or portions of an inspection remotely (hybrid approach). The Inspection Module in WBL has the capabilities to capture whether an inspection was performed onsite, remotely, or with a hybrid approach. Guidance for data-entry in WBL is available in the [WBL User Portal](#).

The inspection start date is the first day onsite. For a remote or hybrid inspection, the inspection start date is the day that the inspector performs an inspection activity such as interviewing licensee staff about licensed activities or reviewing documents provided by the licensee to the inspector. The inspection is not started by contacting the licensee about performing the inspection, scheduling the inspection, reviewing documents previously provided by the licensee, or requesting documents to be reviewed—these activities are considered preparation for the inspection.

The inspection end date is when the final exit meeting is held. The inspection is not considered done upon holding a preliminary onsite exit meeting. The inspection is considered closed in WBL when the results of the inspection have been transmitted to the licensee and filed in the docket; if a notice of violation is issued which requires a response, the inspection is not closed until any response to a notice of violation is received and accepted.

IMPORTANT NOTE

The inspector may also find useful best practices for preparing for and conducting inspections in [NUREG/BR-0334](#), "Materials Inspection and Licensing Handbook: Best Practices."

- a. Pre-inspection activities. The goal of inspection preparation is to ensure that the inspector is sufficiently familiar with the types of uses and the generic requirements applicable to the licensed program. The effort expended on inspection preparation should be based upon the complexity and scope of licensed activities and on the experience level of the individual inspector. Inspection plans may be developed for complex inspections. The extent to which the inspector prepares for routine inspections should be based on expectations set by the supervisor.

To be adequately prepared for an inspection, the inspector should review:

1. the license and all the current licensing documents. The inspector should determine if the license has any unusual license conditions or commitments or both that would affect the approach to the inspection, such as authorization for an incinerator, authorization for use of material at temporary job sites, significant changes in licensed operations, or implementation of security requirements for RSRM;
2. the licensee's recent inspection and enforcement history, including the results of the last inspection and any open items. If the licensee also has an Agreement State license, the inspector should contact the Agreement State to obtain recent inspection and enforcement results. If the licensee has several Agreement State licenses (i.e., national company), the inspector may contact the Agreement State that holds the license for the corporate office and where the company has been most active. Leveraging the collective efforts of the National Materials Program will result in a more risk-informed inspection.
3. any events that have been reported by the licensee during the current inspection cycle;
4. any commitments made by the licensee or restrictions imposed by the NRC as a result of a Confirmatory Action Letter or an order issued since the last inspection;
5. any information on the docket regarding additional inspection emphasis. For example, a license reviewer's note to request a near-term inspection regarding a recent licensing action [see section 07.05];
6. any unique requirements, guidance, questions and answers, or supplemental correspondence pertaining to the license (e.g., licensee responses, requests for relief, and final NRC determinations);
7. any allegations or ongoing investigations by the Office of Investigations [see section 07.01.b];
8. if the licensee is required to report to the National Source Tracking System (NSTS), the NSTS inventory record in advance; and,
9. if the licensee is authorized to possess sufficient quantities of source or special nuclear material to be required to report the possession of these materials to the

Nuclear Materials Management and Safeguards System (NMMSS), a copy of the licensee's inventory generated by the NMMSS contractor, the NMMSS Task 8 – Inspection Report Package [see enclosure 2].

To prepare for a reactive or other non-routine inspection, the inspector will review specific information, as determined by the inspector and the supervisor on a case-by-case basis [See section 2800-07].

The inspector should anticipate whether sensitive or controlled information will be handled during the inspection. The inspector should be aware of minimum handling requirements for sensitive or controlled information (i.e., Safeguards Information, Official Use Only, Proprietary Information, Security-Related Information, and Personally Identifiable Information). The inspector should contact the regional security advisor or refer to the internal web page for guidance on generating, marking, and handling sensitive or controlled information.

The inspector will identify the location(s) of the licensee(s) to be inspected, discuss any special travel-related aspects of the inspection trip with the supervisor (for example, special considerations for remote locations or temporary job sites), make travel arrangements, and obtain the supervisor's approval for the travel itinerary. Before the inspection trip, the inspector or Regional State Agreements Officer shall convey the itinerary to the State radiation control program to give the State personnel an opportunity to observe the routine inspections [See section 2800-11].

The inspector will select appropriate and calibrated radiation detection instrumentation for the inspection. The inspector will wear assigned NRC-issued dosimetry and consider any personal protective equipment requirements for access to licensee sites or based on anticipated hazards that may be encountered. The inspector must be prepared to meet all entry requirements established by the licensee (i.e., view the licensee's safety video, use personal protective equipment, or meet any special requirements for entering sterile environments).

- b. Onsite Inspection Activities. Based on the pre-inspection activities, the inspector should be prepared to evaluate the licensee's performance of its radiation protection program. The inspector should conduct the inspection in a manner that will adequately assess licensee performance relative to the risk-modules identified in the applicable inspection procedure(s).

Some procedures have focus elements instead for risk-modules. These are structured as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures; medical events; or release, loss, or unauthorized use of radioactive material. Section 3 of each program-specific IP describes the applicable risk-modules or focus elements.

Performance-Based, Risk-Informed Approach. The inspector should use a performance-based, risk-informed approach to evaluate the risk-modules and focus elements. A determination regarding safety and compliance with NRC requirements should be based on direct observation of work activities, interviews with licensee workers and contracted personnel performing licensed activities, demonstrations by appropriate workers performing tasks regulated by the NRC, independent measurements of radiological conditions at the licensee's facility, and a review of selected records. Direct examination of these licensed activities and discussions with

cognizant workers should provide the inspector with reasonable assurance of a licensee's ability to safely use licensed material and is preferable to a review of selected records alone.

If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of a risk-module or focus element, the inspection effort expended in reviewing that particular risk-module or focus element will be considered complete. If the inspector determines that the licensee did not meet the performance expectation for a given risk-module or focus element (for example, a potential violation is identified or an incident, reportable or otherwise, occurred), the inspector should conduct a more thorough review of that aspect of the licensee's program in order to identify all pertinent requirements, and to determine the span and significance of performance concern. The increased inspection effort may include additional sampling, determination of whether the licensee's procedures are appropriate, and a review of selected records maintained by the licensee documenting activities and outcomes.

The inspection should cover the period since the last inspection. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, non-compliance, high radiation exposures, or allegations.

IMPORTANT NOTE

The inspector shall not under any circumstances knowingly allow an unsafe work practice or a violation that could lead to an unsafe situation to occur or continue in the inspector's presence in order to provide a basis for enforcement action.

Safety Culture Awareness. In general, there are no specific regulatory requirements for safety culture; however, the inspector should develop a general sense of the licensee's safety culture for licensed activities (e.g., workers have a "questioning attitude" and generally adhere to procedures, workers are duly cautious when engaged in licensed activities, or workers are willing to raise safety concerns). The inspector's conclusions about safety culture may be useful when violations are identified and linked to significant risk (i.e., there are an unacceptable number of occurrences with unacceptable health and safety consequences). More information on NRC activities relating to safety culture can be found at <https://www.nrc.gov/about-nrc/safety-culture.html>.

Other common elements to every inspection are discussed below.

1. Entrance Meeting. After arriving on site, the inspector should inform the licensee's management or licensee management representative(s) of the purpose and scope of the inspection to be performed. This notification should be made as soon as practical after arriving on site. However, in certain instances, the inspector may choose to inform the licensee of his or her presence on site after initial observations of licensed activities currently in progress.

The purpose of the entrance meeting is to inform licensee management or licensee management representative(s) that an inspection is being conducted and to indicate the tentative schedule for discussing or reviewing selected inspection items with various licensee staff personnel. However, in some instances, the inspector may only

need to inform licensee management or licensee management representative(s) of NRC's presence on site and apprise management that an exit meeting will be conducted at the end of the inspection to detail the inspection findings.

The entrance meeting is often an opportune time for the inspector to determine the availability of key personnel to be observed and interviewed. This will enhance inspector efficiency and give the licensee the opportunity to have the most knowledgeable individuals present to respond in the areas being inspected.

The inspector should discuss with the licensee management or licensee management representative(s) any recent issues related to the licensed program, such as equipment issues, excessive or unusual personnel exposures, unexpected releases to the environment, quality assurance issues, loss of material, and any other unusual radiological issues. The licensee representative's responses may help the inspector assess licensee management's awareness of the radiation protection program. The licensee representative's responses may also help the inspector identify any previously unreported events or trends in licensee performance.

When an inspection is likely to involve sensitive information, including but not limited to proprietary, security-related, personally identifiable, and patient information, the inspector should discuss with licensee management or licensee management representative(s) during the entrance meeting how the information will be handled during the inspection.

2. Review of Open Items. Determine whether the licensee took appropriate action in response to cited violations identified during the previous inspection. Determine whether the licensee took the corrective actions as described in its response to the Notice of Violation (NOV) and addressed safety concerns and any open items identified during the previous inspection, including allegations.
3. General Overview. The inspector should understand the current organization size, and scope of the radiation protection program.
 - (a) Organization. Interview cognizant licensee representatives about the current organization of the program. Examine the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Identify the reporting relationship and management structure between the licensee's executive management, the RSO, and, if applicable, the Chairperson and other members of the Radiation Safety Committee (RSC).
 - (b) Scope of Program. Interview cognizant personnel to determine the types, quantities, and use of licensed material, frequency of use, staff size, etc., and any anticipated changes. Determine if the licensee possesses material in accordance with a general license.
4. Observations of Actual Facilities and Licensed Activities. Ideally, the inspector should observe work in progress that involves NRC-regulated activities. Emphasis should be placed on observing licensee performance as it relates to staff training, equipment operation and adequacy, review of licensed work done by contracted personnel, overall management of the licensed program, and integration of safety. If there is no opportunity, then the inspector should ask the workers to demonstrate and explain

selected licensed activities. Note that workers should be asked to perform demonstrations that do not unnecessarily expose themselves to radiation.

IMPORTANT NOTES

- 1.) Inspectors should avoid handling licensee equipment. Inspectors should request that licensee personnel demonstrate the use of equipment and special facilities, open/close containers, or other such activities. This allows the inspector to observe the staff's familiarity with the equipment and knowledge of its use. It also eliminates the possibility of the inspector mishandling or damaging licensee property.
- 2.) It is important to inspect licensed activities at temporary job sites, if possible [See section 05.03.b].

- (a) Perform a walk-through of the licensed facility to make general observations of the condition of the facility and the licensed activities being performed. The walk-through may be performed at any time during the inspection. The inspector may need to return to some areas of the facility at a later time to observe specific activities.
- (b) Conduct inspections of licensed operations, regardless of shift.
- (c) Make direct observations of radiation safety systems and practices in use.
- (d) Make direct observations of physical security systems and storage locations, with particular attention to facilities which possess RSRM quantities or quantities reported to NMMSS and NSTS.

Unless the inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with licensed activities. For example, the inspector should not insist on interviews when: a worker is delayed in performing scheduled work activities (i.e., delayed departure to a temporary job site); a worker is preparing or administering dosages or doses, a worker is providing patient care, or a licensee is dealing with customers or members of the public.

5. Interviews with Licensee Personnel. The inspector should conduct interviews with licensee personnel to identify or confirm health and safety or security problems that may not be immediately evident from other sources such as observations or records review. These interviews can also be used to confirm the implementation of the radiation protection program; to assist the inspector in the understanding of licensee management's awareness of the radiation protection program; and to provide insight into organizational changes, responsibilities, and staffing.
6. Independent and Confirmatory Measurements. Independent measurements are those performed by the inspector without comparison to the licensee's measurements. Confirmatory measurements are those performed by the inspector with comparison to the licensee's measurements. The inspector will perform independent or confirmatory measurements or both in areas of interest, such as

areas of use and storage, effluent release points, and other locations at the inspector's discretion. The inspector should use calibrated, NRC-owned instruments for independent and confirmatory measurements.

7. Record Review. Review of licensee records and other documents should be directed toward verifying that current operations are in compliance. Review of "historical" records may be needed to guide the inspector in determining the extent of condition of any identified issues.

In general, inspectors should use caution before leaving the site with copies of licensee documents, unless they are needed to support apparent violations, or requesting licensees to submit information needed to complete the inspection. When an apparent violation has been identified, the inspector should obtain copies of all records that are needed to support the apparent violation, as appropriate. The inspector should determine whether the licensee has declared the information reviewed or gathered as proprietary and ensure that it is handled accordingly.

