

# **NRC INSPECTION MANUAL**

FSME/MSSA

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MANUAL CHAPTER 2800

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MATERIALS INSPECTION PROGRAM

## CONTENTS

2800-01	PURPOSE.....	1
2800-02	OBJECTIVES.....	1
2800-03	DEFINITIONS .....	1
03.01	Pre-licensing Visit.....	1
03.02	Initial Inspection .....	1
03.03	Initial Security Inspection .....	1
03.04	Inspection.....	1
03.05	Inspection Plan.. .....	2
03.06	Inspection Priorities.....	2
03.07	Reactive Inspection.....	2
03.08	Routine Inspection .....	2
03.09	Risk Significant Radioactive Material. ....	2
03.10	Security Requirements.....	2
03.11	Special Inspection Activities .....	2
03.12	Team Inspections.....	3
03.13	Telephonic Contacts .....	3
2800-04	RESPONSIBILITIES AND AUTHORITIES .....	3
04.01	Director, Office of Federal and State Materials and Environmental Management Programs.....	3
04.02	Regional Administrator.....	3
04.03	Director, Division of Materials Safety and State Agreements.....	3
04.04+	Director, Regional Division of Nuclear Materials Safety .....	4
04.05	Chief(s), Regional Inspection Branch(es).....	4
2800-05	BASIC REQUIREMENTS .....	4
05.01	General Inspection Process .....	6
05.02	Reactive Inspections .....	16
05.03	Initial Inspections.....	17
05.04	Routine Inspections.....	19
05.05	Telephonic Contacts .....	19
05.06	Pre-licensing Visit.....	19
05.07	Third Party Assistance .....	20
2800-06	INSPECTION INTERVALS .....	20
06.01	Scheduling Inspections .....	20
06.02	Combining Inspections.....	20
06.03	Inspections After Escalated Enforcement. ....	21
06.04	Reduction of Inspection Interval.....	21
06.05	Other Changes in Inspection Interval.....	22
06.06	Coordination with Agreement States and Other Regions .....	22
2800-07	SPECIAL INSPECTION ACTIVITIES .....	23
07.01	Expired and Terminated Licenses and Decommissioning Activities .....	23
07.02	Significantly Expanded Programs .....	23
07.03	Reciprocity Inspections .....	24
07.04	Temporary Job Site or Field Office Inspections .....	25
07.05	Team Inspections.....	26

07.06	Abandonment of Licensed Activities .....	27
07.07	Inspection of Generally Licensed Devices .....	28
07.08	Inspection of Master Materials Licenses.....	30
07.09	Inspection of Licensees Holding Nuclear Materials Management and Safeguards System (NMMSS) Accounts .....	28
2800-08	DOCUMENTATION OF INSPECTION RESULTS .....	29
08.01	What Constitutes an Inspection .....	29
08.02	Allegations.....	30
08.03	Documenting Inspection Results.....	31
08.04	Methods of Transmitting Inspection Results. ....	34
2800-09	COORDINATION OF REGIONAL RESPONSIBILITY FOR INSPECTIONS	34
09.01	General .....	34
09.02	Assistance in Inspections.....	35
09.03	Transfer of Responsibility.....	35
2800-10	COORDINATION WITH OTHER AGENCIES.....	35
10.01	Federal Agencies .....	35
10.02	State Agencies .....	38
2800-11	INPUT INTO NRC TRACKING SYSTEMS .....	38
11.01	Input into the Licensing Tracking System .....	38
11.02	Input into the Nuclear Material Events Database .....	39
2800-12	INSPECTION MANUAL CHAPTERS AND INSPECTION PROCEDURES FOR MATERIALS PROGRAM.....	39
	List of Enclosures:.....	40
	Enclosure 1 - Inspection Priority Codes Assigned To Program Codes .....	E1-1
	Enclosure 2 - Telephone Contact Procedures for Priority T Licensees.....	E2-2
	Exhibit 1 – Telephone Contact Questionnaire .....	E2-3
	Exhibit 2 – Standard Response to Licensees Contacted by Telephone .....	E2-6
	Exhibit 3 - Standard Response to Licensees Contacted by Telephone.....	E2-6
	Enclosure 3 – Information for the Nuclear Material Events Database.....	E3-1
	Enclosure 4 – Inspection Manual Chapters and Inspection Procedures.....	E4-1
	Enclosure 5 – Safety Inspection Report and Compliance Inspection (NRC Form 591M).....	E5-1
	Enclosure 6 – Inspection Record .....	E6-1
	Enclosure 8 – Information for the Inspection of Licensees Holding .....	E7-1
	Nuclear Materials Management and Safeguards System Accounts ...	E8-1
	Enclosure 9 - NMMSS Quick References .....	E9-1
	Enclosure 10 - Table 1 - Quantities of Concern Threshold Limits.....	E10-1
	Attachment 1 – Revision History for IMC 2800.....	Att 1-1

## 2800-01 PURPOSE

To establish the inspection program for licensees authorized to possess, use, transfer, and dispose of radioactive material associated with various types of use, i.e., industrial, academic, research and development, manufacturing, distribution, irradiators, well logging, industrial radiography, medical programs, various types of service (i.e., 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 establish the general policy for the materials inspection **program**.

02.02 To describe a performance-based inspection approach and to identify specific conditions of poor performance **that requires 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, relative priorities for routine inspections of all licensees and a program of special inspection activities as specified by the Office of **Federal and State Materials and Environmental Management Programs (FSME)**.

02.05 To aid in the achievement of 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 **Pre-licensing Visit**. A site visit and face-to-face meeting with an entity that does not have an existing Agreement State or U.S. Nuclear Regulatory Commission (NRC) license, is changing ownership to an unknown entity, or is significantly expanding the size or scope (such as a change to the primary program code) of the existing license in order to provide a basis for confidence that radioactive material will be used as specified.

03.02 **Initial Inspection**. An inspection **conducted one year** after a **new** license is issued to a licensee, **or after an amended license has been significantly expanded or changed ownership to an unknown entity**.

03.03 **Initial Security Inspection**. The first security inspection of a licensee that is subject to security requirements by regulation, Order, license condition, or other legally binding requirements. This is conducted prior to the issuance of a licensee. Multiple field offices must undergo inspection as outlines in Section 07.04.

03.04 **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 involve a visit to a licensee's facility and/or temporary jobsite 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 telephone contacts are not considered inspections.

