
INSPECTION PROCEDURE 87143

SELF-SHIELDED IRRADIATOR AND CALIBRATOR DEVICES

Effective Date: 05/16/2022

PROGRAM APPLICABILITY: IMC 2800

87143-01 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.

87143-02 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.

Self-shielded irradiators typically are used for irradiation of blood at blood banks or medical facilities, or for irradiation of small samples, items, or animals at research facilities. Calibrators typically are found at facilities that perform calibration of survey instruments for their own licensed program, or as a commercial service for others. These devices are often authorized as part of broad scope or limited scope licenses that issued for other activities such as research and development. They may, however, be authorized under a limited scope license authorizing only the individual activity.

This procedure is limited to self-shielded irradiator and calibrator devices that do not meet the radiation levels for which regulation under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 36 is required, and which are inspected in accordance with IP 87143. This procedure does not address security requirements of 10 CFR Part 37, which are inspected in accordance with IP 87137.

The structure and the emphasis of the inspection should be on the following risk modules that describe the outcomes of an effective radiation protection program for use of self-shielded

irradiator and calibrator devices. 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 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 activities with self-shielded irradiators or calibrators that may be ongoing during the inspection, with emphasis on those of higher risk. This should include use, storage, and maintenance of self-shielded irradiators and calibrator devices. Installation and removal for disposal or transfer of self-shielded irradiators and calibrator devices should be reviewed when applicable.

02.02 RM-2: Access Controls and Security of Self-Shielded Irradiator and Calibrator Devices

The inspector should observe a representative number of devices to determine if access is appropriately controlled to self-shielded irradiators and calibrator devices and appropriate postings or other warnings are in place. If used, the inspector should observe or have demonstrated warning lights, interlocks, or other alarms used to indicate the source is in use. The inspector should verify that the devices are attended or secured. If applicable, an inspection of security requirements pursuant to 10 CFR Part 37 should be conducted using IP 87137.

02.03 RM-3: Surveys for Contamination and Exposure Control

The inspector should observe licensee radiation workers perform routine leak tests and other surveys to ensure that 1) radiation levels meet requirements for members of the public if storage and use locations are adjacent to public areas; 2) the licensee staff performs adequate leak tests and surveys; and 3) (if the licensee analyzes their own leak tests or other survey samples) the licensee has the necessary analysis instrumentation, appropriately calibrated.

02.04 RM-4: Calibration of Survey Instruments

If the licensee calibrates their own survey instruments, the inspector should review the adequacy of the instrument calibration program, including performance of confirmatory surveys. If the licensee participates in an accreditation program for the calibration of instruments, this RM may be considered supplemental. The inspector should review selected records of the results of participation in those programs and does not need to perform confirmatory measurements or calculations.

02.05 RM-5: Assessment of Dose to Workers and the Public

If monitoring is required, the inspector should review the results of dose assessment for the self-shielded irradiators and calibrator devices. The inspector should also review

results of assessments of public dose due to use of self-shielded irradiator and calibrator devices.

02.06 RM-6: Management Oversight

For most self-shielded irradiator and calibrator devices on a limited scope license, the Radiation Safety Officer (RSO) is usually an ancillary duty for a research scientist who requires the support of upper management for resources and implementation of the radiation protection program. The inspector should assess the effectiveness of the management of the radiation protection program for the self-shielded irradiator and calibrator devices, and the communication between the RSO and management, and the RSO and users of the self-shielded irradiator and calibrator devices, and the overall management of the radiation protection program.

87143-03 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. However, use of most self-shielded irradiator and calibrator devices rarely result in doses that require monitoring. 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 incident reports, and leak tests. Look for licensee identification of issues and resulting corrective actions taken.
- Physical inventory records may also be examined closely to assess the licensee's ability to track items and prevent losses. Other records which support the radiation protection program, such as receipt and transfer of self-shielded irradiator and calibrator devices, 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 Inspection Manual Chapter 2800.

Each of the following elements should be reviewed, as appropriate, during each inspection of a license using self-shielded irradiator and calibrator devices.