In all cases where licensee documents are retained beyond the inspection, inspectors must follow the requirements of IMC 0620, "Inspection Documents and Records." Inspectors shall ensure that the licensee understands that the retained record may become publicly available and shall give the licensee the opportunity to provide redacted copies or to request withholding the information pursuant to the requirements of 10 CFR 2.390(b)(1).

8. Special License Conditions. Verify the licensee's compliance with any special license conditions that are unique to a particular practice, procedure, or piece of equipment used by the licensee. In these instances, the inspector should verify that the licensee understands the additional requirements and maintains compliance with the special license conditions.
9. Communication of Findings. The inspector must advise the licensee of the inspection findings throughout the course of the onsite inspection. The inspector should not wait until the exit meeting to inform the licensee of findings or concerns. The inspector should allow ample time during the inspection for a licensee to correlate information about root cause, consequence, and corrective action for an apparent violation. The inspector shall clearly present apparent violations and confirm the licensees understanding and agreement that a violation occurred, preferably before leaving the site.

The inspector must keep regional management informed of significant findings, such as potential escalated enforcement, identified during the inspection. This will help ensure that the inspector is following appropriate NRC guidance under such circumstances.

Prompt corrective action must be initiated by the licensee for concerns or violations of requirements that affect the security of radioactive materials or safe operation of a licensee facility. The inspector should not leave the site until the concern is fully understood by the licensee and corrective action has been initiated. If the inspector and licensee disagree on the magnitude of concern regarding the security of radioactive materials and safe operation of the facility, the inspector should notify regional management as soon as possible.

10. Exit Meeting. At the conclusion of the inspection, the inspector must conduct an exit meeting. The purpose of the exit meeting is to discuss inspection results. The inspector should inform the licensee that inspection results, including the characterization of any proposed or apparent violations, could change based on NRC management review.

If additional review of an issue is needed, the inspector should conduct a preliminary exit meeting while on site to inform the licensee of any potential findings and the path forward for resolution. As soon as practical after the inspection is completed, the inspector should hold a final exit meeting with licensee management, the licensee's RSO, and other designated individuals, commensurate with the type and significance of the findings. This meeting may be conducted remotely.

During the exit meeting, the inspector should confirm the licensee's understanding of any violations and associated corrective actions. If the licensee disagrees with the findings, the inspector should inform regional management. It may be necessary to continue the inspection or modify the finding(s). The inspector shall inform the licensee about the next steps in the enforcement process.

The inspector should explain safety/security-related concerns or open items identified during the inspection, and the status of any previously identified violations. Although deficiencies identified in some areas (e.g., workers' knowledge of the Part 20 requirements) are not always violations, the inspector should bring such observations to the attention of licensee management at the exit meeting.

c. Applicability of Very Low Safety Significance Issue Resolution Process (VLSSIR)

NOTE: The VLSSIR process cannot be used to resolve known compliance issues, issues where there is a clear indication that a non-compliance occurred but certain details concerning the issue have not been finalized (e.g., specific date, time, location), nor should it be used to establish a staff position.

In some cases, an inspector may identify an issue that results in an unresolved licensing basis question which may take staff considerable effort to resolve. In the context of VLSSIR, the term "licensing basis" refers to all regulations, license conditions, and requirements applicable to a facility or licensee, including, but not limited to, the licensee's written commitments for ensuring compliance. In determining how to proceed, the inspector should consider safety significance of the issue. If the issue is no greater than very low safety significance, further evaluation of the issue can be discontinued using the VLSSIR process. If further evaluation of the issue cannot be discontinued using the VLSSIR process, then resolution of the issue should be continued following existing processes, including the identification of an unresolved issue and/or use of the headquarters technical support for regional activities, e.g., Technical Assistance Request (TAR) process. The Office of Nuclear Material Safety and Safeguards is developing guidance to assist in determining if an issue is no greater than very low safety significance and the documentation of issues dispositioned using this process.

If evaluation of an issue is discontinued using the VLSSIR process, no further staff effort to resolve the issue is necessary. Documentation of the issue should provide an appropriate level of inspection closure, knowledge management, and transparency.

Once a VLSSIR is documented the staff should generally refrain from spending additional inspection resources on the issue.

- d. Post-inspection Activities. After returning from an inspection trip, the inspector shall inform the supervisor of the results of the inspection(s). Even if preliminary findings have been discussed with the supervisor during the inspection, enforcement, safety, security, or regulatory issues should be discussed with the supervisor upon return from the inspection. The inspector shall document the inspection results in accordance with guidance in this IMC [See section 2800-09] and other chapters, as appropriate.
- e. Requests from Licensees for Assistance. On occasion, licensees ask inspectors for help resolving issues. Inspectors may direct licensees to publicly available documents on the NRC website, such as NUREGs, Information Notices, or Regulatory Guides. Inspectors are prohibited from recommending the services of specific individuals or organizations for a project under NRC regulatory jurisdiction. Providing such a recommendation violates 5 CFR 2635.702, which prohibits Federal employees from using public office for endorsement of any product, service, or enterprise. However, the agency also has an obligation to provide assistance where possible in helping individual licensees solve problems that affect public health and safety.

If the inspector receives a request for third party assistance, the inspector may refer the requestor to a professional group, such as the American Nuclear Society, the Conference of Radiation Control Program Directors, Inc. (CRCPD) or the Health Physics Society; qualified consultant(s); equipment manufacturer(s); or licensee(s) that has solved a similar problem. When providing the name(s), the inspector should take special care not to create a perception of endorsing one third party over others. The inspector should also take special care when providing recommendations concerning third parties with whom the recommending staff has a personal or long-standing relationship.

If the inspector receives a request related to an immediate health and safety issue, the inspector should collect sufficient information to determine if immediate assistance is needed. In this case, the inspector may choose to offer immediate technical assistance or may refer the licensee to a specific third party. Following recommendation of a specific third party or a third party with whom the inspector has a personal or long-standing relationship, the inspector should consult with the supervisor on the matter.

05.02 Initial Inspections

Initial inspections of a new license shall be announced and normally completed within

12 months of the date the new license was issued; however, as described below, if the licensee does not yet possess licensed materials or has not yet performed any principal activities², the initial inspection may be rescheduled to within 18 months of license issuance.

2. As defined in 10 CFR Parts 30, 40, or 70, as applicable, principal activities, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or

- a. Scheduling Initial Inspections. Contact the licensee to schedule and announce the initial inspection. During the contact, the inspector should determine if the licensee possesses licensed material or has performed any principal activities. If the licensee possesses licensed materials or has performed principal activities, then the inspector should conduct an inspection in accordance with section 05.01 and other applicable guidance.

If it is determined that the licensee does not possess licensed material or has not performed principal activities, the inspector should:

1. Determine the licensee's plans for future possession of licensed material or plans to perform principal activities.
2. Use the opportunity to discuss the license and applicable regulations with the licensee. The inspector should discuss any unique license conditions and give the licensee an opportunity to ask any regulatory questions.
3. Request the licensee to notify the NRC within 30 days after the receipt of licensed material or initiation of principal activities to aid in the efficiency of scheduling the initial inspection.
4. Document the contact on a conversation record and file the record on the docket and update tracking systems, as appropriate. The record should include the licensee's plans for future possession of material or plans to perform principal activities.
5. Ensure that the inspection due date is set so that an onsite inspection is performed no later than 18 months from license issuance.

- b. Performing initial inspections. During the initial inspection, the inspector should interview licensee personnel to determine if licensed material was received or if principal activities have been performed. Methods for determining if principal activities have been performed include but are not limited to the following: performing a site tour, performing independent measurements, or contacting distributors of licensed material, such as local radiopharmacies, to see if they have distributed material to the licensee. If the licensee has possessed licensed materials or performed principal activities, then the inspector should conduct an inspection in accordance with section 05.01 and other applicable guidance.

If it is determined that the licensee does not possess licensed material or has not performed principal activities, the inspector should:

1. Determine the licensee's plans for future possession of licensed material or plans to perform principal activities. In assessing the licensee's future plans, the inspector should determine if adequate facilities and equipment are in place to safely handle licensed material, as described in the license application.

(continued from previous page) amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

2. Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should discuss any unique license conditions and give the licensee an opportunity to ask any regulatory questions.
 3. Request the licensee to notify the NRC within 30 days after the receipt of licensed material or initiation of principal activities to aid in the efficiency of scheduling future inspections.
 4. Remind the licensee of the requirement in 10 CFR 30.36(d), 10 CFR 40.42(d), or 10 CFR 70.38(d), as applicable, to provide written notification to the NRC within 60 days if no principal activities under the license have been conducted for a period of 24 months.
 5. Document the onsite inspection by completing the appropriate inspection record. The “program scope” description should include the licensee’s plans for future possession of material or plans to perform licensed operations.
 6. Ensure that the due date for the next attempt at an initial inspection is set for 12 months from the date of the onsite inspection. To achieve the goals of cost saving and efficient use of staff time and travel, the date of the next initial inspection may be extended for an additional 6 months.
- c. New licenses excepted from an initial inspection. There are certain circumstances that require a new license to be issued to the licensee, but an initial inspection is not warranted.
1. New licenses that are issued as a result of a change of ownership or transfer of control are not required to receive an initial inspection unless:
 - (a) the organization controlling the licensed activities changes substantially (i.e., changes in key personnel, authorities, or resources associated with the radiation protection program);
 - (b) the licensee significantly increases the types, quantities, or forms of radioactive materials on the license;
 - (c) the licensee significantly increases the different uses authorized on the license (i.e., adds brachytherapy to a diagnostic nuclear medicine license);
 - (d) the licensee significantly increases the number of authorized users; or
 - (e) the new license authorizes one or more new facilities.

If none of these conditions applies, the “last inspection date” and “next inspection date” for the licensee’s previous license still apply to the new license.

2. New licenses that are issued because a licensee did not file a timely application for license renewal. The “last inspection date” and “next inspection date” for the licensee’s previous license still apply to the new license. An expired license may necessitate a non-routine inspection in accordance with section 07.02.

05.03 Routine Inspections

Routine inspection of licensees shall be conducted at intervals in years corresponding to the inspection priority³. If the licensee has possessed material or performed principal activities since the last inspection, the inspector should perform a routine inspection of the facility as defined in the program-specific inspection procedure. If the licensee has not possessed material or performed principal activities since the last inspection, the inspector should follow the instructions in section 05.02(b)(1) through (6), as applicable.

Routine materials inspections should normally be performed on an unannounced basis. However, to improve the efficiency of inspection trips and to reduce agency costs, after consultation with the supervisor, the inspector may contact licensees to verify that the inspection can be performed effectively and efficiently at the intended time.

Routine inspections may include inspections at multiple locations or temporary job sites or both. Locations may include the main facility where principal activities are performed, field office(s), permanent or fixed facilities, the corporate office where records are maintained, or temporary job sites, as authorized on the license. For licenses that require multiple locations to be inspected, the inspection interval is set by the inspection of the office where radiation protection program oversight occurs. Limited scope inspections of other locations may be conducted over the inspection interval but will not reset the next inspection date. The following provides guidance on conducting routine inspections of licenses with multiple locations of use or authorization for temporary job sites:

a. Authorized Locations of Use/Storage

1. If the license authorizes licensed activities to be conducted at multiple locations the inspector should use the following guidance to determine the number of locations that should be inspected (rounded to the nearest whole number greater than zero). The number of locations is the same number of locations as listed as separate line items on the license.

<u>No. of Locations Listed as Line Items on the License</u>	<u>Percentage of Locations to Be Inspected</u>
1-5	40
6-20	30
>20	20

3. The inspection priorities may be found in the NRC public website at the [Materials Licensee Toolkit](#) page.

IMPORTANT NOTE

Inspection of the various authorized locations need to be rotated to assess the licensee's entire program over several inspection cycles. While the locations to inspect should be selected from a risk-informed perspective, the inspector needs to ensure that new or not previously inspected locations are given priority consideration for inspection. For locations of low safety significance, the inspector in consultation with the supervisor can consider whether a remote inspection is acceptable.

