INSPECTION PROGRAM FOR RADIOACTIVE MATERIALS AND RADIATION-PRODUCING DEVICES[1]

STATE OF RHODE ISLAND

DEPARTMENT OF HEALTH

RADIATION CONTROL AGENCY

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[1] This Inspection Manual is based on NRC Inspection Manual Chapter 2800 - Revised 12 September 2017, and supersedes both the October 2016 edition and the November 2017 Interim Revision of the RI Radiation Control Agency *Inspection Manual*: *Radioactive Materials Inspection Program*.

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RI RADIATION CONTROL AGENCY[2] - INSPECTION PROGRAM FOR RADIOACTIVE MATERIALS AND RADIATION-PRODUCING DEVICES

1.0 PURPOSE

To establish the inspection program for licensees[3] authorized to possess, use, transfer and dispose of radioactive material and/or radiation-producing devices 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).

2.0 OBJECTIVES

2.1 To establish the general policy for the RCA inspection program.

2.2 To describe a performance-based inspection approach and to identify specific conditions of poor performance that require more frequent inspection of the licensee.

2.3 To place the major emphasis of the RCA inspection program on timely and thorough follow-up of events, incidents and allegations.

2.4 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 RCA.

2.5 To aid in the achievement of a consistent process of inspection for licensees and to ensure the health and safety of workers and the public.

3.0 DEFINITIONS

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

3.2 **Inspection.** The act of assessing licensee performance to determine whether the licensee is using radioactive material/radiation-producing devices 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 RCA inspector(s), observations of licensed activities, interaction with licensee personnel, independent radiological measurements and transmission of the inspection findings. Pre-licensing visits and telephonic contacts are not considered inspections.

3.3 **Inspection Plan.** A written outline listing the licensee's activities and programs that will be covered during an inspection.

3.4 **Inspection Priorities.** An inspection priority code is assigned to each radioactive material license. The priority code (i.e., 1, 2, 3, 4 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 1A lists the program codes (types of use), along with the assigned priority codes, for radioactive

[2] RI Radiation Control Agency may also be referred to as the RCA or the Agency.

[3] Unless specifically indicated to the contrary, the term "licensee" in this document should be read to include all radiation-producing device (X-Ray) registrants as well as radioactive materials licensees.

material (RAM) licenses. Enclosure 1B lists the program codes, along with the assigned priority codes, for radiation-producing device (X-Ray) registrations. 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.

3.5 **Pre-licensing Visit.** A site visit and face-to-face meeting with an entity for providing a basis for confidence that radioactive material/radiation-producing devices will be used as specified. Staff should use the pre-licensing checklist to determine which applicants require visits.

3.6 **Reactive Inspection.** A special inspection performed in response to an incident, allegation, or information obtained by RCA (e.g., report of a misadministration, information obtained as a result of the issuance of a generic letter or bulletin or other Federal/State 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 on a routine inspection, then it does not satisfy the requirement to inspect the licensee at the routine, established interval.

3.7 **Routine Inspection.** Periodic, comprehensive inspections performed at a specified frequency based on the activities authorized under the license.

3.8 **Risk Significant Radioactive Material (RSRM)**. RSRM refers to the values in § 8.8 of 216 RICR-40-20, *Radiation*. The terms "Quantities of Concern", "Category 1 quantities" and "Category 2 quantities" are synonymous with RSRM.

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

3.10 **Special Inspection Activities.** Those inspection activities specified in § 7.0[4] where special guidance is needed. Those activities cover:

(a) Inspections of expired licenses, terminated licenses and licensees undergoing decommissioning;

(b) Inspections of significantly expanded licensee programs;

(c) Reciprocity inspections;

(d) Temporary job-site or field office inspections;

(e) Team inspections;

(f) Inspections of revoked or abandoned licenses;

(g) General licensee inspections;

(h) Reactive inspections; and

(i) Follow-up to escalated enforcement.

3.11 **Team Inspections.** For the purposes of this Document only, team inspections are defined as those inspections conducted by three (3) or more inspectors, or any materials inspection that includes an inspector from outside the RCA (other than members from NRC or other state radiation control programs organizations). Often, at least one (1) of the inspectors is included on the team because of specialty in a particular field. Team inspections can be routine inspections of a major licensee, or

[4] Unless otherwise specified, all references are to this Document.

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.

3.12 **Telephonic Contacts.** These are contacts, made by telephone and documented in the licensee's I&E file, to determine the status of licensee activities, assess compliance, or to exchange information with the licensee. Examples of telephonic contacts include reminding a licensee that its license is near expiration, calling to determine whether there are sufficient licensee operations to conduct an on-site inspection, or calling to determine whether the licensee actively possesses licensed material. Telephonic contacts are not inspections.

4.0 RESPONSIBILITIES AND AUTHORITIES

4.1 **RCA Administrator:**

(a) Provides overall program direction for the RCA inspection program.

(b) Develops and directs the implementation of policies, programs, and procedures for inspecting applicants, licensees, and other entities subject to RCA jurisdiction.

(c) Ensures, within budget limitations, that the RCA staff includes adequate numbers of inspectors to carry out the inspection program described in this document, including reactive inspections.

(d) Applies inspection resources, as necessary, to deal with significant issues and problems at specific facilities.

4.2 **Supervising Radiological Health Specialist:**

(a) Implements the RCA inspection program.

(b) Reviews and approves inspection schedules.

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

(d) Ensures that RCA inspectors achieve and maintain qualifications, in accordance with RCA requirements.

(e) Evaluates the performance of each inspector during actual inspections at least once during each calendar year.

(f) Proposes changes to the materials inspection program.

5.0 BASIC REQUIREMENTS

5.1 This document designates reactive inspections [See § 5.3] as the highest priority, followed by initial inspections [See § 5.4] and routine inspections [See § 5.5] for the Priority Codes listed in Enclosures 1A and 1B. All routine materials inspections should be performed on an unannounced basis. However, routine inspections of a radiation-producing device registration are typically performed on an announced basis.

(a) The Supervising Radiological Health Specialist shall assign a primary program code, with the most restrictive program code setting the inspection priority for each new or amended license. If a license authorizes activities that can be classified under more than one program code, a secondary program code shall also be assigned. If a license involves more than one category of use [e.g., a medical institution (Program Code 02121, Priority Code 5) which is also authorized

use of a high dose rate remote afterloader unit (Program Code 02230, Priority Code 2)], the category of use associated with the highest priority (most frequent) inspection shall establish the inspection priority for the license.

(b) Inspection plans shall be developed for complex, non-routine inspections. Inspection plans may also be developed for any other inspections, as decided by the Supervising Radiological Health Specialist. After the inspection, the inspection plan may be discarded.

5.2 **General Inspection Process.** The purpose of this document is to describe the types of 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 3 provide more specific guidance for onsite inspection activities of radioactive materials licenses. § 8.0 provides guidance for documenting inspection results.

(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 Supervising Radiological Health Specialist.

(1) To adequately prepare, an inspector shall review:

(i) The license to determine if it has any unusual license conditions that would affect the approach to the inspection (e.g., 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).

(ii) 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).

(iii) Any commitments made by the licensee or restrictions imposed by the RCA as a result of a Confirmatory Action Letter or an Order issued since the last inspection.

(iv) Any notes in the file regarding special inspection emphasis, such as a license reviewer's note to request a near term inspection regarding a significant licensing action [See § 7.2(a)]

(v) Any security requirements, guidance, questions and answers, and/or supplemental correspondence (e.g., licensee responses, requests for relief and final RCA determinations).

(vi) Any allegations trends and a follow-up of the licensee's evaluation and response to the allegation(s), potentially requiring consultation with the Supervising Radiological Health Specialist. [See § 8.2]

(vii) If the licensee is authorized to possess RSRM, review the National Source Tracking System (NSTS) inventory record at least two (2) days in advance.

(2) Prior to a routine inspection, the inspector should review all the current licensing documents and procedures from the licensee's 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 discuss this issue with the Supervising Radiological Health Specialist.

