

APPENDIX B

MEDICAL BROAD-SCOPE INSPECTION REFERENCES*

1. ORGANIZATION AND SCOPE OF PROGRAM

- 10 CFR 35.6 Provisions for research involving human subjects.
- 10 CFR 35.29 Administrative requirements - mobile nuclear medicine service.
- 10 CFR 35.80 Technical requirements - mobile nuclear medicine service.
- License application and applicable license conditions.

2. MANAGEMENT OVERSIGHT

A. Radiation Safety Committee

- 10 CFR 33.13 Requirements for issuance of a Type A specific license of broad scope
- 10 CFR 35.22 Radiation safety committee.
- 10 CFR 35.23 Statements of authority and responsibilities.
- 10 CFR 35.31 Radiation safety program changes.
- Applicable license conditions.

B. Radiation Safety Officer

- 10 CFR 35.21 Radiation safety officer.
- 10 CFR 35.23 Statements of authority and responsibilities.
- 10 CFR 35.900 Radiation safety officer.

C. Audits, Reviews, or Inspections

- 10 CFR 35.22 Radiation safety committee.
- 10 CFR 20.1101 Radiation protection programs.
- 10 CFR 20.2102 Records of radiation protection programs.
- Applicable license conditions.

D. ALARA

- 10 CFR 35.20 Radiation protection programs.

E. Authorized Users

- 10 CFR 35.11 License required.
- 10 CFR 35.13 License amendments.
- 10 CFR 35.25 Supervision.
- Applicable license conditions.

* These references correspond to the sections of IP 87119, Part II of Appendix A, the "Medical Broad-Scope Inspection Record ."

3. FACILITIES

A. Access Control

10 CFR 20.1601 Control of access to high-radiation areas.
10 CFR 20.1602 Control of access to very high-radiation areas.
Applicable license conditions.

B. Engineering Controls

10 CFR 20.1701 Use of process or other engineering controls.
10 CFR 20.1702 Use of other controls
10 CFR 35.90 Storage of volatile gases.
10 CFR 35.205 Control of aerosols and gases.
Applicable license conditions.

4. EQUIPMENT AND INSTRUMENTATION

A. Dose Calibrators - Photon-emitting radionuclides

10 CFR 35.50 Possession, use, calibration, and check of dose
calibrators.
Applicable license conditions.

B. Instrumentation- Alpha- or beta-emitting radionuclides

10 CFR 35.52 Possession, use, calibration, and check of instruments to
measure dosages of alpha- or beta-emitting radionuclides.
Applicable license conditions.

C. Generators

10 CFR 35.204 Permissible molybdenum-99 concentrations.

D. Syringes and Vials

10 CFR 35.60 Syringe shields and labels.
10 CFR 35.61 Vial shields and labels.

E. Survey Instruments

1. Possession

10 CFR 35.120 Possession of survey instrument.
10 CFR 35.220 Possession of survey instruments.
10 CFR 35.320 Possession of survey instruments.
10 CFR 35.520 Availability of survey instrument.
Applicable license conditions.

2. Calibration

10 CFR 35.51 Calibration and check of survey instruments.

F. Safety Component Defects

10 CFR 21.21 Notification of failure to comply or existence of a defect and its evaluation.

5. MATERIAL USE, CONTROL, AND TRANSFER

A. Authorized Uses

10 CFR 31.11 General license for use of byproduct material for certain in-vitro clinical or laboratory testing.

10 CFR 35.53 Measurement of dosages of unsealed byproduct material for medical use.

10 CFR 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies.

10 CFR 35.200 Use of unsealed byproduct material for imaging and localization studies.

10 CFR 35.204 Permissible molybdenum-99 concentrations.

10 CFR 35.300 Use of unsealed byproduct material for therapeutic administration.

10 CFR 35.400 Use of sources for brachytherapy.

10 CFR 35.500 Use of sealed sources for diagnosis.

B. Security and Control

10 CFR 20.1003 Definitions (restricted area and unrestricted area).

10 CFR 20.1801 Security of stored material.

10 CFR 20.1802 Control of material not in storage.

C. Receipt and Transfer of Licensed Material

10 CFR 20.1906 Procedures for receiving and opening packages.

10 CFR 20.1501 General.

10 CFR 20.2103 Records of surveys.

10 CFR 30.41 Transfer of byproduct material.

10 CFR 30.51 Records.

6. THERAPIES

10 CFR 35.75 Release of patients or human research subjects containing radiopharmaceuticals or permanent implants.

10 CFR 35.315 Safety precautions.

Applicable license conditions.