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

**03.06 Inspection Priorities.** An inspection priority code is assigned to **each** radioactive material license. The priority code (i.e., 1, 2, 3, or 5) 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 lists the program codes (types of use) along with the assigned priority codes. The priority represents 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 **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 code** with the shortest routine inspection interval.

**03.07 Reactive Inspection.** A reactive inspection is a special inspection in response to an incident, allegation, or information obtained by NRC (e.g., report of a medical event, **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.

**03.08 Routine Inspection.** Periodic, comprehensive inspections performed at a specified interval, as defined in Enclosure 1 of this Inspection Manual Chapter (**IMC**).

**03.09 Risk Significant Radioactive Material (RSRM).** RSRM refers to the values in Title 10 of the Code of Federal Regulations (10 CFR) Part 73 Appendix I and Enclosure 10: Table 1, "Quantities of Concern Threshold Limits." The terms "Quantities of Concern," "Category 1 quantities," and "Category 2 quantities" are synonymous with RSRM.

**03.10 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 site inspections; 5) team inspections; 6) inspections of **revoked or abandoned licenses**; 7) general licensee inspections; **8) reactive inspections and follow-up to escalated enforcement**; **9) inspections of Master Materials**

Licenses; and 10) inspections of licensees holding Nuclear Materials Management and Safeguards Systems Accounts (NMMSS).

**03.12 Team Inspections.** For the purposes of this **IMC** only, team inspections are defined as those inspections conducted by three or more 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 specialty in a particular field, or at least one of the team members comes from a different region or Headquarters. Team inspections can be routine inspections of a major licensee, or reactive inspections in response to a particular 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 8.3, "NRC Incident Investigation Program."

**03.13 Telephonic Contacts.** These are 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 **a meaningful** 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 of Federal and State Materials and Environmental Management Programs (FSME).** Provides overall program direction for the NRC materials inspection program.

**04.02 Regional Administrator.** **Oversee** implementation of the materials inspection program within their respective region.

**04.03 Director, Division of Materials Safety and State Agreements (MSSA).**

- 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 Regions responsible for materials inspections.

- e. Coordinates with the Regions 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 the Regional Office.
- 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 MSSA to obtain technical assistance, as necessary.
- e. Recommends changes to the materials inspection program to the Director, MSSA.

04.05 Chief(s), Regional Inspection Branch(es).

- a. Proposes changes to the materials inspection program.
- b. Implements the Regional materials inspection program.
- c. Reviews and approves inspection schedules.
- d. Reviews and approves all non-escalated enforcement actions (i.e., Severity Level IV violations) proposed by regional inspection staff, and determines whether violations should be considered for escalated enforcement action.
- e. Ensures that Regional inspectors achieve and maintain qualifications, in accordance with IMC 1246.
- f. Evaluates the performance of each inspector during actual inspections at least once during each fiscal year.

2800-05 BASIC REQUIREMENTS

The Materials Inspection Program designates reactive inspections [See Section 05.02] as the highest priority, followed by initial inspections [See Section 05.03] and routine inspections [See Section 05.04] for the Priority Codes (in ascending numeric order) listed in Enclosure 1. Telephonic contacts [See Section 05.05] are not inspections and are performed as resources permit.

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



1. Since considerable travel is required, inspectors may telephone licensees located in Guam, American Samoa, Hawaii, Alaska, or other remote locations to verify that a routine inspection can be performed before undertaking such travel.
2. Since coordination with pertinent licensee personnel is required as part of an initial security inspection, these security inspections may be announced to ensure that the appropriate personnel will be in attendance. Coordination with the local law enforcement agency is encouraged, but is not required as part of an initial security inspection.
3. 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 would inspect the other portions of the licensee's program during every other routine inspection.

NRC will soon conduct a pilot inspection program for security inspections at a frequency recommended by the Implementation of the Increased Controls Working Group. The results of the pilot program will be used to determine the appropriate security inspection frequency. During the pilot program the security-related program code (01000) will have the following priorities.

- All temporary jobsite industrial radiography licensees (NRC Program code 03320) that possess radioactive material quantities of concern will be assigned a Priority 1 for security and will be inspected annually.
- All licensees possessing Category 1 quantities of radioactive materials and all licensees possessing Category 2 quantities of radioactive materials in unhardened



cesium-chloride (self-shielded and blood) irradiators will be assigned a Priority 2 for security and will be inspected every two years.

- All licensees possessing Category 2 quantities of radioactive materials (including hardened cesium-chloride irradiators with Category 2 quantities of radioactive materials) will be assigned a Priority 3 for security and will be inspected every three years.

Until the pilot program has been initiated, for a licensee that possesses RSRM, the security-related program code (01000) is secondary. Security requirements are inspected at the same frequency as the program code that corresponds to the RSRM. For example, a radiographer (Program Code 03320) has a routine inspection every year, with a security inspection at the same time. A teletherapy user (Program Code 02300) has routine and security inspections every 5 years. The license reviewer should be diligent about assigning correct program codes initially and whenever the scope of the license changes. The NRC's License Fee Collection Branch uses all the license program codes to determine the initial and annual fees.

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 and need not be file or keep it.**

**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. The IPs listed in Enclosure 4 provide more specific guidance for onsite inspection activities. Section 2800-08 provides guidance for **documenting** inspection results.

To provide a reliable, uniformly implemented budgetary basis, the inspector shall charge inspection hours in the Human Resources Management System (HRMS). For routine inspections, the inspector shall designate the hours for the license docket number only to the program-specific **IP (e.g., IP 87121, 87122, 87123, 87124, 87125, 87126, 87127, 87129, 87130, 87131, 87132, 87133, and 87134 [See paragraph 10.01.c.3 for Occupational Safety and Health Administration (OSHA) Interface activities])** within the **TAC Codes** for inspection activities **and** enforcement activities. There are separate **TAC Codes** for reactive inspections, routine inspections, **special inspections, and** allegation follow up. Telephonic contacts are not inspections. **Since the TAC Codes and program activity (PA) Codes change occasionally, please check with your T&A coordinator for the current PA and TAC Codes. Any suggested changes to the Codes should be coordinated with FSME to ensure consistency.**

- 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. The extent to which an inspector prepares for routine inspections should be based on discussions with the

supervisor.

