Current NRC Regulations

Part 1. General Radiation Safety Rules and Regulations

Part 2. Hot Lab Quality Control

REFERENCES FOR CURRENT NRC REGULATIONS: PARTS 20 AND 35

http://www.nrc.gov/reading-rm/doc-collections/cfr/part020/full-text.html

http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/full-text.html

Part 1. General Radiation Safety Rules and Regulations

1. **Unrestricted Area:** Secretarial space, hallways, and certain other areas of a department must qualify as an unrestricted area. The criteria for defining an unrestricted area are listed in 10CFR Part 20 Section 1301.

Each licensee shall conduct operations so that:

- Dose in any unrestricted area does not exceed 0.002 Rem in any one hour.
- Annual dose limit of 0.1 rem for members of the public must not be exceeded

2. Posting of Radiation Safety Rules and Regulations

- General Radiation Safety rules must be posted in each laboratory in which radioactive materials are used. General rules include no smoking, eating, drinking, storing of food, mouth pipetting of radioactive materials, and similar guidelines
- State/NRC regulations and telephone numbers must be posted conspicuously in each Nuclear Medicine Laboratory. Chart supplied by the regulatory agency

3. Declared Pregnant Worker

According to 10CFR Part 20 Section 1208, a female technologist is legally considered a "declared pregnant worker" after she informs her employer in writing that she is pregnant and gives the estimated date of conception (2 required pieces of information).

Radiation Dosimetry Conditions:

- Dose to the embryo/fetus over entire period of gestation (9 mos.) is limited to 0.5 rem.
- Dose should be delivered at a fairly uniform rate over entire gestational period and not delivered in a few large doses.
- Rule permits additional 0.05 Rem if she has >0.45 Rem at the time of notification.

4. Maximum Permissible Dose to Occupationally Exposed Individuals

According to 10CFR Part 20 Section 1201a, which covers Occupational Dose Limits for Adults, the licensee shall control the occupational dose to individual adults to:

- 5.0 Rem (50 mSv) Total Effective Dose Equivalent per year (whole body dose).
- 50.0 Rem (500 mSv) Total Organ Dose Equivalent per year.
- Lens of the Eye - 15.0 (150 mSv) Rem per year
- Extremities - 50.0 Rem (500 mSv) per year

5. Maximum Permissible Dose for Job Changers

According to 10CFR Part 20 Section 1201(f), the current Licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person or facility.

6. Employers' Requirement for Informing Radiation Workers of their Radiation Exposure Levels

Although film badge readings are routinely posted on bulletin board on a monthly basis, every employer is responsible for informing each employee on an annual basis of his cumulative radiation dose. Posting readings on a monthly basis far exceeds this requirement.

7. Dose Calibrator Checks After Normal Working Hours

If a Nuclear Medicine Technologist performed requisite QC testing on the dose calibrator at 7:00 AM this morning and is then called in to perform a stat lung scan at 12:15 tomorrow morning, the elapsed time will be 17 hours and 15 minutes. Even though the elapsed time would be less than 24 hr, he would be required to repeat the constancy test on every setting that might be used that day. The day officially starts at 12:01 AM.

8. Negative Pressure Testing in Rooms in Which Xe-133 is Used

In the past many of us have observed the NRC or State Inspector use a smoke gun to blow a puff of smoke under the closed door in the room in which Xe-133 ventilation studies are performed. The purpose of this test is to ensure that the room is under negative pressure with respect to the hallway. Therefore, our expectation is that the puff of smoke will be drawn into the room. Inspectors find failures occasionally when construction is underway and airflow is diverted from Nuclear Medicine to another location, destroying the required pressure differential. *The test is no longer mentioned in the NRC Regulations and is therefore not mandatory.*

9. ALARA Policy

One of the policies that help to minimize radiation dose to Nuclear Medicine Technologists is called the ALARA Policy. ALARA is the acronym for "As Low As Reasonably Achievable", that is, making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical consistent with the purpose for which the licensed activity is undertaken.

- According to 10CFR Part 20 Section 1101(b), "each licensee shall use, to the extent practicable, procedures and engineering controls to ensure that doses are as low as reasonably achievable (ALARA)."
- According to 10 CFR Part 20 Section.1101(c), each licensee shall periodically (at least annually) review the ALARA Program by the RSO must be performed. This review is typically performed by the Radiation Safety Officer or his designate.

