U.S.NRC

United States Nuclear Regulatory Commission

*Protecting People and the Environment*


# MATERIALS INSPECTION & LICENSING HANDBOOK

**BEST PRACTICES**

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This generic handbook contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U. S. C. 3501 et seq.). These information collections were approved by the Office of Management and Budget, approval number 3150-0011.

The information collections contained in this handbook are covered by the requirements of 10 CFR Part 20, which were approved by the Office of Management and Budget, approval number 3150-0014.

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# MATERIALS INSPECTION & LICENSING HANDBOOK

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# MATERIALS INSPECTION & LICENSING HANDBOOK

## BEST PRACTICES

## PURPOSE



The U.S. Nuclear Regulatory Commission (NRC) developed the Materials Inspection & Licensing Handbook primarily to help new inspectors and reviewers, but the agency also hopes the booklet will assist experienced staff. The materials inspector and reviewer community is extremely diverse and spread out over a large area (four NRC regional offices, NRC Headquarters, 33 Agreement States with additional Agreement States expected). This booklet is modeled on the NRC Inspector Field Observation Best Practices Manual, developed by NRC reactor inspectors, and provides a similar reference for the materials area. The material presented in this handbook was developed by inspectors and license reviewers and includes best practices from all four NRC regions and the Agreement States. The authors compiled this information from individual experiences and suggestions, a review of generic communications, such as information notices, training presentations, and a variety of other sources.

***NOTE: The guidance in this booklet is not intended to be all inclusive or to replace policy or guidance. It is intended to supplement existing inspection procedures, to heighten inspector and reviewer awareness of specific issues, and to improve the effectiveness of materials inspections and licensing. Official policy and guidance are promulgated in NRC's Inspection Manual, licensing guidance, or in appropriate documents issued by individual Agreement States.***


# MATERIALS INSPECTION & LICENSING HANDBOOK

## BEST PRACTICES

# INSPECTION PREPARATION



### *In Office Preparation*

The amount of time you spend preparing for an inspection depends upon your experience level as an inspector and the complexity and scope of the licensed activities. The goal of inspection preparation is to ensure that you are familiar with the uses of licensed material to be inspected and understand the requirements applicable to that licensed program.

- *Make every effort to schedule inspections during periods when work with licensed materials is most likely to be performed.*
- *Review the license to determine if it has any unusual license conditions that would affect the approach to the inspection (e.g., authorization for an incinerator).*
- *Review the licensee's recent inspection and enforcement history (i.e., review the results of the last inspection, nuclear material events database (NMED), and any open items to determine if any events were reported by the licensee during the current inspection cycle). Pay particular attention to commitments and corrective actions for past violations.*
- *Review applicable generic communications to be aware of previously identified hazards and issues associated with the license type that you will inspect.*
- *Review any notes in the licensee's docket file regarding special inspection emphasis (e.g., an amendment for a*

*new medical therapy modality under Title 10 of the* Code of Federal Regulations *(10 CFR), Section 35.1000, "Other medical uses of byproduct material or radiation from byproduct material," must be inspected within 12 months of the date of the amendment [see Inspection Manual Chapter (IMC) 2800, Material Inspection Program).*

» *Provide a copy of the itinerary to the State radiation control agency to give the State personnel an opportunity to observe the inspections.*

» *Assure that appropriate security clearances have been provided to the facility prior to the inspection. To avoid revealing unannounced inspections, this can often be done on a scheduled basis for a 1-year period, allowing inspections at any time.*

» *Assure that the radiation survey instrument planned for use is appropriate to the program to be inspected and is calibrated commensurate with the applicable calibration frequency required for the licensee (e.g., 6 months for radiography licensees in accordance with 10 CFR 34.25, "Radiation survey instruments").*

***Consider preparing a check sheet or "memory jogger" which will help to make sure you carry out all planned activities.***

Use the appropriate inspection procedure and associated Focus Elements as the basis for preparation; in addition ask:

» *What are the potential problem areas for this licensed activity?*

» *What actions or inactions could lead to significant exposures of workers or the public?*

» *What actions or inactions could lead to significant releases of licensed materials to the environment?*

» What actions or inactions could lead to the loss of control of significant quantities of licensed material?

### *Personal Safety*

Assure you have appropriate safety equipment. Consider personal dosimetry (thermoluminescence dosimeter [TLD] or other), survey meter (for independent measurements and personal safety),


*Figure 1. Real environment for gauges*

alarming ratemeter, safety shoes, hard hat, safety glasses, and hearing protection. Some sites require special protective gear, such as Nomex suits; determine whether the licensee will supply the necessary special gear or you need to bring your own. Having appropriate safety equipment reduces the amount of time it will take to begin the inspection and presents a professional image. Learn Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA) regulations so that you can recognize when conditions are unsafe, and know what safety measures to take. Wear your eye, ear, and foot protection when appropriate, even if not required by the licensee.

During the actual inspection: Be careful! Industrial facilities present many potential hazards, and most are non-radiological (e.g., moving vehicles, machinery, unsafe scaffolding, spills, electrical hazards, chemicals, explosives, poor lighting, noise, vibration, extreme temperatures, and confined spaces).

Many licensees require completion of site-specific safety training. It may be necessary to visit the site in advance of the inspection in order to complete safety orientation and training.

***Remember that any confined or air restricted space, tank, or room may develop a hazardous atmosphere or reduced oxygen concentration. Ensure the confined spaces you enter are well-ventilated and that the entry has been evaluated and approved in accordance with an appropriate procedure.***

### *Entrance Interview*

Take the time to do an entrance interview with the most senior management representative available, even if it is just the radiation safety officer (RSO) or other single licensee representative. Ask if there is anyone else in management that they should inform of the inspection.

Let licensee management know:

- *that you are there to conduct an inspection and how long the inspection will take,*
- *what kind of inspection you will be doing and what that generally entails,*
- *the unannounced inspection policy, and*
- *that you will meet with the most senior available management representative at the end of the inspection.*

The discussions should include:

- *Violations from the last inspection, if any,*
- *Unresolved items from previous inspections, and*
- *Bulletins, Orders and other generic communications that affect the site.*

Identify areas you want to focus on, yet be flexible enough to observe other activities occurring during the inspection. Ask what activities are planned during the time you are inspecting and keep asking throughout the inspection. Sometimes you will learn something that management is unaware of and this may lead to important insights into the licensee's program.

If there is a particular activity you want to see immediately upon arriving at the site, say, "I would like to look at 'X' as soon as possible. Can we go there right now? I will go over the inspection plan as we go and then I would like to have a formal entrance interview when we are done there." Most licensees will accommodate such requests.

Ask about scheduling problems that the inspection may cause and modify your inspection plan, if necessary, to minimize the impact on the licensee without compromising the inspection. For example,


*Figure 2. Gauge in use*

schedule inspection activities for which a licensee representative is not needed (e.g. lunch breaks or record reviews) at times when the licensee representative must perform other tasks.


# MATERIALS INSPECTION & LICENSING HANDBOOK

## BEST PRACTICES

# CONDUCT OF INSPECTION



### *Performance-Based Inspection*

A performance-based inspection is an examination and evaluation of results or outcome of performance rather than a prescriptive process, technique, or procedure. Conduct performance-based inspections by observing licensee staff demonstrate their understanding of the proper use and handling of licensed material. Focus on high-risk and rarely-performed licensed activities, activities conducted during backshift hours, and the licensee's response to unusual situations and events. If licensed activities are not being conducted, request licensee staff to demonstrate how licensed activities have been or would be done.