To adequately prepare, an inspector shall review:

1. the license to determine if it has any unusual license conditions that would affect the approach to the inspection, i.e., 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., results of the last inspection and any outstanding open items and determining whether any events have been reported by the licensee during the current inspection cycle.
3. 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. any notes in the file regarding special inspection emphasis, i.e., license reviewer's note to request a near term inspection regarding a significant licensing action. For example, an amendment for a new medical therapy modality under 10 CFR 35.1000 shall be inspected within 12 months of the date of the amendment. **[See Section 07.02.b]**
5. **any security requirements, guidance, questions and answers, and/or supplemental correspondence (e.g., licensee responses, requests for relief, and final NRC determinations).**
6. **any allegations trends and a follow-up of the licensee's evaluation and response to the allegation, potentially requiring consultation with the FSME Allegations Coordinator. [See Section 08.02]**
7. **if the licensee is authorized to possess RSRM, request the National Source Tracking System (NSTS) inventory record at least two days in advance.**

**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 onsite by the licensee. If the documents are not available from the licensee, the inspector should contact the region for assistance. This practice would apply to routine inspections only.

To prepare for a reactive inspection, the inspector will review specific information for reactive inspections as determined by the inspector and his or her supervisor on a case-by-case basis **[See 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 (678) 328-1116 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 package can be found in Enclosure 8 and 9.

Inspectors should anticipate whether or not they will encounter sensitive information during inspection of a licensee. Inspectors should be aware of minimum handling requirements for sensitive-unclassified information, i.e., Safeguards Information, Official Use Only, and Proprietary Information. For current instructions, contact the regional security advisor or refer to the security services web page, <http://www.internal.nrc.gov/sunsi/>.

The inspector should identify the location of the licensee, 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 before the inspection trip, the inspector or Regional State Agreements Officer shall convey the itinerary to the State radiation control agency to give the State personnel an opportunity to observe the routine inspections [See Section 10.02].

Finally, the inspector should select appropriate and calibrated radiation detection instrumentation for the inspection and obtains the necessary inspection forms (such as NRC Form 591M).

- b. Onsite Inspection Activities. Based on the pre-inspection activities, the inspector should be prepared to evaluate a licensee's performance of the licensee's radiation safety and/or security programs. 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.
  - 1. The inspector should conduct the inspection in a manner that will develop conclusions about licensee performance relative to the following focus areas:
    - (a) security and control of licensed material;
    - (b) shielding of licensed material;

- (c) comprehensive safety measures;
- (d) radiation dosimetry program;
- (e) radiation instrumentation and surveys;
- (f) radiation safety training and practices;
- (g) management oversight; and
- (h) licensed activities performed by contracted personnel.

These focus areas 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.

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.

2. The inspector should use a performance-based approach to evaluate the focus areas. 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 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 inspector with reasonable assurance of a licensee's ability to safely use byproduct 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. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, high radiation exposures, or allegations.

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.

3. 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).

4. 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.

5. To have a positive impact on maintaining safety, security, and effectiveness, the inspector should develop a general sense of the licensee's safety culture for licensed activities (i.e., workers have a "questioning attitude" and generally adhere to procedures, workers are duly cautious when engaged in licensed activities, worker relationships with supervisors are conducive to raising 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).
6. 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.

This 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 proprietary information, given the technical area or other considerations of inspection scope, 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 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 of the current and anticipated radiation use 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 material, frequency of use, staff size, etc., and anticipated changes in the range of the radiation use program. Determine if the licensee possesses material in accordance with a general license.
- (d) Observation of Actual Facilities and Licensed Activities. Ideally, the inspector should observe work in progress that involves NRC-regulated activities. 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.** It is of utmost importance to inspect licensed activities at temporary job sites **or activities performed by contracted personnel.** [See Section 07.04]
  - (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.
  - (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) Make direct observations of radiation safety systems and practices in use.
  - (5) 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, if possessing RSRM.**
- (e) Independent and Confirmatory Measurements. Independent measurements are those performed by the inspector without comparison to the licensee's measurements. Confirmatory measurements are those whereby the inspector compares his or her measurements with those of the licensee's.
  - (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 use areas, storage areas, effluent release points, and other locations.
  - (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, the inspector must use NRC's instruments for independent verification of the licensee's measurements. The inspector's instruments must be in current calibration and source checked before they leave the regional office.
- (f) Special License Conditions. If applicable, 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.
- (g) Exit Meeting. At the conclusion of the inspection the inspector should 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 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, the inspector shall hold an exit meeting directly with a senior management representative (and the licensee's RSO, if not present at the preliminary exit meeting). This meeting involving the licensee's management and RSO will usually take place by telephone conference call.

- (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 violations and associated corrective action plans. If the licensee disagrees with a violation, the inspector should contact his or her supervisor before leaving the site to obtain further instructions. It may be necessary to continue the inspection or modify the cited violation. Together, the inspector and supervisor should make decisions about the enforcement strategy. Before leaving the site, the inspector should inform the licensee about the next steps in the enforcement process.

The inspector should explain safety/**security**-related concerns or unresolved items 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., workers' knowledge of the Part 20 requirements) are not always violations, the inspector should bring such deficiencies 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 the results of the inspection trip with his or her supervisor. This discussion should be sufficient to alert management to significant enforcement, safety, **security**, or regulatory issues. This meeting need not be documented, but it should be held in all cases. To complete the inspection, the inspector **shall document** the inspection results in accordance with guidance in this **IMC** [See Section 2800-08] and other chapters, as appropriate. **In cases where an inspector is proposing to disposition a non-escalated enforcement action on an NRC Form 591M, supervisory review and approval is required before the inspector issues NRC Form 591M in the field. NRC Form 591 M can be issued in the field without supervisory approval if there are no findings, an NCV, or Level IV and signed by a supervisor when an 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 **MSSA**, 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 lead to the determination of contributing factors and root causes, and to 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.

Inspections resulting from allegations will be documented in accordance with Management Directive (MD) 8.8, "Management of Allegations."

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 Initial Inspections. Initial inspections of a new licensee or an **amendment for an existing licensee that has a significant expansion of its program** shall be announced and completed within 12 months of the date the new license or amendment was issued by a Regional Office. To schedule the initial inspection, the date in the "next inspection date" **field** in the Licensing Tracking System (LTS) shall be 12 months from the date the new license or amendment was issued. The "last inspection date" data element in the LTS shall be 0 (zero) or blank.

