

VETERINARY USE PROGRAMS

Effective Date: 05/16/2022

PROGRAM APPLICABILITY:IMC 2800

87144-01 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.

87144-02 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 veterinary use program authorizes a small number of radionuclides for animal treatment, usually in unsealed form. Veterinary use of licensed materials is not a medical use as defined in 10 CFR Part 35; therefore, the regulations in Part 35 are not applicable to veterinarians treating animals. Inspection guidance for in vivo use of radionuclides in animals for research purposes is available in Inspection Procedure (IP) 87141, "Limited Scope Academic and Research & Development Programs Including Animal Use."

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 as an appendix 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 issued 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 to workers, 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 Treatment 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 veterinary licenses is usually an ancillary duty for a veterinarian, or may be a consultant health physicist, 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 veterinary radiation protection program, and the communication between the RSO and management.

87144-03 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 which 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 and selective 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 Inspection Manual Chapter (IMC) 2800.

Each of the following elements should be reviewed, as appropriate, during each inspection of a veterinary license using unsealed materials.

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. Veterinary facilities are typically 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.

Veterinary facilities using licensed materials typically use one of the following: Iodine-131 (I-131) for the treatment of hyperthyroidism in cats (this is the most common veterinary use); or Technetium-99m (Tc-99m) in horses for bone scans or other similar evaluations. A new treatment using Tin-117m (Sn-117m) for treatment of osteoarthritis in the elbow joint of dogs recently began to be licensed. Animals treated with licensed materials are released for unrestricted use to their owners in accordance with procedures committed to during the licensing process.

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 1) the types, forms and quantities of materials being used; 2) the activities being performed; and 3) the size of the program.

The inspector should visit the facilities where licensed materials are used and stored (treatment room, waste storage, animal housing facilities, receiving and shipping areas, etc.).

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:
 - room surveys by laboratory staff;
 - calibration stickers on survey instruments; and
 - decay-in-storage records.

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

The typical veterinary program activities result in doses that are measurable and may require monitoring. Both whole body and extremity dosimeters may be used. Inspectors should review dose assessments for radiation workers required to be monitored, or in response to any events. Particular attention may be needed if minors are employed as student interns or volunteers. This may be done anytime during the inspection and will require review of records and interviews.

- 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 20.1501]
 - 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 20.1501]
 - 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. [10 CFR 19.13; 10 CFR 20.2106]

Inspectors have identified poor or incorrect thyroid assays performed and lack of calibrated equipment.

- 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. [10 CFR 20, Subpart C, 10 CFR 20.2106]
- Veterinary licenses handling unsealed licensed materials, which require return of the animal to its owner, must meet public dose limits for release of the animal. The procedure for performing the evaluation to meet public dose limits (100 millirem in one year, or 2 millirem in any one hour) should be contained in license commitments for release of the animals. The inspector should observe the licensee staff perform or demonstrate the surveys they perform to determine if an animal may be released for return to its owner. The inspector should review their results of such surveys for the past 3 years. The inspector should interview staff about their procedures for release for unrestricted use and review the calibration of any survey equipment that affect the dose assessment. [10 CFR 20 Subpart D, 10 CFR 20.2107]

Inspectors have identified licensees that perform poor surveys typically by standing too far away from the animal, therefore underestimating the actual radiation levels.

- Interview licensee staff members to determine if any incidents or events occurred since the last inspection. Through interviews and review of records, determine if they 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. [10 CFR Part 20, Subpart M; 10 CFR 30.50; 10 CFR 40.60; and 10 CFR 70.50]

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 veterinary 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.

- 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, such as a wipe counter, 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. [10 CFR 20.1101(d), 20.1406, and 20.1501]
 - 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.
 - 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; 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 instead of performing wipe surveys; 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.

- Facilities for Waste Storage, Treatment, and/or Disposal
 - Observe licensee staff perform or demonstrate waste treatment and/or disposal activities. Typically, veterinary facilities dispose of wastes by decay-in-storage as specified by license condition. Observe and discuss contamination control and radiation monitoring for release of waste held for decay. Confirm by discussion and review of selected records how frequently waste disposal activities occur; the quantities of licensed materials disposed of; and the typical contamination and radiation levels in the areas where waste storage and handling occur. [10 CFR 20, Subpart K]

Inspectors have identified decay-in-storage surveys performed with inappropriate instruments and performed in areas of elevated background. Inspectors have identified waste storage areas located in outside areas without protection from weather.

03.04 RM-4: Inspection of Veterinary Use of Radionuclides

Licensing of veterinary use is discussed in Appendix D, "Guidance for Laboratory Animal and Veterinary Medicine Uses" of NUREG-1556, Volume 7, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other License of Limited Scope, Including Electron Capture Devices and X-Ray Fluorescence Analyzers." The inspector should review the implementation of the commitments made during licensing. Animals treated with licensed materials are released for unrestricted use to their owners in accordance with procedures committed to during the licensing process.

The most widespread veterinary treatment using licensed materials is the use of I-131 for the treatment of hyperthyroidism in cats. A typical cat receives 3 to 5 millicuries of I-131. The cat is typically held for 2-4 days post-treatment, as specified in license commitments. The veterinarian typically receives unit dosages from a radiopharmacy for injection of the cats, although at least one veterinarian used I-131 capsules for treatment. I-131 is eliminated from the cat primarily through urine and decay.