10. Radiation Safety Program

Like the ALARA Policy, the Radiation Safety Program must also be included in written form in the department's Policy and Procedure Manual. According to 10 CFR Part 20 Section.1101(c), each licensee shall periodically (at least annually) review the radiation protection program content and implementation. This annual review of the radiation safety program must be performed by either the Radiation Safety Officer or his designate (may be a consultant). RSO must inform management of review findings, which must be reviewed by Hospital Administration.

11. Hot Sink Log Book

One is permitted to designate one sink in the laboratory as a "HOT SINK" for disposal of low activity radioactive waste. This waste must be readily soluble or readily dispersible biological material and each liquid waste disposal must be documented by the radioisotope, amount, date, and initials of person involved. Total annual quantity must not exceed 1 Ci for all isotopes for all users on one license.

12. Prescribed Doses/Administered Doses

The famous 10% rule is no longer valid in NRC states. By Federal law all DIAGNOSTIC doses must be within 20% of the prescribed dose. Many agreement states still require that all doses must be within 10% of the prescribed dose. In either case, if a technologist wishes to administer a dose higher than that prescribed, he must receive WRITTEN consent from the prescribing physician. All therapeutic doses must be within 10% of the prescribed dose; a deviation of more than 10% constitutes a recordable event and a deviation of more than 20% constitutes a reportable event.

13. Thyroid Monitoring of Dose Administrators

Historically when one administered a dose of I-131 to a patient with thyroid cancer, one had to have his thyroid counted at 24-72 hr post admin time. According to current NRC regulations, there is no requirement to perform thyroid monitoring 24-72 hr after administration of oral I-131 sodium iodide. The original regulation has been replaced with a vague statement about "timely monitoring of the dose administrator".

14. NRC Definition of an Adult

According to the NRC, an adult is defined as an individual 18 or more years of age

15. Signage for Radiation Areas

There are three designated areas:

- **Radiation Area** - An accessible area where an individual could receive a dose equivalent in excess of 0.005 Rem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.
- **High Radiation Area** - An accessible area where an individual could receive a dose equivalent in excess of 0.1 Rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface the radiation penetrates.
- **Very High Radiation Area** - An accessible area where an individual could receive an absorbed dose in excess of 500 Rads (5 grays) in 1 hour at 1 meter from a radiation source or from any surface that the radiation penetrates. This is strictly a Nuclear Power Plant term and has no applicability to Nuclear Medicine.

16. Lethal Dose limits for exposed individuals

In the previous paragraph, a whole body dose of 500 Rem was mentioned. The LD^{100}_{30} is the whole body dose in humans where 100% of all people die within 30 days. It has a value of ~550 R; the LD^{50}_{30} is the whole body dose in humans where 50% of all people die within 30 days; it has a value of ~350 R. With high-level medical intervention, the LD^{100}_{30} can be increased to ~850 R.

17. Film Badge Monitoring: Who has to be badged?

According to 10 CFR Part 20 Section 1502, monitoring is required if an individual is:

- likely to receive a dose >10% of limits (500 mRem/yr = 5 mSv) or
- is going to enter a high or very high radiation area

18. Types of Licenses

There are three types of radioactive material licenses.

- A **SPECIFIC** license is issued to named persons for a specific use of radioactive materials, for example a Nuclear Cardiology Imaging Center.
- A **GENERAL** license is issued to individuals who have very little chance of causing harm with the materials, for example, a Radioimmunoassay Laboratory. This license also applies to some laboratories and users of certain sealed sources.
- A **BROAD** license is issued to universities and large medical centers for medical use of essentially any radioisotope.

Each institution has only one Radioactive Materials license (RAM License), regardless of the number of users of radioactivity on campus. The institution is the licensee, not the director of Nuclear Medicine or the Director of Radiology or the Radiation Safety Officer.

19. GM Survey and Wipe Tests

A GM Survey of your lab must be performed on a daily basis in any room in which radioisotopes are used. A wipe test must be performed weekly, usually at end of the week

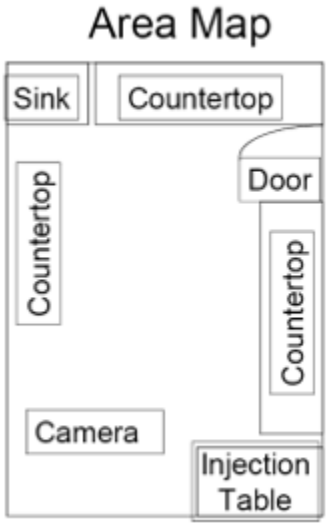
For the **GM Survey:**

- Perform a GM Counter survey of each room in which radioisotopes are used
- 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)

For the **wipe test:**

- An accurate area map must be drawn and 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 > normal room background
- If contamination is found, obligation is to document radioactivity level of the hot spot, decontaminate to background levels, recheck the area using a new wipe, and record the new reading indicating that contamination has been removed.