**Initial Security Inspections must be performed for all RSRM licensees or applicants to verify that security requirements or Increased Controls are implemented before the licensing action is issued allowing the licensee/applicant to take possession of RSRM. In addition to the initial security inspection, an initial inspection for RSRM licensees must also be completed within 12 months of license issuance.**

- a. Initial inspections of all licensees. Once **on site**, the inspector should interview licensee staff (management and technical) to determine if licensed material has been possessed or licensed operations have been performed. Methods for determining if licensed activities have been performed include, but are not limited to the following: performing a site tour, performing confirmatory measurements, and/or contacting distributors of radioactive material, such as local radiopharmacies, to see if they have distributed material to the licensee. If the licensee has possessed licensed materials or performed licensed operations, 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 not possessed licensed material or performed licensed operations, the inspector should:

1. Determine the licensee's plans for future possession of licensed material or

plans to perform licensed operations. 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** unique license conditions.
  3. Request that the licensee notify the NRC before **the** receipt of licensed material or initiation of licensed operations.
  4. Document the onsite inspection by completing a Form 591M. The "program scope" description in the Form 591M should include the licensee's plans for future possession of material or plans to perform licensed operations.
  5. Ensure that the date in the "next inspection date" **field** in the LTS is 12 months from the date of the onsite visit.
- b. 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" data elements in the LTS should remain the same as 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) the organization controlling the licensed activities changes substantially (i.e., changes in key personnel, authorities, or resources associated with the radiation safety 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, then the "last Inspection date" and "next inspection date" **fields** in the LTS should remain the same as for the previous



license.

3. 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” data elements in the LTS should remain the same as for the licensee’s initial license.

**05.04 Routine Inspections.** Routine inspection of licensees shall be conducted at intervals in years corresponding to the inspection priority listed in Enclosure 1.

During the pilot program, security inspections for licensees possessing RSRM are to be conducted at the frequency in 2800-05. Before the pilot program, security inspections for licensees possessing RSRM are to be conducted at the same frequency corresponding to the routine inspection priority listed in Enclosure 1. The security inspection may be conducted at the same time as the routine inspection. If the licensee has possessed material or performed licensed operations 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 licensed operations since the last inspection, the inspector should follow the instructions in Section 05.03(a)(1) through (4).

**05.05 Telephonic Contacts (Priority T).** For certain licensees, the regions shall use telephone contacts at 5-year intervals 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. A telephonic questionnaire is attached as Enclosure 2, Exhibit 1 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 inspection date” data element in the LTS shall be changed to indicate the date of the next telephonic contact. The inspector shall brief the supervisor about the telephonic contact. The inspector shall charge time to HRMS as direct inspection effort under Program Code PA No. 344232E, (generic TAC No. A10159).

**05.06 Pre-licensing Visit.** 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. At a minimum, 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, the inspector should notify his or her management and, following this consultation, 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 should 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

**06.01 Scheduling Inspections.** To achieve the goals of cost saving and efficient use of staff time and travel, inspections (other than initial inspections) may be scheduled within a window around their inspection due **dates**. Inspection of licensees in **Priority Codes** 1, 2, and 3 may vary around their due date by  $\pm 25$  percent. Inspection of **Priority Code 5** licensees and telephonic contact of priority T licensees may vary around their due **dates** by  $\pm 1$  year. Inspections will not be considered "overdue" until they exceed the scheduling window. Inspections may be scheduled before their window if the inspector receives information that warrants earlier inspection.

**06.02 Combining Inspections.** If a licensee holds several licenses with different Program Codes that are assigned different Priority Codes in Enclosure 1, a single inspection may be scheduled whenever practicable to more **effectively** use the inspector's travel **time**.

Issue Date: 07/27/10

20

Effective Date: 10/01/10

2800

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 6 months of the issuance of the escalated enforcement action (Severity Level III or above). This inspection should be in accordance with the guidance in Section 06.04 for reducing the inspection interval, after completion of the escalated enforcement action, to assess the licensee's follow-up actions in response to the previous violations. Regions may perform this follow-up inspection as a part of a routine inspection. If the final escalated enforcement dispositions the violations with enforcement discretion to not cite and results in no NOV, a special inspection is not required.

#### 06.04 Reduction of Inspection Interval.

- a. The inspection interval shall not be extended beyond that specified by the priority system indicated in Enclosure 1. The interval between inspections may be reduced (shortened) and inspections conducted more frequently than specified in the priority system 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 program. Poor compliance history is one indicator of such problems. Lack of management involvement or control over the radiation safety program is another indicator. 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; 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 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 byproduct 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. The designated inspection priority for these licensees should not be changed in the LTS. However, the "next inspection date" field in the LTS should be changed to contain the reduced date for the next inspection. The reduced inspection date should be noted in the LTS.
- c. To document the reduction in the interval between inspections, a brief note (i.e., in the inspection records) should be written by the inspector describing the condition for reducing the interval and be approved and signed by the inspector's immediate supervisor, and placed in the docket file.

**06.05 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 and 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 inspections may be performed by individuals or smaller teams that specifically focus on higher risk licensee activities.

**06.06 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. In these situations, arrangements should be made with the responsible Region or Agreement State program which has jurisdiction to specifically include in their inspections those functions which the inspector is unable to verify. This will ensure that all elements of the security requirements have been implemented. 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 maintain with other records of the licensee's inspection, when possible.

## 2800-07 SPECIAL INSPECTION ACTIVITIES

**07.01 Expired and Terminated Licenses and Decommissioning Activities.** Notification that a license has expired or is being terminated requires prompt action (i.e., within 30 days) to ensure that licensed material has been properly transferred or disposed of, and that all areas where material was used may be safely released for unrestricted use.

Inspectors should be aware of the need for security and control of radioactive materials at these types of facilities. This may be done by **reviewing** the licensee's transfer, disposal, and closeout survey data; **confirming** 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**.

**07.02 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 **are** aware of the following changes in a licensee's scope of use.

- 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 the licensee's activities 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] In that case, the license reviewer, **in consultation with management and administrative staff**, shall ensure that the "next inspection date" data element in the LTS is changed and shall post a notice in the docket file for the inspector [see NUREG-1556, Volume 20, Section 4.12 (Significant Licensing Actions that Warrant Onsite Inspection) and Appendix C (Checklist C.5)].