(3) To prepare for a reactive inspection, the inspector will review specific information for reactive inspections as determined by the inspector and the Supervising Radiological Health Specialist on a case-by-case basis [See § 5.3].

(4) 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 (e.g., Official Use Only, and Proprietary Information).

(5) Finally, the inspector should select appropriate and calibrated radiation detection instrumentation for the inspection and obtain the necessary inspection forms.

(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 RCA 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:

(i) Security and control of licensed material and radiation-producing devices;

(ii) Shielding of licensed material and radiation-producing devices;

(iii) Comprehensive safety measures;

(iv) Radiation dosimetry program;

(v) Radiation instrumentation and surveys;

(vi) Radiation safety training and practices;

(vii) Management oversight; and

(viii) Licensed activities performed by contracted personnel.

(2) These focus areas are structured as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures, misadministrations, or release, loss, or unauthorized use of radioactive material and/or radiation-producing devices. Section 3 of each NRC program-specific IP describes the focus areas.

(3) 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.

(4) The inspector should use a performance-based approach to evaluate the focus areas. A determination regarding safety and compliance with RCA 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 RCA, 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 radioactive material and/or radiation-producing devices and is preferable to a review of selected records alone.

(5) 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.

(6) 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 obtaining 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.

(7) 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.

(8) 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:

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

(ii) A worker is preparing or administering dosages or doses,

(iii) A worker is providing patient care, or

(iv) A licensee is dealing with customers or members of the public.

(9) 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.

(i) 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.

(ii) In all cases where licensee documents are retained beyond the inspection, inspectors must follow the requirements of § 38-2-1, et seq of the Rhode Island General Laws, as amended [RI Gen. Laws]. Inspectors shall ensure that the licensee understands that the retained record will become publicly available and shall give the licensee an opportunity to provide redacted copies or to request withholding the information pursuant to the requirements of RI Gen. Laws § 38-2-2(4)(B).

(10) 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.

(11) The inspector should keep the Supervising Radiological Health Specialist 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 RCA guidance under such circumstances.

(12) 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/or radiation-producing devices 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 the Supervising Radiological Health Specialist immediately.

(13) 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).

(c) **Common Inspection Elements.** Elements common to every inspection are discussed below.

(1) 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.

(i) 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 RCA'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.

(ii) 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.

(iii) 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 or radiation-producing devices). The representative's responses may help the inspector assess licensee management's awareness of the radiation protection program.

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

(2) 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 Statement of Deficiencies (SOD) and followed-up on safety concerns and unresolved issues identified during the previous inspection, including allegations.

(3) 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.

(i) 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).

(ii) Scope of Program. Interview cognizant personnel to determine the types, quantities, and use of radioactive material or radiation-producing devices, 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.

(4) Observation of Actual Facilities and Licensed Activities. Ideally, the inspector should observe work in progress that involves RCA-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 § 7.4]

(i) Perform a walk-through of the licensed facility to make general observations of the condition of the facility and the licensed activities being performed.

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

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

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

(v) 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.

(vi) Make direct observations of physical security systems and storage locations, if possessing RSRM.

(5) 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/her measurements with those of the licensee's.

(i) 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.

(ii) 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.

(iii) 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 RCA'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 office.

(6) 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.

(7) 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. If appropriate, the inspector should prepare Form MAT-6 (RAM) or RCA-9 (X-Ray) 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 RCA management review. [See § 8.4]

(i) 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.

(ii) 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 RCA requirements and the inspector's understanding of the licensee's corrective action plan for each violation [See § 5.2(b)(10) about keeping the licensee informed of apparent violations during the inspection].

(iii) To avoid the formal disputed violation process [See RCA Enforcement Policy], 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 the Supervising Radiological Health Specialist 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 Supervising Radiological Health Specialist 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.

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

(v) 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, the Supervising Radiological Health Specialist should be notified immediately.

(vi) Although deficiencies identified in some areas (i.e., workers' knowledge of the requirements in Parts 1 and 2 of 216 RICR-40-20, *Radiation*) are not always violations, the inspector should bring such deficiencies to the attention of licensee management at the exit meeting and in the cover letter transmitting the inspection report or Statement of Deficiencies (SOD).

(vii) 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.

(viii) For a reactive inspection, the inspector should refer to NRC IP 87103 for specific instructions about the exit meeting. It is particularly important that the inspector keep the Supervising Radiological Health Specialist informed of the inspection details and explain the exit meeting strategy 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 the Supervising Radiological Health Specialist. The inspector should close the meeting and promptly leave the site without lingering for any further discussion before presenting these issues to the Supervising Radiological Health Specialist. The licensee's next opportunity to discuss the findings will be after RCA management has reviewed these matters.

(d) **Post Inspection Activities.** After returning from an inspection, the inspector shall discuss the results of the inspection with the Supervising Radiological Health Specialist. This discussion should be sufficient to alert the Supervising Radiological Health Specialist to significant enforcement, safety, or regulatory issues. This meeting need not be documented, but it should be held in all cases. To complete the inspection, the inspector documents the inspection results in accordance with guidance in this document and the RCA Enforcement Policy. § 8.4 specifies the circumstances under which Form MAT-6 (RAM) or RCA-9 (X-Ray) can be issued in the field without supervisory approval, and signed by the Supervising Radiological Health Specialist when an inspector returns to the office. The form does not need to be reissued unless the characterization of any findings changes during supervisory review.

5.3 **Reactive Inspections.** Inspections performed to follow up on incidents (e.g., misadministration, overexposure, perceived concerns arising from a licensee's response to a generic letter or bulletin and loss or release of significant quantities of radioactive materials) take precedence over the routine inspection program. The Supervising Radiological Health Specialist shall promptly assess the preliminary information received concerning the incident and will determine if a reactive inspection is necessary. The reactive inspection will emphasize the analysis of the sequence of events and the conditions that existed at the time these events occurred. The analysis should assess the licensee's

determination of contributing factors and root causes, and 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.

(a) Reactive inspections involving a misadministration will be performed using the guidance in NRC Management Directive 8.10, "*NRC Medical Event Assessment Program*". All other reactive inspections will be performed using the guidance in NRC IP 87103, "*Inspection of Material Licensees Involved in an Incident or Bankruptcy*".

(b) 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 NRC IP 87103, to ensure the inspection thoroughly addresses the concern.

(c) A narrative inspection report will be written for all reactive inspections. The narrative report will include a discussion of 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 RCA event notification (EN) number if the reactive inspection was initiated by a reportable event. Enclosure 2 provides instructions to properly complete the record for NMED. § 8.3 outlines the methods for documenting inspections.

5.4 **Initial Inspections.**

5.4.1 **Radioactive materials.** Initial inspections of a new licensee shall be announced and normally completed within twelve (12) months of the date the new license was issued. However, as described below, if the licensee does not yet possess licensed materials or has not yet performed any principal activities[5], the initial inspection may be rescheduled to within eighteen (18) months of license issuance.

(a) **Scheduling Initial Inspections.** Contact the licensee to schedule and announce the initial inspection. During the contact, the inspector should determine if the licensee possesses licensed material or has performed any principal activities.

(1) If the licensee possesses licensed materials or has performed principal activities, then the inspector should conduct an inspection in accordance with § 5.2 and other applicable guidance.

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

(i) Determine the licensee's plans for future possession of licensed material or plans to perform principal activities.

(ii) Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should discuss any unique license conditions and give the licensee an opportunity to ask any regulatory questions.

[5] As defined in § 7.3 of 216 RICR-40-20, *Radiation*, *principal activities*, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

(iii) Remind the licensee notify the RCA before receipt of licensed material or initiation of principal activities, as required by license condition.

(iv) Document the contact and enter the record into the docket file. The conversation record should include the licensee's plans for future possession of material or plans to perform principal activities.

(v) Ensure that the due date is set for eighteen (18) months from license issuance.