Conduct independent measurements as a means of evaluating licensee conclusions and identifying opportunities to reduce radiation doses consistent with the "as low as reasonably achievable" (ALARA) concept.

### *Safety*

In general, if activities are conducted in accordance with regulatory requirements, they should be safe. However, safety doesn't necessarily mean only "in compliance." "No violations of regulatory requirements" doesn't necessarily preclude problems. Assess each situation in a holistic fashion, evaluating the state of compliance and whether there has been appropriate attention paid to safety and risk.

### *Trust but Verify*

Trust the licensee to provide you with accurate information; verify the accuracy of selected information you obtain from the licensee.

### *Violations*

When you have identified several violations, focus your effort on identifying the most safety-significant violations and problems and the root causes of the violations (for example, poor management oversight). In addition, ensure that the licensee understands your findings and implements prompt and effective corrective actions to address the violations and the root causes. Do not leave the site until the licensee has adequately addressed the violations and safety concerns.

When you think you have identified a violation, take the time to obtain the applicable "who, what, why, when, where, and how" information and review that information with the radiation safety officer. Ask if you have missed anything or if there is an alternative explanation. Listen to the RSO's point of view to avoid misunderstandings. Keep licensee staff informed about identified violations and concerns throughout the inspection rather than withholding the information until the exit interview.

### *General*

Cross-check records against licensee staff's statements. Verify licensee assumptions (especially by field observation) regarding calculations to show compliance with NRC regulatory requirements.

During the inspection, record the name of each person you speak with and their title. Get the spelling correct. Document what you see and find on your field notes as you are inspecting; avoid waiting until later and trying to remember. Have regulations, including 10 CFR Parts 19, 20, 30, 34, 35, 40, 70, and 71 as well as regulations for other agencies, including 49 CFR Parts 136 and 190. When you are finished with the inspection, take a few minutes and write out your findings before your exit interview with the licensee. If you need help before the exit interview, call one of the senior health physicists or your Branch Chief to discuss the findings of the inspection and your proposed actions.

### *Normal/Backshift Observations*

Inspections conducted during backshifts are often more informative than normal shift inspections. It is easy for other employees on the backshift to believe that no one will check their peformance as long as nothing "bad" happens.

For a licensee authorized to work at a temporary job site, inspectors should make every reasonable attempt to include an unannounced inspection of licensed activities at such a locations. Sometimes this is as easy as asking the licensee not to tell staff at other locations that you are coming.

Observe selected radiation safety committee meetings and training sessions whenever possible. This may provide insights into how the licensed program actually functions.

Ask the licensee if they receive generic communications from the NRC (e.g., newsletters). The NRC's generic communications provide an opportunity for licensees to gain insights on operational experience, including learning from past incidents and problems.

### *Interface with Licensee*

Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should not interfere with licensed activities. For example, an inspector should not insist on interviews when:

- *a worker is delayed in performing scheduled work activities (i.e., delayed departure to a temporary job site),*
- *a worker is preparing or administering patient doses,*
- *a worker is providing patient care, or*
- *a licensee is dealing with customers or members of the public.*

### *Unsafe Acts*

Take prompt action whenever you identify an unsafe condition or a violation that, if not immediately corrected, could result in an individual being harmed. Tactfully intervene by promptly and effectively informing the appropriate individual that what he or she is doing, or is about to do, is contrary to safety or regulatory requirements and request that he or she takes

corrective actions immediately. If time permits, inform an appropriate manager or supervisor of the situation and let them give necessary direction to the person who appears to be about to take an unsafe action.

Examples of unsafe conditions and violations that need to be immediately corrected include, but are not limited to:

- *failure to conduct an adequate survey after radiography source retraction prior to entry into the radiation area,*
- *conduct of licensed activities by an unqualified or unauthorized individual,*
- *preparation for administration of licensed material to a patient without referencing the required written directive, and*
- *non-conservative interpretation of conflicting source position indicators prior to entry into an high dose rate (HDR) afterloader treatment room.*

Immediately notify licensee management and your supervisor of such occurrences. This section is based on the policy in Field Policy No. 14 in NUREG-BR/0075, Rev. 4, "NRC Field Policy Manual."

### *Inspection Opportunities*

During travel, watch for licensed activities being conducted at temporary job sites and alter travel or inspection plans to conduct unplanned, unannounced inspections at temporary job sites.

### *Inspector's Behavior and Attitude*

Do not handle licensed material or operate licensee equipment. Instead, observe authorized licensee staff handle licensed material and operate equipment.

Learn by asking! Do not be afraid to ask the licensee questions that you cannot answer. Doing so will help you learn more about the licensee's activities and radiation safety program. Maintain your integrity and enhance your rapport with licensee staff by admitting if you do not know something.

Watch for, and take advantage of, opportunities to tour normally inaccessible areas or observe rarely conducted activities or operations.


*Figure 3. Good advice*

***Under no circumstance should an inspector "test" the effectiveness of a licensee's security systems by covert means, such as posing as someone else or intentionally causing the actuation of a security alarm. All challenges of a licensee's security system must be conducted with the knowledge of appropriate licensee supervision.***

Be approachable. If people feel intimidated by you, they are far less likely to talk to you.

Maintain a questioning attitude and verify information provided by the licensee and its contractors. Use all your senses. If something is different from what you expected, ask about it.

Use NRC staff colleagues as a resource if you have a question during the inspection.

### *Interview Skills*

Interview licensee staff to determine the status of compliance, assess the effectiveness of training, or evaluate an event. Be aware of what your objective is and what information you need to get from the interview.

Take the time to loosen up the individual. Ask open-ended questions. Avoid leading and "yes or no" questions. Do not try to impress interviewees with your knowledge; it is sometimes advantageous if they think you are less well informed than you actually are. Listen to the interviewee even when you think you know what they are going to say. Control the interview, but let the individual have some time to talk about what they want to talk about. Be prepared to answer appropriate questions.

> ***Seek privacy for interviews whenever possible; interview individuals separately when reviewing an event. Expect contradictions in individual recollections following an event. Use hard facts and techniques such as time-lines to determine the most likely course of the event.***

Control your voice and non-verbal communication; remember your words carry less than 10 percent of the message, tone and body language the rest.

Do not jump all over an employee who gives you the wrong answer or provides information which indicates a violation. Do tell him or her what you are going to do with the information that he or she has provided.

Users of radioactive material are typically not experts in health physics or NRC regulations; sometimes they simply do not understand a question, so when you get a "wrong" answer, try rephrasing the question in plain language; develop a complete picture before you conclude that employees have not been properly trained.

Search for a new or relatively new employee and ask about his or her training experiences.

### *Cameras*

Cameras can be a very useful item during inspections to document work activities and the condition of rooms and equipment. However, always ask the licensee for permission prior to taking any photographs. Ask whether photographs taken reveal proprietary or other sensitive information. Record the response and the fact that you asked. Include something to give scale, but be careful about including faces or otherwise identifying information. Be aware that many mobile devices now contain cameras and that you may not be allowed to carry such mobile devices by some licensees or in some areas.

### *Allegations, Concerns, and Complaints*

Consistent with Management Directive (MD) 8.8, "Management of Allegations," licensees should NOT be made aware that you are looking into allegations during an inspection. Licensees may guess or reasonably conclude that you are, but the inspector should never confirm that fact. In this context, it is important to include allegation issues within the context of the full inspection and investigate non-allegation areas in a comparable level of detail.

