State of Maine
Rules Relating To Radiation Protection

Department of Human Services
Bureau of Health
Division of Health Engineering
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TABLE OF CONTENTS

PART A - GENERAL PROVISIONS (June 1, 2003)

1. Scope... A-1
2. Definitions... A-1
3. Exemptions... A-12
4. Records... A-13
5. Inspections... A-13
6. Tests... A-13
7. Additional Requirements... A-13
8. Violations... A-13
9. Impounding... A-13
10. Prohibited Uses... A-13
11. Interpretations... A-13
12. Communications... A-14
13. The International System of Units (SI)... A-14

PART B - ENFORCEMENT ACTIONS, PROCEDURES AND CIVIL PENALTIES (June 1, 2003)

1. Purpose and Scope... B-1
2. Severity of Violations... B-1
3. Enforcement Conferences... B-2
4. Enforcement Actions... B-3
5. Notice of Violation... B-3
6. Civil Penalties... B-4
7. Adjustment Factors... B-6
8. Orders... B-7
9. Escalation of Enforcement Sanctions... B-9
10. Related Administrative Actions... B-11
11. Referrals to Department of the Attorney General... B-11
12. Public Disclosure of Enforcement Actions... B-11

Appendices

Appendix 1 Severity Categories... B-13

PART C - LICENSING OF RADIOACTIVE MATERIAL (October 1, 2003)

1. Purpose and Scope... C-1

Exemptions

2. Source Material... C-1
3. Radioactive Material Other Than Source Material... C-3

Licenses

4. Types of Licenses... C-7
...NOTE: Attention is directed to the fact that regulation by the State of source material, radioactive material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the State and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

General Licenses

5. General Licenses - Source Material... C-7
6. General Licenses - Radioactive Material Other Than Source Material... C-9

Specific Licenses

7. Filing Application for Specific Licenses... C-16
8. General Requirements for the Issuance of Specific Licenses.... C-19
9. Special Requirements for the Use of Sealed Sources in Industrial Radiography... C-22
10. Special Requirements for Specific Licenses of Broad Scope... C-23
11. Special Requirements for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices which Contain Radioactive Material... C-26
12. Special Requirements for a Special License for Source Material Milling... C-38
13. Issuance of Specific Licenses... C-38
14. Specific Terms and Conditions of License... C-39
15. Expiration and Termination of Licenses... C-39
16. Renewal of Licenses... C-42
17. Amendment of Licenses at Request of Licensee... C-42
18. Agency Action on Applications to Renew and Amend... C-42
19. Persons Possessing a License for Source, Radioactive or Special Nuclear Material in Quantities Not Sufficient to form a Critical Mass on Effective Date of these Regulations... C-42
20. Persons Possessing Naturally Occurring and Accelerator-Produced Radioactive Material on Effective Date of These Regulations... C-42
21. Transfer of Material... C-42
22. Modification, Revocation and Termination of Licenses... C-43
23. Deliberate Misconduct... C-44

Reciprocity

24. Reciprocal Recognition of Licenses... C-45

Appendices

Schedule A Exempt Concentrations of Radioactive Materials Which Are Introduced Into Products... C-49
Schedule B Exempt Quantities of Individual Radioactive Materials... C-53
Schedule C Limits for Broad Licenses... C-55
Schedule D Quantities of Radioactive Material Requiring Consideration of the Need for an Emergency Plan for Responding to a Release... C-57

Appendix A General Provisions... C-59
Table 1 Specific License and Inspection Fees... C-61
Appendix B Naturally Occurring or Accelerator Produced Material.(NARM)... C-65
Appendix C Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning C-67
Appendix D Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning C-69
Appendix E Quantities for Use With Decommissioning C-71

PART D - STANDARDS FOR PROTECTION AGAINST RADIATION (June 1, 2003)

1. Purpose... D-1
2. Scope... D-1
3. Definitions (As used in Part D)... D-1
4. Implementation... D-3

Radiation Protection Programs

5. Radiation Protection Programs... D-3

Occupational Dose Limits

6. Occupational Dose Limits for Adults... D-4
7. Compliance with Requirements for Summation of External and Internal Doses... D-5
8. Determination of External Dose from Airborne Radioactive Material... D-5
9. Determination of Internal Exposure... D-5
10. Determination of Prior Occupational Dose... D-7
11. Planned Special Exposures... D-8
12. Occupational Dose Limits for Minors... D-9
13. Dose to an Embryo/Fetus... D-9

Radiation Dose Limits For Individual Members Of The Public

14. Dose Limits for Individual Members of the Public... D-9
15. Compliance with Dose Limits for Individual Members of the Public... D-10

Testing For Leakage Or Contamination Of Sealed Sources

16. Testing for Leakage or Contamination of Sealed Sources... D-11

Surveys and Monitoring

17. General... D-12
18. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose D-13

Control Of Exposure From External Sources In Restricted Areas

19. Control of Access to High Radiation Areas... D-13
20. Control of Access to Very High Radiation Areas... D-14
21. Control of Access to Very High Radiation Areas -- Irradiators... D-14

Respiratory Protection And Controls To Restrict Internal Exposure In Restricted Areas

22. Use of Process or Other Engineering Controls... D-16
23. Use of Other Controls... D-16
24. Use of Individual Respiratory Protection Equipment... D-17

Storage And Control Of Licensed Or Registered Sources Of Radiation

25. Security of Stored Sources of Radiation... D-19
26. Control of Sources of Radiation not in Storage... D-19

Precautionary Procedures

27. Caution Signs... D-19
28. Posting Requirements... D-20
29. Exceptions to Posting Requirements... D-21
30. Labeling Containers and Radiation Machines... D-21
31. Exemptions to Labeling Requirements... D-21
32. Procedures for Receiving and Opening Packages... D-22

Waste Disposal

33. General Requirements... D-23
34. Method for Obtaining Approval of Proposed Disposal Procedures... D-23
35. Disposal by Release into Sanitary Sewerage... D-24
36. Treatment or Disposal by Incineration... D-24
37. Disposal of Specific Wastes... D-24
38. Transfer for Disposal and Manifests... D-25
39. Compliance with Environmental and Health Protection Regulations.... D-25

Records

40. General Provisions... D-25
41. Records of Radiation Protection Programs... D-25
42. Records of Surveys... D-26
43. Records of Tests for Leakage or Contamination of Sealed Sources... D-26
44. Records of Prior Occupational Dose... D-26
45. Records of Planned Special Exposures... D-26
46. Records of Individual Monitoring Results... D-27
47. Records of Dose to Individual Members of the Public... D-27
48. Records of Waste Disposal... D-28
49. Records of Testing Entry Control Devices for Very High Radiation Areas... D-28
50. Form of Records... D-28

Reports

51. Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation... D-28
52. Notification of Incidents... D-29
53. Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits... D-30
54. Reports of Planned Special Exposures... D-31
55. Reports to Individuals of Exceeding Dose Limits... D-31
56. Reports of Individual Monitoring... D-31
57. Notifications and Reports to Individuals... D-32
58. Reports of Leaking or Contaminated Sealed Sources... D-32

Additional Requirements

59. Vacating Premises... D-32

Radiological Criteria for License Termination

60. General Provisions and Scope... D-32
61. Radiological Criteria for Unrestricted Use... D-33
62. Criteria for License Termination Under Restricted Conditions... D-33
63. Alternate Criteria for License Termination... D-34

64. Public Notification and Public Participation... D-35
65. Minimization of Contamination... D-35

Appendices

Appendix A Protection Factors For Respirators... D-37
Appendix B Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewerage... D-39
Appendix C Quantities1 of Licensed or Registered Material Requiring Labeling... D-73

Appendix D. Requirements for Transfer of Low-Level Radioactive Waste for Disposal at Land Disposal Facilities and Manifests... D-83
Appendix E Reserved... D-97
Appendix F Reserved... D-99
Appendix G Special Requirements Involving Low-Level Radioactive Waste... D-101

PART E - RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS (August 1, 2002)

1. Purpose... E-1
2. Scope... E-1
3. Definitions... E-1
4. Application for a Specific License... E-5

Equipment Control

5. Performance Requirements for Industrial Radiography Equipment... E-6
6. Limits on External Radiation Levels From Radiographic Exposure Devices, Storage Containers and Source Changers... E-7
7. Locking of Radiographic Exposure Devices, Storage Containers and Source Changers... E-8
8. Radiation Survey Instruments... E-8
9. Leak Testing and Replacement of Sealed Sources... E-9
10. Quarterly Inventory... E-9
11. Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments... E-10
12. Permanent Radiographic Installations... E-10
13. Labeling, Storage, and Transportation... E-11

Radiation Safety

14. Conducting Industrial Radiographic Operations.. E-11
15. Radiation Safety Officer for Industrial Radiography... E-12
16. Requirements for Qualifications of Radiographic Personnel... E-12
17. Operating and Emergency Procedures... E-15
18. Personnel Monitoring... E-15
19. Radiation Surveys.. E-16
20. Requirements for Underwater, Offshore Platform, and Lay-Barge Radiography... E-17
21. Surveillance... E-17
22. Posting... E-18
23. Utilization Logs... E-18
24. Reciprocity... E-18
25. Radiation Safety Requirements for the Use of Radiation Machines... E-19

Record Keeping

26. Record Keeping Requirements... E-22

Reporting

27. Reporting Requirements... E-24
28. Records Required at Temporary Job Sites... E-25
29. Specific Requirements for Radiographic Personnel Performing Industrial Radiography... E-25
30. Special Requirements and Exemptions for Radiation Machines in Enclosed Radiography... E-26
31. Prohibitions... E-26
32. Periodic Survey... E-27
33. Radiographer Examination and Certification... E-27

Appendices

Appendix A Subjects to be Covered During the Instruction of Radiographer Trainees... E-31
Appendix B Items to be Covered During the Inspection of Radiographic Equipment.... E-33
Appendix C Items to be Included in Operating and Emergency Procedures... E-35

PART F - X-RAYS IN THE HEALING ARTS (August 1, 2001)

1. Scope... F-1
2. Definitions... F-1
3. General Requirements... F-8
4. Certification of Qualified Experts... F-14
5. General Requirements for All Diagnostic X-ray Systems... F-17
6. Fluoroscopic X-Ray Systems... F-19
7. Radiographic Systems Other Than Fluoroscopic, Dental Intraoral or Veterinarian Systems... F-24
8. Intraoral Dental Radiographic Systems and Podiatric Systems... F-29
9. Veterinary Medicine Radiographic Installations... F-32
10. Mobile Service... F-32
11. Mobile Vans... F-33
12. Bone Densitometry... F-33

Appendices

Appendix A Information on Radiation Shielding Required for Plan Reviews... F-35
Appendix B Design Requirements for an Operator's Booth... F-37
Appendix C Information To Be Submitted by Persons Proposing to Conduct Healing Arts Screening... F-39
Appendix D Characteristics for Qualifying Diagnostic X-ray Experience for Radiological Physicists... F-41
Appendix E Characteristics for Qualifying Diagnostic X-ray Experience for X-ray Technicians... F-43
Appendix F X-Ray Registration Fees... F-45
Appendix G Quality Assurance for Facilities Performing Diagnostic X-ray... F-47

PART G – MEDICAL USE OF RADIOACTIVE MATERIAL (June 1, 2003)

1. Purpose and Scope... G-1
2. Definitions... G-1
3. Maintenance of Records... G-4
4. Provisions for the Protection of Human Research Subjects... G-5
5. License Required... G-5
6. Application for License, Amendment, or Renewals... G-5
7. License Amendments... G-6

8. Notifications... G-7
9. Exemptions Regarding Type A Specific License of Broad Scope... G-7
10. License Issuance... G-8
11. Specific Exemptions... G.8

General Administrative Requirements

12. Authority and Responsibilities for the Radiation Protection Program... G-9
13. Radiation Protection Program Changes.. G-10
14. Supervision... G-10
15. Written Directives... G-10
16. Procedures for Administrations Requiring a Written Directive... G-11

17. Suppliers for Radioactive Material, Sealed Sources or Devices for Medical Use... G-12
18. Training for Radiation Safety Officer... G-12
19. Training for an Authorized Medical Physicist... G-13
20. Training for an Authorized Nuclear Pharmacist... G-13
21. Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and Nuclear Pharmacist... G-14
22. Recentness of Training G-14

General Technical Requirements

23. Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material... G-15
24. Calibration Survey Instruments... G-15
25. Determination of Doses of Unsealed Radioactive Material for Medical Use... G-15
26. Authorization for Calibration, Transmission, and and Reference Sources... G-16
27. Requirements for Possession of Sealed Sources and Brachytherapy Sources... G-16
28. Labeling of Vials and Syringes... G-17
29. Surveys for Ambient Radiation Dose Rate... G-17
30. Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material... G-17
31. Provisions of Mobile Nuclear Medicine Service... G-18
32. Decay in Storage... G-18

Unsealed Radioactive Material – Written Directive Not Required

100. Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for Which a Written Directive Is Not Required... G-19
190. Training for Uptake, Dilution, and Excretion Studies... G-19
200. Use of Unsealed Radioactive Material for Imaging and Localization Studies For Which a Written Directive Is Not Required... G-20
201. Permissible Molybdenum-99 Concentration... G-20
290. Training for Imaging and Localization Studies... G-21

Unsealed Radioactive Material – Written Directive Required

300. Use of Unsealed Radioactive Material for Which a Written Directive Is Required... G-23
301. Safety Instruction... G-23
302. Safety Precautions... G-23
390. Training for Use of Unsealed Radioactive Material for Which a Written Directive Is Required... G-24
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)... G-25
394. Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive In Quantities Greater Than 1.22 Gigabecquerels (33 Millicuries)... G-26

Manual Brachytherapy

400. Use of Sources for Manual Brachytherapy... G-28
401. Surveys After Source Implant and Removal... G-28
402. Brachytherapy Sources Accountability... G-28
403. Safety Instruction... G-28
404. Safety Precautions... G-29
405. Calibration Measurements of Brachytherapy Sources... G-29
406. Decay of Strontium-90 Sources for Ophthalmic Treatments... G-29
407. Therapy-Related Computer Systems... G-30
490. Training for Use of Manual Brachytherapy Sources G-30
491. Training for Ophthalmic Use of Strontium-90... G-31

Sealed Sources for Diagnosis

500. Use of Sealed Sources for Diagnosis... G-32
501. Training for Use of Sealed Sources for Diagnosis... G-32

Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

600. Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit... ... G-33
601. Survey of Patients and Human Research Subjects Treated With a Remote Afterloader Unit... G-33
602. Installation, Maintenance, Adjustment and Repair... G-33
603. Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units... G-33
604. Safety Precautions for Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units... G-34
605. Dosimetry Equipment... G-35
606. Full Calibration Measurements on Teletherapy Units... G-36
607. Full Calibration Measurements on Remote Afterloader Units... G-37
608. Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units... G-38
609. Periodic Spot Checks for Teletherapy Units... G-39
610. Periodic Spot Checks for Remote Afterloader Units... G-40
611. Periodic Spot Checks for Gamma Stereotactic Radiosurgery Units... G-41
612. Additional Requirements for Mobile Remote Afterloader Units... G-42
613. Radiation Surveys... G-43
614. Five Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units... G-43
615. Therapy-Related Computer Systems... G-43
690. Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units... G-43

Cyclotron/PET Facilities

700. Licensing and Registration of Cyclotron / PET Facilities... G-45
701. Supervision of Cyclotron /PET Facilities... G-45
702. Other Applicable Requirements... G-45
703. Cyclotron / PET Facility Accelerator Requirements... G-46
704. Safety Considerations for Cyclotron / PET Facilities.. G-46
705. Cyclotron / PET Facility Nuclear Pharmacy and Radiochemical Production... G-46
706. Rubidium-82 Generator... G-47
790. Training for Cyclotron / PET Facility Authorized Users... G-47
791. Training for Cyclotron / PET Facility Staff... G-48

Training and Experience Requirements

900. Radiation Safety Officer G-49
910. Training for Uptake, Dilution, or Excretion Studies G-49
920. Training for Imaging and Localization Studies G-50
930. Training for Therapeutic Use of Unsealed Radioactive Material G-51
932. Training for Treatment of Hyperthyroidism G-52
934. Training for Treatment of Thyroid Carcinoma G-52
940. Training for Use of Brachytherapy Sources G-52
941. Training for Ophthalmic Use of Strontium-90 G-53
950. Training for Use of Sealed Sources for Diagnosis G-54
960. Training for Use of Therapeutic Medical Devices G-54
961. Training for Authorized Medical Physicist G-55
980. Training for Authorized Nuclear Pharmacist G-55
981. Training for Experienced Nuclear Pharmacists G-55

Other Medical Uses of Radioactive Material or Radiation From Radioactive Material

1000. Other Medical Uses of Radioactive Material or Radiation From Radioactive Material... G-57

Records

2012. Records of Authority and Responsibilities for Radiation Protection Programs... G-58
2013. Records of Radiation Protection Program Changes... G-58
2015. Records of Written Directives... G-58
2016. Records for Procedures for Administrations Requiring a Written Directive... G-58
2023. Records of Calibrations of Instruments Used to Measure Activity of Unsealed Radioactive Material... G-58
2024. Records of Radiation Survey Instrument Calibrations... G-58
2025. Records of Dosages of Unsealed Radioactive Material for Medical Use... G-58
2027. Records of Leak Tests and Inventory of Sealed Sources and Brachytherapy Sources... G-59
2029. Records of Surveys for Ambient Radiation Exposure Rate... G-59
2030. Records of the Relaese of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Materials... G-59
2031. Records of Mobile Nuclear Medicine Services... G-59
2032. Records of Decay-In-Storage... G-59
2201. Records of Molybdenum-99 Concentrations... G-60
2301. Records of Safety Instruction... G-60
2401. Records of Surveys After Source Implant and Removal... G-60
2402. Records of Brachytherapy Source Accountability... G-60
2405. Records of Calibration Measurements of Brachytherapy Sources... G-60
2406. Records of Decay of Strontium-90 Sources for Ophthalmic Treatments... G-61
2602. Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units Teletherapy Units, and Gamma Stereotactic Radiosurgery Units... G-61
2603. Records of Safety Procedures... G-61
2605. Records of Dosimetry Equipment Used With Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units... G-61
2606. Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations... G-61
2609. Records of Periodic Spot-Checks for Teletherapy Units... G-62
2610. Records of Periodic Spot-Checks for Remote Afterloader Units... G-62
2611. Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units... G-63
2612. Records of Additional Technical Requirements for Mobile remote Afterloader Units... G-63
2613. Records of Surveys of Therapeutic Treatment Units... G-64
2614. Records of 5-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units... G-64

Reports

3001. Report and Notification of a Medical Event... G-65
3002. Report and Notification of a Dose to an Embry / Fetus or a Nursing Child... G-66
3003. Report of a Leaking Source... G-67

