UNITED STATES
NUCLEAR REGULATORY COMMISSION
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ALL AGREEMENT STATES, VERMONT

OPPORTUNITY TO COMMENT ON DRAFT REVISION TO INSPECTION MANUAL CHAPTER (IMC) 2800, "MATERIALS INSPECTION PROGRAM" (STC-19-053)

Purpose: To provide Agreement States, as well as any States with pending Agreement State applications, the opportunity to comment on the draft latest revision of the Office of Nuclear Material Safety and Safeguards Inspection Manual Chapter (IMC) 2800, "Materials Inspection Program."

Background: On April 13, 2016, the U.S. Nuclear Regulatory Commission (NRC) issued Staff Requirements Memorandum (SRM) to SECY-16-0009, "Recommendations Resulting from the Integrated Prioritization and Re-Baselining of Agency Activities." Item 110 in this SRM directed the NRC staff to revise IMC 2800 to allow for the addition of more flexibility and logical extensions to the inspection interval of materials licensees.

To more efficiently and effectively address the Commission direction for Item 110, the NRC management and staff divided action on this item into two phases: 1) to specifically address the items listed in the Commission paper; and 2) to conduct a more comprehensive evaluation of the entire NRC materials inspection program.

Phase 1 was completed with the issuance of a revision to IMC 2800, dated September 12, 2017. An electronic copy of September 12, 2017, revision to IMC 2800 can be found in the NRC's Agencywide Document Access and Management System under Accession No. ML17186A204.

During a senior management counterpart meeting in April 2018, management from the Division of Materials Safety, Security, State, and Tribal Programs (MSST) and the Division of Nuclear Materials and Safety (DNMS) for Regions I, III, and IV met and finalized the Phase Two Project plan.

Discussion: In August 2018, a Working Group (WG) composed of NRC and Agreement State inspection management and staff was formed and tasked with performing Phase 2. This activity resulted in substantial changes to IMC 2800 but these changes did not diminish the protection of public health and safety or security of licensed nuclear material. Changes in the following areas were especially noteworthy during this revision: (1) location of use; (2) reactive inspections; (3) remote inspections of exempt distribution licenses; (4) reciprocity; (5) inspection of bankrupt, expired, abandoned, and revoked licensees; (6) coordination of inspection activities between NRC regional offices and State agencies; and (7) inspection documentation.

Additionally, the WG decided to cancel IMC 1220, "Processing of NRC Form 241, 'Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters,' and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20." The licensing information in IMC 1220 was moved to NUREG-1556, Volume 20, Revision 1, "Consolidated Guidance About Materials Licenses: Guidance About Administrative Licensing Procedures," and the inspection information was placed in IMC 2800.

Enclosed for your review and comment is a clean copy of the WG's proposed revised IMC 2800. Also enclosed is a red-line, strike-out version of the revised IMC 2800.

This information request has been approved by OMB 3150-0029 expiration February 28, 2022. The estimated burden per response to comply with this voluntary collection is approximately 16 hours. Send comments regarding the burden estimate to the Information Services Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to infocollects.resource@nrc.gov, and to OMB Office of Information and Regulatory Affairs (3150-0029), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; e-mail: oira_submission@omb.eop.gov. An agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The comment period for this document, which was developed following consultation with the Organization of Agreement States, ends on November 1, 2019. Please provide comments to the individuals named below:

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Enclosures:
1. Clean version of proposed IMC 2800 revision
2. Red-line, strike-out version of revised IMC 2800

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 Initial Inspection. The first inspection conducted after a new license is issued.

03.02 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 a license (and incorporated by “tie-down” conditions). Inspections typically involve a visit to a licensee’s facility and/or temporary job site by inspector(s), observations of licensed activities, interaction with licensee personnel, independent radiological measurements, and transmission of the inspection findings. Pre-licensing visits and onsite security reviews are not inspections.

03.03 Inspection Plan. An inspection plan is a written outline listing the licensee's activities and programs that will be covered during an inspection.

03.04 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 R) 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 R 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 the program code with the shortest routine inspection interval.

03.05 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 to escalated enforcement; 4) reciprocity inspections; 5) inspections of significantly expanded licensee programs; 6) general licensee inspections; and 7) inspections of licensees undergoing decommissioning.

03.06 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.

03.07 Performance-Based Approach. A philosophy that establishes performance and results as the primary bases for regulatory decisionmaking. 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.

03.08 Pre-licensing Site 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.

03.09 Reactive Inspection. A reactive inspection is 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 the activities normally reviewed during a routine inspection, then it does not satisfy the requirement to inspect the licensee at the routine, established interval.

03.10 Remote Contacts. Contacts, made by telephone, e-mail, videoconferencing, etc. to determine the status of licensed activities, assess compliance, and/or to exchange information with the Priority R licensees [See Section 05.04].

03.11 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.

03.12 Risk-Significant Radioactive Material (RSRM). RSRM refers to the values in 10 CFR Part 37, Appendix A. The terms "Quantities of Concern," "Category 1 quantities," and "Category 2 quantities" are synonymous with RSRM.

03.13 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 required documentation and records.

03.14 Security Requirements. Requirements mandated by regulation, Order, license condition, or other legally binding requirements for certain licensees possessing or shipping RSRM.

03.15 Team Inspection. For the purposes of this Inspection Manual Chapter (IMC) only, team inspections are defined as those inspections conducted by more than three 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."

2800-04 RESPONSIBILITIES AND AUTHORITIES

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

a. Provides overall program direction for the NRC materials inspection program.

04.02 Regional Administrator.

a. 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.

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. Coordinates with the regional offices to obtain technical assistance, as necessary.

04.04 Director, Regional Division of Nuclear Materials Safety (DNMS).

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, Regional Materials Inspection Program.

a. Implements the regional materials inspection program.

b. Reviews and approves inspection schedules.

c. Reviews and approves all non-escalated enforcement actions (i.e., Severity Level IV violations) proposed by regional materials inspectors, and determines whether violations should be considered for escalated enforcement action.

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 as appropriate.

f. Proposes changes to the materials inspection program.

2800-05 BASIC REQUIREMENTS

The NRC employs a performance-based, risk-informed approach in its materials inspection program. Reactive inspections [See Section 07.01] are of greatest importance, 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 complete the inspection. When more than three inspectors participate, it is considered a team inspection.

An inspection can only be considered to have been performed if:

1. the licensee possesses or has possessed licensed material since the last

inspection, including material possessed under a “possession-only license” or the licensee is performing or has performed principal activities since the last inspection; or

2. the inspection was an initial inspection performed in accordance with Section 05.02.

The physical presence of the Radiation Safety Officer (RSO) is not required to complete 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 will document the onsite activities by placing a signed note on the docket that briefly summarizes the attempted inspection. Additional attempts will be made until the inspection is completed.

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 MDs, IMCs, and 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.

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.”

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 discussions with the supervisor.

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

1. the license and all the current licensing documents. The inspector should determine if the license has any unusual license conditions and/or commitments 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

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, and/or supplemental correspondence pertaining to the license (e.g., licensee responses, requests for relief, and final NRC determinations).

7. any allegations and/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), review the NSTS inventory record in advance.

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), obtain a copy of the licensee's inventory via the NMMSS contractor [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 or not sensitive information will be encountered during the inspection. The inspector should be aware of minimum handling requirements for sensitive unclassified information (i.e., Safeguards Information, Official Use Only, Proprietary Information, and Personally Identifiable Information). For current instructions, the inspector should contact the regional security advisor or refer to the internal, non-public security services web page at https://drupal.nrc.gov/sunsi.

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 and/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 following focus elements common to every inspection: (1) security and control of licensed material; (2) shielding of licensed material; (3) comprehensive safety measures; (4) radiation dosimetry program; (5) radiation instrumentation and surveys; (6) radiation safety training and practices; (7) management oversight; and (8) licensed activities performed by contracted personnel.

These focus elements 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 focus elements.

Performance-Based, Risk-Informed Approach. The inspector should use a performance-based, risk-informed approach to evaluate the 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 where appropriate, 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 focus element, the inspection effort expended in reviewing that particular focus element will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus element, the inspector should conduct a more thorough review of that aspect of the licensee's program in order to determine the apparent cause(s) of the 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, noncompliance, 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 his or her presence in order to provide a basis for enforcement action.

Safety Culture Awareness. 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).

Other common elements to every inspection are discussed below.

(a) Entrance Meeting. After arriving on site, the inspector should inform the licensee's management representative 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 briefing is to inform licensee management 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 management 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 identify personnel to be interviewed. Scheduling interviews 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 ask the licensee representative to identify any recent problems related to the licensed program, such as equipment failures and unusual radiological problems (e.g., excessive personnel exposures, unexpected releases to the environment, quality assurance problems, loss of material). The representative's responses may help the inspector assess licensee management's awareness of the radiation protection program.

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 during the entrance meeting how the information will be handled during the inspection.

(b) Follow up on Previous Items. Determine whether the licensee followed up on 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 followed up on safety concerns and any open issues identified during the previous inspection, including allegations.

(c) General Overview. The inspector should understand the current organization size, and scope of the radiation protection program.

(1) 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).

(2) 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.

(d) 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].

(1) 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.

(2) Conduct inspections of licensed operations, regardless of shift.

(3) Make direct observations of radiation safety systems and practices in use.

(4) Make direct observations of physical security systems and storage locations, with particular attention to facilities which possess RSRM or NMMSS quantities.

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.

(e) 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.

(f) 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 and/or confirmatory measurements in areas of interest, such as areas of use and/or storage, effluent release points, and other locations at the inspector's discretion. The inspector must use calibrated, NRC-owned instruments for independent and confirmatory measurements.

(g) 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 know whether the licensee has declared the information reviewed or gathered as proprietary.

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).

(h) 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.

(i) 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 control of radioactive materials and/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 control of radioactive materials and safe operation of the facility, the inspector should notify regional management as soon as possible.

(j) 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 proposed enforcement actions, 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 shall hold a final exit meeting with a senior management representative and/or the licensee's RSO or 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 issues 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. Post-inspection Activities. After returning from an inspection trip, the inspector shall inform the supervisor of the results of the inspection(s). Enforcement, safety, security, or regulatory issues should be discussed with the supervisor. The inspector shall document the inspection results in accordance with guidance in this IMC [See Section 2800-09] and other chapters, as appropriate.

d. Requests from Licensees for Assistance. On occasion, licensees ask inspectors for help resolving issues. 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 or 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 activities[1], the initial inspection may be rescheduled to within 18 months of license issuance.

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:

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1 As defined in 10 CFR Part 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 amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

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.

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 for 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, and/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.

   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. Encourage the licensee to notify the NRC within 30 days after the receipt of licensed material or initiation of principal activities.

   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 initial inspection attempt 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 attempt may vary by ± 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 priority. 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/or 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 and/or temporary job sites. 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, and/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 from 1 to 5 locations, the goal is to inspect 40 percent of the locations at the interval specified in this chapter for the type of license. If the license authorizes licensed activities to be conducted from 6 to 20 locations, the goal is to inspect 30 percent of the locations at the interval specified in this chapter for the type of license. If the license authorizes licensed activities to be conducted from more than 20 locations, the goal is to inspect 20 percent of the locations at the interval specified in this chapter for the type of license.

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 regional management can consider whether a remote means of 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 regional management can consider whether it is beneficial to visit the site in person or if the review can be completed remotely.

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.

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 necessary to use licensee transportation or lodging, before accepting transportation or lodging from a licensee, the inspector should obtain approval from the supervisor. This approval should be documented with a brief statement and placed on the docket.

05.04 Remote Contacts (Priority R).

Priority R licensees shall be contacted at 5-year intervals ± 1 year in lieu of an onsite inspection, with the exception of initial or reactive inspections. When preparing to conduct a remote contact, the inspector should follow the general inspection preparation guidance in Section 05.01, above. During the contact, the inspector should inquire about the general Focus Elements, as applicable to the authorized activities on the license. The inspector will document the contact and results in accordance with Section 2800-09. If the inspector identifies a violation during the contact, 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 ± 50 percent. Routine inspections of Priority 3, 4, and 5 licensees and remote contact of Priority R licensees may vary around their due dates by ± 1 year. Inspections will not be considered "overdue" until they exceed the scheduling window.

In rare situations, routine inspections may be scheduled earlier than the window in order to achieve cost savings and efficiencies. For example, in order 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 records and 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.

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 shall be considered for reduction in inspection interval if:

    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. A "management paragraph" appears in the cover letter transmitting the notice of violation on the most recent inspection (i.e., a paragraph that requires the licensee to address adequate management control over the licensed program); or

    4. Poor compliance history over the successive inspections, such as repetitive 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, and placed on the docket. The inspection tracking system 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. In addition, the identification of a Severity Level IV violation is not by itself a basis for concluding a licensee is not a high performer. 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 R licensees are not eligible for this extension.

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 and there has not been the need for a management paragraph;

    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;

    4. In situations where the licensee also conducts work in Agreement States, inspections conducted by the Agreement State(s) have not identified significant findings.

    Normally, a licensee that meets the above criteria will 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, and placed on the docket. The inspection tracking system 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, large-team, high-impact inspection of the license at the normal interval, more frequent limited scope inspections may be performed by individuals or smaller teams 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 a timely inspection from being completed. The bases for altering the scheduling of inspections should be documented, approved and signed by regional management, and placed on the docket. The inspection tracking system must be updated accordingly.

2800-07 NON-ROUTINE INSPECTIONS

07.01 Reactive Inspections.

A reactive inspection will not substitute for 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.

a. Reactive Inspections for Incidents/Events

Inspections performed to follow up on 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.

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 No. 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.

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 explain the exit meeting strategy with his or her supervisor before beginning the meeting.

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."

IMPORTANT NOTE

No reference to follow-up of an allegation or employee concern will be entered in the inspection records, inspection reports, 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 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.

Appropriate security and control of licensed material is of the highest priority in these situations. Staff will determine whether an onsite inspection is needed or if remote contact is acceptable, commensurate with the situation. For bankruptcy cases, additional coordination with the program office and the Office of General Counsel may be required. 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.”

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; 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.

All activities associated with this section must be appropriately documented and placed on the docket for future reference.

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). 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 use remote means of inspection, such as telephone interview, 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 in areas under Federal jurisdiction. The licensee must submit an NRC Form 241, "Report of Proposed Activities in Non-Agreement States" at least 3 days before engaging in the licensed activity. 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.

Commented [MA1]: The working group prefers to eliminate a reciprocity metric to provide maximum discretionary flexibility; however, if a metric is needed, the working group supports the previous recommendation from the Continuous Improvement Working Group in 2007 for 5 percent, with a caveat that ALL reciprocity applicants should be considered using the guidance noted below to help inform the selection of inspections, rather than continue the practice of identifying "candidates".

All reciprocity applicants are eligible for inspection. Reciprocity inspections shall be selected in a risk-informed manner based on the following guidance:

- 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/or 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);
- amount of work in other regulatory jurisdictions (i.e., 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.

Although reciprocity inspections pose unique challenges, such as short lead time and logistics, inspectors should make a reasonable effort to conduct unannounced reciprocity inspections.

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 the inspection tracking system.

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 Decommissioning.

Specific guidance for decommissioning requirements and performing closeout inspections is outlined in NUREG-1757 and IP 83890, respectively.

2800-08 SITE VISITS

08.01 Pre-licensing Visit.

Generally, pre-licensing visits shall be conducted 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.)

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 follow-up, per the guidance in the Pre-licensing Checklist. All 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 of confidence that the applicant will use the

radioactive materials as specified in its license application. Pre-licensing visits must be completed before the issuance of a license.

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 will be prepared to implement the security requirements before the licensing action is issued allowing the applicant/licensee to 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.

2800-09 DOCUMENTATION OF INSPECTION RESULTS

09.01 Required Information to Document Inspections.

All documented inspection results must contain the following minimum information:

1. licensee information (name, location(s) inspected, license number, docket number, contact name, and contact information)

2. inspection information (type, date, and report number)

3. program information (program code(s), priority, inspection procedure(s) used, focus elements reviewed)

4. a description of the scope of the licensee's program;

5. a description of the scope of the inspection;

6. the status of followup items involving prior enforcement, including closure of previously cited violations, or reported licensee events;

7. 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;

8. if applicable, a statement that the licensee's reporting to NMMSS was reviewed in accordance with the procedures described in Enclosure 2;

9. 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;

10. next inspection date, including justification if date is reduced or extended; and,

11. 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(s) 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 inspection record to document inspection results. All inspection documentation shall be filed on the docket, following supervisory review.

1. 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 security-related 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 similar to the depth of detail in an inspection record.

   For reactive inspections for 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 similar to the depth of detail in an inspection record. For medical events, the narrative report must follow the guidance in MD 8.10.

2. Inspection Record. The inspector will document the inspection on an inspection record any time a narrative report is not required, including non-escalated violations. The 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 security-related or sensitive information is included in the inspection record, the inspector must include proper markings.

Commented [MA2]: Will add reference once new format and form number are established.

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.

Commented [MA3]: This may change depending on new form for inspection record. Depends on whether this form and the new form should be numerically sequential for ease of retrieval.

1. 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 security-related information is included in any of the transmitted enclosures, the letter and its enclosures must include proper markings.

2. NRC Form 591M. The inspector may issue an NRC Form 591M for the following circumstances: (1) an inspection that results in no findings; (2) to document non-cited safety violations (NCV); or (3) to document Severity Level IV violations (health and safety only) 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. NRC Form 591M shall also not be used to transmit violations that are willful or repetitive. 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 would require 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 a 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.

