
INSPECTION PROCEDURE 87141

LIMITED SCOPE ACADEMIC AND RESEARCH & DEVELOPMENT PROGRAMS INCLUDING ANIMAL USE

Effective Date: 05/16/2022

PROGRAM APPLICABILITY: IMC 2800

87141-01 INSPECTION OBJECTIVES

- 01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.
- 01.02 To determine if licensed programs are being conducted in accordance with U.S. Nuclear Regulatory Commission (NRC) requirements using a risk-informed, performance-based regulatory approach.

87141-02 INSPECTION REQUIREMENTS

The review of the licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NRC, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records. Additionally, the inspector should use a risk-informed approach to perform the inspection, such as choosing the activities that carry the highest risk to inspect first. This can help ensure that in cases of limited time with the licensee due to varying circumstances, the most risk-significant licensee activities are reviewed for each inspection.

The typical limited scope research and development (R&D) program authorizes a small number of radionuclides for research and development, in unsealed form, and may include in vivo use of radionuclides in animals for research purposes. Separate inspection procedures are available for the typical additional activities such as: self-shielded irradiators and sealed sources and devices (other). Medical and manufacturing activities have separate inspection procedures.

The structure and the emphasis of the inspection should be on the following risk modules that describe the outcomes of an effective limited scope radiation protection program for use of unsealed materials. Risk modules (RMs) are defined as program areas that present higher risk, or expected to effectively reduce risk, to health, safety, and security that are identified in each inspection procedure in order to focus inspection effort on these particular program areas. To consider an inspection complete, the inspector should review applicable RMs based on ongoing activities at the time of the inspection. The RMs that carry the highest risk components should always be completed to the best of the inspector's ability. Additional inspection elements that carry less risk can be found in Appendix A to this inspection procedure. These additional

elements are not required to be reviewed as part of a risk-informed inspection approach, but may be reviewed if the inspector has additional time, if the additional elements are related to safety issues identified in the RMs, or if multiple violations were identified through review of the following RMs.

02.01 RM-1: Observation of Activities

The inspector should observe a representative sample of the range of licensed activities that may be ongoing during the inspection, with emphasis on those of higher risk. This should include activities that span from ordering licensed materials, through the disposal or transfer of licensed materials.

02.02 RM-2: Assessment of Dose to Workers and the Public

The inspector should review the results of dose assessment for all activities under the license for which monitoring of radiation workers is required. Particular attention should be paid to verifying assessments of internal dose, if applicable, to ensure that appropriate procedures are implemented and results are accurate. The inspector should also review results of assessments of public dose due to use of licensed materials and releases of effluents.

02.03 RM-3: Surveys for Contamination and Exposure Control

The inspector should observe licensee radiation workers perform surveys for contamination and exposure to ensure that 1) the licensee has the necessary variety and availability of instrumentation needed to perform surveys of the range of radioactive materials authorized on the license, and 2) the licensee staff performs adequate surveys. Surveys may be performed using fixed or portable radiation survey instruments and monitors; equipment for sample collection; and instrumentation for analyses of samples.

02.04 RM-4: Inspection of Animal Research with Radionuclides

The inspector should inspect areas where licensed materials are used in animals to ensure that potential exposure pathways from use in animals are appropriately monitored. The inspector should observe and discuss radiation safety practices performed by animal handlers, which includes researchers, animal care staff, and those handling animal carcasses and wastes.

02.05 RM-5: Safety and Security of Licensed Materials

The inspector should observe a representative sample of facilities to determine if licensed materials are appropriately attended when in use or secured when in storage. The inspector should observe if licensed materials are used or stored in the vicinity of other hazards or hazardous materials which could increase the risk of release of licensed materials. The inspector should verify that the licensee has adequate inventory controls in place to ensure that all licensed materials are accounted for.

02.06 RM-6: Management Oversight

The Radiation Safety Officer (RSO) of most limited scope R&D licenses is usually an ancillary duty for a research scientist, or an industrial hygienist in the safety office, who

require the support of upper management for resources and implementation of the radiation protection program. The inspector should inspect the effectiveness of the management of the limited scope R&D radiation protection program, and the communication between the RSO and management.

87141-03 INSPECTION GUIDANCE

General Guidance

The following inspection guidance is designed to assist the inspector in evaluating the performance of the licensee's radiation safety program. The guidance is organized by the individual risk modules described above; however, this does not mean that the risk modules should be reviewed in this specific order. Instead, the inspector should use a risk-informed approach to decide which of the risk modules to inspect first. This is likely going to be predicated upon what licensed activities are ongoing when the inspector arrives at the licensed facility. Furthermore, inspectors should not feel constrained by the guidance in this procedure. If an inspector obtains information that indicates that a problem may exist in an area within the NRC's jurisdiction that is not specifically addressed in this procedure, the inspector should redirect, or otherwise expend, inspection effort to address that problem.

An examination of the licensee's records should not be considered the primary part of the inspection program. Rather, observations of activities in progress, equipment, facilities and use areas, etc., will be a better indicator of the licensee's overall radiation safety program than a review of records alone.

Inspectors should be aware that some information, such as dose to workers, can be reviewed only through records. All inspections require some review of records which supplement the direct observations and discussions.

- Priority should be given to examination of records that are closely related to health and safety, such as personnel dose-monitoring records, incident reports, and surveys. Look for trends such as increasing doses or releases; look for unusual doses or survey results; and look for licensee identification of issues and resulting corrective actions taken.
- Other records that support the radiation protection program, such as receipt and transfer of licensed materials, inventory, leak tests, calibration of analytical or portable instruments used to make quantitative measurements, training, audits and radiation protection program reviews, may be reviewed by random sampling and cross-checking until the inspector is satisfied that the records are being maintained and are correct. The inspector may examine records more thoroughly if necessary to determine the extent of a suspected problem.

Common elements to all inspections include entrance and exit meetings with appropriate licensee management, including the radiation safety officer (RSO), observations of facilities and work in progress, independent confirmatory surveys, and the evaluation of program scope and any special license conditions. Specific guidance regarding these common elements can be found in IMC 2800.

Each of the following elements should be reviewed, as appropriate, during each inspection of a limited scope R&D license using unsealed materials, including in animal research.

Specific Guidance

03.01 RM-1: Observation of Activities

The primary inspection activity for unsealed materials should be the observation of activities in progress. Observation begins as soon as the inspector arrives at the site. Academic institutions may have multiple entrances to the campus(es), but most limited scope facilities have use of material in a single building. The inspector should be alert for postings or other indications that licensed materials may be in use as the inspector walks through the facility to meet with the RSO.

Most limited scope licenses authorize the common beta-emitting radionuclides C-14, H-3, P-32, P-33 and S-35. Some may use I-125 and I-131, or gamma-emitting radionuclides more typically associated with medical applications, such as Tc-99m and F-18. In vivo use of licensed materials in animals may be performed. Although specifically-licensed, small sealed sources and devices may be used at a limited scope R&D license, these licensees typically possess sources in liquid scintillation counters that are under a general license which should be reviewed (see IP 87142). A few limited scope R&D programs may release effluents, may process their own radioactive wastes, and may be authorized for additional activities that are described in other inspection procedures.

Note: The inspector should be aware that licensed materials used at limited scope R&D programs may be used with, or in the vicinity of: biological hazards such as viruses, microbes, nanoparticles, etc.; chemical hazards such as strong acids or bases and compounds that may be skin or lung irritants or otherwise harmful; other ionizing radiation hazards such as state-regulated radionuclides and x-ray producing devices; non-ionizing radiation hazards such as lasers; physical hazards such as high-voltage equipment, sharps (needles, scalpels, etc) and other industrial hazards. The inspector should follow the licensee's safety requirements in all areas.

Some areas may require special training prior to entry, and the inspector should be prepared to take the training or to conduct the inspection through alternate means. In rare instances, due to the nature of the associated hazards, the inspector may be prohibited from entry and must conduct the inspection through alternate means than direct, in-person observation. In addition, there are areas in some government agency facilities that may require a specific security clearance for entry, but this should be known prior to the inspection and appropriate means of inspection planned.

The inspector should have an initial plan of the activities to be observed, but this plan may change as a result of new information gathered at the entrance meeting about actual activities that are expected to occur during the time of the inspection. The activities to be observed should be selected based on the types, forms and quantities of materials being used; 2) the activities being performed; and 3) the size of the program. See Appendix B.

The inspector should visit a reasonable number of facilities where licensed materials are used and stored [R&D laboratories, waste treatment and storage areas, analytical laboratories, animal housing facilities, receiving and shipping areas, etc.]. Sampling should be risk-informed by the type of activity and the number of facilities performing that

activity. If the inspector identifies a suspected problem, the sample size may be increased to determine the scope of the problem.

