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(FSME-07-068, July, Other, Materials Inspection Handbook)

July 23, 2007

ALL AGREEMENT STATES, NEW JERSEY, PENNSYLVANIA, VIRGINIA

OPPORTUNITY TO COMMENT ON NRC DRAFT INSPECTOR AND LICENSE REVIEWER HANDBOOK (FSME-07-068)

Purpose: To provide the Agreement States with the opportunity to comment on the U.S. Nuclear Regulatory Commission (NRC) Materials Inspection and Licensing Handbook (Best Practices). **Comments are requested within 30 days of the date of this letter.***

Background: This handbook was developed primarily as an aid for new inspectors to carry with them for use in the field. It was also intended to be a reminder, or knowledge transfer mechanism, for use by more experienced inspectors. The handbook is modeled on the NRC Inspector Field Observation Best Practices Manual developed by, and for, reactor inspectors. The material presented in this handbook was developed by inspectors and license reviewers and combines best practices of all four NRC Regional Offices. The contents of this booklet were compiled from individual experiences and suggestions, a review of Generic Communications such as Information Notices, NRC training presentations, and a variety of other sources. However, the guidance in this handbook is not intended to be all inclusive, but rather to supplement existing NRC inspection procedures to heighten inspector and reviewer awareness and improve the effectiveness of materials inspection and licensing. Official agency guidance and policy are promulgated in NRC's Inspection Manual (or in appropriate documents issued by Agreement States).

Discussion: The contents of the draft document are a starting point for a comprehensive handbook. Any comments or blank spots are an attempt to engage the reviewer for potentially appropriate additional material or revisions. In addition, a number of reference documents are listed. The NRC will review those documents to determine if useful content can be transferred to the handbook and only a limited number of references will remain in the document when it is completed. Please provide comments on the content as well as any opinions on the general approach used in the handbook.

*This information request has been approved by OMB 3150-0029, expiration 07/31/07. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the Records and FOIA/Privacy Services Branch (T-5F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0029), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

FSM E-07-068

Contents: Copy of the Draft NRC Materials Inspection and Licensing Handbook.

Action: Please provide written comments on the Draft NRC Materials Inspection and Licensing Handbook to the point of contact named below. We would appreciate receiving your comments within 30 days from the date of this letter. Comments received after that date will be considered if possible.

NRC Point of Contact: If you have any questions regarding the enclosed guidance document or the correspondence, please contact the individual named below.

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Enclosure: Draft NRC Materials Inspection
and Licensing Handbook

NRC MATERIALS INSPECTION and LICENSING HANDBOOK

BEST PRACTICES

MATERIALS INSPECTION and LICENSING HANDBOOK

BEST PRACTICES

Note to Reviewers of this DRAFT: In this draft, there are empty spots, some questions and some provocative statements. All such material is in italics and seeks to engage the reviewer, hoping they will provide appropriate additional material or revisions. In addition, there is some repetition of information. Reviewers are asked to consider and comment on whether this repetition will be helpful to the eventual use of the document or should be eliminated. A number of reference documents are listed in the text. The writing team will review those documents to determine if useful content can be transferred to the Handbook. Reviewers are invited to comment on the use of those documents and to suggest others for consideration. Only a limited number of references will remain in the document when it is complete. Let us know if you think this is the appropriate approach. Please provide insights that, in your experience, will be helpful to others in doing the job!

We also invite comments on the length of the document. How long should it be?

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PURPOSE

This booklet has been developed primarily for new inspectors, but also as an aid and a reminder for more experienced inspectors, and as a sharing tool for everyone who works in the Materials Programs. The Materials inspector and licensing community is extremely diverse and far flung (four NRC Regional Offices, NRC Headquarters, 33 Agreement States and growing). This booklet is modeled on the NRC Inspector Field Observation Best Practices Manual, developed by NRC Reactor Inspectors. The material presented was developed by inspectors and license reviewers and includes best practices from all four NRC regions and the Agreement States. The contents were compiled 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, but rather to supplement existing inspection procedures, to heighten inspector and reviewer awareness of specific issues and to improve the effectiveness of Materials inspection and licensing. Official agency guidance and policy are promulgated in NRC's Inspection Manual, licensing guidance or in appropriate documents issued by individual Agreement States.

INSPECTION PREPARATION

In Office Preparation: The effort expended on inspection preparation should be based upon the complexity and scope of licensed activities and on the experience level of the individual inspector.

The goal of inspection preparation is to ensure that the inspector is sufficiently familiar with the uses of licensed material approved for the licensee to be inspected and 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, 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.

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Review any notes in the file regarding special inspection emphasis (e.g., an amendment for a new medical therapy modality under 10 CFR 35.1000 shall be inspected within 12 months of the date of the amendment [see MC 2800]). Following the inspection, make sure that you make appropriate notes to assist the next inspector.

In advance of the inspection trip, an NRC inspector should convey the itinerary to the State radiation control agency to give the State personnel an opportunity to observe the inspection(s). 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 one year period, allowing inspections at any time.

Assure that the inspector's radiation survey instrument is appropriate for the program to be inspected and calibrated commensurate with the applicable calibration frequency required for the licensee (e.g., six months for radiography licensees per 10 CFR 34.25).

Consider preparing a check sheet or memory jogger based on your preparation. You don't need to be a slave to it, but it helps to make sure you carry out all planned activities. You can decide to skip items, but at least it is a decision, not forgotten. Develop a checklist of the things to accomplish during the inspection. That way you are able to keep track of the status of the inspection. It will also provide a quick way to write down the name of the licensee you contacted.

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

What are the potential problem areas of the 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 personnel dosimeter (TLD or other), survey meter (independent measurements and personal safety), alarming rate meter, safety shoes, hard hat, safety glasses, hearing protection. Some sites require special protective gear, such as Nomex suits, determine whether the licensee will supply or you need to bring your own. Having appropriate safety equipment reduces the time to start an inspection and presents a professional image.

On Site Preparation

Entrance Interview

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Let licensee management know:

- that you are there
- why you are there
- what you will generally be doing
- approximately how long the inspection will take

Explain unannounced inspection policy

Mention that you will want to meet with a management representative at the end of the inspection and inquire about the most convenient time to do that.

Discussions should include:

- Previous items of non-compliance
- Unresolved items
- Bulletins, orders and other generic communications that affect the site

Prepare well for your inspection and identify areas you want to focus on, but be flexible enough to observe 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 find out something the licensee management does not yet know and this may lead to important insights into the program.

Some RSO's tend to jump into inspection. This can be a help if you want to go immediately to a location or to observe a particular activity, but it can cause reduced efficiency throughout the inspection and annoyance from management. Take the time to do an entrance interview, even if just with the RSO or other single licensee representative. Ask them if there is anyone in management that they should inform of the inspection. Sometimes licensee representatives are more flustered by the inspection than they appear. They will appreciate professionalism and organization on your part.

If there is a particular activity you want to see immediately, say so, "I would like to look at X right now. 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 a request.

Ask about scheduling problems that the inspection is causing and if they need time to make changes. Suggest scheduling lunch breaks or record reviews or other inspection activities that the RSO or licensee representative is not needed so they can perform other tasks or attend meetings.

