NRC Regulation of Nuclear Medicine

John Miliziano M.D.
Morton Plant Hospital
Clearwater, Fl
Nuclear Regulatory Commission
A Brief History

1946 - Congress passed Atomic Energy Act (AEA) creating Atomic Energy Commission (AEC)

Medical importance of radioisotopes recognized before WW II but distribution unregulated. Postwar program for distribution grew out of Manhattan project

Manhattan project publicly announced its program for distributing radioactive isotopes

1954 - AEA amended to add licensing & regulation to authority of AEC

1974 - Energy Reorganization Act split AEC into ERDA & NRC
Nuclear Regulatory Commission

- NRC’s principal statutory authority for regulating medical use of byproduct material - AEA 1954

- NRC accomplishes its mission thru regulations & license conditions

- Title 10 Code of Federal Regulations (10 CFR Parts 0-199) published in Federal Register

- NRC has adopted a risk-informed, performance based approach to regulation. Outcomes rather than procedures.
Nuclear Regulatory Commission

NRC responsible for regulating use of:

- Source material (uranium & thorium)
- Special nuclear material (enriched U & Pu)
- Byproduct material (reactor-produced) $^{99m}$Tc, $^{131}$I, $^{133}$Xe

States regulate other radiation sources

- Naturally occurring RAM (Ra & Rn)
- Particle accelerator-produced RAM ($^{18}$F, $^{57}$Co, $^{67}$Ga, $^{111}$In, $^{123}$I, $^{201}$Tl)
- Radiation producing machines
- 1uCi 14C-Urea Breath testing – No license required
NRC vs. Agreement States

- 13 NRC States *
- 38 Agreement States *(AEA in 1959 authorized states to assume regulatory control - 1962 Kentucky became first AS)
Medical Use of Byproduct Materials

Typical uses are

• Diagnostic studies with unsealed sources
• Therapeutic administrations with unsealed sources
• Diagnostic studies with sealed sources
• Manual brachytherapy with sealed sources
• Therapeutic administrations with sealed sources in devices
Licensing

3 types of licenses for medical use of byproduct material

- General in vitro license
- Specific license of limited scope
  - Issued to a hospital for one or more radiopharmaceuticals.
  - Issued to an individual physician only for an office practice.
- Specific license of broad scope
  - Only for research institutions.
  - For use of any isotope.
Title 10 CFR

Following Parts contain NRC regulations applicable to medical use licensees:

Part 2  Part 32
Part 19*  Part 33
Part 20*  Part 35*
Part 21  Part 40
Part 30*  Part 70
Part 31  Part 71

DOE & prime contractors are EXEMPT from licensing
10 CFR Part 19

Notices, Instructions and Reports to Workers: Inspection and Investigations

“Worker’s Rights” Requirements for

• Posting of notices to workers,
• Instructions to workers (if likely to receive > 0.1 rem)
• Reports of radiation exposure, and
• Options available to workers for NRC inspections regarding radiological working conditions

Interviews can be compelled by subpoena as part of inspections or investigations
10 CFR Part 20

Standards for Protection Against Radiation

- Radiation Protection Program \(\square\) ALARA
- Dose limits for workers and members of public
- Surveys & monitoring
- Control & storage of licensed material
- Signs & posting radiation areas
- Labeling RAM & handling of packages
- Records & reports
- Penalties for noncompliance

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10 CFR Part 20

20.1101 Radiation protection programs

Achieve doses (occupational + member of public) that are ALARA
Periodic Review (at least annually)

20.1201 Occupational dose limits for adults - Employees must be notified of cumulative doses at least yearly.

Annual Dose Limits for Occupationally Exposed Adults (10 CFR 20.1201)

- Skin 0.5 Sv (50 rem)
- Eyes 0.15 Sv (15 rem)
- Elbows to hands 0.5 Sv (50 rem)
- Knees to feet 0.5 Sv (50 rem)
- Internal Organs 0.5 Sv (50 rem)

Total effective dose equivalent TEDE (whole body) 0.05 Sv (5 rem)
Basis for dose limits

- Concern for genetic harm (current data suggests this is not a primary concern as most damage from low dose low LET radiation is repaired)
- Uses a **linear no threshold** model since this is very conservative.