Specific Guidance

03.01 RM-1: Observation of Activities

The primary inspection activity for self-shielded irradiator and calibrator devices should be the observation of activities in progress. Inspection begins as soon as the inspector arrives at the licensee's facility. The inspector should be alert for postings or other indications that self-shielded irradiator and calibrator devices may be in use as the inspector walks through the facility to meet with the RSO.

Most self-shielded irradiator and calibrator devices authorized on a specific license contain Cobalt-60 (Co-60) or Cesium-137 (Cs-137) sources. Calibration facilities may have other types of sources for calibration as well.

Note: The inspector should be aware that self-shielded irradiator and calibrator devices may be located 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 visit a reasonable number of facilities where self-shielded irradiator and calibrator devices are used and stored. 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:

- Observe if facilities for use and storage of self-shielded irradiator and calibrator devices are appropriately secured or attended, and if postings are appropriate. Inspectors should be aware that devices which contain sources may have required labels on the back of the device. [10 CFR 20.1902, 20.1903, 20.1904, and 20.1905]
- 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 appropriate use of self-shielded irradiator and calibrator devices; if applicable, look for use of survey instruments, radiation monitors, and dosimetry.
- Observe performance or demonstration of the following activities: calibration of instruments, if applicable; non-routine maintenance, if applicable; routine maintenance; leak tests and other surveys. Watch for use of appropriate equipment and procedures.
- Interview licensee radiation workers, and selected ancillary persons working in the vicinity of self-shielded irradiator and calibrator devices. Ask questions to determine their understanding of radiation safety practices applicable to their tasks.
- 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.
- The inspectors should be aware that some records of interest will be maintained in work areas where self-shielded irradiator and calibrator devices are used and may be reviewed while at those locations. Typical records in work areas for self-shielded irradiator and calibrator devices are inventory records, and in some cases, "use logs" or other records of use of the devices such as calibration records for instruments that were serviced.

03.02 RM-2: Access Controls and Security of Self-Shielded Irradiator and Calibrator Devices

During the inspection of self-shielded irradiator and calibrator devices, the inspector should observe licensee oversight of the safety and security of the items.

- If the devices include "beam on" warning indicators either on the device or on the room when the device is used, the inspector should observe the actuation of the warning indicator. If the warning indicators are interlocked with beam actuation, the inspector should have the licensee staff demonstrate testing of the interlocks. The inspector should also verify that postings are available and appropriate, if applicable. [10 CFR 20.1601, 20.1602, 20.1902, and 20.1903]
- If the licensee possesses a J. L. Shepherd Mark I or Model 81-22¹ self-shielded irradiator model or another device that has special license conditions for surveys and

¹ These models are subject to enhanced monitoring requirements detailed in an Order dated July 3, 1984 (ADAMS Accession No. ML15210A628)

monitoring, the inspector should observe those activities and interview staff to understand how they meet the special license conditions.

- The inspector should observe how the radiation workers maintain security of the various locations where self-shielded irradiator and calibrator devices are used (attended) and stored (locked or secured to prevent access). [10 CFR 20.1801 and 20.1802]
- For devices that contain Category 1 or 2 quantities of materials pursuant to 10 CFR Part 37, the inspector should use IP 87137 for that portion of the inspection.

Inspectors commonly observe self-shielded irradiator and calibrator devices located in locked laboratories or small rooms. Some self-shielded irradiators or calibrators may be located in a larger room with multiple activities. Inspectors have identified unsecured devices when all staff left the room for some reason; and unlocked doors or doors propped open where materials are used or stored and unattended. Inspectors have identified warning indicators that were not operable.