CONDUCT OF INSPECTION

Performance-based Inspection: Examination and evaluation of required results or outcome of performance rather than a prescriptive process, technique, or procedure.

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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 back shift hours, and the licensee's response to unusual situations and events.

Focus on radiation safety problems (potential and actual) and evaluate outcomes (licensee performance).

Conduct independent measurements as a means of identifying opportunities to reduce radiation doses consistent with As-Low-As-Reasonably-Achievable (ALARA) concepts.

Compliance-based: Some regulations or license conditions are very prescriptive and must be followed as stated. Keep in mind that regulations go through a very specific development process which includes development by the staff, publication for comment and then a determination by the Commission that they should be made a final rule. This makes them very powerful and neither the licensee nor the inspector can make a judgment not to follow a regulation.

Make sure to gather information on regulations that do not make sense or actually cause a safety issue. Gather complete information. What do you do with the information?

Safety: In general, if activities are conducted in accordance with NRC regulatory requirements, they are safe. However, both terms are not always mutually inclusive: i.e., safety doesn't necessarily mean "in compliance" and "no violations of regulatory requirements" doesn't necessarily preclude problems. Identify problems, not violations.

Trust, but Verify: Most licensees think they have a comprehensive program. An inspector's job is to verify an appropriate sample of the information presented by management, or others, to determine that it is accurate. Know the answer before you ask the question. This is a twist on the old saying and means "verify then trust."

General: You don't need to identify every possible violation. Expand discussion. If there are a large number of problems, look for common causes.

When you think you have identified a violation, gather all the elements (requirement, what was done or not done, by whom, when) and then review it with the RSO. Ask if you have missed anything or if there is an alternative explanation. Listen to the RSO's point of view and you will avoid many misunderstandings and embarrassments. Do not wait to identify violations or problems at the exit interview

Interview as many users as possible; spend as much time with rank-&-file workers as possible; you will learn more from them than from the RSO.

Observe the licensee using the device and performing licensed activities; if no work is being done, ask for demonstrations (use, leak tests, shutter tests, interlock tests, maintenance, surveys, etc).

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Users are typically not experts; sometimes they won't understand a question. If so, rephrase it in plain language and don't just assume they are untrained.

Cross-check records against licensee's statements.

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 back shift hours, and the licensee's response to unusual situations and events.

Always leave your survey meter on, preferable with the audio on (except in areas such as the secretary's offices, leave the audio off so you don't upset them). Leave the meter audio on in the car as you drive around so you get used to what normal background sounds like. Then, as you survey labs or other areas, you will 'hear' when an area is contaminated (remember that in some lab areas you will have to watch your probe, not the readout, so that you don't bump into bench top lab equipment etc).

Verify licensee assumptions regarding calculations to show compliance with NRC regulatory requirements.

Normal/Backshift Observations: Inspections on back shifts are often more important than normal shift inspections. It is easy for operators or other employees on back shift to get into the mode that no one ever looks at their performance as long as nothing "bad" happens.

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

Interface with Licensee/Certificate Holder: Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with licensed activities. For example, an inspector should not insist on interviews when:

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

Need a discussion of how to intervene when there is an unsafe condition or a violation that the inspector believes must be corrected immediately. Criteria for a violation that must be corrected immediately?

Inspection Attitude: Maintain a questioning attitude and verify information provided by the licensee and/or its contractors.

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Use all your senses. Observe everything. If something looks or smells unlike you expect, ask about it.

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

Inspection Behavior Do not handle licensed material or operate licensee equipment. Instead, observe licensee staff handle licensed material and operate equipment. Be sure the staff who you request to perform actions is qualified and do not ask them to violate procedures. It is okay to ask them to explain why they can't do something or what a procedure allows.

Watch for, and take advantage of, opportunities to tour normally inaccessible areas.

Under no circumstance should an inspector "test" the effectiveness of a licensee's security staff by any means, such as posing as someone other than himself/herself or intentionally causing the actuation of a security alarm.

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

Review this document to extract appropriate/useful content, if any: Recommending Third Party Assistance to Licensees HPPOS-324 PDR-9308260248

During the inspection be sure you get the name of all the persons you talk with and their titles. Get the spelling correct. Document what you observe in your field notes as you are inspecting. Don't wait until later and try to remember. Have copies of the Part 19, 20, 30 40, 70 71 regulations and DOT 49 CFRs that apply with you. Take a break to consult them if you need to. When you are finished with the inspection, take a few minutes and document your findings before you close out with licensee management. If you need help before the close-out meeting, call one of the Senior HPs or your Branch Chief to discuss the findings of the inspection.

Interview Skills: There are several reasons to interview a licensee employee or contractor or other person. These include: determining the status of compliance, effectiveness of training, or to evaluate an event. Take appropriate time (anywhere from a minute to over an hour, depending on how important and complicated the topic) to plan each interview. Be aware of what your objective is and what you need to get from the interview.

Don't jump all over an employee who gives you the wrong answer. Do tell him/her what you are going to do with the information.

Observe Radiation Safety Committee meetings and training sessions whenever possible.

Seek privacy for important interviews whenever possible.

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Be especially careful to 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.

Ask open ended questions and avoid “yes/no” answers.

Take the time to loosen up the individual.

Let the individual talk.

Control your voice and non-verbal language; interviewees will notice and respond to your reactions (remember your words carry less than 10 percent of the message, tone and body language the rest).

Take notes, but avoid being conspicuous about it. Go over your notes after the interview and fill in details for important interviews.

Get the details if violations are identified.

Listen, Listen, Listen. If you have a message for the person, make it short and clear.

Rewrite this Paragraph: Have licensee staff demonstrate what they do, see if they know how to operate their survey meters, read them correctly, use them properly etc. Have them turn on their meters, and make comparative measurements with them. Have them open doors, refrigerators, etc, rather than you-the-inspector. If something is contaminated or not quite right, the licensee, not you, is responsible. Licensees in the past have been unable to find their meter, read them on the wrong scale, or have non-working batteries. A favorite anecdote comes from an training session: the trainer was describing what happened when he asked a fixed gauge licensee to demonstrate how he would do a leak test. The licensee took a large filter paper circle, opened the gauge port, and waved the filter paper in the radiation beam!

Avoid interviewing the licensee's Regulatory Affairs management and staff. You will get an answer that repeats back the regulation, but offers no information.

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

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 photos reveal proprietary or other sensitive information and record the response and the fact that you asked. Include something to give scale, but be careful about including faces or otherwise identifying specific individuals.

Daily Informal Debriefs: The inspector should advise the licensee representative of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform the appropriate licensee representative.

Observed Safety Issue: Do not allow an unsafe condition, activity or violation to continue, but don't tell the licensee what to do. Point out the facts, and ask how and when they plan to handle the situation. Discuss the importance of responding in a careful, but prompt fashion.

Receipt, Documenting, and Handling of Allegations, Concerns, and Complaints: NRC licensees should NOT be aware that you are looking into allegation(s). Licensees

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may guess or reasonably conclude that you are, but the inspector should never confirm. However, sometimes a question produces useful information (e.g., “Is there something going on at the facility that makes you think that someone might be calling the NRC?”).