(b) **Performing Initial Inspections.** During the initial inspection, the inspector should interview licensee staff (management and technical) to determine if licensed material was received or if principal activities have been performed. Methods for determining if principal activities have been performed include, but are not limited to the following: performing a site tour, performing independent measurements, and/or contacting distributors of licensed material, such as local radiopharmacies, to see if they have distributed material to the licensee.

(1) If the licensee has possessed licensed materials or performed principal activities, then the inspector should conduct an inspection in accordance with § 5.2 and other applicable guidance.

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

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

(ii) Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should discuss any unique license conditions and give the licensee an opportunity to ask any regulatory questions.

(iii) Remind the licensee to notify the RCA before receipt of licensed material or initiation of principal activities, as required by license condition.

(iv) Remind the licensee of the requirement in § 7.6.5 of 216 RICR-40-20 to provide written notification to the RCA within sixty (60) days if no principal activities under the license have been conducted for a period of twenty-four (24) months.

(v) Document the onsite inspection by completing the appropriate inspection record. The "program scope" description should include the licensee's plans for future possession of material or plans to perform licensed operations.

(vi) Ensure that the due date is set for twelve (12) months from the date of the onsite inspection. To achieve the goals of cost saving and efficient use of staff time and travel, the date of the next initial inspection attempt may vary by ± six (6) months.

(c) **New Licenses Exempted From Initial Inspection.** There are certain circumstances that require a new license to be issued to the licensee, but an initial inspection is not warranted.

(1) New licenses that are issued solely as a result of a licensee's change of mailing address are not required to receive an initial inspection, if the licensee's place of use remains the same as on the previous license. The "last inspection date" and "next inspection date" for the licensee's previous license still apply to the new 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:

(i) The organization controlling the licensed activities changes substantially (e.g., changes in key personnel, authorities, or resources associated with the radiation safety program);

(ii) The licensee significantly increases the types, quantities, or forms of radioactive materials on the license;

(iii) The licensee significantly increases the different uses authorized on the license (e.g., adds brachytherapy to a diagnostic nuclear medicine license);

(iv) The licensee significantly increases the number of authorized users; or

(v) The new license authorizes one or more new facilities.

(vi) If none of these conditions applies, the "last inspection date" and "next inspection date" for the licensee's previous license still apply to the new license.

(3) 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 six (6) months have elapsed between the date the initial license expired and the date the renewal application was submitted. The "last inspection date" and "next inspection date" for the licensee's previous license still apply to the new license.

5.4.2 **Radiation-producing devices**. Initial inspections of a new registrant shall be announced and normally completed within six (6) months of the date the new registration was issued for registrants with inspection priorities 1, 2 or 3, and within twelve (12) months for registrants with inspection priority 4. However, if the registrant has not yet performed any principal activities[6], the initial inspection may be rescheduled to within eighteen (18) months of license issuance

(a) **Scheduling Initial Inspections.** Contact the registrant to schedule and announce the initial inspection. During the contact, the inspector should determine if the registrant has performed or is capable of performing any principal activities.

(1) If the registrant has performed or is capable of performing principal activities, then the inspector should conduct an inspection in accordance with § 5.2 and other applicable guidance.

(2) If it is determined that the registrant has not performed principal activities or is not capable of safely operating the radiation-producing device, the inspector should:

(i) Determine the registrant's future plans to perform principal activities.

(ii) Use this opportunity to discuss the license and applicable regulations with the registrant. The inspector should discuss any unique circumstances and give the registrant an opportunity to ask any regulatory questions.

(iii) Remind the registrant to notify the RCA before initiation of principal activities.

(iv) Document the contact and enter the record into the docket file. The conversation record should include the registrant's future plans to perform principal activities.

(v) Ensure that the due date is set for eighteen (18) months from license issuance.

(b) **Performing Initial Inspections.** During the initial inspection, the inspector should interview registrant staff (management and technical) to determine if principal activities have been performed. Methods for determining if principal activities have been performed include, but are

[6] *Principal activities* for radiation-producing devices means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued (i.e., the radiation-producing machine is operational). Storage of radiation-producing devices is not a principal activity.

not limited to, the following: performing a site tour, performing independent measurements, and/or checking logs and advertisements.

(1) If the registrant has performed principal activities, then the inspector should conduct an inspection in accordance with § 5.2 and other applicable guidance.

(2) If it is determined that the licensee has not performed principal activities, the inspector should:

(i) Determine the registrant's future plans to perform principal activities. In assessing the registrant's future plans, the inspector should determine if adequate facilities and equipment are in place to safely perform principal activities.

(ii) Use this opportunity to discuss the license and applicable regulations with the registrant. The inspector should discuss any unique circumstances and give the registrant an opportunity to ask any regulatory questions.

(iii) Remind the registrant notify the RCA before initiation of principal activities.

(iv) Document the onsite inspection by completing the appropriate inspection record. The "program scope" description should include the registrant's future plans to perform principal activities.

(c) **New Licenses Exempted From Initial Inspection.** There are certain circumstances that require a new license to be issued to the registrant, but an initial inspection is not warranted.

(1) New licenses that are issued solely as a result of a registrant's change of mailing address are not required to receive an initial inspection, if the registrant's place of use remains the same as on the previous license. The "last inspection date" and "next inspection date" for the registrant's previous license still apply to the new 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:

(i) The organization controlling the licensed activities changes substantially (e.g., changes in key personnel, authorities, or resources associated with the radiation safety program);

(ii) If none of these conditions applies, the "last inspection date" and "next inspection date" for the licensee's previous license still apply to the new license.

(3) New licenses that are issued because a licensee did not comply with the annual renewal requirement are not required to receive an initial inspection in accordance with this section, unless more than six (6) months have elapsed between the date the initial license expired and the date a new application was submitted. The "last inspection date" and "next inspection date" for the licensee's previous license still apply to the new license.

5.5 **Routine Inspections.** Routine inspection of licensees shall be conducted at intervals in years corresponding to the inspection priority listed in Enclosures 1A (RAM) and 1B (X-Ray). If the licensee has possessed material or performed principal activities since the last inspection, the inspector should perform a routine inspection of the facility as defined in the program-specific inspection procedure. If the licensee has not possessed material or performed principal activities since the last inspection, the inspector should follow the instructions in § 5.4.1(b)(2)(i) through (vi), or § 5.4.2(b)(2)(i) through (iv), as applicable.

5.6 **Pre-licensing Visit.** Generally, pre-licensing visits shall be conducted for new entities that do not have an existing RCA, NRC or other Agreement State license, licensees changing ownership to an unknown entity, or licensees that are significantly expanding the size or scope of their existing license. Reviewers should use the pre-licensing checklists to determine if pre-licensing visits are needed. The

purpose of the pre-licensing visit is to evaluate the applicant's intentions regarding the use of radioactive materials and to forward suspicious applications to the appropriate authority for follow-up, per the guidance in the pre-licensing checklist. At a minimum, all storage and use locations must be visited. By the end of the visit, the reviewer should have observed, collected, and documented sufficient information to provide a basis of confidence that the applicant will use the radioactive materials as specified in its license application. Pre-licensing visits must be completed before the issuance of a license.

5.7 Third Party Assistance

(b) 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 RCA regulatory jurisdiction. However, the RCA also has an obligation to provide assistance where possible in helping individual licensees solve problems that affect public health and safety.

(c) If an inspector receives a request for third party assistance from a licensee for a programmatic problem that allows time for the licensee to conduct research in obtaining assistance, they may refer the requestor to a professional group, such as the American Nuclear Society or Health Physics Society or to a licensee that has solved a similar problem. When providing the name of a licensee that has solved a similar problem, take special care not to create a perception of conflict of interest and ensure that the licensee is not the subject of an ongoing investigation for misconduct by the RCA.

(d) 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 Supervising Radiological Health Specialist. The inspector should not leave the site until the concern is fully understood by the licensee and corrective action has been initiated.

6.0 INSPECTION INTERVALS

6.1 **Scheduling Routine Inspections.** Inspectors should plan to conduct routine inspections close to the due date. However, to achieve the goals of cost saving and efficient use of staff time and travel, routine inspections may be scheduled within a window around their inspection due dates.