During any walk through the licensee's facilities, the inspector should

- Keep the inspector's survey meter on (but with the audible response turned off if walking through public areas where persons unfamiliar with radiation detection may become concerned) and observe if radiation levels are as expected. If unusual or unexpected radiation levels are detected, discuss them with the RSO and staff.
- Conduct surveys and make comparative measurements with licensee staff where appropriate.
- Observe if facilities for use and storage of licensed materials are appropriately secured or attended, and if postings are appropriate.
- Observe radiation workers using licensed materials. If there is no use at the time of the inspection, a demonstration of selected activities may be requested. Watch for use of appropriate protective equipment, dosimetry, survey and monitoring techniques.
- Interview licensee radiation workers, and selected ancillary persons working in the vicinity of licensed materials. Ask questions to determine their understanding of radiation safety practices applicable to their tasks.
- Watch for radiological postings on doors or equipment other than your destination. If the reason for the posting is not apparent, ask about it in order to determine if additional inspection should be done.
- Be aware that some records of interest will be maintained in laboratories and other work areas and may be reviewed while at those locations. Typical records in work areas are:
 - "Use logs" for specialized facilities such as hot cells or hot labs;
 - Postings of maintenance checks of the flow rate and operation of hoods or other air handling systems;
 - Inventory of stock vial material from receipt to disposal;
 - Room surveys by laboratory staff;
 - Calibration stickers on survey instruments;
 - Calibration records of analytical instruments;
 - Waste processing records;
 - Sewer disposal records; and
 - Decay-in-storage records.

03.02 RM-2: Assessment of Dose to Workers and the Public

The typical limited scope R&D program activities result in doses less than 10 percent of limits for workers. However, some specialized activities, as well as incidents or events, have the potential to cause doses that require monitoring. Inspectors should review dose assessments for radiation workers required to be monitored, or in response to any events. This may be done anytime during the inspection and will require review of records and interviews. If worker doses are not required to be monitored, and public

doses are not likely to be exceeded, this Risk Module may be considered as Supplemental Information. [Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1302, 10 CFR 20.1502]

- External radiation and contamination monitoring:
 - During the inspection, observe how radiation workers use the dosimeters and where they are stored. If applicable, observe staff performing contamination monitoring of themselves and their work area. [10 CFR 20, Subparts C, D, F, G, and J]
 - Review records of external monitoring results with year-end totals for the past 3 years, and a sampling of records from dosimetry wear periods throughout the most recent year. Look for unusual or unexpected doses; missing dosimeters in various wear periods; and actual frequency of exchange. Interview staff to determine what follow-up activities were performed. [10 CFR 19.13, 10 CFR 20.2106]

Inspectors have identified some licensees who ignore lost dosimeters and do not account for dose to the worker for that wear period; unusual doses due to incorrect storage of the dosimeter, which then requires adjustment of the dose record of the individual; and use of dosimeters incorrectly by radiation workers (dosimeter not worn; finger rings worn on wrong hand; dosimeters stored near radiation sources; spare dosimeters used by multiple persons; etc.) Inspectors have identified staff performing poor or incorrect contamination surveys.

- Internal Monitoring (if applicable)
 - During the inspection, observe any equipment for internal monitoring, such as thyroid monitoring systems, personal air samplers, and, if applicable, whole body counters. Observe persons being scanned or demonstration of scans. [10 CFR 20, Subparts C, D, F, G, and J]
 - Review internal monitoring results for the past 3 years, and a sampling of individual internal dose assessments performed. This includes direct bioassay such as whole-body counting or thyroid assay; samples collected from individuals (urine, blood, etc.); and indirect assessments such as breathing zone air samples. Look for unusual or unexpected doses and interview staff to determine what follow-up activities were performed. Discuss the method(s) of internal dose sample collection used and interview staff about sample collection, handling, data collection, instrumentation used and its calibration, and any software or hand-calculations used to convert results of samples to dose.

Note: If respiratory protection is used, you will need to review their program to meet 10 CFR Part 20, Subpart H requirements.

Inspectors have identified poor or incorrect bioassay samples collected; analytical methods not sensitive to the types and quantities of radioactive materials in the sample; lack of calibrated equipment; use of software that does not contain the relevant radionuclides; use of the wrong radionuclide Class [D, W, Y] because the chemical form and biological pathway of the radionuclide was not considered.

- If the licensee believes that monitoring is not required, review the licensee's basis for that decision and verify the data and assumptions they used for the determination. Note that some licensees will monitor radiation workers even if monitoring is not required by regulation. If they do perform monitoring, observe if workers are using and storing dosimeters correctly and review a sampling of dosimetry records.
- Limited scope R&D licenses handling unsealed licensed materials are not likely to have impact on public dose unless they release air effluents. If the licensee is required to monitor effluent air, review their results for the past 3 years. Interview staff about their methods for sampling or assessment of releases to determine if data and assumptions are reasonable for the program; review the calibration of any monitoring equipment that affect the dose assessment; and their use of the software to convert sample results to dose. See Appendix A. [10 CFR 20.1101(d), 10 CFR 20.1301, 10 CFR 20.1302]

Inspectors have identified licensees with problems such as non-working air samplers or air monitoring equipment; uncalibrated air samplers and rotameters; incorrect factors in the input data for software; and sample analysis not sensitive for the types and quantities of licensed materials used.

- Interview licensee staff members to determine if any incidents or events occurred since the last inspection. Through interviews and review of records, determine if the incidents or events involved exposure to workers or to members of the public. Through interviews and records review, determine if the licensee took prompt and effective corrective actions, and performed sufficient investigation to assess doses, identify the cause, and prevent recurrence. The inspector should determine if any of the events required notification and, if so, confirm if required reports were made (see RM-6). [10 CFR 20.2103, 2106, 2107, 2201, 2202, 2203; 10 CFR 30.50, 10 CFR 30.52]

Inspectors have identified events with unsealed materials, such as a spill, which was cleaned up but not assessed to determine if any workers had skin contamination, external or internal exposures.

03.03 RM-3: Surveys for Contamination and Exposure Control

At a typical limited scope R&D license, surveys may be performed by authorized users and workers under their supervision. Persons performing surveys should be observed doing surveys or demonstrating surveys. The level of detail of observations, discussions and review of records of surveys and the instrumentation used will depend on the types, forms, and quantities of licensed materials actually used since the last inspection as well as the level of sensitivity necessary for the surveys. [10 CFR 20.1501]

- Observe licensee staff perform (or demonstrate) surveys for contamination control, and if applicable, area radiation levels.
 - Observe and discuss their method of assessing removable contamination and analyzing the samples. Observe if appropriate fixed instrumentation, typically liquid scintillation counters or gamma counters, alpha/beta counters, is available for sample analysis. Discuss with licensee staff how fixed instrumentation is calibrated, with particular attention to instrumentation used to analyze samples to

meet regulatory requirements, such as measurement of removable contamination for release for unrestricted use or transportation, bioassay samples, etc. Additional information for the inspection of sample analyses and associated analytical instrumentation may be found in IP 87126.

- Observe if appropriate portable instruments (such as a meter with a Geiger-Müller (GM) or LEG detector, or ion chamber or microR meter) are readily available and operable. Observe if staff use instrumentation properly, and discuss if the instrumentation is used for qualitative (detection) or quantitative (measurement) purposes. Perform comparative measurements with portable instruments to determine if instruments are operating correctly. Discuss the licensee's action levels and procedures if they are exceeded. Additional information for the inspection of licensees who perform their own instrument calibration may be found in IP 87143.
- Review a sample of survey records to evaluate the typical levels of contamination, how often action levels are exceeded, and the licensee's response to exceeding action levels. [10 CFR 20.2103]

Inspectors have identified licensee staff using inoperable instruments; using the wrong scale or misreading the scale; performing surveys too quickly or at too great a distance from surfaces, or touching surfaces with the probe; using instruments or performing analyses not sensitive to, or not calibrated for, the radionuclides being used. Inspectors have identified inappropriate equipment, such as using a GM detector for surveys of tritium surface contamination (this also applies to other low energy beta and alpha emitters that cannot be detected in very small quantities); inoperable equipment with no batteries or corroded batteries in the survey meter; uncalibrated equipment used for measurements; measurements made that do not meet required minimum sensitivity; calibrations performed improperly; incorrect factors provided in software resulting in incorrect results.