![Graphs showing linear and linear-quadratic models for cancer vs. dose](image-url)
Hormesis

- Possibility that low doses of radiation may be beneficial
Classification of Radiation Effects

• Stochastic effects – cancer / genetic damage
  § Probability of an effect is related to dose
  § Limited by ALARA

• Nonstochastic effects
  § Damage varies with dose
  § Below a certain dose there is no effect
  § Erythema, cataracts
  § None below 10 Rad
20.1207 Occupational dose limits for minors

10\% of dose limits for adult workers

20.1208 Dose to embryo/fetus

During entire pregnancy occupational exposure to a declared (in writing) pregnant woman < 0.5 rem (5 mSv)

Dose should be uniform monthly
Fetal Dose

- >15 rad is associated with congenital defects.
- <5 rad is negligible.
- <10 rad associated with no increased risk of congenital defects (~5% of births have a congenital defect)

- For diagnostic nuclear medicine highest dose is approximately 3.8 rad from $^{67}$Ga
V/Q scan or Chest CT in Pregnancy?

V/Q: 4mCi Tc-MAA -> 10 mrad/mCi -> 40 mrad
   30mCi Xe -> 0.8 mrad/mCi -> 24 mrad
   Total = 64 mrad

Chest CT: 0-200 mrad depending on shielding and area covered

V/Q + CT: Max fetal dose 264 mrad (No known fetal effects below 5000 mrad)
20.1301 Dose limits for members of public

TEDE < 0.1 rem/year (1mSv)

Does NOT include background radiation, medical administration, exposure from released patients (35.75), voluntary participation in medical research programs, and licensee’s disposal of RAM into sewer

Dose in any unrestricted area, exclusive of dose contributions from released patients does not exceed 2 mrem in any 1 hour (2 mrem/h)
## Exposure Estimates

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<td>0.56</td>
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<tr>
<td>Nuclear Medicine</td>
<td>14</td>
<td>0.14</td>
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</table>
10 CFR Part 20

20.1501 General  Surveys and Monitoring
Conduct and record surveys that are
Necessary to demonstrate Part 20 compliance
  Public dose < 0.1 rem/y
  Dose rate < 2 mrem/hr in unrestricted areas
  Occupational dose < 5 rem/y
Reasonable to evaluate radiation levels, quantity of RAM, & potential radiological hazards
20.1502(a)

Supply and require use of monitoring devices by adults likely to receive dose in excess of 10% of annual limit

Minors likely to receive annual external dose in excess of 0.1 rem, lens dose > 0.15 rem, or skin or extremity dose > 0.5 rem

Declared pregnant women likely to receive > 0.1 rem during entire pregnancy

Individuals entering high or very high radiation area ( >0.1 rem / hr at 30cm form the source).

* If you have data to show the limits will not be exceeded then monitoring is not necessary. (front desk staff, secretary, etc.)
20.1502(b)

Monitor occupational intake & internal dose to

- Adults likely to receive an intake in excess of 10% of annual limit on intakes (ALI) $^{131}\text{I} = 3$ Ci
- Minors likely to receive annual internal dose in excess of 0.1 rem
- Declared pregnant women likely to receive internal dose $> 0.1$ rem during entire pregnancy

*NRC acknowledges that only when reasonable possibility for an internal intake due to use of $^{131}\text{I}$ bioassay program
10 CFR Part 20

NM licensees must achieve doses that are ALARA

- Individuals likely to receive occupational dose $> 100$ mrem shall be instructed (10 CFR 19.12)

**YET**

- Individuals do not require monitoring devices for assessment of occupational dose if likely to be $< 500$ mrem (10 CFR 20.1502, 20.1201)

Radiation workers ARE NOT members of the public
10 CFR Part 20

- 20.1801 Security of stored material
- 20.1802 Control of material not in storage

Precautionary Procedures
- 20.1901 Caution signs
- 20.1902 Posting requirements
- 20.1904 Labeling containers
- 20.1906 Procedures for receiving & opening packages
Personnel Monitoring

- OSL - Optically Stimulated Luminescence
  § Body badge
  § Uses an aluminum oxide crystal which stores energy from ionizing radiation.
  § A green laser is used to stimulate the crystal which releases energy in the form of blue light. The intensity of the blue light is related to exposure.
  § Allows instantaneous readings that can be repeated.
  § Minimum detection is 1 mrem for gamma / X-rays and 10 mrem for Beta.
Personnel Monitoring

• TLD - Thrmoluminescent Display
  § Ring badge
  § Contains chemical compounds (lithium fluoride) that retain energy from radiation exposure.
  § When heated, light is emitted in proportion to the exposure.
  § A calibrated PMT records the light and determines exposure.
  § Can only be read once (unlike OSL).
  § Minimum detection is 30 mrem for gamma / X-rays and 40 mrem for Beta
Personnel Monitoring

• Pocket Ion chamber
  § Sealed cylindrical chamber filled with air and a charged quartz fiber.
  § The quartz fiber can be read against a scale through a lens on the device to provide direct measurement of exposure.

