NRC Regulations for Radiation Workers

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Regulations, Licensing and Required Postings
Classroom and Lab Training: NRC Requirements for Residents

Training in the areas of

a) Radiation physics and instrumentation;
b) Radiation protection;
c) Mathematics pertaining to the use and measurement of radioactivity;
d) Chemistry of by-product material for medical use; and
e) Radiation biology.
Work Experience for Imaging and Localization Studies: NRC Requirements for Residents

Must be under the supervision of an AU. Includes:

- ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- calculating, measuring, and safely preparing patient or human research subject dosages;
- using administrative controls to prevent a medical event involving the use of unsealed byproduct materials.
Work Experience for Imaging and Localization Studies: NRC Requirements for Residents

- using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
- administering dosages of radioactive drugs to patients or human research subjects; and
- eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs.
Radionuclide Therapy: Current NRC Requirements for Residents

Work experience for the oral administration of sodium iodide I-131 requiring a written directive must be obtained under the direct supervision of an Authorized User who must also have experience in the oral administration of sodium iodide I-131 for which a written directive is required.
Radionuclide Therapy:
NRC Requirements for Residents

This work experience must involve the following:

a) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
b) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
c) calculating, measuring, and safely preparing patient or human research subject dosages
Radionuclide Therapy: NRC Requirements for Residents

d) using administrative controls to prevent a medical event involving the use of unsealed byproduct materials;
e) using procedures to safely contain spilled radioactive material and using proper decontamination procedures; and
f) administering doses to patients or human research subjects that include at least three cases involving the oral administration of $\geq 33$ mCi of sodium iodide I-131.
REFERENCE FOR CURRENT NRC REGULATIONS


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- Appendix: 10 CFR Parts 20 and 35, outline of subparts
RADIATION SAFETY

RULES AND REGULATIONS
SECRETARIAL SPACE, HALLWAYS, AND CERTAIN OTHER AREAS OF A DEPARTMENT MUST QUALIFY AS AN UNRESTRICTED AREA. WHICH ONE OF THE FOLLOWING 10 READINGS IS THE MAXIMUM ACCEPTABLE IN AN UNRESTRICTED AREA?

<table>
<thead>
<tr>
<th>Reading</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 mRem/hr</td>
<td>1 mRem in 1 hour</td>
</tr>
<tr>
<td>2 mRem/hr</td>
<td>2 mRem in 1 hour</td>
</tr>
<tr>
<td>5 mRem/hr</td>
<td>5 mRem in 1 hour</td>
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<tr>
<td>10 mRem/hr</td>
<td>10 mRem in 1 hour</td>
</tr>
<tr>
<td>20 mRem/hr</td>
<td>20 mRem in 1 hour</td>
</tr>
</tbody>
</table>
Dose Limits for Members of the Public

20.1301 Each licensee shall conduct operations so that:

- Annual dose limit of 0.1 rem for members of the public.
- Dose in any **unrestricted area** does not exceed 0.002 Rem in any one hour.
WHAT IS REGULATION REGARDING POSTING OF RADIATION SAFETY RULES?

1. General Radiation Safety rules (no smoking, eating, drinking, etc), must be posted in each laboratory in which radioactive materials are used.

2. State/NRC regulations and telephone numbers must be posted conspicuously in each Nuclear Medicine Laboratory.

3. Both are required

4. Neither is required
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 IDNS/NRC REGULATIONS AND TELEPHONE NUMBERS

Posted in each laboratory in which radioactive materials are used. Chart supplied by the regulatory agency.
A female technologist enters your office and announces to you that she is pregnant and the estimated date of conception is March 1, 2007 (2 required pieces of information). Is she legally considered a “DECLARED PREGNANT WORKER”? 
20.1208 Limits apply to the embryo/fetus of a declared pregnant woman (formally notified employer of pregnancy in writing).

- Dose to the embryo/fetus over entire period of gestation (9 mos.) is 0.5 rem.
- Dose should be delivered at a fairly uniform rate over entire gestation period and not delivered in a few large doses.
- Dose shall be taken as the sum of the DDE to the declared pregnant woman and dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.
- Rule permits additional 0.05 Rem if she has >0.45 Rem at the time of notification.
The maximum permissible whole body dose to an occupationally exposed individual for one year and to a declared pregnant worker for the 9 months of gestation are, respectively,

- 500 mRem, 100 mRem
- 1000 mRem, 500 mRem
- 5000 mRem, 500 mRem

A pregnant worker is not permitted to work with radiation until after the birth of her baby.
Our occupational dose limits for whole body and extremities are, respectively,
- 5 Rem and 50 Rem
- 50 Rem and 5 Rem
- 15 Rem and 50 Rem
- 5 Rem and 15 Rem
Our annual occupational dose limits for the lens of the eye is

- 5 Rem
- 15 Rem
- 25 Rem
- 50 Rem
Occupational Dose Limits for Adults

20.1201(a) The licensee shall control the occupational dose to individual adults, except from planned special exposures (under 20.1206) to:

- 5.0 Rem Total Effective Dose Equivalent per year.
- 50.0 Rem Total Organ Dose Equivalent per year.
- Lens of the Eye - 15.0 Rem/year
- Extremities - 50.0 Rem/year
If you have accumulated 2,000 mRem at your current institution as of April 15, 2007, and are planning to change jobs, you will be permitted 5,000 additional mRem for the remainder of the calendar year at your new facility. True/False?
Occupational Dose Limits for Adults

20.1201(f) The 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.
How often MUST an employer inform his radiation workers of their radiation exposure levels?
POSTING OF RING/WHOLE BODY FILM BADGE MONTHLY REPORTS

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.
Your technologist performed requisite QC testing on your dose calibrator at 7:00 AM this morning. If the Tech is called in to perform a stat lung scan at 12:15 tomorrow morning, the elapsed time will be 17 hours and 15 minutes.

Since <24 hrs have elapsed, is the Tech required to repeat the QC testing on the dose calibrator?