- Observe the licensee's sampling and monitoring equipment for release of effluent air or water, and/or releases to the public sanitary sewerage system.
 - The inspector should examine air flow patterns and building air intakes and release points to understand the potential for spreading contamination and the need to monitor release pathways.
 - The inspector should observe and discuss with licensee staff the selection of monitoring locations, selection of monitoring equipment, and use of the equipment. Discuss the sample collection methods used, or if an evaluation is performed by calculation.

Inspectors have identified licensee staff unfamiliar with the operation of sampling equipment; equipment not operating correctly; unmonitored effluent release points; use of equipment not sensitive to the radionuclides being analyzed; and errors in data entry, assumptions and calculations.

- For activities with licensed materials that take place on bench top areas, observe the availability of remote handling equipment and portable shielding, and observe licensee staff use or demonstrate how such equipment is used. Observe availability and other equipment that can become contaminated or a source of

contamination through work with licensed materials [centrifuges, refrigerators and freezers, incubators, vacuum systems, trays, and carts, micropipettors, beakers and flasks, gel plates, marking pens, etc.] to determine how licensee staff manage contamination control of such equipment. Confirm, by discussion and review of selected records, the typical contamination levels and release of such equipment for use in laboratories that are not handling licensed materials.

Inspectors have identified contaminated equipment with measurable radiation levels in laboratories where licensed materials were not being used; workers handling stock vials by hand instead of using shielded containers or remote handlers, resulting in extremity doses; and contamination in public hallways from carrying liquids in containers that were leaking or spilled in transit.

- Facilities for Waste Storage, Treatment, and/or Disposal
 - Observe licensee staff perform or demonstrate waste treatment and/or disposal activities such as compacting, disposal of soluble materials to the sanitary sewerage system, decay-in-storage, etc. The type and extent of process and engineering controls will depend on the type of waste treatment. Observe and discuss contamination control and radiation monitoring for each different type of treatment. Confirm by discussion and review of selected records how frequently waste treatment and disposal activities occur; the quantities of licensed materials disposed of; and the typical contamination and radiation levels in the areas where waste disposal treatment and disposal occur. [10 CFR 20.2001-2008]
 - Observe locations of waste storage. Interim waste storage areas may be designated in each laboratory or other area where licensed materials are used or stored. Some limited scope R&D programs designate common waste storage areas for later transfer to a centralized waste facility at the site. Confirm by observation and discussion how waste materials are transferred to the storage locations. Confirm by observation, discussion and review of selected records, how waste storage areas are secured, and how they are monitored for radiation levels and contamination controls. Confirm by observation and discussion how waste streams and waste forms (long-lived, decay-in-storage; solids, liquids; radioactive, chemical, mixed) are identified and controlled to prevent release, and protected from other hazards (such as weather, fire, chemical interactions).

Inspectors have identified licensees who did not account for potential airborne and/or particulate contamination from crushing and compacting activities, resulting in uptakes and spread of contamination. Inspectors have observed decay-in-storage surveys performed with inappropriate instruments and performed in areas of elevated background. Inspectors have found measurable radiation levels in waste containers marked as only holding tritium and carbon-14. Inspectors have identified waste storage areas located in outside areas without protection from weather; which contained both hazardous wastes and radioactive wastes with no clear distinction; and other problems.

03.04 RM-4: Inspection of Animal Use of Radionuclides

Licensed materials may be used in animal studies for a variety of purposes. Some compounds may be labelled with radioactive materials in order to study the biological pathway of the compound in the animal; radioactive compounds proposed for possible

medical use may be tested in animals; and studies of effects of radiation and radioactive compounds may be studied in animals. Animal studies typically are typically performed in mice, rats, rabbits and other small mammals. Inspectors have observed animal studies with other species such as primates, horses, pigs and dogs, and other large mammals; fish and other aquatic species; and insects.

If multiple different studies with animals are performed, the inspector should gather information to determine if the animal studies are performed with different materials and/or by different persons, in order to determine if all such facilities should be inspected or if a sample is sufficient.

- Given the potential for novel approaches to be used in academic and R&D programs, the inspector should interview researchers to understand how the material is administered to the animal and the biological path of the radionuclide (excreted through urine, feces, or breath; retained in bone or specific tissues; etc.) in order to understand where and how licensee staff could be exposed to licensed materials while handling animals. Exposure to licensed materials may be through animal wastes, including bedding; animal breathing; animal carcasses or tissue samples; and radiation emitted from animals. The inspector should, if possible, observe animal handling by researchers and animal caretakers to ensure that workers are implementing good radiation safety practices while handling animals. If observation is not possible, then demonstration is acceptable. Most animals are administered licensed materials by injection, although there are other methods. Animals are handled in order to obtain blood or other samples; scanned for identification of uptake of gamma emitters; and operated on after administration or dissection after sacrifice of the animal.

Inspectors have identified researchers handling animals directly, resulting in excess exposure of extremities. Inspectors have reviewed dose assessments necessary as the results of "needle stick" to the researcher caused by an uncooperative animal.

- The inspector should observe animal housing, use and waste areas for adequate radiation protection and contamination controls appropriate to the types of radionuclides and the labelled compound used, to determine if the radioactive material is appropriately monitored or controlled. The inspector should ensure that appropriate shielding (including syringe shields, if applicable), absorbent materials, personal protective equipment, etc. is available to staff handling animals with licensed materials.

Inspectors have observed that some researchers are unaware of the availability of syringe shields for gamma emitters. Inspectors have identified inadequate shielding in animal housing facilities when staff, who usually work with low energy beta emitters, begin to work with gamma emitters.

- The inspector should observe or have demonstrated, surveys or evaluations performed of animal housing, use and waste areas, with particular attention used for surveys of animal cages and other equipment released for unrestricted use. The inspector should determine if effluent releases containing licensed materials from animal use are monitored, and if assessments of public dose may be required. (Note: fish studies often result in effluent releases.)

Inspectors have identified unmonitored contamination in animal housing areas when poor surveys were performed. Inspectors have identified licensees who did not account for sewer releases of long-lived radionuclides. Inspectors have identified inadequate surveys of waste held for decay in storage.

- The inspector should observe, or have demonstrated, surveys or evaluations performed for the release of the animal for unrestricted use, if animals are returned to the vivarium animal population after laboratory testing. Although this is not typical, it does occur mainly when very short-lived radionuclides are used for studies that do not require sacrifice of the animals. Animals released for unrestricted use must meet the public dose criteria. [10 CFR 20.1301, 10 CFR 20.1302]

Inspectors have identified facilities performing studies of proposed medical compounds who were not familiar with the requirement to meet public dose limits when releasing animals for unrestricted use.

03.05 RM-5: Safety and Security of Licensed Materials

- During the inspection of a limited scope R&D license, the inspector should observe licensee oversight of licensed materials safety and security and discuss identification and corrective actions for material the licensee identified as not appropriately secured from access by the public. The inspector should observe how the radiation workers maintain security of licensed material at the various locations where licensed materials are used and stored. The inspector should discuss licensee practices to protect public access to licensed materials. [10 CFR 20.1801, 10 CFR 20.1802]

At limited scope R&D facilities, inspectors commonly observe licensed materials stored in lock boxes in refrigerators and freezers; locked refrigerators, freezers, storage closets; locked laboratories or storage rooms, etc. Inspectors commonly observe material in use attended by licensee staff, which is acceptable. Inspectors have identified unattended licensed material when staff left the room for some reason; unlocked doors or doors propped open where materials are used or stored and unattended; and doors without handles and locking mechanisms.

- During the inspection of laboratories and other areas where licensed materials are used or stored, the inspector should observe if other hazards are present in that could affect the safety and security of licensed materials. At limited scope facilities where unsealed materials are used, inspectors commonly observe use and storage of hazardous chemicals that could interact with radioactive compounds to cause physical, chemical and biological hazards; equipment with high-voltage and other industrial hazards that could create fire safety concerns; crowded work areas with trip hazards, and other general safety concerns. The inspector should discuss such safety and security concerns with licensee staff if it appears that safe use and storage of licensed materials would be compromised by other hazards.
- During the inspection, the inspector should review and discuss, with the RSO and authorized users at a limited scope R&D program, the licensee's procedures for tracking unsealed licensed materials received, used, stored, and transferred or disposed.