PART H - RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT
(August 1, 2001)

1. Purpose and Scope... H-1
2. Definitions... H-1
3. Equipment Requirements... H-2
4. Area Requirements... H-3
5. Operating Requirements... H-4
6. Personnel Requirements... H-4
7. Periodic Inspection... H-5
8. Annual Registration Fees... H-5

PART I - RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS
(December 1, 1990)

1. Purpose and Scope... I-1

License Procedure

2. License Requirements... I-1
3. General Requirements for the Issuance of a License for Particle Accelerators... I-1
4. Human Use of Particle Accelerators... I-2

Radiation Safety Requirements for the Use of Particle Accelerators

5. [Reserved]... I-2
6. Limitations... I-2
7. Shielding and Safety Design Requirements... I-3
8. Particle Accelerator Controls and Interlock Systems... I-3
9. Warning Devices... I-3
10. Operating Procedures... I-4
11. Radiation Monitoring Requirements... I-4
12. Ventilation Systems... I-5

PART J - NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; AND INSPECTIONS
(August 1, 2002)

1. Purpose and Scope... J-1
2. Posting of Notices to Workers... J-1
3. Instructions to Workers... J-1
4. Notification and Reports to Individuals... J-2
5. Presence of Representative of Licensees or Registrants and Workers During Inspections... J-3
6. Consultation with Workers During Inspections... J-3
7. Requests by Workers for Inspections... J-4
8. Inspections Not Warranted; Informal Review... J-4

PART K - RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES (August 1, 2002)

1. Purpose and Scope... K-1
2. Effect of Incorporation of10 CFR Part 39 (effective date May 17, 2000)... K-1

PART L - TRANSPORTATION OF RADIOACTIVE MATERIAL (August 1, 20002)

1. Purpose... L-1
2. Effect of Incorporation of 10 CFR Part 71 (effective date October 1, 2001)... L-1

PART N – REGULATION AND LICENSING OF TECHNOLOGICALLY ENHANCED NATURALLY OCCURRING RADIOACTIVE MATERIALS (TENORM) (August 1, 2002)

1. Purpose... N-1
2. Scope... N-1
3. Definitions... N-1
4. Exemptions... N-2
5. Standards for Radiation Protection for TENORM... N-3
6. Protection of Workers During Operations... N-3
7. Unrestricted Use and Conditional Relaese... N-3
8. Disposal and Transfer of Waste for Disposal... N-4
9. Prohibition... N-4

General License

10. General License... N-4

Specific Licenses

11. Specific Licenses... N-6
12. Filing Application for Specific License... N-6
13. Requirements for issue of Specific Licenses... N-6
14. Safety Criteria for Products... N-8
15. Table of Doses... N-9
16. Issuance of Specific Licenses... N-9
17. Conditions of Specific Licenses Issued Under N.13.... N-10
18. Expiration and Termination of Specific Licenses... N-11
19. Renewal of Specific Licenses... N-13
20. Amendment of Specific Licenses at Request of Licensee... N-13
21. Agency Action on Applications to Renew and Amend Specific Licenses... N-13
22. Modification and Revocation of Specific Licenses... N-13
23. Agency Action to Remove an Authorized User or a Radiation Safety Officer... N-14
24. Record Keeping Requirements for Site Reclamation... N-15
25. Reciprocal Recognition of Specific Licenses... N-15
26. Financial Assuarnce Arrangements... N-16
27. Effective Date... N-16

Appendices

Appendix A Acceptable Surface Contamination Levels for TENORM N-17

PART X – THERAPEUTIC RADIATION MACHINES (August 1, 2001)

1. Scope... X-1
2. Definitions... X-1
3. Administrative Requirements... X-4
4. General Requirements... X-5
5. Quality Management Program... X-7
6. Therapeutic Radiation Machines of Less Than 500kV... X-7
7. Therapeutic Radiation Machines, Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 kV and Above)... X-12
8. Calibration of Survey Instruments... X-21
9. Shielding and Safety Design Requirements... X-22

Appendices

Appendix A Information on Radiation Shielding Required For Plan Reviews... X-23
Appendix B Quality Management Program... X-27
Appendix C Alternative Quality Management Program... X-31

PART A

GENERAL PROVISIONS

1. **Scope.** Except as otherwise specifically provided, these regulations apply to all persons who receive, possess, use, transfer, own or acquire any source of radiation; provided, however that nothing in these regulations shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission.[1]/

2. **Definitions.** As used in these regulations, these terms have the definitions set forth below. Additional definitions used only in a certain part will be found in that part.

Absorbed dose means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the Gray (Gy) and the rad.

Accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV.

Accelerator-produced material means any material made radioactive by a particle accelerator. See Appendix B of Part C.

Act means 22 MRSA c. 160.

Activity means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

Adult means an individual 18 or more years of age.

Agency means Department of Human Services.

Agreement state means any State with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended.

Airborne radioactive material means any radioactive material dispersed in the air in the form of particulates, dusts, fumes, mists, vapors, or gases.

Airborne radioactivity area means a room, enclosure, or area in which airborne radioactive materials exist in concentrations:

(1) In excess of the derived air concentrations (DACs) specified in Appendix B, Table I of Part D of these regulations, or

(2) To such a degree that an individual present in the area without respiratory protective equipment could exceed ,during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

Air-purifying respirator means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

1/ Attention is directed to the fact that regulation by the State of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the State and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

Alert means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

As low as is reasonably achievable (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

Assigned Protection Factor (APF) means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly trained and fitted users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

Atmosphere-supplying respirator means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SAR's) and self-contained breathing apparatus (SCBA) units.

Atomic energy means all forms of energy released in the course of nuclear fission or nuclear transformation.

Background radiation means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include sources of radiation from radioactive materials regulated by the Agency.

Becquerel (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration or transformation per second (dps or tps).

Bioassay means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these regulations, "radio-bioassay" is an equivalent term.

Brachytherapy means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

Byproduct material means (a) any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material, (b) the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

Calendar quarter means not less than 12 consecutive weeks or more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him of determining calendar quarters for purposes of these regulations except at the beginning of a year.

Calibration means the determination of (a) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (b) the strength of a source of radiation relative to a standard.

CFR means Code of Federal Regulations.

Chelating agent means amine polycarboxylic acids, hydroxy-carboxylic acids, gluconic acid, and polycarboxylic acids.

Collective dose means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

Commencement of construction means any clearing of land, excavation, or other substantial action that would adversely affect the natural environment of a site but does not include changes desirable for the temporary use of the land for public recreational uses, necessary borings to determine site characteristics or other pre-construction monitoring to establish background information related to the suitability of a site or to the protection of environmental values.

Committed dose equivalent ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

Committed effective dose equivalent ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \Sigma w_T, H_{T50}$).

Controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee or registrant for any reason

Critical Group means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

Curie means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material, which decays at the rate of 3.7×10^{10} transformations per second (tps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) = 0.0001 curie = 3.7×10^{7} tps. One microcurie (μCi) = 0.000001 curie = 3.7×10^{4} tps.

Deep-dose equivalent (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

Demand respirator means an atmosphere-supplying respirator that admits breathing air to the face piece only when a negative pressure is created inside the face piece by inhalation.

Decommission means to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license.

Depleted uranium means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

Dentist means an individual duly registered and licensed to practice dentistry or dental surgery or any branch thereof under 32 MRSA §1082.

Disposable respirator means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

Distinguishable from background means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

Dose is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these regulations, "radiation dose" is an equivalent term.

Dose equivalent(H_T) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and the rem .

Dose limits means the permissible upper bounds of radiation doses established in accordance with these regulations. For purposes of these regulations, "limits" is an equivalent term.

Effective dose equivalent (H_E) means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma w_T H_T$).

Effective kilogram means (1) for the source material uranium in which the uranium isotope uranium - 235 is greater than 0.005 (0.5 weight percent) of the total uranium present: 10,000 kilograms, and (2) for any other source material: 20,000 kilograms.

Effective kilograms of special nuclear material means: (1) For plutonium and uranium-233 their weight in kilograms; (2) For uranium with an enrichment in the isotope U-235 of 0.01 (1%) and above, its element weight in kilograms multiplied by the square of its enrichment expressed as a decimal weight fraction; and (3) For uranium with an enrichment in the isotope U-235 below 0.01 (1%), by its element weight in kilograms multiplied by 0.0001.

Embryo / fetus means the developing human organism from conception until the time of birth.

Entrance or access point means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

Explosive material means any chemical compound, mixture, or device, which produces a substantial instantaneous release of gas and heat spontaneously or by contact with, sparks or flame.

Exposure means being exposed to ionizing radiation or to radioactive material.

Exposure means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The units of exposure are the coulomb per kilogram (C/kg) and the roentgen (R).

Exposure rate means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

External dose means that portion of the dose equivalent received from any source of radiation outside the body.

Extremity means hand, elbow, and arm below the elbow, foot, knee, and leg below the knee.

Filtering face piece (dust mask) means a negative pressure particulate respirator with a filter as an integral part of the face piece or with the entire face piece composed of the filtering medium.

Fit factor means a quantitative estimate of the fit of a particular respirator to a specific individual and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

Fit Test means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

Formula quantity means strategic special nuclear material in any combination in a quantity of 5000 grams or more computed by the formula, grams=(grams contained U - 235)+2.5 (grams U - 233+grams plutonium). This class of material is sometimes referred to as a Category I quantity of material.

Generally applicable environmental radiation standards means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

Gray means the SI unit of absorbed dose. One gray (Gy) is equal to an absorbed dose of 1 joule per kilogram (100 rad).

Hazardous waste means those wastes designated as hazardous by the U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

Healing arts means any discipline which involves the diagnosis or treatment of individuals by a practitioner who is licensed for that purpose by the State of Maine, and which discipline, prior to the effective date of these regulations, included the intentional exposure of individuals to sources of radiation for diagnosis or treatment

Helmet means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

High radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

Hood means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

Human use means the internal or external administration of radiation or radioactive material to human beings.

Individual means any human being.

Individual monitoring means the assessment of:

(1) Dose equivalent (1) by the use of individual monitoring devices or (2) by the use of survey data; or

(2) Committed effective dose equivalent (1) by bioassay or (2) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. [See the definition of DAC-hours in Part D].

Individual monitoring devices means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these regulations, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, personal air sampling devices, and optically stimulated luminescence (OSL) devices..

Inspection means an official examination or observation including but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements and conditions of the Agency.

Interlock means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

Internal dose means that portion of the dose equivalent received from radioactive material taken into the body.

Lens dose equivalent (LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

License means a license issued by the Agency in accordance with the regulations adopted by the Agency.

Licensed [or registered] material means radioactive material received, possessed, used, transferred or disposed of under a general or specific license [or registration] issued by the Agency.

Licensee means any person who is licensed by the Agency in accordance with these regulations and the Act.

Licensing State means any State with regulations compatible to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

Limits [See "Dose limits"].

Loose-fitting face piece means a respiratory inlet covering that is designed to form a partial seal with the face.

Lost or missing licensed [or registered] source of radiation means licensed [or registered] source of radiation whose location is unknown. This definition includes licensed [or registered] material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

Major processor means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding 4 times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers or small industrial programs. Type A and B quantities are defined in Section 71.4 of 10 CFR Part 71.

Member of the public means an individual in a controlled or unrestricted area. However, an individual is not a member of the public during any period in which the individual receives an occupational dose.

Minor means an individual less than 18 years of age.

Monitoring means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these regulations, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

NARM means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material. See Appendix B of Part C.

Natural radioactivity means radioactivity of naturally occurring nuclides.

Negative pressure respirator (tight fitting) means a respirator in which the air pressure inside the face piece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Nuclear Regulatory Commission (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

Occupational dose means the dose received by an individual in the course of employment in which the individual's duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received: from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Part G, from voluntary participation in medical research programs, or as a member of the public.

Package means the packaging together with its radioactive contents as presented for transport.

Particle accelerator [see "Accelerator"].

Person means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing but not including Federal Government agencies.

Personnel monitoring equipment [See "Individual monitoring devices"]

Pharmacist means an individual licensed by this State to compound and dispense drugs, prescriptions, and poisons.

Physician means an individual duly registered and licensed to practice medicine or surgery or any branch thereof under 32 MRSA §3270.

Podiatrist means an individual duly registered and licensed to practice podiatry or any branch thereof under 32 MRSA §3552.

Positive pressure respirator means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

Powered air-purifying respirator (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

Pressure demand respirator means a positive pressure atmosphere-supplying respirator that admits breathing air to the face piece when the positive pressure is reduced inside the face piece by inhalation.

Principal activities, as used in this part, means activities authorized by the license, which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

Production facility means production facility as defined in the regulations contained in Part C of these regulations.

Public dose means the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released, under Part G , from voluntary participation in medical research programs.

Pyrophoric liquid means any liquid that ignites spontaneously in dry or moist air at or below 130 °F (54.4 °C). A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

Radiation safety officer means one who has the knowledge and responsibility to apply appropriate radiation protection regulations.

Radioactive material means any solid, liquid, or gas, which emits radiation spontaneously.

Qualified Expert means an individual who is either a Radiological Physicist, or an X-ray Survey Technician (see Part F.4.) and has demonstrated to the satisfaction of the Agency that such individual possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and advise regarding radiation protection needs. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy.

Qualitative fit test (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

Quality factor (Q) means the modifying factor, listed in Tables I and II of A.13 that is used to derive dose equivalent from absorbed dose.

Quantitative fit test (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Rad means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 Gy).

Radiation means ionizing radiation, which includes any or all of the following: gamma and x-rays, alpha and beta particles, high speed electrons, neutrons, high speed protons, and other atomic particles.

Radiation Area means an area, accessible to individuals, in which radiation levels could result in an individual receiving 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.

Radiation dose [See "Dose"].

Radiation machine means any device capable of producing radiation except those, which produce radiation only from radioactive material.

Radioactivity means the transformation of unstable atomic nuclei by the emission of radiation.

Radio-bioassay [See "Bioassay"].

Radiological Physicist means an individual who:

(1) is certified by the American Board of Radiology in therapeutic radiological physics, diagnostic radiological physics, or medical nuclear physics; or

(2) has a bachelor's degree in one of the physical sciences or engineering and three years full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology. The work duties must include duties involving the calibration and spot checks of a medical accelerator or sealed source teletherapy unit; or

(3) has a Master's degree or Doctorate in physics, biophysics, radiological physics, health physics, or engineering; has had 1 year's full-time training in therapeutic radiological physics; and has had 1 year's full-time work experience in a radiotherapy facility where the individual's duties involve calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.

Registrant means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to these regulations and the Act.

Registration means registration with the Agency in accordance with the regulations adopted by the Agency.

Regulations of the U.S. Department of Transportation means the regulations in 49 CFR Parts 100-189.

REM means a special unit of dose equivalent. One millirem (mrem) = 0.001 rem. For the purpose of these regulations, any of the following is considered to be equivalent to a dose of one rem:

(1) An exposure of 1 roentgen of x or gamma radiation.

(2) An absorbed dose of 1 rad due to x, gamma, or beta radiation.

(3) An absorbed dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye.

(4) An absorbed dose of 0.1 rad due to neutrons or high energy protons; or 2.5×10^7 neutrons/square centimeter incident upon the body; or estimating the energy distribution of the neutron flux with reasonable accuracy as indicated in table 2 of A.13.A(5).

Research and development means (a) theoretical analysis, exploration, or experimentation; or (b) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

Residual radioactivity means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes all radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive materials at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Part D.

Restricted area means any area access to which is controlled by the licensee or registrant for purposes of protection of individuals from exposure to radiation and radioactive material. A restricted area shall not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

Roentgen means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs/kilogram of air. (See "Exposure").

Sealed source means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

Self-contained breathing apparatus (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Shallow dose equivalent (H_S), which applies to the external exposure of the skin of the whole body or the skin of an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

SI means the abbreviation for the International System of Units.

Sievert means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert (Sv) is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

Site area emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

Site boundary means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

Source material means

(1) uranium or thorium, or any combination thereof, in any physical or chemical form; or

(2) ores, which contain by weight one-twentieth of one percent (0.05 percent) or more of

a. uranium,

b. thorium, or

c. any combination thereof.

Source material does not include special nuclear material.

Source material milling means any activity that results in the production of byproduct material as defined by definition of byproduct material.

Source of radiation means any radioactive material or any device or equipment emitting, or capable of producing radiation.

Special form means radioactive material, which satisfies the following conditions:

(1) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(2) The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and

(3) It satisfies the test requirements specified by the U.S. NRC. A special form encapsulation designed in accordance with the NRC requirements in effect on June 30, 1983, and constructed prior to July 1, 1985 may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985 must meet requirements of this definition applicable at the time of its design or construction.

Special nuclear material means:

(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Agency declares by order to be special nuclear material after [2] the U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

(2) Any material artificially enriched by any of the foregoing but does not include source material.

2/ This wording is provided for states that cannot automatically adopt changes made by the Nuclear Regulatory Commission.

Special nuclear material in quantities not sufficient to form a critical mass means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175(\text{grams containing U-235})}{350} + \frac{50(\text{gms U-233})}{200} + \frac{50(\text{gms Pu})}{200} = 1$$

Supplied-air respirator (SAR) or airline respirator" means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

Survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, and/or presence of radiological material or other sources of radiation. When appropriate, such an evaluation includes, but is not limited to, a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentration or quantities of radioactive material present.

Test means the process of verifying compliance with applicable regulation.

These regulations means all parts of Maine Rules Relating to Radiation Protection 10-144A CMR 220.

Tight-fitting face piece means a respiratory inlet covering that forms a complete seal with the face.

Total effective dose equivalent (TEDE) means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

Total organ dose equivalent (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in D.46.A(6) of these regulations.

U.S. Department of Energy means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 U.S.C. 5814, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977.)

Unrefined and unprocessed ore means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

Unrestricted area means any area access to, which is neither limited nor controlled by the licensee or registrant. For purposes of these regulations, "uncontrolled area" is an equivalent term.

User seal check (fit check) means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

Waste means those low-level radioactive wastes that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, as amended by P.L. 99-240, effective January 15, 1986; that is, radioactive waste (a) not classified as high-level radioactive waste, spent nuclear fuel, or byproduct material as defined in Section 11e.(2) of the Atomic Energy Act (uranium or thorium tailings and waste) and (b) classified as low-level radioactive waste consistent with existing law and in accordance with (a) by the U.S. Nuclear Regulatory Commission.

Waste handling licensees means persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

Week means 7 consecutive days starting on Sunday.