7. QUALITY MANAGEMENT PROGRAM AND MISADMINISTRATIONS

10 CFR 35.2 Definitions (misadministration and recordable events).

10 CFR 35.32 Quality management program.

10 CFR 35.33 Notifications, reports, and records of misadministrations.

8. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

A. Area Surveys

10 CFR 2.01301 Dose limits for individual members of the public.

10 CFR 20.1302 Compliance with dose limits for individual members of the public.

10 CFR 20.1501 General.

10 CFR 20.2103 Records of surveys.

10 CFR 20.2107 Records of dose to individual members of the public.

10 CFR 35.70 Surveys for contamination and ambient radiation exposure rate.
Applicable license conditions.

B. Leak Tests and Inventories

10 CFR 35.59 Requirements for possession of sealed sources and brachytherapy sources.
Applicable license conditions.

9. TRAINING AND INSTRUCTIONS TO WORKERS

A. General

10 CFR 19.12 Instruction to workers.
Knowledge of 10 CFR Part 20 radiation protection procedures and requirements.

B. Specific

10 CFR 35.900 Radiation Safety Officer.
10 CFR 35.901 Training for experienced Radiation Safety Officer.
10 CFR 35.910 Training for uptake, dilution, and excretion studies.
10 CFR 35.920 Training for imaging and localization studies.
10 CFR 35.930 Training for therapeutic use of unsealed byproduct material.
10 CFR 35.932 Training for treatment of hyperthyroidism.
10 CFR 35.934 Training for treatment of thyroid carcinoma.
10 CFR 35.950 Training for use of sealed sources for diagnosis.
10 CFR 35.970 Training for experienced authorized users.
10 CFR 35.971 Physician training in a three month program.
10 CFR 35.972 Recency of training.
10 CFR 35.980 Training for an authorized nuclear pharmacist.
10 CFR 35.981 Training for experienced nuclear pharmacists.

C. Therapy Training

10 CFR 35.310 Safety instruction.
10 CFR 35.59 Requirements for possession of sealed sources and brachytherapy sources.

D. Supervision

10 CFR 35.25 Supervision.

10. RADIATION PROTECTION

A. General

IP 83822 Radiation Protection.

B. Radiation Protection Program

1. Exposure evaluation

10 CFR 20.1501 General.

2. Programs

10 CFR 20.1101 Radiation protection programs.
10 CFR 35.20 ALARA program.

C. Dosimetry

1. Dose Limits

10 CFR 20.1201 Occupational dose limits for adults.
10 CFR 20.1202 Compliance with requirements for summation of external and internal doses.
10 CFR 20.1207 Occupational dose limits for minors.
10 CFR 20.1208 Doses to an embryo/fetus.

2. External

10 CFR 20.1203 Determination of external dose from airborne radioactive material.
10 CFR 20.1501 Dosimetry processing.
10 CFR 20.1502 Conditions requiring individual monitoring of external and internal occupational dose.
Applicable license conditions.

3. Internal

10 CFR 20.1204 Determination of internal exposure.
10 CFR 20.1502 Conditions requiring individual monitoring of external and internal occupational dose.
10 CFR 20, Subpart H Respiratory protection and controls to restrict internal exposure in restricted areas.
10 CFR 35.205 Control of aerosols and gases.
10 CFR 35.315 Safety precautions - radiopharmaceutical therapy.

D. Records

10 CFR 20.2102 Records of radiation protection programs.
10 CFR 20.2103 Records of surveys.
10 CFR 20.2104 Determination of prior occupational dose.
10 CFR 20.2106 Records of individual monitoring results.

E. Patient Release

10 CFR 35.75 Release of patients or human research subjects containing radiopharmaceuticals or permanent implants.

11. RADIOACTIVE WASTE MANAGEMENT

A. Disposal

10 CFR 35.92 Decay in storage.
10 CFR 20.1904 Labeling containers.
10 CFR 20.2001 General waste disposal requirements.
10 CFR 20.2005 Disposal of specific waste
10 CFR 20.2103 Records of surveys.
10 CFR 20.2108 Records of waste disposal.

B. Effluents

1. General

IP 87102 Maintaining Effluents from Materials
Facilities As Low As Is Reasonably Achievable (ALARA)

2. Release into sanitary sewer

10 CFR 20.2003 Disposal by release into sanitary sewerage.
Applicable license conditions.

3. Release to septic tanks

10 CFR 20.1003 Definitions (sanitary sewerage).
10 CFR Part 20, Limits.
App. B, Table 2

4. Incineration of waste

10 CFR 20.2004 Treatment or disposal by incineration.

5. Control of air effluents and ashes

10 CFR 20.1201 Occupational dose limits for adults.
10 CFR 20.1301 Dose limits for individual members of the public.
10 CFR 20.1501 General.
10 CFR 20.1701 Use of process and other engineering controls.
Applicable license conditions

C. Waste Management

1. General

10 CFR 20.2001 General requirements.
IP 84850 Radioactive Waste Management - Inspection of
Waste Generator Requirements of 10 CFR Part 20
and 10 CFR Part 61

2. Waste compacted

Applicable license conditions.

3. Waste storage areas

10 CFR 20.1801 Security of stored material.
10 CFR 20.1902 Posting requirements.
10 CFR 20.1904 Labeling containers.
Applicable license conditions.

4. Packaging, Control, and Tracking

10 CFR Part 20, Requirements for low-level waste transfer for
Appendix F disposal at land disposal facilities and manifests.
10 CFR 20.2006 Transfer for disposal and manifests.