2. If additional locations, such as a corporate office or a location that houses records pertinent to the inspection, needs to be included for completeness of the inspection, the inspector, in consultation with the supervisor, can consider whether it is beneficial to visit the site in person or if a remote inspection can be performed.
 3. If an inspection identifies program weaknesses (e.g., Severity Level III or above violation(s), multiple Severity Level IV violations, or indications of poor program management/oversight), additional locations may be considered for inspection to determine the extent of the program weaknesses.
 4. For licensees with unique circumstances, on a case-by-case basis, regional management may make a risk-informed decision in how to achieve the intent of Item 1 above. For example, if an authorized location of use listed on the license is solely for the purposes of overnight parking of a vehicle containing licensed material, a temporary job site inspection of that crew in action can serve as a substitute for the location of use. Any deviation from the general goals for inspections of authorized locations shall be documented, signed by regional management, and placed on the docket, and coordinated and communicated to the business line manager (MSST Director).
- b. Temporary Job Sites. For a licensee authorized to work at a temporary job site, inspectors should make a reasonable attempt to include an unannounced inspection of licensed activities at such a location(s).
1. During the inspection of a licensee's main facility where principal activities are performed, the inspector should, through discussions with the licensee and review of licensed material utilization records, ascertain if the licensee is working at the temporary job site location(s).
 2. The inspector may contact the licensee's customer to schedule a temporary job site inspection. The licensee's customer should be requested not to notify the licensee of the inspection.
 3. If an unannounced inspection of the location(s) is not possible, then the inspector should attempt to arrange an announced inspection at the temporary job site(s).
 4. If a temporary job site inspection is not performed, the inspector will include a brief note in the inspection record explaining why a temporary job site could not be inspected (e.g., no licensed activities were scheduled to be performed that day, licensed activities were outside of NRC jurisdiction, etc.)

- c. Off-Shore Waters. For a licensee working in off-shore waters, the inspector should make transportation arrangements through the responsible Federal agency to get to the platform or lay barge to complete an unannounced inspection. If it is necessary to use licensee transportation or lodging, the inspector should obtain approval from the supervisor prior to accepting licensee transportation and/or lodging. This approval should be documented with a brief statement and placed on the docket.

05.04 Inspections of Priority 5R Licenses

Priority 5R licensees shall be contacted at 5-year intervals \pm 1 year in lieu of an onsite inspection. With the exception of initial or reactive inspections, remote inspections are the primary method of inspection for Priority 5R licensees. When preparing to conduct these remote inspections, the inspector should follow the general inspection preparation guidance in section 05.01, above. During the inspection, the inspector should review the appropriate sections of the applicable inspection procedures as corresponding to the authorized activities on the license. The inspector will document the remote inspection in accordance with section 2800-09. If the inspector identifies a violation during the remote inspection, the inspector will discuss the matter with the supervisor to determine if an onsite inspection is warranted.

2800-06 INSPECTION SCHEDULING

06.01 Scheduling Routine Inspections

Inspectors should plan to conduct routine inspections close to the due date. To achieve the goals of cost saving and efficient use of staff time and travel, routine inspections may be scheduled within a window around their inspection due dates. Routine inspections of Priority 1 and 2 licensees may vary around their due date by \pm 50 percent. Routine inspections of Priority 3, 4, 5, and 5R licensees may vary around their due dates by \pm 1 year. Inspections will not be considered "overdue" until the inspection start date exceeds the scheduling window.

In rare situations, routine inspections may be scheduled earlier than the window to achieve cost savings and efficiencies. For example, to optimize travel to a remote location, such as Guam and American Samoa, an inspection of a portable gauge licensee may be scheduled sooner than the window. In addition, inspections may be scheduled before their window if the NRC receives information that warrants earlier inspections. The bases for scheduling the inspection before the window should be documented in the inspection record, signed by the supervisor, and placed on the docket.

If a licensee holds several licenses with different program codes that are assigned different inspection priorities, a single inspection may be scheduled whenever practicable to more efficiently use agency resources. If an inspection is performed outside of the scheduling window to achieve this efficiency, the staff should document this decision and indicate the reduction of the inspection interval was not due to performance or compliance issue.

06.02 Reduction of Inspection Interval

The interval between inspections may be reduced (shortened) and inspections conducted more frequently than the assigned inspection priority based on poor licensee performance. The main consideration in reducing the inspection interval should be evidence of moderate to severe problems in the licensee's radiation protection program.

- a. Specifically, licensees that meet one or more of the following conditions may be considered for reduction in inspection interval:
 - 1. A Severity Level I, II, or III violation results from the most recent inspection; or
 - 2. Issuance of an order as a result of the most recent inspection; or
 - 3. The cover letter transmitting the notice of violation on the most recent inspection contains a paragraph that requires the licensee to address adequate management control over the licensed program or other concerns; or
 - 4. Poor compliance history over successive inspections, such as repetitive violations or a large number of Severity Level IV violations.

The above list is not exhaustive; the inspection interval can be reduced for any other reason deemed appropriate by regional management.

A licensee may have its inspection interval reduced by any length. The reduction shall be valid only until the next inspection, but regional management shall consider the results of the next inspection when determining whether the reduced interval should be continued, changed, or returned to normal.

- b. The assigned inspection priority for these licensees should not be changed. However, the next inspection due date should be changed. The scheduling window defined in section 06.01 still applies based on the licensee's default inspection priority and is not changed by a reduction of inspection interval.
- c. A reduction in the interval between inspections must be documented, approved and signed by regional management, placed on the docket, and communicated to the business line manager (MSST Director). The inspection record in WBL must be updated accordingly.

06.03 Extension of Inspection Interval

The due date for the next inspection may be extended if, in the judgement of the inspector and the supervisor, the licensee is determined to be a high performer. This decision is a matter of judgement because inspections are a snapshot of the licensee's activities at the time the inspector is on site. As a result, the inspector and the supervisor will make this judgement based on the inspector's performance-based observations of the most risk-significant, authorized activities; high past performance; and confidence that the licensee's performance will continue at a high level. If approved, Priority 1 and 2 licensees may be extended to 50 percent of the routine inspection interval and Priority 3 licensees may be extended for up to 1 year in circumstances where the licensee has demonstrated high performance. Priority 4, 5, and 5R licensees are not eligible for this

extension. The decision to extend the next inspection interval should be made at the conclusion of the inspection.

- a. The following criteria should be considered, but is not intended to be all inclusive, in this judgement:
 1. The inspector has observed the licensee conduct its most risk-significant, authorized activities with no significant findings (for example, the inspector observed the licensee's radiography crew perform work at a temporary job site and there were no significant findings);
 2. The past two inspections have identified no escalated enforcement. In addition, the identification of non-escalated violation(s) during the current inspection is not by itself a basis for withholding a consideration for this extension;
 3. There has been no major change to the licensee's radiation protection program (See section 07.05), the licensee's senior management has not changed, and the radiation protection staff has not experienced significant turnover within the last two inspection cycles; and,
 4. In situations where the licensee also conducts work in Agreement States, inspections conducted by the Agreement State(s) have not identified significant findings.

A licensee that meets the above criteria may have its next routine inspection due date extended; however, just because a licensee meets the above criteria does not mean the next scheduled inspection date must be extended. Rather, the above criteria are intended to be a guide for inspection staff to consider when making the judgement about whether to extend the due date.

- b. Any extension in interval between inspections must be documented, approved and signed by regional management, placed on the docket, and communicated to the business line manager (MSST Director). The inspection record in WBL must be updated accordingly.
- c. The extension only applies to the current inspection interval. The assigned inspection priority for the licensee should not be changed. However, the next inspection due date should be changed. The scheduling window defined in section 06.01 still applies based on the licensee's default inspection priority and is not changed by an extension for high performance.
- d. The NRC may reconsider its decision to extend the next inspection due date based on any information received during the inspection interval that warrants a re-evaluation of the extension, such as a reportable event, a substantiated allegation against the licensee, or a significant change to the licensee's radiation protection program. Reconsideration of the next inspection due date should follow the guidance in sections 06.02 or 06.04, as applicable.

06.04 Other Changes in Inspection Interval

At the discretion of regional management, other changes in inspection interval may be made to achieve efficiencies in the use of inspection resources or to reduce regulatory impact on the licensee. This may include more frequent inspections to ensure that

inspectors have the opportunity to sufficiently observe licensee operations and increase public confidence by increasing the inspection focus on higher risk activities, without significantly increasing the regulatory burden on licensees. For example, rather than perform a single, high-impact inspection of the license with multiple inspectors at the normal interval, more frequent limited scope inspections may be performed by one or more inspectors that specifically focus on higher risk licensee activities or separate locations. This may also include deviations from the prescribed inspection interval to accommodate extenuating circumstances that prevent performing a timely inspection. The bases for altering the scheduling of inspections should be documented, approved, and signed by regional management, placed on the docket, and communicated to the business line manager (MSST Director). The inspection record in WBL must be updated accordingly.

2800-07 NON-ROUTINE INSPECTIONS

07.01 Reactive Inspections

A reactive inspection will not substitute a routine inspection unless the scope of the inspection is comprehensive. Depending on the scope and results of the reactive inspection, the inspector and supervisor will determine any change to the next inspection date in the tracking systems. Regional management may, where circumstances warrant, choose to perform a routine inspection alongside a reactive inspection (e.g., licensee is eligible for a routine inspection).

a. Reactive Inspections for Incidents/Events

Inspections performed to review incidents (e.g., medical event, overexposure, perceived concerns arising from a licensee's response to a generic letter or bulletin, loss or release of radioactive materials) take precedence over the routine inspection program. Regional management shall promptly assess the preliminary information received concerning the incident and will determine if a reactive inspection is necessary. Regional management, in consultation with the program office, shall also determine if the event warrants elevation to an SIT, AIT, or IIT. The reactive inspection will emphasize the analysis of the sequence of events and the conditions that existed at the time these events occurred. The analysis should assess the licensee's determination of contributing factors and root causes and the formulation of corrective actions to prevent recurrence.

Generally, issues of compliance will be addressed after all safety issues and program weaknesses are identified and clearly understood.

Reactive inspections involving a medical facility will be performed using the guidance in MD 8.10, "NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility." All other reactive inspections will be performed using the guidance in Inspection Procedure (IP) 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing." An inspection plan may be prepared to ensure that a reactive inspection thoroughly addresses the event and the extent of condition.

The inspector should refer to IP 87103 for specific instructions about the exit meeting. It is particularly important that the inspector keep regional management informed of the inspection details and establish an exit meeting strategy prior to the meeting.

A narrative inspection report will be written in accordance with section 09.02 for all reactive inspections. The narrative report will include a discussion of inspector activities, reviews, observations, the sequence of events leading up to the incident, the contributing and root causes of the event, corrective actions taken or proposed by the licensee, and a discussion of the regulations applying to the incident. The inspector shall annotate inspection reports with the Nuclear Material Events Database (NMED) Event Number and the NRC Event Notification (EN) Number if the reactive inspection was initiated by a reportable event. The inspector should refer to Appendix C of the NMED Coding Manual for instructions to properly “complete” the record in NMED. Appendix C can be found after logging in to NMED by using the following link: <https://nmed.inl.gov/>. The inspector should include as much of the required information as possible in the inspection report or provide the information to the NMED Contractor separately.

b. Reactive Inspections for Allegations

Allegations will be followed up and the results documented and transmitted in accordance with NRC MD 8.8, “Management of Allegations.” There are instances in which the staff will conduct a non-routine inspection in response to allegations.

IMPORTANT NOTE

No reference to follow-up of an allegation or employee concern will be entered in the inspection records, inspection reports, the WBL record, or other documents that will be filed on the docket for the licensee.

In conducting interviews or other activities with licensee personnel, inspectors should be sensitive to areas where employees may be reluctant to raise concerns about the licensee’s program. Even if the licensee addresses an employee’s concern regarding safety issues, there could be underlying factors that could produce a “chilling” effect or reluctance for employees to report such issues. For example, the following questions will help the inspector determine if safety culture problems exist in the licensee’s radiation protection program:

1. Has there been an unexplained change in the number or nature of valid concerns that employees have raised with the licensee or the NRC?
2. Have there been interactions with NRC personnel that suggest that some employees may be hesitant to raise concerns or present information to NRC?
3. Are employee concerns addressed by licensee management in a timely manner?
4. Is the licensee’s corrective action successful in addressing employees’ concerns?

If any indication of a “chilling” effect is found, the inspector shall inform regional management for further review.