Whole body means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

Worker means an individual engaged in work under a license or registration issued by the Agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

Working level (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3E+5 MeV of potential alpha particle energy. The short-lived radon daughters are for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

Working level month (WLM) means an exposure to 1 working level for 170 hours. 2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

Year means the period of time beginning in January used to determine compliance with the provisions of these regulations. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

3. Exemptions.

A. General Provision. The Agency may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of these regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

B. U.S Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this State is exempt from these regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

(1) prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(2) prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;

(3) prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and

(4) any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the State and the Nuclear Regulatory Commission jointly determine:

a. that the exemption of the prime contractor or subcontractor is authorized by law; and

b. that under the terms of the contract or subcontract, there is adequate assurance that the work there under can be accomplished without undue risk to the public health and safety.

4. **Records.** Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these regulations.

5. **Inspections.**

A. Each licensee and registrant shall afford the Agency at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

B. Each licensee and registrant shall make available to the Agency for inspection, upon reasonable notice, records maintained pursuant to these regulations.

C. Inspection frequencies are indicated in Appendix A to Part C, and Part F.3.C for radiation material and x-ray machines respectively.

6. **Tests.** Each licensee and registrant shall perform upon instructions from the Agency, or shall permit the Agency to perform, such reasonable tests as the Agency deems appropriate or necessary including, but not limited to, tests of:

A. source of radiation;

B. facilities wherein sources of radiation are used or stored;

C. radiation detection and monitoring instruments; and

D. other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

7. **Additional Requirements.** The Agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

8. **Violations.** An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

9. **Impounding.** Sources of radiation shall be subject to impounding pursuant to Section 688 (2) of the Act.

10. **Prohibited Uses.**

A. Hand-held fluoroscopic screens shall not be used.

B. Shoe-fitting fluoroscopic devices shall not be used.

11. **Interpretations.** Except as specifically authorized by the Agency in writing, no interpretation of these regulations by an officer or employee of the Agency other than a written interpretation by the legal counsel will be recognized to be binding upon the Agency.

12. **Communications.** All communications and reports concerning these regulations, and applications filed thereunder, should be addressed to the Radiation Control Program, State House Station 11, 161 Capitol Street, Augusta, Maine 04333-0011.

13. **The International System of Units (SI).** The Metric Conversion Act of 1975 (PL 94-168) urged the increasing awareness and use of the International System of Units (SI). The generally accepted regulatory values in the narrative portions of this document are followed by the SI equivalents in parentheses. Where appropriate, schedules and appendices are provided with notes concerning conversion factors. The inclusion of the SI equivalent is for informational purposes only unless otherwise specified.

A. Units of Exposure and Dose

(1) ABSORBED DOSE. The unit of absorbed dose is the gray (Gy) which is equal to 1 joule per kilogram. One rad is equal to 1×10^{-2} gray. Sub-multiples included in this document are the milligray (mGy) and the microgray (μGy).

(2) DOSE EQUIVALENT. The unit of dose equivalent is the sievert (Sv) which is equal to 1 joule per kilogram. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor. One REM is equal to 1×10^{-2} sievert. Submultiples included in this document are the millisievert (mSv) and the microsievert (μSv).

(3) EXPOSURE. The unit of exposure is the coulomb per kilogram (C/kg). One roentgen is equal to 2.58×10^{-4} coulomb per kilogram of air. Submultiples of this unit are the millicoulomb per kilogram (mC/kg) and the microcoulomb per kilogram (μC/kg).

(4) QUALITY FACTORS. As used in these regulations, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

TABLE I

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent[a]
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

[a]Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

(5) If it is more convenient to measure the neutron influence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in A.13.A(4), 0.01 Sv (1 rem) of neutron radiation of unknown energies may, for purposes of these regulations, be assumed to result from a total influence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE II

MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy (MeV)	Quality Factor[a] (Q)	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} rem^{-1})	Fluence/Unit Dose Equiv.[b] (neutrons cm^{-2} Sv^{-1})
(thermal)	2.5E-8	2	980E+6	980E+8
	1E-7	2	980E+6	980E+8
	1E-6	2	810E+6	810E+8
	1E-5	2	810E+6	810E+8
	1E-4	2	840E+6	840E+8
	1E-3	2	980E+6	980E+8
	1E-2	2.5	1010E+6	1010E+8
	1E-1	7.5	170E+6	170E+8
	5E-1	11	39E+6	39E+8
	1	11	27E+6	27E+8
	2.5	9	29E+6	29E+8
	5	8	23E+6	23E+8
	7	7	24E+6	24E+8
	10	6.5	24E+6	24E+8
	14	7.5	17E+6	17E+8
	20	8	16E+6	16E+8
	40	7	14E+6	14E+8
	60	5.5	16E+6	16E+8
	1E+2	4	20E+6	20E+8
	2E+2	3.5	19E+6	19E+8
	3E+2	3.5	16E+6	16E+8
	4E+2	3.5	14E+6	14E+8

[a]Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.
[b]Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

B. Units of Activity. For purposes of these regulations, activity is expressed in the SI unit of becquerel (Bq) or in the special unit of curie (Ci), or their multiples, or disintegrations or transformations per unit of time.

(1) The unit of measurement of radioactivity is the becquerel (Bq) and it is equal to one transformation per second.

(2) One curie is equal to 3.7×10^{10} disintegrations or transformations per second (dps or tps)= 3.7E+10 becquerel (Bq) = 2.22E+12 disintegrations or transformations per minute (dpm or tpm). Multiples included in this document are kilobecquerel (kBq), megabecquerel (MBq), gigabecqueral (GBq), and petabecquerel (PBq).

PART B

ENFORCEMENT ACTIONS, PROCEDURES, AND CIVIL PENALTIES

1. Purpose and Scope.

A. The following statement of general policy and procedure explains the enforcement policy and procedures of the State of Maine Radiation Control Program in initiating enforcement actions. This statement is applicable to enforcement in matters involving the public health and safety, and the environment.

B. The purpose of the enforcement program is to promote and protect the radiological health and safety of the public, including employees' health and safety, and the environment by:

(1) Ensuring compliance with regulations and license conditions;

(2) Obtaining prompt correction of violations and adverse quality conditions which may affect safety;

(3) Deterring future violations and occurrences of conditions adverse to quality; and

(4) Encouraging improvement of licensee and vendor[1]/ performance, and by example, and that of industry, including the prompt identification and reporting of potential safety problems.

C. Consistent with the purpose of this program, prompt and vigorous enforcement action will be taken when dealing with licensees or vendors who do not achieve the necessary meticulous attention to detail and the high standard of compliance which the Agency expects. It is the state's intent that sanctions should be designed to ensure that a licensee or vendor does not deliberately profit from violations of these requirements. Each enforcement action is dependent on the circumstances of the case and requires the exercise of discretion after consideration of these policies and procedures. In no case, however will licensees who cannot achieve and maintain adequate levels of protection be permitted to conduct licensed activities.

2. Severity of Violations.

A. Regulatory requirements have varying degrees of safety or environmental significance. Therefore, the relative importance of each violation must be identified as the first step in the enforcement process.

B. Consequently, violations are categorized in terms of five levels of severity to show their relative importance within each of the following five activity areas:

I. Health Physics;
II. Transportation;
III. Materials Operations
IV. Miscellaneous Matters; and
V. Emergency Preparedness.

1/ The term "vendor" means a supplier of products or services to be used by a licensee or registrant in a licensed or registered facility or activity.

C. Within each activity area, Severity Level I has been assigned to violations that are the most significant and Severity Level V violations are the least significant. Severity Level I and II violations are of very significant regulatory concern. In general, violations that are included in these categories involve actual or high potential impact on the public. Severity Level III violations are cause for significant concern. Severity Level IV violations are less serious but are of more than minor concern; i.e. if left uncorrected, they could lead to a more serious concern. Severity Level V violations are of minor safety or environmental concern.

D. Comparisons of significance between activity areas are inappropriate. For example, the immediacy of any hazard to the public associated with Severity Level I violations in Health Physics is not directly comparable to that associated with Severity Level I violations in Emergency Preparedness.

E. While examples are provided in Appendix 1 for determining the appropriate severity level for violations in each of the five activity areas, the examples are neither exhaustive nor controlling. These examples do not create new requirements. Each is designed to illustrate the significance which the Radiation Control Program places on a particular type of violation of state requirements. Each of the examples is predicated on a violation of regulatory requirement.

F. In each case, the severity of a violation will be characterized at the level best suited to the significance of the particular violation. In some cases, violations may be evaluated in the aggregate and a single severity level assigned for a group of violations.

G. The severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception, or other indication of willfulness. The term "willfulness" as used here embraces a spectrum of violations ranging from deliberate intent to violate or falsify to and including careless disregard for requirements. Willfulness does not include acts which do not rise to the level of careless disregard, e.g. inadvertent clerical errors in a document submitted to the Radiation Control Program. In determining the specific severity level of a violation involving willfulness, consideration will be given to such factors as the position of the person involved in the violation (e.g., first-line supervisor or senior manager), the significance or any underlying violation, the intent of the violator (i.e. negligence not amounting to careless disregard, careless disregard, or deliberateness), and the economic advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation.

H. The Radiation Control Program expects licensees to provide full, complete, timely, and accurate information and reports. Accordingly, unless otherwise categorized in Appendix 1, the severity level of a violation involving the failure to make a required report to the Agency will be based upon the significance of and the circumstances surrounding the matter that should have been reported. A licensee will not normally be cited for a failure to report a condition or event unless the licensee was actually aware of the condition or event, which it failed to report. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter.

3. Enforcement Conferences.

A. Whenever the Agency has learned of the existence of a potential violation for which a civil penalty or other escalated enforcement action may be warranted, or recurring nonconformance on the part of a vendor, the Agency will normally hold an enforcement conference with the licensee or vendor prior to taking enforcement action. The Agency may also elect to hold an enforcement conference for other violations, e.g. Severity Level IV violation, which, if repeated, could lead to escalated enforcement action. The purpose of the enforcement conference is to

(1) Discuss the violations or nonconformance, their significance and causes, and the licensee's or vendor's corrective actions,

(2) determine whether there are any aggravating or mitigating circumstances, and

(3) obtain other information which will help determine the appropriate enforcement action.

B. In addition, during the enforcement conference, the licensee or vendor will be given an opportunity to explain to the Agency what corrective actions (if any) were taken or will be taken following discovery of the potential violation or nonconformance. Licensees or vendors will be told when a meeting is an enforcement conference.

C. When needed to protect the public health and safety, escalated enforcement action, such as the issuance of an immediately effective order modifying, suspending, or revoking a license, will be taken prior to the enforcement conference. In such cases, an enforcement conference may be held after the escalated enforcement action is taken.

4. Enforcement Actions.

A. This Part describes the enforcement sanctions available to the Agency and specifies the conditions under which each may be used. The basic sanctions are notices of violation, civil penalties, and orders of various types. Additionally, related administrative mechanisms such as bulletins and confirmatory action letters, notices of nonconformance and notices of deviation are used to supplement the enforcement program.

B. In selecting the enforcement sanctions to be applied, the Agency will consider enforcement actions taken by other State regulatory bodies having concurrent jurisdiction, such as in environmental or transportation matters. With very limited exceptions, whenever a violation of Agency requirements is identified, enforcement action is taken. The nature and extent of the enforcement action is intended to reflect the seriousness of the violation involved.

C. For the vast majority of violations, action by the Agency is appropriate in the form of a Notice of Violation requiring a formal response from the recipients describing its corrective actions.

D. In situations involving nonconformance on the part of a vendor, a Notice of Nonconformance will be issued.

E. Relatively small number of cases involve elevated enforcement actions. These elevated enforcement actions include civil penalties orders modifying, suspending or revoking licenses; or orders to cease and desist from designated activities.

5. Notice of Violation.

A. Before instituting any proceeding to modify, suspend, or revoke a license or to take other action for alleged violation of any provision of the Radiation Protection Act or these rules or the conditions of the license, the Agency will serve on the licensee or other person subject to the jurisdiction of the Agency a written notice of violation, except as provided in paragraph (3) of this section. The notice of violation will concisely state the alleged violation and will require that the licensee or any other person submit, within twenty (20) working days of the date of the notice or other specified time, a written explanation or statement in reply including:

(1) corrective steps which have been taken by the licensee or other person and the results achieved;

(2) corrective steps which will be taken; and

(3) the date when full compliance will be achieved.

B. Because the State wants to encourage and support licensee initiative for self-identification and correction of problems, the Radiation Control Program will not generally issue a notice of violation for a violation that meets all of the following tests:

(1) It was identified by the licensee;

(2) It fits in Severity Level IV or V;

(3) It was reported; if required;

(4) It was or will be corrected, including measures to prevent recurrence, within a reasonable time; and

(5) It was not a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation.

C. Licensees are not ordinarily cited for violations resulting from matters not within their control, such as equipment failures that were not avoidable by reasonable licensee quality assurance measures or management controls. Generally, however, licensees are held responsible for the acts of their employees. Accordingly, this policy should not be construed to excuse personnel errors. Enforcement actions involving individuals, including licensed operators, will be determined on a case-by-case basis, and must be approved by the Director of the Division of Health Engineering, Department of Human Services.

D. The notice may require the licensee or other person subject to the jurisdiction of the Agency to admit or deny the violation and to state the reasons for the violation, if admitted. It may provide that, if any adequate reply is not received within the time specified in the notice, the Agency may issue an order to show cause why the license should not be modified, suspended or revoked or why such other action as may be proper should not be taken.

E. When the Agency finds that the public health, safety, or interest so requires, or that the violation is willful, the notice of violation may be omitted and an order to show cause issued.

6. Civil Penalties

A. A civil penalty is a monetary penalty that may be imposed for violation of

(1) certain specified licensing provisions of the Radiation Protection Act or these rules, or orders, or

(2) any requirement for which a license may be revoked. Civil penalties are designed to emphasize the need for lasting remedial action and to deter future violations.

B. Before instituting any proceeding to impose a civil penalty authorized under 22 MRSA section 690 of the Radiation Protection Act, the Agency shall serve a written notice of violation upon the person charged. This notice may be included in a notice issued pursuant to Part B.5. The notice of violation shall specify the date or dates, facts, and the nature of the alleged act or omission with which the person is charged, and shall identify specifically the particular provision or provisions of the law, rule, regulation, license, permit, or cease and desist order involved in the alleged violation and shall state the amount of each penalty which the Agency proposes to impose. The notice of violation shall also advise the person charged that the civil penalty may be paid in the amount specified therein, or the proposed imposition of the civil penalty may be protested in its entirety or in part, by a written answer, either denying the violation, or showing extenuating circumstances. The notice of violation shall advise the person charged that upon failure to pay a civil penalty subsequently determined by the Agency, if any, the penalty may, unless compromised, remitted or mitigated, be collected by civil action pursuant to the Act.

C. Generally, civil penalties are imposed for Severity Level I violations and if mitigating circumstances are absent, for Severity Level II violations. Civil penalties are considered for Severity Level III violations, and may be imposed for Severity Level IV violations that are similar to previous violations for which the licensee did not take effective corrective action.

D. In applying this guidance for Severity Level IV violations, the Agency normally considers civil penalties only for similar Severity Level IV violations that occur after the date of the last inspection or within two years, whichever period is greater.

E. Civil penalties will normally be assessed for known and conscious violations of the reporting requirements of these rules and for any willful violation of any Agency requirement including those at any severity level.

F. Within twenty (20) working days of the date of a notice of violation or other time specified in the notice, the person charged may either pay the penalty in the amount proposed or answer the notice of violation. The answer to the notice of violation shall state any facts, explanations, and arguments, denying the charges of violation, or demonstrating any extenuating circumstances, error in the notice of violation, or other reason why the penalty should not be imposed and may request remission or mitigation of the penalty.

G. If the person charged with the violation fails to answer within the time specified in paragraph (F) of this Part, the Agency will issue an order imposing the civil penalty in the amount set forth in the notice of violation described in paragraph (B) of this Part

H. If the person charged with violation files an answer to the notice of violations, the Agency, upon consideration of the answer, will issue an order dismissing the proceeding or imposing, mitigating, or remitting the civil penalty. The person charged may, within twenty (20) working days of the date of the order or other time specified in the order, request a hearing.

I. If the person charged with violation requests a hearing, the Agency will issue an order designating the time and place of hearing.

J. If a hearing is held, an order will be issued after the hearing by the Agency dismissing the proceeding or imposing, mitigating, or remitting the civil penalty.

K. If the civil penalty is not compromised, or is not remitted and if payment is not made within ten (10) working days following either the service of the order described in paragraph (G) or (J) of this section, or the expiration of the time for requesting a hearing described in paragraph (H) of this section, no such request having been made, the Agency may refer the matter to the Attorney General for collection.

L. The Agency may impose different levels of penalties for different severity level violations and different classes of licensees. Tables 1A and 1B show the base civil penalties for various areas. The structure of these tables generally takes into account the gravity of the violation as a primary consideration and the ability to pay as a secondary consideration. Generally, operations involving greater potential consequences to the public and licensee employees will receive higher civil penalties.

M. Regarding the secondary factor of ability of various classes of licensees to pay the civil penalties, it is not the State's intention that the economic impact of a civil penalty be such that it puts a licensee out of business (orders, rather than civil penalties, are used when the intent is to terminate licensed activities) or adversely affects a licensee's ability to safely conduct licensed activities. The deterrent effect of civil penalties is best served when the amounts of such penalties take into account a licensee's "ability to pay." In determining the amounts of civil penalties for licensees for whom the tables do not reflect the ability to pay, the State will consider as necessary an increase or decrease on a case-by-case basis.

N. The Agency attaches great importance to the comprehensive licensee programs for detection, correction, and reporting of problems that may constitute, or lead to, violation of regulatory requirements. This is emphasized by giving credit for effective licensee audit programs when licensees find, correct and report problems expeditiously and effectively. To encourage licensee self-identification and correction of violations and to avoid potential concealment of problems of safety significance, application of the adjustment factors set forth below may result in no civil penalty being assessed for violations which are identified, reported (if required), and effectively corrected by the licensee.

O. On the other hand, ineffective licensee programs for problem identification or correction are unacceptable. In cases involving willfulness, flagrant NRC-identified violations, repeated poor performance in an area of concern, or serious breakdown in management controls, the Agency intends to apply its full enforcement authority where such action is warranted, including issuing appropriate orders and assessing civil penalties for continuing violations on a per day basis, up to statutory limit. In this regard, while management involvement, direct or indirect, in a violation may lead to an increase in the civil penalty, the lack of such involvement may not be used to mitigate a civil penalty.

P. Allowance of mitigation could encourage lack of management involvement in licensed activities and a decrease in protection of the public health and safety.

Q. The State reviews each proposed civil penalty case on its own merits and adjusts the base civil penalty values upward or downward appropriately. Tables 1A and 1B identify the base civil penalty values for different severity levels, activity areas, and classes of licensees.

R. Payment of civil penalties imposed under 22 MRSA section 690 of the Act shall be made by check, draft, or money order payable to the Treasurer of State of Maine, and mailed to: Radiation Control Program, State House Station #11, Augusta, Maine 04333-0011.