If yes, which test(s) must be repeated?
Radiation Safety

Inspection Issues:
When performing the Constancy Test on dose calibrators, one MUST check every setting that might be used that day. The day officially starts at 12:01 AM. If the Tech is called in for a stat lung scan, both 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.
MOCK ORAL: NRC REGULATIONS

The NRC or State Inspector blows a puff of smoke under the closed door in the room in which Xe-133 ventilation studies are performed. What is the purpose of this test, and what should happen to the puff of smoke?
Radiation Safety

Inspection Issues:
Rooms in which Xe-133 gas are used must be under negative pressure. Therefore, smoke should 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.
One of the policies that helps to minimize radiation dose to Nuc Med Techs is called the ALARA Policy. For what does the acronym stand?
ALARA - Acronym for “As Low As Reasonably Achievable”

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.

20.1101(b) Each licensee shall use, to the extent practicable, procedures and engineering controls to ensure that doses are “as low as reasonably achievable (ALARA).”
MOCK ORAL: NRC REGULATIONS

The Radiation Safety Program and the ALARA Policy must be reviewed periodically. Whose job is it to do so, and how often must it be done?

RSO, semiannually
RSO, annually
Director of Radiology, semi-annually
Director of Radiology, annually
Director of Nuclear Medicine, semi-annually
Director of Nuclear Medicine, annually
Radiation Protection Programs

20.1101(c) Each licensee shall periodically (at least annually) review the radiation protection program content and implementation.

An 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.

An annual review of the ALARA Program by the RSO must also take place.
MOCK ORAL: NRC REGULATIONS

One is permitted to designate one sink in the laboratory as a “HOT SINK” for disposal of low-activity radioactive waste. The **institutional** limit is:

- 10 Ci per year for all isotopes
- 1 Ci per year for all isotopes
- 100 mCi per year for all isotopes
- There is no legal limit
Disposal Into Sanitary Sewerage

- Readily soluble material or readily dispersible biological material
- Each liquid waste disposal must be documented by the radioisotope, amount, date, and initials of person involved.
- Monthly average concentration within limits (Appendix B, Table 3)
- Total annual quantity less than 1 Ci for all isotopes for all users on one license
All administered doses must be within ____% of the prescribed dose

5
10
15
20
10% Rule

If radioactive, dose must be calibrated and value obtained must be recorded. By Federal and State law, all doses must be within 10% of the prescribed dose, modifiable only by a physician.
A male patient’s prescribed dose of Tl-201 chloride for a cardiac study was 3 mCi. The technologist inadvertently administered 5 mCi, a 67% overdose. Testicular dose (critical organ in males) was 15 R, kidney dose was 5.1 R, and whole body dose was 2 R.

1. Was this a violation of the law?
2. Was this a reportable or a recordable event?
Diagnostic Recordable Events

1. Incorrect radiopharmaceutical administered to patient **OR**
2. Diagnostic dose differing from prescribed dose by > 10% **OR**
3. Administration by an unprescribed route **AND**
4. Whole body dose < 5 R and single organ dose < 50 R.
Diagnostic Reportable Events
(now called a Medical Event)

1. Incorrect radiopharmaceutical administered to patient OR
2. Diagnostic dose differing from prescribed dose by > 10% OR
3. Administration by an unprescribed route AND
4. Whole body dose > 5 R or a single organ dose > 50 R.
Diagnostic Reportable Events

Action required
1. Document details
2. Notify the NRC/state in writing of the misadministration, giving pertinent details and plans for preventing recurrence
A patient was treated with I-131 NaI for hyperthyroidism. The actual dose was 17 mCi; the prescribed dose was 10 mCi. While this is certainly a violation of the 10% rule, was this a reportable or a recordable event?
Therapeutic Reportable Event

Definition:
- Administered dose not within 20% of prescribed dose

Action required
1. Document details
2. Notify the NRC/state in writing of the misadministration, giving pertinent details and plans for preventing recurrence
You administered a 150 mCi therapeutic dose of I-131 in capsule form to a patient with thyroid cancer. Which of the following is required by law for person performing the dose administration?

- thyroid count at 24-72 hr post admin time
- 24-72 hr urine sample must be counted
- Both of the above
- Neither of the above
THYROID MONITORING LOGBOOK

Thyroid monitoring is required 24-72 hours after administration of I-131 sodium iodide in liquid form. If capsules are used, thyroid monitoring is not required.
The three most significant sources of our background radiation include:

- Cosmic rays
- Flying in aircraft
- Global fallout
- Internal Radioactivity
- Nuclear Power Plants
- Radon and other terrestrial sources
Most significant sources of our background radiation

Cosmic rays
Radon and other terrestrial sources
Internal Radioactivity
According to the NRC, an adult is defined as a person ____ or more years of age

15
18
21
25
Concepts and Definitions

ADULT - An individual 18 or more years of age
A Radiation Area is one in which an individual could receive a dose of ______ mRem in 1 hour at a distance of 30 cm from the source

1
5
50
100
A High Radiation Area is one in which an individual could receive a dose of _____ mRem in 1 hour at a distance of 30 cm from the source

1
5
50
100
Concepts and Definitions

- **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.
What is the $\text{LD}^{100}_{30}$ whole body dose in humans?

What is the $\text{LD}^{50}_{30}$ whole body dose in humans?
the LD_{100}^{30} whole body dose in humans = ~550 R
the LD_{50}^{30} whole body dose in humans = ~350 R
With high-level medical intervention, the LD_{100}^{30} can be increased to ~850 R
An individual **must be** monitored for radiation dose with a film badge if his dose is likely to exceed ____% of the MPD.
Monitoring of Internal and External Doses

20.1502 Monitoring is required if individual is likely to:

- Receive a dose >10% of limits (500 mRem/yr)
- Receive an intake >10% of an ALI
- Individual entering a high or very high radiation area
- Summation of internal and external doses required if both internal and external doses are required to be monitored.
MOCK ORAL: NRC REGULATIONS

The institution in which you did your Radiology Residency has a _______ license

Specific
General
Broad
Types of radioactive material licenses

- **SPECIFIC** - issued to named persons for a specific use of radioactive materials
- **GENERAL** - issued to individuals who have very little chance of causing harm with the materials. Applies to some laboratories and users of certain sealed sources
- **BROAD** - issued to universities and large medical centers for medical use of essentially any radioisotope.
MOCK ORAL: NRC REGULATIONS

A GM Survey of your lab and a wipe test must be performed ______ and _______, respectively.