• Electronic Dosimeter
  § Uses an energy compensated GM tube or solid state electronics to provide direct measurement of exposure.
Revised 10 CFR Part 35

Medical Use of Byproduct Material

Final Rule Became Effective on 10/24/2002 and Agreement States have 3 years to implement

NUREG-1556, Volume 9
Consolidated Guidance About Material Licenses: Program-Specific Guidance About Medical Use Licenses

Licensing guidance for revised 10 CFR part 35
Revised 10 CFR Part 35
Historical Perspective

1997 - Commission directed staff to revise Part 35

Purpose of Part 35 Revision:

- Develop more risk-informed, performance-based regulations for medical use of byproduct material.
- Focus regulations on procedures that pose highest risk to workers, patients, & public.
- Reduce unnecessary regulatory burden (e.g., record keeping, reporting).
Divides byproduct material into 7 types of medical use

- 35.100 Uptake, dilution, & excretion studies
- 35.200 Imaging & localization studies for diagnosis
- 35.300 Unsealed sources for therapy
- 35.400 Sources for manual brachytherapy
- 35.500 Sealed sources for diagnosis
- 35.600 Sealed sources in devices for therapy
- 35.1000 Other medical uses
Part 35 and Nuclear Medicine

- 35.100 Uptake, dilution, & excretion studies
- 35.200 Imaging & localization studies (no WD)
  - 35.100 + 35.200 ⊂ Diagnostic nuclear medicine
- 35.300 Therapeutic Nuclear Medicine (WD)
  - > 30 Ci Na$^{131}$I and any other therapeutic dosage of unsealed byproduct material (32-P, 90-Y)

**Written Directive (WD)** ⊂ AU’s written order for the administration of byproduct material to a specific patient or human research subject

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Old vs. New Part 35 (Final Rule effective on 4/29/2005)
Board Certification & alternate pathways to become AU have changed

35.190 Uptake, Dilution and Excretion Studies
- American Board of Nuclear Medicine
Training and Experience

• **35.290** Imaging and Localization Studies
• American Board of Nuclear Medicine - 2005
• American Board of Radiology - 2006
• American Osteopathic Board of Radiology - 2000
• American Osteopathic Board of Nuclear Medicine - 2006
• Certification Board of Nuclear Cardiology - 2000
Training and Experience

- 35.390 Unsealed byproduct material for which a written directive is required.
- American Board of Nuclear Medicine - 2005
- American Board of Radiology - 2007
- American Osteopathic Board of Radiology - 2007
Training and Experience

- **35.392** Oral administration of I-131 less than 33mCi
- American Board of Nuclear Medicine - 2005
- American Board of Radiology - 2007
- American Osteopathic Board of Radiology – 2000
Training & Experience Requirements

35.390 Training for AU (revised requirement)

(a) Certified by medical specialty board whose certification process is recognized and meets requirement in (b)(2); OR

(b)(1) Completed 700 h consisting of both:
   (i) Classroom & lab training (min of 200 h); AND
   (ii) Supervised work experience; AND

(2) Obtained written attestation signed by preceptor AU documenting (a) & experience with administrations of required dosages or (b)(1) & competency.
Keep a log of your work

5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

<table>
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<tr>
<th>Description of Training</th>
<th>Location</th>
<th>Clock Hours</th>
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</table>
Keep a log of your work

6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)

<table>
<thead>
<tr>
<th>Radionuclide</th>
<th>Type of Use</th>
<th>No. of Cases Involving Personal Participation</th>
<th>Name of Supervising Individual</th>
<th>Location and Corresponding Materials License Number</th>
<th>Dates and/or Clock Hours of Experience</th>
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Radiation Protection Program

Radiation Protection Program (RPP) must be sufficient to ensure compliance with provisions of Part 20 (20.1101) - **Review must be at least annually**

Develop, document & implement RPP

ALARA & Review of RPP

35.24(b) Radiation Safety Officer implements and reviews the RPP - **must review ALARA program at least annually**

35.24(f) Only licensees authorized for materials requiring a written directive must establish a radiation safety committee.
Dose Calibrator

No longer required (35.60 and 35.63) or even mentioned “instruments used to measure the activity of unsealed byproduct material”

35.63 Licensee shall determine & record activity of each dosage

For unit dosages, determination can be made by

1. Direct measurement of radioactivity; or

2. Decay correction, based on activity determined by the Manufacturer or preparer licensed under 32.72 or equivalent Agreement State requirements
Dosages for Medical Use

35.63(d)

Unless otherwise directed by AU, licensee may not use a dosage if it does not fall within prescribed range or if dosage differs from prescribed dosage by more than 20%

Prescribed dosage means specified activity or range of activity as documented in written directive (therapy) or in accordance with directions of AU for diagnostic procedures.