2800-10 COORDINATION AMONG REGIONAL OFFICES

When a license authorizes operations in more than one region, the responsibility for inspection resides with the regional office responsible for the location of the licensee's main facility where principal activities are performed. In the interest of efficiency in use of travel time and funds, the responsible regional office may request another regional office to conduct inspections (assist inspections) of the activities of such licensees when the licensee is operating outside the geographical area of the responsible region. 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.

Rather than request assistance from another region, the responsible region's personnel may perform the inspection activity themselves due to resource constraints in the requested region, familiarity with a complex program, or other extenuating circumstances. In such cases, these activities must be coordinated between regions. As resources allow, the responsible region may be requested to conduct other inspections in the geographic area on behalf of the other region in the interest of efficiency of agency resources.

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 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 States and/or 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 the 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.

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 that are within another agency's regulatory authority. If such concerns are significant, the NRC should inform the appropriate liaisons within the other agency about the concerns.

Except for DOT regulations, it is important that all inspectors recognize and understand that they are not to make decisions regarding activities under the purview of other agencies. In discussing the concerns with the licensee, inspectors are cautioned not to judge whether a given condition is a violation of another agency's rules or regulations, but are to point out concerns to heighten licensee awareness.

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 1980. 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, 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, 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 4 categories of 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, NRC, 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 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, 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.

List of 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

END

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, and/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, "Follow-up of Confirmatory Action Letters (CALs)," is classified "as-needed" because it only applies to a licensee who has been issued a CAL.

MD/IMC/IP No.	Inspection Manual Chapter/Inspection Procedure Title	Routine (R) or As Needed (N)
	MATERIALS SAFETY PROGRAMS	
IMC2810	"Master Material License Oversight and Inspection Program"	N
IMC2815	"Construction and Pre-Operational Inspection of Panoramic, Wet-Source Storage Gamma Irradiators"	N
IP 87121	"Industrial Radiography Programs"	R
IP 87122	"Irradiator Programs"	R
IP 87123	"Well Logging Programs"	R
IP 87124	"Fixed and Portable Gauge Programs"	R
IP 87125	"Materials Processor/Manufacturer Programs"	R
IP 87126	"Industrial/Academic/Research Programs"	R
IP 87127	"Radiopharmacy Programs"	R
IP87128	"Manufacturing and Distribution of Exempt Products"	R

MATERIALS SAFETY PROGRAMS (CONTINUED)		
IP 87129	“Master Materials Program”	N
IP 87130	“Nuclear Medicine Programs – Written Directive Not Required”	R
IP 87131	“Nuclear Medicine Programs – Written Directive Required”	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
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

INCIDENT RESPONSE (CONTINUED)		
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

TRANSPORTATION (CONTINUED)		
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/FOLLOW-UP		
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 Material and Fuel Cycle Issues"	N
IMC 1120	"Preliminary Notifications"	N
IP 92701	"Follow-up"	R
IP 92703	"Follow-up 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 1in 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. 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 particular 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

02.01 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 e-mail 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 e-mail 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 4of Section 3.0:

a. DOE/NRC Form 742, "Material Balance Report,"
b. NMMSS Report TJ-45, "Material Transaction Reports"
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.

02.02 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 e-mail address for primary management point of contact; and/or,

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.

02.03 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 at all times. 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 followup 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-publically 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

ISOTOPE OR ELEMENT	REPORTABLE QUANTITY
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

MATERIAL TYPE	MT CODE
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% Pu^{238} of total Pu by weight is reported as Pu^{238}

Table 3: Activity to Mass Conversion Factors

Isotope	Specific Activity (curies/gram)
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

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	Revision history reviewed for the last four years. Change Office/Division name from reorganization (NMSS/IMNS to FSME/MSSA). Add definition of “pre-licensing visits” and describe scenario in which they are required. (IERP Recommendation I-1a). Add definition of an “initial security inspection” and describe scenario in which they are required. Add definition for “risk significant radioactive material.” Add definition of “security requirements.” Allows for announced visit for the initial security inspection and encourages coordination with local law enforcement. Description of a proposed pilot program on the security inspection frequency’s recommended by the Increased Control Working Group (MPWG Recommendation M-IV.3). Implementation of a secondary program code for security inspections. (MPWG Recommendation M-IV.3). Add language to include awareness of allegation trends during inspection preparation and at the inspection site. (WITS 2008-00158). Notification that inspectors should review NSTS inventory records in advance of inspections. Addition of “Quantities of Concern” Table.	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)
		Include language on inspector review of licensed activities performed by contracted personnel. Requires inspector to verify that prompt corrective actions have been initiated in instances that affect the safe control of material. 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. Inclusion of EDO Field Policy Manual on providing Third Party Assistance (WITS 2009-00082). Allows for health and safety inspections to be completed during the same visit as security inspections Guidance on coordinating with Agreement States and other Regions on licensed activities that cross jurisdictions Revision of Master Materials Licenses (MML) section to be more in line with IMC 2810 for the MML program.		
N/A	ML102800160 11/15/10 CN 10-023	Revised the definitions for pre-licensing visits, initial inspections, and the initial security inspections for additional clarity. 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. Clarification of the process for coordination with Agreement States and other Regions. Made general editorial changes.	N/A	N/A

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	ML17186A204 09/12/17 CN 17-018	• 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. • 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	ML17062A557 ML17186A134

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, (i.e.g., industrial, academic, research and development, manufacturing, distribution, irradiators, well logging, industrial radiography, medical programs, various types of service (i.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 and to identify specific conditions of poor performance that require more frequent inspection of the licensee.

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 continue and enhance risk-informed,establish relative, risk-informed priorities for routine inspections of all licensees and the criteria for extending or reducing inspection intervals based on licensee performance.

and a program of special inspection activities as specified by the Office of Nuclear Material Safety and Safeguards (NMSS).

02.05 To aid in the achievement of 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 Initial Inspection. The first inspection conducted after a new license is issued.03.01 Pre-licensing Visit. A site visit and face-to-face meeting with an entity for providing a basis for confidence that radioactive material will be used as specified. Staff should use the Pre-licensing checklist to determine which applicants require visits.

03.02 Initial Inspection. An inspection conducted after a new license is issued.

03.042 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 a license (and incorporated by "tie-down" conditions). Inspections typically involve a visit to a licensee's facility and/or temporary job site

by ~~NRC~~ inspector(s), observations of licensed activities, interaction with licensee personnel, independent radiological measurements, and transmission of the inspection findings. Pre-licensing visits and onsite security reviews ~~and telephone contacts~~ are not ~~considered~~ inspections.

03.0~~5~~3 Inspection Plan. An inspection plan is a written outline listing the licensee's activities and programs that will be covered during an inspection.

03.0~~6~~4 Inspection Priorit~~ies~~y. ~~An~~ The inspection priority ~~code~~ is assigned to each radioactive material license during the licensing process based on program code(s). The priority ~~code~~ (i.e., 1, 2, 3, 4, ~~or~~ 5, or R) is the interval between routine inspections, expressed in years. ~~The same priority code is assigned to all licenses that authorize that particular type of use. Enclosure 1~~ The list~~s~~ 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 ~~represents~~ is based on the relative risk of radiation hazard. Priority ~~Code~~ 1 represents the greatest risk to the health and safety of workers, members of the public, and the environment, while Priority ~~Code 5~~R represents the lowest risk. Because a license may authorize multiple types of use (i.e., multiple program codes), the inspection priority ~~code~~ for the license is the program code with the shortest routine inspection interval.

03.05 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 to escalated enforcement; 4) reciprocity inspections; 5) inspections of significantly expanded licensee programs; 6) general licensee inspections; and 7) inspections of licensees undergoing decommissioning.

03.06 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.

03.07 Performance-Based Approach. A philosophy that establishes performance and results as the primary bases for regulatory decisionmaking. 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.

03.08 Pre-licensing Site 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~~.~~ ~~07~~09 Reactive Inspection. A reactive inspection is a ~~special~~ 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 the activities normally reviewed during a routine inspection, then it does not satisfy the requirement to inspect the licensee at the routine, established interval.

03.10 Remote Contacts. Contacts, made by telephone, e-mail, videoconferencing, etc. to determine the status of licensed activities, assess compliance, and/or to exchange information with the Priority R licensees [See Section 05.04].

03.11 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.

03.12 Risk-Significant Radioactive Material (RSRM). RSRM refers to the values in 10 CFR Part 37, Appendix A. The terms "Quantities of Concern," "Category 1 quantities," and "Category 2 quantities" are synonymous with RSRM.

03~~.08~~13 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 required documentation and records.

~~03.09 Risk-Significant Radioactive Material (RSRM). RSRM refers to the values in Title 10 of the Code of Federal Regulations (10 CFR) . The terms "Quantities of Concern," "Category 1 quantities," and "Category 2 quantities" are synonymous with RSRM.~~

03.1~~0~~4 Security Requirements. Requirements mandated by regulation, Order, license condition, or other legally binding requirements for certain licensees possessing or shipping RSRM.

~~03.11 Special Inspection Activities. Those inspection activities specified in Section 2800-07 of this IMC where special guidance is needed. Those activities cover: 1) inspections of expired licenses, terminated licenses, and licensees undergoing decommissioning; 2) inspections of significantly expanded licensee programs; 3) reciprocity inspections; 4) temporary job site or field inspections; 5) team inspections; 6) inspections of revoked or abandoned licenses; 7) general licensee inspections; 8) reactive inspections follow-up to escalated enforcement;) inspections of Master Materials Licenses; and 1) inspections of licensees holding Nuclear Materials Management and Safeguards Systems Accounts (NMMSS).~~

03~~.12~~15 Team Inspection~~s~~. For the purposes of this Inspection Manual Chapter (IMC) only, team inspections are defined as those inspections conducted by more than three ~~or more~~ inspectors, or any materials inspection that includes a representative from outside NRC (other than members from a State's ~~R~~radiation ~~C~~control ~~P~~program). Often, at least one of the inspectors is included on the team because of a specialty in a particular field~~, or at least one of the team members~~ and may come~~s~~ from a different region or ~~Headquarters~~ 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 ~~major~~ large or complex licensee, or reactive inspections in response to a ~~particular~~ 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."

~~03.13 Telephonic Contacts. Contacts, made by telephone and documented in the docket file, as well as in the Agencywide Documents Access and Management System (ADAMS), to determine the status of licensee activities, assess compliance of Priority T licensees [See Section 05.05], or to exchange information with the licensee. Examples of telephonic contacts include reminding a licensee that its license is near expiration, calling to determine whether there are sufficient licensee operations to conduct an onsite inspection, or calling to determine whether the licensee actively possesses licensed material. Telephonic contacts are not inspections.~~

2800-04 RESPONSIBILITIES AND AUTHORITIES

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

a. Provides overall program direction for the NRC materials inspection program.

04.02 Regional Administrator.

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

04.03 Director, Division of Materials Safety, Security, State, and Tribal ~~and Rulemaking~~ Programs (MSSTR).

a. Develops and directs the implementation of policies, programs, and procedures for inspecting applicants, licensees, 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. Ensures that operating plans are consistent among the ~~R~~regional offices responsible for materials inspections.

e. Coordinates with the ~~R~~regional offices to obtain technical assistance, as necessary.

04.04 Director, Regional Division of Nuclear Materials Safety (DNMS).

a. Manages the implementation of the inspection program elements performed by their respective ~~R~~region~~al Office~~.

b. Ensures, within budget limitations, that the ~~R~~regional ~~O~~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~~R~~ to obtain technical assistance, as necessary.

e. Recommends changes to the materials inspection program to the Director, MSSTR.

04.05 Chief(s)Supervisor, Regional Materials Inspection Branch(es) Program.

a. Implements the Rregional materials inspection program.

b. Reviews and approves inspection schedules.

c. Reviews and approves all non-escalated enforcement actions (i.e., Severity Level IV violations) proposed by regional materials inspectionrs staff, and determines whether violations should be considered for escalated enforcement action.

d. Ensures that Rregional materials inspectors achieve and maintain qualifications, in accordance with IMC 1248.

e. Evaluates Ensures that the performance of each inspector who routinely performs inspections is evaluated during actual inspections at least once during each fiscal year annually. For qualified inspectors who no longer routinely perform inspections, the individual should be evaluated as appropriate.

f. Proposes changes to the materials inspection program.

2800-05 BASIC REQUIREMENTS

The NRC employs a performance-based, risk-informed approach in its Mmaterials Iinspection Pprogram. The Materials Inspection Program designates rReactive inspections [See Section 0507.0201] as the highest priorityare of greatest importance, followed by initial inspections [See Section 05.0332] and then routine inspections [See Section 05.0443] based on Iinspection for the Ppriority Codes (in ascending numeric order) listed in Enclosure 1. Telephonic contacts [See Section 05.05] are not inspections and are performed as resources permit.

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 complete the inspection. When more than three inspectors participate, it is considered a team inspection.

An inspection can only be considered to have been performed if:

1. the licensee possesses or has possessed licensed material since the last inspection, including material possessed under a “possession-only license” or the licensee is performing or has performed principal activities since the last inspection; or

2. the inspection was an initial inspection performed in accordance with Section 05.02.

The physical presence of the Radiation Safety Officer (RSO) is not required to complete 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 will document the onsite activities by placing a signed note on the docket that briefly summarizes

the attempted inspection. Additional attempts will be made until the inspection is completed.

~~All routine materials inspections should be performed on an unannounced basis, with the exceptions noted below:~~; however,

1. b~~considerable travel is required, inspectors may licensees located in Guam, American Samoa, Hawaii, Alaska, or other remote locations to verify that a inspection can be performed before undertaking such travel.~~

2. ~~For inspection of Master Materials Licensees (MML), the lead region shall notify the MML of the dates of the inspection and the documentation that the MML should have available for the inspectors to review. [See IMC 2810] The lead region should also request assist inspections (i.e., accompaniment inspections and independent inspections) to be completed by the regional offices. The accompaniment inspections will be completed according to the MML's audit schedule with NRC inspectors accompanying the MML's staff during the radiation safety audits of the MML permit holders [See Inspection Procedure (IP) 87129]. NRC inspectors will complete the independent inspections according to the request from the lead region by using the program-specific inspection procedures in Enclosure 4. The independent inspections will be unannounced just as routine inspections of other NRC licensees are unannounced. [See Section 07.08 and IMC 2810]~~

~~The license reviewer shall assign primary and secondary program codes, with the most restrictive program code setting the inspection priority for each new or amended license. In other words, some licenses authorize activities that can be classified under more than one program code. If a license involves more than one type of use, each part of the program shall be inspected in accordance with its assigned priority. For example, a license for a medical institution (Program Code 02121, Priority Code 5) may be amended to authorize use of a high dose rate remote afterloader unit (Program Code 02230, Priority Code 2). The licensee's primary program code would be Program Code 02230. The NRC would inspect activities related to the high dose rate unit during every routine inspection while it cwould inspect the other portions of the licensee's program during every other routine inspection.~~

~~Inspection plans should be developed for complex, non-routine inspections. Inspection plans may also be developed for any other inspections, as decided by the region. After the inspection, the region may discard the inspection plan.~~

05.01 General Inspection Process.

~~The purpose of this IMC is to describe the types of materials inspections and the general inspection program.~~ 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 MDs, IMCs, and IPs for the type of inspection or type of license being inspected. The pertinent MDs, IMCs, and IPs listed in Enclosure ~~4~~ 1 provide ~~more~~ additional specific guidance for onsite inspection activities. Section 2800-0~~8~~9 provides guidance for documenting inspection results.

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."

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 anthe inspector prepares for routine inspections should be based on discussions with the supervisor.

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

1. the license and all the current licensing documents. The inspector should the license to determine if itthe license has any unusual license conditions and/or commitments that would affect the approach to the inspection, i.e.,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, i.e.,including the results of the last inspection and any outstanding open items and determining whether

2.3. any events that have been reported by the licensee during the current inspection cycle.

3.4. 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.

4.5. any notes in the file information on the docket regarding specialadditional inspection emphasis. For example, i.e., a license reviewer's note to request a near-term inspection regarding a significant recent licensing action. [See Section 07.02.b5].

5.6. any security unique requirements, guidance, questions and answers, and/or supplemental correspondence pertaining to the license (e.g., licensee responses, requests for relief, and final NRC determinations).

6.7. any allegations trends and a follow-up of the licensee's evaluation and response to allegations, potentially requiring consultation with the Office Allegations Coordinatorand/or ongoing investigations by the Office of Investigations. [See Section 0807.0201.b]

8. if the licensee is authorized to possess RSRMrequired to report to the National Source Tracking System (NSTS), requestreview the National Source Tracking System (NSTS) inventory record at least two days in advance.

7.9. 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), obtain a copy of the licensee's inventory via the NMMSS contractor [See Enclosure 2].

~~Prior to the inspection, the inspector should review all the current licensing documents and procedures from the docket file. For problems identified during the course of the routine inspection, the inspector should ask the licensee for pertinent procedures and backup licensing documents maintained on site by the licensee. If the documents are not available from the licensee, the inspector should contact the region for assistance, as needed. This practice would apply to routine inspections only.~~

To prepare for a reactive or other non-routine inspection, the inspector will review specific information ~~for reactive inspections~~, as determined by the inspector and ~~his or her~~ the supervisor on a case-by-case basis [See Section 2800-07~~Section 05.02~~].