Daily and daily
Daily and weekly
Weekly and daily
Weekly and weekly
GM Surveys 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 the end of the week.
AREA ROOM MONITORING LOG BOOK

- On a daily basis, survey each room in which radioisotopes are used
- Use a GM counter and record readings
- 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 > normal room background.
What energy window is used when checking for surface contamination?

What is the only commonly used isotope not found on a wipe test?
An open energy window is used since we don't know which isotope has been spilled.

Xe-133 can not be found on a wipe test.
If contamination is found, obligation is to document radioactivity level of the hot spot, decontaminate to background levels, and record the new reading indicating that contamination has been removed.
From the Inspector’s standpoint, the job is not complete until the paperwork is done!
MOCK ORAL: NRC REGULATIONS

- How often must one perform leak-testing on sealed source?
- What are several examples of sealed sources?
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.
Mock Oral: NRC Regulations

How would you define an Agreement State?
Is your state an agreement state or an NRC state?
Which may be more restrictive than the other, an NRC State or an Agreement State?
Agreement States

33/50 states have signed an agreement with the Nuclear Regulatory Commission stipulating that they will be the sole regulators, but will follow Federal guidelines. They may be more restrictive than these guidelines, but not less restrictive.
Agreement States: 2007
Who is the licensee?

a. Director of Nuclear Medicine
b. Director of Radiology
c. Directors of Nuclear Medicine & Radiology
d. The institution
e. Each individual user of radioactivity
ANSWER

a. Director of Nuclear Medicine
b. Director of Radiology
c. Directors of Nuclear Medicine & Radiology
d. The institution
e. Each individual user of radioactivity
Both hand monitoring and treadmill monitoring are required on a(n) _______ basis

- Hourly
- Twice daily
- Daily
- Weekly
Radiation Safety

- hand monitoring is required \textit{daily} for most licensees. Some technologists monitor after every patient or every time they leave the laboratory.
- treadmill monitoring is required on a \textit{daily} basis. Results of these surveys must be recorded in an appropriate logbook.
Which of the following must be trained in Radiation Safety on an annual basis?

- Nuc Med Techs
- All Authorized Users
- Loading Dock personnel who deliver radioactive materials
- Housekeeping
- Security officers accompanying delivery men
Training of Personnel (who should be trained)

- All Authorized Users
- Other personnel
  - Housekeeping
  - Clerical
  - Security
  - Maintenance

Frequency of Training
- Initially
- Annually

Documentation
- Date
- What was covered
- Who gave training
- List of attendees
The NRC Inspector has completed his inspection and it is 5 PM. Only you and the inspector remain in the department, and you both have your coats on, ready to leave for the day. The inspector walks over to the Hot Lab door, opens it, looks around, and begins writing a note on his pad. Has he discovered a citable offense?
Security of Areas in Which Radioactive Materials are Stored

Since there are no technologists present and the room contained radioactive materials, this is considered a breach of security and a citable offense. Anyone could have walked into the room without being challenged and walked away with radioactive materials.
MOCK ORAL: NRC REGULATIONS

What are the rules for opening packages?
- Must all incoming packages be wiped?
- Must they have external reading taken with a GM Counter?
- Must a package containing Xe-133 be monitored for leakage?
Procedures for Opening Packages

20.1906 - Make arrangements to receive when delivered

Take possession expeditiously (within 3 hours)

Monitor for contamination if:
  ■ Package bears DOT radioactive material labels
  ■ Packed is crushed, damaged, or leaking
  ■ Packages containing only gas or special form radioactive material DO NOT need to be monitored for contamination
DOT Radioactive Material Labels

Very low activity Kits (Radioimmunoassay)  Radiopharmaceuticals  Generators
Procedures for Opening Packages

◆ DO NOT need to monitor if package quantity is less than or equal to Type A quantity

◆ Establish, maintain and retain written procedures for safely opening packages received and ensure implementation
Procedures for Opening Packages

- Immediately notify final delivery carrier and NRC Regional Office if:
  - Removable contamination limits are exceeded
  - External radiation exposure rate limits are exceeded
Which of the following packages must be logged into the incoming package log book?
1. A 5 mCi standard of Tc-99m
2. A 10 mCi unit dose of Ga-67 citrate
3. A 100 mCi therapy dose of I-131 NaI
4. A 0.1 mCi dose of Cr-51 Na chromate
5. All of the above
6. None of the above
INCOMING PACKAGE LOGBOOK

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.
INCOMING PACKAGE LOGBOOK

If your license requires you to monitor every package received by your department, results of this monitoring must be recorded in this logbook.
Methods for Conducting Radiation Surveys

Package receipt surveys
- Radiation surveys (surface & one meter, all sides)
- Wipe surveys (all sides)
- Frequency (on all labeled packages unless they contain only a gas or special form material, or package is damaged)
Which of the following is/are acceptable methods of waste disposal?

- Transfer to licensed person/company
- Decay in storage
- Release as effluents within authorized limits
- All of the above
- None of the above
Acceptable Methods Of Waste Disposal

All of the above

20.2001 - Authorized methods of disposal:
- Transfer to licensed person/company
- Decay in storage
- Release as effluents within authorized limits
HOT LAB

RULES AND REGULATIONS
§ 35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material.

(a) For direct measurements performed in accordance with § 35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject.

(b) A licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer’s instructions.

(c) A licensee shall retain a record of each instrument calibration required by this section in accordance with § 35.2060.
MOCK ORAL: NRC REGULATIONS

How often must a dose calibrator be checked for **accuracy** and how is the test performed?

- Daily
- Monthly
- Quarterly
- Annually
- Never
ACCURACY TEST

This test, performed at installation and annually, 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.
## ACCURACY TEST: Pass or Fail?