- The inspector should ascertain whether the licensee is performing non-routine maintenance activities, and whether the licensee is authorized to perform such activities. Maintenance or servicing (beyond routine cleaning), that involves activities such as initially installing or repairing/modifying self-shielded irradiators or calibrators, or replacement or addition of sources to a self-shielded irradiator or calibrator, must be performed by the manufacturer or a person specifically authorized by the NRC or an Agreement State. The license will contain a license condition if the licensee is authorized to perform these activities, and the procedures for this activity may be tied down to the license. Since this activity carries with it more risk than routine maintenance, the inspector should ensure that these procedures are reviewed and discussed with the licensee as part of the routine inspection and observed or demonstrated if possible.
- If sources or devices were installed, removed, re-located within the licensee's facility, transferred to another license, or disposed of since the last inspection, the inspector should discuss these activities with the licensee. These activities are usually required to be performed by the manufacture or a person specifically authorized by the NRC or an Agreement State. If the licensee performed these activities, the inspector should determine if the licensee was authorized, and if the licensee implemented appropriate procedures when performing the activities. The inspector may review records of transfer, disposal, shipping and other associated requirements. For Category 1 or 2 sources, special attention should be paid to the often-temporary security arrangements associated with these evolutions. [10 CFR 20.1906; 10 CFR 30.41 and 30.51; 10 CFR 37.47(b); 10 CFR 71.5 and 49 CFR]

Inspectors have identified licensees who re-located self-shielded irradiators or calibrators, licensees who had sources added or replaced into self-shielded irradiators that were types not authorized on the license, or in quantities not authorized on the license. Inspectors have also identified incomplete or incorrect transfer and shipping procedures, usually because these licensees do not perform these activities often enough to understand all requirements.

03.03 RM-3: Surveys for Contamination and Exposure Control

Radiation surveys may be performed to determine exposure levels in adjacent public areas, during routine and non-routine maintenance activities, or as required by license condition. Radiation level surveys should be reviewed for calibrator devices which have open beams during use. The sources used in these devices rarely are identified as leaking so the inspector may not require much time in this area unless the licensee is analyzing their own leak tests. Leak tests are required by license condition and are the most common survey performed of self-shielded irradiator and calibrator devices to confirm the lack of contamination. [10 CFR 20.1501]

- If the licensee analyzes their own leak test samples, observe and discuss their method of analyzing the samples and determining the level of leakage. Observe if appropriate instrumentation, such as gamma counters or gas-flow proportional counters, are available for leak test sample analysis. Discuss with licensee staff how the analytical instrumentation is calibrated. Review a sample of leak test results and survey records to evaluate the typical levels of contamination, how often action levels are exceeded, and the licensee's response to exceeding action levels. See IP 87126 for additional guidance for inspection of analytical instrumentation, or NUREG-1556, Volume 5, Rev.1, Appendix N, "Model Leak Test Program" for additional information. [10 CFR 20.1501(c) and 10 CFR 20.2103]
- If the self-shielded irradiator and calibrator devices possessed require monitoring for radiation levels, observe if appropriate portable instruments (such as a portable survey instrument with a Geiger-Müller (GM) detector, or an ion chamber), and/or area radiation monitoring instruments, are readily available and operable. Observe if staff use instrumentation properly. Perform comparative measurements with portable instruments to determine if instruments are operating correctly. Discuss the licensee's action levels and procedures if action levels are exceeded. [10 CFR 20.1501(c)]
- Observe persons who perform leak tests or other surveys for contamination and exposure control performing or demonstrating those activities. The level of detail of observations, discussions and review of records of surveys and the instrumentation used for these surveys and analyses will depend on the types, forms, and quantities of self-shielded irradiator and calibrator devices actually used, as well as the level of sensitivity necessary for the surveys.

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; and 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 attached to a ratemeter for evaluation of leak test samples for low-energy beta emitters; 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; and incorrect factors provided in software resulting in incorrect results. Inspectors have identified persons performing leak tests incorrectly, usually by sampling an area where leakage would not be found, or who did not perform required surveys or leak tests.