~~While reviewing the license, the inspector should determine 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). If the licensee is authorized to possess reportable quantities of NMMSS materials, the inspector will contact the NMMSS contractor via telephone at (301) 903-6860 and request a Task 8 Inspection Package. A minimum of seven calendar days should be allowed prior to the start of the inspection trip to allow sufficient time for the package to be mailed to the inspector. The inspector should contact the NMMSS Project Manager, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards if unable to contact the NMMSS contractor.~~

~~Additional information regarding inspection of licensees holding NMMSS accounts including a complete description of the Task 8 Inspection pPackage can be found in Enclosures 7 and 8.~~

The ~~i~~Inspector~~s~~ should anticipate whether or not ~~they will encounter~~ sensitive information will be encountered during the inspection ~~of a licensee~~. The ~~i~~Inspector~~s~~ should be aware of minimum handling requirements for sensitive unclassified information~~,~~ (i.e., Safeguards Information, Official Use Only, ~~and~~ Proprietary Information, and Personally Identifiable Information). For current instructions, the inspector should contact the regional security advisor or refer to the internal, non-public security services web page~~, http://www.internal.nrc.gov/sunsi/~~ at https://drupal.nrc.gov/sunsi.

The inspector ~~should~~ 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 and/or temporary job sites), make travel arrangements, ~~discuss special aspects of the inspection with his or her supervisor (i.e., inspection of temporary job sites),~~ and obtain the supervisor's approval for the travel itinerary. ~~At least one week b~~Before the inspection trip, the inspector or Regional State Agreements Officer shall convey the itinerary to the State radiation control ~~agency~~ program to give the State personnel an opportunity to observe the routine inspections [See Section 2800-11~~Section 10.02~~].

~~Finally, t~~The inspector ~~should~~ will select appropriate and calibrated radiation detection instrumentation for the inspection. ~~and The inspector should obtain the necessary~~

~~inspection forms (such as NRC Form 591M).~~ The inspector ~~should~~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 ~~a~~ the licensee's performance of ~~the licensee's~~its radiation ~~safety and/or security~~ protection program~~s~~. The inspector should conduct the inspection in a manner that will adequately assess licensee performance relative to the following focus elements common to every inspection: (1) security and control of licensed material; (2) shielding of licensed material; (3) comprehensive safety measures; (4) radiation dosimetry program; (5) radiation instrumentation and surveys; (6) radiation safety training and practices; (7) management oversight; and (8) licensed activities performed by contracted personnel.~~The inspector should be prepared to determine if the licensee possesses RSRM and is subject to NRC security requirements. Inspection activities described below include: focus areas, performance-based approach, necessary review and retention of copies of a licensee's records, communication of findings during an inspection, awareness of a licensee's safety culture, and common elements to every inspection.~~

~~c.~~

~~d. The inspector should conduct the inspection in a manner that will develop conclusions about licensee performance relative to the following focus areas:~~

~~e.~~

~~f. security and control of licensed material;~~

~~g.~~

~~h. shielding of licensed material;~~

~~i.~~

~~j. comprehensive safety measures;~~

~~k.~~

~~l. radiation dosimetry program;~~

~~m.~~

~~n. radiation instrumentation and surveys;~~

~~o.~~

~~p. radiation safety training and practices;~~

~~q.~~

~~r. management oversight; and~~

~~s.~~

~~t. licensed activities performed by contracted personnel.~~

b.

These focus ~~areas~~ elements 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 focus ~~areas~~elements.

~~If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of a focus area, the inspection effort expended in reviewing that particular focus area will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus area, the inspector should~~

~~conduct a more thorough review of that aspect of the licensee's program. 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.~~

Performance-Based, Risk-Informed Approach. The inspector should use a performance-based, risk-informed approach to evaluate the focus ~~areas~~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 where appropriate, a review of selected records. Direct examination of these licensed activities and discussions with cognizant workers should provide ~~an~~the inspector with reasonable assurance of a licensee's ability to safely use ~~byproduct~~ licensed material and is preferable to a review of selected records alone.

~~In reviewing the licensee's performance, the inspector should cover the period from the last to current inspection.~~ If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of a focus element, the inspection effort expended in reviewing that particular focus element will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus element, the inspector should conduct a more thorough review of that aspect of the licensee's program in order to determine the apparent cause(s) of the 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, noncompliance, high radiation exposures, or allegations.

IMPORTANT NOTE

~~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). Observations of licensee operations, interviews with staff, review of licensee documents to complement and support inspector observations, and obtain independent and confirmatory measurements should then be conducted. 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.~~

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 his or her presence in order to provide a basis for enforcement action.

~~Unless an 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, an inspector should not insist on interviews when:~~

~~(a) a worker is delayed in performing scheduled work activities (i.e., delayed departure to a temporary job site)~~

~~(b) a worker is preparing or administering dosages or doses,~~

~~(c) a worker is providing patient care, or~~

~~(d) a licensee is dealing with customers or members of the public.~~

~~Review of licensee records and other documents should be directed toward verifying that current operations are in compliance and further review of "historical" records should only occur if the current records are out of compliance and the inspector believes it necessary to determine the presence of a prevalent or persistent problem. If the inspector finds it appropriate when an apparent violation has been identified, the inspector should gather copies, while onsite, of all records that are needed to support the apparent violation. The inspector should know whether the licensee has declared the information reviewed or gathered as proprietary.~~

~~In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (i.e., licensee materials inventories), or make the licensing file more complete.~~

~~In all cases where licensee documents are retained beyond the inspection, inspectors must follow the requirements of IMC 0620. Inspectors shall ensure that the licensee understands that the retained record will 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).~~

~~The inspector should advise the licensee of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee senior management. 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 should keep NRC regional management informed of significant safety and security findings (i.e., safety hazards, personnel overexposures, failure or inability to control access, failure or inability to monitor, detect, and respond to unauthorized access, willful violations, and other potential escalated enforcement issues) identified during the course of the inspection. This will ensure that the inspector is following appropriate NRC guidance under such circumstances.~~

~~Prompt corrective action must be initiated by the licensee for safety and security concerns or violations of requirements that affect safe control of radioactive materials and 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 safe control of radioactive materials and safe operation of the facility, the inspector should notify regional management immediately.~~

Safety Culture Awareness. T~~o have a positive impact on maintaining safety, security, and effectiveness, t~~he inspector should develop a general sense of the licensee's safety culture for licensed activities (~~i.~~e.g., workers have a "questioning attitude" and generally adhere to procedures, workers are duly cautious when engaged in licensed activities, or workers ~~relationships with supervisors~~ are ~~conducive~~ willing to rais~~ing~~e safety concerns) ~~and that the licensee is reviewing work done by contracted personnel in licensed activities~~. 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).

Other ~~C~~common elements to every inspection are discussed below.

(a) Entrance Meeting. After arriving on site, the inspector should inform the licensee's management representative 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 briefing is to inform licensee management 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 management 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~~ is often an opportune time for the inspector to identify personnel to be interviewed. Scheduling interviews 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 ask the licensee representative to identify any recent problems related to the licensed program, such as equipment failures and unusual radiological problems (e.g., excessive personnel exposures, unexpected releases to the environment, quality assurance problems, loss of material). The representative's responses may help the inspector assess licensee management's awareness of the radiation protection program.

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 during the entrance meeting how the information will be handled during the inspection.

(b) Follow up on Previous Items. Determine whether the licensee followed up on 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 followed- up on safety concerns and ~~unresolved issues~~any open issues identified during the previous inspection, including allegations.

(c) General Overview. The inspector should understand the current organization ~~for radiation safety at the facility and the~~ size, and scope of the ~~current and anticipated~~ radiation ~~use~~ protection program.

(1)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 ~~Radiation Safety Officer (~~RSO~~)~~, and, if applicable, the Chairperson and other members of the Radiation Safety Committee (RSC).

(2)~~-~~ Scope of Program. Interview cognizant personnel to determine the types, quantities, and use of ~~byproduct~~licensed material, frequency of use, staff size, etc., and any anticipated changes ~~in the range of the radiation use program~~. Determine if the licensee possesses material in accordance with a general license.

(d) 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 ~~of utmost~~ importan~~ce~~t to inspect licensed activities at temporary job sites, if possible ~~or activities performed by contracted personnel.~~ [See Section 0~~7~~5.0~~4~~3.b].

(1)~~(1)~~ 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.

(2)~~(2)~~ Conduct inspections of licensed operations ~~that are a potentially significant contributor to dose~~, regardless of shift.

~~(3)Perform routine inspections, when applicable, during first run operations.~~

(~~4~~3) ____Make direct observations of radiation safety systems and practices in use.

(~~5~~4) ____ ~~The walk-through may be performed at any time during the inspection. The inspector may need to return to some portions of the facility at a later time to observe specific activities.~~

~~(6)~~Make direct observations of physical security systems and storage locations, with particular attention to facilities which possess ~~if possessing~~ RSRM or NMMSS quantities.

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.

(e) 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.

(~~e~~f) Independent and Confirmatory Measurements. Independent measurements are those performed by the inspector without comparison to the licensee's measurements. Confirmatory measurements are those ~~whereby~~ performed by the inspector ~~compares his or her~~ with comparison to the licensee's measurements ~~with those of the licensee's~~. The inspector will perform Independent and/or confirmatory measurements in areas of interest, such as areas

~~(1) The inspector should perform independent and confirmatory measurements in restricted, controlled, and unrestricted areas of the licensee's facility. Independent measurements should be performed on all inspections, unless exceptional circumstances make it impossible to perform the measurements (e.g., the inspector's detection equipment malfunctions during an inspection trip). Measurements of dose rates at the boundaries of restricted areas should be~~

~~performed at the surfaces of the most accessible planes.~~

~~(2) Examples of measurements that may be performed include area radiation surveys, wipe samples, soil samples, leak tests, and air flow measurements. These measurements should be taken in licensed material~~of use~~ areas,~~ and/or storage~~ areas~~, effluent release points, and other locations at the inspector's discretion.

~~(3) The inspector may ask the licensee to spot-check radiation levels in selected areas, using the licensee's own instrumentation, if the licensee possesses survey instrumentation, to observe survey procedures and the appropriateness of instrumentation for the types of material used. However, t~~The inspector must use calibrated, NRC-owned~~'s~~ instruments for independent and confirmatory ~~verification of the licensee's~~ measurements.~~ The inspector's instruments must be in current calibration and source checked before they leave the regional office.~~

(g) 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 know whether the licensee has declared the information reviewed or gathered as proprietary.

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).

(~~f~~h) Special License Conditions. ~~If applicable, v~~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.

(i) 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 control of radioactive materials and/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 control of radioactive materials and safe operation of the facility, the inspector should notify regional management as soon as possible.

(~~g~~j) Exit Meeting. At the conclusion of the inspection, the inspector ~~should~~ must conduct an exit meeting ~~with the most senior licensee representative present at the facility~~. ~~As appropriate, the inspector should prepare NRC Form 591M before the exit meeting so that the form can be properly executed during the exit meeting.~~ The purpose of the exit meeting is to discuss ~~preliminary~~ inspection results. The inspector should inform the licensee that inspection results, including the characterization of proposed enforcement actions, could change based on NRC management review. ~~[See Section 08.04]~~

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. ~~If a senior management representative is unavailable for the exit meeting, the inspector should hold a preliminary exit meeting with appropriate staff onsite.~~ As soon as practical after the inspection is completed, the inspector shall hold a~~n~~ final exit meeting ~~directly~~ with a senior management representative ~~(~~and/or the licensee's RSO or other designated individuals, ~~if not present at the preliminary exit meeting)~~commensurate with the type and significance of the findings. This meeting may be conducted remotely~~involving the licensee's management and RSO will usually take place by telephone conference call~~.

During the exit meeting, ~~(1) For initial and routine inspections, the inspector should request the meeting and control the meeting for purposes of the inspection. During the meeting, the inspector shall explain any cited violation of NRC requirements and the inspector's understanding of the licensee's corrective action plan for each violation [See Section 05.01.b.4 about keeping the licensee informed of apparent violations during the inspection].~~

~~To avoid the formal disputed violation process [See NRC Enforcement Manual],~~ the inspector should confirm the licensee's ~~agreement and mutual~~ understanding of ~~cited~~ any violations and associated corrective action ~~plan~~s. If the licensee disagrees with ~~a violation~~the findings, the inspector should ~~contact~~ inform ~~his or her supervisor~~regional management ~~before leaving the site to obtain further instructions~~. It may be necessary to continue the inspection or modify the ~~cited violation~~finding(s). ~~Together, the inspector and supervisor should make decisions about the enforcement strategy. Before leaving the site, t~~The inspector ~~should~~ shall inform the licensee about the next steps in the enforcement process.

The inspector should explain safety/security-related concerns or ~~unresolved items~~ open issues identified during the inspection, and the status of any previously identified violations.

~~Prompt corrective actions must be initiated by the licensee for violations of regulatory requirements that affect safe and secure operations of a licensed 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 the licensee disagree on the magnitude of the concern regarding public health and safety and/or security of the facility, regional management should be notified immediately.~~

Although deficiencies identified in some areas (~~i.~~e.g., workers' knowledge of the Part 20 requirements) are not always violations, the inspector should bring such ~~deficiencies~~ observations to the attention of licensee management at the exit meeting ~~and also in the cover letter transmitting the inspection report or NOV~~.

~~At the exit meeting, the inspector should verify whether the licensee considers any materials provided to or reviewed by the inspector to be proprietary in nature. If so, the inspector should ensure proper handling of the information.~~

~~(2) For a reactive inspection, 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 explain the exit meeting strategy with his or her supervisor before beginning the meeting. During the exit meeting, the inspector should explain the preliminary inspection findings including any apparent violations of regulatory requirements. The inspector should ask the licensee to confirm the licensee's understanding of the findings. If the licensee does not provide additional information and disagrees with the preliminary findings and apparent violation(s), the inspector should assure the licensee that the inspector will convey the licensee's disagreement to regional management. The inspector should close the meeting and promptly leave the site without lingering for any further discussion before presenting these issues to regional management. The licensee's next opportunity to discuss the findings will be after the regional management has reviewed these matters.~~

c. Post-inspection Activities. After returning from an inspection trip, the inspector shall ~~discuss~~ inform the supervisor of the results of the inspection(s) ~~trip with his or her supervisor~~. ~~This discussion should be sufficient to alert management to significant e~~Enforcement, safety, security, or regulatory issues should be discussed with the supervisor. ~~This meeting need not be documented, but it should be held in all cases. To complete the inspection, t~~The inspector shall document the inspection results in accordance with guidance in this IMC [See Section 2800-0~~8~~9] and other chapters, as appropriate.

d. Requests from Licensees for Assistance. On occasion, licensees ask inspectors for help resolving issues. 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 or 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. ~~NRC Form 591M can be issued in the field without supervisory approval if there are no findings, an NCV, or Level IVcompleted signed by a supervisor when inspector returns to the office. The form does not need to be re-issued unless the characterization of any findings changes during supervisory review.~~

~~05.02 Reactive Inspections.~~

~~Inspections performed to follow up on 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 , shall also determine if the event warrants a recommendation for an AIT or IIT, rather than a reactive inspection. 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 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 event will be performed using the guidance in Management Directive 8.10, "NRC Medical Event Assessment Program." 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."~~

~~A reactive inspection may be necessary because of staff concern arising from a licensee's response to a generic letter or bulletin. When necessary, an inspection plan will be prepared to ensure that any reactive inspection conducted for this specific purpose adequately addresses the concern arising from the licensee's response. The inspector should be sure to use the inspection plan, as well as IP 87103, to ensure the inspection thoroughly addresses the concern.~~

~~A narrative inspection report will be written 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 No. and/or the NRC event notification (EN) number if the reactive inspection was initiated by a reportable event. Enclosure 3 provides instructions to properly "complete" the record for NMED. Section 08.03 outlines the methods for documenting inspections.~~

05.~~03~~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 activities[1], the initial inspection may be rescheduled to within 18 months of license issuance.

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 th~~is~~e 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.

   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 for 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

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1 As defined in 10 CFR Part 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 amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not 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, and/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 ~~has~~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.

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. Encourage the licensee to notify the NRC within 30 days after the receipt of licensed material or initiation of principal activities.

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 initial inspection attempt 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 attempt may vary by ± 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 solely as a result of a licensee's change of mailing address are not required to receive an initial inspection, if the licensee's place of use remains the same as on the previous license. The "last inspection date" and "next inspection date" for the licensee's previous license.~~

~~2.~~ 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) ~~(a)~~ the organization controlling the licensed activities changes substantially (i.e., changes in key personnel, authorities, or resources

associated with the radiation ~~safety~~ 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.

~~3~~2. New licenses that are issued because a licensee did not file a timely application for license renewal ~~are not required to receive an initial inspection in accordance with this section, unless more than 6 months have elapsed between the date the initial license expired and the date the renewal application was submitted~~. 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.~~04~~03 Routine Inspections.

Routine inspection of licensees shall be conducted at intervals in years corresponding to the inspection priority ~~listed in Enclosure 1~~. 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 05.0~~3~~2(b)(1) through (~~4~~6), as applicable.

Routine materials inspections should normally be performed on an unannounced basis. However, to improve the efficiency of inspection trips and/or 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 and/or temporary job sites. 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, and/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 from 1 to 5 locations,

the goal is to inspect 40 percent of the locations at the interval specified in this chapter for the type of license. If the license authorizes licensed activities to be conducted from 6 to 20 locations, the goal is to inspect 30 percent of the locations at the interval specified in this chapter for the type of license. If the license authorizes licensed activities to be conducted from more than 20 locations, the goal is to inspect 20 percent of the locations at the interval specified in this chapter for the type of license.