During interviews of allegers, follow the same principles as discussed in the section on interviews, above, with added care to protect their identity.

Inspections resulting from allegations will be documented in accordance with MD 8.8. No reference to follow-up of an allegation or employee concern will be entered in the inspection records, inspection reports, or other documents that will be placed in the docket file.

### *Safety Conscious Work Environment (SCWE)*

Review and be aware of the licensee's environment for raising safety concerns. Licensee employees should be encouraged to raise concerns to both their management and to the NRC without fear of retaliation. If the environment appears to discourage the raising of safety concerns, or a licensee employee states a concern in this area, talk with your supervisor to develop an approach to the situation.

Licensees should have a policy for prohibiting harassment and retaliation for raising safety concerns. In addition, clear communications should be established to allow workers to voice concerns regarding safety, job site conditions, problems with meeting regulations, or other conditions that would prevent an employee from performing work in a safe and timely manner. Employee concerns should be addressed and corrective actions implemented when appropriate based on the significance of the issue.

### *Third Party Assistance*

Be cautious in recommending third party assistance (consultants, equipment manufacturers, source manufacturers, etc.) to licensees. NRC employees are prohibited from recommending the services of any particular person or organization for projects under NRC regulatory jurisdiction. Regional procedures govern the appropriate process for recommending sources of assistance to licensees. Generally, referrals to widely known non-profit organizations are allowed (e.g., Health Physics Society, American Association of Physicists in Medicine, Society of Nuclear Medicine). Consult with your supervisor for further direction.

### *Non-Radiological Safety Concerns (OSHA Issues)*

Memoranda of Understanding dated October 21, 1988, and July 26, 1996, between the NRC and OSHA provide for inspector involvement during inspections in the identification and disposition of safety concerns. Notify licensee management and, as appropriate, the NRC regional office OSHA liaison officer of non-radiological hazards personally observed or reported by licensee employees. Remember, OSHA regulations apply to you too!

### *Facility Emergency*

If an emergency or event occurs during an inspection, do not try to do the licensee's job. Stay out of the way, but keep watching. Take notes; include times and who did what. Contact your office, but make sure the licensee makes all necessary reports.

What if the licensee asks for advice? Be factual, not directive. Demonstrate by example that a calm response is usually the most

effective one. Ask occasional questions: "Have you reviewed your procedure? Is there someone, on your staff or otherwise, available to help you?").

### *Personal Emergency*

If a personal emergency occurs during an inspection, ask for appropriate help. Do not try to hide it, tough it out, or ignore a real need. Talk to your supervisor, and get advice on how to handle the emergency with the licensee. Tell the licensee what you are doing (they do not need details, just what is going to happen) or make arrangements for someone else to do it. Do not just disappear.

### *Exit Meeting*

Preferably before leaving the site, clearly present possible violations to the highest level of management available, confirm the licensee's understanding and agreement that a violation occurred, and determine that the licensee's prompt corrective actions will be effective. When the licensee does not agree with your findings, make sure you understand their position well enough to argue it on their behalf. If you can do that, you will be able to explain the licensee's position to your supervisor.

The purpose of the exit meeting is to present the PRELIMINARY inspection findings and provide the licensee an opportunity to provide additional information that could change the findings. When possible, brief the RSO first regarding all of the findings.

Meet with the highest management representative available; from the NRC standpoint, everyone is welcome. However, remember it is their facility and they can control attendance. Outline the specific violations, citing the regulatory requirement and your understanding of proposed corrective actions, if known. Discuss positive findings and observations to send a "balanced" message.

Give licensee management a chance for rebuttal and questions. If the licensee provides a convincing argument or new facts, consider it carefully. Do not be too quick to change your position, but do not be inflexible either. Make sure you understand and can explain to your management the licensee's position.

The message you deliver at the exit meeting is important. Make certain that you take the time necessary to develop the message. Organize your findings, place them in the correct context, and identify any additional informational needs you have.


*Figure 4. Exit sign*




*Radiation Protection*

- **Skin Exposure**

  *Licensee staff should be aware of, and familiar with, the guidance related to skin exposure and reporting requirements, especially if the licensed material they use produces beta or low energy radiation. Review the licensee's system for monitoring, controlling, measuring/calculating, and reporting skin dose from licensed material. Evaluate the appropriate use of dosimeters and dose calculations for normal handling of radioactive material and exposures from contamination. Personnel contamination monitoring (frisking or scanning) should be performed with appropriate detection equipment to detect beta radiation energies on a consistent frequency.*

  *Evaluations of skin exposures near regulatory limits can be difficult. When you need to do such a review, do not hesitate to seek advice from an experienced colleague.*

- **"High" Dosimeters**

  *High or off-scale dosimeter readings must be evaluated by the licensee. The evaluation should include a review of the work performed during the time the dosimeter was worn, exposures received by other workers performing similar work, comparison to area monitors or dosimeters posted*

*in the area, all potential sources of higher dose (temporary or transient) in the work area, potential problems with the dosimeter, and sources of contamination or "false readings" on the dosimeter. This review and dose assessment must be clearly documented and stored with personnel dosimetry records.*

*High or off-scale dosimeters should be promptly reported to the RSO and licensee management. Personnel with high or off-scale dosimetry should be restricted in their work with radioactive material, or more closely monitored, until the review and dose assessment are concluded.*

*Remember that actual exposures in excess of regulatory limits must reported to the NRC Operations Center.*

- **High Radiation Areas:**
  *Effective controls must be in place to warn workers regarding the hazard of high radiation areas, including physical boundaries, postings, and instructions (where appropriate). A dosimeter must be worn by workers entering high-radiation areas.*

### *Training*

In addition to review of records and attending training sessions, evaluate training effectiveness by observing the actual conduct of licensed activities and asking questions of those individuals who actually perform the activities which are the subject of training.

### *Portable Gauges*

There is increased emphasis on the security of portable gauges both in use and in storage. Plan appropriate time to observe field use of gauges and interview the authorized users about their usual practices. In accordance with current requirements, 10 CFR Part 30.34(i), "Security requirements for portable gauges":

- *At least two independent physical controls must be in place to prevent unauthorized removal of a portable gauge when the gauge is not under the control and constant surveillance of an authorized individual. In other words, to be in compliance, the physical controls must be arranged such*

*that in order to take the gauge an unauthorized individual must breach two separate barriers (locks, chains, etc.).*

» *Simply having two chains or cables with locks does not satisfy the security rule unless each chain and lock combination is physically robust enough to provide both a deterrence and a reasonable delay mechanism.*

» *Remember, the NRC interprets "control and maintain constant surveillance" of portable gauges to mean being immediately present or remaining in close proximity to the portable gauge so as to be able to prevent its unauthorized removal. The person maintaining control must have the gauge within their line of sight and be sufficiently attentive to immediately identify an approach to the gauge.*

Determine whether the responsible workers know how to perform gauge maintenance without unnecessary exposures. Pay attention to the details of how the cleaning and maintenance are done to identify gaps in knowledge or poor practices.

### *Fixed Gauges*

Fixed gauges come in a variety of configurations and are used in varied environments. Plan some extra time to fully understand the gauges in the environment in which each is used. This will provide you with valuable information for future inspections or event reviews.