(a) Routine inspection of licensees in Priority Codes 1 and 2 may vary around their due date by ± fifty percent (± 50%).

(b) Routine inspection of Priority Codes 3, 4 and 5 licensees may vary around their due dates by ± one (1) year.

(c) Inspections will not be considered "overdue" until they exceed the scheduling window.

(d) Inspections may be scheduled before their window if the RCA receives information that warrants earlier inspection. The bases for scheduling the inspection before the window should be documented in the inspection records and signed by the Supervising Radiological Health Specialist.

(e) The "next inspection date" for an inspection conducted outside the normal window shall be determined by the Supervising Radiological Health Specialist.

6.2 **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. 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.

6.3 **Inspections After Escalated Enforcement.** If escalated enforcement action has taken place for a particular licensee, a special inspection that focuses on the licensee's corrective actions in response to Severity Level III or above violation(s) shall be scheduled and conducted within twelve (12) months of the issuance of the escalated enforcement action. A follow-up inspection may be performed as a part of a routine inspection. Factors such as the risk-significance, number, and severity level of the violations should be considered in determining when to conduct the follow-up inspection.

6.4 **Reduction of Inspection Interval**

(a) 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:

(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 Statement of Deficiencies (SOD) 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.

(b) The list in § 6.4(a) is not exhaustive. The inspection frequency can and should be reduced for any other reason deemed pertinent by RCA management.

(1) 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.

(2) Another example would be an industrial radiography licensee or a well logging licensee which is authorized to use radioactive material or radiation-producing devices 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 § 7.4]

(c) A licensee that meets the criteria in § 6.4(a) 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 two (2) or three (3) years, rather than five (5), 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 one (1) year rather than two (2), depending on the scope of licensed activities. [See § 6.3]. The reduction shall be valid only until the next inspection, but the Supervising Radiological Health Specialist shall consider the results of the next inspection when determining whether the reduced frequency should be continued, changed, or returned to normal.

(d) The designated inspection priority for these licensees should not be changed. However, the due date should be changed. The scheduling window defined in § 6.1 still applies based on the licensee's default inspection priority and is not changed by a reduction of inspection interval.

(e) To document the reduction in the interval between inspections, a brief note (e.g., in the inspection records) should be written by the inspector describing the condition for reducing the interval and be approved and signed by the Supervising Radiological Health Specialist, and placed in the licensee's I&E file.

6.5 Extension of Inspection Interval

(a) The due date for the next inspection may be extended if, in the judgement of the inspector and the Supervising Radiological Health Specialist, the licensee is determined to be a high performer. This would be a one-time extension. This decision is a matter of judgement because RCA inspections are a snapshot of the licensee's activities at the time an inspector is onsite. As a result, the inspector and the Supervising Radiological Health Specialist will make this judgement based on an inspector's performance-based observations of the most risk-significant, authorized activities; high past performance; and confidence that the licensee's performance will continue at a high level. In addition, the identification of a Severity Level IV violation is not by itself a basis for concluding a licensee is not a high performer. If approved, Priority 1 and 2 licensees may be extended to fifty percent (50%) of the routine inspection interval and Priority 3 licensees may be extended for up to 1 year in circumstances where the licensee has demonstrated high performance. Priority 4 and 5 licensees are not eligible for this extension. Extending the due date of the next inspection for high performance would not constitute a change to a licensee's frequency of inspection. The scheduling window defined in § 6.1 still applies based on the licensee's default inspection priority and is not changed by an extension for high performance.

(b) The following criteria should be considered, but is not intended to be all inclusive, in this judgement:

(1) An inspector has observed the licensee conduct its most risk-significant, authorized activities with no significant findings (for example, an inspector observed the licensee's radiography crew perform work at a temporary jobsite and there were no significant findings);

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

(3) There has been no major change to the licensee's radiation safety program (reference § 7.2), the licensee's senior management has not changed, and the radiation safety staff has not experienced significant turnover within the last two (2) inspection cycles;

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

(c) Normally, a licensee that meets the criteria in § 6.5(b) will be extended. However, just because a licensee meets the criteria in § 6.5(b) does not mean the next scheduled inspection date must be extended. Rather, the above criteria in § 6.5(b) is meant to be a guide for RCA inspection staff to consider when making the judgement about whether to extend the due date.

(d) To document the extension in interval between inspections, the inspector shall include a brief note in the inspection record. The Supervising Radiological Health Specialist will review and approve the extension.

(e) The RCA may reconsider its decision to extend the next inspection due date based on any information received during the inspection interval that warrants a re-evaluation of the extension, such as a reportable event, a substantiated allegation against the licensee, or a significant change to the licensee's radiation safety program. Reconsideration of the next inspection due date should follow the guidance in § 6.4 or § 6.6, as applicable.

6.6 **Other Changes in Inspection Interval.** At the discretion of RCA management, other changes in inspection interval may be made to achieve efficiencies in the use of inspection resources or to reduce regulatory impact on the licensee. This may include more frequent inspections to ensure that inspectors have the opportunity to sufficiently observe licensee operations and increase public confidence by increasing the inspection focus on higher risk activities, without significantly increasing the regulatory burden on licensees. For example, rather than perform a single, large team, high impact inspection of the license at the normal interval, more frequent inspections may be performed by individuals or smaller teams that specifically focus on higher risk licensee activities. This may also include deviations from the prescribed inspection interval to accommodate extenuating circumstances that prevent a timely inspection from being completed. The bases for altering the scheduling of inspections should be documented in the inspection records, signed by Supervising Radiological Health Specialist and placed in the licensee's I&E file.

6.7 **Coordination with NRC and Other Agreement States.** When licensed activities cross jurisdictions or the demonstration of compliance with portions of the security requirements must be made outside of the licensed facility, RCA management will coordinate with the appropriate NRC Regional Office or other 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, RCA 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 this document. In most inspections of temporary job sites or field offices, not all licensee implementation of security requirements can be inspected at these facilities, such as in the case of trustworthiness determinations that have been performed by the human resources division of

the corporation that is located in another jurisdiction. The inspection record or report should reflect that such elements were deferred to the appropriate jurisdiction. A record documenting the inspection findings from the appropriate NRC Regional Office or other Agreement State should be requested and maintained with other records of the licensee's inspection, when possible.

7.0 SPECIAL INSPECTION ACTIVITIES

7.1 **Expired and Terminated Licenses and Decommissioning Activities.**

(a) Notification that a license has expired or is being terminated requires prompt action (i.e., within thirty (30) days) to ensure that licensed material and/or radiation-producing devices have been properly transferred or disposed of, and that all areas where material was used may be safely released for unrestricted use.

(b) Inspectors should be aware of the need for security and control of radioactive materials and/or radiation-producing devices 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 radiation-producing devices; and/or by performance of an inspection that may include independent or confirmatory surveys. The inspector should also review records of disposals, burials, and public dose that may be required to be submitted to the RCA on termination or retirement of the license. Such actions would be conducted as soon as appropriate after notification is received.

(c) 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.

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

7.2 **Significantly Expanded Programs**

(a) 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 inspector and the reviewer should make the Supervising Radiological Health Specialist aware of the following changes in a licensee's scope of use.

(b) Through interviews of licensee staff or observations of licensed activities, the inspector shall determine if:

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

(2) The license authorizes a physical move of a facility or a new use at a temporary jobsite;

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

(4) The licensee has increased the types of uses or disposal (e.g., 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 § 7.6.5 of 216 RICR-40-20, *Radiation*.

(c) If any of the items in § 7.2(b)(1)-(b)(6) 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 Supervising Radiological Health Specialist.

(d) 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. The license reviewer shall consult with the Supervising Radiological Health Specialist about scheduling the inspection.

(e) If during the licensing review process, the reviewer determines that the licensee will possess RSRM, the reviewer shall consult with the Supervising Radiological Health Specialist and add Program Code 01000. An onsite inspection must be performed to verify that the applicant has implemented the security requirements or Increased Controls before issuing the licensing action which allows the applicant/licensee to take possession of RSRM.