AUs should establish policy for prescribed dosages: either specify range of dosages or that dosages may deviate by $\pm \text{“xx”} \%$

** Agreement states may differ on this**

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Medical Event - Diagnostic Reportable Event

- Replaces “misadministration”
- Details of the event must be documented with planned course of action.
- Must notify NRC and referring physician in writing.
- Must notify the patient unless the referring physician will do this or the referring physician thinks this will be harmful.
Diagnostic Reportable Event

• Incorrect radiopharmaceutical administration
  § OR

• Diagnostic dose differing by more than 20% from the prescribed dose
  § OR

• Administration by an incorrect route
  § AND

• Whole body dose > 5R and single organ dose > 50R
Diagnostic Recordable Event

• Incorrect radiopharmaceutical administration
  § OR

• Diagnostic dose differing by more than 20% from the prescribed dose
  § OR

• Administration by an incorrect route
  § AND

• Whole body dose < 5R and single organ dose < 50R
• Administered dose differing by more than 20% from the prescribed dose.

• Details of the event must be documented with planned course of action.

• Must notify NRC and referring physician in writing.

• Must notify the patient unless the referring physician will do this or the referring physician thinks this will be harmful.
Reporting

- Exposure >5 rem to an embryo / fetus unless this was approved by the AU in advance.
- Exposure >5 rem TEDE to a nursing child or dose that has caused unintended permanent dysfunction to an organ or system of the child.
35.70 Surveys of ambient radiation exposure rate

- Only one survey required at end of each day in all areas where unsealed byproduct material requiring a written directive was prepared for use or administered.
- Wipe testing must be performed weekly.
- More general requirements of Part 20 (20.1501) apply. Licensee shall make surveys that may be necessary and which are reasonable to evaluate magnitude & extent of radiation levels & potential radiological hazards.
- Removable contamination & inpatient room surveys no longer required - removable contamination limits (200 dpm/100 cm²) removed.
Isotopes Division & The Subcommittee on Human Applications (1946-1955)
30 mCi of most radioisotopes → no significant hazard

AEC: 30 mCi limit lacked evidence of hazard to PH&S
Change proposed in order to lower cost and increase availability of treatment.
Contamination

- Studies show that exposure to contamination from treated patients is less than 10% of the 5 mSv (0.5 rem) limit and in most cases less than 1% of the limit.
- Contamination from vomiting is not an important source of radiation. I-131 is absorbed within 30 minutes by the GI system.
Patient Release Rule

☞ 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material

NRC changed patient release rule 10 CFR 35.75, effective November 29, 1997

FROM: Activity-based limit (<30 mCi) or
      Dose rate-based limit (<5 mrem/h @ 1m)

TO:   Dose-based limit (<0.5 rem / 5mSv)
<table>
<thead>
<tr>
<th>Radionuclide</th>
<th>COLUMN 1 Activity at or below Which Patients May Be released (GBq)</th>
<th>COLUMN 2 Dose Rate at 1 Meter, at or below Which Patients May Be released* (mSv/hr)</th>
<th>(mrem/hr)</th>
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<td>Au-198</td>
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<td><strong>Y-90</strong></td>
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</table>

*Administered activity / decay corrected activity
Occupancy Factor

E = 0.75 when a physical half-life, an effective half-life, or a specific time period under consideration (e.g., bladder holding time) is less than or equal to 1 day.

E = 0.25 when an effective half-life is greater than 1 day, if the patient has been given instructions, such as:
- Maintain a prudent distance from others for at least the first 2 days;
- Sleep alone in a room for at least the first night;
- Do not travel by airplane or mass transportation for at least the first day;
- Do not travel on a prolonged automobile trip with others for at least the first 2 days;
- Have sole use of a bathroom for at least the first 2 days; and
- Drink plenty of fluids for at least the first 2 days.