Observe the licensee performing licensed activities. If no work is being done, observe demonstrations (use, leak tests, shutter tests, interlock tests, maintenance, surveys, etc.).

Lock-out procedures are key elements of many fixed gauge licensee safety programs. Evaluate compliance with lock-out and tag-out procedures. Observe staff implementing lock-out and tag-out procedures, or observe them demonstrate how they have done it in the past or would do it in the future.

Verify that gauge service and maintenance is conducted by authorized persons. Seek opportunities to observe and review the activities of the service and maintenance contractor.

Take the opportunity to review generally licensed gauges which are present at the facility being inspected. Ask whether the


*Figure 5. Survey meter*

licensee has received and responded to requests from the NRC to register gauges in accordance with 10 CFR Part 31, "General domestic licenses for byproduct."

Inquire if any new gauges are planned for installation. It is often difficult to inspect gauge installations so consult with your supervisor about altering your schedule if you have an opportunity to conduct such an inspection.

### *Broad Scope*

In large broad scope research and development programs it is easy to get lost in the volume of information received. In these situations it is most effective to inspect a cross section of the program. Be sure to include more than just frequent users or users identified by the licensee has having problems. You might want to select a few authorized users from each research building or department. Review the permits they have received from the radiation safety committee or RSO; look at their radioactive material receipts (Did the RSO control these purchases?); look at the audits which include their areas and travel to the laboratories;

follow a container of radioactive material from receipt through use and disposal.

Determine if licensed material is secured, labeled, and posted as required. Interview the laboratory staff who use licensed material to determine if they are adequately trained, have adequate facilities and equipment, use the material safely, wear an appropriate dosimeter, perform proper surveys, and dispose of radioactive waste properly.

Determine where the RSO, radiation safety staff, or auditors have identified problems during surveys or audits. Review the licensee's response to the problems and evaluate the effectiveness of actions to prevent similar problems. Do not "mine" the licensee's audit reports for potential violations; use the audit findings to determine whether the licensee has an effective corrective action program.

Accompany health physics technicians or the RSO on actual laboratory audits. Not only do you learn something about the operation of the laboratory, you learn something about the quality of the audit and the licensee's ability to establish and implement corrective and preventive actions.

Conduct confirmatory surveys. Unexpected radiation levels or contamination can really drive home the importance of following safe use and survey procedures.

Evaluate the staff's understanding of licensee emergency spill procedure by asking technologists in the laboratory what they would do if they dropped and broke a vial of radioactive material.

If a technologist in the laboratory tells you they are not authorized to use radioactive materials, but they are authorized to work in the laboratory with users of radioactive materials, determine that they have received training on maintaining laboratory security, on segregating cold trash from hot trash, and for avoiding exposure to radioactive material.

- ***Contamination Control***
  *Large licensees with many users and many laboratories have many opportunities to lose control of contaminated material,*

*particularly in waste. Carefully review the licensee's program for segregating contaminated waste from other waste. Assure that the licensee has appropriate criteria and instrumentation for free-releasing potentially contaminated material. Pay particular attention to the controls on the collection of contaminated and non-radioactive waste. Past experience has shown that many individuals hired for the janitorial staff do not have good English language skills, so it is important that contaminated waste containers are clearly labeled and that training for service personnel is conducted in the appropriate language.*

- ***Sealed Sources***
  *Large licensees often do not keep meticulous track of sealed sources. Select several sources from the licensee's inventory records and verify that the actual location of each source selected corresponds to its location in the record.*

### *Radiography*

There are many circumstances that may lead to unsafe conditions during radiography. These can be loosely attributed to either human performance or equipment performance. In the area of human performance, failure to survey with a calibrated and operable radiation survey instrument after each exposure to determine that the sealed source has returned to its shielded position has resulted in numerous exposures in excess of regulatory limits (reference 10 CFR 34.49(b), "Radiation surveys"). To be effective, such a survey must include the entire guide tube.

While there is no specific requirement controlling hours of work for radiographers, they often work long hours under significant deadline pressure. During your inspection, be mindful of the effect that fatigue and long hours can have on the performance of repetitive tasks.

In addressing safety problems caused by human performance, 10 CFR 34.41(a),"Conducting industrial radiographic operations," requires that radiography may not be performed if only one qualified individual is present. The regulations in 10 CFR 34.46,"Superv ision of radiographers' assistants," require the radiographer to

directly observe the radiographer's assistant perform radiographic operations. The following brief scenario provides an example of a violation caused by deficiencies in human performance.

The radiographer left the immediate vicinity of the radiographic operations to perform other tasks or moved a distance away and turned his back to the radiographic operation. These actions left the radiographer's assistant alone to monitor the exposed source and the radiation area. During the time that the radiographer was not in the immediate area, he was not capable of providing immediate assistance to prevent unauthorized entry into the radiation area and could not directly observe the radiographer's assistant during radiographic operations.

With regard to equipment performance, ask what the licensee does to identify survey instruments in need of repair. Does the license ensure that repaired instruments are calibrated prior to first use?

Consider the following key points when reviewing equipment inspection and maintenance [10 CFR 34.31(b)(1), "Inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments"]:

- *Does licensee staff examine the distal end of drive cable (near male connector) for wear? Information Notice 97-91, Supp. 1, "Recent Failures Of Control Cables Used On Amersham Model 660 Posilock Radiography Systems," discusses the need for licensees to inspect and maintain drive cables.*
- *Does licensee staff examine the distal end of the male connector for excessive wear and look for the male connector being off-axis relative to the drive cable? (One manufacturer indicates that if the angle of the male connector is >10 degrees, it could cause excessive wear of the distal end of the male connector by friction on the interior lumen of the guide tube.)*
- *Does licensee staff verify that following crank maintenance all of the parts are installed and all staff are aware of changes in the handle configuration?*

» *Does the staff check for loose hardware and know what to do if it is identified?*

» *How does the licensee ensure that radiographic equipment is maintained in accordance with NRC regulatory requirements?*

» *One of the major equipment manufacturers instructed customers to revise their quarterly inspection program to include misconnect tests for each set of drive cables used. The basis for the test is that, although wear of specific components may be within specifications, a misconnect can occur when slightly worn components are used together. What was the licensee's response to this advice?*

» *Does the staff recognize that noises during cranking indicate a potential problem? Do they know how to respond appropriately?*

» *Does the staff use the Posilock indicator or challenge Posilock actuation after source retraction?*

*Figure 6. Radiographer preparing for work*

The NRC does not authorize the use of pipeliner devices because these devices do not meet the performance requirements in 10 CFR 34.20, "Performance requirements for industrial radiography equipment." A pipeliner device is one that is directly connected to the pipe and does not have the "S" tube; the source is exposed by moving a lever or rotor. Pipeliners have been used on offshore barges and platforms in the past. Some licensees argue it is the best device for performing the work in these locations

because quarters are tight and shots must be completed quickly. Watch for the presence or use of these devices.

Licensees may, in response to a particular job or other circumstance, develop a "Permanent Radiographic Installation." This is defined as an enclosed shielded room, cell, or vault not located at a temporary jobsite, in which radiography is performed, without meeting the necessary requirements (see 10 CFR 34.33, "Permanent radiograhic installations." Examine facilities where radiography is performed to determine whether they should be designated as permanent radiographic installations.

### *Medical*

Unless you need to intervene to prevent an unsafe situation, your observation of work activities should not interfere with a patient's care or privacy.

