

NRC INSPECTION MANUAL

MSLB

INSPECTION PROCEDURE 87122

10 CFR PART 36 – PANORAMIC DRY-SOURCE-STORAGE, PANORAMIC WET-SOURCE-STORAGE, AND UNDERWATER IRRADIATOR PROGRAMS

Effective Date: January 29, 2024

PROGRAM APPLICABILITY: IMC 2800

87122-01 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.

87122-02 INSPECTION REQUIREMENTS

This inspection procedure (IP) contains the standard requirements and guidance for inspecting the operation of irradiators subject to the safety requirements in 10 CFR Part 36. These requirements are not applicable to self-contained, dry source storage irradiators, such as those found at hospital blood banks or research institutions, nor are they applicable to irradiators for which dose rates do not exceed 5 gray (500 rad) per hour at 1 meter from the sealed source(s). For inspection guidance related to these irradiators, see IP 87143, "Self-Shielded Irradiator and Calibrator Devices." For inspections of panoramic irradiators under construction, see, Inspection Manual Chapter (IMC) 2815, "Construction and Preoperational Inspection of Panoramic, Wet Source Storage Gamma Irradiators."

Irradiators subject to the requirements of 10 CFR Part 36 typically contain radioactive material quantities of concern, and therefore are subject to the additional security requirements in 10 CFR Part 37. Inspections of these irradiators should always include a review of the licensee's implementation of its access authorization and physical security programs. For guidance on evaluating these programs, see IP 87137, "10 CFR Part 37 Materials Security Programs."

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 should be based on direct observation of irradiator use, interviews with operators, demonstrations by operators performing tasks regulated by NRC, independent observations of equipment condition and 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. If issues are identified, the inspector may refer to appendix A of this procedure for additional areas that may merit inspection.

Irradiators containing radioisotopes such as cobalt-60 require regular source loading and exchanges to maintain desired radiation output. These evolutions carry added risk because of the need to temporarily defeat security measures, safety interlocks, and other controls to permit the removal and installation of sources and other non-routine maintenance. As such, inspectors should consider scheduling the routine inspection or a special inspection during the review period to coincide with a source exchange to ensure that these evolutions receive oversight commensurate with the risk.

Because of system complexity, performance concerns at irradiators often require more extensive review than at other licensees when determining root causes, contributing factors, safety significance and extent of condition. If the licensee's main office is in an Agreement State, the NRC inspection may include the main office location to review its oversight and implementation of the irradiator safety and security programs. The inspector should determine whether a site visit to the main office is necessary to complete the inspection. If an inspection to the main office is necessary, the inspector should notify the Agreement State prior to conducting the inspection, and the inspection should be limited to the NRC licensed activities that have occurred in NRC jurisdiction. If the inspector notices an apparent violation of Agreement State licensed activities, the inspector (1) should immediately inform the licensee and (2) promptly notify the Agreement State through the Regional Agreement State Program Officer.

The structure and the emphasis of the inspection should be on the following risk modules that describe the outcomes of an effective radiation safety program for an irradiator subject to 10 CFR Part 36. Risk modules (RMs) are defined as components in the inspection procedures used to focus the inspection effort on: (1) licensed activities that present higher risk for a particular licensee type, and/or (2) radiation safety program areas that are expected to effectively reduce the risk associated with the use of radioactive material. 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 appendix A to this inspection procedure. These additional elements are not required to be reviewed as part of a risk-informed inspection approach but may be reviewed if the inspector has additional time, if the additional elements are related to safety issues identified in the RMs, or if multiple violations were identified through review of the following RMs.

02.01 RM-1: Shielding and Exposure Control

Verify the licensee utilizes adequate security measures, shielding, radiation monitoring and other engineering and procedural controls to monitor for and minimize radiation exposures and the possibility of contamination during normal operations.

02.02 RM-2: Access and Movement Control

Verify the licensee utilizes adequate engineering and procedural controls to limit access to and control the movement of sources.

02.03 RM-3: Equipment Maintenance

Verify the licensee inspects required equipment at appropriate intervals and maintains this equipment in an operable condition.

02.04 RM-4: Response to Abnormal Conditions

Verify the licensee has developed and implements adequate procedures for abnormal events and emergencies involving irradiators and has effectively trained its staff on responding to these events.

02.05 RM-5: Source Exchanges

Verify the licensee maintains and utilizes adequate compensatory measures to ensure the safety of staff and contractors and the security of material while loading or exchanging irradiator sources.

In reviewing the licensee's performance, the inspector's evaluation should examine the licensee activities from the date of the previous inspection. However, issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, repetitive violations, or excessively high radiation exposures.