**An example of when a program may have been significantly expanded:** an amendment issued for a new medical therapy modality under 10 CFR 35.1000 (Program Code 02240) shall be inspected within 12 months of the date of the amendment. The reviewer shall ensure that the next inspection date data element in the LTS was appropriately changed, the docket file was posted with a **completed** Appendix C **from** NUREG-1556 (Volume 20), and the inspection and licensing supervisors were notified accordingly.

- 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 to LTS. 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" 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 take immediate action to enter information from the form into the Reciprocity Tracking System **before** reciprocity work begins. **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 "next inspection date" **field** in the LTS 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 MSSA, 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). 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 FSME.**

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 Inspection of Generally Licensed Devices. Routine inspections of general licensees [other than reciprocity (10 CFR 150.20)] are not normally performed. However, if a specific licensee also possesses 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 devices [See IP 87124, Focus Element 1]. Additionally, inspectors should make an effort to track down and address missing, orphaned, or abandoned sources during routine inspections. Inspections of general licensees shall also be made to resolve issues such as allegations, incidents, or indications of unsafe practices.

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 regulator. 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 8. 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 8) 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 8.

## 2800-08 DOCUMENTATION OF INSPECTION RESULTS

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 licensed 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 make a telephone call 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 and the "next inspection date" field in the LTS should be changed to reflect the new date. The region should not record an attempted inspection in the LTS as "an inspection."
- c. Regions performing assist inspections will receive credit toward the operating plan goals for conducting each assist inspection.
- d. The HRMS allows the time spent in gathering factual material to be charged against the time budgeted for performing routine inspections. Telephone contacts are not onsite inspections even though they involve direct inspection effort. The inspector should charge their time to HRMS, Program Code PA No. 344232E, (TAC No. A10159). The fact that a telephone contact of a Priority T licensee was made should not be entered into the LTS as an inspection; however, the date of the next telephone contact should be indicated in the "next inspection date" data element in the LTS.
- e. 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. Following 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 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 record (per IMC 0610) to document inspection results.

1. 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 in October 2007 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 to notify the Radiation Safety Officer to perform the inventories.

2. 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. A sample cover letter is provided in Enclosure 7. 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. The inspector must ensure that these instructions are consistent with the current version of EGM-08-002 on sensitive security information issued by the Office of Enforcement.

3. Narrative Inspection Report. A narrative inspection report is required for all team inspections and actions involving an enforcement conference and/or escalated enforcement. 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.



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 8; and,
8. for security inspection with no violations, the inspector should add a statement in the inspection record (e.g., NRC Form 591M Part 3 or Enclosure 5) that the licensee's implementation of security requirements was reviewed and deemed to be adequate.

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 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.

08.04 Methods of Transmitting Inspection Results. Results of inspections may be reported to the licensee by either issuing an NRC Form 591M, or a regional office letter either with or without a Notice of Violation (NOV) to the licensee.

- a. NRC Form 591M Part 1. The inspector will present NRC Form 591M Part 1 to the licensee at the conclusion of the exit interview, or, on rare occasions where consultation with regional management is necessary, the inspector may transmit 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).

- b. Letter to licensee, with or without NOV. When findings are documented in an Inspection Record (Enclosure 6) or in a narrative inspection report, a letter (Enclosure 7) 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.
- 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.

## 2800-09 COORDINATION OF REGIONAL RESPONSIBILITY FOR INSPECTIONS

09.01 General. When a license authorizes operations in more than one region, the

responsibility for inspection shall reside with the regional office in which the licensee's main 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 responsible region's personnel may perform the inspection activity themselves rather than request assistance from another region. In such cases, these activities should be coordinated between regions.

09.03 Transfer of Responsibility. Notwithstanding the above (Sections 09.01 and 09.02), 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. The regional offices should ensure that the appropriate changes are made to the LTS to show which office has the overall responsibility for inspection and enforcement.

## 2800-10 COORDINATION WITH OTHER 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 FSME, 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, 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 and elevate the concerns to the attention of NRC regional management while the inspector is still onsite. [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 MSSA. 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 radioactive materials,
- (b) chemical risk from radioactive materials,
- (c) facility conditions that affect the safety of radioactive materials and thus present a risk to workers or members of the public, and
- (d) facility conditions that result in an occupational risk but do not affect the safety 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.

Time spent on meeting the requirements of IMC 1007 for category (d) conditions are to be charged to IP 93001, "OSHA Interface Activities." Time spent on category (a), (b), and (c) conditions are to be charged to the program-specific inspection procedure.

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 coordinates the sharing of information and coordinating joint or accompaniment 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 Licensing Tracking System (LTS). Enclosure 1 provides a listing of license program codes, associated with this IMC, with the associated inspection priorities. Regions should enter data promptly into the LTS 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 the LTS 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). FSME manages NMED for all materials-related incidents and events. The regional office is responsible for ensuring that FSME 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 can not 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, "Followup 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. Inspection Manual Chapters and Inspection Procedures
5. Safety Inspection Report and Compliance Inspection (NRC Form 591M)
6. Inspection Record
- | 7. **Example of Inspection Cover Letter**
- | 8. Information for the Inspection of Licensees Holding Nuclear Materials Management and Safeguards System Accounts
- | 9. **NMMSS Quick Reference**
- | 10. **Table 1, "Quantities of Concern Threshold Limits"**

**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 <sup>1</sup>	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 <i>only</i> 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

<sup>1</sup> 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)
02220	3	Mobile Medical Service–WD Not Required	Use as a primary code if the license authorizes the mobile service <i>only</i> . 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.
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 <i>only</i>
02400	5	Veterinary–Nonhuman Subjects	Routine diagnosis or therapy on animals. No animal research.
02410	5	<i>In-Vitro</i> 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

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
02600	- <sup>2</sup>	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.
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 <sup>3</sup>	Measuring Systems Analytical Instruments	i.e., x-ray fluorescence analyzers

<sup>2</sup> Program Code 02600 is used only as a secondary code

<sup>3</sup> Priority T denotes a telephone 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 contact interval is 5 years.