7. Adjustment Factors.

A. After considering all relevant circumstances, adjustments to the civil penalty values may be made for the factors described below:

(1) Prompt Identification and Reporting. Reduction of up to 50 percent of the base civil penalty may be given when a licensee identifies the violation and promptly reports the violation to the Agency. In weighing this factor, consideration will be given to, among other things, the length of time the violation existed prior to discovery, the opportunity available to discover the violation, the ease of discovery and the promptness and completeness of any required report. No consideration will be given to this factor if the licensee does not take immediate action to correct the problem upon discovery.

(2) Corrective Action to Prevent Recurrence. Recognizing that corrective action is always required to meet regulatory requirements, the promptness and extent to which the licensee takes corrective action, including actions to prevent recurrence, may be considered in modifying the civil penalty to be assessed. Unusually prompt and extensive correction action may result in reducing the proposed civil penalty as much as 50 percent of the base value shown in Table 1A. On the other hand, the civil penalty may be increased as much as 50 percent of the base value if initiation of corrective action is not prompt or if the corrective action is only minimally acceptable. In weighing this factor, consideration will be given to, among other things, the timeliness of the corrective action, degree of licensee initiative, and comprehensiveness of the corrective action - such as whether the action is focused narrowly to the specific violation or broadly to the general area of concern.

(3) Past Performance. Reduction by as much as 100 percent of the base civil penalty shown in Table 1 may be given for prior good performance in the general area of concern. On the other hand, the base civil penalty may be increased as much as 100 percent for prior poor performance in the general area of concern. In weighing this factor, consideration will be given to, among other things, the effectiveness of previous corrective action for similar problems, overall performance such as prior enforcement history including Severity Level IV and V violations in the area of concern. For example, failure to implement previous corrective action for prior similar problems may result in an increase in the civil penalty.

(4) Prior Notice of Similar Events. The base civil penalty may be increased as much as 50 percent for cases where the licensee had prior knowledge of a problem as a result of a licensee audit, or specific NRC or industry notification, and had failed to take effective preventive steps.

(5) Multiple Occurrences. The base civil penalty may be increased as much as 50 percent where multiple examples of a particular violation are identified during the inspection period.

B. The above factors are additive. However, in no instance will a civil penalty for any one violation exceed $10,000 per day.

C. The duration of a violation may also be considered in assessing a civil penalty. A greater civil penalty may be imposed if a violation continues for more than a day. For example:

(1) If a licensee is aware of the existence of a condition which results in an ongoing violation and fails to initiate corrective action, each day the condition existed may be considered as a separate violation and, as such, subject to a separate additional civil penalty.

(2) If a licensee is unaware of a condition resulting in a continuing violation, but clearly should have been aware of the condition or had an opportunity to correct the condition but failed to do so, a separate violation and attendant civil penalty may be considered for each day that the licensee clearly should have been aware of the condition or had an opportunity to correct the condition, but failed to do so.

(3) Alternatively, whether or not a licensee is aware or should have been aware of a violation that continues for more than one day, the civil penalty imposed for one violation may be increased to reflect the added significance resulting from the duration of the violation.

D. The Tables and the mitigating factors determine the civil penalties which may be assessed for each violation. However, to focus on the fundamental underlying causes of a problem for which enforcement action appears to be warranted, the cumulative total for all violations which contributed to or were unavoidable consequences of that problem may be based on the amount shown in the table for a problem of that Severity Level, as adjusted. If an evaluation of such multiple violations shows that more than one fundamental problem is involved, each of which, if viewed independently, could lead to civil penalty action by itself, then separate civil penalties may be assessed for each such fundamental problem. In addition, the failure to make a required report of an event requiring such reporting is considered a separate problem and will normally be assessed a separate civil penalty, if the licensee is aware of the matter that should have been reported.

8. Orders.

A. An order is a written Agency directive to modify, suspend, or revoke a license to cease and desist from a given practice or activity or to take such other action as may be proper. Orders may be issued as set forth below. Orders may also be issued in lieu of, or in addition to, civil penalties as appropriate.

(1) License Modification Orders are issued when some change in licensee equipment, procedures, or management controls is necessary.

a. The Agency may modify a license by issuing an amendment on notice to the licensee that the licensee may demand a hearing with respect to all or any part of the amendment within twenty (20) working days from the date of the notice or such longer period as the notice may provide.

b. The amendment will become effective on the expiration of the 20-day period during which the licensee may demand a hearing. If the licensee requests a hearing during this 20-day period, the amendment will become effective on the date specified in an order made following the hearing.

(2) Suspension Orders may be used:

a. To remove a threat to the public health and safety or the environment;

b. To stop facility construction when: (a) further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related system or component, to include shielding, or (b) the licensee's quality assurance program implementation is not adequate to provide confidence that construction activities are being properly carried out;

c. When the licensee has not responded adequately to other enforcement action;

d. When the licensee interferes with the conduct of an inspection or investigation; or

e. For any reason not mentioned above for which license revocation is legally authorized.

Suspensions may apply to all or part of the licensed activity. Ordinarily, a licensed activity is not suspended (nor is a suspension prolonged) for failure to comply with requirements where such failure is not willful and adequate corrective action has been taken.

(3) Revocation Orders may be used:

a. When a licensee is unable or unwilling to comply with Maine requirements;

b. When a licensee refuses to correct a violation;

c. When a licensee does not respond to a notice of violation where a response was required;

d. When a licensee refuses to pay as stated in Appendix 1 to Part C.

e. For any other reason for which revocation is authorized under Section 677 of the Radiation Protection Act (e.g., any condition which would warrant refusal of a license on an original application).

(4) Cease and Desist Orders are typically used to stop an unauthorized activity that has continued after notification by the Agency that such Activity is unauthorized.

(5) Show Cause Orders.

a. The Agency may institute a proceeding to modify, suspend, or revoke a license or for such other action as may be proper by serving on the licensee an order to show cause which will:

(i) allege the violations with which the licensee is charged, or the potentially hazardous conditions or other facts deemed to be sufficient ground for the proposed action;

(ii) provide that the licensee may file a written answer to the order under oath or affirmation within twenty (20) working days of its date, or such other time as may be specified in the order;

(iii) inform the licensee of his right, within twenty (20) working days of that date of the order, or such other time as may be specified in the order, to demand a hearing;

(iv) specify the issues; and

(v) state the effective date of the order.

b. A licensee may respond to an order to show cause; by filing a written answer under oath or affirmation. The answer shall specifically admit or deny each allegation or charge made in the order to show cause;, and may set forth the matters of fact and law on which the licensee relies. The answer may demand a hearing.

c. If the answer demands a hearing, the Agency will issue an order designating the time and place of hearing.

d. An answer or stipulation may consent to the entry of an order in substantially the form proposed in the order to show cause;

e. The consent of the licensee to the entry of an order shall constitute a waiver by the licensee of a hearing, findings of fact and conclusions of law, and of all right to seek Agency and judicial review or to contest the validity of the order in any forum. The order shall have the same force and effect as an order made after hearing by the Agency.

B. Orders are made effective immediately, without prior opportunity for hearing whenever it is determined that the public health, interest, or safety so requires, or when the order is responding to a violation involving willfulness. Otherwise, a prior opportunity for a hearing on the order is afforded. For cases in which the Agency believes a basis could reasonably exist for not taking the action as proposed, the licensee will ordinarily be afforded an opportunity to show cause why the order should not be issued in the proposed manner.

9. Escalation of Enforcement Sanctions

A. The Agency considers violations of Severity Levels I, II, or III to be serious. If serious violations occur, the Agency will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. The Agency carefully considers the circumstances of each case in selecting and applying the sanction(s) appropriate to the case in accordance with the criteria described in sections 5, 6, 7, and 8 of this Part.

B. Examples of enforcement actions that could be taken for similar Severity Level I, II or III violations are set forth in Table 2. The actual progression to be used in a particular case will depend on the circumstances. However, enforcement sanctions will normally escalate for recurring similar violations.

C. Normally, the progression of enforcement actions for similar violations will be based on violations under a single license. When more than one facility is covered by a single license, the normal progression will be based on similar violations at an individual facility and not on similar violations under the same license. However, it should be noted that under some circumstances, e.g., where there is common control over some facet of facility operations, similar violations may be charged even though the second violation occurred at a different facility or under a different license. For example, a health physics violation at division 1 of a dual unit hospital that repeats an earlier violation of division 2 might be considered similar.

TABLE 1A - BASE CIVIL PENALTIES

	Health Physics, Operations, EP, and Miscellaneous	Transportation	
		Greater Than Type A Quantity[1]	Type A Quantity or less[2]
a. Industrial users of material[3]	10,000	5,000	2,000
b. Waste disposal licensees	10,000	5,000	2,000
c. Academic or medical institutions[4]	5,000	2,500	1,000
d. Other material licenses	2,000	2,500	1,000
e. X-ray facilities	1,000		

1 Includes quantities requiring Type B packaging.
2 Includes low specific activity waste, low level waste, Type A packages and excepted quantities and articles.
3 Includes industrial radiographers, nuclear pharmacies, and other industrial users.
4 This applies to nonprofit institutions not otherwise categorized under section "a" through "e" in this table.

TABLE 1B - BASE CIVIL PENALTIES

Severity Level	Base Civil Penalty Amount[1]
I	100
II	80
III	50
IV	15
V	5

1 Percent of amount listed in table 1A.

TABLE 2 - EXAMPLES OF PROGRESSIONS OF ESCALATED ENFORCEMENT ACTIONS FOR SIMILAR VIOLATIONS IN THE SAME ACTIVITY AREA UNDER THE SAME LICENSE

Severity of Violation	Number of similar violations from the date of the last inspection or within the previous 2 years (whichever period is greater)		
	1st	2nd	3rd
I	a+b	a+b+c	d
II	a	a+b	a+b+c
III	—	a	a+b

a. Civil penalty.
b. Suspension of affected operations until the Radiation Control Program Manager is satisfied that there is reasonable assurance that the licensee can operate in compliance with the applicable requirements or modification of the license, as appropriate.
c. Show cause for modification or revocation of the license, as appropriate.
d. further action, as appropriate.

10. **Related Administrative Actions.** In addition to the formal enforcement mechanisms of notices of violation, civil penalties, and orders, the Agency also uses administrative mechanisms, such as bulletins, circulars, information notices, generic letters, notices of deviation, notices of nonconformance and confirmatory action letters to supplement its enforcement program. The Agency expects licensees and vendors to adhere to any obligations and commitments resulting from these processes and will not hesitate to issue appropriate orders to licensees to make sure that such commitments are met.

    A. Bulletins, Circulars, Information Notices and Generic Letters are written notifications to groups of licensees identifying specific problems and recommending specific actions.

    B. Notices of Deviation are written notices describing a licensee's failure to satisfy a commitment where the commitment involved has not been made a legally binding requirement. A notice of deviation requests a licensee to provide a written explanation or statement describing corrective steps taken (or planned), the result achieved, and the date when corrective action will be completed.

    C. Confirmatory Action Letters are letters confirming a licensee's or vendor's agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.

    D. Notices of Nonconformance are written notices describing non-licensees' failure to meet commitments which have not been made legally binding requirements by the Agency. Notices of Non-conformances request non-licensees to provide written explanation or statements describing corrective steps (taken or planned), the results achieved, the dates when corrective actions will be completed, and measures taken to preclude recurrence.

11. **Referrals to Department of the Attorney General.** Alleged or suspected criminal violations of the Radiation Protection Act (and of other relevant state laws) are referred to the Department of the Attorney General for investigation. Referral to the Attorney General does not preclude the Agency from taking other enforcement action. However, such actions will be coordinated with the Department of the Attorney General to the extent practicable.

12. **Public Disclosure of Enforcement Actions.** In accordance with the Administrative Procedures Act, all enforcement actions and licensees' responses are publicly available for inspection. In addition, press releases are generally issued for civil penalties and orders. In the case of orders and civil penalties related to violations at Severity Level I, II, or III, press releases are issued at the time of the order or the proposed imposition of the civil penalty. Press releases are not normally issued for Notices of Violation.

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APPENDIX 1

SEVERITY CATEGORIES

The following examples of severity levels are neither exhaustive nor controlling. They reflect only the seriousness of the violation and not the intent of the violator, the history of the violator, the amount necessary to deter future violations, or efforts to correct the violation.

1. Severity Level I - Most Significant Violations.

A. Health Physics.

1. Single exposure of a worker in excess of 25 rems of radiation to the whole body, 150 rems to the skin of the whole body, or 375 rems to the feet, ankles, hands, or forearms;

2. Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;

3. Release of radioactive material to an unrestricted area in excess of ten times the limits of section D.15;

4. Disposal of licensed material in quantities or concentrations in excess of ten times the limits of section D.33;

5. Exposure of a worker in restricted areas of ten times the limits of section D.6.;

B. Transportation.

1. Annual whole body radiation exposure of a member of the public in excess of 0.5 rems of radiation; or

2. Breach of package integrity resulting in surface contamination or external radiation levels in excess of ten times the Agency limits.

C. Materials Operations.

1. Radiation levels, contamination levels, or releases that exceed ten times the limits specified in the license;

2. A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function.

D. Miscellaneous Matters.

1. A Material False Statement (MFS)[2]/ in which the statement made was deliberately false;

2. Falsification of records which the Agency requires be kept of significant information in which the records were deliberately falsified by or with the knowledge of management; or

3. A knowing and intentional failure to provide the notice required by these rules.

2./ In essence, a Material False Statement is a statement that is false by omission or commission and is relevant to the regulatory process. As can be seen in the examples, in determining the specific level of a violation involving material false statements or falsification of records, consideration will be given to such factors as the position of the person involved in the violation (e.g., first line supervisor or senior manager), the significance of the information involved, and the intent of the violator (i.e., negligence not amounting to careless disregard, careless disregard, or deliberateness0. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation.

4. Possession of licensable quantities of radioactive material without a license, or loss of control of a source of radiation.

5. Refusing authorized Agency personnel access to facilities, records and/or equipment to conduct inspections or investigations.

E. Emergency Preparedness. In an emergency, licensee failure to promptly (a) correctly identify the event, (b) make required notifications to responsible Federal, State, and local agencies, or (c) respond to the event (e.g. assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff).

2. Severity Level II - Very Significant Violations.

A. Health Physics.

1. Single exposure of a worker in excess of 5 rems of radiation to the whole body, 30 rems to the skin of the whole body or 75 rems to the feet, ankles, hands or forearms;

2. Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;

3. Release of radioactive material to an unrestricted area in excess of five times the limits of Part D.15;

4. Failure to make an immediate notification as required by Parts D.51 and 52;

5. Disposal of license material in quantities or concentrations in excess of five times the limits of Part D.33.;

6. Exposure of a worker in restricted areas in excess of five times the limits of Part D.6.;

7. An x-ray system having a malfunction such that inadvertent exposures could occur e.g., a system such that when the exposure switch is activated, not one but repeated exposures occur, or the timer fails to terminate exposure, or exposure initiated without utilizing the exposure switch.

8. A fluoroscopic x-ray system with a tabletop entrance exposure rate of greater than or equal to 25 R/min. at the point where the center of the useful beam enters the patient, except:

   a. During recording of fluoroscopic images, or

   b. When an optional high level control is activated.

9. A fluoroscopic system such that the entire x-ray beam is not intercepted by the primary protective barrier, or

10. Therapy systems which exhibit excessive leakage and/or inoperable door interlocks, shutters, timers, etc.

11. Therapy system, with improper operator/patient communication/observation.

B. Transportation.

1. Breach of package integrity resulting in surface contamination or external radiation levels in excess of Agency requirements;

2. Surface contamination or external radiation levels in excess of five times Agency limits that did not result from a breach of package integrity; or

3. Failure to make required initial notifications associated with Severity Level I or II violations.

C. Material Operations.

1. Radiation levels, contamination levels, or releases that exceed five times the limits specified in the license; or

2. A system designed to prevent or mitigate a serious safety event being inoperable.

D. Miscellaneous Matters.

1. A MFS or a reporting failure, involving information which, had it been available to the Agency and accurate at the time the information should have been submitted, would have resulted in regulatory action or would likely have resulted in the Agency seeking further information;

2. A MFS in which the false statement was made with careless disregard;

3. Deliberate falsification of records which the Agency requires be kept involving significant information; or

4. A failure to provide the notice required.

5. Failure to register sources of radiation or services as required by these rules.

6. Action by management to discriminate against an employee for attempting to communicate or for actually communicating with the Agency.

E. Emergency Preparedness.

1. Licensee failure to meet or implement more than one emergency planning standard involving assessment or notification.

3. Severity Level III - Significant Violations.

A. Health Physics.

1. Single exposure of a worker in excess of 3 rems of radiation to the whole body, 7.5 rems to the skin of the whole body, or 18.75 rems to the feet, ankles, hands or forearms;

2. A radiation level in an unrestricted area such that an individual could received greater than 100 millirem in a one hour period or 500 millirem in any seven consecutive days;

3. Failure to make a 24-hour notification as required by Part D.52.

4. Substantial potential for an exposure or release in excess of Part D of these rules, whether or not such exposure or release occurs (e.g., entry into high radiation areas, such as under reactor vessels or in the vicinity of exposed radiographic sources, without having performed an adequate survey, operation of a radiation facility with a nonfunctioning interlock system);

5. Release of radioactive material to an unrestricted area in excess of the limits of D.15;

6. Improper disposal of licensed material not covered in Severity Level I or II;

7. Exposure of worker in restricted areas in excess of the limits of Part D.6.;

8. Release for unrestricted use of contaminated or radioactive material or equipment which poses a realistic potential for significant exposure to members of the public, or which reflects a programmatic (rather than isolated) weakness in the radiation control program;

9. Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic, rather than an isolated weakness in radiation protection;

10. Conduct of licensee activities by a technically unqualified person;

11. Significant failure to control licensed material;

12. Failure to use exposure reduction devices properly (e.g., collimators, filtration);

13. For a fluoroscopic system where the maximum allowable tabletop exposure rate is 5 R/min., test values of greater than or equal to 7 R/min. (uncorrected), but less than 25 R/min. Correspondingly, for a maximum allowable rate of 10 R/min., test values of greater than or equal to 14 R/min. (uncorrected) but less than 25 R/min. are included;

14. A radiographic x-ray system having positive beam limitation where the x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, is such that either the length or the width of the x-ray field differs from that of the image receptor by greater than 10 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.

15. Intraoral dental systems capable of operations in the above 50 kVp range for which the field size at the cone tip is greater than or equal to 9 centimeters or which exhibit a minimum SSD less than 16 centimeters.

16. Dental radiographic systems in which it is possible to produce x-rays with the timer in the zero or off position.

17. Mammographic x-ray systems in which the edge of the x-ray field at the chestwall extends beyond the edges of the image receptor by more than 5 percent of the source to image receptor distance.