<table>
<thead>
<tr>
<th>Standard</th>
<th>Energy (keV)</th>
<th>expected value (mCi)</th>
<th>measured value (mCi)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co-57</td>
<td>122</td>
<td>2.48</td>
<td>2.51</td>
</tr>
<tr>
<td>Cs-137</td>
<td>662</td>
<td>3.38</td>
<td>3.29</td>
</tr>
<tr>
<td>Co-60</td>
<td>1,332</td>
<td>1.55</td>
<td>1.52</td>
</tr>
</tbody>
</table>
MOCK ORAL: NRC REGULATIONS

How often must a dose calibrator be checked for constancy and how is the test performed?

Daily
Monthly
Quarterly
Annually
Never
CONSTANCY TEST

This test, performed at installation and daily, 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.
## CONSTANCY TEST USING Cs-137: Pass or Fail?

<table>
<thead>
<tr>
<th>Isotope Setting</th>
<th>Reading (µCi)</th>
<th>Mon</th>
<th>Tues</th>
<th>Wed</th>
<th>Thu</th>
<th>Fri</th>
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<tbody>
<tr>
<td>Cs-137</td>
<td>123</td>
<td>124</td>
<td>122</td>
<td>126</td>
<td>124</td>
<td></td>
</tr>
<tr>
<td>Ga-67</td>
<td>223</td>
<td>224</td>
<td>222</td>
<td>226</td>
<td>224</td>
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<tr>
<td>Tl-201</td>
<td>163</td>
<td>164</td>
<td>162</td>
<td>166</td>
<td>164</td>
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<tr>
<td>Tc-99m</td>
<td>243</td>
<td>244</td>
<td>242</td>
<td>246</td>
<td>244</td>
<td></td>
</tr>
<tr>
<td>I-131</td>
<td>313</td>
<td>314</td>
<td>312</td>
<td>316</td>
<td>314</td>
<td></td>
</tr>
<tr>
<td>I-123</td>
<td>193</td>
<td>194</td>
<td>192</td>
<td>196</td>
<td>194</td>
<td></td>
</tr>
<tr>
<td>In-111</td>
<td>283</td>
<td>284</td>
<td>282</td>
<td>286</td>
<td>284</td>
<td></td>
</tr>
<tr>
<td>Xe-133</td>
<td>433</td>
<td>434</td>
<td>432</td>
<td>436</td>
<td>434</td>
<td></td>
</tr>
</tbody>
</table>
How often must a dose calibrator be checked for **linearity** and how is the test performed?

- Daily
- Monthly
- Quarterly
- Annually
- Never
LINEARITY TEST

This 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 48 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.
## LINEARITY TEST: Pass or Fail?

<table>
<thead>
<tr>
<th>Elapsed time (hr)</th>
<th>expected value</th>
<th>measured value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>300</td>
<td>300</td>
</tr>
<tr>
<td>1</td>
<td>267</td>
<td>272</td>
</tr>
<tr>
<td>2</td>
<td>238</td>
<td>241</td>
</tr>
<tr>
<td>3</td>
<td>212</td>
<td>209</td>
</tr>
<tr>
<td>6 (1 HL)</td>
<td>150</td>
<td>148</td>
</tr>
<tr>
<td>12 (2 HL)</td>
<td>75</td>
<td>72.4</td>
</tr>
<tr>
<td>24 (4 HL)</td>
<td>18.75</td>
<td>19.1</td>
</tr>
</tbody>
</table>
How often must a dose calibrator be checked for geometry and how is the test performed?

Daily
Monthly
Quarterly
Annually
At Installation
GEOMETRY TEST

This test, performed at installation, 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 water to 2 ml, 3 ml, 5 ml, and 10 ml. 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.
Geometry Test: 25 mCi of Tc-99m
**GEOMETRY TEST: 10 ml SYRINGE**

**Pass or Fail?**

<table>
<thead>
<tr>
<th>Sample Volume</th>
<th>Activity (mCi)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5</td>
<td>25.5</td>
</tr>
<tr>
<td>1.0</td>
<td>25.3</td>
</tr>
<tr>
<td>2.0</td>
<td>25.0</td>
</tr>
<tr>
<td>3.0</td>
<td>24.8</td>
</tr>
<tr>
<td>4.0</td>
<td>24.7</td>
</tr>
<tr>
<td>5.0</td>
<td>24.5</td>
</tr>
<tr>
<td>8.0</td>
<td>24.4</td>
</tr>
</tbody>
</table>
Within what limits must the expected and measured readings on a dose calibrator be?

- 5%
- 10%
- 15%
- 20%
DOSE CALIBRATOR QC SPECIFICATIONS

- Deviation from standard or expected values 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
## Classification of Impurities

<table>
<thead>
<tr>
<th>Type</th>
<th>Example</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radionuclidic</td>
<td>Mo-99</td>
<td>Radiation Dose, Poor Image Quality</td>
</tr>
<tr>
<td>Radiochemical</td>
<td>HR Tc</td>
<td>Poor Image Quality, Altered Radiation Dose</td>
</tr>
<tr>
<td>Chemical</td>
<td>Al^{3+}</td>
<td>Poor Image Quality</td>
</tr>
<tr>
<td>TYPE OF IMPURITY</td>
<td>METHOD</td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Radionuclidic</td>
<td>Dose Calibrator or Multichannel Analyzer</td>
<td></td>
</tr>
<tr>
<td>Radiochemical</td>
<td>Thin Layer Chromatography</td>
<td></td>
</tr>
<tr>
<td>Chemical</td>
<td>Colorimetric</td>
<td></td>
</tr>
</tbody>
</table>
DETECTION OF RADIONUCLIDE IMPURITIES

(e.g., Mo-99 Breakthrough)
What is the upper limit of Mo-99 breakthrough in a generator eluate and how is the test performed?

- 0.15 µCi Mo/mCi Tc at time of elution
- 0.15 µCi Mo/mCi Tc at time of administration
- 10 ppm

Not a mandatory test for generators
What is the upper limit of $\text{Al}^{3+}$ breakthrough in a generator eluate and how is the test performed?