87122-03 INSPECTION GUIDANCE

General Guidance

The following inspection guidance is designed to assist the inspector in evaluating the performance of an irradiator licensee's radiation safety program. The guidance is organized by the individual RMs 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.

Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Verification should use a performance-based, risk-informed approach and be accomplished through discussions, observations, and demonstrations with qualified licensee staff. An examination of the licensee's records should not be considered the primary part of the inspection effort. For example, observations of operations in progress, equipment, and facilities will be a better indicator of the licensee's overall radiation safety program than a review of records. The inspector should selectively examine records demonstrating compliance with periodic requirements (such as instrument calibration certificates, inspection and maintenance checks and training attendance records) until the inspector is satisfied that the required records are maintained, and that the licensee tracks and maintains compliance effectively. Other records that are more closely related to health and safety and security (such as personnel dose monitoring records and reports of major malfunctions and operating problems) should be examined in detail with qualified licensee staff.

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, the evaluation of program scope and

any special license conditions. Specific guidance regarding these common elements can be found in IMC 2800.

Each of the following elements should be reviewed, as appropriate, during each inspection of an operational irradiator licensee.

Specific Guidance

03.01 RM-1: Shielding and Exposure Control

Irradiators contain very large quantities of radioactive material and exposures to unshielded sources can be lethal. It is therefore of critical importance that irradiator facilities are built and maintained in a manner that minimizes and monitors for radiological hazards. Inspectors should prioritize independent evaluations of radiation shielding, demonstrations of area monitoring capabilities, and the conduct of periodic surveys to ensure that occupational and public doses are ALARA.

a. Radiation shielding

Inspectors should conduct thorough independent surveys of restricted and unrestricted areas of the licensee's facility to confirm the continued adequacy of irradiator shielding, with special emphasis on areas where shielding may be less robust such as directly above the irradiation room, areas where ducting or wireways pass through shielding, edges of walls and doors where shielding meets and/or overlaps, and any areas where cracks or other defects are visible in walls. While performing these surveys, inspectors should note any changes or modifications that the licensee may have made to its facility without prior NRC approval.

In addition to the public dose limits in 10 CFR Part 20.1301, dose rates in restricted areas are further limited by 10 CFR 36.25 as follows:

- Dose rates may not exceed 2 millirems per hour at:
 - Any normally occupied location 30 cm or more from the wall of a room where exposed irradiator sources are present
 - 30 cm over the edge of a pool at an underwater irradiator with sources in the fully shielded position
 - 1 m from the shield of a dry source storage panoramic irradiator
- Dose rates may not exceed 20 millirems per hour at 5 cm from the shield of a dry source storage panoramic irradiator.

Any area where dose rates exceed 2 millirems per hour (regardless of occupancy) must be locked, roped off, or posted.

b. Area monitoring and periodic surveys

Per 10 CFR 36.57, irradiator licensees are required to perform their own surveys at specified intervals with survey meters calibrated at least annually. Consider asking the licensee to perform confirmatory surveys of the facility as well to assess the operability and adequacy of their instruments as well as the proficiency of their personnel in

performing their own surveys. Records of the licensee's surveys should be reviewed if independent or confirmatory surveys identify any abnormal readings, to determine the extent of condition.

In addition to this periodic radiation monitoring, some irradiator licensees are also required by 10 CFR 36.29 to maintain continuous radiation monitoring capabilities. For underwater irradiators, this includes a radiation monitor over the pool to detect abnormal radiation levels. For panoramic irradiators, this includes a monitor to detect radiation levels in the radiation room before personnel entry. For irradiators with automatic product conveyor systems, this also includes a monitor to detect loose radioactive sources that may be carried towards the product exit.

Request that the licensee demonstrate the operability these monitors, if required and present, using a check source or other test method to verify their functionality.

c. Sealed source leak testing and pool water quality

To further limit exposure to radiation in unrestricted areas, irradiator licensees are required by 10 CFR 36.59 to implement measures for detection of leaking sealed sources. Similar to other leak test requirements, an irradiator source is considered leaking if more than 200 becquerels (5 nanocuries) of activity is detected. Sources in dry storage irradiators must be leak tested at intervals not to exceed six months. Inspections of this area should focus on the collection of these leak tests, with special attention on the efficacy of the collection methods and ALARA practices implemented while in proximity of the irradiator.