Diagram of an Area Map of one room



20. Leak Testing of Sealed Sources

All sealed sources (gamma counter calibration sources, dose calibrator standards, spot markers, etc) must be leak-tested every 6 months and results of this testing recorded in the appropriate logbook. If a source is found to be leaking radioactivity, it should be very carefully packed to prevent contamination and should be returned to the manufacturer for proper disposal.

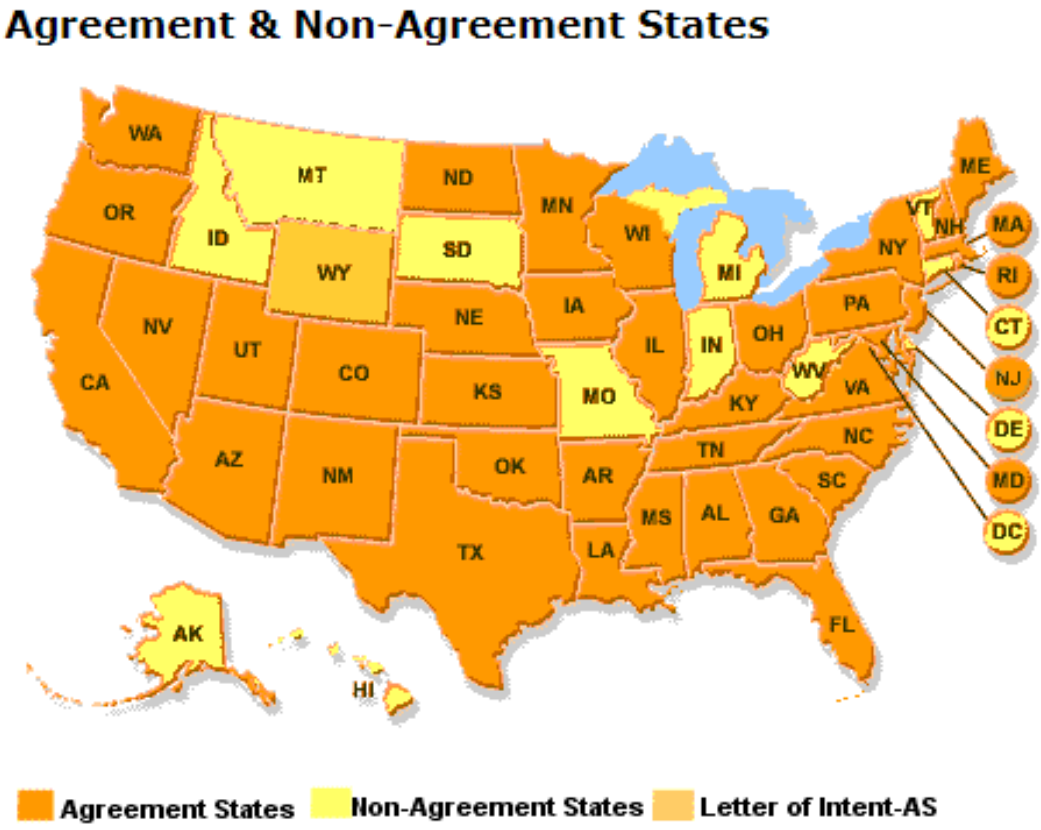
21. Agreement States

37 of the 50 states have signed an agreement with the Nuclear Regulatory Commission (see map below) stipulating that they will be the sole regulators, but will follow Federal guidelines. They may choose to be more restrictive than the Federal guidelines, but not more lenient.

For example, **in an NRC State**, one can receive a high dose therapy with I-131 and be

sent home. If the physician chooses to hospitalize the patient, then **the release criterion is a radiation level below 7 mR/hr at 1 meter.** Some Agreement States choose to be more restrictive and require hospitalization of the patient until his radiation level drops below 5 mR/hr at 1 meter from the patient's chest.

Finally, the map of the Agreement States is outdated and here is the current map. If you prefer to work with the original instead of the figure below, it is available at https://scp.nrc.gov/asdirectory.html.



22. Daily Monitoring Issues

Hand monitoring by Nuclear Medicine Technologists is required daily for most licensees. Some technologists choose to monitor their hands after every patient or every time they leave the laboratory. Treadmill monitoring is also required on a daily basis. Results of these surveys must be recorded in an appropriate logbook.