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 regional management can consider whether a remote means of 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 regional management can consider whether it is beneficial to visit the site in person or if the review can be completed remotely.

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.

b. Temporary Job Sites. For a licensee authorized to work at a temporary job site, inspectors should make ~~every~~ 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 necessary to use licensee transportation or lodging, before accepting transportation or lodging from a licensee, the inspector should obtain approval from the ~~individual's immediate~~ supervisor. This approval should be documented with a brief statement and placed on the docket.

05.0~~5~~4 ~~Telephonic~~ Remote Contacts (Priority ~~T~~R).

~~For certain~~ Priority R licensees~~, the regions~~ shall ~~use telephone~~ be contact~~s~~ed at 5-year intervals ± 1 year in lieu of an onsite inspection, with the exception of initial or reactive inspections. ~~Enclosure 1 designates these licensees as priority T. As defined in Section 2800-03, telephonic contacts are useful for staying in touch with priority T licensees. Procedures for using the telephonic contacts are included as Enclosure 2.~~ When preparing to conduct a remote contact, the inspector should follow the general inspection preparation guidance in Section 05.01, above. ~~A telephonic questionnaire is attached as Enclosure 2, Exhibit 1~~During the contact, the inspector should inquire about the general Focus Elements, as applicable to the authorized activities on the license. The inspector will document the contact and results in accordance with Section 2800-09. If the inspector identifies a violation during the contact, the inspector will discuss the matter with the supervisor to determine if an onsite inspection is warranted. ~~and standard responses back to licensees contacted by telephone are included as Exhibits 2 and 3. This questionnaire should be completed, signed by the inspector, and placed in the docket file, and the next date shall be . The inspector shall brief their supervisor about the telephonic contact.~~

~~05.06 Pre-licensing Visit.~~

~~Generally, Pre-licensing visits shall be conducted 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 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 follow-up, per the guidance in the Pre-licensing Checklist. At a minimum, all 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 of confidence that the applicant will use the radioactive materials as specified in its license application. Pre-licensing visits must be completed before the issuance of a license.~~

~~05.07 Third Party Assistance.~~

~~On occasion licensees ask inspectors for recommendations for obtaining help solving programmatic problems. Inspectors are prohibited from recommending the services of 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 an inspector receives a request for third party assistance from a licensee for a programmatic problem that allows time for the licensee to conduct research in obtaining assistance, they may refer the requestor to a professional group, such as the American Nuclear Society or Health Physics Society or to a licensee that has solved a similar problem. When providing the name of a licensee that has solved a similar problem, take special care not to create a perception of conflict of interest and ensure that the licensee is not the subject of an ongoing investigation for misconduct by NRC's Office of Investigation.~~

~~If an inspector receives a request related to an immediate health and safety issue, the inspector should refer the licensee to an appropriate equipment manufacturer or, following management approval, to one or more qualified consultants/contractors who can provide prompt safety assistance. Special care should be taken in connection with providing recommendations concerning consultants with whom the recommending staff has a personal or long standing relationship. Following the action, document the event and the justification for the action, and provide a copy to the Office of the Executive Director for Operations. The inspector should not~~

~~leave the site until the concern is fully understood by the licensee and corrective action has been initiated.~~

2800-06 INSPECTION ~~INTERVALS~~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 ~~I~~inspections of ~~licensees in~~ Priority ~~Codes~~ 1 and 2 licensees may vary around their due date by ± 50 percent. Routine inspections of Priority ~~Code~~ 3, 4, and 5 licensees and remote~~telephonic~~ contact of ~~p~~Priority ~~T~~R licensees may vary around their due dates by ± 1 year. Inspections will not be considered "overdue" until they exceed the scheduling window.

In rare situations, routine inspections may be scheduled earlier than the window in order to achieve cost savings and efficiencies. For example, in order 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 records and signed by the supervisor and placed on the docket.

~~06.02 Combining Inspections.~~

If a licensee holds several licenses with different ~~P~~program ~~C~~codes that are assigned different inspection ~~P~~priority~~ies~~ ~~Codes in Enclosure 1~~, a single inspection may be scheduled whenever practicable to more ~~effectively~~ efficiently use ~~the inspector's travel time~~ agency resources. ~~Inspections for determining compliance with security requirements may be conducted at the same time as the health and safety inspections. In determining whether to combine inspections on a continuing basis, consideration should be given to not "over-inspect" a lower-priority license versus the need and desirability to inspect a licensee's total activities for a more complete assessment of its safety and compliance performance. The priority designations of the lower-priority licenses shall not be changed in these cases; the more frequent inspections of lower-priority licenses shall be handled only in the scheduling process.~~

~~06.03 Inspections After Escalated Enforcement.~~

~~If escalated enforcement action has taken place for a particular licensee, a special inspection that focuses on Severity Level III or above violation(s) shall be scheduled and conducted within months of the issuance of the escalated enforcement action (Severity Level III or above). Regions may perform this follow-up inspection as a part of a routine inspection. follow-up~~

06.0~~4~~2 Reduction of Inspection Interval.

The interval between inspections may be reduced (shortened) and inspections conducted more frequently than ~~specified in the priority system~~the assigned inspection priority based on ~~the basis of~~ poor licensee performance. The main consideration in reducing the inspection interval

should be evidence of moderate to severe problems in the licensee's radiation ~~safety~~ protection program. ~~Poor compliance history is one indicator of such problems. Lack of management involvement or control over the radiation safety program is another indicator.~~

a. Specifically, licensees that meet one or more of the following conditions shall be considered for reduction in inspection interval if:

   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. A "management paragraph" appears in the cover letter transmitting the notice of violation on the most recent inspection (i.e., a paragraph that requires the licensee to address adequate management control over the licensed program); or

   4. ~~An event requires a reactive inspection~~Poor compliance history over the successive inspections, such as repetitive or a large number of Severity Level IV violations~~; or~~

   ~~5. Repetitive violations occur~~.

   The above list is not exhaustive; the inspection interval can ~~and should~~ be reduced for any other reason deemed ~~pertinent~~ appropriate by regional management. ~~An example would be an enforcement conference where the outcome did not include escalated enforcement action, but did indicate the need for the licensee to improve some aspect(s) of its compliance program.~~

   ~~Another example would be an industrial radiography licensee or a well logging licensee which is authorized to use byproductradioactive material at temporary job sites and the current inspection was limited to an office inspection and no temporary job site inspection was completed during the current inspection. [See Section 07.04]~~

   A licensee ~~that meets the above criteria~~ may have its inspection interval reduced by any length. ~~For example, a priority 5 licensee with a poor performance record could be rescheduled for its next inspection in 2 or 3 years, rather than 5 years, depending on the scope of licensed activities. Or a priority 2 licensee with a Severity Level III or above violation could be rescheduled for its next inspection in 1 year, although a follow up inspection to focus on the Severity Level III or above violation may have already been completed within 6 months. [See Section 06.03]~~ 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. ~~b.~~ The ~~designated~~ 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. ~~To document the~~A reduction in the interval between inspections~~s, a brief note (i.e., in the~~

~~inspection record) should be written by the inspector describing the condition for reducing the interval and be~~ must be documented, approved and signed by ~~the inspector's immediate supervisor~~ regional management, and placed ~~in the docket file~~on the docket. The inspection tracking system 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 would be a one-time extension.~~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. In addition, the identification of a Severity Level IV violation is not by itself a basis for concluding a licensee is not a high performer. 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 R licensees are not eligible for this extension.~~Eof the next inspection high wouldconstitute a~~

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. ~~2.~~ The past two inspections have identified no escalated enforcement and there has not been the need for a management paragraph;

   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;

   4. In situations where the licensee also conducts work in Agreement States, inspections conducted by the Agreement State(s) have not identified significant findings.

   Normally, a licensee that meets the above criteria will 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, and placed on the docket. The inspection tracking system 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 ~~safety~~protection program. Reconsideration of the next inspection due date should follow the guidance in Sections 06.04~~2~~ or 06.0~~6~~4, 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, ~~large~~ large-team, ~~high~~ high-impact inspection of the license at the normal interval, more frequent limited scope inspections may be performed by individuals or smaller teams 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 a timely inspection from being completed. The bases for altering the scheduling of inspections should be documented, approved and signed by regional management, and placed on the docket. The inspection tracking system must be updated accordingly.

~~06.0 Coordination with Agreement States and Other Regions.~~

~~When licensed activities cross jurisdictions or the demonstration of compliance with portions of the security requirements must be made outside of the licensed facility, regional management will coordinate with the other Region or Agreement State to ensure that each regulatory authority is aware of inspection effort, scope, and results. When a licensee has licenses issued by multiple jurisdictions or the inspection being performed is the result of a notification of reciprocity, regional management will, when possible, coordinate joint inspections of security requirements with other jurisdictions. The scope and scheduling of reciprocity inspections and inspections of temporary job sites or field offices should be consistent with IMC 2800 and IMC 1220. In most inspections of temporary job sites or field offices, not all licensee implementation of security requirements can be inspected at these facilities, such as in the case of trustworthiness determinations that have been performed by the human resources division of the corporation that is located in another jurisdiction. The inspection record or report should reflect that such elements were deferred to the appropriate jurisdiction. A record documenting the inspection findings from the other Region or Agreement State should be requested and maintained with other records of the licensee's inspection, when possible.~~

2800-07 ~~SPECIAL~~ NON-ROUTINE INSPECTIONS ~~ACTIVITIES~~

07.01 Reactive Inspections.

A reactive inspection will not substitute for 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.

a. Reactive Inspections for Incidents/Events

Inspections performed to follow up on 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.

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 No. 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.

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 explain the exit meeting strategy with his or her supervisor before beginning the meeting.

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."

IMPORTANT NOTE

No reference to follow-up of an allegation or employee concern will be entered in the inspection records, inspection reports, 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 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.

07.0~~1~~2 Inspections of Bankrupt, Expired, Abandoned, ~~Expired, and~~or ~~Terminated~~Revoked Licenses ~~and Decommissioning Activities~~.

If the staff becomes aware of a change in the circumstances of a licensee, ~~Notification that a license has expired or is being terminated requires~~ prompt action ~~(i.e., within 30 days)~~ may be necessary to ensure that licensed material has been properly secured, transferred, or disposed of, and that ~~all~~ areas where material was used ~~may~~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.

Appropriate security and control of licensed material is of the highest priority in these situations. Staff will determine whether an onsite inspection is needed or if remote contact is acceptable, commensurate with the situation. For bankruptcy cases, additional coordination with the program office and the Office of General Counsel may be required. 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."

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; 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 ~~i~~inspector~~s~~ should be ~~aware~~ knowledgeable of the ~~need for~~ security and control requirements ~~of~~ for the applicable licensed ~~radioactive~~ materials at the~~se~~ ~~types of~~ facilit~~ies~~y 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 ~~This may be done by~~ review~~ing~~ 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~~ing~~ that an authorized recipient ~~has~~ received the material~~;~~. ~~and/or by performance of an inspection that may include independent or confirmatory measurements.~~ 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. ~~Such actions would be conducted as soon as appropriate after notification is received.~~

~~If an inspection is performed, the inspector should also verify that the licensee is complying with regulations for timely decontamination and decommissioning, and meeting the required schedules for licensee action, as specified in the decommissioning timeliness rule.~~

~~Specific guidance for decommissioning requirements and performing closeout inspections is outlined in NUREG-1757 and IP 83890, respectively.~~
All activities associated with this section must be appropriately documented and placed on the docket for future reference.

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). 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 use remote means of inspection, such as telephone interview, 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 in areas under Federal jurisdiction. The licensee must submit an NRC Form 241, "Report of Proposed Activities in Non-Agreement States" at least 3 days before engaging in the licensed activity. 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.~~[INSERT TITLE]".~~
~~a. The recipient of the NRC Form 241 is the NRC Region in which the Agreement State that issued the license is located (licensing region).~~

~~b. IMC 1220 details the process for scheduling the inspection of the licensee operating under reciprocity. The licensing region shall forward the form to the NRC regional office having jurisdiction in the area of the licensee's proposed activities (inspecting region).~~

~~c. The inspecting region shall follow the policy and guidelines found in IMC 1220, Appendix III, for performing inspections of reciprocity licensees. IMC 1220 details the percentage of reciprocity licensees to be inspected each year. The inspectors shall use the program-specific procedures which are used for equivalent NRC-licensed activities.~~

~~d. The inspecting region is responsible for initiating enforcement action and taking other follow-up actions, as appropriate for the inspection. In addition, the inspecting region shall send copies of inspection and enforcement documentation to the licensing region and to the Agreement State radiation control agency which issued the license that is the basis for the general license under 10 CFR 150.20~~
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) ~~that have U.S. Nuclear Regulatory Commission (NRC) jurisdiction in~~ shall conduct reciprocity inspections for work performed within their assigned jurisdictions~~the area(s) in which the Agreement State licensees will operate shall take the following action:~~. 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.

All reciprocity applicants are eligible for inspection. Reciprocity inspections shall be selected in a risk-informed manner based on the following guidance:

- need for a ~~R~~reactive inspection~~s~~ based on ~~recent or~~ on-going event;
- review of ~~to~~ an allegation, as it relates to the work being conducted under reciprocity;
- ~~I~~inspection priority and/or scope of work to be performed;~~—~~
- inspection, ~~E~~enforcement, and incident history (e.g., discussions with regulatory agency that issued license, NMED, National Enforcement Database, etc.);
  ~~Scope of the work to be performed~~
- ~~D~~duration (i.e., length of work/storage or number of visits in a calendar year);
- ~~A~~amount of work in other regulatory jurisdictions (i.e., ~~how many~~ number of inspections of this entity in a given year under the National Materials Program);
- ~~N~~new or unique technology; or,
- ~~A~~any other situation as deemed appropriate by the regional management.

Commented [MA1]: The working group prefers to eliminate a reciprocity metric to provide maximum discretionary flexibility; however, if a metric is needed, the working group supports the previous recommendation from the Continuous Improvement Working Group in 2007 for 5 percent, with a caveat that ALL reciprocity applicants should be considered using the guidance noted below to help inform the selection of inspections, rather than continue the practice of identifying "candidates".

Although reciprocity inspections pose unique challenges, such as short lead time and logistics, inspectors should make a reasonable effort to conduct unannounced reciprocity inspections. 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.

~~1.1. Frequency Inspections of Agreement State licensees operating under general licenses under 10 CFR 150.20 should be conducted using the same provisions used for equivalent NRC-licensed activities, except as specifically defined in this chapter. These provisions include, but are not limited to, inspection processes and inspection records as defined in NRC Manual Chapter 2800 (MC 2800). However, the inspection frequencies for reciprocity licensees are not subject to the provisions in MC 2800 and are not to be extended for good licensee performance.~~

~~To determine if a reciprocity licensee should be a candidate for inspection, the region processing the initial NRC Form 241 request should do the following:~~
~~a. Determine if the reciprocity licensee has had NRC escalated enforcement in the past 2 years.~~
~~b. Review the Nuclear Materials Event Database (NMED) to determine if the reciprocity licensee has had a significant NMED event (e.g., source disconnects, lost sources, overexposures) in the past 2 years. If NRC has inspected the reciprocity licensee (in the field), in the last calendar year, and the licensee has not had escalated enforcement or a significant NMED event in the past 2 years, then the reciprocity licensee is NOT to be considered a candidate for inspection. All other reciprocity licensees are to be considered candidates for inspection.~~

~~The percentages of inspections of reciprocity licensees to be inspected each year are based on the number of candidates for inspection per region. The percentages of inspections by program code and priority should be as follows, with Priorities 1 through 3 as Core Inspections and the remaining priorities as non-Core Inspections:~~
~~Priorities 1, 2, and 3 program codes - 20 percent of the candidate licensees from the candidate pool are to be inspected each year.~~
~~All other program codes - Are to be inspected each year, as resource and inspection schedules permit.~~

~~NOTE: If the work to be performed by the reciprocity licensee (who is a candidate for inspection) is within a Region other than the Region that received the Form 241, the Region receiving the Form 241 should promptly notify the Region where the work is to be done of the Accession Number of the Form 241 and supporting documentation.~~
~~NOTE: In cases where a licensee performs reciprocity activities in several regions, the Region with the first opportunity to inspect the licensee at a work site should do so. The completed inspection should be recorded as a completion for the inspecting Region. The inspecting Region should notify the Regional Office responsible for the area in which the Agreement State licensee is located.~~

~~2. Location~~
~~Inspections of Agreement State licensees operating under reciprocity in areas of NRC jurisdiction pose many difficulties, such as short lead time and logistics. Nevertheless, reciprocity inspections are to be conducted during actual field work. Such inspections should be unannounced, but may be announced, when necessary, in the interest of effectiveness and efficiency.~~

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 the inspection tracking system.

07.0~~2~~5 Significantly Expanded Programs.

~~During routine inspections of licensed facilities, inspectors should evaluate if licensed activities have significantly increased or decreased since the last inspection. A license reviewer may request a near-term onsite inspection for a significant licensing action that was recently completed. Both the inspectors and the reviewers should make their supervisors aware of the following changes in a licensee's scope of use.~~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.