Anyone who possesses a sealed source can collect a leak test sample, however one must be specifically authorized to analyze them. If the licensee analyzes its own leak tests, refer to appendix M of NUREG-1556, Volume 6, which describes a model leak test program for dry-source storage irradiator sealed sources that licensees can incorporate into their radiation safety program by reference. Regardless of who analyzes them, records of these tests can be reviewed but should normally be limited to confirming that the source(s) are current on their leak tests and that the licensee's tracking mechanisms include leak testing at the required frequency.

Sources in pool irradiators must be leak tested in the above manner within 6 months before being transferred to the licensee. Once in the pool, however, licensees are not required to leak test each individual source. Instead, they must monitor the pool water for contamination each day that the irradiator operates. This monitoring may be done either by using a radiation monitor on a pool water circulating system or by analysis of a pool water sample. Inspectors should request that the licensee demonstrate the operability of their pool water radiation monitor, if present, using a check source or other test method to confirm its required functionality. Otherwise, inspectors can request that the licensee demonstrate the implementation of its procedure for pool water sample collection and analysis, with emphasis on the adequacy of radiation detection instrumentation. This procedure, as well as the licensee's procedures for response to the detection of a leaking source and/or pool water contamination, must be part of the licensee's operating and emergency procedures. Note that remediation of leakage and/or contamination is generally considered a non-routine operation for irradiator licensees and as such requires prior approval from the NRC to perform.

03.02 RM-2: Access and Movement Control

It is also of critical importance that irradiator facilities are operated in a manner that minimizes radiological risk to workers. Inspectors should prioritize observations of the proper functioning of irradiator access and source movement controls and evaluate circumstances when those controls could be bypassed.

a. Function of personnel access controls

Inspectors should always request that irradiator licensees demonstrate the operability a selection of access controls to confirm their required functionality. Inspectors should be considerate of but should not feel unduly constrained by licensee production or operations when reviewing this risk module. If the licensee expresses concern about the impact of these demonstrations, consider planning this part of the inspection to coincide with regularly scheduled preventative maintenance checks, shift changes, operator breaks, or other down time.

If it is not possible to observe functional testing of these or other controls, inspectors should instead interview the operators who perform them and ask that they step through the accompanying procedures and/or checklists. Inspectors should then also review an expanded selection of records of preventative maintenance (see RM-3).

For panoramic irradiators:

- Each entrance to the radiation room must have a door or other physical barrier to prevent inadvertent entry of personnel if sources are not in the shielded position.
 - Product conveyor systems may serve as barriers if they reliably and consistently function as one (for example: totes that continuously occupy the entrance and exit during operation, or a door which closes between tote movements).
 - It must not be possible to move the sources out of their shielded position if the door or barrier is open.
 - Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position.
 - The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources.
 - The doors and barriers must not prevent an individual inside the radiation room from leaving.
- Each entrance to the radiation room must have an independent backup access control to detect personnel entry while the sources are exposed.
 - Detection of entry must cause the sources to return to their fully shielded position.
 - Detection of entry must activate a visible and audible alarm to make the individual entering the room aware of the hazard. It must also alert at least one

other individual who is on-site, trained to respond, and prepared to promptly render or summon assistance.

- The radiation monitor described in RM-1 that detects levels in the radiation room before personnel entry must be integrated with the personnel access door locks to prevent room access when radiation levels are high.
 - The monitor must activate the alarm mentioned in the bullet above if personnel attempt to enter while radiation levels are high (i.e., when sources are not in their fully shielded position)
 - The monitor may be in the maze but may not be in the direct radiation beam.
- Before the sources are moved from their shielded position, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position, with enough time for them to leave the room before the sources move.
- Each radiation room must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position. Normally, this control cuts pneumatic air to the source hoists, and its functionality can be confirmed with sources already in their shielded position by confirming that air is indeed cut. Under no circumstances should this functionality be checked by having an individual remain in the radiation room during startup or operation of the irradiator.
- If the radiation room has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location (this can be done via interlocks or via startup procedure). The function of this interlock is most effectively confirmed during a source reloading.

Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to this barrier's keys, and unauthorized entry with the barrier locked must activate an intrusion alarm who will alert an individual prepared to respond or summon assistance. This individual does not necessarily need to be on-site.

b. Function of movement controls

Inspectors should also request that the licensee demonstrate the operability a selection of panoramic irradiator movement controls to confirm their required functionality. It is important to remember that these and other controls have been incorporated into regulations due to past incidents in which these features were not present or were bypassed (see next section).

- The mechanism that moves the sources must require a key to actuate.
- Only one key may be in use at any time, and only operators or facility management may possess it.
- The key must be attached to a portable radiation survey meter by a chain or cable.