Chilling effect: Be aware that your actions can cause a chilling effect for communicating with inspectors during your inspection or a future inspection.

Interviews of allegeders: Don’t ask leading questions. Ask open ended questions. Don’t try to impress interviewees with your knowledge. It is OK, and sometimes to your advantage, 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. Maintain control over the interview.

Include allegation issues within the context of the full inspection.

Investigate non-allegation areas in a comparable level of detail.

Inspections resulting from allegations will be documented in accordance with Management Directive (MD) 8.8, “Management of Allegations.” 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 filed in the docket file for the licensee.

Processing and Handling of Non-Radiological Safety Concerns (OSHA Issues): Memoranda of Understanding (MOUs) dated October 21, 1988, and July 26, 1996, between the U.S. Nuclear Regulatory Commission and the Occupational Safety and Health Administration (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! Wear your eye, ear, and foot protection when appropriate, even if not required by the licensee.

Need short paragraph on confined space entry. Some licensees are not sufficiently sensitive to the dangers and inspectors need to be aware.

Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2005-18: GUIDANCE FOR ESTABLISHING AND MAINTAINING A SAFETY CONSCIOUS WORK ENVIRONMENT (Any part useful for Materials licensees?)

Close-Out Meeting (Exit): Preferably before leaving the site, the inspector shall clearly present apparent violations, confirm the licensee’s understanding and agreement that a violation occurred, and determine that the licensee’s prompt corrective actions will be effective to prevent similar violations. 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 it to your supervisor.

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Purpose is to present the PRELIMINARY inspection findings and provide the licensee an opportunity to provide additional information that could change the findings.

Take some time to prepare for the exit meeting.

For large programs, brief the RSO first regarding all findings.

At least meet with highest management representative available, but everyone is welcome. However, remember it is their facility and they can control attendance. Outline the specific violations, including the regulatory requirement and your understanding of proposed corrective actions (if known). Be prepared to discuss the basis for regulatory requirements that are cited.

Discuss positive findings to send a “balanced” message.

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

The licensee is ultimately responsible for the safety of its licensed activities.

NRC and Agreement States assure protection of the public health and safety through regulation of the users.

Regulators and licensees are not natural adversaries - the common goal is operation with adequate safety.

Proper design, fabrication and construction, procedures, and training contribute towards safe operations, but we cannot inspect a licensee into safety.

The message you deliver at the exit meeting is important. Make certain that you take the necessary time to develop the message. If possible, plan the exit meeting for the morning after you complete the inspection. This will give you time overnight to consider your findings, place them in the correct context, and identify any additional informational you need.

Be sure to convey the results of the inspection to the licensee so they know if there are violations. If there are findings that need to be discussed with NRC management before it can be decided if your observations are violations, tell the licensee it is an open item and you will get back to them. Meet with your Branch Chief upon return to the office to inform the Chief how the inspections went. Document your findings to support your conclusions.

Facility Emergency: Don't try to do the licensee's job for them. Stay out of the way, but keep watching. Take notes, include times and who did what. Contact your office, but don't make reports for the licensee. What if the licensee asks for advice? Be

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factual, not directive. Demonstrate by example that a calm response is usually the most effective one. Ask an occasional question: "Have reviewed your procedure", "Is there someone on your staff, or otherwise available to you, who could help?"

Personal Emergency: If a personal or medical emergency occurs during an inspection, ask for help. Do not try to cover up, tough it out, or ignore a real need.

Talk to your supervisor to get advice on how to handle the situation with the licensee. Tell the licensee what you are doing (they don't need details, just what is going to happen) or make arrangements with someone else to do it. Don't just disappear.

FUNCTIONAL AREAS

Radiation Protection:

Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2002-10 REVISION OF THE SKIN DOSE LIMIT IN 10 CFR PART 20

Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2003-04 USE OF THE EFFECTIVE DOSE EQUIVALENT IN PLACE OF THE DEEP DOSE EQUIVALENT IN DOSE ASSESSMENTS

Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2004-01 METHOD FOR ESTIMATING EFFECTIVE DOSE EQUIVALENT FROM EXTERNAL RADIATION SOURCES USING TWO DOSIMETERS

Review this document to extract appropriate/useful content, if any: Posting of High Radiation Areas HPPOS-242 PDR-9111220087

Respiratory Protection:

Rules of Thumb: (6CE), Exposure from one ml "drop" of P-32 on 1 cm² of skin will exceed the skin dose limit (50 Rem shallow dose-equivalent) in 85 seconds.

High Radiation Areas:

Thoughts on evaluation of "high" dosimeters?

Training: Evaluate training by observing the actual conduct of licensed activities and asking questions of those individuals who actually perform the activities. Focus on the activities the individuals perform. If the individual is only authorized to work with 50 microcuries of P-32, it is more important for you to evaluate his/her knowledge of high energy beta emitters, the use of

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gloves, and the potential for skin/extremity overexposures. It is not as appropriate to ask them about shielding required for cobalt-60 sources.

Gauges, Portable:

Barriers to secure portable gauges:

- Dual, independent physical controls must prevent removal of the portable transportation case containing the gauge from the vehicle or facility and dual, independent physical controls must prevent removal of the portable gauge from the transportation case.
- Simply having two chains or cables with locks would not satisfy the security rule unless each chain and lock combination were physically robust enough to provide both a deterrence and a reasonable delay mechanism.
- The NRC staff 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 unauthorized removal of the portable gauge.

In ~9 minutes, an unshielded 10 mCi ¹³⁷Cs source can deliver 5 rem to a worker's extremities at a 1 cm distance; some gauges contain sources with even higher activities.

Learn from past incidents, study program weaknesses, and emphasize licensee's investment in their gauges. It is particularly important to pass on industry experience to licensees. There is a remarkable amount of “It can't/won't happen to us.” out there. Look for any exposures that indicate poor work practices. Do workers know how to perform maintenance without unnecessary exposures?

Direct observation of licensed activities provides the best evaluation of a licensee's performance.

Gauges, Fixed:

Evaluate compliance with lock-out/tag-out procedures. Talk to the staff that actually does the procedures.

Verify that gauge service and maintenance is conducted by authorized persons.

Interview the staff person who actually takes wipe test samples.

Fixed gauge licensees often have generally licensed gauges; inspector should plan to look into this. Comment on registration requirements and follow up on missing gauges (TI)

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Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2006-25: REQUIREMENTS FOR THE DISTRIBUTION AND POSSESSION OF TRITIUM EXIT SIGNS AND THE REQUIREMENTS IN 10 CFR 31.5 AND 32.51a

Fixed gauges are subject to OSHA lock-out/tag-out standard specified in 29 CFR 1910.147. Many licensees are unaware that their gauges are subject to the OSHA standard; address during inspection.

Industrial facilities present a multitude of potential hazards that are mostly non-radiological (e.g., moving vehicles, machinery, unsafe scaffolding, spills, electrical hazards, chemicals, explosives, poor lighting, noise, vibration, extreme temperatures, and confined spaces).

Learn OSHA/MSHA regulations so that you can recognize when conditions are unsafe, and to know what safety measures should be taken.