07.02 Inspections of Bankrupt, Expired, Abandoned, or Revoked Licenses.

If the staff becomes aware of a change in the circumstances of a licensee, prompt action may be necessary to ensure that licensed material has been properly secured, transferred, or disposed of, and that areas where material was used can be safely

released for unrestricted use, as appropriate. Indications of a change in circumstances could include:

- notification of a bankruptcy;
- license expiration;
- issuance of an order suspending or revoking a license;
- undeliverable/returned mail;
- lack of response to correspondence or other communications; or,
- appearance of abandonment of licensed operations.

The Materials Safety and Tribal Liaison Branch (MSTB) in MSST has the lead for the coordination of activities associated with bankruptcy notifications. The MSTB project manager responsible for bankruptcy notifications may request assistance for inspection support to the regions when dealing with a licensee bankruptcy notification. Appropriate security and control of licensed material are the highest priorities in these situations. Staff will determine whether an onsite inspection is needed or if a remote inspection is acceptable, commensurate with the situation. Additional guidance for bankruptcy cases can be found in NUREG-1556, Vol. 15, Rev. 1, "Consolidated Guidance About Materials Licenses – Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses." For additional information on bankrupt, expired, abandoned, or revoked license, see NUREG-1556, Volume 20, "Consolidated Guidance About Materials Licenses – Guidance About Administrative Licensing Procedures."

Staff should use all available resources to determine the status of the licensee's program and licensed materials. Available resources may include onsite inspection; internet searches; communications with current tenants or landlords; consulting the local county or municipal land title office for property transfer records; making telephone contacts with last known suppliers; making contacts with local fire and police departments and the U.S. Postal Service; or coordination with other NRC offices, such as the Office of the Chief Financial Officer, Office of General Counsel, the Office of Investigations, or the Office of Nuclear Security and Incident Response, which may have access to other Federal or law enforcement tools.

The inspector should be knowledgeable of the security and control requirements for the applicable licensed materials at the facility and ensure that applicable controls are in place. The inspector also should be knowledgeable of the required information to ensure that the facility can appropriately be released for unrestricted use. The inspector should review the licensee's transfer, disposal, and closeout survey data and other records, such as leak tests to determine potential for contamination. The inspector should perform independent or confirmatory measurements as part of any onsite inspection. If transferred, the inspector should confirm that an authorized recipient received the material. The inspector should also review records of disposals, burials, and public dose that may be required to be submitted to the NRC on termination or retirement of the license.

If all attempts to locate the licensee are unsuccessful, the NRC regional office should prepare a written record of all methods used in the attempt to locate the missing licensee. The record should include the following:

- Actions taken to locate the missing licensee.

- An evaluation of the health and safety and security risks and consequences related to the missing licensee.
- A conclusion as to why further effort will not be expended to find the licensee or the licensed material.

All activities associated with this section must be appropriately documented and placed on the docket for future reference. See IP 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing," for additional inspection information regarding abandoned radioactive materials.

07.03 Follow-up Inspection to Escalated Enforcement

If escalated enforcement action has taken place for a particular licensee, a non-routine inspection that focuses on the licensee's corrective actions in response to Severity Level III or higher violation(s) shall be conducted. This inspection should be conducted within 12 months of the issuance of the escalated enforcement action (Severity Level III or higher). If regional management determines not to perform the follow-up inspection, the rationale for not conducting the follow-up inspection shall be documented. In determining when to conduct the follow-up inspection, regional management should consider the risk-significance, number, and severity level of the violations. This follow-up inspection may be performed as a part of a routine inspection. In some instances, the inspector may conduct a remote inspection to achieve the objective(s) of the follow-up inspection.

07.04 Reciprocity Inspections

In 10 CFR 150.20, the NRC grants a general license to any person, with a specific license from an Agreement State authorizing use at temporary job sites, to conduct the same activity authorized by the State license in areas under Federal jurisdiction. The Agreement State licensee must submit an NRC Form 241, "Report of Proposed Activities in Non-Agreement States" at least 3 days before engaging in each activity for the first time in a calendar year. The processing of the NRC Form 241 is performed in accordance with NUREG-1556, Volume 20, Revision 1, "Consolidated Guidance About Materials Licenses – Guidance About Administrative Licensing Procedures."

It is the practice of the NRC to conduct inspections of Agreement State licensees operating in NRC jurisdiction. The NRC recognizes that reciprocity applicants receive routine inspections from the regulatory agency that issues their license. Reciprocity inspections do not follow the frequency requirements for routine inspections. The regional office(s) shall conduct reciprocity inspections for work performed within their assigned jurisdictions. Reciprocity inspections shall be performed in a performance-based, risk-informed manner in accordance with program-specific procedures which are used for equivalent NRC-licensed activities. The regional office may establish their own goals and methods of achieving the objectives of this section.

All reciprocity applicants are eligible for inspection. Decisions concerning reciprocity inspections should be risk informed. Risk informed decision making includes a risk component and a deterministic component. The risk component is provided by applying the risk triplet (i.e., What can go wrong? How likely is it? What are the consequences?). The deterministic component is provided by the Agreement State licensing and inspection process. The Agreement State licensing process provides for a baseline review of a licensee's radiation program and the inspection process provides a review of

its ability to execute that program. Because the NRC's determination as to whether to conduct a reciprocity inspection takes into account both the risk component and the deterministic component, this determination is risk-informed and not just risk-based (i.e., solely based on risk information). The Be RiskSMART framework provides an approach to considering these sorts of decisions (see non-public <https://usnrc.sharepoint.com/teams/Be-riskSMART>).

When evaluating an activity for risk, high risk activities are those that have a higher probability of a failure in either equipment or procedure and a high consequence to public health and safety due to either exposure of personnel or contamination. Operations with a higher probability of failure can generally be considered to include non-routine operations (e.g., repairs or modifications). Operations with a high consequence to public health and safety can generally be construed to include activities performed by a licensee with an assigned Priority 1 and/or Priority 2 inspection priority. The most common activities meeting both these criteria include source exchange, as well as repair or modification of medical equipment containing large sources such as self-shielded irradiators or gamma stereotactic radiosurgery units. Since these are infrequently performed, high consequence evolutions, possibly conducted outside the licensee's originally licensed locations of use, high consideration should be given for conducting an inspection. To facilitate open and transparent communication and coordination with licensees, these inspections should typically be announced to provide certainty that the activity will be conducted while NRC inspectors are present. If, after reviewing the Form 241, the regional office decides not to conduct a reciprocity inspection for a high-risk activity, the rationale for this decision should be documented. Documentation should include an assessment of the risk of the activity (qualitative or quantitative), inspection resource challenges, licensee past performance, or other information supporting the decision to not conduct the inspection.

Decisions concerning whether to conduct a reciprocity inspection will also be needed for lower risk activities (i.e., not high-risk activities as defined above). These activities may include (but are not limited to) those of licensee with an assigned inspection priority 3 and 5 or those activities that do not directly affect sources of any size or directly affect sources of lower activity (e.g., in-field use of portable moisture density gauges, support for materials licensees' decommissioning activities). When making such decisions, the lower risk of these activities and ongoing Agreement State oversight provides a basis for not expending NRC resources to conduct a reciprocity inspection. However, in a few cases, there may be sufficient justification for the expenditure of NRC resources to conduct a reciprocity inspection of a low-risk activity; in these cases, the decision should be documented. The basis for conducting such an inspection may include any of the criteria contained below and, particularly, past performance information available from either the NRC or Agreement States concerning enforcement and/or inspection results. Announcing a low risk inspection may or may not be necessary. That decision is left to the discretion of the organization performing the inspection.

An eligible licensee may be selected for a reciprocity inspection considering the risk-informed guidance in this section and the following:

- need for a reactive inspection based on on-going event;
- review of an allegation, as it relates to the work being conducted under reciprocity;
- inspection priority and scope of work to be performed;

- inspection, enforcement, and incident history (e.g., discussions with regulatory agency that issued license, NMED, National Enforcement Database, etc.);
- duration (i.e., length of work/storage or number of visits in a calendar year);
- knowledge of work in other regulatory jurisdictions (e.g., number of inspections of this entity in a given year under the National Materials Program);
- new or unique technology; or,
- any other situation as deemed appropriate by the regional management.

Results from inspection of Agreement State licensees working in NRC jurisdiction (reciprocity inspections) should be shared with the Agreement State(s) that issued the specific license. This can be achieved by including the Agreement States on distribution for reports that are sent to licensees. Although sharing information on clear inspections may not be of as much value, sharing information on reciprocity inspections that result in escalated enforcement or multiple Severity Level IV violations could be of value to the Agreement State program in risk-informing future inspection activities.

Announcing a reciprocity inspection is appropriate and consistent with accomplishing the goal for selecting and conducting reciprocity inspections of high-risk activities. However, unannounced reciprocity inspections for lower risk activities are appropriate despite the unique challenges of this practice, such as short lead time and logistics. One method of preserving this goal is to contact the licensee's client to obtain the work schedule to help ensure that actual field work may be observed.

Reciprocity inspection documentation shall be prepared in accordance with section 2800-09. Copies of reciprocity inspection documentation shall be sent to: 1) the regulatory agency that issued the license; 2) the State contacts for the State in which the work occurred; 3) the NRC regional office in which the Agreement State is located; and 4) other NRC offices, in accordance with existing procedures.

The region that conducted the reciprocity inspection is responsible for entering any pertinent information about the inspection and resulting enforcement actions into WBL.

Additional context pertaining to the guidance in this section is available in memorandum dated November 13, 2020, "Guidance for Performing NRC Reciprocity Inspections" ([ML20314A232](#).)

07.05 Significantly Expanded Programs

At the discretion of regional management, a non-routine inspection may be necessary upon the identification during the licensing process of a significantly expanded program in accordance with NUREG-1556, Volume 20, Revision 1.

07.06 Inspections of Material Possessed Under a General License

Inspections of general licensees under 10 CFR Parts 31, 40, and 70 are not normally performed. However, if a specific licensee also possesses material under a general license, the inspector should verify the adequacy of the licensee's accountability of the materials, especially those that require registration under 10 CFR 31.5. Inspections of general licensees may be conducted in response to allegations, incidents, or indications of unsafe practices and as resources permit.

07.07 Inspections of Licensees Undergoing or Transitioning to Decommissioning

At some point in time, licensees will discontinue operations involving radioactive material. For example, the licensee may choose to immediately quit operations, suspend operations for extended periods of time, allow the license to expire, or enter bankruptcy. Some of these actions may become permanent and require decommissioning of the facility. When transitioning from operations to decommissioning, licensees may be required to implement the reporting and decommissioning timeliness requirements provided in 10 CFR 30.36, 40.42, and 70.38 regarding the expiration and termination of licenses and decommissioning of sites, buildings, or outdoor areas. These regulations also require some licensees to submit decommissioning plans to the NRC for review and approval prior to start of remediation.

When a facility suspends or discontinues operations with the intent to terminate or decommission, the licensee must continue to implement all license conditions and regulatory requirements related to decommissioning including material security and control, and financial assurance requirements, as appropriate, or until such time the license is amended or terminated. It is important that the nuclear materials licensing and inspection organization coordinates and communicates with the materials decommissioning licensing and inspection organization during the licensee transition from operations to decommissioning. This is to facilitate resource planning and to ensure the appropriate level of oversight is implemented.

Smaller facilities may conduct decommissioning and submit a license termination application to the NRC without any prior notification. Whether a licensee is required to notify the NRC of its transition from operations to decommissioning depends on several factors including levels of contamination present inside and outside of the authorized areas of use (10 CFR 30.36(d)). For example, if the remediation of the facility will involve destructive removal of contaminated equipment and structures, prior permission may have to be obtained from the NRC before commencing with decommissioning. In this situation, a qualified decommissioning inspector should review the decommissioning-related data and provide an evaluation to materials licensing regarding the adequacy of the data to support the proposed license amendment.

Once a site or a portion of a site enters decommissioning, the inspection program may shift from IMC 2800 to IMC 2602, Decommissioning Fuel Cycle, Uranium Recovery, and Materials Inspection Program.” For the portions of the license that is undergoing decommissioning under IMC 2602, the inspection of decommissioning-related activities may be the responsibility of qualified decommissioning inspectors rather than qualified materials inspectors.