- The lock for the source control must be designed so that the key may not be removed if the sources are in the unshielded position.
- The door to the irradiation room must require the same key.
- Actuation of the source movement mechanism must cause an audible signal to indicate that the sources are leaving the shielded position.
- The console must indicate when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.
- The control console must have a control that can promptly return the sources to the shielded position.
- Each control must remain clearly marked as to its function.

c. Bypassing interlocks and controls

Regulations in 10 CFR Part 36 require access controls to prevent inadvertent entry of personnel if irradiator sources are not in a shielded position but does not address the deliberate defeat of interlocks in order to effect repair of systems inside the irradiator causing the interlocks to prevent entry. Such actions, while not necessarily prohibited, can and have posed grave risks to operators who inadvertently entered an irradiator room while sources were not fully shielded.

As part of their interviews with irradiator operators, inspectors should determine the extent to which the licensee has defeated or otherwise bypassed interlocks for any reason, such as to effect repairs of the irradiator. Each instance should be carefully reviewed to determine the reason for the bypass and to evaluate the licensee's response. If the licensee has procedures or established practices for bypassing interlocks, inspectors should also review these to determine if they are adequate to protect workers from radiation exposure.

Through these interviews, inspectors should also evaluate operators' knowledge and understanding of the functions and limitations of irradiator safety equipment, particularly the access and movement controls and methods to verify radiation levels inside the irradiator. Operators should have a method of determining the position of the source rack and radiation levels inside the irradiator other than use of a portable survey meter during entry. Operators should also have a clear understanding of events that would require them to implement emergency response procedures rather than normal operating procedures.

03.03 RM-3: Equipment Maintenance

Irradiator operations rely on a variety of required safety equipment to minimize radiological risks, and licensees must inspect and maintain this equipment periodically. Inspectors should prioritize independent evaluations of safety equipment and observations or demonstrations of required equipment checks.

a. Condition of required equipment

In addition to previous observations of the condition and function of monitoring systems, access controls, and movement controls, inspectors should also evaluate the condition and operability of additional safety-related equipment against the design and performance requirements of 10 CFR 36, subpart C, while touring the licensee's facility and observing irradiator operations or demonstrations. Examples include, but are not limited to:

- Inspect the source rack and sources, with attention warped source rods, physical damage from drops or collisions with product, and corrosion which could suggest poor water quality. Confirm that all latches and other mechanisms to keep the sources in place or in racks are present and secure.
- Inspect the hoists and cables for lifting source racks (or for lowering product), with attention to the amount of wear on the cables. Discuss with licensee staff the rate of cable wear and frequency of replacement. The use of incorrect grease has been known to accelerate cable wear.
- If the irradiator has a product conveyor system, inspect the barrier or guides that prevent the product from touching the source rack for damage, which could suggest improper re-installation of the barrier, a deformed tote, or a malfunctioning conveyor system.
- Confirm that the irradiator pool has a physical barrier such as a railing or cover in place to prevent personnel from accidentally falling into the pool during normal operations. This is often removed for source exchanges but must be re-installed prior to operation.
- Check the bottom of the pool and surface of the pool water for debris, which could suggest problems with the water handling system. Confirm that a visible indicator is used to clearly show when pool water level is below the normal low level or above the normal high levels.
- Inspect the pool water handling system and confirm that:
 - The system maintains water conductivity at 20 microsiemens per centimeter or less.
 - The system maintains water clarity so that sources can be seen clearly.
 - Leaks from the system are minimized, but if present do not drain to unrestricted areas without being monitored.
- Inspect a selection of electrical wiring and equipment in the radiation room to check for damage from prolonged irradiation. The licensee must be able to verify that this equipment was selected to minimize failures from such exposure.
- Confirm that the heat and/or smoke detectors in the irradiation room of a panoramic irradiator activate an audible alarm by asking the licensee to demonstrate their functionality.

- Inspect the irradiator console to confirm that all required lights, indicators, and controls are operable, and that none are damaged, covered up or bypassed.

b. Inspection and maintenance checks

Irradiator licensees are required to perform a series of inspection and maintenance checks as outlined in 10 CFR 36.61. The frequencies of these checks are not specified in the regulations because the checks are governed by the irradiator and the facility's specific design and operation. Instead, licensees are required to develop and commit to frequencies that will be specified in their license, application, or renewal.

It's important to note that these are the minimum set of items that need to be checked, and that the irradiator manufacturers may recommend or require additional checks such as for product positioning and movement components to help minimize the likelihood of irradiator malfunctions.

Ideally, inspectors should observe operators and other staff perform inspection and maintenance checks that occur as scheduled during the routine inspection. If no such checks are scheduled to occur during the inspection, request demonstrations and interviews as per the guidance in RM-2 for access and movement controls.