18. Therapy systems which fail to maintain proper surveys, calibrations, spot checks or operating procedures.

B. Transportation.

1. Breach of package integrity

2. Surface contamination or external radiation levels in excess of, but less than a factor of five above Agency requirements that did not result from a breach of package integrity;

3. Any noncompliance with labeling, placarding, shipping paper, packaging loading, or other requirements that could reasonably result in the following:

   a. Improper identification of the type, quantity, or form of material;

   b. Failure of the carrier or recipient to exercise adequate controls; or

   c. Substantial potential for personnel exposure or contamination, or improper transfer of material; or

4. Failure to make required initial notification associated with Severity Level III violations.

C. Materials Operations.

1. Failure to control access to licensed materials for radiation purposes as specified by Agency requirements;

2. Possession or use of unauthorized equipment or materials in the conduct of licensee activities which degrades safety;

3. Use of radioactive material on humans where such use is not authorized;

4. Conduct of licensed activities by a technically unqualified person;

5. Radiation levels, contamination levels, or releases that exceed the limits specified in the license; or

6. Medical therapeutic misadministrations.

7. Failure to obtain appropriate Agency approval before moving to a new use and/or storage location.

D. Miscellaneous Matters.

1. An MFS not amounting to a Severity Level I or II violation; or

2. Deliberate falsification, or falsification by or with the knowledge of management of records which the Agency requires be kept that did not involved signification information.

E. Emergency Preparedness.

1. Violations of lesser severity than Severity Level II violations.

4. Severity Level IV - Violations.

A. Health Physics

1. Exposures in excess of the limits of Parts D.6 or D.16. not constituting Severity Level I, II, or III violations;

2. A radiation level in an unrestricted area such that an individual could receive greater than 2 millirem in a one-hour period or 100 millirem in any seven consecutive days;

3. Failure to make a 30-day notification required by Part D.51.;

4. Failure to make a follow-up written report as required by Parts D.53., D.54, and J.4.; or

5. Any other matter that has more than minor safety or environmental significance.

6. A capacitor storage radiographic system such that the standby radiation is greater than 3.0 mR/hr, but less than 25 mR/hr.

7. Systems equipped with positive beam limitation devices which do not allow the field size to be reduced to a size less than that of the image receptor.

8. Systems equipped with positive beam limiting devices which do not provide for an automatic return to PBL from a reduced field size.

9. Mobile radiographic systems for which the minimum source to skin distance is less than 27.5 centimeters.

10. Mammographic systems manufactured after October 1977 for which the edges of the x-ray field on the right or left sides extend beyond the edges of the image receptor. If manufactured prior to November 1977 and the edges of the x-ray field on either side extend beyond the edge of the image receptor by more than 5 percent of the SID.

B. Transportation.

1. Package selection or preparation requirements which do not result in a breach of package integrity or surface contamination or external radiation levels in excess of Agency requirements; or

2. Other violations that have more than minor safety or environmental significance.

C. Material Operations.

1. Failure to maintain patients hospitalized who have cobalt-60, cesium-137, or iridium-192 implants or to conduct required leakage or contamination tests, or to use properly calibrated equipment;

2. Other violations that have more than minor safety or environmental significance; or

3. Failure to report medical diagnostic misadministrations.

D. Miscellaneous Matters.

1. A false statement caused by an inadvertent clerical or similar error involving information which, had it been available to the Agency and accurate at the time the information should have been submitted, would probably not have resulted in regulatory action or the Agency seeking additional information.

2. Unless specified in a more severe category, changes in procedures or other conditions of a license or certificate of registration of which the Agency was not informed (e.g., change of address, expiration of certificate of registration); or

E. Emergency Preparedness.

1. Violations of lesser severity than Severity Level III violations.

5. Severity Level V - Minor Violations.

A. Health Physics.

1. For a fluoroscopic x-ray system where the maximum allowable tabletop exposure rate is 5 R/min., test values of greater than 5.0 R/min. (uncorrected), but less than 7.0 R/min. Correspondingly, if the maximum allowable tabletop exposure rate is 10 R/min., test values of greater than 10.0 R/min. (uncorrected) but less than 14.0 R/min. are included.

2. Other violations that have minor safety or environmental significance.

B. Transportation.

1. Other violations that have minor safety or environmental significance.

C. Materials Operations.

1. Other violations that have minor safety or environmental significance.

D. Miscellaneous Matters.

1. Other violations that have minor safety or environmental significance.

E. Emergency Preparedness.

1. Other violations that have minor safety or environmental significance.

PART C

LICENSING OF RADIOACTIVE MATERIAL

1. Purpose and Scope.

A. This Part and Parts G and L provide for the licensing of radioactive material and the assignment of fees for such licenses.[1]/ No person shall receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific license or general license (registration required) issued pursuant to this part or as otherwise provided in this part or in a specific license or general license (registration required)issued pursuant to Parts G or L. Fees are specifically addressed in Appendix A to Part C.

B. In addition to the requirements of this part, all licensees are subject to the requirements of Parts A, D, and J and L of these regulations. Licensees engaged in industrial radiographic operations are subject to the requirements of Part E, licensees using sealed sources radionuclides in the healing arts are subject to the requirements of Part G and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Part K of these regulations.

EXEMPTIONS

2. Source Material.

A. Any person is exempt from this part to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

B. Any person is exempt from this part to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

C. Any person is exempt from this part to the extent that such person receives, possesses, uses, or transfers:

(1) any quantities of thorium contained in:

a. incandescent gas mantles,

b. vacuum tubes,

c. welding rods,

d. electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium,

e. germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium,

f. rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or

[1]/ Attention is directed to the fact that regulation by the State of source material, radioactive material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the State and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

g. personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;

(2) source material contained in the following products:

a. glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material,

b. glassware containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass, or ceramic used in construction, or

c. glass enamel and glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983 [2]; or

d. piezoelectric ceramic containing not more than 2 percent by weight source material;

(3) photographic film, negatives, and prints containing uranium or thorium;

(4) any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;

(5) uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

a. the counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR Part 40,

b. each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM",

c. each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED", and

d. this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering;

(6) natural or depleted uranium metal used as shielding constituting part of any shipping container provided that:

a. the shipping container is conspicuously and legibly impressed with the legend "CAUTION-RADIOACTIVE SHIELDING-URANIUM", and

b. the uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of one-eighth inch (3.2 mm);

(7) thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either

[2] On July 25, 1983, the exemption of glass enamel or glass enamel frit was suspended. The exemption was eliminated on September 11, 1984.

a. the shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens, or

b. the receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments;

(8) uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcuries of uranium; or

(9) thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that

a. the thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and

b. the thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

D. The exemptions in C.2.C do not authorize the manufacture of any of the products described.

3. Radioactive Material Other Than Source Material.

A. Exempt Concentrations

(1) Except as provided in C.3.A(2), any person is exempt from this part to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Schedule B of this Part.

(2) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under C.3.A(1) or equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, except in accordance with a specific license issued pursuant to C.11.A. or the general license provided in C.23.

B. Exempt Quantities.

(1) Except as provided in C.3.B.3 and 4, any person is exempt from these regulations to the extent that such person receives possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Schedule B of this part.

(2) Any person who possesses radioactive material received or acquired under the general license formerly provided in C.6.F(4)b(ii) is exempt from the requirements for a license set forth in this part to the extent that such person possesses, uses, transfers or owns such radioactive material. Such exemption does not apply for radium-226.

(3) This paragraph (C.3.B) does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(4) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under C.3.B or equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 or by the Agency pursuant to C.11.B which license states that the radioactive material may be transferred by the licensee to persons exempt under C.3.B or the equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State.

C. Exempt Items.

(1) Certain Items Containing Radioactive Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from these regulations to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products[3]/

a. Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:

(i) 25 millicuries of tritium per timepiece.

(ii) 5 millicuries of tritium per hand.

(iii) 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial).

(iv) 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per any other timepiece.

(v) 20 microcuries of promethium-147 per watch hand or 40 microcuries of promethium-147 per other timepiece hand.

(vi) 60 microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).

(vii) The levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(a) For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface.

(b) For pocket watches, 0.1 millirad per hour at 1 centimeter from any surface.

(c) For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.

(viii) One microcurie of radium-226 per timepiece in timepieces acquired prior to the effective date of these regulations.

b. Lock illuminators containing not more than 15 millicuries of tritium or not more than 2 millicuries of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium-147 will not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.

c. Precision balances containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part.

d. Automobile shift quadrants containing not more than 25 millicuries of tritium.

e. Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas.

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[3]/ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing radioactive material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

f. Thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat.

g. Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of radioactive material:

(i) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube.

(ii) 1 microcurie of cobalt-60.

(iii) 5 microcuries of nickel-63.

(iv) 30 microcuries of krypton-85.

(v) 5 microcuries of cesium-137.

(vi) 30 microcuries of promethium-147.

And provided further, that the radiation dose rate from each electron tube containing radioactive material does not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.[4]/

h. Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, a source of radioactive material, provided that:

(i) Each source contains no more than one exempt quantity set forth in Schedule B of this part, and

(ii) Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Schedule B of this part, provided that the sum of such fractions shall not exceed unity.

(iii) For purposes of this paragraph, 0.05 microcurie of americium-241 is considered an exempt quantity under Schedule B of this section.

i. Spark gap irradiators containing not more than 1 microcurie of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons (11.4 liters) per hour.

(2) Self-Luminous Products Containing Radioactive Material.

a. Tritium, Krypton-85, or Promethium-147. Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in C.3.C.2. does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

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[4]/ For purposes of C.3.C.1.(g), "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

b. Radium-226. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie of radium-226, which were acquired prior to the effective date of these regulations.

(3) Gas and Aerosol Detectors Containing Radioactive Material.

a. Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission [5]/ pursuant to Section 32.26 of 10 CFR Part 32; or a Licensing State pursuant to C.11.C, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

b. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State shall be considered exempt under C.3.C(3)a, provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of C.11.C.

c. Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under C.3.C(3)a, provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of C.11.C.

(4) Resins Containing Scandium-46 and Designed for Sand Consolidation in Oil Wells. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium-46.

(5) Radioactive drug: Capsules containing carbon-14 urea for "in-vivo" diagnostic use for humans.

(a) Except as provided in paragraphs (b) and (c) of this section, any person is exempt from the requirements for a license set forth in the regulations in this part and part G of 10-144A CMR 220, provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 μCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in-vivo" diagnostic use for humans.

(b) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to part G of 10-144A CMR 220.

(c) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsule shall apply for and receive a specific license pursuant to C.7 of this part.

[5]/ Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity, or other product containing radioactive material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(d) Nothing in this section relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

LICENSES

4. Types of Licenses. Licenses for radioactive materials are of two types: general and specific.

A. General licenses provided in this part are effective without the filing of applications with the Agency or the issuance of licensing documents to the particular person, although the filing of a registration form with the Agency may be required by the particular general license. The general licensee is subject to all other applicable portions of these regulations and any limitations of the general license.

B. Specific licenses require the submission of an application to the Agency and the issuance of a licensing document by the Agency. The licensee is subject to all applicable portions of these regulations as well as any limitations specified in the licensing document.

C. The Agency may incorporate, in any license or registration issued pursuant to these regulations, at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's or registrant's receipt, possession, use and transfer or radioactive material as it deems appropriate or necessary in order to:

(a) Promote the common defense and security;
(b) Protect health or minimize danger to life or property;
(c) Protect restricted data;
(d) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license or registration as may necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

D. Each general licensee or registrant that is required to register by this Part shall make all necessary reports as required by C.14.D of this Part.

E. Each general licensee or registrant, that is required to file an application to the Agency by this Part, shall file the applicable form with the Agency annually and include all addresses for locations of use by the registrant. This includes, but is not limited to the verification, correction, and in addition to the information provided in a request for information from the Agency.

GENERAL LICENSES

5. General Licenses - Source Material.

A. A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and State and local government agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial or operational purposes. A person authorized to use or transfer source material, pursuant to this general license may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

B. Persons who receive, possess, use, or transfer source material pursuant to the general license issued in C.5.A. are exempt from the provisions of Parts D and J of these regulations to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this part.

C. Persons who receive, posses, use, or transfer source material pursuant to the general license in C.5.A. are prohibited from administering source material, or the radiation there from, either externally or internally, to human beings except as may be authorized by the Agency in a specific license.

D. A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

E. Depleted Uranium in Industrial Products and Devices.

(1) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of C.5.D(2), (3), (4), and (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in C.5.E(1). applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to C.11.L. or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.

(3) a. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by C.5.D(1) shall file Agency Form HHE 860 "Registration Certificate - Use of Depleted Uranium Under General License," with the Agency and pay the registration fee referenced in Appendix A of this Part. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium or 30 days after the effective date of these regulations for depleted uranium acquired prior to the effective date. The registrant shall furnish on Agency Form HHE 860 the following information and such other information as may be required by that form:

(i) name and address of the registrant;

(ii) a statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in C.5.D(1). and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(iii) name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in C.5.D(3)a(ii).

b. The registrant possessing or using depleted uranium under the general license established by C.5.D(1). shall report in writing to the Agency any changes in information furnished by him in Agency Form HHE 860 "Registration Certificate - Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by C.5.E(1):

a. Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium.

b. Shall not abandon such depleted uranium.

c. Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of C.21. In the case where the transferee receives the depleted uranium pursuant to the general license established by C.5.E(1), the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form HHE 860. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulations equivalent to C.5.E(1)., the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form HHE 860 accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this regulation.

d. Within 30 days of any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium pursuant to such transfer.

e. Shall not export such depleted uranium except in accordance with the license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by C.5.E(1). is exempt from the requirements of Parts D and J of these regulations with respect to the depleted uranium covered by that general license.

6. General Licenses - Radioactive Material Other Than Source Material.

A. Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of A.4 through A.9, C.3.A(2), C.14, C.21, C.22, and Parts D, J and L of these regulations.

(1) Static Elimination Device. Devices designed for use as static eliminators, which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device.

(2) Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device or a total of not more than 50 millicuries of hydrogen-3 (tritium) per device

B. Certain Detecting, Measuring, Gauging or Controlling Devices and certain devices for producing light or an ionized atmosphere.

(1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provision of C.6.B(2), (3), (4), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) The general license in C.6.B(1) applies only to radioactive material contained in devices, which have been manufactured or initially transferred and labeled in accordance with the specifications contained in:

(i) a specific license issued by the Agency pursuant to C.11.D, or

(ii) in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in Section 179.21 of the Code of Federal Regulations, Title 21.

(3) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in C.6.B(1) shall file Agency Form HHE 861 "Registration Certificate - Use of Fixed Measuring, Gauging or Controlling Devices", Agency Form HHE 862 "Registration Certificate - Use of Portable Measuring, Gauging or Controlling Devices" or Agency Form HHE 864 "Registration Certificate for use of Static Eliminators, Electron Capture Devices, Gas Chromatographs, or Other Devices which Contain Radioactive Material Under a General License" with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such device or 30 days after the effective date of these regulations for devices acquired prior to the effective date. The general licensee shall furnish such information as may be required by that form as well as the annual fee referenced in Appendix A of this Part and:

a. shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

b. shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, however,

(i) devices containing only krypton need not be tested for leakage of radioactive material, and

(ii) devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

c. shall assure that other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(i) in accordance with the instructions provided by the labels, or

(ii) by a person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such activities;

d. shall maintain records showing compliance with the requirements of C.6.B(3)b. and c. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by C.6.B(3)b. shall be maintained for 1 year after the next required leak test is performed or until the sealed source is transferred or disposed. Records of tests of the on/off mechanism and indicator required by C.6.B(3)b. shall be maintained for 1 year after the next required test of the on/off mechanism and indicator is performed or until the sealed source is transferred or disposed. Records which are required by C.6.B(3)c. shall be maintained for a period of 3 years from the date of the recorded event or until the device is transferred or disposed;

e. upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the Agency a report containing a brief description of the event and the remedial action taken; and in the case of detection of 0.005 microcurie or more removable contamination of the premises or the environs, a plan for ensuring that the premises are acceptable for unrestricted use, must be furnished to the Agency within 30 days. Under these circumstances the criteria set out in Part D, ``Radiological criteria for unrestricted use," may be applicable, as determined by the Agency on a case-by-case basis;

f. shall not abandon the device containing radioactive material;

g. except as provided in C.6.B(3)h., shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State whose specific license authorizes him to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the Agency a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

h. (i) Shall transfer to another general licensee as authorized in paragraph C.6.B(3)i of this section, or to a person authorized to receive the device by a specific license issued under this Part, or the section of this Part that authorizes waste collection, or equivalent regulations of an Agreement State, or as otherwise approved under paragraph C.6.B(3)h(iii) of this section.

(ii) Shall furnish a report to the Agency within 30 days after the transfer of a device to a specific licensee or export. The report must contain:

(A) The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;

(B) The name, address, and license number of the person receiving the device (license number not applicable if exported); and

(C) The date of the transfer.

(iii) Shall obtain written Agency approval before transferring the device to any other specific licensee not specifically identified in paragraph C.6.B(3)h(i) of this section.

i. shall transfer the device to another general licensee only:

(i) where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this regulation and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Agency:

(a) the manufacturer's (or initial transferor's) name;

(b) The model number and the serial number of the device transferred

(c) the name and mailing address of the transferee; and

(d) the name, title and phone number of the responsible individual identified by the transferee in accordance with paragraph l of this section to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(ii) where the device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee; and

j. shall comply with the provisions of D.51. and D.52. of these regulations for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Parts D and J of these regulations.

k. Shall respond to written requests from the Agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the Radiation Control Program Manager and provide written justification as to why it cannot comply.

l. Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

m. Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Radiation Control Program Manager within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.

n. May not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by paragraph (c)(2) of this section need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(4) The general license in C.6.B.(1) does not authorize the manufacture or import of devices containing radioactive material.

(5) The general license provided in C.6.B.(1) is subject to the provisions of A.4 through A.9., C.14., C.21., C.22. and Part L of these regulations.

C. Luminous Safety Devices for Aircraft.

(1) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

a. each device contains not more than 10 curies of tritium or 300 millicuries of promethium-147; and

b. each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.

(2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in C.6.C.1. are exempt from the requirements of Part D and Part J of these regulations except that they shall comply with the provisions of D.51. and D.52.

(3) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

(4) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

(5) This general license is subject to the provisions of A.4. through A.9., C.14., C.21., C.22. and Part L of these regulations.

D. Ownership of Radioactive Material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this part, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

E. Calibration and Reference Sources.

(1) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of C.6.E. (4) and (5), americium-241 in the form of calibration or reference sources:

a. Any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material; and

b. any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes him to receive, possess, use, and transfer special nuclear material.

(2) A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of C.6.E. (4) and (5) to any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material.