7.3 **Reciprocity Inspections.** § 7.10 of 216 RICR-40-20, *Radiation* grants a general license[7] to any person, with a specific license from the NRC or another Agreement State authorizing use at temporary job-sites, to conduct the same activity in Rhode Island, except in areas under exclusive Federal jurisdiction. The licensee must have a current RCA Form MAT 9I (*Initial Application for Proposed Activities in Rhode Island Except for Areas Under Exclusive Federal Jurisdiction*) on file with the RCA or submit a new RCA Form MAT 9I. In addition, the licensee must submit an RCA Form MAT 9N (*Report of Proposed Activities in Rhode Island Except for Areas Under Exclusive Federal Jurisdiction*) at least three (3) days before engaging in the licensed activity. The RCA shall take immediate action on the report and enter the information into the Reciprocity Tracking System before reciprocity work begins.

(a) The RCA shall perform inspections of reciprocity licensees in accordance with the following guidelines:

(1) Core Inspections (Program Codes with Inspection Priorities 1, 2 and 3): At least twenty percent (20%) of the eligible reciprocity licensees are to be inspected each calendar year.

(2) Non-core Inspections (All other Program Codes): Are to be inspected each calendar year as resource and inspection schedules permit.

(3) Repeat inspections of the same reciprocity licensee in a given calendar year are only conducted to confirm corrective action for previously cited items of noncompliance.

(b) NRC and other Agreement State licensees are to be inspected using the same program-specific procedures used for equivalent RCA-licensed activities.

(c) The Supervising Radiological Health Specialist shall send copies of inspection and enforcement documentation to the appropriate NRC Regional Office or other Agreement State radiation control agency which issued the license that is the basis for the general license under § 7.10 of 216 RICR-40-20, *Radiation*.

7.4 **Temporary Job-Site or Field Office Inspections**

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

[7] Reciprocity will not typically be authorized for radiation-producing devices. The radiation-producing device must be registered with the RCA prior to use in RI.

(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 due date may indicate a reduced inspection interval. [See § 6.4]

(b) **Permanent Field Offices.** A license which authorizes licensed activities to be conducted from multiple permanent facilities (main office plus field offices) shall be inspected in accordance with the following criteria:

(1) Number of facilities to be inspected:

(v) If the license authorizes licensed activities to be conducted from two (2) or three (3) permanent facilities [main office plus one (1) or two (2) field offices], only one (1) location must be inspected at the interval specified in this document for the type of license.

(vi) If the license authorizes licensed activities to be conducted from four (4) to ten (10) permanent facilities [main office plus three (3) to nine (9) field offices] at least two (2) locations must be inspected at the interval specified in this document for the type of license.

(vii) If the license authorizes licensed activities to be conducted from more than ten (10) permanent facilities (main office plus more than nine (9) field offices), about twenty percent (20%) of the locations should be inspected at the interval specified in this document for the type of license.

(viii) 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 (e.g.., Severity Level III or above violation(s), multiple Severity Level IV violations indicative of poor program management/ oversight), the Supervising Radiological Health Specialist should consider expanding the initial review to include additional satellite locations to determine the extent of the weakness.

(c) Inspection of a licensee working in off-shore waters is not conducted by the RCA. This is a NRC Only activity.

(d) If a temporary job-site inspection is not performed, a brief note will be written in the inspection records, giving an explanation for the missed temporary job-site inspection.

7.5 **Team Inspections.**

(a) Examples of situations where team inspections may be appropriate are:

(1) Routine inspections of major licensees (i.e., broad-scope academic, broad-scope medical licensees, and large processors/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.

(2) Reactive inspections of any type of licensee where one or more specialists are needed on the team (of three or more inspectors).

(3) 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.

(4) Inspections of any type (routine or reactive) that include team members from outside the RCA and NRC or other state radiation control programs, such as members from the Department of Transportation (DOT), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA). For inspections of any type that involve participation by outside agencies, the inspector should contact the Supervising Radiological Health Specialist before making the first contact with the outside agency.

(b) Inspection plans should be considered for all routine team inspections of major, broad-scope academic or medical licensees, large manufacturers, or in cases where team members from agencies outside the RCA (other than NRC or other state radiation control programs) are involved [i.e., examples in §§ 7.5(a)(1)-(a)(4)].

7.6 **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 Supervising Radiological Health Specialist's 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 or types of radiation-producing devices.

7.7 **Inspection of Generally Licensed Devices.** Routine inspections of general licensees (other than reciprocity) are not normally performed. However, if a specific licensee also possesses generally licensed devices that require registration under § 7.1(C) of 216 RICR-40-20, *Radiation*, the inspector should verify the adequacy of the licensee's control and accountability of the devices [See NRC 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 shall also be made to resolve issues such as allegations, incidents or indications of unsafe practices.

8.0 DOCUMENTATION OF INSPECTION RESULTS

8.1 **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[8] 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 § 5.4.

(3) If it is possible to inspect records or other items according to license conditions or RCA 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.

(4) If the RSO is not onsite, the inspector shall attempt 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 licensee's I&E file, signed by the inspector that briefly summarizes the attempted inspection. The Supervising Radiological Health Specialist will determine when another attempt will be made to inspect the licensee.

(c) A reactive inspection will not substitute for a routine inspection unless the scope of the inspection is comprehensive.

8.2 **Allegations**

(a) 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 I&E file for the licensee. Further guidance about "chilling" effect is contained in §§ 8.2(b) and (c).

(b) 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 RCA?

(2) Have there been interactions with RCA personnel that suggest that some employees may be hesitant to raise concerns or present information to RCA?

(3) Are employee concerns addressed by licensee management in a timely manner?

(4) Is the licensee's corrective action successful in addressing employees' concerns?

(c) If any indication of a "chilling" effect is found, the inspector shall inform the Supervising Radiological Health Specialist for further review and follow-up.

[8] This includes a registrant who possesses or has possessed one or more radiation-producing devices.

8.3 **Documenting Inspection Results**

(a) **Types of Documentation.** The inspector shall document inspection results by completing either Form MAT-6 (RAM) or RCA-9 (X-Ray), an RCA approved inspection checklist or a narrative inspection report, as directed by the Supervising Radiological Health Specialist.

(1) **Form MAT-6 or RCA-9.** An inspector may issue a Form MAT-6 (RAM) or RCA-9 (X-Ray), while still in the field, for:

(ix) an inspection that results in no findings; or

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

(xi) to document a Severity Level V violation that does not require an amendment to the license to correct and is not willful or repetitive in nature:

(a) The Severity Level V violation being documented in this manner must be corrected while the inspector is present, or can be easily corrected within thirty (30) days of the date of the inspection; and

(b) Any corrective actions must be listed on the Form MAT-6 (RAM) or RCA-9 (X-Ray).

(xii) With the approval of the Supervising Radiological Health Specialist, the Form MAT-6 (RAM) or RCA-9 (X-Ray) may also be used 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.

(a) The Severity Level IV violation being documented in this manner must be corrected while the inspector is present, or can be easily corrected within thirty (30) days of the date of the inspection; and

(b) Any corrective actions must be listed on the Form MAT-6 (RAM) or RCA-9 (X-Ray).

(xiii) Form MAT-6 (RAM) or RCA-9 (X-Ray) may NOT be used to transmit non-cited or cited security-related violations.

(2) **Inspection Checklist.** An inspector may document non-escalated violations by use of an RCA approved inspection checklist. The licensee will be issued a cover letter, with a Statement of Deficiencies, that should not contain any security-related information.

(3) **Narrative Inspection Report.**

(xiv) 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. The licensee will be issued a cover letter, with the applicable RCA enforcement action, that should not contain any security-related information.

(xv) Narrative inspection reports may be used to document other types of inspections at the discretion of the Supervising Radiological Health Specialist.