E = 0.125 when an effective half-life is greater than 1 day if the patient has been given instructions, such as:
- Follow the instructions for E = 0.25 above;
- Live alone for at least the first 2 days; and
- Have few visits by family or friends for at least the first 2 days.
Exposure Calculation

\[ D(\infty) = \frac{34.6 \ \Gamma \ Q_0 \ T_P \ E}{r^2} \]

Occupancy factor that accounts for different

\[ E = \text{occupancy times and distances when an individual} \]
\[ \text{is around a patient} \]

Example: Thyroid cancer patient treated with 200mCi I-131 and occupancy
factor of .25

\[ D = 0.007612 \times 200\text{mCi} \times 0.299 \]
\[ D = 4.55 \text{ mSv} (0.455 \text{ rem}) \]
Criteria for patient release

- Written instructions must be provided to patients on how to maintain doses to others ALARA. If it is likely that individuals may be exposed to >0.1 rem (1 mSv)
- Maintain records for 3 years.
  - Radiopharmaceutical
  - Patient name
  - Dose
  - Date/Time of injection
  - Name of person administering the dose
Surgery in patients receiving therapeutic Radionuclides

• Within 24 hours of I-131
  4 Body fluids will be collected and contained in a closed system.
  4 Surgeon and staff will wear protective gear.
  4 Monitoring of OR staff if contamination occurs during surgery.
Disposal of Byproduct Material

35.92 Decay-in-storage

Licensee may hold byproduct material with Tp < 120 d for decay before disposal

10 half lives

Monitors radioactivity at surface before disposal. Activity must be indistinguishable from background

Remove or obliterate all radiation labels

Licensee must retain a record of each disposal
Purity Checks

- Radionuclide purity
  - Mo-99 concentration
  - Tc-99 – Not a radiation safety issue (Not tested for) but may affect labeling by preventing complete reduction of Tc-99m

- Chemical purity
  - Aluminum breakthrough
  - Excess may cause liver (Tc-MDP) and lung (SCOL) uptake

- Radiochemical purity
  - Reduction state of Tc-99m (>95% should be +7)
  - Poor labeling may occur if not +7 (Exception is with Tc-SCOL)
Mo-99 Concentration

- 35.204 Permissible molybdenum concentration
  (a) Licensee may not administer to humans a radiopharmaceutical that contains more than 0.15 Ci of Mo-99 per mCi of Tc-99m at the time of administration.

  (Licensee is not required to have a dose calibrator and still doesn’t need one)

  (Commercial radiopharmacy suppliers indicate that Mo/Tc activity ratio good until expiration time)
Mo-99 Concentration

Moly pig shields all the 140KeV Tc photons but only 50% of the Mo-99 740 keV and 780 keV photons.

Maintain records for 3 years: Moly/Tc ratio, Date/Time, Name of person performing the check.
Transient Equilibrium

- Mo-99  T1/2 - 66 hr (Parent T1/2 is 10-100x daughter T1/2)
- Tc-99m  T1/2 = 6 hr
- Occurs in approximately 4 daughter half-lives
Chemical Purity - Aluminum

- <10 ug/ml (Fission produced Mo-99)
- Aurin tricarboxylic acid spot test
Radiopharmaceutical QC – Tc-MDP

Solvent Front

Free TcO4 (A)

Cut Line

(B) Tc-99m diphosphonate
Hydrolyzed reduced Tc

(A)

Free TcO4
Tc-99m diphosphonate
(C)

Hydrolyzed reduced Tc

(D)

% Free TcO4

\[ \frac{A}{A+B} \]

% Reduced TcO4

\[ \frac{D}{C+D} \]

% MDP Tag

100 – (%free +% reduced)

Acetone

Bottom of Strip

Distilled H2O

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Radiopharmaceutical QC

Tc-99m Ceretec

% Tagged = \( \frac{B \times 100}{A + B} \)

%B should be > 80%

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<table>
<thead>
<tr>
<th>Example</th>
<th>Test</th>
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<td>Radionuclide purity:</td>
<td>Tc/Moly</td>
</tr>
<tr>
<td>Radiochemical purity:</td>
<td>Reduced Tc</td>
</tr>
<tr>
<td>Chemical purity:</td>
<td>Aluminum</td>
</tr>
</tbody>
</table>
Licensees may develop their own procedures to comply with Part 35, but these procedures not submitted as part of license application (except for procedures required by Subpart H of therapy devices).

Unreasonable to expect many licensees to deviate from “guidance” if first time its alternative is examined is during an inspection; thus “guidance” likely to become de facto regulation.