- Inspectors commonly observe that unsealed materials are received in liquid form in a vial from which aliquots are used as needed, which requires different inventory procedures than those typically used for inventory of sealed sources and devices. Inspectors commonly observe unsealed inventory procedures that require tracking of materials by staff in individual laboratories, reported to radiation safety staff who oversee inventory for all the licensed materials. Inspectors should confirm that the total inventory includes both unsealed and sealed materials.
- Inspectors should request a current inventory that demonstrates that licensed quantities actually possessed (in use, storage and waste) are within the license limits. Inspectors may review selected records of receipt, inventory, transfer and disposal to determine the typical types and quantities of licensed materials used, and to identify unusual types or quantities that may merit additional inspection. Inspectors should determine if the licensee also tracks the inventory of materials possessed under a general license.
- If the licensee transfers and ships licensed materials to other sites or other licensees, the inspectors should review applicable transfer requirements in 10 CFR, and packaging and shipping requirements under the Department of Transportation. See Inspection Procedure 86740.

Inspectors have identified licensees who did not include radioactive wastes in the inventory of licensed materials. Inspectors have found incomplete or incorrect transfer and shipping procedures, usually because these licensees do not perform these activities often enough to understand all requirements. Inspectors have identified missing sealed sources, and sealed sources not in the location listed in the licensee's inventory. Inspectors have found licensees unaware of materials possessed under a general license.

- During the inspection the inspector should observe if postings of areas are available and appropriate to the radiological hazard. Inspectors at these facilities most commonly observe "Caution – Radioactive Materials" postings as well as the NRC Form 3. Inspectors have identified, usually at small facilities where radiation safety activities are an ancillary duty for a licensee researcher or other staff member, postings of "Caution- Radiation Area" signs although no radiation area exists. Although this does not seem significant, first responders who are trained to observe postings may respond to emergencies inappropriately if the posting is incorrect. [10 CFR 20.1901-1906]

03.06 RM-6: Management Oversight

A typical limited scope R&D program using unsealed materials is required to have an RSO that performs activities as required by the license commitments. Important activities include developing and implementing the radiation safety procedures; responding to events with licensed materials; and reviewing the radiation protection program to ensure it is effective and to identify areas where improvement is needed.

- The inspector should interview licensee staff, including management representatives, to understand:

- the licensee's organization and management of the persons who implement the radiation protection program and the persons who use and store licensed materials;
 - the level of involvement of licensee management in oversight of the radiation protection program;
 - the relationship and authority between the RSO, and the authorized users, and licensee management; and
 - how the RSO ensures that the inventory of licensed materials meet the license limits.
- The inspector should interview the RSO and other licensee staff to determine if the RSO is conducting oversight activities as required license commitments. The inspector should determine if the RSO seeks out areas for improvement; responds to events; takes corrective and preventive actions; and implements improvements.
 - The inspector should read all the annual radiation program reviews for at least the past 3 years, and discuss the activities by the licensee staff that support the annual review of the radiation protection program. The inspector should review other licensee actions to identify problems, take corrective actions, and implement preventive measures. The inspector may review selected records of these activities.
 - The inspector should review the records of incidents and events since the last inspection. The inspector should determine if any of the incidents and events were reportable or could have resulted in doses in excess of limits to workers or the public. If so, the inspector should review the licensee's dose assessments to determine adequacy. Inspectors have identified licensees who do not perform correct or adequate bioassay sampling and measurement, and therefore did not identify adequately assess dose. Inspectors have identified licensees who were unaware of various reporting requirements and did not report required events.

87141-04 RESOURCE ESTIMATE

The length of time necessary for completing this inspection will depend on three major factors:

1. The quantities and forms of licensed materials authorized on the license;
2. The range of activities authorized on the license to be performed, along with the range of activities able to be observed during the onsite inspection; and
3. The scope of the licensed program, including the number of locations (buildings or laboratories); the number of radiation workers under the supervision of the authorized users named on the license; and the frequency of activities performed with licensed materials.

A typical limited scope R&D inspection may take a single inspector 4 to 8 hours to complete the inspection.

87141-05 REFERENCES

A listing of IMCs and IPs, applicable to the inspection program for materials licensees, can be found in IMC 2800. 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.

END

Appendixes:

Appendix A: Additional Inspection Elements

Appendix B: Considerations for Selecting Activities to be Observed

Attachment:

Attachment 1: Revision History for IP 87141

Appendix A: Additional Inspection Elements

87141A-01 PURPOSE

The guidance in this Appendix is intended to supplement inspection requirements and associated guidance provided in this procedure. The additional inspection guidance provided herein may be used as time allows or to assist in completing a rounded performance-based inspection.

87141A-02 BACKGROUND

Risk modules are defined as program areas that present higher risk, or expected to effectively reduce risk, to health, safety, and security that are identified in each inspection procedure in order to focus inspection effort on these particular program areas. The risk profile for each licensed program could be different and some programs may need more in-depth review. Therefore, the additional inspection elements included herein may be used to expand the scope inspection effort and/or supplement the risk modules in this procedure.

87141A-03 GUIDANCE

03.01 Facility Security

- a. Through direct observation, determine that all entrances to licensee facilities are normally closed, locked or otherwise secured to prevent unauthorized entry. This should include main facility gates, main building entrances, doors to waste storage facilities, etc.
 - Through observations, verify that use and storage areas are locked and have limited and controlled access. At a minimum, radioactive material use areas should be under constant surveillance during normal business hours when licensee personnel are present or physically secured against unauthorized access. Storage areas should be physically secured when unattended.
 - Evaluate licensee practices regarding access controls including control of keys and access codes to ensure only currently authorized individuals have access to licensed materials.
 - Ensure licensee practices include testing of interlock systems, as applicable. (such as for hot cells)

If the inspector finds any entrance or area to be unsecured, the inspector should determine, through questioning of licensee staff, the reason for the area or entrance being unsecured. The inspector should determine if the licensee failed to follow established procedures in securing the area or if additional training of staff is needed. The inspector should determine if the licensee's facility is configured to separate working areas from unrestricted areas.

03.02 Receipt and Transfer of Licensed Materials

- a. Through observations and interviews of licensee personnel, verify that the licensee: 1) properly secures package receipt areas, such as loading docks or other shipping and

receiving areas; 2) inspects packages for damage; 3) performs appropriate package receipt surveys; 4) opens packages in a safe manner; 5) assures that packages are properly prepared for transport; and 6) controls packages in a secure manner prior to pickup by courier personnel or transport by licensee personnel. If the inspector is unable to observe the receipt of packages, the inspector should request that personnel who normally receive packages for the licensee demonstrate package receipt processes and surveys.

1. If packages are left unattended, the inspector should assess the licensee's receipt procedures, including instructions provided to couriers, to assure that packages are being delivered to the appropriate location(s).
 2. If surveys of packages (whether during receipt or preparation for shipment) are not adequate to verify that radiation and contamination levels are within regulatory limits, the inspector should interview licensee staff and the RSO further to assess worker knowledge. Deficiencies regarding instrumentation should be reviewed in more depth.
- b. Through interviews of licensee personnel and review of selected transfer documentation, verify that the licensee has an adequate method of determining that recipients of radioactive shipments are licensed to receive the forms and quantities of such materials.

03.03 Comprehensive Safety Measures

The inspector should be attentive to potential industrial safety hazards, for referral to the U.S. Department of Labor's Occupational Safety and Health Administration (see Manual Chapter 1007). The focus should be on potential non-radiological hazards personally observed or brought to the inspector's attention by licensee staff.

- a. Operational Limits. Through observation, discussions with licensee staff and review of product specification information, verify that the licensee operates process equipment within the equipment manufacturers or industry consensus operational limits. Such limits may include temperature, humidity, vibration, or radiological considerations. In addition, such equipment may be subject to periodic preventative maintenance requirements/recommendations. If so, verify that such maintenance is performed.
- b. Industrial/Chemical Hazards. Verify that the licensee controls the use/storage of hazardous (corrosive or combustible) chemicals near process equipment which could degrade their performance or render safety features inoperable. If the licensee is required to implement an emergency plan, verify that the plan includes these hazards, as appropriate, as initiating events.

Fire Protection. In many cases, the risk posed to radiological safety by fires is comparable to or exceeds the risk from other events involving licensed activities. During the course of inspection of the licensee facilities, the inspector should be alert to potential fire hazards. An effective licensee fire protection program should (1) prevent fires from starting, (2) rapidly detect, control, and extinguish those fires that do occur, and (3) provide protection for structures, systems, and components important to safety so that a fire that is not promptly extinguished by fire suppression activities will not prevent the licensee from taking actions to safely control licensed material and prevent the spread of contamination and unnecessary exposures to workers or the public.