~~a. Through interviews of licensee staff or observations of licensed activities, the inspector shall determine if:~~

~~1. the licensee has recently increased the types, quantities, and uses of radioactive material and if these actions have resulted in the possession of RSRM;~~

~~2. the license authorizes a physical move of a facility or a new use at a temporary jobsite;~~

~~3. the license authorizes new (i.e., since the previous inspection) satellite facilities where materials will be used or stored;~~

~~4. the licensee has increased the types of uses or disposal (i.e., incineration or decay-in-storage) of radioactive material;~~

~~5. the number of authorized users has significantly increased or decreased; and~~

~~6. the licensee has ceased activities at the entire site or in any building or area as defined in 10 CFR 30.36(d).~~

~~If any of the above items demonstrates a possibility that the licensed activities have significantly changed, then the inspector should document the changes to the licensee's program in the inspection records and notify the inspection supervisor.~~

~~b. A license reviewer may request a special inspection, if, during the licensing review process, it is determined that the licensee's program has significantly expanded or activities have ceased. [See the six points in the preceding paragraph]~~

~~c. If during the licensing review process, the reviewer determines that the licensee will possess RSRM, the reviewer, in consultation with management and administrative staff, should add Program Code 01000. An onsite inspection must be performed to verify that the applicant has implemented the security requirements or Increased Controls before the licensing action is issued allowing the applicant/licensee to take possession of RSRM.~~

07.03 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 in areas under Federal jurisdiction. The licensee must submit an NRC Form 241, "Report of Proposed Activities in Non-Agreement States" at least 3 days before engaging in the licensed activity.

a. The recipient of the NRC Form 241 is the NRC Region in which the Agreement State that issued the license is located (licensing region).

b. IMC 1220 details the process for scheduling the inspection of the licensee operating under reciprocity. The licensing region shall forward the form to the NRC regional office having jurisdiction in the area of the licensee's proposed activities (inspecting region).

c. The inspecting region shall follow the policy and guidelines found in IMC 1220, Appendix III, for performing inspections of reciprocity licensees. IMC 1220 details the percentage of reciprocity licensees to be inspected each year. The inspectors shall use the program-specific procedures which are used for equivalent NRC-licensed activities.

d. The inspecting region is responsible for initiating enforcement action and taking other follow-up actions, as appropriate for the inspection. In addition, the inspecting region shall send copies of inspection and enforcement documentation to the licensing region and to the Agreement State radiation control agency which issued the license that is the basis for the general license under 10 CFR 150.20.

07.04 Temporary Job Site or Field Office Inspections.

a. Temporary Job Sites. For a licensee authorized to work at a temporary job site, inspectors shall make every reasonable attempt to include an unannounced inspection of licensed activities at such a location(s).

1. During the inspection of a licensee's principal place of business, 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 the 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 write a brief note in the inspection records explaining the missed temporary job site inspection. In certain cases, the may indicate a reduced inspection interval. [See Section 06.04]

b. Permanent Field Offices. Each licensing region is responsible for requesting an assist

~~inspection (i.e., an inspection conducted by one region at the request of another region) at each permanent field office to be inspected, if these locations are outside the geographical area of the licensing region. The inspecting region should provide complete documentation and recommend enforcement action to the licensing region, which will distribute the documentation, initiate enforcement action, and take other follow-up actions, as appropriate to the case. [See Section 09.02]~~

~~1. If the license authorizes licensed activities to be conducted from two or three permanent facilities (main office plus one or two field offices), only one location must be inspected at the interval specified in this chapter for the type of license. If the license authorizes licensed activities to be conducted from 4 to 10 permanent facilities (main office plus 3 to 9 field offices) at least 2 locations must be inspected at the interval specified in this chapter for the type of license. If the license authorizes licensed activities to be conducted from more than 10 permanent facilities (main office plus more than 9 field offices), about 20 percent of the locations should be inspected. Inspection of various field offices should be rotated to assess the licensee's entire program over several inspection cycles.~~

~~2. If the license does not authorize licensed activities at the main office location, the inspection should include the main office location to verify the licensee's audit program was implemented to determine the performance of its field office activities.~~

~~3. If an inspection identifies significant program weaknesses (i.e., Severity Level III or above violation(s), multiple Severity Level IV violations indicative of poor program management/oversight), the licensing region should consider expanding the initial review to include additional satellite locations to determine the extent of the weakness.~~

~~c. Off-Shore Waters. For a licensee working in off-shore waters, the regional staff should either make travel arrangements to accompany another Federal agency to the rig to complete an unannounced inspection or contact the rig operators, or appropriate licensee contact, to request the licensee to provide travel arrangements to the platform or lay barge when work is in progress. Before accepting transportation or lodging from the licensee, staff should obtain approval from the individual's immediate supervisor. This approval should be documented with a brief statement in the inspection records. NRC should reimburse the provider for the cost of transportation, lodging, or other services accepted during the course of inspections.~~

~~07.05 Team Inspections.~~

~~[NOTE: This section is included solely for team inspections of materials licensees. The term "team inspections" is used here only for the purposes of this IMC. The requirements of other IMCs or IPs for team inspections or team assessments of nuclear reactors and fuel cycle facilities do not apply.]~~

~~Regional offices shall conduct team inspections of major licensees within the region as needed. Regional management, in consultation with MSTR, shall decide whether to conduct a team inspection involving agencies outside the NRC (other than State radiation control agencies). Examples where team inspections may be appropriate are:~~

a. Routine inspections of major licensees (i.e., broad-scope academic, broad-scope medical licensees, and large processor/manufacturers). As an example, a team inspection should be considered when the size or complexity of operations at a broad-scope licensee goes beyond that which one or two inspectors can cover in a week. Team inspections are also appropriate when the team will include an expert in a specialty discipline other than health physics, such as a medical physicist, human factors specialist, fire protection specialist, engineer, or other specialized fields.

b. Reactive inspections of any type of licensee where one or more specialists are needed on the team (of three or more inspectors). Also, reactive inspections of any licensee where at least one of the three or more inspectors is from another region or from Headquarters.

c. Routine inspections of major licensees within the year before license renewal. Team inspections are appropriate methods to assess licensees' strengths and weaknesses, and to provide feedback to the licensing process. Such team inspections should include license reviewers on the team. However, pre-licensing visits are not considered inspections, and team inspections should not take the place of pre-licensing visits.

d. Inspections of any type (routine or reactive) that include team members from outside the NRC and the State radiation control agencies, such as members from the Department of Transportation (DOT), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and OSHA. For inspections of any type that involve participation by outside agencies (other than State radiation control agencies), the region should coordinate through the NRC Regional State Liaison Officer with the outside agency. For inspections that include FDA participation, the Region should coordinate with NMSS.

At regional management discretion, inspection plans may be developed for all team inspections. Inspection plans should be considered for team inspections of major, broad-scope academic or medical licensees, large manufacturers, or in cases where team members from agencies outside the NRC (other than State radiation control agencies) are involved. [See examples (a) and (d) in this section]

07.06 Abandonment of Licensed Activities.

Returned, undeliverable mail to licensees should trigger an immediate follow-up. The follow-up should include a telephone call to the licensee to establish the licensee's physical address. If telephone contact is not established, then an inspector should be sent to the licensee's site. The regional decision of when to send an inspector to a licensee's site should be based on the complexity of the licensed activities, and the types and quantities of licensed material.

07.07 Inspections of Material Possessed Under a General Licensed Devices.

Routine iInspections of general licensees [other than reciprocity (10 CFR 150.20)] under 10 CFR Parts 31, 40, and 70 are not not normally performed. However, if a specific licensee also possesses material under a generally licensed devices that require registration under 10 CFR Part 31, the inspector should verify the adequacy of the licensee's control and accountability of the materialsdevices [See IP 87124, Focus Element 1], especially those that require registration under 10 CFR 31.5. Additionally, inspectors should make an effort to track down and address missing, orphaned, or abandoned sources during routine inspections. Inspections of general

licensees may shall also be made to resolve issues such as conducted in response to allegations, incidents, or indications of unsafe practices and as resources permit.

07.07 Inspections of Licensees Undergoing Decommissioning.

Specific guidance for decommissioning requirements and performing closeout inspections is outlined in NUREG-1757 and IP 83890, respectively.

07.08 Inspection of Master Materials Licenses.

An MML is a multi-site, multi-regional material (byproduct, source, and/or special nuclear material) license issued to a Federal organization that authorizes the licensee to undertake a limited number of activities as a regulatornormally performed by the NRC. The MML authorizes the licensee to issue permits for the possession and use of licensed material listed on the MML license, and ties the licensee to a framework for oversight and internal licensee inspection of the MML permittees. These internally managed licensing and inspections programs are similar to NRC's. IMC 2810, among other things, establishes the program for NRC's oversight of the licensee's performance and biennial review of the MML's radiation control program and established a system for handling findings, including enforcement. IP 87129 provides specific guidance for NRC's inspection of an MML.

Each licensing region (Lead Region) has assigned the project management responsibilities for the MML to a designated NRC staff member (NRC MML Project Coordinator). One of the coordinator's responsibilities is the routine inspection of the MML. As such, the Lead Region requests other of the NRC's regional offices (Assisting Regions) to complete assist inspections (accompaniment inspections and independent inspections).

a. For accompaniment inspections, the Assisting Region's inspectors shall implement IP 87129 while accompanying the MML's staff during routine radiation safety audits of the MML's permit holders. The purpose of the accompaniment inspection is to determine whether or not the MML's staff are inspecting the permit holders in accordance with NRC's inspection policies and procedures [See Enclosure 4]. In addition, the inspectors shall obtain information deemed necessary by the Lead Region for special issues relating to the inspection.

    1. IP 87129 includes forms to document the accompaniment inspections.

    2. IMC 2810 provides specific guidance on the responsibilities of NRC inspectors.

All allegations received by NRC inspectors shall be forwarded to the Lead Region MML Coordinator and Office Allegation Coordinator for action by the Lead Region. If independent follow up by NRC is needed, the Lead Region may request the assisting Region to assist with the follow up for the allegation.

07.09 Inspection of Licensees Holding Nuclear Materials Management and Safeguards System (NMMSS) Accounts.

The NMMSS is the Federal database for current and historical data on the receipt, shipment, and inventory adjustment of certain source and special nuclear materials that are listed in Enclosure 7. The United States government uses the NMMSS data to comply with certain international requirements for tracking certain source and special nuclear materials. The

~~NMMSS database is operated by a contractor on behalf of the U.S. Department of Energy and the NRC.~~

~~During each routine inspection of a licensee holding a NMMSS account, the inspector will:~~

1. ~~Review the licensee's inventory records of licensed materials and compare them to the information that the licensee has reported to NMMSS.~~

2. ~~Compare licensee transaction data reported to NMMSS for certain source and special nuclear material (see Enclosure 7) with the receipt, transfer and disposal records maintained by the licensee in accordance with 10 CFR 40.61 or 74.19.~~

3. ~~At a minimum, physically assess the presence of a representative sample of the NMMSS-reportable material that the licensee claims to possess according to the licensee's most recent report to NMMSS.~~

4. ~~Provide the licensee with the NMMSS summary of the licensee's administrative information and explain the process for making any needed changes.~~

~~Additional information about reviewing NMMSS records is contained in Enclosure 7.~~

2800-08 SITE VISITS

08.01 Pre-licensing Visit.

Generally, pre-licensing visits shall be conducted 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.)

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 follow-up, per the guidance in the Pre-licensing Checklist. All 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 of confidence that the applicant will use the radioactive materials as specified in its license application. Pre-licensing visits must be completed before the issuance of a license.

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 will be prepared to implement the security requirements before the licensing action is issued allowing the applicant/licensee to 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.

2800-09~~8~~ DOCUMENTATION OF INSPECTION RESULTS

09.01 Required Information to Document Inspections.~~08.01 What Constitutes an Inspection.~~

~~The following guidance is provided to assist in determining when activities constitute an inspection.~~

~~a. An inspection will be considered to have been performed if:~~

~~1. the inspection involves a licensee that possesses or has possessed licensed material since the last inspection, including material possessed under a "possession-only license" or that is performing or has performed activities since the last inspection; or~~

~~2. the inspection is an initial inspection that has been performed in accordance with Section 05.03.~~

~~If it is possible to inspect records or other items according to license conditions or NRC regulations, such activities should be inspected and be recorded as an inspection, whether the radiation safety officer (RSO) is present or not, including those licenses that have expired or are being processed for termination.~~

~~If the RSO is not onsite, the inspector shall to contact the RSO about the inspection. At the conclusion of the inspection, the inspector shall re-contact the RSO to explain the inspection results. If the inspector is unsuccessful in announcing the inspection to the RSO, the inspector shall make a follow-up telephone call to the RSO as soon as possible after the onsite inspection.~~

~~b. An inspection will not be considered to have been performed if the licensee or licensee's representatives are not available to assist with the inspection, and the inspector is unable to perform inspection activities. The inspector will document the on-site activities by placing a note in the docket file, signed by the inspector that briefly summarizes the attempted inspection. Together, the inspector and his or her supervisor should determine when another attempt will be made to inspect the licensee.~~

~~c. Regions performing assist inspections will receive credit toward the operating plan goals for conducting each assist inspection.~~

~~d. A reactive inspection will not substitute for a routine inspection unless the scope of the inspection is comprehensive.~~

~~08.02 Allegations.~~

~~Allegations will be followed up and the results documented and transmitted in accordance with NRC Management Directive 8.8, "Management of Allegations." No reference to follow-up of an allegation or employee concern will be entered in the inspection records, inspection reports, or other documents that will be filed in the docket file for the licensee. The Ffollowing is further guidance about "chilling" effect.~~

~~a. 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 an inspector determine if problems exist in the licensee's safety 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?~~

~~b. If any indication of a "chilling" effect is found, the inspector shall inform regional management for further review and follow-up.~~

~~08.03~~

All documented inspection results must contain the following minimum information:

1. licensee information (name, location(s) inspected, license number, docket number, contact name, and contact information)

2. inspection information (type, date, and report number)

3. program information (program code(s), priority, inspection procedure(s) used, focus elements reviewed)

4. a description of the scope of the licensee's program;

5. a description of the scope of the inspection;

6. the status of followup items involving prior enforcement, including closure of previously cited violations, or reported licensee events;

7. 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;

8. if applicable, a statement that the licensee's reporting to NMMSS was reviewed in accordance with the procedures described in Enclosure 2;

9. 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;

10. next inspection date, including justification if date is reduced or extended; and,

11. 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(s) 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.

~~a. Types of documentation.~~ The inspector shall complete either ~~NRC Form 591M (Enclosure 5), Inspection Record (Enclosure 6), or~~ a narrative inspection re~~cord~~port ~~(per IMC 0610)~~ or an inspection record to document inspection results. All inspection documentation shall be filed on the docket, following supervisory review.

~~NRC Form 591M, "Safety Inspection Report and Compliance Inspection" (Enclosure 5). An inspector may issue an NRC Form 591M Part 1, while still in the field, for:~~

~~(a) an inspection that results in no findings; or~~

~~(b) to document a non-cited safety violation (NCV); or~~

~~(c) to document a Severity Level IV violation (health and safety only) that does not require an amendment to the license to correct and is not willful or repetitive in nature. The Severity Level IV violation being documented in this manner must be corrected while the inspector is 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 Part 1.~~

~~When NRC Form 591M Part 1 is used to document the results of an inspection, NRC Form 591M Part 3 must also be completed. Enclosure 5 of this Chapter provides the format for documenting the results of an inspection using NRC Form 591M. The inspector must ensure that each cited and non-cited violation on the form includes: a brief statement of the circumstances, including the date(s) of the violation or NCV and the facts necessary to demonstrate that a requirement was not met; reference to the regulation, license condition or other legally binding requirement that was violated; and a description of the licensee's corrective actions. NRC Form 591M Part 1 may not be used to transmit non-cited or cited security-related violations. Following are examples of cited violations on an NRC Form 591M:~~

~~10 CFR 20.1101(c) requires the licensee to annually review the content and implementation of the radiation protection program. During years 2006 and 2007, the licensee did not complete the review. The licensee will complete the review within 30 days for the period of January 2006 through September 2007. The licensee intends to complete future reviews in October of each year by completing NUREG-1556, Volume 2, Appendix I, Radiation Safety Program Audit.~~

~~As required by 10 CFR 34.29, the licensee did not perform a quarterly physical inventory during~~

~~the period from February 25, 2007, to October 24, 2007, to account for all sealed sources and devices containing depleted uranium. The licensee will implement an automated reminder system within 30 days to notify the Radiation Safety Officer to perform the inventories.~~

~~1. Inspection Record, Enclosure 6. An inspector may document non-escalated violations in an inspection record conforming to the requirements of Enclosure 6.~~

~~The inspector must ensure that each cited and non-cited violation in Enclosure 6 includes: a brief statement of the circumstances, including the date(s) of the violation or NCV and the facts necessary to demonstrate that a requirement was not met; reference to the regulation or license condition that was violated; and a description of the licensee's corrective actions.~~

~~The licensee will be issued a cover letter, with or without a Notice of Violation. The cover letter should not contain any security-related information. If security-related or sensitive information has to be conveyed to the licensee, the inspector will prepare a separate enclosure with the proper Sensitive Unclassified Non-Safeguards Information (SUNSI) or Safeguards Information – Modified Handling (SGI-M) markings.~~

1. Narrative Inspection Report. A narrative inspection report is required for ~~all~~ 1) team inspections, 2) ~~and actions~~ inspections involving ~~an enforcement conference and/or~~ 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 security-related 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 similar to the depth of detail in an inspection record.