1 ppm
10 ppm
100 ppm

Not a mandatory test for generators
<table>
<thead>
<tr>
<th>TEST</th>
<th>FREQUENCY</th>
<th>SPECIFICATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mo Breakthrough</td>
<td>Every Elution</td>
<td>&lt;0.15 µCi Mo/mCi Tc at ( t_{\text{administration}} )</td>
</tr>
<tr>
<td>Al(^{3+} ) Breakthrough</td>
<td>Every Elution</td>
<td>&lt;10 ppm of Al(^{3+} ); may be expressed as µg/ml</td>
</tr>
<tr>
<td>TEST</td>
<td>FREQUENCY</td>
<td>SPECIFICATIONS</td>
</tr>
<tr>
<td>------------------</td>
<td>------------------</td>
<td>-----------------------------------------------------</td>
</tr>
<tr>
<td>Mo Breakthrough</td>
<td>First Elution</td>
<td>&lt;0.15 $\mu$Ci Mo/mCi Tc at $t_{administration}$</td>
</tr>
<tr>
<td>$Al^{3+}$ Breakthrough</td>
<td>First Elution</td>
<td>&lt;10 ppm of $Al^{3+}$; may be expressed as $\mu$g/ml</td>
</tr>
</tbody>
</table>
QC Test Procedures for Mo/Tc Generator

Mo-99 Breakthrough:

Mo-99 is assayed FIRST directly in the special lead pig supplied by the manufacturer of your dose calibrator. Tc-99m is THEN assayed directly in the plastic sleeve. Activity (µCi) of Mo-99 is divided by activity (mCi) of Tc-99m to obtain a ratio.
Mo-99 Breakthrough Test

Step 1

Special Pb pig designed for use with your dose calibrator

Step 2

Plastic sleeve designed for use with your dose calibrator
QC Test Procedures for Mo/Tc Generator

Mo-99 Breakthrough:

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.
QC Test Procedures for Mo/Tc Generator

Mo-99 Breakthrough:

If this ratio is <0.15 \mu Ci 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.
Radiation Safety

Inspection Issues:
Regarding generator QC testing, the most common citation is for failure to report Mo-breakthrough as a ratio, e.g., 0.01 mCi µCi/mCi Tc. Those people still using generators are very conscientious about performing the test, even when called in for a stat scan.
Radiochemical Impurities in $^{99m}$Tc Radiopharmaceuticals

Free Tc Chemical form: pertechnetate, $\text{TcO}_4^-$

Hydrolyzed Reduced Tc: Chemical form is probably $\text{TcO(OH)}_2\cdot\text{H}_2\text{O}$, a hydrated Tc-oxide

For $^{99m}$Tc MAG3, possible impurity is $^{99m}$Tc tartrate

For $^{99m}$Tc HMPAO, there are stereochemical impurities.
<table>
<thead>
<tr>
<th>SYSTEM</th>
<th>IMPURITY MEASURED</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Silica Gel/0.9% saline</td>
<td>Hydrolyzed Reduced Tc</td>
</tr>
<tr>
<td>2. Paper/acetone or paper/MEK</td>
<td>Free Tc (Pertechnetate)</td>
</tr>
</tbody>
</table>

THIN LAYER CHROMATOGRAPHY SYSTEMS OF Tc-99m COMPOUNDS

Tc-99m DTPA, MDP, GH, PYP, HDP, MAA, SC
Tc-99m CHROMATOGRAPHY: SEPARATION ON STRIP

<table>
<thead>
<tr>
<th>SYSTEM</th>
<th>SEPARATION OF RADIOCHEMICAL SPECIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silica Gel/saline</td>
<td>HR Tc in bottom half; all other species in top half.</td>
</tr>
<tr>
<td>Paper/acetone or paper/MEK</td>
<td>Free Tc in top half; all other species in bottom half.</td>
</tr>
</tbody>
</table>
 EXCEPTION TO THE RULE

For insoluble Tc-99m Radiopharmaceuticals (e.g., Tc-MAA, Tc-SC), it is only necessary to test for the presence of free Tc. No simple system can effectively separate colloidal HR Tc from an insoluble product, so HR Tc cannot be measured in these products. We therefore ignore its presence.
STRIP DESIGN

top of strip 6 cm
solvent front 5 cm
cut line 3 cm
origin 1 cm
strip bottom 0 cm
CALCULATIONS

% Impurity = \frac{\text{CPM in half of strip}}{\text{CPM in whole strip}} \times 100\%

Labeling efficiency = 100\% - \% \text{HR Tc} - \% \text{Free Tc}
Migration Patterns of Tc-MDP

Paper/acetone

Si gel/saline

Free Tc

Tc-MDP

HR Tc
What is Radiochemical Purity of Tc-MDP?

Paper/acetone

1,000

99,000

Si gel/saline

99,000

1,000

Free Tc

Tc-MDP

HR Tc
Results

\[
\% \text{ free Tc} = \frac{1,000}{1,000 + 99,000} = 1 \%
\]

\[
\% \text{ HR Tc} = \frac{1,000}{1,000 + 99,000} = 1 \%
\]

Therefore,

\[
\% \text{ Tc-MDP} = 100 \% - 2 \% = 98\%
\]
DETECTION OF CHEMICAL IMPURITIES
(e.g., Al$^{3+}$ Breakthrough)
QC TEST PROCEDURES FOR Mo/Tc GENERATOR

**Aluminum Ion Breakthrough:** Al$^{3+}$ ion 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 $\mu$g/ml.
Aluminum Ion Breakthrough Test

Special paper saturated with aluminon reagent, sensitive to Al$^{3+}$ on a ppm basis

If “generator eluate” spot is less red than “Al$^{3+}$ standard” spot, then eluate has passed the Al$^{3+}$ ion breakthrough test.
Administration Method: I-131 NaI Solution

Step 1: Long needle at end of the therapy administration device is inserted in the vial and the tip of the needle is then positioned at bottom of vial.

Step 2: Patient drinks I-131 NaI solution through device.
Administration Method: I-131 NaI Solution

Step 3. 10 ml of water is then injected into vial while patient continues to drink through the device to rinse vial and insure that patient receives entire dose.