If in doubt about conditions at a site, err on the margin of safety - never take unnecessary risks

Many industrial facilities require completion of site-specific safety training, and can require inspectors to provide their own safety gear; it may be necessary to come to the site in advance of the inspection in order to complete safety orientation training.

In addition to standard OSHA protective personal equipment, it may be necessary to use safety vests, harnesses, respirators or other specialized safety equipment to gain access to areas where industrial RAM is used; use of such equipment may require additional training (*Should this be in Inspection preparation or Occupational Safety?*)

Interview as many users as possible; you will learn more from them than from the RSO.

Observe the licensee using the device, performing licensed activities; if no work is being done, ask for demonstrations (use, leak tests, shutter tests, interlock tests, maintenance, surveys, etc).

Users are typically not experts; sometimes they won't understand a question, so rephrase it in plain language; don't just assume they are untrained.

Cross-check records against statements made by licensee staff.

Review this document to extract appropriate/useful content, if any: Installation of Fixed Gauges HPPOS-305 PDR-93062220177

Broad Licenses:

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Review this document to extract appropriate/useful content, if any: IE Information Notice: No. 80-22 BREAKDOWNS IN CONTAMINATION CONTROL PROGRAMS

Review the disposal of supposedly clean trash in the nearby county sanitary landfill. Interview janitors regarding the process/procedure used for trash pick-up/removal. Make sure there is training provided in appropriate language(s).

Review this document to extract appropriate/useful content, if any: Authorization of Employee Eating and Drinking Areas in Labs at Veterans Administration Medical Center, Martinez, California HPPOS-318 PDR-9306280312

Sealed sources

Observe or review uses, procedures and practices used by the licensee.
Observe licensee security and controls for sealed sources.
Review the sealed source inventory: do a "scavenger hunt."

In some large broad scope R&D, programs it is easy to get lost in the volume of information received. In these programs, it is best to inspect a cross section of the program. Identify a sample of authorized users - don't just identify heavy users or iodimators, or users where the licensee has identified problems - get a real cross section. You might want to select a few authorized users from each research building or department. Check to see the permits they have received from the RSC or RSO, look at their RAM receipts (did the RSO control these purchases), look at licensee audits, travel to the lab and follow a RAM vial from receipt through use and disposal. Check to see if the material is properly stored, and if the labs properly posted and secured. Interview the laboratory staff regarding who used the material, if they are adequately trained, if they have adequate facilities and equipment, if they wear appropriate dosimetry, if they perform proper surveys, if they dispose of the material properly, what problems the RSO has identified, and if these conditions still exist (if so, why...).

Accompany HP techs or the RSO on an actual laboratory audit. Not only can you learn something about the operation of the lab, but you learn something about the quality of the audit and the licensee's ability to bring about corrective and preventive actions.

Make confirmatory surveys. They get the licensee's attention and they can really drive home the importance of following the safe use of procedures.

Ask technologists in the lab what they would do if they dropped and broke a vial of RAM they are authorized to work with. They should be able to give you a very good recitation of the emergency spill procedures. Knowing the emergency procedures will enhance safety in the lab much more than if the technologist knows the limits for sink disposals.

In the labs, talk to a cross section of the staff, not just the authorized user or her/his chief technologist. Anyone who is authorized to work with RAM is fair game. If a technologist in the lab tells you they are not authorized to use radioactive materials, but they are

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authorized to work in the lab with users of radioactive materials, make sure they have received training (maintaining lab security, recognizing cold trash from hot trash, etc.).

Radiography:

What does the licensee do to identify survey instruments in need of repair and ensure that repaired instruments are calibrated prior to first use?

Ensure that radiographic equipment, radiation survey instruments, and/or personnel monitoring devices are used as required by 10 CFR 34. Failure to use radiographic equipment, radiation survey instruments, and/or personnel monitoring devices as required by 10 CFR 34 is an example of a Severity Level III violation in the NRC Enforcement Policy.

Failure to survey the radiographic exposure device and the guide tube with a calibrated and operable radiation survey instrument after each exposure when approaching the device or the guide tube to determine that the sealed source has returned to its shielded position has resulted in numerous overexposures (reference 10 CFR 34.49(b)).

Equipment Inspection and Maintenance (10 CFR 34.31(b)(1)):

- Examine distal end of drive cable (near male connector) for wear. IN 97-91, Supplement 1 discusses the need for licensees to inspect and maintain drive cables.
- Examine the distal end of the male connector for excessive wear. Also look for the male connector being off-axis relative to the drive cable (Per Amersham: If the angle of the male connector is > 10 degrees, it could cause excessive wear of the distal end of the male connector incident to friction on the interior lumen of the guide tube).
- Verify that crank maintenance does not include assembly that compromises the design safety features of the system (e.g., all of the parts are installed, 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?
- AEA issued a Bulletin instructing customers to revise their quarterly inspection program to include misconnect tests for each set of drive cables used. The basis for the tests 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 the Bulletin?

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- Does the staff recognize that noises during cranking indicate a potential problem, and do they know how to respond appropriately?
- Does the staff reference the labels on the crank showing what direction to turn it in order to expose and retract the source?
- Does the staff use the Posilock indicator and/or challenge Posilock actuation after source retraction?
- Make sure that NDS MN RA-500 battery checks include LED and audible signals in accordance with the operator's manual.

10 CFR 34.41(a) requires that radiography may not be performed if only one qualified individual is present. 10 CFR 34.46 requires the radiographer to directly observe the radiographer's assistant perform radiographic operations. An example of violations of 10 CFR 34.41(a) and 10 CFR 34.46 is provided below:

A radiographer left the immediate vicinity of the radiographic operations to take articles to a truck, leaving the radiographer's assistant alone to monitor the exposed source and the radiation area. The radiographer returned to the area of the radiographic operations prior to the conclusion of the ongoing radiographic exposure. The radiographer walked approximately 60 feet from the area of the radiographic operations to a company truck, leaving the radiographer's assistant alone for 1-3 minutes while a radiographic exposure was in progress. While the radiographer was away from the radiographic operations, he could still hear the voice of the radiographer's assistant if the assistant required assistance from the radiographer. The radiographer had his back to the area of the radiographic operations and the radiographer's assistant during a portion of the radiographer's walk to the truck. During the period that the radiographer had his back to the area of the radiographic operation, the radiographer could not observe the radiation area. Therefore, the radiographer would not be capable of providing immediate assistance to prevent unauthorized entry into the radiation area. Also, the radiographer could not directly observe the radiographer's assistant while the assistant was alone during radiographic operations.

10 CFR 20.1003 defines "survey" as an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. As appropriate, the evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present. 10 CFR 20.1501 requires that licensees make, or cause to be made, surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present. The following is an example of a violation of 10 CFR 20.1501:

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A licensee measured the exposure rate at the perimeter of a posted radiation area while a radiography source was exposed during the first shot at a temporary job site to confirm compliance with the public dose limits in 10 CFR 20.1301. During preparation for the second shot, the licensee changed the position of the sealed source. However, the licensee failed to measure the exposure rate at the perimeter of the posted radiation area while the radiography source was exposed during the second shot and the licensee failed to evaluate, by calculations or other means, whether or not compliance with the public dose limits in 10 CFR 20.1301 were achieved during the second shot.