Another common veterinary treatment is the use of Tc-99m in horses for bone scans, or other similar evaluations. At least one veterinary facility used Tc-99m for lung scans. Tc-99m has been used occasionally on zoo animals, dogs, and other pets. Horses are typically administered 100 to 200 millicuries of the Tc-99m-labelled compound, typically received as a unit dosage from a radiopharmacy. Horses are large animals and become a significant source of external radiation to workers handling them. Tc-99m is eliminated from the horse primarily through urine and decay.

A new treatment using Tin-117m (Sn-117m) for treatment of osteoarthritis in the elbow joint of dogs recently began to be licensed. Dogs are administered up to 3 millicuries of Sn-117m into the elbow joint in a colloidal form which does not get eliminated from the animal. It is the decay of the radionuclide in place that reduces the inflammation from osteoarthritis. The manufacturer of the colloidal material received approval for procedures which allow the dog to be returned to the family, who must limit direct contact with the dog for a prescribed period of time (see ML20303A293 (reviewer notes) and ML20269A277 (technical evaluation)). [10 CFR 20.1301 and 20.1302]

- The inspector should interview veterinary staff 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 at veterinary facilities is mainly from radiation exposure while handling animals, or from animal wastes, including bedding. The inspector should, if possible, observe animal handling by veterinary staff 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.

Veterinary staff often must handle animals directly, resulting in measurable whole body and extremity exposures, especially at equine facilities handling large individual dosages in large animals during scanning. Inspectors have reviewed dose assessments necessary as the results of “needle stick” when an uncooperative animal causes the researcher to hit him/herself with a syringe needle.

- 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, usually limited to syringe shields, is available. The inspector should ensure that veterinary staff have appropriate personal protective equipment, and that staff minimize the time spent in the vicinity of treated animals and maximize distance from treated animals being held prior to release to the owners. [10 CFR 20.1401]

Inspectors have observed that some researchers are unaware of the availability of syringe shields for 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. [10 CFR 20.1401 and 20.1501]

Inspectors have identified unmonitored contamination in animal housing areas when poor surveys were performed and 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, for return to the owner. [10 CFR 20.1301, 20.1302, and 20.1501]

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 veterinary 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.

- At veterinary facilities, inspectors commonly observe unit dosages of licensed materials stored in the veterinary “pharmacy” area. Waste held for decay in storage is normally in a separate area which should be secured from public access. Animal housing may be within a secured building, and areas with access limited to veterinary staff during the work day. However, individual cages and stalls are not

expected to be locked, for other safety considerations for the animals and staff. Inspectors commonly observe material in use attended by licensee staff, which is acceptable. [10 CFR 20.1801 and 20.1802]

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.

- During the inspection, the inspector should review and discuss, with the RSO and authorized users at the veterinary program, the licensee's procedures for tracking unsealed licensed materials received, used, stored, and transferred or disposed of. Inspectors should discuss the licensee's practice for unused dosages. [10 CFR 30.41 and 30.51]

Inspectors have identified licensees who did not include radioactive wastes in the inventory of licensed materials; or were unaware of, or did not meet, the applicable unity rule.

- 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 may not seem significant, first responders who are trained to observe postings may respond to emergencies inappropriately if the posting is incorrect. [10 CFR 19.11; 10 CFR 30.41 and 30.51]

03.06 RM-6: Management Oversight

A typical veterinary program using unsealed materials is required to have an RSO that performs activities as required by the license commitments. This is typically an ancillary duty of one of the veterinarians or may be a consultant health physicist. 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 by 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. [10 CFR 20.1101 and 20.2102]
- 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. [10 CFR Part 20, Subpart M; 10 CFR 30.50; 10 CFR 40.60; and 10 CFR 70.50]

87144-04 RESOURCE ESTIMATE

The length of time necessary for the 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 veterinary inspection may take a single inspector 4 to 8 hours to complete the inspection at a single location. Additional time will be required if multiple locations need to be inspected.

87144-05 REFERENCES

- Appendix D, "Guidance for Laboratory Animal and Veterinary Medicine Uses," NUREG-1556, Volume 7, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other License of Limited Scope, Including Electron Capture Devices and X-Ray Fluorescence Analyzers," February 2018
- Technical Evaluation Report for the Exubriion Therapeutics Proposed License Application Template for the Release of Dogs Following Treatment with a Tin-117m Colloid (ADAMS Accession No. ML20269A277)

- “Notes to License Reviewers Evaluating License Applications to Treat Dogs with Synovetin OA® (ADAMS Accession No. ML20303A293)
- 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

Appendix:

Appendix A: Additional Inspection Elements

Attachment:

Attachment 1: Revision History for IP 87144

Appendix A: Additional Inspection Elements

87144A-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.

87144A-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.

87144A-03 GUIDANCE

03.01 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 pick-up 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.

03.02 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.
- c. 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's 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."

- d. 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 licensees 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.

03.03 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.

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.

03.04 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).”

03.05 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).

03.06 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.

03.07 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.

03.08 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.

03.09 Training

- a. 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.

- b. 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).
- c. 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.
- d. 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.

03.10 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, 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.

03.11 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.

03.12 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

Attachment 1: Revision History for IP 87144

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	ML22053A244 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	ML22053A245