Inspectors should always consider reviewing a selection of records related to inspection and maintenance checks. The primary objective of this review should be to confirm the licensee's overall ability to track and perform the required maintenance at the committed frequencies. The size of the selection should be informed by sophistication of the licensee's tracking mechanisms, but also by the observations and demonstrations already made and any performance concerns that may have arisen. For example, records of checks that were not observed or discussed should be prioritized for review, as should any checks in which operators demonstrated a lack of competency.

Utilization logs kept at the irradiator console should also be evaluated as part of this review with attention to equipment issues and any adverse trends in irradiator operation. These logs can also be evaluated to provide additional confirmation that the checks were performed at the required frequencies, if for example the record for a specific instance of a check cannot be located.

03.04 RM-4: Response to Abnormal Conditions

Because of the severity of potential consequences of malfunctions, operating problems and emergencies involving irradiators, it is also very important that licensees develop and implement adequate emergency procedures to minimize the likelihood and severity of radiological consequences. Inspectors should prioritize observations of the response to any abnormal conditions that occur during an inspection and interview operators to evaluate their understanding of and adherence to procedures and radiation safety best practices. Refer to NUREG-1345 for more information on notable abnormal events that have occurred at irradiator facilities.

a. Past or ongoing incidents

Inspectors should always inquire during the inspection entrance meeting or other initial conversations with licensee staff as to whether any incidents involving the irradiator have occurred since the last inspection. In addition to the reporting requirements of in Parts 20, 30, and 37, irradiator licensees must also report the following per 10 CFR 36.83:

- a source stuck in an unshielded position
- any fire or explosion in a radiation room
- damage to the source racks
- failure of the cable or drive mechanism used to move the source racks
- inoperability of the access control system
- detection of radiation source by the product exit monitor
- detection of radioactive contamination attributable to licensed radioactive material
- structural damage to the pool liner or walls
- abnormal water loss or leakage from the source storage pool
- pool water conductivity exceeding 100 microsiemens per centimeter

These incidents must be reported in the same manner as safety equipment failures subject to 10 CFR 30.50, i.e., by telephone within 24 hours and a written report within 30 days.

If any of the above have occurred (whether reported or not), carefully review the circumstances of the incident, the licensee's root cause analysis and their corrective actions. Inspectors should interview staff involved in the incident and perform an independent root cause analysis to confirm that the licensee's corrective actions were adequate and effective at preventing the recurrence of similar incidents.

If an incident or other abnormal condition occurs during the inspection, the inspector should pause all routine inspection activities and allow the licensee and its staff to respond without encumbrance. The inspector should confirm that they are wearing all required dosimetry, that their survey meter is on (whether audible will depend on the circumstances), and that they minimize potential interference with operators and staff but maintain maximum awareness of local conditions and any instructions from the licensee. Inspectors should not instruct nor advise licensees during this time unless an imminent safety issue becomes apparent that the licensee does not notice. Inspectors should also maintain, to the extent practical, close coordination with NRC management throughout.

b. Operator training, safety reviews and performance evaluations

Through observations of irradiator operations, inspection and maintenance activities, actual or simulated response to abnormal conditions, training activities, and through other discussions and demonstrations, inspectors should always seek to confirm that irradiator operators demonstrate proficiency in:

- fundamentals of radiation protection
- applicable regulatory requirements
- operation of the irradiator
- licensee operating and emergency procedures

Inspectors should also confirm that operators recall receiving instruction in case histories of accidents or problems involving irradiators. Appendix A of NUREG-1556, Volume 6, includes a list of NRC Information Notices on irradiator events.

In addition to receiving training on these topics, individuals must also pass a written test and must have received on-the-job training or simulator training in the use of the irradiator and must demonstrate the ability to implement relevant portions of the licensee's operating and emergency procedures before being allowed to operate an irradiator without supervision.

Licensees must also conduct safety reviews and performance evaluations for each irradiator operator at least annually, as described in their license or renewal application. The safety review must include, along with information required by 10 CFR 36.51(d), an emergency drill and a written test on the information presented. The safety performance evaluations, which need not be concurrent with safety reviews, must ensure that each operator follows regulations, licensed conditions, and operating and emergency procedures during their duties. Licensees must discuss the results of these evaluations with each operator, along with instructions on how to correct any mistakes or deficiencies.