(3) A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of C.6.E. (4) and (5) to any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material.

(4) The general licenses in C.6.E.(1),(2) and (3) apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Agency, any Agreement State or Licensing State pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 of the regulations of the U.S. Nuclear Regulatory Commission.

(5) The general licenses provided in C.6.E(1), (2) and (3) are subject to the provisions of A.4 through A.9, C.14, C.21, C.22, and Parts D, J and L of these regulations. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

a. shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of americium-241, 5 microcuries of plutonium, or 5 microcuries of radium-226 in such sources;

b. shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

(i) The receipt, possession, use and transfer of this source, Model_____, Serial No._____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM-241). (PLUTONIUM)[6]/
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.
(Name of manufacturer or importer)

(ii) The receipt, possession, use and transfer of this source, Model_____, Serial No._____, are subject to a general license and the regulations of any Licensing State. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS RADIUM-226.
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.
(Name of manufacturer or importer)

c. shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive the source;

d. shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

[6]/ Showing only the name of the appropriate material

e. shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

F. General License for Use of Radioactive Material for Certain *In- Vitro* Clinical or Laboratory Testing.

(1) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of C.6.F. (2), (3), (4), (5), and (6), the following radioactive materials in prepackaged units for use in *in-vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation there from, to human beings or animals:

a. Iodine-125, in units not exceeding 10 microcuries each;

b. Iodine-131, in units not exceeding 10 microcuries each;

c. Carbon-14, in units not exceeding 10 microcuries each;

d. Hydrogen-3 (tritium), in units not exceeding 50 microcuries each;

e. Iron-59, in units not exceeding 20 microcuries each;

f. Cobalt-57, in units not exceeding 10 microcuries each;

g. Selenium-75, in units not exceeding 10 microcuries each;

h. Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each;

(2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by C.6.F.(1). until he has filed Agency Form HHE 863, "Certificate- In Vitro Testing with Radioactive Material Under General License", with the Agency as well as the registration fee referenced in Appendix A to this Part and received from the Agency a validated copy of Agency Form HHE 863 with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on Agency Form HHE 863 the following information and such other information as may be required by that form:

a. Name and address of the physician, veterinarian, clinical laboratory or hospital;

b. the location of use; and

c. a statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out *in-vitro* clinical or laboratory tests with radioactive material as authorized under the general license in C.6.F.(1). and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by C.6.F.(1). shall comply with the following:

a. The general licensee shall not possess at any one time, pursuant to the general license in C.6.F.(1)., at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of 200 microcuries.

b. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

c. The general licensee shall use the radioactive material only for the uses authorized by C.6.F.(1).

d. The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

e. The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in C.6.F.(1). as required by D.16. of these regulations.

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to C.6.F.(1).:

a. Except as prepackaged units, which are labeled in accordance with the provisions of an applicable specific license, issued pursuant to C.11.G. or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under C.6.F or its equivalent, and

b. unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(i) This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in-vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation there from, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.
(Name of manufacturer)

(ii) This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in-vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation there from, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.
(Name of manufacturer)

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of C.6.F.1. shall report in writing to the Agency, any changes in the information furnished by him in the "Certificate - In-Vitro Testing with Radioactive Material Under General License", Agency Form HHE 880. The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of C.6.F.(1). is exempt from the requirements of Part D and Part J of these regulations with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in C.6.F.(1). shall comply with the provisions of D.16, D.28, and D.29 of these regulations.

G. Ice Detection Devices.

(1) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer of such device pursuant to the licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in C.6.G.(1).,

a. shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of D.16 of these regulations;

b. shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

c. are exempt from the requirements of Part D and Part J of these regulations except that such person shall comply with the provisions of D.33, D.51, and D.52.

(3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(4) This general license is subject to the provisions of A.4., through A.9., C.14., C.21., C.22., and Part L of these regulations.

SPECIFIC LICENSES

7. Filing Application for Specific Licenses.

A. Applications for specific license shall be filed on a form prescribed by the Agency.

B. The Agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Agency to determine whether the license should be modified or revoked.

C. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on their behalf.

D. An application for a license may include a request for a license authorizing one or more activities.

E. All sections of the application must be completed, clearly and concisely, with the applicable required information.

F. Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

G. Emergency Planning

(1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in "Schedule D -- Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must contain either:

a. An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rem to the thyroid or an intake of 2 milligrams of soluble uranium; or

b. An emergency plan for responding to a release of any radioactive material and to any associated chemical hazards directly incident thereto.

(2) One or more of the following factors may be used to support an evaluation submitted under paragraph G.(1)a. of this section:

a. The radioactive material is physically separated so that only a portion could be involved in an accident;

b. All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

c. The release fraction in the respirable size range would be lower than the release fraction shown in Schedule D due to the chemical or physical form of the material;

d. The solubility of the radioactive material would reduce the dose received;

e. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Schedule D;

f. Operating restrictions or procedures would prevent a release fraction as large as that shown in Schedule D; or

g. Other factors appropriate for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted under paragraph G.(1)a. of this section must include the following information:

a. Facility description. A brief description of the licensee's facility and area near the site.

b. Types of accidents. An identification of each type of radio-active materials accident for which protective actions may be needed.

c. Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

d. Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

e. Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

f. Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

g. Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Agency; also responsibilities for developing, maintaining, and updating the plan.

h. Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify this Agency immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

i. Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the Agency.

j. Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

k. Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

l. Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

m. Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, title III, Pub. L. 99 - 499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it the Agency. The licensee shall provide any comments received within the 60 days to the Agency with the emergency plan.

8. **General Requirements for the Issuance of Specific Licenses.** A license application will be approved if the Agency determines that:

A. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these regulations in such a manner as to minimize danger to public health and safety or property;

B. The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

C. The issuance of the license will not be inimical to the health and safety of the public; and

D. The applicant satisfies any applicable special requirements in C.9, C.10. or C.11. and Part E, Part G, and Part K of these regulations.

E. Environmental Report, Commencement of Construction. In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, source material milling, or for the conduct of any other activity which the Agency determines will significantly affect the quality of the environment, the Agency, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other pre-construction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

F. Financial Surety for Decommissioning, Recovery or Site Reclamation.

(1) Each applicant for a specific license authorizing the possession and use of special nuclear material, source material, or radioactive material in quantities and amounts in excess of those indicated in Table F.1 shall submit a decommissioning funding plan in the event of planned or unplanned decommissioning, recovery, or site reclamation. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of quantity of each isotope to the applicable value in Part C, Appendix E.

TABLE F.1

Type	Exceeding
Special Nuclear Material	10^5 times Part C, App. E
Source Material	100 μCi in readily dispersible form
Radioactive Material	Half-life greater than 120 days and 10^5 times Part C, App. E

(2) Each applicant for or holder of a specific license authorizing possession and use of special nuclear material, source material, or radioactive material in excess of those indicated in Table F.2 shall either:

a. Submit a decommissioning funding plan as described in paragraph (4) of this section; or

b. Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by Table F.2 of this section using one of the methods described in paragraph (4) of this section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material.

(3) Each funding plan must contain a cost estimate for decommissioning, recovery or reclamation, and a description of the method of assuring funds for such including means of adjusting cost estimates and associated funding levels over the life of the facility.

TABLE F.2

Type of Radioactive Material	Exceeding	Assurance Amount
Special Nuclear	Greater than 10^4 but less than or equal to 10^5 times the applicable quantities*	$500,000
	Greater than 10^3 but less than or equal to 10^4 times the applicable quantities*	$100,000
Source Material	Greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form	$150,000
Radioactive Material	Half life greater than 120 days and in quantities:	
	Greater than 10^4 but less than or equal to 10^5 times the applicable quantities in unsealed form*	$750,000
	Greater than 10^3 but less than or equal to 10^4 times the applicable quantities in unsealed form*	$150,000
	Greater than 10^{10} times the applicable quantities in sealed sources	$75,000

**As indicated in Part C, App. E

(4) Financial assurance must be provided by one or more of the following methods:

a. Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets that will retain their value over the projected operating life of the facility and that are in an amount such that the principal plus accumulated earnings would be sufficient to pay the necessary costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

b. A surety method insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are contained in Appendix C of this Part. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test are as contained in Appendix D of this Part. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any other situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance must contain the following conditions:

(i) The surety or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Agency, the beneficiary, and the licensee of its intention not to renew. The surety or insurance must also provide that the beneficiary may automatically collect prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Agency within 30 days after receipt of notification of cancellation.

(ii) The beneficiary of the surety or insurance must be a trustee acceptable to the Agency such as an appropriate state or Federal government agency or a major financial organization.

(iii) The surety or insurance must remain in effect until the Agency has terminated the license.

c. An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by the periodic deposit of a prescribed amount into an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of the periodic deposits plus accumulated earnings would be sufficient to pay the necessary costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

d. In the case of State, or local government licensees, a certification that the appropriate government entity will be guarantor of funds.

e. Other funding methods, which are demonstrated by the applicant or licensee to provide comparable assurance to methods, listed in paragraphs (4)(a) through (c) of this section.

f. Each person licensed under this Part shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Agency. Before licensed activities are transferred or assigned in accordance with this Part, licensees shall transfer all records described in this paragraph to the new licensee. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the Agency considers important to decommissioning consists of:

(i) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete.

These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(ii) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes, which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(iii) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or radioactive materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:

(a) All areas designated and formerly designated restricted areas as defined in D.3;

(b) All areas outside of restricted areas that require documentation under C.8.F.(4)(f)(i);

(c) All areas outside of restricted areas where current and previous wastes have been buried as documented under D.48; and

(d) All areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in Part D or apply for approval for disposal under D.34.

(iv) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

9. Special Requirements for The Use of Sealed Sources in Industrial Radiography.

A. In addition to the requirements set forth in C.8, a specific license for use of sealed sources in industrial radiography will be issued if:

(1) the applicant will have an adequate program for training radiographers and radiographer trainees and submits to the Agency a schedule or description of such program which specifies the:

a. initial training,

b. periodic training,

c. on-the-job training,

d. means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with Agency regulations and licensing requirements, and the operating and emergency procedures of the applicant, and

e. means to be used by the licensee to determine the radiographer trainees knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;

(2) the applicant has established and submits to the Agency satisfactory written operating and emergency procedures described in E.14 of these regulations;

(3) the applicant will have an internal inspection system adequate to assure that these regulations, license provisions, and the applicant's operating and emergency procedures are followed by radiographers and radiographer trainees; the inspection system shall include the performance of internal inspections at intervals not to exceed 3 months and the retention of records of such inspections for 2 years;

(4) the applicant submits to the Agency a description of his overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program;

(5) the applicant who desires to conduct his own leak tests has established adequate procedures to be followed in leak testing sealed sources for possible leakage and contamination and submits to the Agency a description of such procedures including:

a instrumentation to be used,

b. method of performing tests, e.g., points on equipment to be smeared and method of taking smear, and

c. pertinent experience of the person who will perform the test; and

(6) the licensee shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.

10. Special Requirements for Specific Licenses of Broad Scope. This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of such licenses. [7]

A. The different types of broad licenses are set forth below:

(1) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multi-curie range.

[7] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing radioactive material whose subsequent possession, use transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(2) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Schedule C, for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed there under, is the quantity specified for the radionuclide in Schedule C, Column I. If two or more radionuclides are possessed there under, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Schedule C, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(3) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Schedule C, for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed there under, is the quantity specified for that radionuclide in Schedule C, Column II. If two or more radionuclides are possessed there under, the possession limit is determined for each as follows: For each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in Schedule C, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

B. An application for a Type A specific license of broad scope will be approved if:

(1) the applicant satisfies the general requirements specified in C.8.;

(2) the applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(3) the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

a. the establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

b. the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

c. the establishment of appropriate administrative procedures to assure:

(i) control of procurement and use of radioactive material;

(ii) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(iii) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with C.10.B.(3). prior to use of the radioactive material.

C. An application for a Type B specific license of broad scope will be approved if:

(1) the applicant satisfies the general requirements specified in C.8.; and

(2) the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

a. the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and

b. the establishment of appropriate administrative procedures to assure:

(i) control of procurement and use of radioactive material,

(ii) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures, and

(iii) review, approval and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with C.10.C.(2). prior to use of the radioactive material.

D. An application for a Type C specific license of broad scope will be approved if:

(1) the applicant satisfies the general requirements specified in C.8;

(2) the applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

a. a college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering, and

b. at least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

(3) the applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

E. Specific licenses of broad scope are subject to the following conditions:

(1) Unless specifically authorized, persons licensed pursuant to C.10 shall not:

a. conduct tracer studies in the environment involving direct release of radioactive material;

b. receive, acquire, own, possess, use or transfer devices containing 100,000 curies or more of radioactive material in sealed sources used for irradiation of materials;

c. conduct activities for which a specific license issued by the Agency under C.9., or, C.11. or Part G is required; or

d. add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

(2) Each Type A specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(3) Each Type B specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(4) Each Type C specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of C.10.D.

11. Special Requirements for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices which Contain Radioactive Material.

A. Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations.

(1) In addition to the requirements set forth in C.8., a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under C.3.A.(1) will be issued if:

a. the applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentrations is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and

b. the applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Schedule A, the re-concentration of the radioactive material in concentrations exceeding those in Schedule A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(2) Each person licensed under C.11.A. shall file an annual report with the Agency which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to C.11.A. during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

B. Licensing the Distribution of Radioactive Material in Exempt Quantities.[8]/

(1) An application for a specific license to distribute NARM to persons exempted from these regulations pursuant to C.3.B. will be approved if:

a. the radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

[8]/ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing radioactive material whose subsequent possession, use transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

b. the radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

c. the applicant submits copies of prototype labels and brochures and the Agency approves such labels and brochures.

(2) The license issued under C.11.B.(1) is subject to the following conditions:

a. No more than 10 exempt quantities; shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

b. Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to C.4.A. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 mrem (5 μSv) per hour.

c. The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

(i) identifies the radionuclide and the quantity of radioactivity; and

(ii) bears the words "Radioactive Material".

d. In addition to the labeling information required by C.11.B.(2)c., the label affixed to the immediate container, or an accompanying brochure, shall:

(i) state that the contents are exempt from Licensing State requirements;

(ii) bear the words "Radioactive Material--Not for Human Use--Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited--Exempt Quantities Should Not Be Combined", and

(iii) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

(3) Each person licensed under C.11.B. shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under C.3.B. or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Agency. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to C.11.B. during the reporting period, the report shall so indicate.

C. Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under C.3. will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32. The maximum quantity of Radium-226 in each device shall not exceed 0.1 microcurie (3.7 kBq). NARM radionuclides are found in Appendix B to Part C.

D. Licensing the Manufacture, distribute or initially transfer Devices to Persons Generally Licensed Under C.6.D.

(1) An application for a specific license to manufacture, initially transfer or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under C.6.D or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State will be approved if:

a. the applicant satisfies the general requirements of C.8.;

b. the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(i) the device can be safely operated by persons not having training in radiological protection,

(ii) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in one year a dose in excess of 10 percent of the limits specified in D.6., and

(iii) under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses

Organ	Dose
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15 rem (150 mSv)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200 rem (2 Sv)
Other organs	50 rem (500 mSv)

c. each device bears a durable, legible, clearly visible label or labels approved by the Agency, which contain in a clearly identified and separate statement:

(i) instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information),

(ii) the requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity, and

(iii) the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(a) The receipt, possession, use, and transfer of this device, Model_____[9]/, Serial No._____[9]/ are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL
(Name of manufacturer or distributor)

(b) The receipt, possession, use, and transfer of this device, Model_____[9]/, Serial No._____,[9]/ are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL
(Name of manufacturer or distributor)

d. Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, ``Caution-Radioactive Material," the radiation symbol described in Part D, and the name of the manufacturer or initial distributor.

e. Each device meeting the criteria of Part C, bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, ``Caution-Radioactive Material," and, if practicable, the radiation symbol described in Part D.

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Agency will consider information, which includes, but is not limited to:

a. primary containment (source capsule);
b. protection of primary containment;
c. method of sealing containment;
d. containment construction materials;
e. form of contained radioactive material;
f. maximum temperature withstood during prototype tests;
g. maximum pressure withstood during prototype tests;
h. maximum quantity of contained radioactive material;
i. radiotoxicity of contained radioactive material; and
j. operating experience with identical devices or similarly designed and constructed devices.

[9]/ The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

(3) In the event the applicant desires that the general licensee under C.6.D, or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, he shall include in his application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive in one year a dose in excess of 10 percent of the limits specified in D.6.

(4) Each person licensed under C.11.D. to initially transfer devices to generally licensed persons shall:

a. Furnish a copy of the general license contained in C.6.D to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in C.6.D.

b. Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's, Agreement State's or Licensing State's regulation equivalent to C.6.D, or alternatively, furnish a copy of the general license contained in C.6.D to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the Agreement State or the Licensing State. If a copy of the general license in C.6.D is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State under requirements substantially the same as those in C.6.D.

c. Report to the Agency all transfers of such devices to persons for use under the general license in C.6.D.

(1)The required information for transfers to general licensees includes:

(i) The identity of each general licensee by name and address for the location of use, if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

(ii)The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(iii) the date of transfer

(iv) the type, model number and serial number of the device transferred;, and

(v) the quantity and type of radioactive material contained in the device.

(2) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user.

(3) For devices received from a Part C general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(4) If the licensee makes changes to a device possessed by a Part C general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(5) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(6) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(7) If no transfers have been made to persons generally licensed under C.6.D. during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter.

d. Reports to Other Agencies.

(i) Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 32.52 of 10 CFR Part 32.

(ii) Report to the responsible State Agency all transfers of devices manufactured and distributed pursuant to C.11.D for use under general license in that State's regulations equivalent to C.6.D..

(iii) Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.

(iv) If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

(v) If no transfers have been made to general licensees within a particular State during the reporting period, this information shall be reported to the responsible State Agency upon request of the agency.

e. Keep records showing the name, address, and the point of contact for each general licensee to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in C.6.D., or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of C.11.D.(4).

f. If a device containing byproduct material is to be transferred for use under the general license contained in this Part, each person that is licensed or registered under this Part shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(i) A copy of the general license contained in Part C; if any paragraphs **in this section** do not apply to the particular device, those paragraphs may be omitted.

(ii) A copy of the applicable sections of Parts C and D;

(iii) A list of the services that can only be performed by a specific licensee;

(iv) Information on acceptable disposal options including estimated costs of disposal; and

(v) An indication that the Agency's policy is to issue high civil penalties for improper disposal.

g. If byproduct material is to be transferred in a device for use under an equivalent general license of an Agreement State, the Nuclear Regulatory Commission or a Licensing State, each person that is licensed under this Part shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(i) A copy of the Agreement State's, US Nuclear Regulatory Commission's, or Licensing State's regulations equivalent to Parts C and D or a copy of Parts C and D. If a copy of the Agency regulations is provided to a prospective general licensee in lieu of the appropriate regulations, it shall be accompanied by a note explaining that use of the device is regulated by another Agreement State, the US Nuclear Regulatory Commission or Licensing State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted.