Obtain patient permission before observing dose administrations. Observe an authorized individual administer material listed in 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required," or have them demonstrate how it was or would be administered. Look for good use of time, distance, and shielding to reduce radiation exposure when preparing and administering doses. If possible, discuss the written directive components and the release criteria with the authorized user. If the licensee is releasing a patient to their home, observe the authorized user questioning the patient or family about the home environment and compare the information collected to the release criteria in NUREG-1556, Volume 9, "Consolidated Guidance about Materials Licenses Licenses: Program-Specific Guidance About Medical Use Licenses."

Interview selected staff who care for patients hospitalized in accordance with 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material," to determine if they are properly trained (i.e., size and appearance of sources, safe handling and shielding of sources, patient and visitor control, and medical emergency/death response). Review both the licensees planned and actual responses to such emergencies.

Some key questions:

» *Does the licensee understand the definition of a "medical event" (with special focus on 10 CFR 35.3045(a)(3), "Report and notification of a medical event")?*

» *Does the licensee take action to separate exposure from x-ray and exposure from licensed material?*

» *How does the licensee account for variation in dose calibrator response due to geometrical variation (differences in container size and shape) and differences in container composition (plastic vs. glass) for pure beta emitters (e.g., strontium-89, phosphorus-32, samarium-153)?*

### *Supervision*

There is a wide variety of skill and knowledge level in the staff involved with medical programs using licensed material.

» *Does the RSO oversee all aspects of the radiation safety program, including those that he or she is less comfortable with?*

» *If the licensee relies on a consultant to complete required tasks, what does it do to ensure that the tasks are completed as required? Does the licensee audit the consultant's work or observe that the consultant conducts the required tasks?*

### *Brachytherapy*

This treatment modality presents many opportunities for medical events and radiation safety occurrences such as lost or misplaced sources. This is especially true for licensees who employ the modality infrequently.

Does the licensee take actions to ensure that the brachytherapy applicator and sources are adequate to deliver the radiation dose prescribed on the written directive? For example, does the licensee perform acceptance testing to ensure that sources stay in position within the applicator? Does the licensee ensure that the dummy sources are the same physical size as the actual sources?

Review written directives and ensure all required components are present. If possible, observe an implant after obtaining permission from the patient and the authorized user. Confirm that

written instructions are provided to patients who are released with permanent implants.

Review post-implant dosimetry and note any differences from the pre-implant dosimetry. Discuss any differences with the licensee. If it appears that a medical event may have occurred, discuss this possibility with the licensee and obtain copies of all documentation for further review.

### *High Dose Rate Afterloader*

More licensees are using this modality and there are a number of considerations that are specific to the use of HDRs.

Ask the licensee to demonstrate its daily checks and compare your observations to the license commitments and the regulations. Consider asking the licensee to demonstrate that the connector must be fully engaged and connected to the correct channel before the treatment can begin (a connection failure was the cause of at leat one mammosite medical event). Also consider asking the licensee to demonstrate that the fitting for the connector is appropriately varied by type of treatment; and that the HDR or accelerator switch prohibits dual operation.

Observe selected staff demonstrate implementation of the licensee's emergency response procedures using different scenarios (e.g., stuck source in patient, source does not fully retract into unit at end of treatment).

### *Gamma Stereotactic Radiosurgery (GSR or Gamma Knife)*

This is a very complex modality. Great care and consistency are needed to avoid medical events.

- *Ask the licensee to demonstrate its daily checks; compare your observations to their license commitments and the regulations.*
- *Ask the licensee to demonstrate patient setup and double checks.*
- *Ask the licensee to describe its procedures for security of the unit and the unit's keys, and how they implement the physical presence requirements.*
- *Review a sample of treatment plans and ask the authorized medical physicist to walk you through the planning stages.*

» *Ask what the licensee has done to prevent common medical events. For example, a GSR unit A medical event occurred with a GSR unit because a microphone clip came off of the patient couch and jammed the collimator jaws. What has the licensee done to prevent this type of occurrence?*

### *Radio-Pharmacies*

These licensees frequently have problems with hand exposures and the implementation of their ALARA program. Since speed and technique are very important factors in determining the actual hand exposure received, look at individual exposures and the licensee's evaluation of and response to them. Also, compare the licensee's instructions for placement of extremity dosimetry to actual implementation. Assure that the location of highest exposure is measured, and if not, assure that appropriate changes are made.

For pharmacies that dispense beta-emitters, verify that geometry dependence tests include appropriate use of calibration factors and the entire range of containers and product volumes used. Assure that container size (3 ml vs. 30 ml), product volume (1 ml dosage vs. 10 ml dosage), and container materials (plastic vs. glass) are considered.

While the constraint rule, 10 CFR 20.1101(d), "Radiation protection programs," applies to most licensees, it is most often an important consideration at radio-pharmacies handling iodine-131. Examine the licensee's assumptions, measurements, and calculations to demonstrate compliance with the rule.

### *Panoramic Irradiators*

There are NRC publications (NUREG-1345, "Review of events at large pool-type irradiators and lessons learned from accidents at industrial radiation facilities, IAEA, 1996," Information Notice 89-82, "Recent Safety-Related Incidents at Large Irradiators," Information Notice 91-14, "Recent Safety-Related Incidents at Large Irradiators," Information Notice 94-89, Equipment Failures at Irradiator Facilities), and other literature which discuss safety hazards, past accidents, and near-misses at large panoramic irradiators. Use this guidance to enhance preparation for panoramic irradiator inspections.

*Figure 7. Laboratory safety*

Determine by interviewing a sample of operators and maintenance personnel if the licensee ever bypasses interlocks or any other safety systems. Determine how the licensee either prevents such bypasses or exercises appropriate management controls when a bypass is deemed necessary.

Pay particular attention to the procedures for testing interlocks. It is difficult to review the actual design and "wiring" of the interlock logic when a programmable logic controller is used. This makes effective testing of interlocks especially important. Does the licensee keep printouts of the interlock tests, showing the date and details of completion? Use these to verify other records.

Consider looking closely at the controls over access to handling tools for sources. Access to these tools affects both safety and security.

### *Self-Shielded Irradiators*

Self-shielded irradiators, especially those in which the source itself does not move, do not normally present a radiation safety problem. However, self-shielded irradiators with moving parts periodically require repair, and during repairs there is an increase in the potential for dose. Assure that only an authorized service provider has performed work which could affect the source shielding. Determine whether the licensee has had any mechanical problems with the irradiator and who it would call if mechanical problems occur.

### *Well Logging*

These licensees make frequent transfers of radioactive sources from storage containers to logging tools and back to the container in field conditions. Past incidents have shown that well logging sources do, periodically, fall off the handling tools during source transfers. Logging crews usually discover that the source has become detached and recover it quickly and safely. However, the potential for unnecessary exposures and for exposures exceeding the dose limit is high whenever such an event occurs. Pay particular attention to the implementation of the licensee's procedures requiring logging personnel to perform a confirmatory radiation survey, before leaving the well site, to confirm the proper transfer of sealed sources to their shielded containers. Examine whether loggers know the procedure and always have a working radiation detection meter to perform the survey.