Inspectors may consider attending licensee training sessions to confirm the required information is included and effectively communicated to attendees, observing on-the-job or simulator training, and observing or requesting a demonstration of a safety performance evaluation. Documentation of training, including slides and other content, results of performance evaluations, written tests, and records of attendance can be sampled to confirm that the licensee provides training to all operator at the required frequencies. Attention should also be paid to the results of performance evaluations and how the licensee communicates and addresses these results.

c. Operating & emergency procedures

Licensees are required to have and follow operating and emergency procedures that include the various radiation safety aspects in 10 CFR 36.53. Licensees must include an outline of these procedures in their license (or renewal) application which describes these aspects. Licensees may thereafter revise these procedures without prior NRC approval, but only if the conditions of 10 CFR 36.53(c) are met.

Inspectors should confirm that the licensee makes current versions of its operating and emergency procedures readily available to irradiator operators, either by posting copies of the procedures at its facilities, or by clearly posting a notice of where to find the procedures. Inspectors should also review any changes that the licensee has made to its procedures to confirm that they have been approved by the NRC or otherwise meet the conditions of 10 CFR 36.53(c).

03.05 RM-5: Source Exchanges

Source loadings and exchanges carry added risk for irradiator operations and other personnel because of the need to temporarily defeat security measures, safety interlocks, and other controls to permit the removal and installation of sources and other non-routine maintenance. Inspectors should consider observing these activities when possible (even if during a subsequent inspection), to evaluate the licensee's compensatory measures and source handling and accountability practices.

a. Compensatory measures

To accommodate movement of large shipping casks, manipulation of sources, and other non-routine maintenance during a reload, the licensee may need to perform one or more of the following:

- possess licensed material in shipping casks outside of the irradiation room
- remove the roof plug in the irradiation room
- remove pool barriers
- prop open personnel access doors
- remove shipping totes which may have otherwise served as barriers to the irradiation room via the product maze
- bypass pool water level alarms and makeup pumps to accommodate casks in the pool
- defeat any other interlock to permit repairs on associated components

Inspectors should start their inspection of a source exchange before it begins to evaluate the licensee's considerations and preparations for compensatory measures. Inspectors should thereafter remain vigilant that the licensee maintains these measures (notably, those for security) while established measures are bypassed.

b. Source handling

The handling of sources during a loading or exchange are considered non-routine operations and must be performed by entities specifically licensed to do so. In most cases, the irradiator or source manufacturer dispatches field service personnel to perform this work using specialized equipment to handle sources.

Inspectors should prioritize observing the handling of irradiator sources to confirm that authorized personnel are knowledgeable, utilize adequate ALARA practices, wear appropriate dosimetry as required, and use radiation survey instruments as necessary. These observations may constitute a separate inspection of the entity specifically licensed to perform the work.

For pool irradiators, sources are typically manipulated using several specialized long-handled tools that are lowered into the pool and operated from the surface to enable movement of sources below a considerable depth of water (10 to 20 feet). These tools are typically made of aluminum for lightness, with hollow cores to allow water in for shielding. Regardless of construction, 10 CFR 36.33(g) limits the dose rate on contact with such tools to 2 millirems per hour. The tools should also be long enough so that if an individual were to attempt to lift a source out of the pool entirely with them, the wall or ceiling of the irradiation room would interfere and prevent that from happening.

For dry-source storage irradiators, sources are typically manipulated using transfer casks that are carefully mated to the irradiator to allow sources to be remotely passed from the irradiator directly to the transfer cask, which is then carefully mated to the

shipping cask to allow the source to be remotely passed from the transfer cask directly to the shipping cask. Careful planning and procedural adherence are critical to ensure that the potential for direct exposure to an unshielded source is minimized for these manual operations.

c. Source receipt, transfer, and accountability

Source exchanges can involve numerous manipulations of sources, especially at panoramic irradiators where sources are often added, moved, and removed to ensure an even dose distribution for product irradiation. Licensees often assign an operator or other knowledgeable staff to oversee and confirm every source movement.

Inspectors should ensure that the licensee's measures for source receipt, transfer, and accountability carefully account for all material added to and removed from its inventory of licensed material. In addition, inspector should confirm that all sources put into a pool irradiator have been tested for leakage by the licensee beforehand or by a transferor within 6 months of the transfer.

In addition to physically checking individual sources for contamination prior to shipment, irradiator or source manufacturers will typically flush transport casks containing sources with distilled water upon delivery and filter the steam created upon contact with the high-activity sources. These filters will then be measured for contamination prior to the sources being transferred to the irradiator licensee.

87122-04 RESOURCE ESTIMATE

Inspections of radiation safety programs for irradiator operations typically take a full day or 8 hours, not including a review of access authorization and physical security programs under IP 87137. Reloading activities at irradiator facilities typically warrant 1 to 2 days of additional effort.