(b) **Required Information to Document Inspections.** All documented inspection results [a Form MAT-6 (RAM) or RCA-9 (X-Ray), inspection checklist or narrative inspection report] shall 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 closed violations identified during a previous inspection;

(5) Each cited and non-cited violation includes:

(i) a brief statement of the circumstances, including the date(s) of the violation or non-cited violation and the facts necessary to demonstrate that a requirement was not met; and

(ii) reference to the regulation or license condition that was violated; and

(iii) a description of the licensee's completed and anticipated corrective actions for any identified violations.

(6) A succinct description of the scope of the licensee's program; and

(7) For inspections that include a review of 216 RICR 40-20-8 [10 CFR Part 37] requirements with no violations, the inspector should include a non-publicly available inspection record describing the licensee's implementation of security requirements.

(8) 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 shall also be included as part of the inspection record.

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

(10) Each inspection record [i.e., a Form MAT-6 (RAM) or RCA-9 (X-Ray), an inspection checklist or narrative inspection report] must be signed by both the inspector and the Supervising Radiological Health Specialist.

8.4 **Methods of Transmitting Inspection Results.** Results of inspections shall be reported to the licensee by either issuing Form MAT-6 (RAM) or RCA-9 (X-Ray) or a letter [with or without a Statement of Deficiencies (SOD)] to the licensee.

(a) **Form MAT-6 (RAM) or RCA-9 (X-Ray).**

(1) The inspector will present Form MAT-6 (RAM) or RCA-9 (X-Ray) to the licensee at the conclusion of the exit interview, or, when consultation with the Supervising Radiological Health Specialist is necessary, the inspector may transmit Form MAT-6 (RAM) or RCA-9 (X-Ray) from the RCA's office.

(2) The Form MAT-6 (RAM) or RCA-9 (X-Ray) shall include the name of the responsible inspector. The inspector shall sign the completed Form MAT-6 (RAM) or RCA-9 (X-Ray).

(3) Supervisory review is required, but is not necessary prior to issuance of Form MAT-6 (RAM) or RCA-9 (X-Ray) to the licensee.

(4) If no changes are needed after supervisory review, the Supervising Radiological Health Specialist will sign the final signature block and the completed form will be put in the licensee's I&E file.

(5) If changes are needed after supervisory review, Form MAT-6 (RAM) or RCA-9 (X-Ray) will be reissued to the licensee, and both the original and the revised completed form will be put in the licensee's I&E file.

(c) **Letter to Licensee (With or Without SOD).** When findings are documented in an inspection checklist or narrative inspection report, a letter shall be used to inform the licensee of the results of the inspection. The letter will be a publicly available document. If security-related information is transmitted to the licensee the information should be placed in a separate enclosure to the letter with the proper markings, as specified in § 8.4(d).

(d) **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 SOD, inspection record and any other separate enclosure are appropriately protected, handled and marked in accordance with the RCA security guidance. All cover letters to licensees will be publicly available and should not contain sensitive information. Security-related information should not be made available to the public

9.0 COORDINATION OF REGIONAL RESPONSIBILITY FOR INSPECTIONS [RESERVED - NRC ONLY]

10.0 COORDINATION WITH OTHER AGENCIES

10.1 RCA does not conduct inspections of licensee compliance with the requirements of other State or Federal agencies (except for DOT). However, RCA 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 to identified concerns, the RCA inspector must inform the Supervising Radiological Health Specialist, who may coordinate the information with the appropriate agency.

10.2 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. The inspector shall also advise the licensee of the inspector's obligation to inform the Supervising Radiological Health Specialist of these concerns.

11.0 INPUT INTO NRC TRACKING SYSTEMS

11.1 **Input into the Nuclear Material Events Database (NMED)**

(a) USNRC/NMSS manages NMED for all material-related incidents and events. The Supervising Radiological Health Specialist is responsible for ensuring that NMSS is notified of all material-related incidents. The Supervising Radiological Health Specialist shall also forward annotated copies (with the NMED event #, event notification or both on each document) of all documentation regarding a material incident (i.e., "Preliminary Notifications," reports of misadministrations, follow-up inspection reports) to the NMED contractor and the NRC NMED Project Manager.

(b) The Supervising Radiological Health Specialist is responsible for ensuring that sufficient information is provided for the NMED item to be considered "complete." For documents that are not publicly available, the Supervising Radiological Health Specialist must redact the non-publicly available information from the document. Only publicly available information can be placed into NMED.

(c) The target for ensuring that NMED records are complete is sixty (60) days from the date the event is reported. The Supervising Radiological Health Specialist shall provide the information

outlined in Enclosure 2 to classify a record as “complete.” If there is a reason that the Supervising Radiological Health Specialist cannot obtain the required information, that reason should be forwarded to the NMED contractor and to the NRC NMED Project Coordinator

12.0 INSPECTION MANUAL CHAPTERS AND INSPECTION PROCEDURES FOR MATERIALS PROGRAM

12.1 The IMCs and IPs listed in Enclosure 3 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.

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

Enclosure 1A - Inspection Priority Codes Assigned to RAM Program Codes

Program Code	Category Title	Remarks	Priority Code
01000	RSRM Licensee	Licensee subject to 216-RICR 40-20-8 (10 CFR 37) requirements	Vary[9]
01100	Academic Type A Broad	Radiation Safety Committee (RSC)-approved users; 216-RICR-40-20-7.6.20(B)	3
01110	Academic Type B Broad	Radiation Safety Officer (RSO)-approved users; 216-RICR-40-20-7.6.20(C)	5
01120	Academic Type C Broad	Authorized Users specifically named in the license; 216-RICR-40-20-7.6.20(D)	5
02110	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.	2
02120	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.	3
02121	Medical Institution - WD not required	Used as primary code *only* for diagnostic nuclear medicine and diagnostic types of use under 216-RICR-40-20-9.12.1.	5
02200	Medical Private Practice - WD required	[Same remark as 02120]	3
02201	Medical Private Practice - WD not required	[Same remark as 02121]	5
02210	Eye Applicators - Sr-90	Institution or Private Practice	3
02220	Mobile Medical Service-WD not required	Use as a primary code if the license authorizes the mobile service *only*. Use as a secondary code if the license authorizes medical use at a central facility (i.e., institution or private practice facility) in addition to the mobile service.	3
02230	High-Dose Rate Remote Afterloader	Use as a primary code	2
02231	Mobile Medical Service-WD required	Use as a primary code. Includes mobile HDR and non-HDR modalities under 216-RICR-40-20-9.	2
02240	Medical Therapy - Other Emerging Technology	Medical therapy modalities used under 216-RICR-40-20-9.12.1. (e.g., liquid sources, microspheres and IVB devices.	2
02300	Teletherapy	Treatment of human subjects *only*	5
02310	Gamma Stereotactic Radiosurgery (GSR)	Treatment of human subjects *only*	2

[9] 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	Category Title	Remarks	Priority Code
02400	Veterinary Nonhuman Subjects	Routine diagnosis or therapy on animals. No animal research.	5
02410	*In-Vitro* Testing Laboratories	Licenses are issued to individuals or facilities which are not included in larger programs described by Program Codes 02110 or 02120.	5
02500	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.	2
02511	Medical Product Distribution - Prepared Radio-pharmaceuticals - 216 RICR-40-20-7.6.16.	Distribution of prepared radiopharmaceuticals to authorized medical licensees.	5
02513	Medical Product Distribution – Sources & Devices - 216 RICR-40-20-7.6.17.	Therapy sources, calibration and reference sources	5
02600	Production of PET Radioactive Drugs - 216 RICR-40-20-7.6.1(I) (Secondary Code)	Used as secondary code to identify those entities that meet the criteria in 216-RICR-40-20-7.6.1(I). See primary code for inspection priority	--[10]
02700	Radium-226 Luminous Products & Sources up to 10 Times under 216 RICR-40-20-7.7.8	For luminous products containing Ra-226 authorized under 216-RICR-40-20-7.7.8	5
02710	Radium-226 Luminous Products & Sources Greater Than 10 Times under 216 RICR-40-20-7.7.8	For luminous products containing Ra-226 authorized under 216-RICR-40-20-7.7.8	3
03110	Well Logging Radioactive and/or Special Nuclear Material (SNM) Tracer and Sealed Sources	Use of sealed or unsealed sources for exploration of oil, gas, or minerals in wells.	3
03111	Well Logging Radioactive and/or SNM Sealed Sources Only	Exploration of oil, gas, or minerals in wells; study of subsurface potable aquifers.	3
03112	Well Logging Radioactive Only - Tracers Only	Exploration of oil, gas, or minerals in wells	3
03113	Field Flooding Studies	Injection of unsealed radioactive materials for tracing oil and gas reservoirs.	3
03120	Measuring Systems - Fixed Gauges	Non-portable gauges for measurement or control of material density, flow, level, thickness or weight, etc.	5

[10] Program Code 02600 is used only as a secondary code.