### *Decommissioning*

These are often complex operations involving a wide range of activities and risks. Worker radiation exposures are often not significant, but frequent surveys and evaluations are important because the licensee often does not have completely reliable information about every area of the site. Areas to be considered for particular attention are:

- **Radiological Instrumentation**
  *Always make sure that the instrument you or the licensee is using can adequately measure the isotope of interest. Instruments should have a current calibration sticker. Verify that a daily source check has been performed prior to the use of the instrument. Verify that the licensee has taken into consideration that very cold and hot weather can affect an instrument's response. For example, in very cold weather, additional detectors may be kept in a warming area so they can be changed frequently to keep them as warm as possible.*

- **Surveys**
  *Observe workers performing surveys. The licensee should be able to provide you with the minimum detectable activity*

*(MDA) and scan speed for the detectors being used for the survey. As a rule of thumb, gamma scanning soil with a sodium iodide (NAI) detector should be performed at about 0.5 meters per second (1.5 feet per second), depending on conditions. When surface scanning with an alpha scintillator, the probe should be kept less than 1 cm (0.5 inch) from the surface. Hand frisking of skin and clothing should be performed with the probe 1 centimeter (0.5 inch) from the surface and at a speed of 2 to 5 centimeters per second (1–2 inches per second).*

- **Radiation Protection Standards and Practices**
  *Verify that workers are adhering to proper radiation protection standards and practices. For example, verify that workers are wearing radiation dosimeters in conformance with facility-specific requirements and are maximizing the use of low-dose waiting areas. During contaminated area entries, observe workers and verify that they are properly donning anti-contamination clothing before entering the area and properly removing their protective clothing upon exiting the area. Verify that workers passing tools and other equipment across contaminated area boundaries are following good radiation protection practices.*

- **Sinks, Drains, and Ventilation Systems**
  *Areas occasionally neglected by a licensee during decommissioning activities are the sinks, drains, and ventilation systems. Through discussion with the licensee, verify that these areas were adequately addressed, including the potential for the reconcentration of contamination at a downstream location which could lead to a localized hot spot. Optimally, the licensee has collected samples at points downstream of these locations.*

- **Vacuums**
  *Vacuums with high efficiency particulate–air (HEPA) filters are commonly used during decommissioning activities. Verify the licensee is regularly checking the dose rates of the units containing the filter as well as the hose lines. As contamination builds up on the filter, it can result in elevated*

*dose rates around the unit, and occasionally a hot particle can lodge in the vacuum hose creating a localized high dose area.*

- **Electrical**
  *Verify that areas are adequately illuminated and sufficient electrical outlets are available for the decommissioning work being performed. Some decommissioning facilities will install a new electrical system and deactivate the existing system to minimize the potential for cutting into a "live" wire. Watch for electrical cords and equipment that may be located in standing water, or in low areas that may flood during rainy weather, or that create a tripping hazard for workers.*

- **Scaffolding**
  *Temporary scaffolding may be erected during some decommissioning activities. Verify that it is erected in accordance with the licensee's scaffolding erection procedures. Verify scaffolding is not directly attached to instrument racks or piping supports, does not interfere with the operation of equipment such as ventilation dampers, and does not block access to fire protection equipment such as hose reels, fire extinguishers, and fire doors.*

- **Heavy Loads**
  *The movement of heavy loads, such as sea/land containers, B-25 boxes, or other demolition material, can be a significant safety concern if these loads were to fall unexpectedly. Keep cognizant of heavy load lifts. Verify to the extent practicable that they are being conducted safely. Verify that the crane or lifting device is rated above the weight of the load being lifted. Verify the rigging is in good physical condition and has been properly inspected and maintained. Look at the general condition of the crane or lifting device. Immediately inform licensee personnel about any cracks indicative of an overloaded condition.*

- **Safety**
  *During any decommissioning or demolition work, personal safety is the number one concern. Verify that an appropriate focus on safety exists with management and is consistently communicated to the workers.*

***Inspections of decommissioned sites often entail surveys of older and poorly maintained buildings. Caution should be exercised any time there is a need to conduct surveys on roofs and around roof-top ventilation points. Always discuss the structural integrity of roofs and other structures with the licensee prior to conducting surveys in any area that may pose a safety risk.***

- **Personal Protective Equipment**
  *Verify personnel are wearing all required personal protective equipment (PPE) such as hearing protection, eye protection, and head protection. Additional protection may be required based on local conditions, such as double hearing protection in designated areas; the use of a lanyard with a break-away feature for the display of identification badges and dosimetry; tucking in of neckties and other loose clothing in the vicinity of rotating equipment; and footwear that protects against injury due to falling objects.*

- **Fall-Related Injuries**
  *Verify that ladders are sturdy and do not wobble. Verify that licensee personnel are using ladders in a safe manner, including the use of ties and blocking. A ladder tender can also help avoid a fall. No one should ever stand on the top step of a ladder. Another area of concern occurs when personnel attempt to carry items up or down a ladder. Be aware of this when walking to or from an activity and ensure that no one is carrying more than what is safe. Anyone on a ladder should have three points of contact at all times (i.e., 2 feet and 1 hand, or 2 hands and 1 foot). Verify that workers use safety harnesses, when required.*

- **Heat Stress Awareness**
  *Some decommissioning work involves high heat and humidity levels. Verify that licensee personnel have taken adequate precautions to protect workers from heat-related stress.*

- **Tanks and Pools**
  *If tanks or pools contain pumps or hoses for maintaining*

*the cleanliness of the water or for vacuuming, verify that an inadvertent drain-down cannot occur from back-suction. Temporary hoses should not be left unattended with one end underwater. For hoses or lines that will be left in a tank or pool for an extended period, verify that the suction line is kept near the top of the water. This assures that, in case a back-suction event does inadvertently occur, only a minimal amount of water will be drained.*

- **Asbestos, Lead, Mercury, and PCBs**
  *Sites being decommissioned and demolished often contain asbestos, switches containing mercury, lead paint, PCBs or other hazardous materials. These materials may or may not be mixed waste (i.e., are also radiologically contaminated), but in either case will require special handling. Verify that the licensee is looking for these materials and has a process for handling and disposing of them.*

### *Transportation*

Carefully review the specific regulatory requirements involved in transportation issues, since there are many exemptions, depending on the specific circumstances involved. Assure that the licensee has considered the appropriate regulatory requirements for the materials they are shipping.

Avoid hasty conclusions regarding radiation or contamination levels on packages containing radioactive material from shipper to receiver, even if the receiver's numbers seem to indicate a violation. Investigate. Many differences can be explained by variation in instrumentation or measurement technique. While these differences may indicate a violation, have all the facts and understand the situation before you decide.

### *Event Review*

Follow-up on the licensee's response to events that occurred since the last inspection. Focus on notification, reporting, and corrective actions to prevent similar events.

For reenactments, consider using a locking tape measure, a stop watch, a still camera (digital, if possible), a video camera (digital,

if possible), or a tape recorder. Digital video is the most efficient way to establish time, sequence of events, and relative locations. Multiple reenactments may be necessary, especially if dose rates are high and the series of movements is complex.

Fully evaluate the licensee's corrective actions to prevent similar events or violations and observe any licensee equipment modifications to determine if there is potential compromise of the equipment's designed safety features.

Evaluate whether there are generic implications of the event.