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
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 under 10 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
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

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
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	- <sup>4</sup>	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 under 10 CFR 31.10
03244	5	General License Distribution - 32.71	For certain <i>in-vitro</i> 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

<sup>4</sup> Program Code 03235 is used only as a secondary code for certain licensees authorized to operate a noncommercial incinerator to dispose of radioactive waste



Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
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 <i>in vivo</i> 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 <i>only</i> .
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

Issue Date: 07/27/10

Effective Date: 10/01/10

E1-6

2800

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 <sup>5</sup>	Decommissioning of Byproduct Material Facilities	(See <b>IMC</b> 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

<sup>5</sup> 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)
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
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

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
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
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. Using the LTS report of licensees due for inspection, select a Priority T licensee to interview by telephone. [See Section 05.05]
  - b. 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 8. Section 2, "NMMSS Inspection Process," describes preparation steps and onsite steps which should be adapted to complete this telephonic contact procedure.

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.

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.

- c. 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.
- d. 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
- e. 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.
  - f. 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]

Issue Date: 07/27/10

Effective Date: 10/01/10

E2-5

2800

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]

## 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, FSME. 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 can not 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

Issue Date: 07/27/10

Effective Date: 10/01/10

- 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 4 – Inspection Manual Chapters and Inspection Procedures

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 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
IP 87127	"Radiopharmacy Programs"	R
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 87135	"Panoramic and Underwater Irradiator Security Program" (Non-Public)	N

IMC/IP No.	Inspection Manual Chapter/Inspection Procedure Title	Routine (R) or As Needed (N)
MATERIALS SAFETY PROGRAMS (CONTINUED)		
IP 87136	"Manufacturer and Distribution (M&D) Security Program" (Non-Public)	N
CONDUCT OF INSPECTIONS		
IMC 0300	"Announced and Unannounced Inspections"	R
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"	N
IMC 1246	"Formal Qualification Programs in Nuclear Material Safety and Safeguards Program 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		
IMC 1301	"Response to Radioactive Material Incidents That Do Not Require Activation of the NRC Incident Response Plan "	N
IMC 1302	"Follow-up Actions and Action Levels for Radiation Exposures Associated with Materials Incidents Involving Members of the Public"	N
IMC 1303	"Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy (DOE)"	N
IMC 1330	"Response to Transportation Accidents Involving Radioactive Materials"	N
IMC 1360	"Use of Physician and Scientific Consultants in the Medical Consultant Program"	N
IP 87103	"Inspection of Materials Licensees Involved in an Incident or Bankruptcy"	N

Issue Date: 07/27/10

Effective Date: 10/01/10

E4-2

2800

IMC/IP No.	Inspection Manual Chapter/Inspection Procedure Title	Routine (R) or As Needed (N)
LOW-LEVEL WASTE/WASTE MANAGEMENT		
IMC 2401	"Near-Surface Low-Level Radioactive Waste Disposal Facility Inspection Program"	N
IP 84750	"Radioactive Waste Treatment and Effluent and Environmental Monitoring"	R
IP 84850	"Radioactive Waste Management - Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61"	R
IP 84900	"Low-Level Radioactive Waste Storage"	R
DECOMMISSIONING INSPECTIONS		
IMC 2602	"Decommissioning Oversight and Inspection Program For Fuel Cycle Facilities and Materials Licensees"	N
IP 83890	"Closeout Inspection and Survey"	N
IP 87104	"Decommissioning Inspection Procedure for Materials Licensees"	N
RADIATION PROTECTION		
IP 83822	"Radiation Protection"	R
IP 87102	"Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)"	R
TRANSPORTATION		
IMC 1330	"Response to Transportation Accidents Involving Radioactive Materials"	N
IP 86740	"Inspection of Transportation Activities"	R
IP 86750	"Solid Radioactive Waste Management and Transportation of Radioactive Materials"	R
IP 81120	"Inspection Requirements and Guidance for Additional Security Measures for the Physical Protection in Transit for Radioactive Material Quantities of Concern" (Non-Public)	N

<b>IMC/IP No.</b>	<b>Inspection Manual Chapter/Inspection Procedure Title</b>	<b>Routine (R) or As Needed (N)</b>
<b>REPORTS/COMMUNICATIONS/FOLLOW-UP</b>		
<b>IMC 0610</b>	<b>"Nuclear Material Safety and Safeguards Inspection Reports"</b>	<b>R</b>
<b>IMC 0620</b>	<b>"Inspection Documents and Records"</b>	<b>R</b>
<b>IMC 0730</b>	<b>"Generic Communications Regarding Material and Fuel Cycle Issues"</b>	<b>N</b>
<b>IMC 1120</b>	<b>"Preliminary Notifications"</b>	<b>N</b>
<b>IP 92701</b>	<b>"Follow-up"</b>	<b>R</b>
<b>IP 92703</b>	<b>"Follow-up of Confirmatory Action Letters <b>or Orders</b>"</b>	<b>N</b>
<b>INTERACTIONS WITH OTHER FEDERAL AGENCIES</b>		
<b>IMC 1007</b>	<b>"Interfacing Activities between Regional Offices of NRC and OSHA"</b>	<b>R</b>
<b>IP 93001</b>	<b>"OSHA Interface Activities"</b>	<b>N</b>

## Enclosure 5 – Safety Inspection Report and Compliance Inspection (NRC Form 591M)

<b>NRC FORM 591M PART 1</b> <b>(06-2010)</b> <b>10 CFR 2.201</b>		<b>U.S NUCLEAR REGULATORY COMMISSION</b>	
<b>SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION</b>			
1. LICENSEE/LOCATION INSPECTED:   REPORT NUMBER(S)		2. NRC/REGIONAL OFFICE	
3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION	
<b>LICENSEE:</b>  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: <div style="margin-top: 10px;"> <input type="checkbox"/> 1. Based on the inspection findings, no violations were identified.         </div> <div style="margin-top: 10px;"> <input type="checkbox"/> 2. Previous violation(s) closed.         </div> <div style="margin-top: 10px;"> <input type="checkbox"/> 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):         </div> <div style="margin-top: 40px;"> <input type="checkbox"/> 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         </div>			
<b>Statement of Corrective Actions</b>			
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)

Issue Date: 07/27/10

Effective Date: 10/01/10

E5-1

2800

**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

(Continued)

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		
<b>SUPPLEMENTAL INSPECTION INFORMATION</b>			
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)

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
--------------------	-------------	----------------

### 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)

Issue Date: 07/27/10

Effective Date: 10/01/10

E6-3

2800

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 – Example of Inspection Cover Letter Transmitting Inspection Report (includes optional paragraphs for Severity Level IV Notices of Violation, Notices of Violation associated with green SDP findings, Non-Cited Violations, and apparent violations subject to a conference)

{Date}

{Contact Name}  
{Licensee Name}  
{Licensee Address}  
{Town, State Zip}

License Number: {xx-xxxx}  
Inspection Number: {xxxx-xx}

Dear {Contact Name}:

On {Date(s) of inspection}, {Inspector(s) name} of the Nuclear Regulatory Commission, conducted a routine health, safety and security inspection at the above address of activities authorized by the above listed Agency license. The inspection consisted of observations by the inspectors, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with {name(s)} at the conclusion of the inspection.