During each inspection involving radioactive material, materials inspectors should inquire about the licensee's plans for continued operations at the various locations of use. If the inspector discovers that a licensee has suspended or ended operations at a particular facility, the inspector should still verify the safety and security of licensed material that may remain there. The inspector should pay close attention to decommissioning activities conducted at broad scope licensees, since these licensees are authorized to add and remove locations of use, within limitations. Materials inspectors may request the support of decommissioning inspectors to determine whether the licensee conducted a sufficient radiological survey.

Details about the NRC's decommissioning process are provided in NUREG-1757, "Consolidated Decommissioning Guidance," Volumes 1-3. Details about radiological surveys that are acceptable to the NRC to support decommissioning are provided in NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)."

2800-08 SITE VISITS

08.01 Pre-licensing Visit

Generally, pre-licensing visits shall be conducted prior to issuance of a license for new entities that do not have an existing Agreement State or NRC license, licensees changing ownership to an unknown entity, or licensees that are significantly expanding the size or scope of their existing license. Reviewers should use the Pre-licensing Checklists to determine if pre-licensing visits are needed. The Pre-licensing Checklist can be found on the Materials Security Toolbox at <https://scp.nrc.gov/controls.html>. (Authorization and a password are required to access this website.)

Please note that the pre-licensing visit is not an inspection. The purpose of the pre-licensing visit is to evaluate the applicant's intentions regarding the use of radioactive materials and to forward suspicious applications to the appropriate authority for review, per the guidance in the Pre-licensing Checklist. All of the applicant's proposed storage and use locations must be visited. By the end of the visit, the reviewer should have observed, collected, and documented sufficient information to provide a basis for the determination if the applicant will use the radioactive materials as specified in its license application.

08.02 Onsite Security Review

If the applicant/licensee will possess RSRM for the first time, an onsite security review must be performed to verify that the applicant is prepared to implement the additional security requirements before the licensing action is issued allowing the applicant/licensee to take possession of RSRM. Please note that this onsite security review is not an inspection, because the applicant/licensee is not subject to the requirements of 10 CFR Part 37 until they take possession of RSRM. The RSRM Checklist and guidance contains information about onsite security reviews. The RSRM Checklist and guidance can be found on the Materials Security Toolbox at <https://scp.nrc.gov/controls.html>. (Authorization and a password are required to access this website.)

2800-09 DOCUMENTATION OF INSPECTION RESULTS

09.01 Required Information to Document Inspections

All documented inspection results must contain the following minimum information:

- a. licensee information (name, location(s) inspected, license number, docket number, contact name, and contact information)
- b. inspection information (type, date, and report number)
- c. program information (program code(s), priority, and inspection procedure(s) used;

- d. a description of the scope of the licensee's program;
- e. a description of the scope of the inspection;
- f. the status of open items, including previously cited violations or reported licensee events;
- g. sufficient information to support any cited violations or non-cited violations, as well as a description of completed and anticipated corrective actions for any identified violations;
- h. if applicable, a statement that the licensee's reporting to NMMSS was reviewed in accordance with the procedures described in Enclosure 2;
- i. if applicable, a description of the licensee's compliance with Part 37 requirements. The inspector should include this information in a non-publicly available inspection record;
- j. next inspection date, including justification if date is reduced or extended; and,
- k. inspector and supervisor signatures.

Any subsequent inspector should be able to refer to the inspection record to prepare for an inspection, through review of the scopes of the program and the inspection. Any subsequent inspector should be able to determine easily what corrective actions were expected to be taken in response to any findings, and why any non-cited violation was not cited.

The inspector must document findings with enough detail to make it clear what requirement was violated, how it was violated, who violated the requirement (use titles only, names should be avoided, if possible), and when it was violated (including dates, or period of time of non-compliance, if known). If the licensee provides immediate or long-term corrective action for the violation, this information should also be included as part of the inspection record.

09.02 Documenting Inspection Results

The inspector shall complete either a narrative inspection report or an NRC Form 592M, "Materials Inspection Record," to document inspection results. The Form 592M may be generated from WBL or obtained from the NRC Forms Library. All inspection documentation shall be filed on the docket, following supervisory review.

- a. Narrative Inspection Report. A narrative inspection report is required for 1) team inspections, 2) inspections involving the potential for escalated enforcement, 3) reactive inspections for incidents/events, and 4) any other inspection at the discretion of NRC management. Additional guidance on inspection reports can be found in IMC 0610, "Nuclear Material Safety and Safeguards Inspection Reports." If controlled or sensitive information is included in the narrative report, the inspector must include proper markings.

For cases of escalated enforcement, the narrative report should address in detail the areas of concern and any violations that were identified. Other areas that were inspected may be documented in a manner like the depth of detail in an inspection record.

For reactive inspections associated with incidents/events, the narrative report should address in detail the areas of concern, root cause of incident/event, corrective actions to prevent recurrence, and any violations that were identified. Any other areas that were inspected may be documented in a manner like the depth of detail in an inspection record. For medical events, the narrative report must follow the guidance in MD 8.10.

- b. NRC Form 592M. The inspector will document the inspection on an NRC Form 592M any time a narrative report is not required, including non-escalated violations. This inspection record will include the required information specified in section 09.01, above. Inspection record documentation does not need to be as detailed and formal as a narrative inspection report. If controlled or sensitive information is included in the inspection record, the inspector must include proper markings.

09.03 Methods of Transmitting Inspection Results

Results of inspections may be reported to the licensee by either issuing a letter with or without a formal Notice of Violation (NOV) to the licensee or an NRC Form 591M, "Materials Inspection Report."

- a. Letter to licensee, with or without NOV. When findings are documented in a narrative inspection report, a letter must be used to inform the licensee of the results of the inspection. A letter may also be used when findings are documented in an inspection record. A formal NOV will be enclosed, as applicable. The letter will be a publicly available document. If controlled or sensitive information is included in any of the transmitted enclosures, the letter and its enclosures must include proper markings.
- b. NRC Form 591M - Inspection Report. The inspector may issue an NRC Form 591M for the following circumstances, with exceptions in the next paragraph: (1) an inspection that results in no findings; (2) to document non-cited violations (NCV); or (3) to document Severity Level IV violations that were corrected while the inspector was present or can be easily corrected within 30 days of the date of the inspection. Any corrective actions must be listed on the NRC Form 591M.

NRC Form 591M shall not be used to transmit non-cited or cited security-related violations pursuant to 10 CFR Part 37. These inspection results must be transmitted via letter with formal NOV and must include proper markings, as appropriate.

NRC Form 591M is usually not used to transmit a cited violation where the corrective actions taken by the licensee include an amendment of the license. These inspection findings are typically transmitted via letter with formal NOV for tracking purposes. However, if the amendment request is received by NRC prior to issuance of the inspection results, the inspector may transmit the violation on an NRC Form 591M.

The inspector may present the completed and signed NRC Form 591M to the licensee prior to leaving the site. The inspector may also transmit the completed and signed NRC Form 591M from the office.

Although there is no expectation that NRC Form 591M reports be sent to the Agreement States, it may be of benefit to transmit electronically any formal Notices of Violation and/or inspection reports that involve escalated enforcement actions. This is especially useful if the NRC licensee also holds a license from an Agreement State, which could allow the Agreement State program to risk-inform the next inspection of that licensee, or the date of the next planned inspection. In cases where the NRC licensee holds multiple Agreement State licenses, the report should be sent to the Agreement State in which the NRC inspection was performed. In cases where the inspection of a licensee holding multiple Agreement State licenses was performed in a non-agreement state (NRC state),

the inspection report should be sent to the Agreement State where the licensee's corporate office is located, if outside of NRC jurisdiction.

2800-10 COORDINATION AMONG REGIONAL OFFICES

The responsible regional office for licensing and inspection is assigned in accordance with the guidance in NUREG-1556, Volume 20, Rev. 1, "Consolidated Guidance About Materials Licenses - Guidance About Administrative Licensing Procedures." In the interest of efficiency in the use of travel time and funds, the responsible regional office may request another regional office to conduct inspections (assist inspections) of their corresponding licensees when the licensee is operating outside the geographical area of the responsible region. The responsible region may also request assistance to other regional offices to conduct inspections within the responsible region's geographical area when there are workload or resource constraints, to benefit from staff experience or familiarity with a specific program, to support developmental opportunities, or due to other extenuating circumstances. In such cases, these activities must be coordinated between regions with as much anticipation as possible and agreed upon by management in the affected regions.

The inspecting region should provide complete documentation and any recommended enforcement action(s) to the responsible region, which will distribute the documentation, initiate enforcement action, and take other follow-up actions, as appropriate.

When a license has an address that places the inspection responsibility in one region, and operations under the license routinely or predominantly occur within another region, the inspection responsibility may be transferred to the region in which the operations are performed. This transfer shall be done with a documented mutual agreement of the regional offices involved.

2800-11 COORDINATION WITH STATE AGENCIES

For NRC inspections in both Agreement and non-Agreement States, State radiation control program personnel shall be notified in advance of the inspection. Under routine circumstances, the notification should be made at least one week in advance of the inspection. Whenever possible, for reactive inspections, the State should be notified before the start of the inspection so that any public inquiries that may come to the State may be referred to the NRC.

State personnel may observe NRC inspections, so long as their presence does not affect the inspection. Observers should be informed that information gathered during the inspection is pre-decisional and shall not be disclosed until the final inspection results are issued.

Given the number of national licensees that have multiple licenses in both Agreement States and NRC jurisdictions, the Agreement States and NRC should coordinate inspection activities and share results, as appropriate. For example, if a work crew at a temporary job site in Agency One's jurisdiction has its "home" office in Agency Two's jurisdiction, the inspector may contact Agency Two to obtain information on "corporate" matters, such as trustworthy and reliability determinations, dosimetry, training, etc., as well as the licensee's compliance history in Agency Two's jurisdiction. This information may help the inspector perform a more efficient and informed inspection by leveraging the collective efforts of the National Materials Program. The inspection documentation should reflect that such elements were deferred to the appropriate

jurisdiction. A record documenting the inspection findings from another agency should be requested and maintained with other records of the inspection, when possible.

Contact information for State radiation control programs can be obtained through the Regional State Agreement Officer or can be found at <https://www.nrc.gov/agreement-states.html#agreement-states>.

2800-12 COORDINATION WITH FEDERAL AGENCIES

NRC does not conduct inspections of licensee compliance with the requirements of other Federal agencies, except the U.S. Department of Transportation (DOT); however, NRC inspectors may identify concerns during an inspection that are within another agency's regulatory authority. The inspector should discuss the concerns with the licensee; however, inspectors are cautioned not to judge whether a given condition is a violation of another agency's rules or regulations. The inspector may also discuss the concerns with the appropriate liaisons within the other agency to determine if a formal referral is necessary.

In the case of complaints or allegations involving another federal agency's jurisdiction, the inspector should withhold the information from the licensee management and submit the concern(s) to the appropriate NRC liaison as soon as practicable after the onsite inspection to forward to the appropriate agency.

NRC has entered into several Memoranda of Understanding (MOUs), with other Federal agencies. A listing of MOUs by year can be found at the following website: <https://www.nrc.gov/reading-rm/doc-collections/memo-understanding/>. Please note that this listing only goes back to 1984. Older MOUs may need to be obtained by other means.