Step 4. Rinse step is repeated once with 10 ml of water
therapy administration device
Precautions to be Observed with Low-Dose I-131 Therapy Outpatient

**Radiation Exposure** – There are three basic principles to keep in mind:

- Minimize the time spent in close contact with others - radiation dose to another person is proportional to exposure time.
- The Inverse Square Law is your best friend!
- Good hygiene prevents contamination of others; good toilet hygiene and careful and thorough washing of your hands will reduce the possibility of contamination.
Precautions to be Observed by you with Low-Dose I-131 Therapy Outpatient

- Keep distance to minimize personal radiation dose
- Everyone involved with patient must wear film badge
- Gloves must be used by the dose administrator
- Every participant in therapy must have thyroid counted 24 hr post dose
Precautions to be Observed by Patient following Low-Dose I-131 Therapy

- Males patients are instructed to sit while urinating to avoid contaminating environment
- Patients are instructed to not share anything with anyone for 7-10 days
Sleep alone for the first three days after treatment. During this period, avoid kissing, sexual intercourse and avoid prolonged physical contact.

It is particularly important to minimize contact with children and pregnant women because the thyroid glands of children and the unborn are more sensitive to the effects of radiation than those of adults.
Precautions to be Observed by Patient following Low-Dose I-131 Therapy

- Radioiodine treatment is contraindicated during pregnancy.
- If patient is planning to become pregnant after receiving I-131 NaI therapy, we recommend a waiting period of 1 year following treatment. (Other practitioners advise shorter periods)
Precautions to be Observed by Patient following Low-Dose I-131 Therapy

Ideally, an adult other than the patient should care for a baby for 3 days following treatment. If not possible, then patient can do everything necessary, except breast feeding. This activity must stop and may not be resumed as radio-iodine in breast milk may cause unwanted effects, e.g., an underactive thyroid.

During the first 3 days after treatment, the patient should minimize close contact, e.g., holding the baby in her lap, for more than a short time.
Precautions to be Observed by Patient following Low-Dose I-131 Therapy

- Wash hands thoroughly with soap and plenty of water each time you go to the toilet.
- Keep the toilet especially clean. Be sure to flush it 2 or 3 times after each use.
- Rinse the bathroom sink and tub thoroughly after you use them. Clean bathroom habits will reduce the chances of others becoming contaminated by the radioiodine in your saliva and sweat.
Precautions to be Observed by Patient following Low-Dose I-131 Therapy

- No one else should be able to accidentally use your personal effects (toothbrush, washcloth, etc.) since iodine might be spread that way.
- Drink plenty of liquids such as water or juices. This will make you urinate more frequently and help the radioiodine to leave your body more rapidly, thus lowering the amount of radioiodine remaining in your body.
Precautions to be Observed by Patient following Low-Dose I-131 Therapy

- Use disposable eating utensils for the first few days after treatment, or wash your utensils separately. This will reduce the chance of contaminating other family members with the radioiodine in your saliva.
- Use separate towels and washcloths. Launder your bath towels, bed linens, and underclothing separately.
Precautions to be Observed with High-dose I-131 Therapy Patient

In addition to all of the precautions listed above,

- Keep distance to minimize radiation dose
- Patient must be assigned a private room
- Everyone involved with patient must wear film badge
- Gloves must be used by patient to handle telephone, bed controls, radio/TV control
Keep distance to minimize personal radiation dose
Patient assigned a private room
Everyone involved with patient must wear film badge
Gloves must be used by patient to handle telephone, bed controls
Precautions to be Observed with High-dose I-131 Therapy Patient

- Housekeeping not allowed in room until room is released by RSO
- No visitors for at least 24 hr (some practitioners permit 30 min visit)
- No bed baths
- Patient must stay in bed unless instructed otherwise
No visitors allowed for at least 24 hr
No bed baths
Patient must stay in bed unless instructed otherwise
Precautions to be Observed with High-dose I-131 Therapy Patient

- Absorbent pads taped to floor from toilet to bed
- Patient must use disposable items for food service
- Diagnostic blood samples taken by Nuclear Medicine
Absorbent pads taped to floor from toilet to bed
Precautions to be Observed with High-dose I-131 Therapy Patient

- If patient dies, notify attending physician immediately
- Room must be surveyed by RSO prior to release for next use.
- Every participant in therapy must have thyroid counted 24 hr post dose
If patient dies, attending physician must be notified immediately.
Room must be surveyed by RSO prior to release for next use.
Room must be surveyed by RSO prior to release for next use.
Every participant in therapy must have thyroid counted 24 hr post dose
What is the release criterion in an Agreement State for patients treated with high-dose therapy for thyroid Ca with I-131 NaI?

- 5 mR/hr at 1 m from chest
- 5 mR/hr at 10 cm from chest
- 7 mR/hr at 1 m from chest
- 7 mR/hr at 10 cm from chest
- None of the above
What is the release criterion in an NRC State for patients treated with high-dose therapy for thyroid Ca with I-131 NaI?

- 5 mR/hr at 1 m from chest
- 5 mR/hr at 10 cm from chest
- 7 mR/hr at 1 m from chest
- 7 mR/hr at 10 cm from chest
- None of the above
Release Criteria For Patients Treated With High Doses Of I-131 NaI For Thyroid Ca

- **Agreement State:** 5 mR/hr at 1 m from chest = 30 mCi of residual activity of I-131

- **NRC Regulated State:** 7 mR/hr at 1 m from chest = 33 mCi of residual activity of I-131
A patient was treated with I-131 NaI for thyroid cancer. Which signs must be on the door to the room in which he was treated?