(ii) A list of the services that can only be performed by a specific licensee;

(iii) Information on acceptable disposal options including estimated costs of disposal; and

(iv) The name or title, address, and phone number of the contact at the appropriate regulatory agency from which additional information may be obtained.

h. An alternative approach to informing customers may be proposed by the licensee for approval by the Agency.

i. Each device that is transferred after February 19, 2002 must meet the labeling requirements in this Part.

j. If a notification of bankruptcy has been made this Part or the license is to be terminated, each person licensed under Part C shall provide, upon request, to the Agency and to any appropriate Agreement State, Nuclear Regulatory Commission or Licensing State, records of final disposition required under this Part.

E. Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under C.6.C will be approved subject to the following conditions:

(1) The applicant satisfies the general requirements specified in C.8; and

(2) the applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, 32.101, of 10 CFR Part 32 or their equivalent.

F. Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under C.6.E. An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under C.6.E will be approved subject to the following conditions:

(1) The applicant satisfies the general requirement of C.8; and

(2) the applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

G. Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of C.6.F will be approved if:

(1) The applicant satisfies the general requirements specified in C.8.

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

a. Iodine-125 in units not exceeding 10 microcuries (370 kBq) each.

b. Iodine-131 in units not exceeding 10 microcuries (370 kBq) each.

c. Carbon-14 in units not exceeding 10 microcuries (370 kBq) each.

d. Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.

e. Iron-59 in units not exceeding 20 microcuries (740 kBq) each.

f. Cobalt-57 in units not exceeding 10 (370 kBq) microcuries each.

g. Selenium-75 in units not exceeding 10 microcuries (370 kBq) each.

h. Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.

(3) Each prepackaged unit bears a durable, clearly visible label:

a. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 (185 Bq) microcurie of americium-241 each; and

b. displaying the radiation caution symbol described in D.27. and the words, **"CAUTION, RADIOACTIVE MATERIAL"**, and **"Not for Internal or External Use in Humans or Animals"**.

(4) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

a. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation there from, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.
(Name of manufacturer)

b. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation there from, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a Licensing State.
(Name of manufacturer)

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in D.33. of these regulations.

H. Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under C.6.G will be approved subject to the following conditions:

(1) the applicant satisfies the general requirements of C.8, and

(2) the criteria of Sections 32.61, 32.62, 32.103 of 10 CFR Part 32 are met.

I. Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Part G Licenses.

(1) An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Part G for the uses listed in Part G.100, 200 and 300 will be approved if:

a. The applicant satisfies the general requirements specified in C.8. of this part;

b. The applicant submits evidence that the applicant is at least one of the following:

(i) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer, or

(ii) Registered or licensed with a state agency as a drug manufacturer; or

(iii) Licensed as a pharmacy by a State Board of Pharmacy; or

(iv) Operating as a nuclear pharmacy within a Federal medical institution.

c. The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(i) The applicant satisfies the following labeling requirements: (i) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words **"CAUTION, RADIOACTIVE MATERIAL"** or **"DANGER, RADIOACTIVE MATERIAL"**; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

(ii). A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words **"CAUTION, RADIOACTIVE MATERIAL"** or **"DANGER, RADIOACTIVE MATERIAL"** and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee described by paragraph (1)(b)(iii) or (iv) of this section:

a. May prepare radioactive drugs for medical use, as defined in Part G.2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraph (2)b and (2)c of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in Part G.

b. May allow a pharmacist to work as an authorized nuclear pharmacist if:

(i) This individual qualifies as an authorized nuclear pharmacist as defined in Part G.2,

(ii) This individual meets the requirements specified in Part G and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with paragraph (2)c of this section.

c. The actions authorized in paragraphs (2)a and (2)b of this section are permitted in spite of more restrictive language in license conditions.

d. May designate a pharmacist (as defined in Part G.2) as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the Agency under this part.

e. Shall provide to the Agency a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Commission or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to paragraphs (2)b(i) and (2)b(iii) of this section, the individual to work as an authorized nuclear pharmacist.

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

a. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

b. Check each instrument for constancy and proper operation at the beginning of each day of use.

(4) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

J. Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to Part G.200 will be approved if:

(1) the applicant satisfies the general requirements specified in C.8.;

(2) the applicant submits evidence that:

a. the generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

b. the manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(3) the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(4) the label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

(5) the label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

a. adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

b. a statement that this generator or reagent kit (as appropriate) is approved for use by persons licensed by the Agency pursuant to Part G.200 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The labels, leaflets or brochures required by C.11.J are in addition to the labeling required by FDA and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

NOTE: Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the Agency for use by persons licensed pursuant to Part G.200 may submit the pertinent information specified in C.11.J.

K. Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part G for use as a calibration or reference source or for the uses listed in Part G.400. and G.500 will be approved if:

(1) The applicant satisfies the general requirements in C.8 of this part.

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

a. the radioactive material contained, its chemical and physical form, and amount,

b. details of design and construction of the source or device,

c. procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

d. for devices containing radioactive material, the radiation profile of a prototype device,

e. details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

f. procedures and standards for calibrating sources and devices,

g. legend and methods for labeling sources and devices as to their radioactive content, and

h. instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, the instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the name of source or device is licensed by the Agency for distribution to persons licensed pursuant to Part G sections G.400. and G.500. or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, provided, that such labeling for sources which do not require long term storage (e.g., gold-198 seeds) may be on a leaflet or brochure which accompanies the source.

(4) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(5) In determining the acceptable interval for test of leakage of radioactive material, the Agency will consider information that includes, but is not limited to:

a. primary containment (source capsule),

b. protection of primary containment,

c. method of sealing containment,

d. containment construction materials,

e. form of contained radioactive material,

f. maximum temperature withstood during prototype tests,

g. maximum pressure withstood during prototype tests,

h. maximum quantity of contained radioactive material,

i. radiotoxicity of contained radioactive material, and

j. operating experience with identical sources or devices or similarly designed and constructed sources or devices.

L. Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.

(1) An application for specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to C.5.D or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

a. the applicant satisfies the general requirements specified in C.8;

b. the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in one year a radiation dose in excess of 10 percent of the limits specified in D.6.; and

c. the applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the Agency will approve an application for a specific license under C.11.L only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The Agency may deny any application for a specific license under C.11.L if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to C.11.L a shall:

a. maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

b. label or mark each unit to:

(i) identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(ii) state that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State;

c. assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

d. (i) furnish a copy of the general license contained in C.5.D and a copy of HHE Form 860 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in C.5.D, or

(ii) furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to C.5.D and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in C.5.D and a copy of HHE Form 860 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in C.5.D;

e. report to the Agency all transfers of industrial products or devices to persons for use under general license in C.5.D. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under C.5.D during the reporting period, the report shall so indicate;

f. (i) report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40,

(ii) report to the responsible State Agency all transfers of devices manufactured and distributed pursuant to C.11.L for use under a general license in that State's regulations equivalent to C.5.D,

(iii) such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person,

(iv) if no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission,

(v) if no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State Agency; and

g. keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in C.5.D or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

12. Special Requirements for Issuance of Specific Licenses for Source Material Milling. *Reserved.*

13. Issuance of Specific Licenses.

A. Upon a determination that an application meets the requirements of the Act and the regulations of the Agency, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

B. The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:

(1) minimize danger to public health and safety or property;

(2) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) prevent loss or theft of material subject to this part.

14. Specific Terms and Conditions of License.

A. Each license issued pursuant to this part shall be subject to all provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

B. No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect and to all valid rules, regulations and orders of the Agency and shall give its consent in writing.

C. Each person licensed by the Agency pursuant to this part shall confine his use and possession of the material licensed to the locations and purposes authorized in the license.

D. Each licensee or registrant shall notify the Agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(1) The licensee;

(2) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(3) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(4) This notification must indicate:

a. The bankruptcy court in which the petition for bankruptcy was filed; and

b. The date of the filing of the petition.

15. Expiration and Termination of Licenses

A. Except as provided in C.16.B and paragraph D of this section, each specific license expires at the end of the day, in the month and year stated in the license.

B. Each licensee shall notify the Agency immediately, in writing, and request termination of the license when the licensee decides to terminate all activities involving materials authorized under the license. The notification and request for termination of the license must include the reports and information specified in paragraphs .E.(1)d and e of this section. The licensee is subject to the provisions of paragraphs E and F of this section, as applicable.

C. Each licensee shall notify the Agency immediately, in writing, and request termination of the license when no principal activities under the license have been conducted for a period of 24 months, or no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements.

D. No less than 30 days before the expiration date specified in a specific license the licensee shall either:

(1) Submit an application for license renewal under C.16; or

(2) Notify the Agency in writing if the licensee decides not to renew the license.

E. (1) If a licensee does not submit an application for license renewal under C.16, the licensee shall, on or before the expiration date specified in the license:

a. Terminate use of radioactive, source, or special nuclear material, as appropriate;

b. Remove radioactive contamination to the extent practicable except for those procedures covered by paragraph C.15.E.(3) of this section;

c. Properly dispose of source material;

d. Submit a completed form, Certificate of Disposition of Material; and

e. Submit a radiation survey report of the premises to confirm the absence of radioactive materials or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner. The licensee shall, as appropriate:

(i) Report levels of radiation in units of microrads per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces and report levels of radioactivity in units of disintegrations per minute (or microcuries) per 100 square centimeters for removable and fixed surfaces, microcuries per milliliter for water, and picocuries per gram for contaminated solids such as soils, or concrete; and

(ii) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(2) If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. If the information submitted under this paragraph and paragraphs .E(1)d and e of this section is adequate, the Agency will notify the licensee in writing that the license is terminated.

(3) a. If detectable levels of residual radioactive contamination attributable to activities conducted under a license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as contamination until the Agency notifies the licensee in writing that the license is terminated. During this time the licensee is subject to the provisions of paragraph E of this section.

b. In addition to the information submitted under paragraphs E.(1)d and e of this section the licensee shall submit a plan for decontamination, if required, as regards residual radioactive contamination remaining at the time the license expires.

c. The licensee shall also submit a plan for completion of decommissioning, recovery, or site reclamation if the procedures necessary to carry these out have not been previously approved by the Agency.

F. The proposed decommissioning, recovery, or site reclamation plan, if required by paragraph C.15.E(3) or by license condition, must include:

(1) Discussion of these planned activities;

(2) Description of methods used to assure protection of workers and the environment against radiation hazards during such activities;

(3) A description of the planned final radiation survey; and

(4) An updated detailed cost estimate, comparison of that estimate with present funds set aside, and plans for assuring the availability of adequate funds for completion of decommissioning, recovery or site reclamation.

(5) The proposed plan will be approved by the Agency if the information therein demonstrates that the objectives of the plan will be completed as soon as is reasonable and that the health and safety of workers and the public will be adequately protected.

G. Each licensee who possesses residual radioactive material, source material, or special nuclear material under paragraph C.15.E(3), following the expiration date specified in the license, shall:

(1) Limit actions involving source radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and

(2) Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the Agency notifies the licensee in writing that the license is terminated.

H. As the final step in decommissioning, the licensee shall-

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting Maine Form HHE-892 or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in D.60 through D.65. The licensee shall, as appropriate-

a. Report levels of gamma radiation in units if millirem per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of microcuries per 100 square centimeters - removable or fixed - for surfaces, microcuries per milliliter for water, and picocuries per gram for solids such as soils or concrete; and

b. Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

I. Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Agency determines that:

(1) Radioactive material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3) a. A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in D.60 through D.65; or
b. Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in D.60 through D.65.

(4) Records required by Part D have been received.

16. Renewal of Licenses.

A. Applications for renewal of specific licenses shall be filed in accordance with C.7.

B. In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the application has been finally determined by the Agency.

17. Amendment of Licenses at Request of Licensee. Applications for amendment of a license shall be filed in accordance with C.7. and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment.

18. Agency Action on Application to Renew and Amend. In considering an application by a licensee to renew or amend his license, the Agency will apply the criteria set forth in C.8, and C.9., C.10 or C.11 and Part E, Part G, and Part K of these regulations as applicable.

19. Persons Possessing a License for Source, Radioactive or Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass on Effective Date of These Regulations. Any person who, on the effective date of these regulations, possesses a general or specific license for source, radioactive, or special nuclear material in quantities not sufficient to form a critical mass, issued by the U.S. Nuclear Regulatory Commission, shall be deemed to possess a like license issued under this part and the Act, such license to expire either 90 days after receipt from the Agency of a notice of expiration of such license, or on the date of expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier.

20. Persons Possessing Naturally Occurring and Accelerator-Produced Radioactive Material on Effective Date of These Regulations. Any person who, on the effective date of these regulations, possesses NARM for which a specific license is required by the Act or this part shall be deemed to possess such a license issued under the Act and this part. Such license shall expire 90 days after the effective date of these regulations; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the Agency. NARM radionuclides are shown in Appendix B to Part C.

21. Transfer of Material.

A. No licensee shall transfer radioactive material except as authorized pursuant to this section.

B. Except as otherwise provided in the license and subject to the provisions of C.21.C and D, any licensee may transfer radioactive material:

(1) to the Agency with prior approval of the agency;

(2) to the U.S. Department of Energy;

(3) to any person exempt from these regulations to the extent permitted under such exemption;

(4) to any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the agency, the U.S. Nuclear Regulatory Commission, any Agreement State or any Licensing State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Agency, any Agreement State or any Licensing State; or

(5) as otherwise authorized by the Agency in writing.

C. Before transferring radioactive material to a specific licensee of the Agency, the U.S Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

D. The following methods for the verification required by C.21.C are acceptable:

(1) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;

(2) the transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

(3) for emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date provided, that the oral certification is confirmed in writing within 10 days;

(4) the transferor may obtain other sources of information compiled by a reporting service from official records of the Agency, the U.S. Nuclear Regulatory Commission, the licensing agency or an Agreement State or a Licensing State as to the identity of licensees and the scope and expiration dates of licenses and registration; or

(5) when none of the methods of verification described in C.21.D (1) through (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain a record confirmation from the Agency, the U.S. Nuclear Regulatory Commission, or the licensing agency of an Agreement State or a Licensing State that the transferee is licensed to receive the radioactive material.

(6) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of Part L.

22. Modification, Revocation and Termination of Licenses.

A. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations and orders issued by the Agency.

B. Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule, regulation, or order of the Agency.

C. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefore, facts of conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

D. The Agency may terminate a specific license upon request submitted by the licensee to the Agency in writing.

23. Deliberate Misconduct.

A. Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's or applicant's activities in this part, may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Agency; or

(2) Deliberately submit to the Agency, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Agency.

B. A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures Part B.

C. For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee, certificate of registration holder or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Agency; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

RECIPROCITY

24. Reciprocal Recognition of Licenses.

A. Licenses of Radioactive, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

(1) Subject to these regulations, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or any Agreement State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State provided that:

a. the licensing document does not limit the activity authorized by such document to specified installations or locations;

b. the out-of-state licensee notifies the Agency in writing at least 3 working days prior to engaging in such activity and receive Agency approval. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document and HHE form 865. If, for a specific case, the 3 working day period would impose an undue hardship on the out-of-state licensee, he may, upon application to the Agency, obtain permission to proceed sooner. The Agency requires that the applicable Maine annual license fee accompany the initial request for reciprocity (see table 1 to appendix A of this part). This reciprocity fee will cover a period of one year from the time of application, at which time a new fee submittal will be required. This requirement does not waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in C.23.A(1).

c. the out-of-state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Agency;

d. the out-of-state licensee supplies such other information as the Agency may request; and

e. the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in C.23.A(1) except by transfer to a person:

(i) specifically licensed by the Agency or by the U.S. Nuclear Regulatory Commission to receive such material, or

(ii) exempt from the requirements for a license for such material under C.3.

(2) Notwithstanding the provisions of C.23.A(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in C.6.B(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in this State provided that: 7

a. the device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an Agreement State;

b. such person shall assure that any labels required to be affixed to the device under regulations of the authority, which licensed manufacture of the device, bear a statement that "Removal of this label is prohibited";

c. Such person shall file Agency Form HHE 867 "Registration Certificate – Service of Generally Licensed devices". The form shall be submitted within 30 days after the first entry or 30 days after the effective date of these regulations for persons in state prior to the effective date. The general licensee shall furnish such information as may be required by that form as well as the annual fee referenced in Appendix A of this Part. This registration fee will cover a period of one year from the time of application, at which time a new fee submittal will be required.

(3) The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency the U.S. Nuclear Regulatory Commission or an Agreement State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

B. Licenses of Naturally Occurring and Accelerator-Produced Radioactive Material.

(1) Subject to these regulations, any person who holds a specific license from any Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State provided that:

a. the licensing document does not limit the activity authorized by such document to specified installations or locations;

b. the out-of-state licensee notifies the Agency in writing at least 3 working days prior to engaging in such activity and receive Agency approval. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document and HHE form 865. If, for a specific case, the 3 working day period would impose an undue hardship on the out-of-state licensee, he may, upon application to the Agency, obtain permission to proceed sooner. The Agency requires that the applicable Maine annual license fee accompany the initial request for reciprocity (see table 1 to appendix A of this part). This reciprocity fee will cover a period of one year from the time of application, at which time a new fee submittal will be required. This requirement does not waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in C.23.B(1).

c. the out-of-state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Agency;

d. the out-of-state licensee supplies such other information as the Agency may request; and

e. the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in C.23.B(1) except by transfer to a person:

(i) specifically licensed by the Agency or by another Licensing State to receive such material, or

(ii) exempt from the requirements for a license for such material under C.3.

(2) Notwithstanding the provisions of C.23.B(1), any person who holds a specific license issued by a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in C.6.B(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in this State provided that:

a. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by a Licensing State;

b. Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

c. Such person shall file Agency Form HHE 867 "Registration Certificate – Service of Generally Licensed devices". The form shall be submitted within 30 days after the first entry or 30 days after the effective date of these regulations for persons in state prior to the effective date. The general licensee shall furnish such information as may be required by that form as well as the annual fee referenced in Appendix A of this Part. This registration fee will cover a period of one year from the time of application, at which time a new fee submittal will be required.