   For reactive inspections for 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 similar to the depth of detail in an inspection record. For medical events, the narrative report must follow the guidance in MD 8.10.

~~For cases of escalated enforcement, the narrative report should address only the areas of concern and any violations that were identified. A cover letter with a narrative inspection report, and the applicable NRC enforcement action, will be sent to the licensee. The cover letter should not contain any security-related or sensitive information. If security-related or sensitive information is conveyed to the licensee, the inspector should prepare a separate enclosure with the proper markings. The narrative report should also contain the information described below.~~

2. Inspection Record. The inspector will document the inspection on an inspection record any time a narrative report is not required, including non-escalated violations. The 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 security-related or sensitive information is included in the inspection record, the inspector must include proper markings.

~~2.~~

Commented [MA2]: Will add reference once new format and form number are established.

~~b. Required Information to Document Inspections. All documented inspection results (NRC Form 591M (Enclosure 5), Inspection Record (Enclosure 6), or narrative inspection report must contain the following minimum information:~~

~~1. the procedure(s) used;~~

~~2. the focus areas examined;~~

~~3. the status of follow-up items involving prior enforcement or reported licensee events;~~

~~4. sufficient information to support cited violations, non-cited violations, and closed violations identified during a previous inspection;~~

~~5. description of completed and anticipated corrective actions for any identified violations;~~

~~6. a succinct description of the scope of the licensee's program;~~

~~7. if applicable, a statement that the licensee's reporting to NMMSS was reviewed in accordance with the procedures described in 07-09 and Enclosure 7; and,~~

~~8. for inspection with no violations, the inspector should inspection record (e.g., NRC Form 591M Part 3 or Enclosure) the licensee's implementation of security requirements.~~

~~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.~~

~~Any subsequent inspector should be able to refer to the inspection record to prepare for an inspection to easily determine what corrective actions were taken, and why a non-cited violation was not cited.~~

~~All inspection documentation shall be filed in the licensee's docket file. For medical events, the narrative report must follow the guidance in Management Directive 8.10. Additional guidance on inspection reports can be found in IMC 0610, "Inspection Reports." Narrative inspection reports may be used to document other types of inspections at the discretion of regional management.~~

~~Each type of report (591M, inspection record, and narrative report) must be signed following Supervisory review. In addition the three types of reports must be placed in the Agencywide Documents Access and Management System (ADAMS) or the Safeguards Information Local Area Network and Electronic Safe (SLES) system, following Supervisory review.~~

0~~8~~9.0~~4~~3 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~~, or a regional office letter either with or without a Notice of Violation (NOV) to the licensee~~.

Commented [MA3]: This may change depending on new form for inspection record. Depends on whether this form and the new form should be numerically sequential for ease of retrieval.

1. 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 security-related information is included in any of the transmitted enclosures, the letter and its enclosures must include proper markings.

2. NRC Form 591M~~ Part 1~~. The inspector may issue an NRC Form 591M for the following circumstances: (1) an inspection that results in no findings; (2) to document non-cited safety violations (NCV); or (3) to document Severity Level IV violations (health and safety only) 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. NRC Form 591M shall also not be used to transmit violations that are willful or repetitive. 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 would require 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 a NRC Form 591M.

   The inspector ~~will~~may present the completed and signed NRC Form 591M ~~Part 1~~ to the licensee~~ at the conclusion of the exit interview~~ prior to leaving the site.~~, or, on rare occasions where consultation with regional management is necessary,~~ ~~t~~The inspector may also transmit the completed and signed NRC Form 591M ~~Part 1~~ from the ~~regional~~ office.~~ NRC Form 591M Part 1 may not be used to transmit security related non-cited or cited violations.~~

   ~~The NRC Form 591M, "Safety Inspection Report and Compliance Inspection," shall include the name of the responsible inspector. The inspector shall sign the completed Form 591M Part 1. Supervisory review is required, but is not necessary prior to issuance of Form 591M Part 1, to the licensee. If no changes are needed after supervisory review, the supervisor will sign the final signature block and the completed form will be put in ADAMS (only one form is maintained since it provides record of both the finding communicated to the licensee, and the final approved action). If changes are needed after supervisory review, Form 591M Part 1 will be reissued to the licensee, and both the original Part 1 and the revised completed form will be put in ADAMS (both versions are maintained in order to provide record of both the initial finding communicated to the licensee and the final approved action).~~

~~a. Letter to licensee, with or without NOV. When findings are documented in an~~
~~b. Inspection Record (Enclosure 6) or in a narrative inspection report, a letter shall be used to inform the licensee of the results of the inspection. The letter will be a publicly available document. If security-related information is transmitted to the licensee the information should be placed in a separate enclosure to the letter with the proper SUNSI or SGI-M markings. SUNSI and SGI-M should not be made available to the public.~~

c. Marking of Inspection Documentation. Information relative to the licensee's physical protection measures (security-related information) is sensitive information and needs to be protected. The inspector should ensure that the NOV, documentation of findings (i.e., NRC Form 591M Part 3 (Enclosure 5), Inspection Record (Enclosure 6), or narrative inspection report), and any other separate enclosure are appropriately protected, handled and marked in accordance with the SUNSI and SGI-M guidance. All cover letters to licensees will be publicly available and should not contain sensitive information. SUNSI and SGI-M should not be made available to the public.

2800-109 COORDINATION OF AMONG REGIONAL RESPONSIBILITY FOR INSPECTIONSOFFICES

09.01 General.

When a license authorizes operations in more than one region, the responsibility for inspection shall resides with the regional office responsible for the location ofin which the licensee's main facility where principal activities are performedmain office is located. The main office means the corporate office, normally the street address listed in item 2 of the license.

09.02 Assistance in Inspections.

In the interest of efficiency in use of travel time and funds, the responsible regional office may request another regional office to conduct inspections (assist inspections) of the activities of such licensees when the licensee is operating outside the geographical area of the responsible region. [See Section 07.04(b)] Because of the close proximity of a licensed facility to the responsible region's boundary, 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.

Rather than request assistance from another region, the responsible region's personnel may perform the inspection activity themselves rather than request assistance from another region due to resource constraints in the requested region, familiarity with a complex program, or other extenuating circumstances. In such cases, these activities should must be coordinated between regions. As resources allow, the responsible region may be requested to conduct other inspections in the geographic area on behalf of the other region in the interest of efficiency of agency resources.

09.03 Transfer of Responsibility.

Notwithstanding the above (Sections 09.01 and 09.02), Wwhen 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 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 States and/or 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 the 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.

2800-1~~0~~2 COORDINATION WITH ~~OTHER~~ FEDERAL AGENCIES

~~10.01 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 that are within another agency's regulatory authority. If such concerns are significant ~~and the licensee demonstrates a pattern of unresponsiveness~~, the NRC ~~regional office, in coordination with NMSS,~~ should inform the appropriate liaisons within the other agency about the concerns.

Except for DOT regulations, it is important that all inspectors recognize and understand that they are not to make decisions regarding activities under the purview of other agencies. ~~Thus, i~~In discussing the concerns with the licensee, inspectors are cautioned not to judge whether a given condition is a violation of another agency's rules or regulations, but are to point out concerns to heighten licensee awareness. ~~For example, if an inspector identified concerns for lack of fire protection, then it would be appropriate to encourage the licensee to advise the local fire department of conditions in the facility and to take prompt action to correct the situation. The inspector would also advise the licensee of the inspector's obligation to inform the NRC supervisor who may coordinate the information with OSHA as per IMC 1007.~~

In the case of complaints or allegations involving another federal agency's jurisdiction, the inspector should withhold the information from the licensee management and ~~elevate~~ submit the concern(s) to the ~~attention of NRC regional management while the inspector is still onsite~~ appropriate NRC liaison as soon as practicable after the onsite inspection to forward to the appropriate agency. ~~[See Section 08.02]~~

NRC has entered into several Memoranda of Understanding (MOUs), with other Federal agencies~~, which outline agreements regarding items such as exchange of trade secret information and evidence in criminal proceedings. These MOUs are published in the NRC Rules and Regulations (Volume IV) and copies may be obtained from the regional office or MSTR.~~ . 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 1980. 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, 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, 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 4 categories of hazards that may be associated the licensed materials:

(a) radiation ~~risk from~~ hazards produced by radioactive materials,

(b) chemical ~~risk from~~ hazards produced by radioactive materials,

(c) facility conditions that affect the safety of radioactive materials and thus present an increased risk to workers ~~or members of the public~~, and

(d) facility conditions that result in an occupational ~~risk but do not affect the safety~~ 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, NRC, 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 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, 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.

~~10.02 State Agencies.~~

~~For routine NRC inspections in both Agreement and non-Agreement States, State radiation control program personnel shall be notified of the inspection at least one week in advance, by telephone, e-mail, or facsimile.~~

~~State personnel interested in participating may do so as observers as long as their presence does not affect NRC's inspection program. State personnel should be informed that information gathered during the inspection is confidential and pre-decisional and shall not be disclosed.~~

~~Whenever possible, for reactive inspections of NRC licensees in Agreement States, State radiation control program personnel should be notified before the start of the inspection so that any public inquiries that may come to the State radiation control agency may be referred to the appropriate regional office.~~

~~2800-11 INPUT INTO NRC TRACKING SYSTEMS~~

~~11.01 Input into the Web-Based Licensing System (WBL).~~

~~Enclosure 1 provides a listing of license program codes, associated with this IMC, with the associated inspection priorities. Regions should enter data promptly into WBL at the time a new license is issued or an inspection has been performed, including the dates for initial inspections of new licensees, the last inspection date, and the next inspection date for licensees already inspected. When changes are made to the next inspection date (reductions in the inspection intervals), regions should enter the data for the revised next inspection date into WBL and enter the Special Inspection Code on the Inspection and Enforcement Screen, as described in Section 06.04(b).~~

~~11.02 Input into the Nuclear Material Events Database (NMED).~~

~~manages NMED for all materials-related incidents and events. The regional office is responsible for ensuring that is notified of all material-related incidents. The regional office shall also forward annotated copies (with the NMED event number, event notification, or both on each document) of all documentation regarding a materials incident (i.e., "Preliminary Notifications," reports of medical events, follow-up inspection reports) to the NMED contractor and the NRC NMED Project Manager.~~

~~The regional office is responsible for ensuring that sufficient information is provided for the NMED item to be considered "complete." For documents that are publicly available, entry into ADAMS meets the requirement for forwarding documents. For documents that are not publicly available, the regional office must redact the non-publicly available information from the~~

~~document so that the document can be placed in ADAMS as publicly available. Only publicly available information can be placed into NMED.~~

~~The target for ensuring that NMED records are complete is 60 days from the date the event is reported. The regional office shall provide the information outlined in Enclosure 3 to classify a record as "complete." If there is a reason that the regional office cannot obtain the required information, that reason should be forwarded to the NMED contractor and to the NRC NMED Project Coordinator.~~

~~2800-12 INSPECTION MANUAL CHAPTERS AND INSPECTION PROCEDURES FOR MATERIALS PROGRAM~~

~~The IMCs and IPs listed in Enclosure 4 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 IMC in addition to several specific procedures, may be needed to adequately evaluate the licensee's program.~~

~~IMCs and IPs in this section 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 byproduct 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, "Follow-up of Confirmatory Action Letters (CALs)," is classified "as-needed" because it only applies to a licensee who has been issued a CAL.~~

List of Enclosures:

1. ~~Inspection Priority by Program Codes~~

~~2. Telephone Contact Procedures for Priority T Licensees~~

~~Exhibit 1 Telephone Contact Questionnaire~~
~~Exhibit 2 Standard Response to Licensees Contacted by Telephone (Concerns, Inspection to follow)~~
~~Exhibit 3 Standard Response to Licensees Contacted by Telephone (No Concerns/Violations)~~

~~3. Information for the Nuclear Material Events Database~~

~~4.~~ Management Directives, Inspection Manual Chapters, and Inspection Procedures

~~5. Safety Inspection Report and Compliance Inspection (NRC Form 591M)~~

~~6. Inspection Record~~

~~7~~2. Information for the Inspection of Licensees Holding Nuclear Materials Management and Safeguards System Accounts

~~8. NMMSS Quick Reference~~

~~9. Inspection Hours in the Human Resources Management System~~

END

Enclosure 1 – Inspection Priority Codes Assigned To Program Codes

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
01000	Vary[2]	RSRM Licensee	Licensee subject to ICs or Security Order requirements
01100	3	Academic Type A Broad	Radiation Safety Committee (RSC)-approved users;33.13
01110	5	Academic Type B Broad	Radiation Safety Officer (RSO)-approved users; 33.14
01120	5	Academic Type C Broad	Authorized Users specifically named in the license; 33.15
02110	2	Medical Institution Broad	RSC-approved users for possession and use of a wide range of radionuclides in medical research, diagnosis, and therapy and research and development.
02120	3	Medical Institution□Written Directive (WD) Required	Used as primary code and may be used with the secondary codes for research and development, as appropriate. Used as secondary code when the license also authorizes certain medical therapy modalities.
02121	5	Medical Institution□WD Not Required	Used as primary code *only* for diagnostic nuclear medicine and diagnostic types of use under 35.1000.
02200	3	Medical Private Practice□WD Required	[Same remark as 02120]
02201	5	Medical Private Practice□WD Not Required	[Same remark as 02121]
02210	3	Eye Applicators Strontium-90 (Sr-90)	Institution or Private Practice
02220	3	Mobile Medical Service□WD Not Required	Use as a primary code if the license authorizes the mobile service *only*. Use as a secondary code if the license authorizes medical use at a central facility (i.e., institution or private practice facility) in addition to the mobile service.
02230	2	High-Dose Rate Remote After loader (HDR)	Use as a primary code.

[2] The Priority Code for the Security-Related Inspection varies depending on the Priority Code of the associated Program Code for health and safety inspections. The security-related inspection interval shall be the same as the health and safety interval for the related materials program category.

~~Program Code~~	~~Priority Code~~	~~Category Title~~	~~Remarks (from NUREG-1556, Vol. 20, Appendix G)~~
~~02231~~	~~2~~	~~Mobile Medical Service—WD Required~~	~~Use as a primary code. Includes mobile HDR and non-HDR modalities under 10 CFR Part 35~~
~~02240~~	~~2~~	~~Medical Therapy—Other Emerging Technology~~	~~Medical therapy modalities used under 10 CFR 35.1000, i.e., liquid sources, microspheres, and intravascular brachytherapy devices.~~
~~02300~~	~~5~~	~~Teletherapy~~	~~Treatment of human subjects only~~
~~02310~~	~~2~~	~~Gamma Stereotactic Radiosurgery (GSR)~~	~~Treatment of human subjects *only*~~
~~02400~~	~~5~~	~~Veterinary—Nonhuman Subjects~~	~~Routine diagnosis or therapy on animals. No animal research.~~
~~02410~~	~~5~~	~~*In-Vitro* Testing Laboratories~~	~~Licenses are issued to individuals or facilities which are not included in larger programs described by Program Codes 02110 or 02120.~~
~~02500~~	~~2~~	~~Nuclear Pharmacies~~	~~Receive bulk material used to prepare single-use dosages or multi-dose products which are distributed to authorized medical licensees. Sealed sources are re-distributed in the original packaging to authorized clients.~~
~~02511~~	~~5~~	~~Medical Product Distribution — 32.72 Prepared Radiopharmaceuticals~~	~~Distribution of prepared radiopharmaceuticals to authorized medical licensees.~~
~~02513~~	~~5~~	~~Medical Product Distribution — 32.74 Sources and Devices~~	~~Therapy sources, calibration and reference sources~~
~~02600~~	~~-[3]~~	~~Production of PET Radioactive Drugs — 30.32(j) (Secondary Code)~~	~~Used as secondary code to identify those entities that meet the criteria in 10 CFR 30.32(j). See primary code for inspection priority~~
~~02700~~	~~5~~	~~Radium-226 Luminous Products & Sources up to 10 Times 31.12(a)(4) & (5)~~	~~For luminous products containing Ra-226 authorized under 10 CFR 31.12~~
~~02710~~	~~3~~	~~Radium-226 Luminous Products & Sources Greater Than 10 Times 31.12(a)(4) & (5)~~	~~For luminous products containing Ra-226 authorized under 10 CFR 31.12~~
~~03110~~	~~3~~	~~Well Logging Byproduct and/or Special Nuclear Material (SNM) Tracer and Sealed Sources~~	~~Use of sealed or unsealed sources for exploration of oil, gas, or minerals in wells.~~

~~[3] Program Code 02600 is used only as a secondary code~~

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
03111	3	Well Logging Byproduct and/or SNM Sealed Sources Only	Exploration of oil, gas, or minerals in wells; study of subsurface potable aquifers.
03112	3	Well Logging Byproduct Only – Tracers Only	Exploration of oil, gas, or minerals in wells
03113	3	Field Flooding Studies	Injection of unsealed byproduct materials for tracing oil and gas reservoirs
03120	5	Measuring Systems Fixed Gauges	Non-portable gauges for measurement or control of material density, flow, level, thickness, or weight, etc.
03121	5	Measuring Systems Portable Gauges	Moisture/density gauges contain gamma and neutron sources used for measurements in soils, compacted soils and road surfacing materials.
03122	T[4]	Measuring Systems Analytical Instruments	i.e., x-ray fluorescence analyzers
03123	T	Measuring Systems Gas Chromatographs	Quality control testing of samples from industrial process and environmental conditions.
03124	T	Measuring Systems Other	instrument calibrators, Krypton-85 (Kr-85) leak detectors
03130	5	Inspection Systems	Fixed or mobile non-intrusive inspection systems
03210	2	Radionuclide Production Using an Accelerator	Covers activities that take place once radioactive materials are produced by the accelerator. It does not include the operation of the accelerator.
03211	2	Manufacturing and Distribution Broad – Type A	RSC-approved users under 10 CFR 33.13
03212	5	Manufacturing and Distribution Broad – Type B	RSO-approved users under10 CFR 33.14
03213	5	Manufacturing and Distribution Broad – Type C	Authorized Users specifically named in the license under 10 CFR 33.15
03214	5	Manufacturing and Distribution Other	Smaller firms that require a more restrictive license.
03215	3	Manufacture, Assembly, Disassembly, Repair of Products Containing Radium-226	For certain items and self-luminous products containing Ra-226 authorized under 10 CFR 31.12

[4] Priority T R denotes a telephone remote contact made by an inspector to evaluate the radiation protection program for Program Codes 03122, 03123, 03124, 03220, 11210, 22130, 22160, and 22161. The telephone remote contact interval is 5 years ± 1 year.

