

APPENDIX B

RADIOPHARMACY INSPECTION REFERENCES

1. ORGANIZATION AND SCOPE OF PROGRAM

License application and applicable license conditions.

2. MANAGEMENT OVERSIGHT

A. Authorized Nuclear Pharmacist

10 CFR 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material, for medical use under 10 CFR Part 35.

B. Radiation Safety Officer

Applicable license conditions.

C. Audits, Reviews, or Inspections

10 CFR 20.1101 Radiation protection programs.
10 CFR 20.2102 Records of radiation protection programs.
Applicable license conditions.

D. As Low As Reasonably Achievable

10 CFR 20.1101 Radiation protection programs.
Applicable license conditions.

3. FACILITIES

A. Access Control

10 CFR 20.1601,1602 Control of access to high/very high radiation areas.
10 CFR 20.1801 Security of stored material.
10 CFR 20.1802 Control of material not in storage.
Applicable license conditions.

B. Engineering Controls

10 CFR 20.1101 Radiation protection programs.
Applicable license conditions

4. EQUIPMENT AND INSTRUMENTATION

A. Dose calibrator and Assay Instrumentation

10 CFR 32.72 Manufacturing, preparation, or transfer.
Applicable license conditions.

B. Survey Instruments

10 CFR 20.2103 Records of surveys.
Applicable license conditions.

C. 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. 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.

B. Receipt and Transfer of Licensed Material

10 CFR 20.1302 Compliance with dose limits for individual members of
the public.
10 CFR 20.1906 Procedures for receiving and opening packages.
10 CFR 20.1501 Surveys.
10 CFR 20.2103 Records of surveys.
10 CFR 30.41 Transfer of byproduct material.
10 CFR 30.51 Records of receipt and transfer.
10 CFR 32.72 Manufacturing, preparation, or transfer.

6. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

A. Area Surveys

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.
Applicable license conditions.

B. Leak Tests and Inventories

Applicable license conditions.

7. TRAINING AND INSTRUCTIONS TO WORKERS

General

10 CFR 19.12 Instruction to workers.
10 CFR 30.33 General requirements for issuance of
specific licenses.
Knowledge of 10 CFR Part 20 radiation protection procedures and
requirements.
Applicable license conditions.

8. RADIATION PROTECTION

A. Radiation Protection Program

- 1. Exposure evaluation
10 CFR 20.1501 General.
- 2. Programs
10 CFR 20.1101 Radiation protection programs.

B. 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.Applicable license conditions.
- 2. External
 - 10 CFR 20.1203 Determination of external dose from airborne radioactive material.
 - 10 CFR 20.1501 General.
 - 10 CFR 20.1502 Conditions requiring individual monitoring of external and internal occupational dose.Applicable license conditions.

C. Records

- 10 CFR 19.13 Reports to workers.
 - 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.
- Applicable license conditions.

9. RADIOACTIVE WASTE MANAGEMENT

A. Disposal

- 10 CFR 20.1904 Labeling containers.
- 10 CFR 20.2001 General requirements.
- 10 CFR 20.2103 Records of surveys.
- 10 CFR 20.2108 Records of waste disposal.
- 10 CFR 20.2003 Disposal by release into sanitary sewerage.
- IN 94-07 Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20.

B. Effluents

1. General

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

2. Release to septic tanks

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

3. Incineration of waste

10 CFR 20.2004 Treatment or disposal by incineration.

4. 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 or 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, Appendix G
Requirements for Transfers of Low-Level Radioactive Waste
Intended for Disposal at Licensed 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 characteristics.

5. Transfer

10 CFR Part 20, Appendix G
Requirements for Transfers of Low-Level Radioactive Waste
Intended for Disposal at Licensed Land Disposal Facilities and
Manifests.

10 CFR 20.2001 General requirements.
10 CFR 20.2006 Transfer for disposal and manifests.

6. Records

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

10. 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.

11. TRANSPORTATION

A. General

10 CFR 71.5 Transportation of licensed material.

B. Shippers - Requirements for Shipments and Packaging

1. General Requirements

49 CFR Part 173, Class 7 (radioactive) materials.
Subpart I
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.

a. All quantities

10 CFR 71.4 Definitions.
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 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.
- 49 CFR 172.400-450 Labeling.
- 49 CFR 172.500-560 Placarding.
- 49 CFR 172.600- 606 Emergency response information.

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 Purpose and scope of this part and responsibility for compliance and training.
- 49 CFR 177.816 Driver training.
- 49 CFR 177.842 Loading and unloading: Class 7 (radioactive) material.

12. 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 32.72 Manufacture, preparation, or transfer for commercial distribution.
- Applicable license conditions.

13. POSTING AND LABELING

- 10 CFR 19.11 Posting of notices to workers.
 - 10 CFR 21.6 Posting requirements.
 - 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.
- Applicable license conditions

14. INDEPENDENT AND CONFIRMATORY MEASUREMENTS

No references.

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

Enforcement Policy	Maintained on NRC Enforcement Web page	
NRC Enforcement Manual	Maintained on NRC Enforcement Web page	

16. PERSONNEL CONTACTED

No references.

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