Program Code	Category Title	Remarks	Priority Code
03121	Measuring Systems - Portable Gauges	Moisture/density gauges containing gamma and neutron sources used for measurements in soils, compacted soils and road surfacing materials.	5
03122	Measuring Systems - Analytical Instruments	For example, x-ray fluorescence analyzers	5
03123	Measuring Systems - Gas Chromatographs	Quality control testing of samples from industrial process and environmental conditions.	5
03124	Measuring Systems - Other	Instrument calibrators, Krypton-85 (Kr-85) leak detectors	5
03130	Inspection Systems	Fixed or mobile non-intrusive inspection systems	5
03210	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.	2
03211	Manufacturing and Distribution Broad - Type A	RSC-approved users under 216-RICR-40-20-7.6.20(B)	2
03212	Manufacturing and Distribution Broad - Type B	RSO-approved users under 216-RICR-40-20-7.6.20(C)	5
03213	Manufacturing and Distribution Broad - Type C	Authorized Users specifically named in the license under 216-RICR-40-20-7.6.20(D)	5
03214	Manufacturing and Distribution Other	Smaller firms that require a more restrictive license.	5
03215	Manufacture, Assembly, Disassembly, Repair of Products Containing Radium-226	For certain items and self-luminous products containing Ra-226 authorized under 216-RICR-40-20-7.7.8	3
03218	Nuclear Laundry	**NOT USED IN RHODE ISLAND**	N/A
03219	Decontamination Services	Cleaning of scrap materials for authorized release for unrestricted use.	3
03220	Leak Test Services 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.	5
03221	Instrument Calibration Services Only – Source ≤ 100 Curies	Commercial calibration service	5
03222	Instrument Calibration Services Only – Source > 100 Curies	Commercial calibration service	5
03225	Other Services - Source ≤ 100 Curies	Commercial servicing for industrial gauge and HDR licensees	5
03226	Other Services - Source > 100 Curies	Commercial servicing for teletherapy, irradiators, and GSR units containing a total activity in the unit during servicing that is > 100 Curies.	2
03231	Waste Disposal (Burial)	**NOT USED IN RHODE ISLAND**	N/A

Program Code	Category Title	Remarks	Priority Code
03232	Waste Disposal Service - Prepackaged Only	**NOT USED IN RHODE ISLAND**	N/A
03233	Waste Disposal Service - Incineration	**NOT USED IN RHODE ISLAND**	N/A
03234	Waste Disposal Service - Processing and/or Repackaging	**NOT USED IN RHODE ISLAND**	N/A
03235	Incineration-Noncommercial (Secondary Code)	**NOT USED IN RHODE ISLAND**	N/A
03236	Waste Treatment Service (Other Than Compaction)	**NOT USED IN RHODE ISLAND**	N/A
03240	General License Distribution – 216 RICR-40-20-7.6.11(B)	For fixed gauges authorized under 216-RICR-40-20-7.6.11(B)	5
03241	General License Distribution - 216 RICR-40-20-7.6.12(A)	For luminous aircraft safety devices authorized under 216-RICR-40-20-7.7.3	5
03242	General License Distribution - 216 RICR-40-20-7.6.13(A)	For calibration and reference sources authorized under 216-RICR-40-20-7.7.4(A)	5
03243	General License Distribution - 216 RICR-40-20-7.6.14(A)	For ice detection devices authorized under 216-RICR-40-20-7.7.6	5
03244	General License Distribution - 216 RICR-40-20-7.6.15(A)	For certain *in-vitro* clinical testing kits authorized under 216 RICR-40-20-7.7.7	5
03250	Exempt Distribution – 10 CFR 32.11: Exempt Concentrations and Items	**NRC-ONLY LICENSE TYPE**	N/A
03251	Exempt Distribution - 10 CFR 32.14: Certain Items	**NRC-ONLY LICENSE TYPE**	N/A
03252	Exempt Distribution - 10 CFR 32.17: Resins	**NRC-ONLY LICENSE TYPE**	N/A
03253	Exempt Distribution – 10 CFR 32.18: Small Quantities	**NRC-ONLY LICENSE TYPE**	N/A
03254	Exempt Distribution - 10 CFR 32.22: Self-luminous products	**NRC-ONLY LICENSE TYPE**	N/A
03255	Exempt Distribution. – 10 CFR 10 CFR 32.26: Smoke Detectors	**NRC-ONLY LICENSE TYPE**	N/A
03256	Exempt Distribution - 10 CFR 32.21: Carbon-14 Urea Capsules	**NRC-ONLY LICENSE TYPE**	N/A
03310	Industrial Radiography – Fixed Location	Permanent radiographic installation (PRI) or designated field station. Use as secondary code, except when the license authorizes the PRI *only*.	2
03311	Industrial Diagnostic Systems	A sealed source used for diagnostic scanning at industrial sites	2

Program Code	Category Title	Remarks	Priority Code
03320	Industrial Radiography - Temporary Jobsites	Use as primary code for multiple temporary customer locations	1
03510	Irradiators Self-Shielded ≤ 370 TBq (10,000 curies)	Not external beam	5
03511	Irradiators - Other ≤ 370 TBq (10,000 curies)	Panoramic (in air or under water) units; includes converted teletherapy units	5
03520	Irradiators Self-Shielded > 370 TBq (10,000 curies)	Not external beam	5
03521	Irradiators - Other > 370 TBq (10,000 curies)	Panoramic (in air or under water) units; includes sterilization (mega-curie) units	2
03610	Research and Development Broad - Type A	RSC-approved users under 216-RICR-40-20-7.6.20(B)	3
03611	Research and Development Broad - Type B	RSO-approved users under 216-RICR-40-20-7.6.20(C)	5
03612	Research and Development Broad - Type C	Authorized users specifically named in the license under 216-RICR-40-20-7.6.20(D)	5
03613	Research and Development - Broad -Multisite-Multiregional	**NRC-ONLY LICENSE TYPE**	N/A
03620	Research and Development - Other	Non-human research subjects	5
03710	Civil Defense	Instrument calibration and training	5
03800	Radioactive Material Possession-Only - Permanent Shutdown	Principle activities ceased, license termination request pending; packaging and shipping operations authorized; decontamination and decommissioning not authorized	3
03810	Radioactive Material Standby - No Operations	Principle activities ceased, licensee undecided about terminating the license, packaging and shipping operations authorized, D&D not authorized	3
03900	Decommissioning of Radioactive Material Facilities	D&D may have been authorized according to an approved plan under 10 CFR 30.36	D[11]
11200	Source Material Other < 150 Kilograms	Research or manufacturing of consumer products	5
11210	Source Material Shielding	Possession and use	5
11220	Source Material Military Munitions Indoor Testing	**NRC-ONLY LICENSE TYPE**	N/A
11221	Source Material Military Munitions Outdoor Testing	**NRC-ONLY LICENSE TYPE**	N/A

