



Surviving An Inspection

After reviewing this tutorial, participants should

- Know the basics of licensure by the NRC and State regulatory agencies
- Be able to state the difference between agreement states and non-agreement states
- Be familiar with the radiation safety rules that must be posted in every department
- Be familiar with film badge readings, their interpretation, and the frequency of measurement
- Be able to list the various requirements for maintaining radiation safety-related log books in the lab and the required frequency of entry
- Be familiar with logging in of generators and radiopharmaceuticals and logging out and recording patient doses and radioactive waste
- Be familiar with basic rules of radiation safety
- Be familiar with the "inspection issues" that represent the most commonly appearing citations during state and federal inspections.

Regulatory Issues

- Licensure by State Department of Nuclear Safety/Homeland Security or NRC
- Current License required or a "Timely Filed Notice"

Question- Who Is Licensed?

- Director of Nuclear Medicine
- Director of Radiology
- Directors of Nuclear Medicine & Radiology
- The Institution
- Each Individual User of Radioactivity

Answer d. The Institution

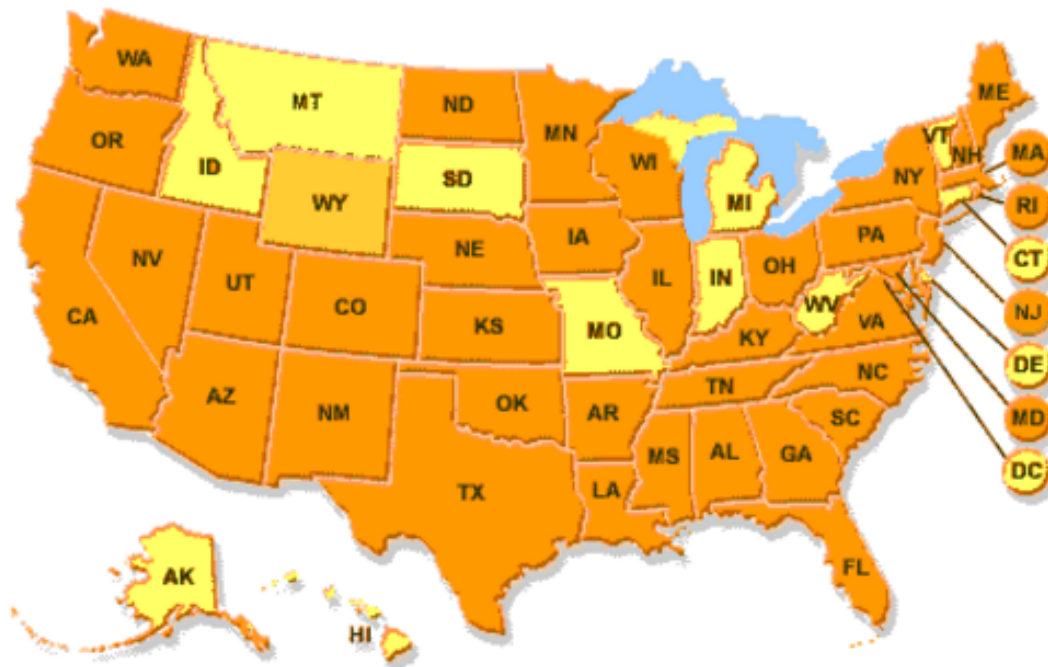
Who Are the Inspectors?

- Nuclear Regulatory Commission
- State Department of Nuclear Safety/Homeland Security
- State Department of Public Health
- JCAHO
- OSHA
- ACNP (Voluntary)

Agreement States Vs Non-Agreement States

- There are 38 Agreement States
- Agreement States abide by all NRC regulations but additional regulations are decided upon by each state.

Agreement & Non-Agreement States



Agreement States **Non-Agreement States** **Letter of Intent-AS**

SURVIVING AN INSPECTION

Preparation for an Inspection

- We MUST be aware of our Day to Day Obligations and the Expectations of the Inspectors.
- Record data on a daily basis- assume inspector is coming tomorrow. It is impossible to retrace your steps after a relatively short period of time.
- Don't "create" missing data- it makes inspectors mad!!
- Have an Outside Expert perform a mock inspection
- Determine your level of preparedness
- Identify any deficiencies
- Recommend corrective procedures
- Keep Up-To-Date All Necessary Logbooks

Thyroid Monitoring Logbook

All Nuclear Medicine personnel involved in use of I-131 sodium iodide in quantities >1 mCi should have a routine thyroid count performed every 6 months; in addition, 24 hours after an iodination procedure or administration of I-131 sodium iodide in liquid form, the thyroid should be counted.

Leak Testing Of Sealed Sources

All sealed sources (gamma counter calibration sources, dose calibrator standards, etc) must be leak-tested every 6 months and results of this testing recorded in the appropriate logbook.

Area Room Monitoring Log Book

- On a daily basis, survey each room in which radioisotopes are used with a GM counter
- Record Model # & Serial # of meter used
- Record background reading
- Record actual reading; specify units, cpm or mR/hr
- Specify "action level" (criterion for immediate action to be taken)

- An accurate area map must be drawn and, on a weekly basis, 5-7 dry wipes are taken in each room in which radioisotopes are used. Results of the counting procedure are correlated with the area map to identify areas with count rates higher than normal room background.
- An open energy window is used since we don't know which isotope has been spilled. The only isotope not found on a wipe test is Xe-133.

If contamination is found, your obligation is to:

- Document the radioactivity level of the hot spot
- Decontaminate to background levels
- Record the new reading indicating that contamination has been removed

Personnel Monitoring Log Book

At the end of the day, each technologist is obligated to monitor his/her hands with a Geiger counter to detect inadvertent contamination. Results of this survey are recorded in the appropriate logbook on a daily basis.