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
03218	3	Nuclear Laundry	Cleaning of protective clothing contaminated with radioactive materials.
03219	3	Decontamination Services	Cleaning of scrap materials for authorized release for unrestricted use.
03220	T	Leak Test Service Only	Commercial service organizations provide leak test kits to clients, perform measurement of leak test samples from clients, and issue reports of leak test results.
03221	5	Instrument Calibration Services Only – Source Less Than Or Equal To 100 Curies	Commercial calibration service
03222	5	Instrument Calibration Services Only – Source Greater Than 100 Curies	Commercial calibration service
03225	5	Other Services – Source Less Than Or Equal To 100 Curies	Commercial servicing for industrial gauge, and HDR licensees
03226	2	Other Services – Source Greater Than 100 Curies	Commercial servicing for teletherapy, irradiators, and GSR units containing a total activity in the unit during servicing that is greater than 100 curies.
03231	2	Waste Disposal (Burial)	Commercial and non-commercial
03232	3	Waste Disposal Service Prepackaged Only	pick up, transfer, and storage; opening packages not authorized
03233	2	Waste Disposal Service Incineration	Commercial operation
03234	2	Waste Disposal Service Processing and/or Repackaging	receipt, open, compact, re-package, and transfer to authorized burial
03235	-[5]	Incineration, Non-Commercial	(Secondary Code)
03236	2	Waste Treatment Service (Other Than Compaction)	Includes multiple, complex physical and chemical waste treatment processes
03240	5	General License Distribution – 32.51	For fixed gauges authorized under 10 CFR 31.5
03241	5	General License Distribution – 32.53	For luminous aircraft safety devices authorized under 10 CFR 31.7
03242	5	General License Distribution – 32.57	For calibration and reference sources authorized under 10 CFR 31.8
03243	5	General License Distribution – 32.61	For ice detection devices authorized

[5] Program Code 03235 is used only as a secondary code for certain licensees authorized to operate a noncommercial incinerator to dispose of radioactive waste

			~~under 10 CFR 31.10~~

~~Program Code~~	~~Priority Code~~	~~Category Title~~	~~Remarks (from NUREG-1556, Vol. 20, Appendix G)~~
~~03244~~	~~5~~	~~General License Distribution – 32.71~~	~~For certain *in-vitro* clinical testing kits authorized under 10 CFR 31.11~~
~~03250~~	~~5~~	~~Exempt Distribution – 32.11: Exempt Concentrations and Items~~	~~For residual material in a product authorized under 10 CFR 30.14~~
~~03251~~	~~5~~	~~Exempt Distribution – 32.14: Certain Items~~	~~For manufactured products authorized under 10 CFR 30.15~~
~~03252~~	~~5~~	~~Exempt Distribution – 32.17: Resins~~	~~For synthetic plastic resins authorized under 10 CFR 30.16~~
~~03253~~	~~5~~	~~Exempt Distribution – 32.18: Small Quantities~~	~~For individual quantities authorized under 10 CFR 30.18~~
~~03254~~	~~5~~	~~Exempt Distribution – 32.22: Self-Luminous Products~~	~~For devices authorized under 10 CFR 30.19~~
~~03255~~	~~5~~	~~Exempt Distribution – 32.26: Smoke Detectors~~	~~For devices authorized under 10 CFR 30.20~~
~~03256~~	~~5~~	~~Exempt Distribution – 32.21 Carbon-14 Urea Capsules~~	~~For *in vivo* diagnostic use authorized under 10 CFR 30.21~~
~~03310~~	~~2~~	~~Industrial Radiography Fixed Location~~	~~Permanent radiographic installation (PRI) or designated field station. Use as secondary code, except when the license authorizes the PRI *only*.~~
~~03311~~	~~2~~	~~Industrial Diagnostic Systems~~	~~A sealed source used for diagnostic scanning at industrial sites~~
~~03320~~	~~1~~	~~Industrial Radiography Temporary Job Sites~~	~~Use as primary code for multiple temporary customer locations~~
~~03510~~	~~5~~	~~Irradiators Self Shielded Less Than Or Equal To 10,000 Curies~~	~~Not external beam~~
~~03511~~	~~5~~	~~Irradiators Other Less Than Or Equal To 10,000 Curies~~	~~Panoramic (in air or under water) units; includes converted teletherapy units~~
~~03520~~	~~5~~	~~Irradiators Self Shielded Greater Than 10,000 Curies~~	~~Not external beam~~
~~03521~~	~~2~~	~~Irradiators – Other Greater than 10,000 curies~~	~~Panoramic (in air or under water) units; includes sterilization (mega-curie) units~~
~~03610~~	~~3~~	~~Research and Development Broad – Type A~~	~~RSC-approved users under 10 CFR 33.13~~
~~03611~~	~~5~~	~~Research and Development Broad – Type B~~	~~RSO-approved users under 10 CFR 33.14~~
~~03612~~	~~5~~	~~Research and Development Broad – Type C~~	~~Authorized users specifically named in the license under 10 CFR 33.15~~
~~03613~~	~~2~~	~~Research and Development Broad – Multisite Multiregional~~	~~Master Materials Licenses~~
~~03620~~	~~5~~	~~Research and Development Other~~	~~Non-human research subjects~~
~~03710~~	~~5~~	~~Civil Defense~~	~~Instrument calibration and training~~
~~03800~~	~~3~~	~~Byproduct Material Possession Only – Permanent Shutdown~~	~~Principle activities ceased, license termination request pending; packaging and shipping operations authorized; decontamination and decommissioning not authorized~~

~~Program Code~~	~~Priority Code~~	~~Category Title~~	~~Remarks (from NUREG-1556, Vol. 20, Appendix G)~~
~~03810~~	~~3~~	~~Byproduct Material Standby – No Operations~~	~~Principle activities ceased, licensee undecided about terminating the license, packaging and shipping operations authorized, D&D not authorized~~
~~03900~~	~~D[6]~~	~~Decommissioning of Byproduct Material Facilities~~	~~(See IMC 2602) D&D may have been authorized according to an approved plan under 10 CFR 30.36~~
~~11200~~	~~5~~	~~Source Material Other Less than 150 Kilograms~~	~~Research or manufacturing of consumer products~~
~~11210~~	~~T~~	~~Source Material Shielding~~	~~Possession and use~~
~~11220~~	~~5~~	~~Source Material Military Munitions Indoor Testing~~	~~Depleted Uranium (DU); results in fragmentation of DU~~
~~11221~~	~~5~~	~~Source Material Military Munitions Outdoor Testing~~	~~DU~~
~~11230~~	~~5~~	~~Source Material General License Distribution – 40.34~~	~~DU products and devices authorized under 10 CFR 40.25~~
~~11300~~	~~5~~	~~Source Material Other Greater than 150 Kilograms~~	~~Research or manufacturing of consumer products~~
~~11700~~	~~5~~	~~Rare Earth Extraction and Processing~~	~~Generates waste products containing source material not related to the nuclear fuel cycle~~
~~11800~~	~~2~~	~~Source Material Possession Only – Permanent Shutdown~~	~~Principle activities ceased, license termination request pending; packaging and shipping operations authorized; decontamination and decommissioning (D&D) not authorized~~
~~11810~~	~~2~~	~~Source Material Standby – No Operations~~	~~Principle activities ceased, licensee undecided about terminating the license, packaging and shipping operations authorized, D&D not authorized~~
~~11900~~	~~D~~	~~Decommissioning of Source Material Facilities~~	~~(See IMC 2602) D&D may have been authorized according to an approved plan under 10 CFR 40.42~~
~~21310~~	~~5~~	~~Critical Mass Material – University~~	~~Greater than 350 grams of enriched Uranium-235 (U-235), greater than 300 grams of Uranium-233 (U-233), greater than 200 grams of Plutonium, or any combination thereof~~

~~[6] The Priority D denotes a decommissioning inspection as determined under IMC 2602, Decommissioning Inspection Program, for Program Codes 03900, 11900, 21325, and 22200. These inspections are scheduled at times when the licensee is performing decommissioning activities at the site.~~

~~Program Code~~	~~Priority Code~~	~~Category Title~~	~~Remarks (from NUREG-1556, Vol. 20, Appendix G)~~
~~21320~~	~~5~~	~~Critical Mass Material – Other Than Universities~~	~~Greater than 350 grams of enriched U-235, greater than 300 grams of U-233, greater than 200 grams of Plutonium, or any combination thereof~~
~~21325~~	~~D~~	~~Decommissioning of Critical Mass – Other Than Fuel Fabrication~~	~~(See IMC 2602) D&D may have been authorized according to an approved plan under 10 CFR 70.38~~
~~22110~~	~~3~~	~~Special Nuclear Material Plutonium – Unsealed, Less than Critical Mass~~	~~Less than 200 grams, total, for biological and chemical testing and instrument calibration~~
~~22111~~	~~3~~	~~Special Nuclear Material, U-235 and/or U-233 – Unsealed, Less than a Critical Mass~~	~~Less than 350 grams U-235 and/or less than 300 grams U-233 for biological and chemical testing and instrument calibration~~
~~22120~~	~~5~~	~~SNM Plutonium – Sealed Neutron Sources, Less than 200 Grams~~	~~Plutonium-beryllium howitzer for instrument calibration, teaching and demonstration purposes, and industrial applications~~
~~22130~~	~~T~~	~~Power Sources with Byproduct and/or Special Nuclear Material~~	~~Heat or power generators for remote locations~~
~~22140~~	~~5~~	~~Special Nuclear Material Plutonium – Sealed Sources in Devices~~	~~Gauges~~
~~22150~~	~~5~~	~~Special Nuclear Material Plutonium – Sealed Sources Less than a Critical Mass~~	~~Less than 200 grams, total, for biological and chemical testing and instrument calibration~~
~~22151~~	~~5~~	~~Special Nuclear Material, U-235 and/or U-233 Sealed Sources, Less than a Critical Mass~~	~~Less than 350 grams U-235 and/or less than 300 grams U-233 for biological and chemical testing and instrument calibration~~
~~22160~~	~~T~~	~~Pacemaker – Byproduct, and/or Special Nuclear Material – Medical Institution~~	~~Surgical implantation, follow-up, recovery, and disposal of devices~~
~~22161~~	~~T~~	~~Pacemaker – Byproduct, and/or Special Nuclear Material – Individual~~	~~Possession of a surgically implanted device by the recipient while in the United States~~

~~Program Code~~	~~Priority Code~~	~~Category Title~~	~~Remarks (from NUREG-1556, Vol. 20, Appendix G)~~
~~22162~~	~~2~~	~~Pacemaker – Byproduct and/or Special Nuclear Material – Manufacturing and Distribution~~	
~~22170~~	~~5~~	~~Special Nuclear Material General License Distribution (70.39)~~	~~Includes calibration or reference sources authorized under 10 CFR 70.19~~
~~22200~~	~~D~~	~~Decommissioning of Other SNM Facilities – Less than Critical Mass~~	~~(See IMC 2602) D&D may have been authorized according to an approved plan under 10 CFR 70.38~~
~~23300~~	~~2~~	~~SNM Possession Only (Non-Fuel) – Permanent Shutdown~~	~~Principle activities ceased, license termination request pending; packaging and shipping operations authorized; decontamination and decommissioning (D&D) not authorized~~
~~23310~~	~~2~~	~~SNM Standby (Non-Fuel) – No Operations~~	~~Principle activities ceased, licensee undecided about terminating the license, packaging and shipping operations authorized, D&D not authorized~~

~~END~~

Enclosure 2 - Telephone Contact Procedures for Priority T Licensees

1. PROGRAM OBJECTIVES: The NRC developed telephone contact procedures to maintain safety for materials possessed by certain licensees (Priority T) after the initial inspection was completed and the inspector determined that the licensee had satisfactorily implemented the radiation protection program. Thereafter, an inspector will interview the Priority T licensee at 5-YEAR intervals for the duration of the license.

2. PROCEDURES

a. Obtain the license file and identify the licensee's point of contact and review pertinent details of the license that will be needed to evaluate the licensee's responses to the interview questionnaire. (Exhibit 1)

NOTE: If the license authorizes nuclear-powered cardiac pacemaker devices that contain special nuclear material (i.e., Program Codes 22160 or 22161), the inspector should refer to the guidance contained in Enclosure 7. Section 2, "NMMSS Inspection Process," describes preparation steps and onsite steps which should be adapted to complete this telephonic contact procedure.

b. For example, the inspector should request the NMMSS contractor to send the "Task 8 Inspection Package" which contains inventory data the licensee has reported to NMMSS. The inspector should also request the licensee to transmit a facsimile of their current inventory record. Compare the licensee's current record with the NMMSS report data.

c. If discrepancies exist, the licensee must assess the situation and verify the fact that NMMSS-reportable quantities are lost or missing or were incorrectly reported to NMMSS. The licensee is responsible for contacting the NMMSS contractor to correct the database.

d. Telephone the licensee and complete each item of Exhibit 1, as appropriate for the type of use authorized by the license. If a question is not applicable for the type of use, then indicate "N.A." for the answer.

e. The inspector should promptly notify their supervisor if the licensee describes any significant problem. The supervisor should determine whether an inspection of the facility or a letter transmitting regulatory concerns is needed. If an inspection is warranted, the inspector should note that decision on Exhibit 1 and provide the completed questionnaire and license file to the supervisor for further action. Use Exhibit 2, "Standard Response to Licensees Contacted by Telephone (Concerns, Inspection to Follow)," to notify the licensee that a follow-up inspection may be scheduled in the near future. Following is a list of problems which may warrant an onsite inspection.

1. licensee is unaware of licensed material or NRC regulations for possession, use, transfer, and disposal

2. change in ownership or bankruptcy proceedings

3. a qualified radiation safety officer or authorized user was not routinely involved

4. ~~unsecured or unshielded material~~

5. ~~doses in excess of 10 CFR Part 20 limits~~

6. ~~excessive radiation levels or leaking sources~~

7. ~~lost, stolen, or missing licensed material~~

8. ~~non-routine event threatens safe, secure storage (i.e., special maintenance or handling, fire, explosion, or damage from a natural disaster)~~

9. ~~decommissioning activities~~

f. ~~If no problem is evident from the licensee's responses, use Exhibit 3, "Standard Response to Licensees Contacted by Telephone (No Concerns/Violations.)" to provide the licensee with appropriate documentation.~~

g. ~~With the supervisor's concurrence, the inspector may sign the letter and provide the package to the administrative staff.~~

~~Exhibit 1 – Telephone Contact Questionnaire~~

~~Instructions: Complete this questionnaire as per the program objectives and procedures for Enclosure 2.~~

~~Name and title of Interviewer~~ ~~Signature of Interviewer~~	
~~Date of this Interview~~ ~~Date of Previous Interview~~	
~~QUESTIONS~~	~~ANSWERS~~
~~Licensee Name, Address, and URL~~	
~~Licensee's Point of Contact (Name, Address, Phone and FAX Numbers, and URL)~~	
~~License Number~~ ~~Docket Number~~	
~~1. Name and Title of person responsible for radiation safety program:~~	
~~2. Describe how you prevent: (a) use by unauthorized personnel and (b) loss or theft.~~	
~~3. Describe how you maintain shielding, restrict access, and control contamination from unsealed material to prevent individuals from becoming exposed to radiation.~~	
~~4. Describe how you determine radiation doses to workers and members of the public from licensed activities. What was the maximum dose received since the last NRC telephone contact or inspection?~~	
~~5. Describe radiation area surveys around licensed activities. What survey instrument (SI) was used? SI's last calibration date? What were the typical radiation levels and at what distance?~~	

QUESTIONS	ANSWERS
~~6. Describe leak testing of the sealed source(s). How often and who analyzed the leak test samples? What were the most recent results?~~	
~~7. Describe physical inventory of all byproduct material and NMMSS-reportable materials in your possession. When was the last inventory completed? Were all the sources located?~~	
~~8. Describe your provisions for repair and maintenance of your device or source holder.~~	
~~9. Describe any unusual events involving the byproduct material or the device(s) in which it is used (i.e., fire, explosion, natural disaster.)~~	

~~Exhibit 2 – Standard Response to Licensees Contacted by Telephone (Concerns, Inspection to Follow)~~