[11] 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	Category Title	Remarks	Priority Code
11230	Source Material General License Distribution - 10 CFR 40.34	**NRC-ONLY LICENSE TYPE**	N/A
11300	Source Material Other > 150 Kilograms	**NRC-ONLY LICENSE TYPE**	N/A
11700	Rare-Earth Extraction and Processing	**NOT USED IN RHODE ISLAND**	N/A
11800	Source Material Possession Only - Permanent Shutdown	**NOT USED IN RHODE ISLAND**	N/A
11810	Source Material Standby - No Operations	**NOT USED IN RHODE ISLAND**	N/A
11900	Decommissioning of Source Material Facilities	**NOT USED IN RHODE ISLAND**	N/A
21310	Critical Mass Material - University	**NRC-ONLY LICENSE TYPE**	N/A
21320	Critical Mass Material - Other Than Universities	**NRC-ONLY LICENSE TYPE**	N/A
21325	Decommissioning of Critical Mass - Other Than Fuel Fabrication	**NRC-ONLY LICENSE TYPE**	N/A
22110	SNM Plutonium - Unsealed - Less than Critical Mass	**NOT USED IN RHODE ISLAND**	N/A
22111	SNM U-235 and/or U-233 - Unsealed - Less than Critical Mass	**NOT USED IN RHODE ISLAND**	N/A
22120	SNM Plutonium - Sealed Neutron Sources < 200 Grams	**NOT USED IN RHODE ISLAND**	N/A
22130	Power Sources with Radioactive and/or SNM	**NOT USED IN RHODE ISLAND**	N/A
22140	SNM Plutonium - Sealed Sources in Devices	**NOT USED IN RHODE ISLAND**	N/A
22150	SNM Plutonium - Sealed Sources Less than a Critical Mass	**NOT USED IN RHODE ISLAND**	N/A
22151	SNM U-235 and/or U-233 Sealed Sources Less than Critical Mass	**NOT USED IN RHODE ISLAND**	N/A
22160	Pacemaker Radioactive, and/or SNM - Medical Institution	**NOT USED IN RHODE ISLAND**	N/A
22161	Pacemaker Radioactive, and/or SNM - Individual	**NOT USED IN RHODE ISLAND**	N/A

Program Code	Category Title	Remarks	Priority Code
22162	Pacemaker Radioactive and/or SNM - Manufacturing and Distribution	**NOT USED IN RHODE ISLAND**	N/A
22170	SNM General License Distribution – 10 CFR 70.39	**NOT USED IN RHODE ISLAND**	N/A
22200	Decommissioning of Other SNM Facilities - Less than Critical Mass	**NOT USED IN RHODE ISLAND**	N/A
23300	SNM Possession-Only (Non-Fuel) - Permanent Shutdown	**NOT USED IN RHODE ISLAND**	N/A
23310	SNM Standby (Non-Fuel) - No Operations	**NOT USED IN RHODE ISLAND**	N/A

Enclosure 1B - Inspection Priority Codes Assigned to X-Ray Registration Categories

Program Code	Remarks	Priority Code
DEF	Facilities performing diagnostic radiography limited to intra-oral dental procedures and/or extra-oral dental procedures, including panoramic procedures and cephalometric procedures.	4
HRF	Facilities performing general purpose diagnostic radiographic procedures (including fluoroscopy) in an institution licensed by the State of Rhode Island as a hospital.	1
RAD	Facilities performing general purpose diagnostic radiographic procedures (including fluoroscopy) outside of an institution licensed by the State of Rhode Island as a hospital.	1
RTF	Facilities utilizing one or more therapeutic radiation machines, including dedicated therapy simulator(s).	1
SRF	➢ Facilities performing diagnostic radiography (excluding fluoroscopy) limited to a single category of specific radiographic procedures, as specified on the facility's application. ➢ Facilities performing only chiropractic or podiatric procedures. ➢ Facilities utilizing x-ray system(s) solely for human subject research in accordance with Institutional Review Board (IRB) approval.	2
SRM	Facilities performing two (2) or more categories of specific diagnostic radiography procedures (excluding fluoroscopy), as specified on the facility's application.	2
VEF	Facilities performing diagnostic radiography limited to veterinary procedures.	2
IRF	Facilities utilizing X-ray equipment to perform industrial radiographic procedures.	1
IRA	Facilities utilizing a Category A industrial radiation machines as defined in Part 6 of 216-RICR-40-20.	2
IRB	Facilities utilizing a Category B industrial radiation machines as defined in Part 6 of 216-RICR-40-20.	3
OTH	Facilities utilizing X-ray equipment for non-healing arts applications not otherwise defined in 216-RICR-40-20.	3
PAF	Facilities utilizing particle accelerators not authorized for human use.	1

Enclosure 2 – Information for the Nuclear Material Events Database [NMED]

1.0 RCA staff shall forward copies of all documentation regarding a material incident (i.e., "Preliminary Notifications," reports of misadministrations, follow-up inspection reports) to the Supervising Radiological Health Specialist. For documents that are not publicly available, the Supervising Radiological Health Specialist must redact the non-publicly available information from the document in order for the document to be placed into NMED. Only publicly available information can be placed into NMED.

2.0 The NMED Event No. and/or the event notification number must be annotated on each document. The Supervising Radiological Health Specialist 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 sixty (60) days from the date the event is reported. The information identified below must be provided to classify a record as "complete."

3.0 Basic Information:

3.1 **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.

3.2 **Source/Radioactive Material:**

(a) Isotope and activity;

(b) Manufacturer;

(c) Model and serial number;

(d) Leak test results, if applicable

3.3 **Device/Associated Equipment:**

(a) Manufacturer;

(b) Model and serial number;

(c) Description of any equipment problems

4.0 Additional Information Is Required or Specific Event Types Listed Below:

4.1 **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

4.2 **Misadministration (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

4.3 **Overexposure (NMED CODE: EXP):**

(a) Radiation source and activity;

(b) Exposure dose;

(c) Exposure type (whole body, extremity, etc.)

4.4 **Transportation (NMED CODE: TRS):**

(a) Type of transport;

(b) Identity of shipper;

(c) Package type;

(d) ID number, if applicable

Enclosure 3 – Inspection Manual Chapters and Inspection Procedures

DOCUMENT #	IMC/IP DOCUMENT TITLE	CATEGORY
	INCIDENT RESPONSE MATERIALS SAFETY PROGRAM	
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 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	Manufacturer and Distribution (M&D) Security Program (Non-Public)	N
IP 87136	Panoramic and Underwater Irradiator Security Program (Non-Public)	N
IP 87137	10 CFR Part 37 Materials Security Inspections	N
	CONDUCT OF INSPECTIONS	
IMC 0330	Guidance for NRC Review of Licensee Draft Documents	N
IP 40002	Inspections to Review Allegations	N
IP 87250	Locating Missing Materials Licensees	N
IP 93812	Special Inspections	N
	INCIDENT RESPONSE	
IMC 1302	Follow-up Actions and Action Levels for Radiation Exposures Associated with Materials Incidents Involving Members of the Public	N
IMC 1330	Response to Transportation Accidents Involving Radioactive Materials	N
IP 87103	Inspection of Material Licensees Involved in an Incident or Bankruptcy	N
	LOW-LEVEL WASTE/WASTE MANAGEMENT	
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

DOCUMENT #	IMC/IP DOCUMENT TITLE	CATEGORY
	DECOMMISSIONING INSPECTIONS	
IP 83890	Closeout Inspection and Survey	N
IP 87104	Decommissioning Inspection Procedure for Materials Licensees	N
	RADIATION PROTECTION	
IP 83822	Radiation Protection	R
IP 87102	Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)	R
	TRANSPORTATION	
IMC 1330	Response to Transportation Accidents Involving Radioactive Materials	N
IP 86740	Inspection of Transportation Activities	R
IP 86750	Solid Radioactive Waste Management and Transportation of Radioactive Materials	R
IP 81120	Inspection Requirements and Guidance for Additional Security Measures for the Physical Protection in Transit for Radioactive Material Quantities of Concern (Non-Public)	N
	REPORTS/COMMUNICATIONS/FOLLOW-UP	
IMC 0620	Inspection Documents and Records	R
IMC 1120	Preliminary Notifications	N
IP 92701	Follow-up	R
IP 92703	Follow-up of Confirmatory Action Letters or Orders	N