The following MOUs contain information that is relevant to inspection activities:

- a. U.S. Department of Transportation (DOT). The NRC/DOT MOU, "Transportation of Radioactive Materials" – published in the Federal Register July 2, 1979 (44 FR 38690), delineates DOT's and NRC's respective responsibilities for regulating safety in transportation of radioactive materials.
- b. U.S. Department of Justice (DOJ)
 1. The NRC/DOJ Federal Bureau of Investigation (FBI) MOU, "Cooperation Regarding Threat, Theft, or Sabotage in U.S. Nuclear Industry" – published in the Federal Register May 16, 2000, provides a basis for contingency response planning, coordination, and cooperation between the FBI and the NRC, to deal effectively with threats, and with acts associated with theft or sabotage attempts against NRC-licensed nuclear facilities and activities.
 2. The NRC/DOJ MOU published in the Federal Register December 14, 1988, provides for coordination between the two agencies for matters that could lead to NRC enforcement action, as well as DOJ criminal prosecution. The MOU also facilitates exchange of information on matters within their respective jurisdictions.

c. U.S. Department of Labor (DOL)

1. The NRC/DOL MOU, "Cooperation Regarding Employee Protection Matters" published in the Federal Register October 27, 1998, provides coordination of employee protection provisions in section 211 of the Energy Reorganization Act of 1974. Section 211 prohibits a licensee, applicant, or contractor or subcontractor of same from discriminating against any employee who assisted or participated, or is about to assist or participate, in an NRC inspection.
2. The NRC/DOL Mine Safety and Health Administration (MSHA) MOU, "Facilitation of Coordination and Cooperation in Areas of Mutual Jurisdiction and Concern," published in the Federal Register January 4, 1980, clarified the regulatory roles for NRC and MSHA for milling of source material, including inspection of an operating uranium mill.
3. The NRC/DOL Occupational Safety and Health Administration (OSHA), MOU, "Worker Protection at NRC-licensed Facilities" – published in the Federal Register October 31, 1988 (53 FR 43950), was designed to ensure that there will be no gaps in the protection of workers at NRC-licensed facilities where the OSHA also has health and safety jurisdiction. At the same time, the MOU is designed to avoid NRC and OSHA duplication of effort in those cases where it is not always practical to sharply identify boundaries between the NRC's responsibilities for nuclear safety and the OSHA's responsibilities for industrial safety.

Specific guidance on the responsibilities and interfacing activities for reporting non-radiological hazards to OSHA can be found in IMC 1007. There are four categories of occupational hazards that may be associated the licensed materials:

- (a) radiation hazards produced by radioactive materials;
- (b) chemical hazards produced by radioactive materials;
- (c) facility conditions that affect the safety of radioactive materials and thus present an increased risk to workers; and,
- (d) facility conditions that result in an occupational hazards that do not involve the use of licensed materials.

Generally, NRC has jurisdiction over categories (a), (b), and (c). OSHA has authority and responsibility for category (d). Through this MOU, NRC supports OSHA by reporting category (d) conditions to the licensee and OSHA so appropriate action(s) can be taken.

d. U.S. Environmental Protection Agency (EPA)

1. The NRC/EPA MOU, "Regulation of Radionuclide Emissions," published in the Federal Register November 3, 1980, defines in general terms the respective roles of the two agencies and establishes a framework of cooperation for avoiding unnecessary duplication of effort and for conserving resources in establishing, implementing, and enforcing standards for airborne radionuclide emissions from sources and facilities licensed by the NRC.

2. The NRC/EPA MOU published in the Federal Register November 16, 1992, was designed to foster NRC/EPA cooperation in protecting health and safety and the environment on issues relating to the regulation of radionuclides in the environment.
3. The NRC/EPA MOU published in the Federal Register December 22, 1992, concerns "Clean Air Act Standards for Radionuclide Releases from Facilities Other than Nuclear Power Reactors Licensed by NRC or its Agreement States." The MOU was designed to ensure that facilities other than nuclear power reactors, licensed by the NRC, will continue to limit air emissions of radionuclides to levels that result in protection of the public health with an ample margin of safety.
- e. U.S. Department of Health and Human Services (DHHS). The NRC/DHHS FDA MOU (ML023520399) published in the Federal Register December 23, 2002, renewed with minor changes the MOU signed by NRC and FDA on August 26, 1993. The MOU delineates the sharing of information and the coordination of joint inspections or inspection accompaniments between NRC and FDA for areas of joint regulatory interest (i.e., medical devices, drugs, and biological products using byproduct, source, or special nuclear material).
- f. U.S. Department of Energy (DOE). The NRC/DOE Office of Waste Management MOU, "Concerning the Management of Sealed Sources," published in the Federal Register January 7, 2000 (65 FR 1184), addresses the problem of unwanted and uncontrolled radioactive materials ("orphan" sources) and defines agreed-upon roles and responsibilities of the NRC and DOE in situations where the NRC is the lead Federal agency, where immediate health and safety hazards have been addressed, and where assistance with the transfer of radioactive material is determined to be necessary for continued protection of public health and safety and the environment.

2800-13 COORDINATION AND REPORTING FOR ALTERATIONS IN THE IMPLEMENTATION OF THE INSPECTION PROGRAM

Any actions or decisions associated with the implementation of the inspection program taken by regional management that are not consistent with the guidance contained this IMC is considered an alteration to the implementation of the inspection program. Such alterations must be approved by regional management, documented, coordinated and communicated to the MSST Division Director which serves as the Nuclear Materials Users Business Line manager. The licensee docket should include documentation concerning the implementation of the inspection program and the communication and coordination with the MSST Division Director should be as soon as practicable but not later than the next quarterly performance management reporting.

2800-14 INSPECTION PROGRAM FEEDBACK

Supervisors and inspectors are expected to identify issues and challenges in implementing the materials inspection program, including any associated IMCs and IPs, and to recommend changes for consideration. Any such feedback or recommendations should be submitted to NMSS via the process described in IMC 0801, "Inspection Program Feedback Process." Staff is encouraged to send a copy of the feedback or suggestions to the MSST/MSTB Branch Chief which is the responsible organization for changes to this manual chapter and also post it in the [NMSS Inspection Guidance and Feedback SharePoint site](#).

END

Enclosures:

1. Management Directives, Inspection Manual Chapters, and Inspection Procedures
2. Information for the Inspection of Licensees Holding Nuclear Materials Management and Safeguards System Accounts

Appendix:

Appendix A: Inspection Program Modifications during Pandemics or other Situations Impacting Travel to Perform Inspections

Enclosure 1 – Management Directives, Inspection Manual Chapters,
and Inspection Procedures

The Management Directives (MDs), Inspection Manual Chapters (IMCs), and Inspection Procedures (IPs) listed here comprise the inspection program for material licensees. This list is organized into various topics. These documents are to be used as guidelines for inspectors in determining the inspection requirements for operational and radiological safety aspects of various types of licensee activities. In performing an inspection, an MD, IMC, or multiple IPs may be needed to adequately evaluate a licensee's program.

MDs, IMCs, and IPs in the table below are classified into two categories: Routine (R) and As-Needed (N). "Routine" (R) means those IMCs and IPs that are generally used to evaluate licensee performance. For example, the IP 87100-series includes procedures for routine inspections of certain types of use of licensed material, e.g., industrial/academic, medical, industrial radiography, gauges, etc. However, all "routine" IMCs and IPs are not appropriate for each inspection. For example, IP 84900, "Low-Level Waste Storage," would not be appropriate for inspection of a fixed or portable gauge licensee that stores devices, unless the devices were designated for disposal. "As-Needed" (N) means those IMCs and IPs that are specifically used for a certain situation. For instance, IMC 1120, "Preliminary Notifications," is classified "as-needed," because it only applies to certain events. Similarly, IP 92703, "Followup of Confirmatory Action Letters (CALs)," is classified "as-needed" because it only applies to a licensee who has been issued a CAL.

<u>MD/IMC/IP No.</u>	<u>Inspection Manual Chapter/Inspection Procedure Title</u>	<u>Routine (R) or As Needed (N)</u>
MATERIALS SAFETY PROGRAMS		
IMC 2810	"Master Material License Oversight and Inspection Program"	N
IMC 2815	"Construction and Preoperational Inspection of Panoramic, Wet-Source Storage Gamma Irradiators"	N
IP 87121	"Industrial Radiography Programs"	R
IP 87122	"Irradiator Programs"	R
IP 87123	"Well Logging and Tracer Study Programs "	R
IP 87124	"Fixed Nuclear Gauge Programs"	R
IP 87125	"Materials Processor/Manufacturer Programs"	R
IP 87126	"Broad Scope Academic and Research & Development Programs"	R
IP 87127	"Radiopharmacy Programs"	R
IP 87128	"Manufacturing and Distribution of Exempt Products"	R

MATERIALS SAFETY PROGRAMS (CONTINUED)		
IP 87129	"Master Materials Program"	N
IP 87130	"Nuclear Medicine Programs"	R
IP 87132	"Brachytherapy Programs"	R
IP 87133	"Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs"	R
IP 87134	"Medical Broad-Scope Programs"	R
IP 87137	"10 CFR Part 37 Materials Security Inspections"	N
IP 87139	"Portable Nuclear Gauge Programs"	R
IP 87140	"Source, Special Nuclear Material, and Other Alpha Emitter Use Programs"	R
IP 87141	"Limited Scope Academic and Research & Development Programs Including Animal Use"	R
IP 87142	"Sealed Sources and Devices (Other) Used in Measuring Systems, Analytical Instruments, Calibration and Checking of Instruments, and Similar Purposes"	R
IP 87143	"Self-Shielded Irradiator and Calibrator Devices"	R
IP 87144	"Veterinary Use Programs"	R
CONDUCT OF INSPECTIONS		
IMC 0330	"Guidance for NRC Review of Licensee Draft Documents"	N
IMC 0312	"Technical Assistance for Radiation Safety Inspections at Nuclear Fuel Facilities and Materials Licensees' Sites"	N
IMC 1248	"Formal Qualification Programs for Federal and State Material and Environmental Management Programs"	R
IP 40002	"Inspections to Review Allegations"	N
IP 87250	"Locating Missing Materials Licensees"	N
IP 93800	"Augmented Inspection Team"	N
IP 93812	"Special Inspection"	N

INCIDENT RESPONSE		
MD 8.3	"NRC Incident Investigation Program"	N
MD 8.10	"NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility"	N
IMC 1301	"Response to Radioactive Material Incidents That Do Not Require Activation of the NRC Incident Response Plan"	N
IMC 1302	"Follow-up Actions and Action Levels for Radiation Exposures Associated with Materials Incidents Involving Members of the Public"	N
IMC 1303	"Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy (DOE)"	N
IMC 1330	"Response to Transportation Accidents Involving Radioactive Materials"	N
IMC 1360	"Use of Physician and Scientific Consultants in the Medical Consultant Program"	N
IP 87103	"Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing"	N
LOW-LEVEL WASTE/WASTE MANAGEMENT		
IMC 2401	"Near-Surface Low-Level Radioactive Waste Disposal Facility Inspection Program"	N
IP 84750	"Radioactive Waste Treatment and Effluent and Environmental Monitoring"	R
IP 84850	"Radioactive Waste Management – Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61"	R
IP 84900	"Low-Level Radioactive Waste Storage"	R
DECOMMISSIONING INSPECTIONS		
IMC 2602	"Decommissioning Oversight and Inspection Program For Fuel Cycle Facilities and Materials Licensees"	N
IP 83890	"Closeout Inspection and Survey"	N
IP 87104	"Decommissioning Inspection Procedure for Materials Licensees"	N

RADIATION PROTECTION		
IP 83822	"Radiation Protection"	R
IP 87102	"Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)"	R
TRANSPORTATION		
IMC 1330	"Response to Transportation Accidents Involving Radioactive Materials"	N
IP 86740	"Inspection of Transportation Activities"	R
IP 86750	"Solid Radioactive Waste Management and Transportation of Radioactive Materials"	R
IP 81120	"Inspection Requirements and Guidance for Additional Security Measures for the Physical Protection in Transit for Radioactive Material Quantities of Concern" (Non-Public)	N
REPORTS/COMMUNICATIONS/FOLLOWUP		
MD 8.8	"Management of Allegations"	N
IMC 0610	"Nuclear Material Safety and Safeguards Inspection Reports"	R
IMC 0620	"Inspection Documents and Records"	R
IMC 0730	"Generic Communications Regarding Materials and Fuel Cycle Issues"	N
IMC 1120	"Preliminary Notifications"	N
IP 92701	"Followup"	R
IP 92703	"Followup of Confirmatory Action Letters or Orders"	N
INTERACTIONS WITH OTHER FEDERAL AGENCIES		
IMC 1007	"Interfacing Activities between Regional Offices of NRC and OSHA"	R

Enclosure 2 – Information for the Inspection of Licensees Holding Nuclear Materials
Management and Safeguards System (NMMSS) Accounts

1.0 BACKGROUND

The Nuclear Materials Management and Safeguards System (NMMSS) is the United States (U.S.) Government's database for current and historical data on the receipt, shipment, and inventory adjustment of certain source and special nuclear materials (SNM). NMMSS data is also used to satisfy the reporting requirements of international agreements that the United States is part of regarding the tracking of certain source and SNM. The NMMSS database is operated by a contractor on behalf of the U.S. Department of Energy (DOE) and the NRC.