Review this document to extract appropriate/useful content, if any: NRC INFORMATION NOTICE 96-04: INCIDENT REPORTING REQUIREMENTS FOR RADIOGRAPHY LICENSEES 10 CFR 34.30

Review this document to extract appropriate/useful content, if any: NRC INFORMATION NOTICE 2001-03: INCIDENT REPORTING REQUIREMENTS FOR RADIOGRAPHY LICENSEES 10 CFR 30.50 and 34.101

Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2005-15: REPORTING REQUIREMENTS FOR DAMAGED INDUSTRIAL RADIOGRAPHIC EQUIPMENT

Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2005-10: PERFORMANCE-BASED APPROACH FOR ASSOCIATED EQUIPMENT IN 10 CFR 34.20

Review this document to extract appropriate/useful content, if any: NRC BULLETIN 95-01: QUALITY ASSURANCE PROGRAM FOR TRANSPORTATION OF RADIOACTIVE MATERIAL

Review this document to extract appropriate/useful content, if any: Information Notice No. 87-47: TRANSPORTATION OF RADIOGRAPHY DEVICES (Update of Information Notice No. 81-02, January 23, 1981)

Permanent Radiographic Installation: An enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.

Field Station: A facility where licensed material may be stored or used and from which equipment is dispatched.

Location of Use: Specific location identified on the license where material is stored or used, may or may not be where the licensee does not dispatch from (e.g. permanent radiographic installation, field stations, and storage locations).

Temporary Jobsite: A location where radiographic operations are conducted and where licensed material may be stored other than those location(s) of use authorized on the license.

The NRC does not authorize pipeliner devices. A pipeliner device is one that is directly connected to the pipe and does not have the "S" tube. The source is attached to a rotor.

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It was used on offshore platforms in close work proximity and currently in some Agreement States. The device does not meet the performance requirements in § 34.20.

Medical:

Interview selected staff who care for patients hospitalized in accordance with 10 CFR 35.75 to determine if they are properly trained (e.g., size and appearance of sources, safe handling and shielding of sources, patient and visitor control, and medical emergency/death response). Review the licensee's responses to such emergencies.

Unless you need to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that your presence does not interfere with patient care or a patient's privacy.

Obtain patient permission before observing dose/dosage administrations. *Suggestion for text.*

When inspecting 35.300 activities, have the technologist or whoever gives the dosage, actually go through the motions for giving the capsule/liquid to the patient. It has been done the in the worst way (the tech picked it up with her hand, albeit gloved, and put it in the patients mouth) to the best way (the capsule was placed by the tech into a medicine cup in its original lead pig, and the patient took the medicine cup out and poured the capsule in their mouth).

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 to prepare and dispense product (including container size [3 ml vs. 30 ml], product volume [1 ml dosage vs. 10 ml dosage], and container materials [plastic vs. glass]).

Does the licensee understand the definition of a "medical event" (with special focus on 10 CFR 35.3045(a)(3))?

How does the licensee account for geometrical variation (plastic vs. glass) for pure beta emitters (e.g., Sr-89, P-32, Sm-153)?

35.27 Supervision:

- Does the RSO oversee all aspects of the radiation safety program, including those that he/she is less comfortable with?
- If the licensee relies on a consultant to complete tasks required by the NRC, what does it do to ensure that the tasks are completed as required (e.g., audit the consultant's work, observe the consultant conduct the required tasks, etc.)?

Brachytherapy:

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Does the licensee take actions to ensure that the brachytherapy applicator/source apparatus is adequate to deliver the radiation dose prescribed on the written directive? For example, do they do acceptance testing to ensure that sources stay in position within the applicator? Do they ensure that the dummy sources are the same physical size as the sources used for brachytherapy?

If the licensee uses a Wang applicator, how does it ensure that the sources cannot move down the center of the spring?

HDR:

How does the licensee know that an attempt to expose the source with the catheter not locked into channel one results in no source exposure?

How does the licensee know that an attempt to expose the source through Channel one with the applicator locked into Channel two results in no source exposure?

Have the medical physicist and authorized user go through the motions of different emergency scenarios (i.e. stuck source in patient, source doesn't fully retract into unit at end of treatment, etc.). You can usually tell who's been actually doing dry runs as required instead of just talking about it.

GSR:

Is the GSR X, Y, and Z hardware labeled to avoid confusion during patient set-up?

How does the licensee assure that the fiducial box is properly positioned on the stereotactic frame prior to MRI?

If one of the fiducial box plates is missing, how does the licensee prevent from assuming it's the posterior plate?

Is the fiducial box marked legibly?

What does the licensee do to prevent overriding the fiducial box safety feature due to excessive force when clamping the box onto the stereotactic frame?

On 8/22/05, a medical event occurred with a Leksell Gamma Knife because a patient microphone clip came off of the patient couch and jammed the collimator jaws. What has the licensee done to prevent this from happening at their facility?

Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2002-06 EVALUATING OCCUPATIONAL DOSE FOR INDIVIDUALS EXPOSED TO NRC-LICENSED MATERIAL AND MEDICAL X-RAYS

Review this document to extract appropriate/useful content, if any: INFORMATION NOTICE 2004-02: STRONTIUM-90 EYE APPLICATORS: NEW CALIBRATION VALUES AND USE

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Review this document to extract appropriate/useful content, if any: INFORMATION NOTICE 2003-22: HEIGHTENED AWARENESS FOR PATIENTS CONTAINING DETECTABLE AMOUNTS OF RADIATION FROM MEDICAL ADMINISTRATIONS

Radio Pharmacies:

How does the licensee account for geometrical variation (plastic vs. glass) for pure beta emitters (e.g., Sr-89, P-32, Sm-153)?

Hand Exposures, ALARA program

Constraint Rule

Review this document to extract appropriate/useful content, if any: INFORMATION NOTICE 97-04: IMPLEMENTATION OF A NEW CONSTRAINT ON RADIOACTIVE AIR EFFLUENTS

Review this document to extract appropriate/useful content, if any: INFORMATION NOTICE 2003-12: PROBLEMS INVOLVED IN MONITORING DOSE TO THE HANDS RESULTING FROM THE HANDLING OF RADIOPHARMACEUTICALS

Irradiators, Panoramic:

Verify that the licensee does not bypasses interlocks or any other safety systems.

Check the accessibility of handling tools.

Pay particular attention to procedures for testing interlocks.

Review this document to extract appropriate/useful content, if any: Information Notice No. 89-82: RECENT SAFETY-RELATED INCIDENTS AT LARGE IRRADIATORS x Significant contamination of pool water remaining unnoticed, which could have been detected sooner, had the pool water been continuously circulated and monitored through the demineralizer. x An uncontrolled descent of a shipping cask into an irradiator pool, due to brake malfunction on a lifting crane. x Leaks in the irradiator pool caused by localized caustic stress corrosion in pool liner welds.

