

Radiation Safety Program Review

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Requirements for Radiation Protection Program Review

**PA Title 25 Chapter 219.2 c and NRC's 10
CFR 20 Requires:**

**“The licensee shall, at intervals not to
exceed 12 months, review the radiation
protection program content and
implementation.**

What is your “Radiation Protection Program” ?

1. It is the “Radiation Safety Manual” in your supervisor’s office
2. It is commitments made to regulatory agencies to obtain licensure (in amendment and renewal letters). Remember, that the amendment or renewal letter sent to obtain an amendment or renewal is part of you license, as it is referenced therein. You must have it as accessible as you do the scrollwork license pages.
3. It is policies in the policy manual that pertain to radiation safety, i.e. the “radiation worker pregnancy policy”.
4. It is the PA Title 25 Chapter 219, 220, and 224 regulations.
5. It is the NRC’s 10 CFR 19, 20, and 35 regulations
6. It is NRC Regulatory Guides, like 10.8 with Model Program Templates referenced in license renewals. Also NRC Nuregs such as 1556 Vol. 9, 1516, 1492. In addition, there are NRC information notices to licensees and the NRC’s NMSS newsletter.

All these documents should be in the Nuclear Medicine Department, not just the RSO’s office.

Regulatory Guide 10.8 Rev. 2, '87

This is by far the heart of your radiation protection program, as it contains all of the following Model Programs:

Appendix A Training

Appendix B Radiation Survey Instruments

Appendix C Dose Calibrators

Appendix D Personnel Monitoring

Appendix F Radiation Safety Committee

Appendix G A.L.A.R.A. Program

Appendix H Sealed Source Leak Testing

Appendix I Rules for Safe Use of Radioactive Materials

Appendix J Contamination Spill Handling

Appendix K Ordering & Receipt of Radioactive Packages

Appendix L Radioactive Package Opening Instructions

Appendix M Record Keeping for Administered Doses

Appendix N Area Surveys

Appendix O Radioactive Gases and Aerosols

Appendix P I-131 Unsealed Source Therapies >30 mCi

Appendix Q Brachytherapy Sealed Source Therapies

Appendix R Radioactive Waste Handling

Appendix T Radiation Safety Program Changes

Appendix U Recommended Support Equipment

Appendix V Filing System, Appendix W Bibliography

Appendix X Compatibility Issues with 10 CFR 20

NRC Records For Medical Programs

- **Radiation Safety Committee Meeting Minutes**
- **Ministerial Changes**
- **Misadministration/Recordable Event**
- **D.C. Act. Lin, Geom., Constancy, and Accuracy**
- **Survey Meter Calibrations**
- **Sealed Source Leak Tests**
- **Sealed Source Inventories/Surveys/Certificates**
- **Xenon Clearance Times**
- **Xenon Room Air Balance**
- **Xenon Trap Checks**

- **Patient dose administration log**
- **Package Receipt, Transfer, or Disposal**
- **Radioactive Waste Disposal**
- **Personnel Monitoring Records**
- **Wipe Tests and Area Surveys**
- **Bioassay Monitoring**
- **Unsealed Source and LDR Brachytherapy
Patient Room Surveys-before and after patient
occupancy**
- **Unsealed Source Patient Release Documents
and Patient-Specific Calculations**

N.R.C. Notification Reporting Requirements

1. Fires and Explosions - notify within 4 hrs. if regulatory limits exceeded, or within 24 hrs. after damage of any licensed material and if the material is >5 X Appendix B 10CFR20 A.L.I (both).

2. Exposures - Immediately for >25 REM

- Within 24 hrs. for > 5REM (body), 15 REM (eye), 50 REM skin**
- Within 30 days for: Exposures >10 CFR20 for adults, minor (under 18), fetus, or member of public, or any limit in the license**

3. Levels of Radiation or Concentrations of Radioactive Material - within 30 days for: in access of any limit in license, any situation $>10 \times 10$ CFR 20 (excluding individuals).

A) Within 4 hrs. following discovery of: an event that could exceed regulatory limits

B) Within 24 hrs. following restricted access situation that lasts > 24 hrs.