87122-05 REFERENCES

A listing of IMCs and IPs, applicable to the inspection program for materials licensees, can be found in IMC 2800. These documents are to be used as guidelines for inspectors in determining the inspection requirements for operational and radiological safety aspects of various types of licensee activities.

END

Appendix:

Appendix A: Additional Inspection Elements

Attachment:

Revision History for IP 87122

Appendix A: Additional Inspection Elements

87122A-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.

87122A-02 BACKGROUND

Risk modules (RMs) are defined as components in the inspection procedures used to focus the inspection effort on: (1) licensed activities that present higher risk for a particular licensee type, and/or (2) radiation safety program areas that are expected to effectively reduce the risk associated with the use of radioactive material. 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.

87122A-03 GUIDANCE

03.01 Criteria for Radiation Detection Instrumentation

Irradiator licensees are expected to commit to the criteria in NUREG-1556, Volume 6, section 8.10.2, for survey instruments and radiation monitors.

In addition to these criteria, Part 36 requires that portable (i.e., hand-held) radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates. These meters must be calibrated at least annually to an accuracy of ± 20 percent for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used.

03.02 Personnel Monitoring

a. Personnel dosimetry

Operators must wear personnel dosimeters capable of detecting high energy (i.e., 1-2 MeV) photons in normal and accident dose ranges while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. Film badges must be replaced and evaluated (i.e., read) at least monthly. Other dosimeters that require replacement must be replaced at least quarterly and evaluated promptly after replacement. Other dosimeters that do not require replacement must be evaluated at least quarterly.

Dosimeters that measure deep dose should be worn on the trunk of the body (i.e., between belt and neck) for the most accurate measure of this dose. Dosimeters that measure shallow dose should be worn with the active portion of the detector facing the radiation source to avoid undercounting this dose by self-shielding the dosimeter.

b. Direct reading dosimeters

Other individuals who enter the radiation room of a panoramic irradiator must wear a dosimeter, which may be an ion chamber or electronic pocket dosimeter. For groups of visitors into these areas, only two people in the group are required to wear one.

Dosimeters used to meet these requirements must be checked for their response to radiation within $\pm 30\%$ of true radiation dose.

Since these dosimeters measure deep dose, they should be worn on the trunk of the body as well.

03.03 Comprehensive Safety Measures

a. Irradiating explosive or flammable materials

Irradiation of explosive materials and more than small quantities of flammable material with a flash point below 140 °F is prohibited under 10 CFR 36.69, unless a licensee has received prior, written authorization from the NRC. See NUREG-1556, Volume 6, appendix D for additional information on the topic.

b. Ozone

The inspector should be aware of the potential health hazard of ozone within the radiation facility. Irradiators with large sources are typically equipped with ventilation systems to exhaust ozone (and nitrogen oxides), produced by irradiation of air. Such facilities could be expected to also have operative ozone monitors as well as procedures to restrict access of personnel to areas when ozone concentrations exceed limits established by the Occupational Safety and Health Administration (OSHA). Also, note that ozone can be detected by odor at a concentration which is 15 percent of the OSHA concentration limit; ozone odor does not necessarily indicate that an air concentration of ozone warranting concern is present. Concerns in this area should be referred to OSHA.

03.04 Management Oversight

a. Licensee Management and Radiation Safety Staff

All licensees are responsible for developing their own radiation safety programs and are accountable for the actions of all personnel and contractors who implement them. It is therefore essential that licensees maintain strong management control and oversight of these programs to provide reasonable assurance to the NRC of the ongoing protection of the health and safety of workers and the general public, and of sustained compliance with regulatory requirements.

Panoramic irradiator licensees, like all other specific licensees, must appoint a RSO who agrees to oversee the ongoing implementation the radiation safety program. Senior management should provide the RSO with adequate time, resources, and support to fulfill this assignment, and with the authority, organizational freedom, and managerial prerogative to direct personnel as it pertains to the safe and secure use of licensed material, and to terminate any such use that the RSO deems unsafe.

The RSO may delegate certain aspects of the radiation safety program to other individuals who may not be approved by the NRC or named on a license. Panoramic

irradiator licensees, for example, may delegate the conduct of required inspection and maintenance checks to plant staff responsible for all preventative maintenance on-site. Such delegation may be on a temporary or ongoing basis; in either case, the RSO is still responsible for the oversight provided by these delegates.