Through observation and discussion with the licensee, while touring the facilities, assess firesafe conditions and equipment, i.e., that: (1) work areas are generally uncluttered and free of combustible debris, (2) incompatible materials (i.e., materials labeled as “corrosive”, “flammable”, or “oxidizer”) are isolated from each other and enclosed by fire resistant barriers, (3) fire detection systems are operable, (4) fire suppression systems are operable, (5) portable fire extinguishers are unexpired (check maintenance tags), (6) electric switches and electric motors are explosion-proof, arc welders or open flames are administratively controlled in work areas that also contain flammable or combustible liquids or gases or highly reactive chemicals, and that (7) the local fire department is involved with the licensee’s fire protection program.

Problems/deficiencies noted by the inspector should be promptly brought to the licensee’s attention and discussed with Regional management. Additional guidance for reporting fire protection concerns can be found in IMC 1007 “Interfacing Activities Between Regional Offices of NRC and OSHA.”

- c. Natural Hazards. Depending on the licensee’s geographic location, it could be susceptible to natural hazards, such as tornadoes, flooding, and earthquakes. Verify that those licensee’s have considered the impact of such hazards in the design and modification of areas critical to safety; the selection and location of facilities for the storage of large quantities of radioactive materials, including radioactive waste storage facilities; and in the development of emergency procedures and contingency plans, when applicable.

03.04 Transportation

Verify that the licensee's procedures and documentation are sufficient to ensure that licensed material is packaged and transported (or offered for transport) in accordance with 10 CFR Part 71 and U. S. Department of Transportation (DOT) regulations for transportation of radioactive materials.

- Observe the preparation of radioactive materials for shipment. Verify that the proper packaging is used for the type of materials/devices shipped. Verify that the licensee properly marks and labels packages in accordance with DOT requirements. Verify that the licensee performs appropriate examinations to confirm that package radiation and contamination levels are within applicable DOT limits prior to offering them for transport. Verify that proper shipping papers are prepared for each package/shipment and that, if necessary, the licensee maintains and offers appropriate placards to common carriers. Examine any incidents that were required to be reported to the DOT.
- If the licensee tests and certifies its own DOT Type A packaging materials, review test procedures and required certification documentation for selected packages. Verify that the packaging materials are used in the same or similar configurations as in their certification testing.
- Verify that any DOT Type B containers are used in accordance with their Certificates of Compliance (COCs) issued by the NRC. The licensee must maintain copies of the COCs for the packages that it has used and ensure that it follows the instructions and limitations of the COCs when preparing the packages for shipment.

For further inspection guidance refer to IP 86740, "Inspection of Transportation Activities." Inspectors should also refer to "[Hazard Communications for Class 7 \(Radioactive\) Materials](#)." These field reference charts, related to hazard communications for transportation of radioactive materials, are useful field references for determining compliance with the transportation rules on labeling, placarding, shipping papers, and package markings. They also contain references to the DOT regulatory requirements.

03.05 Waste Management

- a. Waste Storage and Disposal. Verify that the waste is protected from fire and the elements, that package integrity is adequately maintained, that the storage area is properly ventilated, and that adequate controls are in effect to minimize the risk from other hazardous materials. Verify that the licensee has appropriate methods to track the items in storage.

Inspection effort should be directed at verifying that written procedures have been established in a manner approved by management. The procedures should be readily available to any persons having responsibility for low-level waste classification and preparation for transfer of such wastes to land disposal facilities.

Verify that storage for decay is not causing elevated radiation doses to waste processing workers. If applicable, confirm that the resident time of waste at the facility does not exceed the time limit authorized in the license. For licensees who have implemented an interim waste storage program, verify that the program is consistent with the license. For further guidance on interim waste storage, see Information Notice 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees."

Examine monitoring systems. Review and evaluate a sample of the procedures and other administrative and physical controls for the release and disposal of radioactive waste.

The inspector should determine whether radioactive material labels have been removed or defaced from discarded materials, being careful to not endanger him or herself to biological, chemical, or physically hazardous waste (e.g., sharp objects). Ensure that wastes prepared for shipment to a disposal site comply with applicable standards and regulations regarding chemical and physical form, stability, type of container, and labeling. Also ensure that the licensee implements an adequate QC program as required by Appendix F of 10 CFR Part 20 to ensure compliance with applicable regulations.

For further inspection guidance, refer to IP 84850, "Radioactive Waste Management-Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61."

- b. Effluents. Examine the waste release records generated since the last inspection, all annual or semiannual reports, all pertinent non-routine event reports, and a random selection of liquid and airborne waste release records. Review selected procedures for both liquid and airborne systems and verify that the licensee's procedures are being followed. The verification can be made by observations of an operation, a review of selected records, interviews with workers, etc.

For liquid wastes, determine if the licensee has: identified all sources of liquid waste; evaluated treatment methods to minimize concentrations (such as the use of retention tanks); and complied with the regulatory requirements for disposal in the publicly-owned sanitary sewerage system. If the licensee disposes of liquid wastes to surface waters, ground waters, or a private sanitary sewerage treatment system, determine whether the licensee is in compliance with the regulations and all applicable license restrictions.

For airborne radioactivity, determine if the licensee has identified all routes of airborne releases to the environment and complies with the regulations and all applicable license restrictions. For a licensee authorized to dispose of radioactive material by incineration, determine compliance with 10 CFR 20.2004 and license requirements, and discuss with the licensee its methods for evaluating concentrations in the ash.

Determine compliance with license conditions relating to environmental monitoring. If applicable, observe sampling stations and equipment for adequacy. Review a sample of procedures, records, and reports to verify that the licensee has established and is maintaining an environmental monitoring program, if required in the license.

Review the licensee's ALARA goals, where applicable, and determine if the licensee has implemented these goals. Determine if the licensee has calculated annual doses resulting from air effluents and if the doses: (1) are within the licensee's ALARA goals (as described in its radiation protection program); (2) exceed the licensee's ALARA goals; or (3) are uncertain because there is insufficient information or basis for determination. Review the licensee's history in meeting ALARA goals, and its corrective actions when the goals were not met.

Verify that the licensee's air effluents, excluding Radon-222 and its daughters, have not exceeded the constraint limit in 10 CFR 20.1101. Information on evaluating air effluents is available in Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors." If the licensee estimated or measured a dose greater than 0.1 millisievert (10 mrem) per year, from air emissions to the nearest individual member of the public, the licensee should have notified NRC [10 CFR 20.2203(a)(2)(vi)]. If the licensee has notified NRC that its air effluents have exceeded the constraint level, the inspector should review the effectiveness and timeliness of the licensee's corrective actions. Records of the results of measurements and calculations needed to evaluate the release of radioactive effluents to the environment are required pursuant to 10 CFR 20.2103(b)(4).

For further inspection guidance, refer to IP 87102, "Maintaining Effluents from Materials Facilities As Low As Reasonably Achievable (ALARA)."

03.06 Reports to Workers

10 CFR 19.13(b) requires that each licensee shall advise each worker annually of the worker's dose, as shown in dose records maintained by the licensee. Verify, through discussions with workers and management, and through records review, that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required (and, therefore, dose records are required). The licensee must advise these workers of internal and external doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. The report to the individual must be in writing and must contain all the information required in 10 CFR 19.13(a).

03.07 ALARA

The licensee should, in addition to complying with regulatory requirements and license conditions, make reasonable efforts to maintain radiation exposures and releases of radioactive materials in effluents to unrestricted areas ALARA. This can be accomplished by the implementation of good radiation planning and practices, and by the commitment, from management and workers, to policies that prevent departure from ALARA practices. Also, licensees are required to keep occupational doses and doses to members of the public ALARA, in 10 CFR 20.1101(b).

Assess the licensee's ALARA practices, and verify implementation of any ALARA commitments in licensing documents, by reviewing:

- (a) A written commitment by high-level management to minimize worker exposure by the implementation of clearly defined procedures and policies;
- (b) That licensee personnel are made aware of management's commitment to keep occupational exposures ALARA;
- (c) That the radiation safety staff have been given authority to assure ALARA procedures and policies are carried out;
- (d) That workers are adequately trained, not only in the radiation safety procedures, but also in the ALARA philosophy;
- (e) That management and its designees perform periodic audits to find out how exposures and effluent releases might be lowered;
- (f) That modifications to procedures, equipment, and facilities have been made to reduce exposures at reasonable costs, where possible;
- (g) That the licensee has QA and QC programs, where applicable; and
- (h) That the licensee has a functioning and effective preventive maintenance program, where applicable.

Review and evaluate engineering controls to assure that, for example, exhausts from ventilated enclosures are adequately treated to reduce emissions to the out-of-plant environs to the lowest reasonably achievable levels within regulatory limits. Evaluate ventilated enclosures to assure that they are adequate to minimize internal exposures. Review shielding and the use of remote handling tools to assure that facilities and equipment are adequate to reduce exposure (both internal and external) to the lowest reasonably achievable levels within regulatory limits.