10 CFR 61.55 Waste classification.
10 CFR 61.56 Waste characterization.

5. Transfer

10 CFR Part 20, Appendix F Requirements for low-level waste transfer for disposal at land disposal facilities and manifests.
10 CFR 20.2001 General requirements.
10 CFR 20.2006 Transfer for disposal and manifests.
10 CFR 30.41 Transfer of byproduct material

6. Records

10 CFR 20.2103 Records of surveys.
10 CFR 20.2108 Records of waste disposal.

12. DECOMMISSIONING

10 CFR 30.35 Financial assurance and record-keeping for decommissioning.
10 CFR 30.36 Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.
IMC 2602 Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees.
IP 87104 Decommissioning Inspection Procedure for Materials Licensees.
IMC 2605 Decommissioning Procedures for Fuel Cycle and Materials Licensees.
NUREG/BR-0241 NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees.

13. TRANSPORTATION

A. General

NRC Charts Hazard Communication for Class 7 (Radioactive) Materials.
10 CFR 71.5 Transportation of licensed material.
TI 2515/133 Implementation of Revised 49 CFR Parts 100-179 and 10 CFR Part 71.

B. Shippers - Requirements for Shipments and Packaging

1. General Requirements

49 CFR Part 173, Subpart I Class 7, radioactive material.
49 CFR 173.24 General requirements for packagings and packages.
49 CFR 173.448 General transportation requirements.
49 CFR 173.435 Table of A₁ and A₂ values for radionuclides.

2. Transport Quantities

10 CFR 71.4 Definitions of quantities.

a. All quantities

10 CFR 71.4 Definitions of quantities.

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| | 49 CFR 173.410 | General design requirements. |
| | 49 CFR 173.441 | Radiation level limitations. |
| | 49 CFR 173.443 | Contamination control. |
| | 49 CFR 173.475 | Quality control requirements prior to each shipment of Class 7 (radioactive) materials. |
| | 49 CFR 173.476 | Approval of special form Class 7 (radioactive) materials. |
| b. | Limited quantities | |
| | 49 CFR 173.421 | Excepted packages for limited quantities of Class 7 (radioactive) materials. |
| | 49 CFR 173.422 | Additional requirements for excepted packages containing Class 7 (radioactive) materials. |
| c. | Type A quantities | |
| | 49 CFR 173.412 | Additional design requirements for Type A packages. |
| | 49 CFR 173.415 | Authorized Type A packages. |
| | 49 CFR 178.350 | Specification 7A; general packaging, Type A . |
| d. | Type B quantities | |
| | IP 86740, Section 2 | Inspection of transportation activities. |
| e. | LSA material and SCO | |
| | 49 CFR 173.403 | Definitions. |
| | 49 CFR 173.427 | Transport requirements for low specific activity (LSA) Class 7 (radioactive) materials and surface contaminated objects (SCO). |
| 3. | HAZMAT Communication Requirements | |
| | 49 CFR 172.200-205 | Shipping papers. |
| | 49 CFR 172.300-338 | Marking packages. |
| | 49 CFR 172.400-450 | Labeling packages. |
| | 49 CFR 172.500-560 | Placarding vehicles. |
| | 49 CFR 172.600-604 | Emergency response information and guidance. |
| C. | HAZMAT Training | |
| | 49 CFR 172.702 | Applicability and responsibility for training and testing. |
| | 49 CFR 172.704 | Training requirements. |
| D. | Transportation by Public Highway | |
| | 49 CFR 171.15 | Immediate notice of certain hazardous materials incidents. |
| | 49 CFR 171.16 | Detailed hazardous materials incident reports. |
| | 49 CFR 177.800 | Responsibility for compliance and training. |

49 CFR 177.816 Driver training.
49 CFR 177.842 Loading and unloading: Class 7 (radioactive) material.

14. NOTIFICATIONS AND REPORTS

10 CFR 19.13 Notifications and reports to individuals.
10 CFR 20.2201 Reports of theft or loss of licensed material.
10 CFR 20.2202 Notification of incidents.
10 CFR 20.2203 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.
10 CFR 30.50 Reporting requirements.
10 CFR 35.14 Notifications (RSO, authorized users, and nuclear pharmacists).

15. POSTING AND LABELING

10 CFR 19.11 Posting of notices to workers.
10 CFR 20.1902 Posting requirements.
10 CFR 20.1903 Exemptions to posting requirements.
10 CFR 20.1904 Labeling containers.
10 CFR 20.1905 Exemptions to labeling requirements.
10 CFR 21.6 Posting requirements.

16. INDEPENDENT AND CONFIRMATORY MEASUREMENTS

No references.

17. VIOLATIONS, NON-CITED VIOLATIONS AND OTHER SAFETY ISSUES

NUREG/BR-0195, Rev.1 NRC Enforcement Manual.
NUREG-1600 General Statement of Policy and Procedures for NRC Enforcement Actions.

18. PERSONNEL CONTACTED

No references.

19. PERFORMANCE EVALUATION FACTORS

IP 87101 Performance Evaluation Factors.

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