- Interview senior managers whose responsibilities include the radiation safety program to discuss their awareness of and involvement in the program. Specific areas of management focus should include significant events, audit findings and other performance issues, the adequacy of resources committed to the program, and open and timely communications with the NRC. Indicators of strong management control and oversight include but are not limited to:
 - An awareness of and commitment to a positive safety culture within the organization
 - The consistent implementation of radiation safety best practices across the organization
 - Thorough self-assessment and corrective action mechanisms
- Interview radiation safety staff to discuss their duties, with emphasis on confirming a high level of understanding of radiation protection principles, regulatory requirements, and the scope and status of the program. These staff should feel comfortable and confident with the time resources and support given to them by management to implement the program.

Common Required Communications with the NRC

- changes requiring a license amendment
- transferring control of the license
- voluntary or involuntary bankruptcy
- discontinuing all licensed activities
- decommissioning certain facilities
- reportable incidents
- manufacturing defects in safety-related equipment
- responding to select generic communications

b. Audit Activities

Irradiator licensees are responsible for the continuing effectiveness of their radiation safety program, as well as their access authorization and physical security programs. At a minimum, licensees must review the content and implementation of these programs at least annually. A comprehensive example audit checklist is available in appendix E to NUREG-1556, Volume 14, to assist licensees in meeting this requirement for radiation safety programs.

Licensees may audit their own programs; however, even a modest measure of independence, such as having a senior manager perform the audit, can enhance the efficacy of these reviews. Some licensees may even hire knowledgeable outside consultants to review their programs.

- Observe or ask for demonstrations of audit activities. Note that some activities may include observations of employee job performance, area surveys, etc. that are congruent with activities discussed in other sections of this procedure.

- Interview radiation safety staff and other personnel (including contractors) involved in audit activities to discuss the overall status of the radiation safety program, and any recent findings they may have identified or been made aware of. Individuals overseeing and auditing the program should be familiar with the scope, status, and nature of licensed activities, and demonstrate a commitment to proactive and ongoing self-improvement of safe operations, rather than waiting for annual audits or periodic regulatory inspections to identify and/or address issues.
- Review documentation of audits and other program reviews completed since the last inspection. The review should identify and thoroughly describe any conditions that negatively impact the program, the cause of the conditions, and any corrective actions recommended or taken, including those necessary to preclude repetition of the condition. These reviews should also include a reassessment of adverse conditions identified in previous reviews.
- Sample a selection of records and/or tracking mechanisms (if any) relating to the completion of periodic requirements to independently confirm the adequacy of the licensee's audits and the effectiveness of its routine oversight of the program. Some periodic requirements applicable to panoramic irradiators include, but are not limited to:
 - inspection and maintenance checks
 - sealed source leak tests for dry source storage irradiators
 - pocket dosimeter and portable radiation survey meter calibrations
 - pool water conductivity meter calibrations
 - annual occupational exposure notifications
 - annual safety reviews and performance evaluations for irradiator operators

If the inspector identifies a deficiency, such as the non-timely completion of a periodic requirement, the scope of their review for that aspect should be expanded to determine whether the issue is isolated or has programmatic significance.

03.05 American National Standards Institute (ANSI) Irradiator Categories

- Category I – Self Shielded Irradiator (ANSI N43.7)

An irradiator in which the sealed source is completely contained in a dry container constructed of solid materials, the sealed source is shielded at all times, and human access to the sealed source and the volume undergoing irradiation is not physically possible in its designed configuration (see IP 87143).

- Category II – Dry Source Storage (ANSI N43.12)

A controlled human access irradiator in which the sealed source is contained in a dry container constructed of solid materials, and the sealed source is fully shielded when not in use; the sealed source is exposed within a radiation volume that is maintained inaccessible during use by an entry control system.

- Category III – Underwater Irradiator (ANSI N43.15)

An irradiator in which the sealed source is contained in a storage pool (usually containing water), the sealed source is shielded at all times, and human access to the

sealed source and the volume undergoing irradiation is physically restricted in its designed configuration and proper mode of use.

- Category IV – Wet Source Storage Irradiator (ANSI N43.10)

A controlled human access irradiator in which the sealed source is contained in a storage pool (usually containing water), and the sealed source is fully shielded when not in use; the sealed source is exposed within a radiation volume that is maintained inaccessible during use by an entry control system.

END

Attachment 1: Revision History for IP 87122

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)
	ML030300273 12/31/02 CN 02-047	Issued to assess a licensee's radiation safety program for an irradiator authorized under 10 CFR Part 36 and to replace IP 87112.		N/A
N/A	ML23328A197 12/21/23 CN 23-039	Revised in its entirety. 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	ML23328A167