C) Within 24 hrs. following an event $>5 \times 10$ CFR 20 ALI and and restricted access lasts > 24 hrs.

4. Loss and Theft - within 30 days following discovery, unless $1000 \times$ Appendix C of 10 CFR 20, then immediately

5. Medical Misadministrations (>10% written directive)

a) Call 1-301-816-5100 next day

b) Submit report in 15 days

c) Notify physician and patient within 24 hrs.

d) Submit report to patient in 15 days

6. Contaminated Packages - immediately notify carrier and NRC when <22 dpm/cm² (half life <10 days); external levels >200 mREM on package (when T.I is <10)

7. Equipment or Device Failure notify NRC within 24 hrs call 1-301-816-5100, and submit report within 30 days

8. Medical Treatment or Contaminated Individual - within 24 hrs., with report in 30 days

How Long to Keep Records

**Keep personnel monitoring records forever.
Keep all other records for at least 3 yrs.,
unless either a State or NRC inspector has
not been to your institution for >3 yrs., in
which case you must keep the records back
to the date of your last inspection(s) if
greater than 3 yrs.**

Annual In-Service Training

- 1. Type of radiation (beta or gamma), and appropriate handling**
- 2. Proper posting of signs, and recognition of meaning**
- 3. Relative risks in perspective to specific tasks and materials**
- 4. Location of storage of radioactive materials (restr. Vs. unrestr.)**
- 5. A.L.A.R.A./Q.M.P./Pregnancy/Personnel Monitoring Policies**
- 6. Who to contact with safety concerns**
- 7. Location of regulations and license conditions**
- 8. How to respond for a spill, accident, or other emergency**
- 9. Proper use of radiation survey meters, proper pkg. receipt**
- 10. Handling and control of radioactive waste**

Restrictions for the Cessation of Breast-feeding Following Nuclear Medicine

- 1. I-131, NaI, (any) complete cessation**
- 2. Ga-67, (4 mCi) Citrate, cessation for 1 month**
- 3. I-111 WBC, (0.5 mCi), cessation 1 week**
- 4. Tl-201, chloride, (1 mCi), cessation 2 weeks**
- 5. Tc-99m and F-18 agents, cessation 1 day**

Candidates For I-131 Patient Release Program

1. Patient must not use public transportation
2. Patient must not have small children present at home
3. Patient must be able to sleep by themselves for at least one night
4. Patient must be able to isolate personal hygiene and food utensils, and clothing from the rest of the family for 3 days
5. Patient must take written responsibility for personnel contamination improperly disposed
6. Patient-Specific calculations must be made prior to ordering a dose
7. Patient must receive a copy of home care instructions

Wipe-Testing Packages and Surfaces

I-131 limit 200 dpm/100 cm²

Restricted (posted and controlled) areas limit: 20,000 dpm/100cm²

Unrestricted Area (not posted or controlled) limit:

2000 dpm/100 cm²

100 cm² is 4'' x 4''

300 cm² is allowed or 7'' x 7''

When 300 cm² is used the “dpm” limits above increase by a factor of “3”

This is not allowed for the I-131 limit and for package monitoring, only weekly area wipe testing.

Note: 22 dpm/cm² = 2200 dpm/100cm² approx. = 2000 dpm/cm²

Efficiency and Minimum Detectable Activity

DPM = net (gross cpm - bkg cpm) cpm/ efficiency (decimal)

Efficiency in % = $\frac{20 \text{ cpm gross} - 10 \text{ cpm bkg}}{\text{dpm}} \times 100$

Minimum Detectable Activity = M.D.A. = the minimum amount of radioactivity that a detector can count with statistical reliability

$M.D.A. = 3 \times \left[\frac{\text{std. cpm} + \text{bkg. cpm}}{\text{counts/min/uCi}} \right]^{1/2}$

Unit Review

Exposure Unit: Roentgen or Coulomb/Kg (X-ray or gamma only)

Absorbed Dose Unit: RAD or Gray

Unit of Dose Equivalence: REM or Sievert

Radioactivity Unit: Ci or Bq

Mega, Kilo, Deci, centi, milli, micro, nano, pico

Conversions: 1 RAD = 1 cGy

37 MBq = 1 mCi

1 R = 1 RAD = 1 cGy = 1 REM = 1 cSv approximately for X-rays and Gammas in Medicine

Regulatory Limits

Occupational: >18 yrs. Old: 5 REM (5000 mREM)/yr.