Caution: Radioactive Materials
Caution: Radiation Area
Caution: Airborne Radioactivity Area
None of the above
Signage for I-131 Therapy

🔹 Caution: Radiation Area
🔹 Airborne Radioactivity Area
Radiation Safety

Inspection Issues:
regarding administration of I-131 NaI: for inpatients, 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 hospitalized radioactive patients must be observed.
MOCK ORAL: NRC REGULATIONS

Match the sections of the Code of Federal Regulations with the topic covered in each section

Part 19  Inspections/Instructions to Workers
Part 20  Human use of Radioisotopes
Part 35  Radiation Protection Standards
MOCK ORAL: NRC REGULATIONS

Match the sections of the Code of Federal Regulations with the topic covered in each section

Part 19 → Inspections/Instructions to Workers
Part 20 → Human use of Radioisotopes
Part 35 → Radiation Protection Standards
10 CFR Part 19: Notices, Instructions and Reports to Workers: Inspection and Investigation

- Postings
- Reporting problems
- Inspections
10 CFR Part 20

Standards for Protection Against Radiation
10 CFR Part 20: Outline of Topics

- Subpart A - General Provisions
- Subpart B - Radiation Protection Programs
- Subpart C - Occupational Dose Limits
- Subpart D - Radiation Dose Limits for Individual Members of the Public
- Subpart E - [Reserved]
- Subpart F - Surveys and Monitoring
- Subpart G - Control of Exposure from External Sources in Restricted Areas
Radiation Protection Program Records

20.2102 - Licensee shall maintain records including:

- Provisions of radiation protection program (retain for life of license)
- Audits and other reviews (retain for 3 years)
Retention of Survey Records

20.2103 - 3 YEARS -

- Data from required surveys and calibrations

UNTIL LICENSE TERMINATION -

- Survey results used to assign doses
- Measurements and calculations to assign intakes
- Air sampling and bioassay data for respiratory protection program
- Effluent releases and off site doses
Radiation Safety Program
What Should Your Radiation Safety Program provide?

- Maintain personnel exposures “ALARA” as well as exposures to the general public (NRC Reg. Guide 8.10).
  - For personnel safety and everyone’s well being
  - Keep radiation levels under control
- Maintain compliance with radioactive material license conditions and applicable regulations.
  - Two items which all licensees must follow to guide the Radiation Safety Program
What Factors Will Determine The Extent Of Your Radiation Safety Program?

- Types of radioactive material licenses
  - SPECIFIC - issued to named persons for a specific use of radioactive materials
  - GENERAL - issued to individuals who have very little chance of causing harm with the materials
    - Some laboratories
    - Some sealed sources
  - BROAD - issued to universities and large medical centers for medical use of essentially any radioisotope.
What Factors Will Determine The Extent Of Your Radiation Safety Program?

Form of Radioactive Material Used

- Sealed Sources
  - Gauges
  - Radiation Therapy
  - Irradiators
- Liquid Form
  - Research
  - Nuclear Medicine
- Gas Form
  - Nuclear Medicine
- Combination of the Above
  - Gas as a Sealed Source (Kr-85)
  - Liquid as a Sealed Source (Cs-137)
What Factors Will Determine The Extent Of Your Radiation Safety Program?

Activity of Radioactive Material Used

<table>
<thead>
<tr>
<th>Microcurie</th>
<th>Curie</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research</td>
<td>Radiation Therapy</td>
</tr>
<tr>
<td>Check Sources</td>
<td>Irradiators</td>
</tr>
<tr>
<td>Millicurie</td>
<td>Megacurie</td>
</tr>
<tr>
<td>Gauges</td>
<td>Irradiator</td>
</tr>
<tr>
<td>Medicine</td>
<td>Power Plants</td>
</tr>
</tbody>
</table>
What Factors Will Determine The Extent Of Your Radiation Safety Program?

Purpose for Which Radioactive Material is Used
- Small quantity in-vitro laboratory (I-125, Co-57)
- Research laboratory (P-32, H-3)
- Nuclear Medicine (Tc-99m)
- Radiation Therapy (I-131, Co-60)
- Portable gauges (Am/Be)
- Fixed gauges (Cs-137)
- Industrial Radiography (Ir-192, Co-60)
- Irradiator (Co-60)
What Should Your Radiation Safety Program Consist Of?

◆ Development of policies and procedures for each aspect of your program.
  ■ Examples in Regulatory Guides or Licensing Guides
◆ Documentation of records
  ■ Must be completed properly and thoroughly
  ■ Should be organized
◆ Implementation and reviews
  ■ Make sure policies are being followed
# Radiation Safety Program Policies and Procedures

**ALARA Policies**
- Management Commitment
- Radiation Safety Officer’s duties and responsibilities
  - Review program
  - Review occupational exposures
  - Review any radiation safety documentation

**Review instances of deviation from good ALARA practices**

**Personnel Monitoring**
- **External**
  - Film badges
- **Internal**
  - Thyroid burden
  - Whole body counting
  - Urinalysis
  - Fecal analysis
Ordering and Receiving Radioactive Material

- Individuals authorized to order
- Receiving material during normal work hours
- Receiving material during off duty hours
- Documentation
Methods and Occasions for Conducting Radiation Surveys

- Package receipt surveys
  - Radiation surveys (surface & one meter, all sides)
  - Wipe surveys (all sides)
  - Frequency (on labeled packages unless they contain only a gas or special form material, or package is damaged)
PART 35-MEDICAL USE OF BYPRODUCT MATERIAL

Subpart A--General Information

- 35.1 Purpose and scope.
- 35.2 Definitions.
- 35.5 Maintenance of records.
- 35.6 Provisions for research involving human subjects.
- 35.7 FDA, other Federal, and State requirements.
- 35.8 Information collection requirements: OMB approval.
- 35.11 License required.
- 35.12 Application for license, amendment, or renewal.
- 35.13 License amendments.
- 35.14 Notifications.
- 35.15 Exemptions regarding Type A specific licenses of broad scope.
- 35.18 License issuance.
- 35.19 Specific exemptions.
Part 35-Medical Use of Byproduct Material

Subpart B--General Administrative Requirements

- 35.24 Authority/responsibility for the radiation protection program.
- 35.26 Radiation protection program changes.
- 35.27 Supervision.
- 35.40 Written directives.
- 35.41 Procedures for administrations requiring a written directive.
- 35.49 Suppliers for sealed sources or devices for medical use.
- 35.50 Training for Radiation Safety Officer.
- 35.51 Training for an authorized medical physicist.
- 35.55 Training for an authorized nuclear pharmacist.
- 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.
- 35.59 Recentness of training.
PART 35-MEDICAL USE OF BYPRODUCT MATERIAL