NRC and Agreement State licensees are required by Title 10 of the *Code of Federal Regulations* (CFR) Parts 40.64(a) and (b), 72.76, 72.78, 74.13, 74.15, 150.16, and 150.17 to submit reports to NMMSS if they ship, receive, or adjust their onsite inventories for materials that are equal to or greater than the quantities shown in table 1 in section 3.0, below.

NMMSS is also used to provide information to the U.S. Department of State to satisfy agreements with other nations that require the accounting of foreign-obligated source material and SNM imported to and exported from the United States. Foreign-obligated source material is source material that is tracked by NMMSS in accordance with treaty or agreement obligations that the United States has with other nations to treat nuclear materials in a manner consistent with that treaty or agreement. For example, certain source material may be sold by or to the United States with the understanding that the material will only be used for peaceful purposes such as power generation and not used in a nuclear weapons program.

In practice, all foreign-obligated source material in the United States is located at fuel cycle facilities. It is not expected that any foreign-obligated material would be found at a licensee facility inspected under IMC 2800. However, if the inspector identifies source material with documented foreign obligations, then the inspector should immediately notify the NRC's NMMSS Project Manager in the Division of Fuel Management. The inspector should include the material within the scope of the inspection under IMC 2800 until further notice. The material is routinely inspected under IMC 2600, "Fuel Cycle Facility Operational Safety and Safeguards Inspection Program."

SNM is the focus of the remainder of the inspection guidance in this enclosure. NMMSS tracks quantities of subject material by material type (MT) and does not track licensee inventories of NMMSS-reportable material down to the item level. For example, NMMSS cannot provide information regarding the model number and serial number of devices or sources containing NMMSS-reportable material at a facility. Table 2 of section 3.0 indicates the MT codes for the materials that NRC requires to be reported to NMMSS.

In preparing for the inspection, the inspector should sum the masses for each MT reported by NMMSS and be prepared to do the same during the inspection when examining the licensee's inventory records. Table 3 of section 3.0 indicates the specific activities for the materials likely to be seen during an inspection. These factors may be used to convert between grams and activity units (curies) when comparing licensee and NMMSS records.

2.0 NMMSS INSPECTION PROCESS

- 2.01 Preparation: If the licensee is authorized to possess NMMSS-reportable quantities of materials, the inspector will contact the NMMSS contractor by telephone at (301) 903-6860 or by email at NMMSS@nnsa.doe.gov and request a "Task 8 Inspection Package." If unable to contact the NMMSS contractor, the inspector should notify the NRC's NMMSS Project Manager by email at NMMSS.Resource@nrc.gov. The inspector should request the package approximately seven calendar days prior to the start of the inspection trip to allow sufficient time for the package to be provided to the inspector.

The Task 8 Inspection Package contains three documents that are described in table 4 of section 3.0:

- a. DOE/NRC Form 742, "Material Balance Report";
- b. NMMSS Report TJ-45, "Material Transaction Reports"; and,
- c. NMMSS Report D-3, "Licensee Administrative Information"

Each licensee reports to NMMSS using a Reporting Identification Symbol (RIS) code. Some licensees can have more than one RIS code. The RIS code is a unique combination of three or four letters that is assigned to each reporting organization by the DOE or NRC for the purpose of identification.

Inspectors are cautioned that at a minimum, NMMSS data is Sensitive – Unclassified Official Use Only (OUO) information. Because it will generally be necessary to take NMMSS data on the inspection, inspectors must be familiar with, and comply with, the OUO information storage and handling requirements specified in NRC Management Directive (MD) 12.6, "NRC Sensitive Unclassified Information Security Program." Any losses or compromise of OUO data must be reported in accordance with MD 12.6. Inspectors must also be cautious with regard to handling licensee information that may be classified, sensitive, or proprietary.

- 2.02 Onsite Inspection: During each inspection of a licensee holding a NMMSS account, the inspector shall:
- a. Discuss the location of all NMMSS-reportable material possessed by the licensee. Obtain and review the most recent record of physical inventory of SNM performed by the licensee. Compare the licensee's inventory records with the information documented in the licensee's NMMSS account on the DOE/NRC Form 742, "Material Balance Report," provided by the NMMSS contractor.
 - b. Review the records documenting the receipt, transfer and disposal of material maintained by the licensee in accordance with 10 CFR 74.19(a)(1). Compare these records to the data in the NMMSS Report TJ-45 and determine that the licensee has accounted for the quantities of materials received, possessed, transferred, and disposed since the licensee submitted the most recent DOE/NRC Form 742, "Material Balance Report."
 - c. Verify the information listed on the licensee's inventory record by walking down the licensee's facility and (if practicable) visually identifying, at a minimum, a representative sample of the materials that the licensee reported to NMMSS on the most recently submitted DOE/NRC Form 742. If appropriate, verify the presence of the subject material with a radiation survey instrument. The intent of the measurement is to verify

the presence of radioactive material rather than to determine the quantity or specific isotopic identity of the material present.

NOTE: The inspector should not ask licensee personnel to open any container or otherwise change the container's shielding or security to facilitate this survey.

If the licensee possesses NMMSS-reportable material in sufficient quantity to be subject to NMMSS requirements (i.e., table 1) and has not reported the material, or if discrepancies exist between the licensee's inventory records and the most recently submitted DOE/NRC Form 742, the licensee's corrective actions must include contacting the NMMSS contractor to revise and reconcile their reported holdings of NMMSS-reportable material. The licensee must adequately evaluate any discrepancy to determine if, in fact, NMMSS-reportable materials are lost or otherwise missing. The inspector must collect sufficient information to support potential short-term NRC regulatory actions, such as the preparation of a Confirmatory Action Letter or an order, and potential longer term escalated enforcement actions.

- d. Provide responsible licensee personnel with a copy of NMMSS Report D-3, which summarizes the administrative information contained in NMMSS about the licensee. Review the administrative information listed in the NMMSS Report D-3 with licensee personnel to ensure that the information is up to date. This information includes, but is not limited to:
 - 1. physical or delivery address (for transmitting information by methods that cannot use a post office box);
 - 2. name, telephone number, FAX number, and e-mail address for primary technical point of contact;
 - 3. name, telephone number, fax number, and email address for primary management point of contact; and,
 - 4. the license numbers of NRC or Agreement State licenses that authorize the possession of subject material.
 - e. The inspector should verify the licensee is using the correct RIS code(s). When the inspector reviews the NMMSS Report D-3 they can confirm the licensee's administrative information and RIS code(s) on record with NMMSS.
 - f. If corrections to any NMMSS data are needed, the licensee should contact the NMMSS contractor directly.
- 2.03 Inspection Documentation: The inspector should include a statement that the licensee's reporting to NMMSS was reviewed. The statement should be recorded in the inspection documentation, along with the results of the overall inspection.

Because inspection findings and much of the data used in these inspections are "Business Proprietary" or "Sensitive – Unclassified Official Use Only," inspection documentation must be properly protected. Information discussing the quantities and forms of NMMSS-reportable materials possessed by the licensee shall not be included in any inspection documentation unless the information is vital to adequately document any violations or other issues that require corrective or other follow-up action by the licensee

or the NRC. Any inspection records that must contain information about quantities and forms of NMMSS-reportable materials will be profiled in ADAMS as “non-publicly available” documents.

Provide a copy of any inspection documentation that includes a violation of NMMSS reporting requirements to the NRC’s NMMSS Project Manager.

3.0 NMMSS QUICK REFERENCES

Table 1: NMMSS Reportable Quantities

<u>ISOTOPE OR ELEMENT</u>	<u>REPORTABLE QUANTITY</u>
Plutonium-238	0.1 gram
Plutonium	1 gram
Enriched uranium	1 gram uranium-235
Uranium-233	1 gram
Foreign-obligated thorium	1 kilogram
Foreign-obligated natural uranium	1 kilogram
Foreign-obligated depleted uranium	1 kilogram

Table 2: NMMSS Material Types

<u>MATERIAL TYPE</u>	<u>MT CODE</u>
Foreign-obligated depleted uranium*	MT 10
Enriched uranium	MT 20
Plutonium	MT 50
Uranium 233	MT 70
Foreign-obligated normal uranium*	MT 81
Plutonium 238	MT 83**
Foreign-obligated thorium*	MT 88
Uranium in cascade	MT 89

* Only source material that has foreign obligations is subject to NMMSS reporting requirements.

** Plutonium that is more than 10% Pu²³⁸ of total Pu by weight is reported as Pu²³⁸

Table 3: Activity to Mass Conversion Factors

<u>Isotope</u>	<u>Specific Activity (curies/gram)</u>
Uranium 234	6.2×10^{-3}
Uranium 235	2.2×10^{-6}
Uranium 238	3.3×10^{-7}
Plutonium 238	17.3
Plutonium 239	0.063
Plutonium 240	0.23
Plutonium 241	104
Plutonium 242	0.004

Table 4: Task 8 Inspection Package Descriptions

DOE/NRC Form 742, Material Balance Report	Licensee-submitted summary of NMMSS-reportable materials, by material type, possessed by the licensee
NMMSS Report TJ-45	Listing of all Form 741 transactions involving NMMSS reportable materials reported by the licensee, including receipts, transfers and disposals, since the most recent material balance report.
NMMSS Report D-3	Summary of licensee administrative information on record in NMMSS

For more details, the inspector should refer to NUREG/BR-0006, "Instructions for Completing Nuclear Material Transaction Reports (DOE/NRC Forms 741 and 740M)," and NUREG/BR-0007, "Instructions for the Preparation and Distribution of Material Status Reports (DOE/NRC Forms 742 and 742C)."

END

Appendix A: Inspection Program Modifications During Pandemics or Other Situations Impacting Travel to Perform Inspections

2800A-01 PURPOSE

Pandemics, epidemics, or other widespread illnesses or diseases primarily affect people and develop more gradually, spread more widely, and could persist longer than other natural phenomena. During these times, the U.S. Nuclear Regulatory Commission's (NRC's) inspection implementing strategy should be agile and allow for flexibility in the completion of the materials inspection program at affected facilities. The inspection program provides reasonable assurance that licensees are in compliance with their license commitments and the applicable regulations. Licensees have the ultimate responsibility to safely operate their facilities and/or perform their authorized activities in accordance with their licenses and supporting documents.

During the time of a pandemic, epidemic, or other widespread illness or disease, the NRC will use a graded approach to meet the objectives of the oversight program. A graded approach allows for deferring or rescheduling planned inspections, conducting inspections leveraging remote means, or a combination of these actions, while seeking to maintain as much of the normal inspection program as possible. This is based on the conditions being experienced and information and guidance from Federal, State, and local government agencies, keeping in full view the health and safety of the personnel involved.

This guidance can be leveraged to consider modifications to the inspection program in certain situations that temporarily affect travel to conduct on-site inspections. This may include national emergencies due to hurricanes, tornadoes, flooding, earthquakes, fires, or national security events.

2800A-02 OBJECTIVES

To provide guidance for implementing the materials inspection program to maintain appropriate oversight of licensed activities in the event of a pandemic, epidemic, other widespread illness or disease, or other situations impacting travel to perform inspections; herein generally referred as situations impacting travel to perform inspections.

2800A-03 APPLICABILITY

Inspection Manual Chapter (IMC) 2800, "Materials Inspection Program."

2800A-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Director, Office Nuclear Material Safety and Safeguards (NMSS)

Provides overall program direction for the NRC materials inspection program.

04.02 Regional Administrator(s)

Oversees implementation of the materials inspection program within their respective region.

04.03 Director, Division of Materials Safety, Security, State, and Tribal Programs (MSST)

- a. Develops and directs the implementation of policies, programs, and procedures for inspecting licensees, applicants, and other entities subject to NRC jurisdiction.
- b. Assesses the effectiveness, uniformity, and completeness of implementation of the materials inspection program.
- c. Approves changes to the materials inspection program.
- d. Coordinates with the regional offices to obtain technical assistance, as necessary.

04.04 Director(s), Regional Division of Radiological Safety and Security (DRSS)

- a. Manages the implementation of the inspection program elements performed by their respective region.
- b. Ensures, within budget limitations, that the regional office staff includes adequate numbers of inspectors to carry out the inspection program described in this chapter, including reactive inspections.
- c. Applies inspection resources, as necessary, to deal with significant issues and problems at specific facilities.
- d. Coordinates with MSST to obtain technical assistance, as necessary.
- e. Recommends changes to the materials inspection program to the Director, MSST.