Further, and equally important, if licensee uses own procedures, not “guidance” procedures, what process will inspectors follow?
Nuclear Medicine Radiation Protection Program – “Things To Do”

Regulations require written procedures for compliance

- Audit Program - annually review content and implementation
- Occupational & Public Dose
- Minimization of Contamination
- Operating & Emergency Procedures
- Material Receipt & Accountability
- Ordering & Receiving
- Opening Packages
- Sealed Source Inventory
- Use Records
Radioactive packages

<table>
<thead>
<tr>
<th></th>
<th>Surface</th>
<th>1 meter</th>
</tr>
</thead>
<tbody>
<tr>
<td>White-I</td>
<td>0.5 mrem/hr</td>
<td>0 mrem/hr</td>
</tr>
<tr>
<td>Yellow-II</td>
<td>50.0 mrem/hr</td>
<td>1 mrem/hr (Radiopharmaceuticals)</td>
</tr>
<tr>
<td>Yellow-III</td>
<td>200.0 mrem/hr</td>
<td>10 mrem/hr (Generators)</td>
</tr>
</tbody>
</table>

* Must be checked within 3 hours of arrival or within 3 hours of the next working day.
* Results must be logged.
Nuclear Medicine Radiation Protection Program – “Things To Do”

- Leak Tests
- Area Surveys
- Written directive procedures (therapy)
- Safe Use of Unsealed Licensed Material
- Spill Procedures
- Patient Release After Therapy
- Safety Procedures for Hospitalized Therapy Patients
- Procedures for Diagnostic Sealed Sources & Devices
- Mobile Medical Service
- Waste Management
# Spills Procedure

<table>
<thead>
<tr>
<th>Major vs Minor</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Tc-99m</td>
<td>100 mCi</td>
</tr>
<tr>
<td>Tl-201</td>
<td>100 mCi</td>
</tr>
<tr>
<td>Ga-67</td>
<td>10 mCi</td>
</tr>
<tr>
<td>In-111</td>
<td>10 mCi</td>
</tr>
<tr>
<td>I-131</td>
<td>1 mCi</td>
</tr>
</tbody>
</table>
Spill Kit

- 6 pairs disposable gloves
- 2 disposable lab coats
- 2 paper hats
- 2 pair shoe covers
- 1 roll of absorbant paper with plastic backing
- 6 plastic trash bags with ties
- Radioactive material labeling tape
- 1 marking pen
- 3 Radioactive material labeling tags
- Supplies for 10 wipe samples
- Clipboard with spills report form / pencil
- Emergency Procedures Manual

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“Things to Do” Checklist

Daily – prior to administering the first dose

- Dose calibrator constancy (± 10%)
Ionization Chamber

• Dose Calibrator
  ‣ Cannot differentiate radionuclides
  ‣ Must be calibrated for each radionuclide to be measured

• Geiger-Muller Counter
  ‣ Detects individual events but not their energy
  ‣ Good for area surveys
“Things to Do” Checklist

Daily

› Survey meter constancy
› Well counter constancy
“Things to Do” Checklist

Weekly
  ‣ Area wipe tests (5-7 sites per room)

Monthly
  ‣ Film and ring badge readings

Quarterly ??
  ‣ Radiation Safety Committee meetings ✗ no requirements for frequency of meetings (RSC now applies to free-standing clinics)

Semi-Annually
  ‣ Sealed source leak test and inventory
    • Not required for: byproduct material with T1/2 <30 days
      byproduct material that is a gas
      sources <100uCi of Beta emitter
“Things to Do” Checklist

Quarterly - Dose calibrator linearity
Annually - Dose calibrator accuracy (± 10%)

Sleeve Method or Decay method

Standard sources to check accuracy

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“Things to Do” Checklist

Annually

• Well counter & thyroid uptake probe efficiency (± 5%)
• Survey meter calibration (± 20%)
• Personnel training & review of radiation protection program.
“Things to Do” Checklist

As Needed

Dose calibrator geometric variation (installation & after repairs)

Incident reports (spills, medical event, etc)

Therapy documentation – WDs, hospitalization and/or release
Guide for Diagnostic Nuclear Medicine and Radiopharmaceutical Therapy

Nuclear Regulatory Commission Regulation of Nuclear Medicine: Guide for Diagnostic Nuclear Medicine and Radiopharmaceutical Therapy

Jeffry A. Siegel, Ph.D.

Developed in collaboration with SNM/ACNP and NRC

Stand-alone document applicable to practice of DNM and RP therapy represents first attempt by stakeholder professional organization to provide guidance in implementation of NRC regulations (10 CFR Part 35)

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