Subpart C--General Technical Requirements

- 35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material.
- 35.61 Calibration of survey instruments.
- 35.63 Determination of dosages of unsealed byproduct material for medical use.
- 35.65 Authorization for calibration, transmission, and reference sources.
- 35.67 Requirements for possession of sealed sources and brachytherapy sources.
- 35.69 Labeling of vials and syringes.
- 35.70 Surveys of ambient radiation exposure rate.
- 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.
- 35.80 Provision of mobile medical service.
- 35.92 Decay-in-storage.
PART 35-MEDICAL USE OF BYPRODUCT MATERIAL

Subpart D--Unsealed Byproduct Material - Written Directive Not Required

35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

35.190 Training for uptake, dilution, & excretion studies.

35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

35.204 Permissible molybdenum-99 concentration.

35.290 Training for imaging and localization studies.
PART 35-MEDICAL USE OF BYPRODUCT MATERIAL

Subpart E--Unsealed Byproduct Material -Written Directive Required

35.300  Use of unsealed byproduct material for which a written directive is required.

35.310  Safety instruction.

35.315  Safety precautions.

35.390  Training for use of unsealed byproduct material for which a written directive is required.

35.392  Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).

35.394  Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).
PART 35-MEDICAL USE OF BYPRODUCT MATERIAL

Subpart F--Manual Brachytherapy

- 35.400  Use of sources for manual brachytherapy.
- 35.404  Surveys after source implant and removal.
- 35.406  Brachytherapy sources accountability.
- 35.410  Safety instruction.
- 35.415  Safety precautions.
- 35.432  Calibration measurements of brachytherapy sources.
- 35.433  Decay of Sr-90 sources for ophthalmic treatments.
- 35.457  Therapy-related computer systems.
- 35.490  Training for use of manual brachytherapy sources.
- 35.491  Training for ophthalmic use of strontium-90.
PART 35-MEDICAL USE OF BYPRODUCT MATERIAL

Subpart G--Sealed Sources for Diagnosis

35.500 Use of sealed sources for diagnosis.
35.590 Training for use of sealed sources for diagnosis.
PART 35-MEDICAL USE OF BYPRODUCT MATERIAL

Subpart H--Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

35.600  Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.
35.604  Surveys of patients and human research subjects treated with a remote afterloader unit.
35.605  Installation, maintenance, adjustment, and repair.
35.610  Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
35.615  Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
35.630  Dosimetry equipment.
PART 35-MEDICAL USE OF BYPRODUCT MATERIAL

Subpart H--CONTINUED

35.630  Dosimetry equipment.
35.632  Full calibration measurements on teletherapy units.
35.633  Full calibration measurements on remote afterloader units.
35.635  Full calibration measurements on gamma stereotactic radiosurgery units.
35.642  Periodic spot-checks for teletherapy units.
35.643  Periodic spot-checks for remote afterloader units.
35.645  Periodic spot-checks for gamma stereotactic radiosurgery units.
35.647  Additional technical requirements for mobile remote afterloader units.
35.652  Radiation surveys.
35.655  Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.
35.657  Therapy-related computer systems.
35.690  Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
PART 35-MEDICAL USE OF BYPRODUCT MATERIAL

Subpart I- RESERVED
PART 35-MEDICAL USE OF BYPRODUCT MATERIAL

Subpart J--Training and Experience Requirements

- 35.900  Radiation Safety Officer.
- 35.910  Training for uptake, dilution, and excretion studies.
- 35.920  Training for imaging and localization studies.
- 35.930  Training for therapeutic use of unsealed byproduct material.
- 35.932  Training for treatment of hyperthyroidism.
- 35.934  Training for treatment of thyroid carcinoma.
- 35.940  Training for use of brachytherapy sources.
- 35.941  Training for ophthalmic use of strontium-90.
- 35.950  Training for use of sealed sources for diagnosis.
- 35.960  Training for use of therapeutic medical devices.
- 35.961  Training for an authorized medical physicist.
- 35.980  Training for an authorized nuclear pharmacist.
- 35.981  Training for experienced nuclear pharmacists.
PART 35-MEDICAL USE OF BYPRODUCT MATERIAL

Subpart K--Other Medical Uses of Byproduct Material or Radiation from Byproduct Material

35.1000 Other medical uses of byproduct material or radiation from byproduct material.
### PART 35-MEDICAL USE OF BYPRODUCT MATERIAL

**Subpart L--Records**

- **35.2024** Records of authority & responsibilities for radiation protection programs.
- **35.2026** Records of radiation protection program changes.
- **35.2040** Records of written directives.
- **35.2041** Records for procedures for administrations requiring a written directive.
- **35.2060** Records of calibrations of instruments used to measure the activity of unsealed byproduct materials.
- **35.2061** Records of radiation survey instrument calibrations.
- **35.2063** Records of dosages of unsealed byproduct material for medical use.
- **35.2067** Records of leaks tests and inventory of sealed sources and brachytherapy sources.
- **35.2070** Records of surveys for ambient radiation exposure rate.
- **35.2075** Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.
- **35.2080** Records of mobile medical services.
- **35.2092** Records of decay-in-storage.
- **35.2204** Records of molybdenum-99 concentrations.
- **35.2310** Records of safety instruction.
PART 35-MEDICAL USE OF BYPRODUCT MATERIAL

Subpart L—Records (CONTINUED)

35.2404 Records of surveys after source implant and removal.
35.2406 Records of brachytherapy source accountability.
35.2432 Records of calibration measurements of brachytherapy sources.
35.2433 Records of decay of strontium-90 sources for ophthalmic treatments.
35.2605 Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
35.2610 Records of safety procedures.
35.2630 Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
35.2632 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.
35.2642 Records of periodic spot-checks for teletherapy units.
35.2643 Records of periodic spot-checks for remote afterloader units.
35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units.
35.2647 Records of additional technical requirements for mobile remote afterloader units.
35.2652 Records of surveys of therapeutic treatment units.
35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.
PART 35-MEDICAL USE OF BYPRODUCT MATERIAL

Subpart M--Reports

35.3045 Report and notification of a medical event.

35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.

35.3067 Report of a leaking source.
PART 35-MEDICAL USE OF BYPRODUCT MATERIAL

Subpart N--Enforcement

35.4001 Violations.
35.4002 Criminal penalties