Review this document to extract appropriate/useful content, if any: NRC INFORMATION NOTICE 96-54: VULNERABILITY OF STAINLESS STEEL TO CORROSION WHEN SENSITIZED

Irradiators, Self- Shielded:

Well Logging:

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Review this document to extract appropriate/useful content, if any: NRC INFORMATION NOTICE 2004-003: RADIATION EXPOSURES TO MEMBERS OF THE PUBLIC IN EXCESS OF REGULATORY LIMITS CAUSED BY FAILURES TO PERFORM APPROPRIATE RADIATION SURVEYS DURING WELL-LOGGING OPERATIONS

Service Licenses:

Decommissioning:

Go to <http://r3intra.nrc.gov/dnms2006/index.htm> for decommissioning inspection guidance.

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, which gives the date that the next calibration is due. Verify that a daily source check has been performed prior to the use of the instrument to verify operability. Because very cold and very hot weather can effect an instrument's response, verify that the licensee has taken this into consideration for the instruments they are using. 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. As a rule of thumb, gamma scanning soil with a NaI detector should be performed at about ½ m/s, depending on conditions, and when surface scanning with an alpha scintillator, the probe should be kept < 1 cm from the surface. Hand frisking of skin and clothing should be performed with the probe ½ inch from the surface and at a speed of 1-2 in/s.

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 dosimetry in conformance with facility-specific requirements and 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 doffing 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 and do not violate or compromise radiation boundaries.

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 re-concentration of contamination at a downstream location which could lead to a localized hot spot. Optimally, the licensee has collected samples at points downstream to verify if this is an issue.

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Vacuums: Vacuums with 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 in its entirety 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.

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. Look at the general condition of the crane or lifting device. Immediately inform licensee personnel about any cracks indicative of an overloaded condition.

Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2005-25: CLARIFICATION OF NRC GUIDELINES FOR CONTROL OF HEAVY LOADS

SAFETY: During any decommissioning/demolition work, personal safety is the number one concern. Verify that this attitude exists with management and is consistently communicated to the workers.

Inspections of decommissioned sites often entail surveys of older and poorly maintained buildings and manufacturing plants. 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-

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away” feature for the display of identification badges and dosimetry; tucking in of neckties and any other loose clothing in the vicinity of rotating equipment; and footwear that is in good condition and protects against injury due to falling objects.

Fall-Related Injuries: Verify that ladders are sturdy and do not wobble. Verify that licensee personnel using ladders do so in a safe manner. A ladder tender, or securing the ladder, helps to avoid a fall. No one should ever stand on the top step of a ladder. Another area of concern involving ladders can occur when personnel attempt to carry items with them when climbing up or down a ladder. Be aware of this when walking to/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.

Confined Space Entry: Environments in which the oxygen levels are limited or unknown are considered to be confined space areas of which their entry is required to be strictly controlled. Verify that personnel accessing these areas are qualified, that a confined space entry permit has been obtained and posted, and that other confined space entry requirements are met. ? *Personal Safety?*

Tanks/ 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 can't occur due to a 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 in case a back-suction does inadvertently occur, only a minimal amount of water can be drained.

Asbestos, Lead, Mercury, PCBs: Sites being decommissioned/demolished often contain asbestos, switches containing mercury, and paint with lead and/or PCBs. 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:

Review this document to extract appropriate/useful content, if any: NRC GENERIC LETTER 95-09: MONITORING AND TRAINING OF SHIPPERS AND CARRIERS OF RADIOACTIVE MATERIALS

Review this document to extract appropriate/useful content, if any: Information Notice No. 92-72: EMPLOYEE TRAINING AND SHIPPER REGISTRATION REQUIREMENTS FOR TRANSPORTING RADIOACTIVE MATERIALS

Review this document to extract appropriate/useful content, if any: Information Notice No. 90-82: REQUIREMENTS FOR USE OF NUCLEAR REGULATORY COMMISSION-

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(NRC-)APPROVED TRANSPORT PACKAGES FOR SHIPMENT OF TYPE A
QUANTITIES OF RADIOACTIVE MATERIAL

Explanation of removable contamination limits.

Review this document to extract appropriate/useful content, if any: Information Notice
No. 80-32 Rev. 1: CLARIFICATION OF CERTAIN REQUIREMENTS FOR
EXCLUSIVE-USE SHIPMENTS OF RADIOACTIVE MATERIALS

Review this document to extract appropriate/useful content, if any: Clarification of
Certain Requirements for Exclusive-Use Shipments of Radioactive Materials HPOS-
084 PDR-9111210232

Don't jump on small differences in radiation levels from shipper to receiver, even if the receiver's numbers seem to indicate a violation. Investigate first. There must be a reason for the difference other than calibration and measurement difference for a violation to exist (e.g., changing conditions during transport).

Event Review:

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

For re-enactments, consider using a locking tape measure, stop watch, still camera (digital, if possible), video camera (digital, if possible), and/or tape recorder. Digital video is the best/easiest way to establish time, sequence of events, and relative locations. Multiple re-enactments may be necessary, especially if dose rates are high and the series of movements is complex.

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

Evaluate the "extent of condition" (i.e., are there generic implications?).

Medical Event Follow-Up: Reactive inspections involving a medical event will be performed using the guidance in Management Directive 8.10, "NRC Medical Event Assessment Program."

Obtain medical event details (e.g., chronology of events, etc.).

Identify the root causes and contributing factors associated with the medical event.

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Obtain the licensee's assessment of the patient effects associated with the medical event.

What are the licensee's corrective actions to prevent similar medical events/violations?

Review implementation of procedures for administrations requiring a written directive.

Evaluate compliance with medical event notification requirements:

Medical event reported to the NRC Operations Center next calendar day post discovery?

15 day written report to NRC?

15 day written report to patient (if patient requested it)?

Referring physician and patient (if applicable) informed about the medical event within 24 hours of discovery?

15 day written report provided to the referring physician (if he/she is not the licensee)?

Does everyone understand what a written directive is and when it is necessary?

Fuel Facilities: *Should we include?*

Always double check yourself prior to enter a controlled area and verify that you have all your PPE required.

If you are in a controlled area without your required PPE, notify your supervisor and resident inspector (where applicable) and let them know. If it is missing shoe covers, notify the HP personnel onsite for proper decontamination if necessary.

Always wear gloves and do not put your hands in the lab coats pockets (the lab coat might be contaminated).

Always make sure your pants are not too close to the floor, you might have to surrender them if they become contaminated.

Do not wear jewelry.

Prior to entering a control area, notify the supervisor at the area, or report to the control room and let the operators know that you are in the controlled area.

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Prior to opening a door, ALWAYS read all signs carefully, no matter how familiar you are with the site.

Do not assume it's okay to stay if you hear an alarm, always ask what it means.

If you are not comfortable to look around by yourself, request a tour at the beginning of the inspection (especially if you have not been there for a while, things change and FCF are always changing).

At the beginning of the inspection, ask for the status of the plant and if there is any area that you need to be aware of (e.g., airborne controlled area, radiation work permits, etc, that needs special PPE and approvals, prior to go in if needed).

'Trust but verify' or verify and then trust. Either way, always confirm the facts.

Wear appropriate clothing especially for environmental protection inspections and on observations on drills. Weather is a factor that always needs to be considered.

As a courtesy, always call your Branch Chief and let them know the outcome of the inspection prior to the exit meeting.