“Based on the results of this inspection, the NRC has determined that a Severity Level IV violation(s) of NRC requirements occurred. [Alternatively, for violations associated with green SDP findings, use: “Based on the results of this inspection, the NRC has identified issues that were evaluated under the risk significance determination process as having very low safety significance (green). The NRC has also determined that violations are associated with these issues.] The(se) violations was (were) evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC’s Web site at (<http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>)).”]

The violation(s) is (are) cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it (them) are described in detail in the subject inspection report. The violation(s) is (are) being cited in the Notice because [An explanation MUST be included that clearly articulates why an NOV is being issued in terms of the Section VI.A criteria they met. This explanation may be expanded, where warranted, to convey the appropriate message to the licensee in terms of those actions that require additional attention. In addition, for Severity Level IV citations beyond the normal Section VI.A criteria, this explanation must include the basis for issuing the citation, notwithstanding the normal policies.]

[Include either the “response required” or the “no response required” paragraph:

Issue Date: 07/27/10  
Effective Date: 10/01/10

E7-1

2800

"You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. [Other specific responses required should be addressed as appropriate.] [Add the following sentence for material and fuel cycle licensees: "For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," is enclosed."] The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements."

Or, for Severity Level IV NOVs where the region has determined that no response is required, the preceding paragraph can be replaced by the following paragraph:

"The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed on the docket in [indicate correspondence, e.g., "Inspection Report No. (XXXXXXXX/YYYNNN), LER YY-NNN, or letter from Licensee] dated (date). Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice."]

[For inspection reports with NCVs, include the following paragraph:

"Based on the results of this inspection, the NRC has (also) determined that (number) (additional) Severity Level IV violation(s) of NRC requirements occurred. [Alternatively, for NCVs associated with green SDP findings, use: Based on the results of this inspection, the NRC has (also) identified (additional) issues that were evaluated under the risk significance determination process as having very low safety significance (green). The NRC has also determined that violations are associated with these issues.] These violations are being treated as Non-Cited Violations (NCVs), consistent with Section VI.A of the Enforcement Policy. The(se) NCVs are described in the subject inspection report. If you contest the violation(s) or significance of the(se) NCV(s), you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Regional Administrator, Region \_\_; (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001; and (3) (the Name of the NRC Resident Inspector) at (Plant Name) facility."]

[Include the next three paragraphs if apparent violations are being addressed and a predecisional enforcement conference is being confirmed ("conference letter"):

“In addition, (number) apparent violation(s) was (were) identified and is (are) being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. [The narrative that follows should briefly discuss the nature of the apparent violation(s).] Since the NRC has not made a final determination in this matter, no Notice of Violation is being issued for these inspection findings at this time. In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review.

An open (A closed) predecisional enforcement conference to discuss this (these) apparent violation(s) has been scheduled for (date). The decision to hold a predecisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. The conference will provide an opportunity for you to provide your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision.

You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding the(se) apparent violation(s) is required at this time.”]

Sincerely,

John Doe, Director  
Division of Nuclear Materials Safety

Enclosure: Appendix A, Notice of Violation



## Enclosure 8 – 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 10 CFR Parts 40, 72, 74, and 150 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.

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 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**, 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."

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.

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

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 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 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 (telephone (678) 328-1116) and request a "Task 8 Inspection Package." If unable to contact the NMMSS contractor, the inspector should notify the **NMSS/FCSS** NMMSS Project Manager. 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 Task 8 Inspection Package contains three documents which are described in Table 4, on page 6:

- a. DOE/NRC Form 742, "Material Balance Report,"
- b. NMMSS Report TJ-45
- c. NMMSS Report D-3

Inspectors are cautioned **that** at a minimum, NMMSS data is Sensitive-Unclassified Official Use Only (OUO) information. Since 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-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 inspector should not ask licensee personnel to open any container or otherwise change the container's shielding 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 shipping address (for transmitting information via nonpostal methods that cannot use a post office box)
  2. telephone number, FAX number, and e-mail address for primary technical point of contact
  3. telephone number, fax number, and e-mail address for primary management point of contact
  4. the license numbers of NRC or Agreement State licenses that authorize the possession of subject material
- e. If corrections to any NMMSS data are needed, the licensee should contact the NMMSS contractor directly by telephone.

02.03 Inspection Documentation: If applicable, the inspector should include a statement that the licensee's reporting to NMMSS was reviewed in accordance with the procedures described in Enclosure 7. The statement should be recorded under the "Program Scope" in Part 3 of NRC Form 591M, "Safety Inspection Report and Compliance Inspection," along with the results of the overall inspection.

Since 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) that documents a violation of NMMSS reporting requirements to the NMSS/FCSS, NMMSS Project Manager.