03.08 Event Evaluation

Through reviews of dosimetry reports and annual licensee evaluations of public dose, and interviews of the RSO and selected licensee personnel, verify that the licensee has not experienced any events, since the last inspection, involving exposures to occupational workers or members of the public that were in excess of any regulatory limit.

- Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the NRC.
- For incidents or unusual occurrences that were not required to be reported, verify that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

03.09 Instrumentation

Through observations of portable radiation detection and measurement equipment in use and available for use, determine whether the quantity and type are adequate for the licensee's radiation detection and measurement needs. Verify that instruments used to meet regulatory requirements (area and transportation surveys) have been calibrated at the required frequency.

- a. If the licensee uses a vendor to calibrate instruments, verify through interviews of the RSO that the vendor is authorized by the NRC or an Agreement State to perform that service.
- b. If the licensee performs maintenance/repair on survey instruments, through interviews of appropriate licensee personnel and the RSO, determine whether the licensee possesses instrument manufacturer manuals and that any replacement parts used are "like-for-like."
- c. Through observations and demonstrations, determine whether selected licensee survey instruments in use and available for use are operational (battery check) and respond appropriately to radiation (instrument source check). Compare licensee instrument readings to NRC instrument. Verify that licensee's instrument response is comparable to NRC instrument (± 20 percent).
- d. Through interviews of the RSO and workers, and by observation, verify that licensee has a system for tagging out inoperable and out-of-service survey instruments.
- e. Through observations and interviews of the RSO and workers, determine whether the licensee's instrumentation for performing bioassay measurements is adequate for those measurements. Verify that bioassay probes and scalers are compatible. Verify that licensee staff perform a response check using appropriate sources and a suitable background measurement before taking bioassay measurements.
- f. Through observations and interviews of the RSO and workers, assess the procedures and methods, and equipment used by the licensee to assure compliance with air-monitoring and air-handling commitments requirements (such as flow rates into hoods, air flows in ventilation systems, differential pressures in cells, in glove boxes, and across filter systems).
- g. Assess the equipment used by the licensee to satisfy these measurements. If appropriate, verify that air measurement equipment is functional and calibrated at the required frequency. Examine a representative sample of sampling gauges and data recorders and verify that it is operating within its design specifications. Using a properly calibrated hand-held anemometer, spot-check the linear airflow rate (corrected for altitude, when necessary) at the face of several hoods to verify that it meets the commitments made in

the license. Using smoke tubes, visualize the airflow at the hood face to ensure that no excessive turbulence is present that may result in the spread of radioactive contamination.

03.10 Training

1. Authorized Users. Authorized users may either be named in the license application or be appointed by the licensee, depending on the type of license issued and/or the wording in the license. For those appointed by the licensee, verify through interviews that the authorized user has knowledge commensurate with operational duties. In cases where users are specified by license condition, determine that the licensed materials they use conform to the license condition.

Determine that the authorized users are personally performing or, if permitted in the license, supervising, the authorized work, rather than someone else not named in the license. The level of supervision will depend on the wording in the license conditions or regulations. Some licenses have conditions such as "... used by or under the supervision of" For other types of licensees, supervision is defined in the regulations. For some licenses that have the condition "... under the direct supervision of ..," the authorized user must be physically present at the facility, for easy contact or to observe the individual(s) working. Another phrase used is "... may only be used by" Finally, "... under the direct supervision and physical presence of ..." means the authorized user must directly supervise and be present at the work station. Considering the many license condition phrases and regulations, the inspector must exercise judgment when assessing the role of the authorized users.

When the wording of the license condition is "... used by or under the supervision of ...," an authorized user named on the license is considered to be supervising the use of licensed materials when he/she directs personnel in the conduct of operations involving the licensed material. This does not mean that the authorized user must be present at all times during the use of such materials. The authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, and is responsible for the supervision of operations involving the use of licensed materials whether he/she is present or absent.

2. General Training. Certain kinds of training and instruction are found in the regulations; how they are implemented will be found in the license. Discuss with the licensee how, and by whom, training is conducted, and the content of the training provided to workers (generally found in the license application).
3. 10 CFR Part 19-Required Training. Verify, through interviews of selected licensee personnel, that initial instructions have been given to individuals who, in the course of employment, are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Under the basic instructions, it is management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of NRC regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NRC requirements. Also verify that authorized users and workers understand the mechanism for raising safety concerns.

4. Training Required by License Commitments. Of the training program elements in the license application, training given to authorized users, and those individuals under the supervision of authorized users, is of primary importance. One or more users of radioactive materials should be interviewed to determine their understanding of the training that they have received, both in the basic instructions and that specified in the license application. For some licensees, this includes specific training needed to perform infrequent procedures and prepare and use radioactive material in research studies or in production. Note that the training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities.

The inspector should also observe related activities and discuss the radiation safety training received by selected individuals to assure that appropriate training was actually received by these individuals. Authorized users and supervised individuals should understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, and "dry runs" for more complex or hazardous operations.

Determine if ancillary workers (such as janitorial or clerical staff), contract workers, and visitors are informed about basic radiation safety practices for the type of material used by the licensee.

Determine, by observing and interviewing workers, if training and experience are adequate to enable users to safely undertake activities authorized by the license and whether they are aware of the risks involved. Examine the licensee's program for on-the-job training of new workers. Determine if there is adequate retraining for workers if there are regulation changes and/or radiation safety program changes that affect the workers. Review workers' knowledge of the risks associated with the licensed activities.

03.11 Operating and Emergency Procedures

Operating and emergency procedures will be found in license applications and may vary from step-by-step procedures to more generalized procedures for licensees with lower inspection priority. The emergency procedures may be approved by NRC and reviewed and updated by the licensee. However, licensees who follow the guidance in the appropriate NUREG 1556 series will likely develop procedures, including emergency procedures that have not received specific NRC review and approval.

- a. Review and evaluate the licensee's process for controlling documents (procedures) and making revisions to procedures. Revisions to operating procedures should be reviewed by licensee health physics staff to ensure that the revisions do not adversely affect radiological safety. Select a sample of operating or process areas and verify that pertinent procedures are available to personnel, are current, and are in use in those selected areas. If no operations are being performed, ask workers to describe their work and the procedures that govern their work activities. Determine whether process activities use procedures for reference or are required to be used "in-hand."
- b. During interviews of selected licensee personnel, propose hypothetical emergency scenarios to assess the worker's knowledge and understanding of the licensee's emergency procedures. The scenarios should include those types of accidents

appropriate to the licensee's program (i.e., contaminated packages identified during receipt surveys, fires, contamination events involving large quantities of licensed materials).

- c. If the licensee is required to have and implement an emergency plan, pursuant to 10 CFR 30.32(i), evaluate in-plant procedures for handling accidents including evacuation, prevention of spread of contamination, securing sources, handling accident victims, and any other major portions of the emergency plan. Verify, by discussions with workers, and review of procedures, that the emergency plan has been implemented and is being maintained. Verify that lines of communication with outside organizations that may be called on to assist in an emergency are current and tested. Ensure that biennial emergency plan drills and/or exercises include observation by NRC staff.
- d. Some licensees may have agreements with other agencies (e.g., fire, law enforcement, and medical organizations) regarding response to emergencies. Discuss with the licensee's representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

03.12 Posting and Labeling

- a. The inspector should determine through observation whether proper caution signs are being used at access points to areas containing radioactive materials, radiation areas, and those areas containing airborne radioactive materials. 10 CFR Section 20.1903 provides exceptions to posting caution signs. The inspector should also selectively observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.
- b. Areas with radiation hazards should be conspicuously posted, as required by 10 CFR 20.1902. Depending on the associated hazard, controls may include tape, rope, or structural barriers to prevent access. If volatile radioactive materials are used in an area, such as area should be controlled for airborne contamination. High-radiation areas should be strictly controlled to prevent unauthorized or inadvertent access. Such controls may include, but are not limited to, direct surveillance, locking the high-radiation area, warning lights, and audible alarms. Areas occupied by radiation workers for long periods of time and common-use areas should be controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program.
- c. The inspector should also examine locations where notices to workers are posted. Applicable documents, notices, or forms should be posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply.

03.13 Senior Management Responsibilities

The NRC holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes under emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding NRC regulations and license provisions and to terminate unsafe activities involving byproduct material.