### *Medical Event Follow-Up*

Reactive inspections involving a medical event require special attention and must be performed using the guidance in MD 8.10, "NRC Medical Event Assessment Program." Take particular care to:

- *Obtain all details of the event (i.e., a chronology).*
- *Identify the root causes and contributing factors.*
- *Obtain the licensee's assessment of the effects on the patient.*
- *Understand the licensee's corrective actions to prevent similar medical events or violations.*
- *Review the licensee's implementation of procedures for administrations requiring a written directive. Do all appropriate staff understand what constitutes a written directive and when one is necessary?*
- *Evaluate compliance with medical event notification requirements, including proper reporting to the NRC Operations Center, referring physician and patient (if appropriate) within 24 hours of discovery; 15-day written report to NRC, physician, and patient (if requested).*

### *Service Providers*

Analytical laboratories and other licensees authorized to provide services using or related to nuclear materials are included in this group. During inspection, assess whether licensees are getting accurate and reliable services from the providers. Keep in mind that it is primarily the customer's responsibility to assure reliable service. The agency often gets information generated by service

providers during other inspections and in the licensing process. Keep in mind that failing to provide accurate service may not be a violation for the service provider.

When inspecting a licensee conducting inservice leak tests, reviewers should scrutinize the details of the equipment and procedures so that they can conclude a good leak test analysis can be performed for each radionuclide tested. Check their minimum detectable activity calculations, and their calibration procedures and standards, especially if they are testing for nickel-63 or other non-gamma emitters.

Review of calibration is even more important for analytical labs that do wipe test analysis, and analysis of water and soil and other samples. Review their control charts to ensure that the equipment is maintained and operable, check their minimum detectable activity, understand the standard geometries for which they are calibrated and how they deal with new geometries or sample types, and look at their participation and results in cross-check programs.

At instrument calibration facilities, check the National Institute of Standards and Technology (NIST)-traceability of sources used to calibrate the various meters and detectors. Review the procedures for calibrating the very low and very high ranges and verify that the calibration facility produces accurate readings (some facilities may be narrow with walls that cause too much backscatter).

For licensees installing or servicing devices containing radioactive material, it is very important to observe the activities of service staff in the field, and evaluate their radiation safety practices in action. Ensure that the individual has adequate survey instrumentation and dosimetry, and adequate understanding of safety procedures required by the license and of the procedures for servicing the device.

### *Reciprocity*

Determining whether the NRC or an Agreement State has jurisdiction for reciprocity purposes can be complex and confusing. In general, Federal licensees are regulated by the NRC; non-Federal licensees operating in areas subject to exclusive Federal

*Figure 8. Radiography equipment*

jurisdiction are also regulated by the NRC. Indian reservations are subject to exclusive Federal jurisdiction under most circumstances. Non-Federal licensees operating in areas that are not subject to exclusive Federal jurisdiction are regulated by the Agreement State in which the facility is located.

Experience has shown that the Federal agency responsible for the location where the licensed activities occur is the best source for a decision about whether the NRC or the Agreement State has jurisdiction. It is the responsibility of the licensee to operate in compliance with NRC and Agreement State regulations and it normally has a relationship with the entity that controls the site of the licensed activity. Therefore it is usual to expect that the licensee will obtain the information necessary to make a correct jurisdictional decision.

Agreement State licensees will usually be authorized to work within NRC jurisdiction if they are authorized to work at temporary job sites in their licensing jurisdiction and can comply with the requirements of 10 CFR 150.20, "Recognition of Agreement State licenses."

Radiography at nuclear power plant sites cannot be performed under the 10 CFR Part 50, "Domestic licensing of production and utilization facilities," license and must be performed under a valid license which authorizes radiography. Nuclear power plants are not areas of exclusive Federal jurisdiction for purposes of reciprocity. Therefore, within each state, Agreement States have jurisdiction over radiography at nuclear power plants.


# MATERIALS INSPECTION & LICENSING HANDBOOK

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## SECURITY ISSUES



The public and other governmental bodies have an increased interest in the security of licensed material. Therefore, reviewers must assess the overall security posture of the licensee as well as security issues described in the inspection procedures. Encourage licensees to be sensitive to and report unusual events as recommended by NRC generic communications.

There is significant evidence that many violations of the "Orders Imposing Increased Controls" (Increased Control Order) are caused by licensees not thoroughly understanding the requirements in the order and, therefore, not implementing them. Be prepared to take additional time to review the bases for any violations of the Increased Control Order and assure that the licensee knows where to find the implementing guidance. Additional attention during the inspection has improved the licensee's ability to plan, present, and implement effective corrective actions.

Information security has become of even greater importance in the post-9/11 environment. In the same way that all licensees have received other generic communications from the NRC, be sure that the licensee has a copy of and has considered the guidance in Regulatory Issue Summary 2005-31, "Control of Security-related Sensitive Unclassified Nonsafeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material."


# MATERIALS INSPECTION & LICENSING HANDBOOK

## BEST PRACTICES

## LICENSING

### *General*

Re-read a deficiency letter, safety evaluation report, or license after a break. Ask yourself whether a reasonable technical person who read only the licensee's correspondence and your letter would understand your conclusions and questions.

Before completing a licensing action ask yourself:

- » *What has the licensee requested?*
- » *Does the package of letter, enclosures, and license respond to each of the licensee's requests?*
- » *Did I recognize and address all potential safety issues?*
- » *Should I ask my colleagues for their insights?*

Guidance documents may not address all safety issues. Focus on safety issues and ask questions to satisfy the goal of safe operation. For example, no rule limits the number of facilities one Radiation Safety Officer may service. However, reviewers have recognized that it could become a safety issue when a radiation safety officer has responsibility for too many facilities and reviewers have developed further questions to address that issue.

### *Medical*

The regulations in 10 CFR Part 35 are largely performance-based (except for prescriptive elements of 10 CFR 35.600, " Use of a sealed

source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit"). Therefore, license reviewers have few procedures to review. However, confirming that proposed authorized individuals meet the necessary requirements is one of the most important, potentially safety-significant aspects of medical licensing, particularly for authorized users and authorized medical physicists associated with therapy authorizations. It is also one of the most difficult assignments to complete. Take the time to properly review these parts of the licensee's application. Review previous medical enforcement cases to familiarize yourself with how qualifications were found deficient.

Review the licensee's therapy facilities and procedures against the applicable American Association of Physicists in Medicine (AAPM), American National Standards Institute (ANSI), and National Council on Radiation Protection and Measurements (NCRP) documents. There are several new AAPM and NCRP documents that have not received program office review (e.g., NCRP Reports No. 147, "Structural Shielding Design For Medical X-ray Imaging Facilities," and 151, "Structural Shielding Design And Evaluation For Mega Voltage X- And Gamma-ray Radiotherapy Facilities (2005)"). If a licensee bases its submission on one of these documents, consider preparing a technical assistance request.

### *Service Licenses*

The main guidance document for licensing service providers is NUREG-1556, Volume 18, Consolidated Guidance About Materials Licenses: "Program-Specific Guidance About Service Providers." An important objective of licensing these organizations is assuring that each service provider is prepared to operate safely with respect to its own workers, the customer, the general public and the environment. However, since other licensees rely on these organizations to conduct key activities for them, you should also assess how well prepared they are to provide accurate and reliable services.