03.04 RM-4: Calibration of Survey Instruments

If the licensee calibrates their own survey instruments, or if the licensee is performing calibration as a service for others, the inspector should review the adequacy of the instrument calibration program. Calibrated instruments are required in order to make good measurements; therefore, it is important to determine if instruments are properly calibrated. If the licensee participates in an accreditation program for the calibration of instruments, this Risk Module may be considered supplemental. Otherwise, the scope of the review of the calibration program will depend on the types of calibrations performed (alpha, beta, or gamma-emitting detectors), the variety of instruments to be calibrated, and the number of instruments that are calibrated by the licensee. [10 CFR 20.1501(c); 10 CFR 20.2103(a)]

- If the licensee calibrates only their own instruments or room monitors, they most likely committed to NUREG-1556, Volume 5 Rev. 1, Appendix I “Radiation Monitoring Instrument Specifications and Model Radiation Survey Instrument Calibration Program” (or a similar appendix in another NUREG-1556 volume. Otherwise, alternate procedures for calibration were approved as commitments in the license. Most licensees who calibrate their own instruments typically are performing calibration of portable GM detectors or ion chambers, for response to gamma radiation from a Cs-137 source. The inspector should confirm that the licensee’s instruments are appropriately and adequately calibrated.
 - The inspector should verify that the licensee possesses a calibration source or device that is appropriate for the radiation to be detected, and the range of radiation levels to be measured.
 - The inspector should verify that the calibrator device and the calibration facility for a gamma field is adequately set up. Instrument calibration procedures included in the NUREG 1556 consolidated license guidance.
 - Minimize beam spread from the calibrator source
 - Prevent or reduce issues related to scatter of radiation back into the primary beam
 - Allow reading of survey instrument radiation levels without requiring staff to be in the beam field
 - If the licensee calibrates instruments for beta or alpha radiation, or for purposes such as surface contamination measurements, the inspector should verify that

appropriate calibration sources are used; and that calibration quantities and conversion coefficients are appropriately used; efficiencies appropriately determined, and other factors such as self-absorption, backscatter, etc. are addressed as needed.

- The inspector should verify that the licensee's standards for calibration are adequate (National Institute of Standards and Technology (NIST) traceable, appropriate for radiations to be detected, etc.), and the licensee's procedures and calculations ensure that instruments are appropriately and correctly calibrated. If the documentation of NIST-traceable standards is not available, the licensee should contact the manufacturer/distributor of the source to determine how it is NIST-traceable.
- 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."
- If the licensee calibrates instruments as a service for others, the licensee may have committed to a NUREG-1556 procedure for calibration or may have submitted alternate procedures which were approved as commitments to the license.
 - If the calibration service provider licensee is implementing quality assurance programs that include participation in an accreditation program that provides independent assessments of the capability of the calibrations provided, then the inspector may consider this to be a supplemental area of inspection, or limit the inspection to a review of selected records the results of participation in those programs.
 - If the calibration service provider does not participate in an accreditation program, then the inspector should review the licensee's quality assurance (QA) and quality control (QC) procedures for ensuring that instruments that are calibrated are accurate, consistent, and sufficiently sensitive for measurements to be performed. The inspector should review and discuss with licensee staff the methods and results of in-house assessments of performance of the licensee's calibration programs.

Inspectors have identified licensees who used the manufacturer's instrument efficiency in the licensee's calculations, which are established under ideal conditions and may be significantly different in field conditions; licensees who did not use National Institute of Standards and Technology (NIST)-traceable standards; licensees who did not know how to calibrate instruments used for surface contamination measurements rather than radiation level measurements; and instruments that were repaired incorrectly, affecting the operation of the instrument.

03.05 RM-5: Assessment of Dose to Workers and the Public

The typical activities with self-shielded irradiators result in doses less than 10 percent of limits for workers or the public; therefore, this risk module may be considered a supplemental area of inspection for self-shielded irradiators. The typical activities with calibrator devices may result in doses that require monitoring. For either type of device,

specialized activities and incidents or events, may cause doses that require external monitoring. Internal monitoring is rarely a concern with such devices unless significant leakage occurs. 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. [10 CFR Part 20, Subpart C]

- If applicable, observe how radiation workers use the dosimeters and where they are stored.
- If applicable, 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 deliberate exposure of dosimeters using the licensed devices. In addition, 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 radiation surveys or assessments of incidents.