Be sensitive of what you are told, and let it be known to your Branch Chief.

Always call another inspector, or a HQ expert on a matter, when you need more information to clarify an issue or a possible issue.

If going to a site where there is a resident inspector, always let him/her know of your presence. Meet with them/him/her to verify your SATs, and if you are in the good guy letter list, prior to showing up on site.

When observing activities, always ask an operator for the procedure, (knowing the current revision) and observe each step that the operator executes. Before hand, determine which part of the process you want to observe to be more efficient.

Always interview the operator, the supervisor, team leader and the manager, so you can determine if there is any deficiency.

When reviewing documents, you should take a sample. If problems arise, expand your scope and verify whether it is a localized problem or if the problems exist in other areas too.

On an ORR, it is best to go through all the P&IDs, Procedures, SARs, ISAs, Facility Change reviews, and then go out to the field. It can be all or a vertical slice depending on the situation of the facility... On a regular inspection it is better to use a vertical slice.

Define horizontal and vertical slices

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If management tells you there is nothing scheduled that they are aware of that week to observe (like a maintenance activity), look around because things break down and all of a sudden you can find a maintenance activity.

Do not spend too much time reading; select the documents that are relevant to your inspection. Licensees tend to give you more than you need, and sometimes it is more for your information than it is necessary for the scope of the inspection. Make time to look around/tour the plant.

Always look for calibrations of equipment, shutdown of equipment, and training of personnel that you are interviewing.

Plan ahead your inspection and the things you want to accomplish from the inspection.

If you have an issue, let the licensee know right away so they can start evaluating it and make the appropriate corrective actions.

It is good to brief the licensee on the status of the inspection by the end of each day, or prior to the exit meeting.

When you have a finding, always evaluate the safety significance. Always consult your Branch Chief, and let the licensee know too.

Get organized, keep track of the time, and be aware of how you are setting up interviews. Managers are usually very busy with their daily schedule and sometimes they are not available. You will want to set up those meetings as soon as possible at the beginning of the inspection, do not wait until half-way through the inspection to set it up. It is the same for observing plant activities.

If you are waiting for some information on an issue, spend your time in another area of the inspection. Do not stop to wait for the information, but keep going. Sometimes there is a lot to accomplish in less than a week of time on the site.

For an ORR, it is good to have the material for review prior to the inspection (if possible). It gets overwhelming if you until you arrive at the site to start working on it. Of course, it depends if the licensee has the information available for us (the NRC) to review. Sometimes, they are still approving documents as the ORR is on-going.

Follow-up inspections: Let the licensee know about items so they can have the information available to you on a reasonable time for review and confirmation (depending on the status).

Follow the licensee's procedures; do not act like you are the maximum authority because it usually gets you in trouble.

When reviewing data and graphs, make sure you understand exactly what it means. It may look like it is ok, when really it is not. One time I questioned some environmental

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data, and the licensee found that there was an error in their newly installed program (it had the wrong units).

When the inspection where certain information is sensitive or confidential, or you are not quite sure, limit your telephone conversations and let them know that you want to meet them in person. This way, you can get your information without worrying about a security infraction.

In the FCF, none of the sites are the same. Be very sensitive when talking to them, you do not want to release any information that it is proprietary (which means you need to know and be sensitive on what is confidential, proprietary, or sensitive to each site). Never assume that they know.

Drive around the area, and note the time and distance to the fire and police stations relative to the plant. Compare the time and distance with the license, emergency plan, or pre-fire plans. Get "lost" and ask for directions. Ditto for hospitals. Go to the emergency room, and ask if they are prepared to deal with HF burns. Similar for licensees with emergency plans.

Reciprocity:

(SP-96-022)

Exclusive federal jurisdiction

A single site can have mixed jurisdiction

Indian reservations are federal jurisdiction

Make the facility answer the jurisdictional question

Radiography at nuclear power plant sites

Radiography cannot be performed under the Part 50 license

State can issue a license or is allowed to require reciprocity at NPP

Storage counts as a type of use (hence, it counts toward their allotted number of days)

Reciprocity also applies on the waterways

Licensee has to follow both the tie-down commitments on their out-of-state specific license and your regulations

Review this document to extract appropriate/useful content, if any: Policy and Guidance Directive FC 83-19, "Jurisdiction at Reactor Facilities" HPPOS-265 PDR-9306070303

SECURITY ISSUES

Cell Phones:

Materials Inspection and Licensing Handbook (Draft)

PDA's, Calculators, Cameras:

Security Orders:

Increased Controls:

Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2003-08 PROTECTION OF SAFEGUARDS INFORMATION FROM UNAUTHORIZED DISCLOSURE

Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2007-15: UNESCORTED ACCESS TO MATERIALS FOR NON-MANUFACTURER AND DISTRIBUTOR SERVICE PROVIDERS

Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2007-07: CLARIFICATION OF INCREASED CONTROLS FOR LICENSEES THAT POSSESS COLLOCATED RADIOACTIVE MATERIAL DURING TRANSPORTATION ACTIVITIES

Review this document to extract appropriate/useful content, if any: NRC INFORMATION NOTICE 2007-16: Common Violations of the Increased Controls Requirements and Related Guidance Documents

Information Security:

Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2002-15: NRC APPROVAL OF COMMERCIAL DATA ENCRYPTION SYSTEMS FOR THE ELECTRONIC TRANSMISSION OF SAFEGUARDS INFORMATION

Review this document to extract appropriate/useful content, if any: NRC 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

LICENSING

Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2004-17: REVISED DECAY-IN-STORAGE PROVISIONS FOR THE STORAGE OF RADIOACTIVE WASTE CONTAINING BYPRODUCT MATERIAL

Review this document to extract appropriate/useful content, if any: REGULATORY ISSUE SUMMARY 2007-05: STATUS AND PLANS FOR IMPLEMENTATION OF NRC REGULATORY AUTHORITY FOR CERTAIN NATURALLY-OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL (Separate Section on NARM?)

Materials Inspection and Licensing Handbook (Draft)

Review this document to extract appropriate/useful content, if any: NRC GENERIC LETTER 99-01: RECENT NUCLEAR MATERIAL SAFETY AND SAFEGUARDS DECISION ON BUNDLING EXEMPT QUANTITIES

Review this document to extract appropriate/useful content, if any: DISTRIBUTION OF GEMS IRRADIATED IN RESEARCH REACTORS (GENERIC LETTER 88-04; SEE ALSO GENERIC LETTER 86-11, DATED JUNE 25, 1986)

Long term storage of radioactive waste may be an issue again soon. Any thoughts or lessons regarding it?

Review this document to extract appropriate/useful content, if any: NRC Licensed Facilities Requesting to Name a Consultant Physicist as their Full-Time Radiation Safety Officer HPPOS-307 PDR-9306240030

1. Always step back from your written communications and re-read your work. Read what you have written, hopefully after a break or preferably the next day. If someone at another company nearby found your letter would they have some idea of what you are talking about.

Be sure you are not immersing yourself into the issue so much that you assume anyone who reads your work would also be familiar with your thoughts.