- **Nuclear Laundries**
  *In licensing a nuclear laundry, it is very important to assure that the functions of laundering reusable garments and*

*other reuseable items does not become confused with with the functions of a waste broker. The NRC usually requires nuclear laundry licensees to return non-launderable material to the customer rather than dispose of it as radioactive waste. This discourages customers from including non-launderable material in their laundry shipments. However, the use of dissolvable garments has caused some blurring of this position. See letter from Paul R. Lohaus to UniTech Services Group, Inc., dated October 23, 2002 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML022960614).*

*Review of a laundry license application should include a careful review of the processing and disposal of waste water. There is a history of nuclear laundries causing increased concentrations of radioactive material at public sewage treatment facilities even though they meet all regulatory requirements for discharges.*

- **Decommissioning Contractors:**
  *In addition to NUREG-1556, Volume 18, important guidance for licensing decommissioning contractors is found in Policy and Guidance Directive FC-94-02, "Licensing Site Remediation Contractors for Work at Temporary Job Sites." An important consideration for these licenses is the fact that site owners and operators may not have radiation safety programs in place that are adequate to ensure safe and effective decommissioning of the site. Therefore, it may be appropriate for a decommissioning or remediation contractor to operate under its own license at temporary job sites and provide the radiation safety program under which the work is performed.*

  *If the site owner and operator (i.e., the customer) also holds a license issued by the NRC or an Agreement State, the service license should require the establishment of a written agreement between the licensee and the customer. This agreement should specify which licensed activities will be performed under the customer's license and supervision, and which licensed activities will be performed under the service*

*licensee's license and supervision. This agreement should include commitments by both licensees to ensure safety and it should specify whether there are any commitments by the service licensee to help the customer clean up the temporary job site if there is an accident or event.*

*Normally licenses authorizing decommissioning or remediation activities as a service require that the licensee notify the NRC or Agreement State regulator prior to beginning activities at a temporary job site.*

### *Decommissioning*

For licensees that have been active for a long time and are now decommissioning either all or part of their facilities, reviewers should evaluate all old licensing and inspection documentation to see what and where radioactive materials were used in the past. This documentation may be helpful in evaluating the licensee's historical review for the buildings, rooms, and special facilities that the licensee is requesting to be removed from the license. The licensee's current staff may not be familiar with the site history, and may lack adequate records of where and what types of radioactive material were used in the past.

The guidance for approving the release of potentially contaminated solid material from a decommissioning site is complex. Important documents providing part of the guidance are contained in the ADAMS package "Update on case-specific licensing decisions on controlled release of solid materials from licensed facilities (ADAMS Accession No. ML030020655)."

### *Financial Assurance*

When removing facilities or radionuclides from a license and reducing the associated financial assurance, the licensee must demonstrate that facilities in which these radionuclides were or might have been used do not have residual contamination exceeding the license termination criteria found in Subpart E of 10 CFR Part 20, "Radiological criteria for license termination." The licensee may use the a dose assessment method or the screening criteria described in NUREG-1757, Vol. 2, Rev. 1, "Consolidated

Decommissioning Guidance: Characterization, Survey, and Determination of Radiological Criteria," to prepare the assessment to demonstrate the facilities meet the regulatory requirement. The licensee may be able to use the survey method described in NUREG-1757, Vol. 2, Rev. 1, Appendix B, "Simple Approaches for Conducting Final Radiological Surveys." If the licensee's internal survey criteria are more restrictive than the screening values, the licensee's periodic survey results may provide information to support a demonstration that a particular facility meets the license termination criteria.


# MATERIALS INSPECTION & LICENSING HANDBOOK

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## WORKSHEETS

The following pages include simplified worksheets for financial assurance (FA).

*License No.* _____

10 CFR 40.36 "Financial assurance and recordkeeping for decommissioning, source material in readily dispersible form"

| Radionuclide Authorized | Quantity Authorized | Quantity Requiring FA | Fraction |
|---|---|---|---|
| uranium - natural | | 10 mCi | |
| uranium - depleted | | 10 mCi | |
| thorium - natural | | 10 mCi | |
| thorium-230 | | 10 mCi | |
| thorium-232 | | 10 mCi | |
| thorium-230 (from BPM license) | | 10 mCi | |
| If sum of fractions is:<br>≤ 1, no FA is required.<br>> 1 but ≤ 10, $225,000 certification amount is required.<br>> 10, a Decommissioning Funding Plan (DFP) is required. | | | |

*License No.* _____

10 CFR 30.35, "Financial assurance and recordkeeping for decommissioning, byproduct material (BPM), unsealed materials"

| Radionuclide Authorized In Unsealed Form | Quantity Authorized | Quantity Requiring Fa | Fraction |
|---|---|---|---|
| Any BPM 3–83 | | 0.01 mCi (Most restrictive radionuclide from 10 CFR Part 30, App B) | |
| Any BPM > 83 | | 0.01 mCi (Most restrictive radionuclide from 10 CFR 30, App B) | |
| hydrogen 3 | | 1000 mCi | |
| carbon 14 | | 100 mCi | |
| strontium 90 | | 0.100 mCi | |
| cesium 137 | | 10 mCi | |
| lead 210 | | 0.01 mCi | |
| polonium 210 | | 0.01 mCi | |
| radium 226 | | 0.01 mCi | |
| americium 241 | | 0.01 mCi | |
| If sum of fractions is:<br>≤ 1, no FA is required.<br>> 1 but ≤ 10, $225,000 certification amount is required.<br>> 10 but ≤100, $1,125,000 certification amount is required.<br>> 100, a Decommissioning Funding Plan (DFP) is required. | | | |

*License No.* _____

10 CFR 70.25, "Financial assurance and recordkeeping for decommissioning, special nuclear material, unsealed materials"

| Radionuclide Authorized | Quantity Authorized | Quantity Requiring Fa | Fraction |
|---|---|---|---|
| uranium 233 | | 0.01 mCi | |
| uranium 235 | | 0.01 mCi | |
| Specific Activity of uranium 235 = [0.4 + 0.38(enrichment) + 0.0034(enrichment)$^2$] E-6 curies per gram (see Note 3 to Appendix B to 10 CFR Part 20) | | | |
| plutonium 238 | | 0.01 mCi | |
| plutonium 239 | | 0.01 mCi | |
| plutonium 240 | | 0.01 mCi | |
| plutonium 241 | | 0.01 mCi | |
| plutonium 242 | | 0.01 mCi | |
| plutonium 244 | | 0.01 mCi | |
| If sum of fractions is:<br>≤ 1, no FA is required.<br>> 1 but ≤ 10, $225,000 certification amount is required.<br>> 10 but ≤100, $1,125,000 certification amount is required.<br>> 100, a Decommissioning Funding Plan (DFP) is required. | | | |


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# ACKNOWLEDGMENTS

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BEST PRACTICES

# SUMMARY THOUGHTS AND SUGGESTIONS

***Stop - Look - Listen - Learn***

Stop and stand in an area for 5 to 10 minutes. It is amazing what will stand out or who will walk by with an interesting story.

Go to a location where licensed material is in use, and just watch. When you know what "normal" looks like, "abnormal" will jump out at you.

Watch for and take advantage of opportunities to tour normally inaccessible areas or to observe rarely performed activities.

Nothing substitutes for "being there." You have to get into areas, wait for activities, climb, look at things, and get dirty.

Learn by asking! Do not be afraid to ask the licensee questions that you cannot answer. Doing so will help you learn more about the licensee's activities radiation and safety program. Maintain your integrity and enhance your rapport with licensee staff by admitting if you do not know something.

***Suggestions for Improvements or Additions***

Please e-mail comments, suggestions for improvement or additions, and your best practices relative to materials inspection or licensing to R1MatBookCmts@nrc.gov.

## *NOTES*

## NOTES

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