04.05 Supervisor(s), Regional Materials Inspection Program

- a. Implements the regional materials inspection program.
- b. Reviews and approves inspection schedules.
- c. Reviews enforcement actions in accordance with NRC enforcement guidance.
- d. Ensures that regional materials inspectors achieve and maintain qualifications, in accordance with IMC 1248.
- e. Ensures that the performance of each inspector who routinely performs inspections is evaluated during actual inspections at least once annually. For qualified inspectors who no longer routinely perform inspections, the individual should be evaluated at an appropriate frequency, as established by regional management, relative to their other assigned duties.
- f. Proposes changes to the materials inspection program and encourages inspectors to propose changes to the materials inspection program in accordance with section 2800-14.

04.06 Supervisor, Materials Safety and Tribal Liaison Branch (MSTB)

- a. Facilitates coordination among the regions in the implementation of the materials inspection program to ensure a consistent application of this guidance.

- b. Coordinates with the regional offices to obtain or provide technical assistance, as necessary.
- c. Recommends, to the Director of MSST, the development of inspection guidance, policies, or changes needed in the inspection program, based on the programmatic oversight of the materials inspection program during situations impacting travel to perform inspections.

2800A-05 GUIDANCE

This guidance provides considerations for implementing the materials inspection program during situations impacting travel to perform inspections. The following guidance may be used notwithstanding the agency decision to activate the Agency Pandemic Plan. If the Agency Pandemic Plan is activated, the regions and headquarters would coordinate to maintain the identified mission essential functions and may use this guidance to accomplish those functions, as appropriate.

Open communications and coordination between MSST and the regional offices is essential during a declared pandemic, or other situations impacting travel to perform inspections. The regions should report to MSST any challenges to meet the timeliness of the inspection program per IMC 2800 and any strategies to mitigate any impacts to the agency oversight function.

Effective communication and coordination between the regions and headquarters will promptly identify any needed programmatic or technical support or guidance for the implementation of the inspection program. MSST and the regions should reach alignment on the prioritization of support activities in order to utilize resources wisely during situations impacting travel to perform inspections.

NMSS or the regional offices may supplement, alter, or suspend the provisions of this guidance by memorandum as the situation warrants. Since pandemics, or other situations impacting travel to perform inspections may present with its very own characteristics, impacts, and challenges, this guidance may be insufficient or inadequate for a particular pandemic or situation in the future. Therefore, the regions should promptly notify the MSST Director and the MSTB Branch Chief should the guidance in this Appendix be insufficient or inadequate while facing a pandemic or other situations impacting travel to support inspection activities. NMSS will promptly coordinate and provide the needed guidance and direction consistent with the agency response to the situation.

During the during the Coronavirus Disease 2019 (COVID-19) pandemic, NMSS supplemented the guidance in IMC 2800 with a series of communications to the regions, mostly memorandums. For details of these communications and information regarding NMSS' assessment of inspection activities during the COVID-19 pandemic, visit [ML21294A368](#) - November 24, 2021 - COVID-19 Public Health Emergency Oversight Activities Assessment Phase B Report.

- a. The regions and headquarters are expected to make a reasonable effort to complete the inspection program as detailed in IMC 2800. During the pandemic or other situations impacting travel to perform inspections, the regions and headquarters should consider modifications to the planned inspections as follows: (1) assess inspection procedure(s) and licensee personnel support to determine whether the inspection can be performed

remotely or with a hybrid approach; and (2) determine whether the on-site inspection needs to be postponed or deferred.

- b. The Regional Administrator, with concurrence from the Director of NMSS, or vice versa, may suspend implementation of the inspection program should conditions warrant. If this occurs, the primary function of inspectors and the implementing office would be to maintain situational awareness and the ability to respond to any events or emergency situations.
- c. Regions are expected to maintain the ability to evaluate and respond to events during a pandemic or other situation that affect traveling to licensed facilities for inspections. Regional management, in coordination with NMSS, would decide on the appropriate inspection approach for an incident or event during this period. If on-site response by NRC personnel is not possible, then the regions should remotely collect as much information as possible on the event. For example, the NRC may be able to perform some level of remote monitoring depending on the availability, connectivity, and usefulness of remote technologies for inspectors to provide effective oversight of safety and security activities, including site information (e.g., meetings, corrective action program, or other data). If direct on-site response is appropriate, the regions may consider limiting the response, such as having a single inspector respond to the facility or provide technical assistance remotely.
- d. Inspection activities should be announced and coordinated with the licensee in advance to determine to travel on-site or conduct an inspection remotely or with a hybrid approach. Cross-regional support can be used to conduct inspection activities.
- e. The inspectors should discuss with their licensees the need to maintain situational awareness of the licensees' ability to cope with the challenges associated with a pandemic or other situation that affect traveling to licensed facilities for inspections. Inspectors may use Regulatory Issue Summary [2010-04, "Monitoring the Status of Regulated Activities during a Pandemic,"](#) (ML100539611) dated May 25, 2010, and other appropriate guidance as a resource. The regulatory issue summary includes several questions that inspectors should consider during routine business contacts with licensees. The information obtained will enable the NRC to effectively respond to licensees with potential challenges. Inspectors should recognize that during a pandemic or other situations impacting travel to perform inspections, licensees' resources may be strained. Therefore, inspectors should work with licensees to obtain the best information possible given the circumstances.
- f. During the COVID-19 pandemic, NMSS provided regulatory options for licensees to seek regulatory relief that may be necessary during the COVID-19 pandemic (ML20094G166) and provided guidance, including templates, for granting exemptions to certain regulatory requirements or license conditions. The inspector(s) should maintain awareness of licensing exemptions and notices of enforcement discretion approved by the agency due to the pandemic or other situations impacting travel to perform inspections in preparations for inspections.
- g. Materials licensees may close their facilities or perform limited operations with minimal staffing during a pandemic or other situations impacting travel to perform inspections. Inspectors should verify that the licensees have taken needed measures to secure the radioactive material and to ensure that activities are conducted safely and do not pose an undue risk to public health and safety. Additionally, the inspectors should evaluate

deferred maintenance and any other deferral of safety and/or security commitments, and operational status, to inform any adjustments to the inspection program during situations impacting travel to perform inspections.

- h. Materials licensees operating in hospitals may discourage visits from inspectors during a pandemic, or other local emergency as their resources and priorities shift to attending patients and their own staff health and safety. After determining licensee ability to support inspection activities, the inspector will align with their management in postponing the inspection and any needed notification and documentation of these decisions.
- i. Inspectors should be cautious when conducting on-site inspections and accessing licensee facilities during a pandemic or other situations impacting travel to perform inspections, using judgment to not unnecessarily risk its own health and the health of licensee employees.
- j. NRC staff members visiting sites should follow any licensee plans or protocols in place in response to a pandemic or other situation affecting the licensee facilities. Additionally, inspectors should follow any applicable Federal, State, or local health screening guidance in effect to determine if it is appropriate to enter a site and interact with licensee personnel. If licensees are conducting health screenings to permit access to licensee facilities, inspectors should generally comply with those requests similar to their adherence to Occupational Safety and Health Administration or other industrial safety requirements. Inspectors should contact their management if the licensee denies access to their facilities to facilitate inspection. The inspector and their management will determine the path forward for that inspection and document in the docket.

2800A-06 REFERENCES

Regulatory Issue Summary 2010-04, "Monitoring the Status of Regulated Activities during a Pandemic"

"COVID-19 Public Health Emergency Oversight Activities Assessment Phase B Report," November 24, 2021 ([ML21294A368](#))

Attachment 1: Revision History for IMC 2800

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
N/A	ML101790431 07/27/10 CN 10-016	<p>Revision history reviewed for the last four years.</p> <p>Change Office/Division name from reorganization (NMSS/IMNS to FSME/MSSA).</p> <p>Add definition of “pre-licensing visits” and describe scenario in which they are required. (IERP Recommendation I-1a).</p> <p>Add definition of an “initial security inspection” and describe scenario in which they are required.</p> <p>Add definition for “risk significant radioactive material.”</p> <p>Add definition of “security requirements.”</p> <p>Allows for announced visit for the initial security inspection and encourages coordination with local law enforcement.</p> <p>Description of a proposed pilot program on the security inspection frequency’s recommended by the Increased Control Working Group (MPWG Recommendation M-IV.3).</p> <p>Implementation of a secondary program code for security inspections. (MPWG Recommendation M-IV.3).</p> <p>Add language to include awareness of allegation trends during inspection preparation and at the inspection site. (WITS 2008-00158).</p> <p>Notification that inspectors should review NSTS inventory records in advance of inspections.</p> <p>Addition of “Quantities of Concern” Table.</p> <p>Include language on inspector review of licensed activities performed by contracted personnel.</p> <p>Requires inspector to verify that prompt corrective</p>	N/A	ML101520679

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
		<p>actions have been initiated in instances that affect the safe control of material.</p> <p>Allows for the issuance of Form 591M in the field, but requires supervisory review. If changes are made to the 591M, the form is reissued to the licensee.</p> <p>Inclusion of EDO Field Policy Manual on providing Third Party Assistance (WITS 2009-00082).</p> <p>Allows for health and safety inspections to be completed during the same visit as security inspections</p> <p>Guidance on coordinating with Agreement States and other Regions on licensed activities that cross jurisdictions</p> <p>Revision of Master Materials Licenses (MML) section to be more in line with IMC 2810 for the MML program.</p>		
N/A	ML102800160 11/15/10 CN 10-023	<p>Revised the definitions for pre-licensing visits, initial inspections, and the initial security inspections for additional clarity.</p> <p>Eliminated the discrepancy for when a Form 591M can be issued in the field. Removal of Enclosure 7 and replacing it with a reference to Enforcement Guidance.</p> <p>Clarification of the process for coordination with Agreement States and other Regions. Made general editorial changes.</p>	N/A	N/A
N/A	ML17186A204 09/12/17 CN 17-018	<ul style="list-style-type: none"> Change Office/Division name from reorganization (FSME/MSSA to NMSS/MSTR). Revised to include criteria for flexibility within the inspection priorities/intervals, as directed in SECY-16-0009. 	N/A	ML17062A557 ML17186A134

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
		<ul style="list-style-type: none"> Referenced to the License Tracking System (LTS) were deleted and references to the Web-Based Licensing System (WBL) were added. Consolidated all related HRMS guidance into a new enclosure. 		
N/A	ML20031D677 03/02/20 CN 20-012	<p>Complete re-write of IMC 2800 to provide the following:</p> <ul style="list-style-type: none"> Enhanced coordination and communication among the regional offices and the Agreement States Allowed flexibility for in-office reviews Revised how inspections are documented Added reciprocity inspection information from IMC 1220 (IMC 1220 deleted) 	N/A	ML20029E868 ML20029E869
N/A	ML23102A025 06/16/23 CN 23-017	<p>Revision of 2800 as a result of Phase 3 of the updates to Inspection Manual Chapter 2800 Working Group efforts.</p> <ul style="list-style-type: none"> Incorporate Very Low Safety Significance Issue Resolution Process. Define risk-modules. Update Enclosure 1 with most current list of Inspection Procedures. Incorporate lessons learned from the implementation of the inspection program during the COVID-19 pandemic including a new Appendix A – Inspection Program Modifications During Pandemics or Other Situations Impacting Travel to Perform Inspections, and defining hybrid, onsite, and remote inspection. Added a new section on 07.07 Inspections of Licensees Undergoing or Transitioning to Decommissioning. (continued on next page) Additional guidance to leverage the collective effort of the National Materials Program. 	N/A	ML23102A027

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
		<p>(continued from prior page)</p> <ul style="list-style-type: none"> • Align 2800 with data entry fields and guidance for the inspection module in the Web-based Licensing System (WBL). • Incorporate a section for the coordination and documentation of alteration to the implementation of IMC 2800. • Revised Enclosure 2 – Information for the Inspection of Licensees Holding Nuclear Materials Management and Safeguards System (NMMSS) Accounts, to update with current practices and information. • Updated sections as a result of comments received on the draft guidance that was provided for comments to the regions and to the Agreement States. • Updated guidance due to reflect or reference additional guidance issued by the program office, NMSS (reciprocity, bankruptcy, use of inspection module in WBL, etc.). 		