Enclosure 9 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<sup>238</sup> of total Pu by weight is reported as Pu<sup>238</sup>

Table 3: Activity to Mass Conversion Factors

Isotope	Specific Activity (curies/gram)
Uranium 234	$6.2 \times 10^{-3}$
Uranium 235	$2.2 \times 10^{-6}$
Uranium 238	$3.3 \times 10^{-7}$
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
NMMSS Report D-3	Summary of licensee administrative information on record in NMMSS

NMMSS CONTRACTOR CONTACT TELEPHONE NO.: (678) 328-1116

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

Enclosure 10 - Table 1 - Quantities of Concern Threshold Limits

Radionuclides	Category 1		Category 2	
	Terabecquerels (TBq)	Curies (Ci) <sup>1</sup>	Terabecquerels (TBq)	Curies (Ci) <sup>1</sup>
Americium-241	6x10 <sup>1</sup>	1.6x10 <sup>3</sup>	6x10 <sup>-1</sup>	1.6x10 <sup>1</sup>
Americium-241/Be	6x10 <sup>1</sup>	1.6x10 <sup>3</sup>	6x10 <sup>-1</sup>	1.6x10 <sup>1</sup>
Californium-252	2x10 <sup>1</sup>	5.4x10 <sup>2</sup>	2x10 <sup>-1</sup>	5.4
Curium-244	5x10 <sup>1</sup>	1.4x10 <sup>3</sup>	5x10 <sup>-1</sup>	1.4x10 <sup>1</sup>
Cobalt-60	3x10 <sup>1</sup>	8.1x10 <sup>2</sup>	3x10 <sup>-1</sup>	8.1
Cesium-137	1x10 <sup>2</sup>	2.7x10 <sup>3</sup>	1	2.7x10 <sup>1</sup>
Gadolinium-153	1x10 <sup>3</sup>	2.7x10 <sup>4</sup>	1x10 <sup>1</sup>	2.7x10 <sup>2</sup>
Iridium-192	8x10 <sup>1</sup>	2.2x10 <sup>3</sup>	8x10 <sup>-1</sup>	2.2x10 <sup>1</sup>
Promethium-147	4x10 <sup>4</sup>	1.1x10 <sup>6</sup>	4x10 <sup>2</sup>	1.1x10 <sup>4</sup>
Plutonium-238	6x10 <sup>1</sup>	1.6x10 <sup>3</sup>	6x10 <sup>-1</sup>	1.6x10 <sup>1</sup>
Plutonium-239/Be	6x10 <sup>1</sup>	1.6x10 <sup>3</sup>	6x10 <sup>-1</sup>	1.6x10 <sup>1</sup>
Radium-226	4x10 <sup>1</sup>	1.1x10 <sup>3</sup>	4x10 <sup>-1</sup>	1.1x10 <sup>1</sup>
Selenium-75	2x10 <sup>2</sup>	5.4x10 <sup>3</sup>	2	5.4x10 <sup>1</sup>
Strontium-90 (Y-90)	1x10 <sup>3</sup>	2.7x10 <sup>4</sup>	1x10 <sup>1</sup>	2.7x10 <sup>2</sup>
Thulium-170	2x10 <sup>4</sup>	5.4x10 <sup>5</sup>	2x10 <sup>2</sup>	5.4x10 <sup>3</sup>
Ytterbium-169	3x10 <sup>2</sup>	8.1x10 <sup>3</sup>	3	8.1x10 <sup>1</sup>
<sup>1</sup> The regulatory standard values are given in TBq. Curie (Ci) values are provided for practical usefulness only and are rounded after conversion.				



### Calculations Concerning Multiple Sources or Multiple Radionuclides

The "sum of fractions" methodology for evaluating combinations of multiple sources or multiple radionuclides, is to be used in determining whether a facility or activity meets or exceeds the threshold limits and is thus subject to the physical and/or information security requirements of this part.

I. If multiple sources and/or multiple radionuclides are present in a facility or activity, the sum of the fractions of the activity of each of the radionuclides must be determined to verify the facility or activity is less than the Category 1 or 2 limits of Table 1, as appropriate. Otherwise, if the calculated sum of the fractions ratio, using the following equation, is greater than or equal to 1.0, then the facility or activity meets or exceeds the threshold limits of Table 1 and the applicable physical and/or information security provisions of this part apply.

II. Use the equation below to calculate the sum of the fractions ratio by inserting the actual activity of the applicable radionuclides from Table 1 or of the individual sources (of the same radionuclides from Table 1) in the numerator of the equation and the corresponding threshold activity limit from the Table 1 in the denominator of the equation. Sum of the fraction calculations must be performed in metric values (i.e., TBq) and the numerator and denominator values must be in the same units.

$R_1$  = activity for radionuclides or source number 1

$R_2$  = activity for radionuclides or source number 2

$R_N$  = activity for radionuclides or source number n

$AR_1$  = activity limit for radionuclides or source number 1

$AR_2$  = activity limit for radionuclides or source number 2

$AR_N$  = activity limit for radionuclides or source number n

$$\sum_1^n \left[ \frac{R_1}{AR_1} + \frac{R_2}{AR_2} + \frac{R_n}{AR_n} \right] \geq 1.0$$

-END-

# ATTACHMENT 1

## Revision History for IMC 2800

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number
NA	07/27/10 CN 10-016	<p>Revision history reviewed for the last four years</p> <p>Change Office/Division name from reorganization (NMSS/IMNS to FSME/MSSA)</p> <p>Add definition of “pre-licensing visits” and describe scenario in which they are required. (IERP Recommendation I-1a)</p> <p>Add definition of an “initial security inspection” and describe scenario in which they are required.</p> <p>Add definition for “risk significant radioactive material.”</p> <p>Add definition of “security requirements.”</p> <p>Allows for announced visit for the initial security inspection and encourages coordination with local law enforcement</p> <p>Description of a proposed pilot program on the security inspection frequency’s recommended by the Increased Control Working Group (MPWG Recommendation M-IV.3)</p> <p>Implementation of a secondary program code for security inspections. (MPWG Recommendation M-IV.3)</p> <p>Add language to include awareness of allegation trends during inspection preparation and at the inspection site. (WITS 2008-00158)</p>	NA	NA	ML101520679

Issue Date: 07/27/10  
Effective Date: 10/01/10

Att. 1-1

2800

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number
		<p>Notification that inspectors should review NSTS inventory records in advance of inspections</p> <p>Addition of "Quantities of Concern" Table.</p> <p>Include language on inspector review of licensed activities performed by contracted personnel</p> <p>Requires inspector to verify that prompt corrective actions have been initiated in instances that affect the safe control of material</p> <p>Allows for the issuance of Form 591M in the field, but requires supervisory review. If changes are made to the 591M, the form is reissued to the licensee</p> <p>Inclusion of EDO Field Policy Manual on providing Third Party Assistance (WITS 2009-00082)</p> <p>Allows for health and safety inspections to be completed during the same visit as security inspections</p> <p>Guidance on coordinating with Agreement States and other Regions on licensed activities that cross jurisdictions</p> <p>Revision of Master Materials Licenses (MML) section to be more in line with IMC 2810 for the MML program</p>			

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Att 1-2

2800