Non-Occupational: 0.5 REM or 500 mREM/yr.

<18 yrs. old Occupational: <0.250 REM or 250 mREM/yr.

General Public: <500 mREM/yr. Total (<100 mREM from any one event from licensed activities desired)

Fetal dose: (As measured on the skin of the mother): <0.5 REM/9 mo. Or 500 mREM/9 mo., not to exceed 50 mREM/mo. To the declared pregnant woman only

Eyes: 15 REM or 15,000 mREM/yr.

Skin and Extremities: 50 REM or 50,000 mREM/yr

Nuclear Medicine Department Policies

- 1. Pregnancy Policy**
- 2. Personnel Monitoring Policies**
- 3. Radiation Safety Manual, Policy & Procedure Manual, and Q.C. Manual**
- 4. Q.M.P.**
- 5. A.L.A.R.A.**
- 6. Protective Clothing**

According to J.N.M.T., "Components of Preparedness for Nuclear Medicine Technologists", Sept. '99, p.237-240, the technologist should be prepared to do the following...

- 1. Recognize the proper posting and thresholds for cautionary signs in restricted vs. unrestricted areas**
- 2. Understand how to confirm the proper operation and to properly use and select radiation survey meters (measurement or detection) and trigger or action levels**
- 3. Receive and prepare radioactive material packages for transport, including proper surveys, wipe tests, and knowledge of NRC and DOT regulations and trigger or action levels**
- 4. Understand your personnel monitoring record results, TEDE's, A.L.A.R.A. levels of action, and types of monitors**
- 5. Understand proper shielding for Tl-201 vs, F-18 and for beta or positron-emitter shielding**

- 6. Understand exposure limitation and dose calculations including patient-specific dose calculation for I-131 therapy patient release**
- 7. Understand the differences in a “Medical Event”, “Misadministration”, “Recordable Event”, and an “unintended deviation” in protocol**
- 8. Recognize what the required postings are, such as: licenses, rules for safety, prescribed dose ranges, Sect. 206, Notices to Employees, and associated documents**
- 9. New orientations should include what might be different in your license versus others**
- 10. You should know Standard International Unit conversions for Ci vs. Bq, R vs. Coulomb/kg, RAD vs. Gray, REM vs. Sievert, and the prefixes, Mega, Milli, Kilo, Centi, Micro, nano, and pico, etc.**

From Nureg 1556 and 10 CFR 19

- 1. Your obligation to report unsafe conditions, but through the proper channels**
- 2. Worker's rights, and protection from employer retribution**
- 3. Who to ask for clinical, radiation safety, or radiopharmaceutical questions**
- 4. You should understand how to perform a bioassay and when it is required**
- 5. You should know when it is necessary to add internal exposures to external exposures, and how to properly monitor for Xenon or aerosols, if they are used**
- 6. You should understand all the specific requirements for record-keeping, decontamination, surveys, patient release criteria, room preparation and safety actions for an in-patient I-131 patient, if you have them in your practice**

- 6. How to calculate dpm from cpm ($dpm = cpm / \text{eff.}$). How to determine and recognize the importance of M.D.A. of your equipment**
- 7. Control the release of radioactive materials and disposal through decay, biowaste streams, biological or other liquid release limitations including proper records, monitoring, and measurement technique**
- 8. Describe what should be on a label of a vial or syringe of nuclear medicine**
- 9. Understand radiation safety differences between a nuclear cardiology operation vs. a P.E.T. operation**
- 10. How to reduce undesired exposures using time, distance, and shielding in nuclear medicine (diagnostic and therapeutic)**