23. Radiation Safety Training

The following groups of people must undergo annual Radiation Safety Training:

- Nuclear Medicine Technologists
- All Authorized Users
- Loading Dock personnel who deliver radioactive materials
- Housekeeping involved in Hot Lab cleaning
- Security officers accompanying delivery men

24. Lab Security

Consider this scenario: an NRC Inspector has completed his inspection at 5 PM and has his coat on, ready to leave. The only other person present is the one leading the inspector on the department tour and he also has his coat on. On impulse, the inspector walks over to the Hot Lab door, opens it, looks around, and closes the door. He has discovered a citable offense. Since there are no technologists or other personnel present and the room contained radioactive materials, this is considered a breach of security. Anyone could have walked into the room without being challenged and walked away with radioactive materials.

25. Opening Packages Containing Radioactive Material

According to 10 CFR Part 20 Section 1906, which deals with Procedures for Opening Packages, one should take possession of packages expeditiously (within 3 hours). Packages containing only a radioactive gas, e.g.., Xe-133, or special form radioactive material do not need to be monitored for contamination.

Incoming Package Log Book

Every package containing radioisotopes must be logged in appropriately. This includes recording the radionuclide, product name, chemical form, physical form, and lot number; the time, date, and activity at time of calibration; the time, date, and activity at time of receipt; shipper's package identifying number, and initials of person receiving the package. In addition, if your license requires you to monitor every package received by your department, results of this monitoring must be recorded in this logbook.

Examples of packages that must be logged into the incoming package log book include

- A 5 mCi standard of Tc-99m
- A 10 mCi unit dose of Ga-67 citrate
- A 100 mCi therapy dose of I-131 NaI
- A 0.1 mCi dose of Cr-51 Na chromate
- A 0.010 mCi dose of I-125 HSA

26. Acceptable Methods of Waste Disposal

According to 10 CFR Part 20 Section 2001, the authorized methods of disposal include:

- Transfer to licensed person/company
- Decay in Storage
- Release as effluents within authorized limits (Nuclear Power Plants

HOT LAB QUALITY CONTROL

RADIOISOTOPE DOSE CALIBRATORS

The current NRC regulations no longer mention the accuracy, constancy, linearity, and geometry tests. According to 10 CFR Part 20 Section 35.60, a licensee shall calibrate the radioisotope dose calibrator in accordance with nationally recognized standards or the manufacturer's instructions. The bottom line: current manufacturers' recommendations are identical to the old NRC regulations so our requirements for the accuracy, constancy, linearity, and geometry tests are annually, daily, quarterly, and at installation, respectively.

Deviation from standard or expected values for all dose calibrator tests must be within ± 10%. If Deviation >10%, then obligation is to record value, note repair or recalibration of instrument, retest, and record new values. In addition to the above steps, every dose must be corrected mathematically until the instrument is repaired. There is NO LONGER a reporting requirement.

The **accuracy test** is performed at installation and annually. It is designed to show that the calibrator is giving correct readings throughout the entire energy scale that we are likely to encounter. Low, medium, and high energy standards (usually Co-57, Ba-133 or Cs-137, and Co-60, respectively), are measured in the dose calibrator using appropriate settings. Standard and measured values are compared.

This Accuracy Test is a pass:

Standard	Energy (keV)	expected value (mCi)	measured value (mCi)
Co-57	122	2.48	2.51
Cs-137	662	3.38	3.29
Co-60	1,332	1.55	1.52

The **constancy test** is performed at installation and daily. It measures instrument precision and is designed to show that a long-lived source, usually 30 y Cs-137, yields reproducible readings on a daily basis on all isotope settings we are likely to use. The Cs-137 source is placed in the dose calibrator. Activity is then measured on the Cs-137 setting and all other settings used on a daily basis. Values are recorded in the dose calibrator logbook and are compared with recent values to determine if instrument is maintaining constancy on a daily basis.

This Constancy Test is a pass:

SETTING	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY
Cs-137	123	124	122	126	124
Ga-67	223	224	222	224	226
Tl-201	163	164	162	166	164
Tc-99m	243	242	244	246	244
I-131	313	314	312	316	314
I-123	193	192	194	196	194
In-111	283	284	282	286	284
Xe-133	433	434	432	436	434
Cs-137	123	124	122	126	124

The **linearity test**, performed at installation and quarterly, is designed to prove that the dose calibrator readout is linear for sources varying from the μCi range through the mCi range. A high activity Tc-99m source (50-300 mCi) is measured at T_0 and at predetermined time intervals up to 72 hours. Expected and actual measurements are compared (and may be analyzed graphically) to determine if the instrument is linear throughout the activity range we are likely to encounter.