Incoming Package Logbook

- Every package containing radioisotopes must be logged in appropriately. This includes recording the product name, lot number, calibrated activity and date, received activity and date, shipper's package number, and initials of person receiving the package.
- If your license requires you to monitor every package received by your department, results of this monitoring must be recorded in this logbook.

Hot Sink Log Book

- One sink in each laboratory may be designated as a "hot sink". This is the only permissible location for disposing of radioactive liquid waste. Each liquid waste disposal must be documented by the radioisotope, amount, date, and initials of person involved.
- The usual limit for hospitals is 1 Curie per year (all radioisotopes) for all liquid waste for the entire institution.

Treadmill Monitoring Logbook

- Assuming your institution monitors the treadmill on a daily basis (or with any other frequency), results of these surveys must be recorded in an appropriate logbook.

RADIOPHARMACEUTICAL MANUFACTURING LOG BOOK

Generator Elution Data

- Mo-99 breakthrough
- Al³⁺ ion breakthrough
- Hydrolyzed reduced Tc

Radiopharmaceutical disposition

Radiopharmaceutical QC

Dose Calibrator QC Logbook

- Accuracy Test
- Constancy Test
- Linearity Test
- Geometry Test

Posting Of Radiation Safety Rules

- General rules, e.g., no smoking, eating, drinking, storing of food, mouth pipetting of radioactive materials, posted in each laboratory in which radioactive materials are used.

Posting Of State/NRC Regulations And Telephone Numbers

- Posted in each laboratory in which radioactive materials are used. Chart supplied by the regulatory agency

Posting Of Ring/Whole Body Badge Monthly Reports

- Should be posted on bulletin board on a monthly basis. Employer is responsible for informing each employee on an annual basis of his cumulative radiation dose.

Inspectors' Favorite Places to Look

- Training Records
- Injection Policy
- Dose Calibrator QC Logbook
- Incoming Package Logbook
- Personnel Monitoring Logbook
- Temperature Monitoring Logbook
- High-dose I-131 Therapy Records

Inspector's Favorite Tricks:

- A technologist is taken aside and asked questions
- The inspector extracts a vial from the waste bin and asks you to show entry of this vial in incoming package logbook.
- The inspector asks you to prove that you performed QC on your dose calibrator when on call on a legal holiday or a Sunday.
- The technologist's hands and shoes are monitored without warning.
- GM Counter monitoring of "cold" trash bin
- Monitoring of the treadmill and the surrounding environment.

Guidelines for a Successful Inspection

General

- Keep the inspector in the back of your mind every working day. Try to think like the inspector when completing documentation.
- Make sure than an item of non-compliance from a previous inspection has been corrected- that's the first place the inspector will look.
- Don't panic during an inspection- be confident, polite, and honest. Sense of humor is a plus.
- Don't offer any information other than what the inspector requests.
- Be personally responsible for your continuing education requirements
- Pay close attention to suggestions and recommendations made during the exit interview.
- Murphy's Law favors the Inspector!

Specific

- Linearity checks are usually performed on a timely basis, but often are not taken out to the lowest dose level one would use clinically. A reasonable level is 30 mCi, comparable to doses of iodinated compounds or Cr-51 labeled RBCs
- Inspectors often see people drawing doses, injecting patients, eluting generators and handling eluate without gloves. Be prepared during an inspection- wear gloves if there is a chance you will be working with radioactivity in the inspector's presence.
- Survey meters must undergo a brief operational check before each use. Results must be recorded at least quarterly as well as after calibration, repair, or battery change.
- Room survey records are not complete unless they include the make, model, and serial # of the instrument used. In addition, if a well counter is used for wipe tests, the make, model and serial # must be recorded in the logbook.
- When performing the Constancy Test on dose calibrators, one MUST check every setting that might be used that day. For example, when called in for a stat lung scan, both the Tc-99m and Xe-133 settings should be checked. Often a ventilation study is added on and one forgets to check the calibrator for Xe-133.
- An annual review of the radiation safety program must be performed by either the Radiation Safety Officer or his designate (may be a consultant). Results must be reviewed by Hospital Administration. An annual review of the ALARA Program must also take place.
- Brachytherapy records must indicate complete accountability for records of all inventory items. There should be a conversion factor for converting Radium units to mCi.
- Rooms in which Xe-133 gas are used must be under negative pressure. Inspectors find failures occasionally when construction is underway and airflow is diverted from Nuclear Medicine to another location, destroying the required pressure differential.
- Frequent failure for unit dose users is the calibration, dating, timing, and initialing the dose record.
- A minor issue is Continuing Education credits. Most NMTs are conscientious, but occasionally license renewal is held up due to failure to obtain enough credits.
- All authorized users are required to undergo radiation safety training on an annual basis.
- Hand monitoring might be required daily, or every time you leave the laboratory, depending upon license requirements for your institution.

- Inspectors like to review High Dose Iodine therapy procedures, especially issues related to dose calibration, patient dose administration procedures and safety precautions taken, and waste disposal records.
- Incoming package logbooks are kept up well, in general. Inspectors are most likely to ask to see log-in of a package received on the weekend or on a holiday.
- Regarding administration of I-131 Na iodide: If the patient has been admitted, then, regardless of the dose of I-131 (whether 8 mCi or 200 mCi), nursing instructions must be distributed, signage must be posted on the door, room surveys must be performed, and all required precautions for the hospitalized radioactive patient must be observed.
- Regarding generator QC testing, the most common failure is to not report Mo-breakthrough as a ratio, e.g., 0.01 mCi mCi/mCi Tc. Those people still using generators are very conscientious about performing the test, even when called in for a stat scan.



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