2. Do not get stuck into focusing only on guidance documents. They may not anticipate all safety issues. Always step back before completing a licensing action and ask two basic questions:

A) What has the licensee requested? Did I answer all their requests; and

B) Did I recognize and address all potential safety issues including those which may not be covered by guidance?

3. Do not overly rely on specific definitions in the regulations in determining if any regulatory involvement is appropriate. Focus on any safety issues instead and ask questions to satisfy the goal of assuring the operation will be performed safely rather than does the regulation indicate that the licensee can do it without providing additional details. For example there may not be any rule which limits the number of facilities one RSO may service but when some reviewers recognized this may become a safety issue further questions were developed to address that.

One final philosophical point:

Always apply a performance based approach when licensing and inspecting. Resist pressures to indicate the licensee met the letter of the law and therefore they are ok. You may not be able to write a violation or deny a license request, but you should nevertheless try to communicate and resolve any potential safety concerns you identify. An example could be that the licensee shows you that they have secured the room containing byproduct materials, but you notice the padlock being used is of poor quality and you would not lock your own bicycle with such a lock.

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In such a case you should point this out to the licensee and perhaps they will agree to improve the situation. Of course it is always easier to walk away and say nothing. This is so often where regulatory agencies breakdown because they know of weaknesses in the industry, but fail to address them unless responding to an accident or specific regulations are established. Concerns about regulatory burden have increased this trend; however, we need to at least communicate all the safety concerns identified so that each is given consideration.

Prelicensing Reviews:

Radiation Protection:

High Radiation Areas:

Training:

Gauges, Portable:

Gauges, Fixed:

Broad Licenses:

Guidance on incineration clear enough in NUREG?

Radiography:

Medical:

Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2002-23: AVAILABILITY OF GUIDE FOR DIAGNOSTIC NUCLEAR MEDICINE

10 CFR Part 35 regulations are performance-based (except for prescriptive elements of newly-added 35.600).

License reviewers have few procedures to review; performance/procedures evaluated during inspections.

Confirming that proposed authorized individuals meet the requirements is often the most difficult aspect of medical licensing.

Confirming that proposed authorized individuals meet the requirements is one of the most important, potentially safety significant aspects of medical licensing, particularly for AU and AMP therapy authorizations (35.300/400/600/1000).

Nuclear Laundries:

Little written guidance

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What can we say about release criteria?

Make sure they do not become a waste disposal licensee

List letters on dissolvable garments

Paragraph on sewer and sludge, NPDES

Review this document to extract appropriate/useful content, if any: OTHER INFORMATION: GUIDANCE ON RADIOACTIVE MATERIALS IN SEWAGE SLUDGE AND ASH AT PUBLICLY OWNED TREATMENT WORKS (STP-00-056)

Review this document to extract appropriate/useful content, if any: INFORMATION NOTICE 94-07: SOLUBILITY CRITERIA FOR LIQUID EFFLUENT RELEASES TO SANITARY SEWERAGE UNDER THE REVISED 10 CFR PART 20

Irradiators:

Well Logging:

Service Licenses:

? Several Locations for guidance

Review this document to extract appropriate/useful content, if any: OTHER INFORMATION: RESPONSE TO CONGRESSIONAL INQUIRY REGARDING RELEASE OF SOLID MATERIAL CONTAINING VERY LOW LEVELS OF RADIOACTIVE MATERIAL (SP-00-026) Anything useful in this? Still apply?

Review this document to extract appropriate/useful content, if any: PROGRAM MANAGEMENT INFORMATION: NRC GUIDANCE ON CASE-SPECIFIC RELEASE OF SOLID MATERIALS LICENSING DECISIONS (STP-00-070)

There is also an old memo on this subject that may still apply. Is it available in existing guidance?

Review this document to extract appropriate/useful content, if any: Application of the Financial Assurance Requirement in 10 CFR 30.35, 40.36, and 70.25 to Waste Brokers Located in Agreement States HPPOS-309 PDR-9306240427

Review this document to extract appropriate/useful content, if any: Decommissioning Contractor HPPOS-281 PDR-9306160199

Transportation:

Materials Inspection and Licensing Handbook (Draft)

Decommissioning:

Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2004-08 RESULTS OF THE LICENSE TERMINATION RULE ANALYSIS

Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2000-09: STANDARD REVIEW PLAN FOR LICENSEE REQUESTS TO EXTEND THE TIME PERIODS ESTABLISHED FOR INITIATION OF DECOMMISSIONING ACTIVITIES (Is this issue covered by most up-to-date guidance?)

Review this document to extract appropriate/useful content, if any: NRC REGULATORY ISSUE SUMMARY 2002-02: LESSONS LEARNED RELATED TO RECENTLY SUBMITTED DECOMMISSIONING PLANS AND LICENSE TERMINATION PLANS (important thoughts for decommissioning plan reviews)

Should we include thoughts and/or information on transfer of records?

Financial Assurance:

Review this document to extract appropriate/useful content, if any: Statements of Intent by Government "Controlled" Entities HPPOS-315 PDR-9306250281

Include Summary Table? Might not be at all useful for Agreement States

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License No.

10 CFR 30.35, 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 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			
≤ 1 , no FA is required.			
> 1 but ≤ 10 , \$225,000 certification amount is required.			
> 10 but ≤ 100 , \$1,125,000 certification amount is required.			
> 100 , a DFP is required.			

Materials Inspection and Licensing Handbook (Draft)

License No.

10 CFR 40.36, 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			
≤ 1 , no FA is required.			
> 1 but ≤ 10 , \$225,000 certification amount is required.			
> 10 , a DFP is required.			

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License No.

10 CFR 70.25, special nuclear material, unsealed

Radionuclide Authorized	Quantity Authorized	Quantity requiring FA	Fraction
uranium - enriched 2%		0.01 mCi	
uranium - enriched 1%		0.01 mCi	
** Specific Activity = $[0.4 + 0.38(\text{enrichment}) + 0.0034(\text{enrichment})^2]$ E-6 curies per gram			
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			
≤ 1 , no FA is required.			
> 1 but ≤ 10 , \$225,000 certification amount is required.			
> 10 but ≤ 100 , \$1,125,000 certification amount is required.			
> 100 , a DFP is required.			

In order to remove the radionuclides listed in items [INSERT] from your license, you must demonstrate that facilities in which these radionuclides were used do not have residual contamination exceeding the license termination criteria found in Subpart E of 10 CFR Part 20. You may use the a dose assessment method or you may use screening criteria, as described in NUREG-1757 "Consolidated NMSS Decommissioning Guidance" (NUREG-1757), Volume 2, "Characterization, Survey, and Determination of Radiological Criteria". You may be able to use the survey method described in NUREG-1757, Volume 2, Appendix B, "Simple Approaches for Conducting Final Radiological Surveys". If your internal criteria is more restrictive than the screening values, the criteria may be used to demonstrate that the facility meets the license termination criteria.

Confirm..... certain radionuclides were never used at your facility, you may provide documentation. When removing facilities from a license and reducing financial assurance, must

Materials Inspection and Licensing Handbook (Draft)

make sure that contamination does not remain.

REFERENCES

Acknowledgments

SUMMARY THOUGHTS AND SUGGESTIONS

Suggestions for Improvements and/or Additions

NOTES