03.06 RM-6: Management Oversight

A typical program using self-shielded irradiators and calibrator devices 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 for use of the devices; training of users of the self-shielded irradiators and calibrator devices; responding to events with self-shielded irradiator and calibrator devices; 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 1) the licensee's organization and management of the persons who implement the radiation protection program and the persons who use and store self-shielded irradiator and calibrator devices; 2) the level of involvement of licensee management in oversight of the radiation protection program; and 3) the relationship and authority between the RSO, and the authorized users, radiation workers, and licensee management.
- 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 provides adequate training; seeks out areas for improvement; responds to events; takes corrective and preventive actions; and implements improvements. [10 CFR 19.12]
- The inspector should review all the annual radiation program reviews for at least the past 3 years and discuss the licensee's activities that support the annual review of

the radiation protection program. The inspector should review other licensee audits or assessments used 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. [10 CFR Part 20, Subpart M; 10 CFR 30.50]

Inspectors have identified licensees who were unaware of various reporting requirements and did not report required incidents or events.

87143-04 RESOURCE ESTIMATE

The length of time necessary for this inspection will depend on the number and location of such devices, but typically may take about 2 to 4 hours for inspection of a single device at one location that is used by only a few radiation workers, not including the time necessary for inspection of security under 10 CFR Part 37, if applicable (see IP 87137). If the licensee calibrates instruments, an additional 2 to 4 hours may be required to inspect the adequacy of the calibration program, depending on the variety of instruments and sources used in the calibration program.

87143-05 REFERENCES

- NCRP Report No. 112, "Calibration of Survey Instruments Used In Radiation Protection for the Assessment of Ionizing Radiation Fields and Radioactive Surface Contamination (1991)
- Safety Report Series No. 16, "Calibration of Radiation Protection Monitoring Instruments, IAEA Safety Series, 2000
- ASTM E181-17 "Standard Test Methods for Detector Calibration and Analysis of Radionuclides" June 1, 2017

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 87143

Appendix A: Additional Inspection Elements

87143A-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.

87143A-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.

87143A-03 GUIDANCE

03.01 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 equipment within the equipment manufacturers or industry consensus operational limits. Such limits may include temperature, humidity, vibration, or radiological considerations. For many self-shielded irradiators, the weight of shielding limits the locations where such devices may be used or stored. 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. For example, licensees have cleaned sealed sources with harsh or acidic solutions, resulting in release of licensed materials from foil or plated sources.
- 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 licensees' 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.

03.02 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.

The inspector should review: the licensee's hazardous material training; packages and associated documentation; vehicles (including placarding, cargo blocking, and bracing, etc.); shipping papers; and any incidents reported to Department of Transportation (DOT). Verify that the licensee's procedures and documentation are sufficient to ensure that licensed material is transported in accordance with 10 CFR Part 71 and DOT regulations for transportation of radioactive materials.

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

03.03 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).

03.04 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.

03.05 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.

03.06 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. Interview workers, other than operators, to verify that, pursuant to 10 CFR 19.12, 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). Individuals should understand the radiation protection requirements associated with their assigned activities. 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.

If any concerns are identified regarding the level of knowledge of staff, examine records of training and attendant examinations or tests (if applicable) to the extent that the inspector is satisfied that the training program is being implemented as required. Where examinations are required, read a few of the examination questions to ascertain that they are indicative of what the worker should know to carry out responsibilities.

- 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.

03.07 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.

- 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."
- 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).
- 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. The inspector may make arrangements to observe the next biennial emergency plan drill and/or exercises.
- 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.

03.08 Posting and Labeling

- 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. When applicable, the inspector should also examine signals and alarms to determine proper operation. The inspector should also selectively observe the labeling on packages or other

containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

- 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. 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.
- 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.

03.09 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 87143

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	ML22053A100 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	ML22053A101