~~Licensee Name [License No.]~~
~~Address [Docket No.]~~

~~ATTENTION: [Licensee Point of Contact, Title]~~

~~SUBJECT: TELEPHONE INTERVIEW TO EVALUATE THE RADIATION SAFETY PROGRAM~~

~~Sir or Madam:~~

~~On [date], a U.S. Nuclear Regulatory Commission (NRC) inspector conducted a telephone interview with [name] of your staff. The interview was an examination of activities conducted under your license as they relate to radiation safety and to compliance with NRC rules and regulations and with the conditions of your license. As a result of this examination of your licensed activities, we noted regulatory concerns that are specified below. These concerns may be further evaluated during an onsite inspection at your facility in the near future.~~

~~*(List regulatory concerns. For any concern that appears to rise to a violation or otherwise to indicate lack of programmatic oversight, the region should promptly conduct an inspection and take enforcement action, as appropriate, based on the results of the inspection.)*~~

~~In particular, you should examine your license and the NRC's regulations to determine how you can correct the apparent regulatory concerns listed above. The points listed below are especially important for your radiation safety program:~~

1. ~~control access to and prevent loss of licensed material, ensure proper transfers and disposal of licensed material, and promptly report to NRC loss or theft of licensed material~~
2. ~~maintain shielding of licensed material to reduce radiation exposure~~
3. ~~implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material evaluate radiation exposures to workers and members of the public~~
4. ~~use properly calibrated survey instruments to monitor radiation levels~~
5. ~~ensure that workers are knowledgeable, skilled, and empowered to implement the radiation protection program~~
6. ~~ensure that upper level managers are aware of the radiation protection program, that annual audits of the program are completed, and that appropriate action is taken for past performance, present conditions, and future needs~~

~~If you have any questions about this matter, please contact me at [phone, fax, email address].~~

~~Sincerely, [Inspector Name, Title]~~

~~Exhibit 3 - Standard Response to Licensees Contacted by Telephone (No Concerns/Violations)~~

~~Licensee Name [License No.]~~
~~Address [Docket No.]~~

~~ATTENTION: [Licensee Point of Contact, Title]~~

~~SUBJECT: TELEPHONE INTERVIEW TO EVALUATE THE RADIATION SAFETY PROGRAM~~

~~Sir or Madam:~~

~~On [date], a U.S. Nuclear Regulatory Commission (NRC) inspector conducted a telephone interview with [name] of your staff. The interview was an examination of activities conducted under your license as they relate to radiation safety and to compliance with NRC rules and regulations and with the conditions of your license. No regulatory concerns were identified.~~

~~If you have any questions about this matter, please contact me at [phone, fax, email address].~~

~~Sincerely,~~

~~[Inspector Name, Title]~~[1]

~~Enclosure 3 – Information for the Nuclear Material Events Database~~

~~The regional office shall forward copies of all documentation regarding a material incident (i.e., "Preliminary Notifications," reports of medical events, follow-up inspection reports) to the NMED contractor and the NRC NMED Project Manager, NMSS. For publicly available documents, entry into ADAMS meets the requirement for forwarding the documents. For documents that are not publicly available, the regional office must redact the non-publicly available information from the document in order for the document to be placed into ADAMS as publicly available. Only publicly available information can be placed into NMED.~~

~~The NMED Event No. and/or the event notification number must be annotated on each document. The regional office is responsible for ensuring that sufficient information is provided for the NMED item to be considered "complete." The basic information along with the additional specific information for certain types of events, outlined below, constitute a "complete" record.~~

~~The target for ensuring "complete" NMED records is 60 days from the date the event is reported. The information identified below must be provided to classify a record as "complete." If there is a reason that the required information cannot be obtained, that reason should be forwarded to the NMED contractor and the NRC NMED Project Manager.~~

~~Basic Information:~~

~~1. Essential Details~~

- ~~a. narrative event description~~
- ~~b. report identification number~~
- ~~c. event date and notification date~~
- ~~d. licensee/reporting party information (name, license number, and address)~~
- ~~e. location (site) of event~~
- ~~f. whether the event is NRC reportable and the applicable reporting requirement~~
- ~~g. cause and corrective actions~~
- ~~h. notifications: local police, FBI, and other States, as needed~~
- ~~i. identify any possible generic safety concerns/potential for others to experience the same event~~

~~2. Source/Radioactive Material:~~

- ~~a. isotope and activity~~
- ~~b. manufacturer~~

~~c. model and serial number~~
~~d. leak test results, if applicable~~

~~3. Device/Associated Equipment:~~
~~a. manufacturer~~
~~b. model and serial number~~
~~c. description of any equipment problems~~

~~Additional information is required for the specific event types listed below:~~
~~1. Release of Licensed Material or Contamination (NMED CODE: RLM):~~
~~a. release type (air or water)~~
~~b. contamination (person or surface)~~
~~c. isotope and activity released~~

~~2. Medical event (NMED CODE: MD2):~~
~~a. procedure administered~~
~~b. dose intended and actual dose administered~~
~~c. isotope and activity administered~~
~~d. organ targeted~~
~~e. notifications: patient, referring physician~~

~~3. Overexposure (EXP):~~
~~a. radiation source and activity~~
~~b. exposure dose~~
~~c. exposure type (whole body, extremity, etc.)~~

~~4. Transportation (TRS):~~
~~a. type of transport~~
~~b. identity of shipper~~
~~c. package type~~
~~d. ID number, if applicable~~

Enclosure 41 – 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, and/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, "Follow-up of Confirmatory Action Letters (CALs)," is classified "as-needed" because it only applies to a licensee who has been issued a CAL.

MD/IMC/IP No.	Inspection Manual Chapter/Inspection Procedure Title	Routine (R) or As Needed (N)
MATERIALS SAFETY PROGRAMS		
~~IMC1220~~	~~"Processing of NRC Form 241, Inspection of Agreement State Licensees Operating Under the Reciprocity Provisions of 10 CFR 150.20"~~	~~N~~
IMC2810	"Master Material License Oversight and Inspection Program"	N
IMC2815	"Construction and Pre-Operational Inspection of Panoramic, Wet-Source Storage Gamma Irradiators"	N
~~IMC 2882~~	~~"Transfer of NRC License Files to Agreement State(s)"~~	~~N~~
IP 87121	"Industrial Radiography Programs"	R
IP 87122	"Irradiator Programs"	R
IP 87123	"Well Logging Programs"	R
IP 87124	"Fixed and Portable Gauge Programs"	R
IP 87125	"Materials Processor/Manufacturer Programs"	R
IP 87126	"Industrial/Academic/Research Programs"	R

MD/IMC/IP No.	Inspection Manual Chapter/Inspection Procedure Title	Routine (R) or As Needed (N)
IP 87127	"Radiopharmacy Programs"	R
IP87128	"Manufacturing and Distribution of Exempt Products"	R

MATERIALS SAFETY PROGRAMS (CONTINUED)		
IP 87129	"Master Materials Program"	N
IP 87130	"Nuclear Medicine Programs – Written Directive Not Required"	R
~~MATERIALS SAFETY PROGRAMS (CONTINUED)~~		
IP 87131	"Nuclear Medicine Programs – Written Directive Required"	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
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 ~~in Nuclear~~ for Federal and State Material ~~Safety~~ and ~~Safeguards~~ Environmental Management Programs ~~Area~~"	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

INCIDENT RESPONSE (CONTINUED)		
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
~~INCIDENT RESPONSE~~		
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

TRANSPORTATION (CONTINUED)		
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/FOLLOW-UP		
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 Material and Fuel Cycle Issues"	N
IMC 1120	"Preliminary Notifications"	N
IP 92701	"Follow-up"	R
IP 92703	"Follow-up 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 5 – Safety Inspection Report and Compliance Inspection (NRC Form 591M)

NRC FORM 591M PART 1 U.S NUCLEAR REGULATORY COMMISSION
(06-2010)
10 CFR 2.201

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
REPORT NUMBER(S)	

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☐ 1. Based on the inspection findings, no violations were identified.

☐ **2.** Previous violation(s) closed.

☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied

Non-cited violation(s) were discussed involving the following requirement(s):

☐ 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR			
Branch Chief			

NRC FORM 591M PART 1(06-2010)

NRC FORM 591M PART 2 U.S NUCLEAR REGULATORY COMMISSION
(06-2010)
10 CFR 2.201

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: REPORT NUMBER(S)		2. NRC/REGIONAL OFFICE
3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION

(Continued)

NRC FORM 591M PART 3 (06-2010)

NRC FORM 591 M PART 3 (06-2010)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE REPORT NUMBER(S)	2. NRC/REGIONAL OFFICE

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION

6. INSPECTION PROCEDURES	7. INSPECTION FOCUS AREAS

SUPPLEMENTAL INSPECTION INFORMATION

1.PROGRAM	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER

☐ Main Office Inspection Next Inspection Date: _____

☐ Field Office Inspection _____ ☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

~~Enclosure 6 – Inspection Record~~

~~Region ___ Inspection Report No._____ License No.~~
~~Docket No. _____~~
~~Licensee (Name and Address):~~

_____
_____

~~Location (Authorized Site) Being Inspected~~

~~Licensee Contact: _____ Telephone _____ No.~~
~~Priority: _____ Program Code: __~~

~~Date of Last Inspection: Date of This Inspection: _~~

~~Type of Inspection: ( ) Initial ( ) Announced ( ) Unannounced~~
~~( ) Routine ( ) Special~~

~~Next Inspection Date: _____ ( ) Normal ( ) Reduced~~
~~Justification for reducing the routine inspection interval:~~

~~Summary of Findings and Actions:~~

~~( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued~~
~~( ) Non-cited violations (NCVs)~~
~~( ) Violation(s), Form 591 issued~~
~~( ) Violation(s), regional letter issued~~
~~( ) Follow-up on previous violations~~

~~Inspector(s) _____ Date _____~~
~~(Name)~~

_____
~~(Signature)~~

~~Approved _____ Date _____~~
~~(Name)~~

_____
~~(Signature)~~

~~PART I LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY~~

~~1. AMENDMENTS AND PROGRAM CHANGES:~~

~~(License amendments issued since last inspection, or program changes noted in the license)~~

~~AMENDMENT #~~	~~DATE~~	~~SUBJECT~~

~~2. INSPECTION AND ENFORCEMENT HISTORY:~~

~~(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)~~

~~3. INCIDENT/EVENT HISTORY:~~

~~(List any incidents, or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)~~

~~PART II - INSPECTION DOCUMENTATION~~

~~1. ORGANIZATION AND SCOPE OF PROGRAM:~~

~~(Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority)~~

~~2. SCOPE OF INSPECTION:~~

~~(Identify the inspection procedure(s) used and focus areas evaluated. If records were reviewed, indicate the type of record and time periods reviewed)~~

~~Inspection Procedure(s) Used:~~

~~Focus Areas Evaluated:~~

~~3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:~~

~~(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)~~

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

(State the requirement, how and when the licensee violated the requirement, and the licensee's proposed corrective action plan. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

5. PERSONNEL CONTACTED:

(Identify licensee personnel contacted during the inspection, including those individuals contacted by telephone.)

Use the following identification symbols:

Individual(s) present at entrance meeting
* Individual(s) present at exit meeting

END

Enclosure ~~7~~2 – Information for the Inspection of Licensees Holding Nuclear Materials ~~M~~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, ~~and~~ 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 ~~on page 5~~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 ~~an~~the inspector identifies source material with documented foreign obligations, then the inspector should immediately notify the ~~Office of Nuclear Materials Safety and Safeguards, Division of Fuel Cycle Safety and Safeguards,~~ NRC's NMMSS Project Manager. 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."

~~NOTE: An inspector can readily identify foreign-obligated source material because NMMSS reports the quantity as "kilograms."~~

~~While the license and licensee records typically use units of radioactivity to quantify NMMSS-reportable materials, NMMSS uses units of mass (i.e., "grams") for inventory data in records and reports.~~

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 particular facility. Table 2 ~~on page 5~~ 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 ~~on page 6~~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

02.01 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 e-mail at NMMSS@nnsa.doe.gov ~~-~~and request a "Task 8 Inspection Package." If unable to contact the NMMSS contractor, the inspector should notify the ~~NMSS/FCSS~~ NRC's NMMSS Project Manager by e-mail at NMMSS.Resource@nrc.gov. The inspector should request the package approximately ~~A minimum of~~ seven calendar days ~~should be allowed~~ prior to the start of the inspection trip to allow sufficient time for the package to be ~~mailed~~ provided to the inspector.

The Task 8 Inspection Package contains three documents ~~which~~that are described in Table 4~~, on page 6~~of Section 3.0:

a. DOE/NRC Form 742, "Material Balance Report,"
b. NMMSS Report TJ-45, "Material Transaction Reports"
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. ~~Since~~ 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 ~~to the NRC's Division of Facility Security~~ in accordance with MD 12.6. Inspectors must also be cautious with regard to handling licensee information that may be classified, sensitive, or proprietary. ~~For more information, contact the appropriate regional or NSIR security advisor.~~

02.02 On ~~S~~site 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:	~~An~~ 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 ~~c~~Confirmatory ~~a~~Action ~~l~~Letter or an ~~o~~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 ~~shipping~~ delivery address (for transmitting information ~~via nonpostal~~ 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 e-mail address for primary management point of contact; and/or,

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 by telephone.

02.03 Inspection Documentation: If applicable, tThe inspector should include a statement that the licensee's reporting to NMMSS was reviewed in accordance with the procedures described in the EGM 08-002. The statement should be recorded under the "Program Scope" in Part 3 of NRC Form 591M, "Safety Inspection Report and Compliance Inspectionin the inspection documentation," along with the results of the overall inspection.

Since 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 at all times. Information discussing the quantities and forms of NMMSS-reportable materials possessed by the licensee shall not be included in NRC Form 591M or in any other 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-publically available" documents.

Provide a copy of any inspection report (i.e., NRC Form 591M or Enclosure 6 (Inspection Report), or narrative report) documentation that documents includes a violation of NMMSS reporting requirements to the NMSS/FCSS, NRC's NMMSS Project Manager.

Table 1: NMMSS Reportable Quantities

ISOTOPE OR ELEMENT	REPORTABLE QUANTITY
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

MATERIAL TYPE	MT CODE
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% Pu^{238} of total Pu by weight is reported as Pu^{238}

Table 3: Activity to Mass Conversion Factors

Isotope	Specific Activity (curies/gram)
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 transactions involving NMMSS-reportable materials reported by the licensee, including receipts, transfers and disposals, since the most recent DOE/NRC Form 742~~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

~~NMMSS CONTRACTOR CONTACT TELEPHONE NO.: (301) 903-6860~~

~~Contact the NMMSS Project Manager, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Materials Safety and Safeguards for technical questions.~~
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)."

~~Enclosure 9 – Inspection Hours in the Human Resources Management System~~

~~To provide a reliable, uniformly implemented budgetary basis, the inspector shall charge inspection hours in the Human Resources Management System (HRMS). Since the CAC Codes and program activity (PA) Codes change occasionally, please check with your T&A coordinator for the current PA and CAC Codes. Any suggested changes to the Codes should be coordinated with NMSS to ensure consistency. The inspector should consider the following guidance when charging time:~~

- ~~For routine, reactive and special inspections, the inspector shall designate the hours for the license docket number only to the specific program codes within the CAC Codes for inspection activities and enforcement activities.~~

- ~~For reciprocity inspections and tracking, the inspector shall designate the hours to the CAC designated for reciprocity inspections.~~

- ~~For non-routine phone inquiries from licensees outside of the inspection process (i.e., questions on compliance), the inspector shall designate the hours for the license docket number only to the specific program codes within the CAC Codes for inspection activities.~~

- ~~he inspector shall charge all time to the general inspection CAC Code.~~

END

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	Revision history reviewed for the last four years. Change Office/Division name from reorganization (NMSS/IMNS to FSME/MSSA). Add definition of “pre-licensing visits” and describe scenario in which they are required. (IERP Recommendation I-1a). Add definition of an “initial security inspection” and describe scenario in which they are required. Add definition for “risk significant radioactive material.” Add definition of “security requirements.” Allows for announced visit for the initial security inspection and encourages coordination with local law enforcement. Description of a proposed pilot program on the security inspection frequency’s recommended by the Increased Control Working Group (MPWG Recommendation M-IV.3). Implementation of a secondary program code for security inspections. (MPWG Recommendation M-IV.3). Add language to include awareness of allegation trends during inspection preparation and at the inspection site. (WITS 2008-00158). Notification that inspectors should review NSTS inventory records in advance of inspections. Addition of “Quantities of Concern” Table.	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)
		Include language on inspector review of licensed activities performed by contracted personnel. Requires inspector to verify that prompt corrective actions have been initiated in instances that affect the safe control of material. 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. Inclusion of EDO Field Policy Manual on providing Third Party Assistance (WITS 2009-00082). Allows for health and safety inspections to be completed during the same visit as security inspections Guidance on coordinating with Agreement States and other Regions on licensed activities that cross jurisdictions Revision of Master Materials Licenses (MML) section to be more in line with IMC 2810 for the MML program.		
N/A	ML102800160 11/15/10 CN 10-023	Revised the definitions for pre-licensing visits, initial inspections, and the initial security inspections for additional clarity. 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. Clarification of the process for coordination with Agreement States and other Regions. Made general editorial changes.	N/A	N/A

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	ML17186A204 09/12/17 CN 17-018	• 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. • 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	ML17062A557 ML17186A134