Through observations, interviews, and the review of selected records, determine that senior licensee management is fulfilling its responsibility of ensuring the effective operation of the radiation safety program. Specific areas of management focus should include:

- Maintaining awareness of significant events such as the loss or theft of licensed materials. Maintaining radiation safety, security and control of radioactive materials, and compliance with regulations.
- Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that members of the public and workers are adequately protected from radiation hazards and that compliance with regulations is maintained.
- Obtaining the NRC's prior written consent before transferring control of the license (10 CFR 30.34(b)).
- Notifying the appropriate NRC regional administrator in writing, immediately following filing of petition for voluntary or involuntary bankruptcy (10 CFR 30.34(h)).
- Assuring the appropriate response, when applicable, to generic communications from the NRC.
- Assuring that adequate provisions have been made to fund the safe and effective decommissioning of licensee facilities. (10 CFR 30.35)
- Notifying the NRC of the decision to discontinue licensed activities or to decommission a facility in which licensed activities took place. (10 CFR 30.36)
- Notifying the NRC of defects or other radiation safety equipment malfunctions in accordance with the requirements of 10 CFR, Part 21.
- Maintaining awareness of issues and measures to ensure worker performance and safety are not being compromised due to safety significant human performance issues.

END

Appendix B: Considerations for Selecting Activities to be Observed

87141B-01 PURPOSE

The purpose of this appendix is to identify and describe three factors to be considered in determining the activities to be observed during a risk-informed performance -based inspection of facilities that may be authorized for a wide range of uses of licensed materials. The programs that have a wide range of uses may include licensees performing research and development (R&D), or licensees performing manufacturing. The three factors are: 1) the quantities and forms of materials used; 2) the activities performed; and 3) the size of the program (number of locations and persons). A description of the variations that have been observed in inspections is listed in order of higher to lower probable risk from the licensed activities.

87141B-02 BACKGROUND

Programs that authorize a wide variety of radioactive materials and forms, a wide variety of uses, and/or a large number of locations with a large number of users may provide a challenge to inspectors in determining the activities to be observed during the inspection. Such programs were more common in the past. Diverse and changing research activities introduce new uses of radioactive materials, therefore inspectors may not be familiar with the range of activities discussed in this appendix. The appendix describes the range of materials, uses, and program sizes that have been observed by inspectors of such programs, arranged in order of higher to lower complexity and risk. Each section provides guidance to inspectors who are inspecting a program that may include that activity. This information may be used by inspectors to select the activities to be observed during the inspection, and to perform the inspection.

87141B-03 GUIDANCE

The inspector should consider the following areas for selecting activities to be observed at licensee facilities where primarily unsealed materials are used for activities covered by this inspection procedure: a) the quantities and forms of the licensed materials; b) the activities performed; and c) the size of the program.

- a. Quantities and forms of licensed materials handled. Below is a prioritized list of the quantities and forms of licensed materials that may be used by licensees. The inspector should prioritize observations of materials that present the highest risk to the health safety of workers and the public.
 1. Unsealed beta/gamma emitters in curie quantities that require remote handling and containment such as hot cells or glove boxes.

The inspector should observe the use of remote handling equipment, and the use of other radiation protection equipment (lab coats, gloves, dosimetry, survey instruments, etc.). The inspector should perform surveys to confirm adequacy of the containment shielding. The inspector should identify the location(s) of effluent release points and monitoring systems if applicable. The inspector should discuss routine and emergency safety procedures with licensee staff in this area. The inspector should review laboratory maintenance, use and survey records, if maintained in the area. The inspector should determine if material is appropriately secured and controlled in use and in storage. If the licensee has multiple areas

using these types and quantities of materials, the inspector should determine if all need to be reviewed, or if a sample is sufficient.

2. Unsealed beta/gamma emitters in tens-to hundreds of millicuries that may require remote handling and/or containment in glove boxes or hoods.

The inspector should observe the use of remote handling equipment and other radiation protection equipment [lab coats, gloves, dosimetry, survey instruments, etc), and should observe licensee staff perform surveys. The inspector should perform surveys to confirm adequacy of the containment. The inspector should identify the location(s) of effluent release points and monitoring systems if applicable. The inspector should discuss routine and emergency safety procedures with licensee staff in this area. The inspector should review laboratory maintenance, use and survey records, if maintained in the area. The inspector should determine if material is appropriately secured and controlled in use and in storage. If the licensee has multiple areas, the inspector should determine if all need to be reviewed, or if a sample is sufficient.

3. Unsealed beta emitters in millicurie quantities that may become (i) airborne as dusts or volatile gases, and may require use of a hood or glove box; (ii) high-energy beta emitters that could result in extremity doses, and may require use of beta-shields; and/or (iii) chemical/physical forms that may absorb through skin or react with other chemicals in the area. See IP 87141.

The inspector should observe the use of hoods or other equipment to control potentially airborne materials; determine through observation and discussion if any effluent releases (air, sewer or other effluent) require monitoring and evaluation; confirm that licensee staff use appropriate shielding and dosimetry if medium/high-energy beta emitters are used; observe the use appropriate radiation protection for handling the material; and observe staff performing surveys. The inspector should discuss routine and emergency safety procedures with licensee staff in this area. The inspector should review laboratory maintenance, use and survey records, if maintained in the area. The inspector should determine if material is appropriately secured and controlled in use and in storage. If larger programs have multiple facilities for such studies, if all need to be reviewed, or if a sample is sufficient.

4. Unsealed alpha emitters, especially in forms that could become airborne or volatile, and whose energies require careful surveys in order to determine if use results in contamination of areas. This includes byproduct, source, and special nuclear material. See IP 87140.

The inspector should observe the licensee staff appropriately control and contain alpha emitters. The inspector should pay particular attention to the methods used to survey for alpha contamination to determine if surveys are performed slowly enough and have sufficient sensitivity to identify the spread of alpha contamination. This is especially important if surveys for release for unrestricted use are performed, because the NRC screening values for most alpha emitters is very small (examples are 101 dpm/100 cm² for uranium, 7 dpm/100cm² for thorium). The inspector should discuss routine and emergency safety procedures with licensee staff in this area. The inspector should review laboratory maintenance, use and survey records, if maintained in the area. The inspector should determine if material is appropriately secured and controlled in use and in storage. If multiple laboratories handle alpha-

emitting material, the inspector should determine if all areas need to be inspected or if a sample is sufficient. Note: NRC screening values for release may be found in NUREG-1757 "Consolidated Decommissioning Guidance, Volume 2."

5. Unsealed beta emitters in microcurie quantities which do not likely require airborne containment. See IP 87141.

The inspector should observe licensee staff use appropriate handling methods and radiation protection equipment (typically: have absorbent material on the work area bench, wear gloves and lab coats, use low-Z material shielding); use of available survey instruments and liquid scintillation counters (LSC); and perform surveys. The inspector should discuss routine and emergency safety procedures with licensee staff in this area. The inspector should review laboratory use and survey records, if maintained in the area. The inspector should determine if material is appropriately secured and controlled in use and in storage. Most licensees will have multiple laboratories in this category, and a sample of 5-10 laboratories or 10-20 percent of all such laboratories, whichever is larger, is usually sufficient.

6. Small sealed sources and/or devices (electron capture detector (ECDs) used in gas chromatographs or chemical monitors, x-ray fluorescence (XFR) devices, Mossbauer sources, check sources, calibration sources and standards, or other sources not covered by other inspection procedures). This includes sources and devices possessed under a general license. See IP 87142.

The inspector should observe if such sources and devices are present in laboratories during the inspection. The inspector can develop a list of sources/devices observed in the laboratories, for later review of physical inventory and leak test records, to be sure that such sources and/or devices observed are included. Another method of sampling, when the licensee possesses tens to hundreds of sources, is to select a random sample (10-20 percent) of such devices from the current inventory, then visit each designated location to confirm by observation that the sources are present, and observe workers use of the sources and/or devices the sources at that time. The inspector may review inventory and leak test records by selecting a random sample of sources and devices to determine that the sources were consistently on the inventory and were leak tested if required.

- b. Activities performed. The following activities are not often performed at most licensed facilities and therefore may require additional review and preparation by the inspector. These activities often require more complex safety procedures and additional training which should be evaluated by the inspector.

1. Synthesis of compounds

Synthesis activities tend to generate more contamination and more waste products than most laboratory bench top activities. The inspector should, if possible, observe the process from opening the incoming material, through the various steps of the process to the collection and use of the final labelled compound and the disposal of waste materials. The inspector should determine if adequate surveys are performed in each step to protect workers and public during the process, and that material is accounted for, and secured. If multiple synthesis activities are performed, the inspector should gather information to determine if the activities are performed with

different materials and/or by different persons, in order to determine if all such facilities should be inspected or if a sample is sufficient.