This Linearity Test is a Pass:

Elapsed time (hr)	Expected reading (mCi)	Measured reading mCi
0	300	300
1	267	272
2	238	241
3	212	209
6	150	148
12	75	72.4
24	18.75	19.1
48	1.17	1.19
72	0.073	0.074
78	0.036	0.037

The **geometry test**, performed at installation and after repair of the dose calibrator, is designed to show that correct readings can be obtained regardless of the sample size or geometry. 0.5 ml of Tc-99m in a 10 ml syringe (activity 25 mCi) is measured in the dose calibrator and the value obtained is recorded. The activity is then diluted with sterile water to 1 ml, 2 ml, 3 ml, 4 ml, etc. At each of these points a reading is taken and the value recorded. Data are then evaluated to determine the effect of sample geometry on the dose calibrator reading. If instrument is geometry-dependent, it may be necessary to routinely correct readings obtained when using calibrator.

This Geometry Test is a Pass:

Sample Volume	Activity (mCi)	Sample Volume
0.5	25.5	0.5
1.0	25.3	1.0
2.0	25	2.0
3.0	24.8	3.0
4.0	24.7	4.0
5.0	24.5	5.0
6.0	24.3	6.0

2. Types of Impurities in the Hot Lab

The three types of impurities and an example of each are listed in the following chart:

TYPE	EXAMPLE	EFFECT
Radionuclidic	Mo-99	Poor Image Quality Altered Radiation Dose
Radiochemical	Hr Tc	Poor Image Quality Altered Radiation Dose
Chemical	Al^{3+}	Poor Image Quality

Methods used to quantify these three types of impurities:

TYPE OF IMPURITY	**QUANTIFICATION METHOD**
Radionuclidic	Dose Calibrator or Multichannel Analyzer
Radiochemical	Thin Layer Chromatography
Chemical	Colorimetric

Mo-99 Breakthrough Test

Mo-99 is assayed FIRST on the Mo-99 setting directly in the special lead pig supplied by the manufacturer of your dose calibrator. Tc-99m is THEN assayed on the Tc-99m setting directly in the plastic sleeve. Activity (μCi) of Mo-99 is divided by activity (mCi) of Tc-99m to obtain a ratio. If this ratio is <0.15 μCi Mo-99 per mCi of Tc-99m at time of administration, the generator eluate has passed the Mo-99 Breakthrough Test. As a rule of thumb, if the ratio is <0.038 at time of elution, the material will be suitable for injection for at least 12 hours.

If test is performed in reverse order, failure is extremely likely due to residual charge on ionization chamber that takes a few minutes to dissipate.

Specifications for Mo-99 Breakthrough Test

In NRC States:

TEST	FREQUENCY	SPECIFICATIONS
Mo Breakthrough	First Elution	<0.15 μCi Mo/mCi Tc at $t_{administration}$

In some Agreement States:

TEST	**FREQUENCY**	**SPECIFICATIONS**
Mo Breakthrough	Every Elution	<0.15 μCi Mo/mCi Tc at $t_{administration}$

Al^{3+} Ion Breakthrough Test

According to current NRC regulations, the Al^{3+} Breakthrough test is no longer mandatory. If performed, the upper limit of Al^{3+} Breakthrough is 10 ppm of Al^{3+}; may be expressed as μg/ml. Al^{3+} ion breakthrough is measured colorimetrically. A drop of the eluate is placed on one end of a special test paper; a drop of a standard solution of Al^{3+}, concentration 10 ppm, is placed on the other end of the test strip. If the color at the center of the drop of eluate is less red than that of the standard solution, the eluate has passed the Al^{3+} Ion Breakthrough Test. Units may be also be expressed as μg/ml.

Specifications For Aluminum Ion Breakthrough Test

In NRC States and Agreement States:

TEST	**FREQUENCY**	**SPECIFICATIONS**
Mo Breakthrough	Test No Longer Required	<10 ppm if you choose to perform test

Most Commonly Appearing Tc-99m Radiochemical Impurities

The chart below identifies the two most commonly observed radiochemical impurities

TYPE OF IMPURITY	CHEMICAL FORM
Free Tc	Pertechnetate, TcO_4^{-1}
Hydrolyzed Reduced	Tc probably TcO(OH)2.H2O, hydrated Tc-oxide

- Free Tc localizes in the choroid plexus, salivary glands, thyroid, and gastric mucosa
- HR Tc localizes in the liver and spleen.
- Both are therefore undesirable as they decrease image quality and often increase radiation dose to the patient.

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