2. Use of licensed material in animals. See IP 87141 and IP 87144.

There are many ways in which licensed materials may be introduced into animals for study; each has its own safety and security issues according to the type of animal, the route of introduction, and the biological fate of the radionuclide. The inspector should, if possible, observe: animal handling with licensed materials; animal housing, use and waste areas for adequate radiation protection and contamination control appropriate to the types of radionuclides and the compound labelled to determine that the route of excretion (e.g. urine, feces, exhalation, or uptake in tissue) of the radioactive material is appropriately monitored or controlled; surveys or evaluations for the release of the animal for unrestricted use, if that is done (return to owner after veterinary treatment or return to the vivarium animal population after laboratory testing). If multiple different studies with animals are performed, the inspector should gather information to determine if the animal studies are performed with different materials and/or by different persons, in order to determine if all such facilities should be inspected or if a sample is sufficient.

3. Effluent releases, monitoring and evaluation (this includes any environmental monitoring of ground and surface water, soil, plants and animal samples if necessary).

If the licensee releases effluents that require monitoring, the inspector should review the location of releases and monitoring points, and the equipment used, to ensure that the release is properly sampled and collected. The inspector should observe the equipment used for sample analysis, if performed on site (see below) to ensure that measurements of the samples are correct. The inspector should review the method used to convert the data from the measurement to a value for comparison to effluent release limits or dose to workers or public. If the licensee has multiple effluent releases, the inspector should evaluate at least one of each type of release (air, water, sewer).

4. Internal dose assessment – This may be a direct assay or may be indirect through sample collection. Bioassay may be required routinely, or only if an uptake is suspected.

If the licensee is required to perform internal dose assessment, the inspector should observe direct measurements used to support internal dose assessment (thyroid monitoring is common for persons handling millicuries of radioiodines, or whole-body counters for gamma emitters). The inspector should evaluate direct measurement systems to ensure they are used correctly and in calibration. Indirect measurement used to evaluate internal dose could include collection of samples of urine, feces, or exhaled air, according to the route of excretion of the radionuclide and the compound to which it was attached. The inspector should review indirect assessment collection method(s) (such as grab sample, 24-hour total collection), and other relevant data to be collected (time of collection start/end, time of suspected intake, results of contamination surveys etc.) to determine if good sample collection methods are employed. Poor bioassay sample collection is usually the major source of error in a bioassay evaluation. If samples are analyzed by the licensee, the inspector should observe the equipment and method(s) used (see below). The inspector should

review the licensee's method of assessing dose from the sample results (hand calculations, computer codes, etc.).

5. Analysis of samples (such as unrestricted release wipes, leak test, bioassay, effluent, soil, etc.) by the licensee. See Section 03.03.

If the licensee is performing analysis of samples they collect (or analysis of samples as a commercial activity), the inspector should observe the instruments available for analysis of the samples collected and analyzed by the licensee. The inspector should determine if the instruments are appropriately calibrated for the types of material(s) and the geometry(ies) of the sample(s); and if the analyses are performed with sufficient sensitivity for the material being evaluated. The inspector should review a sample of control charts and calibration records for analytical instruments, and results of any cross-check analysis programs in which the licensee may participate (this is most likely for laboratories analyzing effluent, environmental and bioassay samples). If instrumentation is not appropriately calibrated, then the sample results are not meaningful.

6. Waste processing.

Some higher-risk waste processes that may be used at typical laboratory facilities are: compaction of solid dry waste; solidification of liquid wastes; treatment of mixed wastes to remove one of the hazards; crushing of liquid scintillation vials to consolidate the scintillation fluid; incineration of wastes, such as animal carcasses. Lower-risk waste activities include disposal of 10 CFR 20.2005 specific wastes, release of soluble materials by sewer disposal, packaging of dry waste, and decay-in-storage activities.

If the licensee is processing waste (as opposed to storage for transfer to a licensed facility, or storage for decay), the inspector should observe licensee staff performing processes if possible. The inspector should observe availability and use of remote handling equipment and/or shielding if applicable; use of personal protective equipment by licensee staff; performance of facility surveys; and the use of calibrated and operable monitoring equipment if applicable. NOTE: If waste disposal records are maintained in the waste storage and processing areas, the inspector should review selected records while at the location(s).

7. Calibration of portable survey instruments by the licensee. See IP 87143.

If the licensee calibrates their own portable survey instruments, it is important to review the capability of the licensee's calibration, to ensure that the survey instruments used are accurate. The inspector should observe licensee staff performing a calibration. The inspector should observe if access to the source and the beam are appropriately controlled during calibration and that any safety/warning indicators are operable and used. The inspector should perform surveys to confirm if radiation doses during calibration result in radiation levels in excess of public limits, if applicable (such as from sky shine or beam scatter through adjacent walls); or in excess of posting and monitoring requirements for workers. The inspector should discuss the calibration facility and monitoring with licensee staff, to ensure that the proximity of walls or other equipment in the room do not create backscatter that could affect the dose rate measurement within the beam. The inspector should perform comparative measurements with the licensee.

8. Broad scope procedures to approve their own authorized users, uses, and facilities.

If the licensee authorizes its own users and uses of licensed materials under a license of broad scope, the inspector should interview members of the Radiation Safety Committee (Type A broad scope) or responsible management (Types B and C broad scope) who oversee the radiation protection program, and interview the Radiation Safety Officer and radiation safety staff who implement the radiation protection program. The inspector should evaluate the level of involvement of committee members and/or management in the approval of new users and uses, criteria for approval, and in the annual review of the radiation protection program,

- c. The size of the program. Licensed programs that span multiple locations may require the inspector to prioritize facilities to be observed. The larger the program, the more information the inspector will need to gather at the beginning of the inspection regarding where and what activities are taking place in order to determine what, when, and where to inspect. Below the list of factors that should be considered in selecting sufficient activities to be observed.

1. The number of separate locations/campuses: Broad scope licenses may have multiple campuses or locations (note in licensing, a contiguous property is considered a single location): If a licensee authorizes multiple locations, the inspector should review Section 05.03.a. of IMC 2800 to determine the number of locations required to be inspected.
2. The number of buildings and the number of laboratories: Broad scope licenses usually authorize activities in multiple laboratory buildings or other locations. Typically, there will be multiple laboratories that use licensed materials in a given building. Limited scope licensees typically have all licensed activities in one building. Activities by authorized users usually occur in laboratories, but licensed materials also may be used or stored in locations such as shipping/receiving, the radiation safety staff analytical laboratory and/or storage areas, waste storage and handling areas, etc.

The inspector should gather information during the beginning of the inspection to determine the current number of buildings/laboratories authorized to use material, AND the number who are actively using material, to adjust the plan of inspection. The inspector should visit 5-10 active laboratories and use/storage areas, OR 10-20 percent of all active laboratories and use/storage areas, whichever is larger. Some of these locations may be selected based on the types, quantities, and activities performed, and others may be randomly selected.

3. The number of authorized users and other radiation workers: A limited scope license usually names persons on the license who may use, or supervise the use of, licensed materials. A broad scope program approves its own authorized users.

During the beginning of the inspection, the inspector should gather information about the number of persons who are considered "authorized users" actively using licensed materials, and the number of radiation workers who are under the supervision of authorized users. The inspector should interview 5-10 persons, OR 10-20 percent of all persons considered to be actively working with licensed materials, whichever is larger. Some of the persons may be selected according to the types, quantities, or activities performed with licensed materials, and others may be selected.

4. The frequency of work with licensed materials: Use of unsealed materials for laboratory research has steadily declined over the past 20 years. Some broad scope programs that received 100-200 packages each week 10 years ago may now receive only 100-200 packages each year. Daily use of radionuclides in laboratories is rare. It is more usual for licensed materials to be used sporadically for a particular study over several days to a few weeks, then not at all for weeks or months.

During the entrance meeting, the inspector should gather information about the use of licensed materials expected to occur during the time of the inspection, so that activities may be observed. The inspector should also gather information about the frequency of use from discussion and review of package ordering and receipt records. The inspector may use this information to adjust the inspection plan on site.

END

Attachment 1: Revision History for IP 87141

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
N/A	ML22053A005 04/26/22 CN 22-008	New Inspection Procedure. Guidance was previously contained in IP 87126. Specific changes include: (1) divided inspection guidance into risk-modules; (2) included inspectors' observations; (3) updated inspection guidance; (4) added an estimated level of effort to complete an inspection; and (5) developed new appendix titled "Additional inspection elements."	N/A	ML22053A006