C. The Agency may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

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SCHEDULE A

EXEMPT CONCENTRATIONS OF RADIOACTIVE MATERIALS WHICH ARE INTRODUCED INTO PRODUCTS *(PART C.3.A)*

Element (atomic number)	Isotope	Column I Gas Concentration µCi/ml 1/	Column II Liquid and Solid Concentration µCi/ml 2/
Antimony (51)	Sb-122		$3X10^{-4}$
	Sb-124		$2X10^{-4}$
	Sb-125		$1X10^{-3}$
Argon (18)	Ar-37	$1X10^{-3}$	
	Ar-41	$4X10^{-7}$	
Arsenic (33)	As-73		$5X10^{-3}$
	As-74		$5X10^{-4}$
	As-76		$2X10^{-4}$
	As-77		$8X10^{-4}$
Barium (56)	Ba-131		$2X10^{-3}$
	Ba-140		$3X10^{-4}$
Beryllium (4)	Be-7		$2X10^{-2}$
Bismuth (83)	Bi-206		$4X10^{-4}$
Bromine (35)	Br-82	$4X10^{-7}$	$3X10^{-3}$
Cadmium (48)	Cd-109		$2X10^{-3}$
	Cd-115m		$3X10^{-4}$
	Cd-115		$3X10^{-4}$
Calcium (20)	Ca-45		$9X10^{-5}$
	Ca-47		$5X10^{-4}$
Carbon (6)	C-14	$1X10^{-6}$	$8X10^{-3}$
Cerium (58)	Ce-141		$9X10^{-4}$
	Ce-143		$4X10^{-4}$
	Ce-144		$1X10^{-4}$
Cesium (55)	Cs-131		$2X10^{-2}$
	Cs-134m		$6X10^{-2}$
	Cs-134		$9X10^{-5}$
Chlorine (17)	Cl-38	$9X10^{-7}$	$4X10^{-3}$
Chromium (24)	Cr-51		$2X10^{-2}$
Cobalt (27)	Co-57		$5X10^{-3}$
	Co-58		$1X10^{-3}$
	Co-60		$5X10^{-4}$
Copper (29)	Cu-64		$3X10^{-3}$
Dysprosium (66)	Dy-165		$4X10^{-3}$
	Dy-166		$4X10^{-4}$
Erbium (68)	Er-169		$9X10^{-4}$
	Er-171		$1X10^{-3}$
Europium (63)	Eu-152		$6X10^{-4}$
	(Tr=9.2 hr)		
	Eu-155		$2X10^{-3}$

1/ Values are given in Column I only for those materials normally used as gases.
2/ µCi/gm for solids.

Element (atomic number)	Isotope	Column I Gas Concentration µCi/ml 1/	Column II Liquid and Solid Concentration µCi/ml 2/
Fluorine (9)	F-18	$2X10^{-6}$	$8X10^{-3}$
Gadolinium (64)	Gd-153		$2X10^{-3}$
	Gd-159		$8X10^{-4}$
Gallium (31)	Ga-72		$4X10^{-4}$
Germanium (32)	Ge-71		$2X10^{-2}$
Gold (79)	Au-196		$2X10^{-3}$
	Au-198		$5X10^{-4}$
	Au-199		$2X10^{-3}$
Hafnium (72)	Hf-181		$7X10^{-4}$
Hydrogen (1)	H-3	$5X10^{-6}$	$3X10^{-2}$
Indium (49)	In-113m		$1X10^{-2}$
	In-114m		$2X10^{-4}$
Iodine (53)	I-126	$3X10^{-9}$	$2X10^{-5}$
	I-131	$3X10^{-9}$	$2X10^{-5}$
	I-132	$8X10^{-8}$	$6X10^{-4}$
	I-133	$1X10^{-8}$	$7X10^{-5}$
	I-134	$2X10^{-7}$	$1X10^{-3}$
Iridium (77)	Ir-190		$2X10^{-3}$
	Ir-192		$4X10^{-4}$
	Ir-194		$3X10^{-4}$
Iron (26)	Fe-55		$8X10^{-3}$
	Fe-59		$6X10^{-4}$
Krypton (36)	Kr-85m	$1X10^{-6}$	
	Kr-85	$3X10^{-6}$	
Lanthanum (57)	La-140		$2X10^{-4}$
Lead (82)	Pb-203		$4X10^{-3}$
Lutetium (71)	Lu-177		$1X10^{-3}$
Manganese (25)	Mn-52		$3X10^{-4}$
	Mn-54		$1X10^{-3}$
	Mn-56		$1X10^{-3}$
Mercury (80)	Hg-197m		$2X10^{-3}$
	Hg-197		$3X10^{-3}$
	Hg-203		$2X10^{-4}$
Molybdenum (42)	Mo-99		$2X10^{-3}$
Neodymium (60)	Nd-147		$6X10^{-4}$
	Nd-149		$3X10^{-3}$
Nickel (28)	Ni-65		$1X10^{-3}$
Niobium (Columbium (41)	Nb-95		$1X10^{-3}$
	Nb-97		$9X10^{-3}$
Osmium (76)	Os-185		$7X10^{-4}$
	Os-191m		$3X10^{-2}$
	Os-191		$2X10^{-3}$
	Os-193		$6X10^{-4}$
Palladium (46)	Pd-103		$3X10^{-3}$
	Pd-109		$9X10^{-4}$
Phosphorus (15)	P-32		$2X10^{-4}$

1/ Values are given in Column I only for those materials normally used as gases.
2/ µCi/gm for solids.

Element (atomic number)	Isotope	Column I Gas Concentration µCi/ml 1/	Column II Liquid and Solid Concentration µCi/ml 2/
Platinum (78)	Pt-191		$1X10^{-3}$
	Pt-193m		$1X10^{-2}$
	Pt-197m		$1X10^{-2}$
	Pt-197		$1X10^{-3}$
Potassium (19)	K-42		$3X10^{-3}$
Praseodymium (59)	Pr-142		$3X10^{-4}$
	Pr-143		$5X10^{-4}$
Promethium (61)	Pm-147		$2X10^{-3}$
	Pm-149		$4X10^{-4}$
Rhenium (75)	Re-183		$6X10^{-3}$
	Re-186		$9X10^{-4}$
	Re-188		$6X10^{-4}$
Rhodium (45)	Rh-103m		$1X10^{-1}$
	Rh-105		$1X10^{-3}$
Rubidium (37)	Rb-86		$7X10^{-4}$
Ruthenium (44)	Ru-97		$4X10^{-3}$
	Ru-103		$8X10^{-4}$
	Ru-105		$1X10^{-3}$
	Ru-106		$1X10^{-4}$
Samarium (62)	Sm-153		$8X10^{-4}$
Scandium (21)	Sc-46		$4X10^{-4}$
	Sc-47		$9X10^{-4}$
	Sc-48		$3X10^{-4}$
Selenium (34)	Se-75		$3X10^{-3}$
Silicon (14)	Si-31		$9X10^{-3}$
Silver (47)	Ag-105		$1X10^{-3}$
	Ag-110m		$3X10^{-4}$
	Ag-111		$4X10^{-4}$
Sodium (11)	Na-24		$2X10^{-3}$
Strontium (38)	Sr-85		$1X10^{-3}$
	Sr-91		$7X10^{-4}$
	Sr-92		$7X10^{-4}$
Sulfur (16)	S-35	$9X10^{-8}$	$6X10^{-4}$
Tantalum (73)	Ta-182		$4X10^{-4}$
Technetium (43)	Tc-96m		$1X10^{-1}$
	Sr-89		$1X10^{-4}$
	Tc-96		$1X10^{-3}$
Tellurium (52)	Te-125m		$2X10^{-3}$
	Te-127m		$6X10^{-4}$
	Te-127		$3X10^{-3}$
	Te-129m		$3X10^{-4}$
	Te-131m		$6X10^{-4}$
	Te-132		$3X10^{-4}$
Terbium (65)	Tb-160		$4X10^{-4}$

1/ Values are given in Column I only for those materials normally used as gases.
2/ µCi/gm for solids.

Element (atomic number)	Isotope	Column I Gas Concentration μCi/ml 1/	Column II Liquid and Solid Concentration μCi/ml 2/
Thallium (81)	Tl-200		$4X10^{-3}$
	Tl-201		$3X10^{-3}$
	Tl-202		$1X10^{-3}$
	Tl-204		$1X10^{-3}$
Thulium (69)	Tm-170		$5X10^{-4}$
	Tm-171		$5X10^{-3}$
Tin (50)	Sn-113		$9X10^{-4}$
	Sn-125		$2X10^{-4}$
Tungsten (Wolfram) (74)	W-181		$4X10^{-3}$
	W-187		$7X10^{-4}$
Vanadium (23)	V-48		$3X10^{-4}$
Xenon (54)	Xe-131m	$4X10^{-6}$	
	Xe-133	$3X10^{-6}$	
	Xe-135	$1X10^{-6}$	
Ytterbium (70)	Yb-175		$1X10^{-3}$
Yttrium (39)	Y-90		$2X10^{-4}$
	Y-91m		$3X10^{-2}$
	Y-91		$3X10^{-4}$
	Y-92		$6X10^{-4}$
	Y-93		$3X10^{-4}$
Zinc (30)	Zn-65		$1X10^{-3}$
	Zn-69m		$7X10^{-4}$
	Zn-69		$2X10^{-2}$
Zirconium (40)	Zr-95		$6X10^{-4}$
	Zr-97		$2X10^{-4}$
Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years		$1X10^{-10}$	$1X10^{-6}$

1/ Values are given in Column I only for those materials normally used as gases.
2/ μCi/gm for solids.

NOTE 1: Many radioisotopes disintegrate into isotopes, which are also radioactive. In expressing the concentrations in Schedule A the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of Part C. where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Schedule A for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

EXAMPLE:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} +$$

$$\frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} = 1$$

NOTE 3: To convert μCi/ml to SI units of megabecquerels per liter multiply the above values by 37.

SCHEDULE B

EXEMPT QUANTITIES OF INDIVIDUAL RADIOACTIVE MATERIALS *(C.3.B)*

Radioactive Material	MicroCuries	Radioactive Material	MicroCuries
Antimony-122 (Sb 122)	100	Gallium-67 (Ga 67)	100
Antimony-124 (Sb 124)	10	Gallium-72 (Ga 72)	10
Antimony-125 (Sb 125)	10	Germanium-68 (Ge 68)	10
Arsenic-73 (As 73)	100	Germanium-71 (Ge 71)	100
Arsenic-74 (As 74)	10	Gold-195 (Au 195)	10
Arsenic-76 (As 76)	10	Gold-198 (Au 198)	100
Arsenic-77 (As 77)	100	Gold-199 (Au 199)	100
Barium-131(Ba 131)	10	Hafnium-181 (Hf 181)	10
Barium-133 (Ba 133)	10	Holmium-166 (Ho 166)	100
Barium-140 (Ba 140)	10	Hydrogen-3 (H 3)	1,000
Bismuth-210 (Bi 210)	1	Indium-111 (In 111)	100
Bromine-82 (Br 82)	10	Indium-113m (In 113m)	100
Cadmium-109 (Cd 109)	10	Indium-114m (In 114m)	10
Cadmium-115m Cd 115m)	10	Indium-115m (In 115m)	100
Cadmium-115 (Cd 115)	100	Indium-115 (In 115)	10
Calcium-45 (Ca 45)	10	Iodine-123 (I 123)	100
Calcium-47 (Ca 47)	10	Iodine-125 (I 125)	1
Carbon-14 (C 14)	100	Iodine-126 (I 126)	1
Cerium-141 (Ce 141)	100	Iodine-129 (I 129)	0.1
Cerium-143 (Ce 143)	100	Iodine-131 (I 131)	1
Cerium-144 (Ce 144)	1	Iodine-132 (I 132)	10
Cesium-129 (Cs 129)	100	Iodine-133 (I 133)	1
Cesium-131 (Cs 131)	1,000	Iodine-134 (I 134)	10
Cesium-134m (Cs 134m)	100	Iodine-135 (I 135)	10
Cesium-134 (Cs 134)	1	Iridium-192 (Ir 192)	10
Cesium-135 (Cs 135)	10	Iridium-194 (Ir 194)	100
Cesium-136 (Cs 136)	10	Iron-52 (Fe 52)	10
Cesium-137 (Cs 137)	10	Iron-55 (Fe 55)	100
Chlorine-36 (Cl 36)	10	Iron-59 (Fe 59)	10
Chlorine-38 (Cl 38)	10	Krypton-85 (Kr 85)	100
Chromium-51 (Cr 51)	1,000	Krypton-87 (Kr 87)	10
Cobalt-57 (Co 57)	100	Lanthanum-140 (La 140)	10
Cobalt-58m (Co 58m)	10	Lutetium-177 (Lu 177)	100
Cobalt-58 (Co 58)	10	Manganese-52 (Mn 52)	10
Cobalt-60 (Co 60)	1	Manganese-54 (Mn 54)	10
Copper-64 (Cu 64)	100	Manganese-56 (Mn 56)	10
Dysprosium-165 (Dy 165)	10	Mercury-197m (Hg 197m)	100
Dysprosium-166 (Dy 166)	100	Mercury-197 (Hg 197)	100
Erbium-169 (Er 169)	100	Mercury-203 (Hg 203)	10
Erbium-171 (Er 171)	100	Molybdenum-99 (Mo 99)	100
Europium-152(Eu152)9.2h	100	Neodymium-147 (Nd 147)	100
Europium-152(Eu152)13yr	1	Neodymium-149 (Nd 149)	100
Europium-154 (Eu 154)	1	Nickel-59 (Ni 59)	100
Europium-155 (Eu 155)	10	Nickel-63 (Ni 63)	10
Fluorine-18 (F 18)	1,000	Nickel-65 (Ni 65)	100
Gadolinium-153 (Gd 153)	10	Niobium-93m (Nb 93m)	10
Gadolinium-159 (Gd 159)	100	Niobium-95 (Nb 95)	10

Radioactive Material	MicroCuries	Radioactive Material	MicroCuries
Niobium-97 (Nb 97)	10	Strontium 92 (Sr 92)	10
Osmium-185 (Os 185)	10	Sulphur-35 (S 35)	100
Osmium-191m (Os 191m)	100	Tantalum-182 (Ta 182)	10
Osmium-191 (Os 191)	100	Technetium-96 (Tc 96)	10
Osmium-193 (Os 193)	100	Technetium-97m (Tc 97m)	100
Palladium-103 (Pd 103)	100	Technetium-97 (Tc 97)	100
Palladium-109 (Pd 109)	100	Technetium-99m (Tc 99m)	100
Phosphorus-32 (P 32)	10	Technetium-99 (Tc 99)	10
Platinum-191 (Pt 191)	100	Tellurium-125m (Te 125m)	10
Platinum-193m (Pt 193m)	100	Tellurium-127m (Te 127m)	10
Platinum-193 (Pt 193)	100	Tellurium-127 (Te 127)	100
Platinum-197m (Pt 197m)	100	Tellurium-129m (Te 129m)	10
Platinum-197 (Pt 197)	100	Tellurium-129 (Te 129)	100
Polonium-210 (Po 210)	0.1	Tellurium-131m (Te 131m)	10
Potassium-42 (K 42)	10	Tellurium-132 (Te 132)	10
Potassium-43 (K 43)	10	Terbium-160 (Tb 160)	10
Praseodymium-142(Pr142)	100	Thallium-200 (Tl 200)	100
Praseodymium-143(Pr143)	100	Thallium-201 (Tl 201)	100
Promethium-147 (Pm 147)	10	Thallium-202 (Tl 202)	100
Promethium-149 (Pm 149)	10	Thallium-204 (Tl 204)	10
Rhenium-186 (Re 186)	100	Thulium-170 (Tm 170)	10
Rhenium-188 (Re 188)	100	Thulium-171 (Tm 171)	10
Rhodium-103m (Rh 103m)	100	Tin-113 (Sn 113)	10
Rhodium-105 (Rh 105)	100	Tin-125 (Sn 125)	10
Rubidium-81 (Rb 81)	10	Tungsten-181 (W 181)	10
Rubidium-86 (Rb 86)	10	Tungsten-185 (W 185)	10
Rubidium-87 (Rb 87)	10	Tungsten-187 (W 187)	100
Ruthenium-97 (Ru 97)	100	Vanadium-48 (V 48)	10
Ruthenium-103 (Ru 103)	10	Xenon-131m (Xe 131m)	1,000
Ruthenium-105 (Ru 105)	10	Xenon-133 (Xe 133)	100
Ruthenium-106 (Ru 106)	1	Xenon-135 (Xe 135)	100
Samarium-151 (Sm 151)	10	Ytterbium-175 (Yb 175)	100
Samarium-153 (Sm 153)	100	Yttrium-87 (Y 87)	10
Scandium-46 (Sc 46)	10	Yttrium-88 (Y 88)	10
Scandium-47 (Sc 47)	100	Yttrium-90 (Y 90)	10
Scandium-48 (Sc 48)	10	Yttrium-91 (Y 91)	10
Selenium-75 (Se 75)	10	Yttrium-92 (Y 92)	100
Silicon-31 (Si 31)	100	Yttrium-93 (Y 93)	100
Silver-105 (Ag 105)	10	Zinc-65 (Zn 65)	10
Silver-110m (Ag 110m)	1	Zinc-69m (Zn 69m)	100
Silver-111 (Ag 111)	100	Zinc-69 (Zn 69)	1,000
Sodium-22 (Na 22)	10	Zirconium-93 (Zr 93)	10
Sodium-24 (Na 24)	10	Zirconium-95 (Zr 95)	10
Strontium-85 (Sr 85)	10	Zirconium-97 (Zr 97)	10
Strontium-89 (Sr 89)	1	Any radioactive material not listed above other than alpha emitting radioactive material	0.1
Strontium 90 (Sr 90)	0.1		
Strontium 91 (Sr 91)	10		

NOTE: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above by 37.

SCHEDULE C

LIMITS FOR BROAD LICENSES *(C.10)*

Radioactive Material	Col I* Curies	Col II** Curies	Radioactive Material	Col I* Curies	Col II** Curies
Antimony-122	1	0.01	Gallium-72	10	0.1
Antimony-124	1	0.01	Germanium-71	100	1
Antimony-125	1	0.01	Gold-198	10	0.1
Arsenic-73	10	0.1	Gold-199	10	0.1
Arsenic-74	1	0.01	Hafnium-181	1	0.01
Arsenic-76	1	0.01	Holmium-166	10	0.1
Arsenic-77	10	0.1	Hydrogen-3	100	1
Barium-131	10	0.1	Indium-113m	100	1
Barium-140	1	0.01	Indium-114m	1	0.01
Beryllium-7	10	0.1	Indium-115m	100	1
Bismuth-210	0.1	0.001	Indium-115	1	0.01
Bromine-82	10	0.1	Iodine-125	0.1	0.001
Cadmium-109	1	0.01	Iodine-126	0.1	0.001
Cadmium-115m	1	0.01	Iodine-129	0.1	0.001
Cadmium-115	10	0.1	Iodine-131	0.1	0.001
Calcium-45	1	0.01	Iodine-132	10	0.1
Calcium-47	10	0.1	Iodine-133	1	0.01
Carbon-14	100	1	Iodine-134	10	0.1
Cerium-141	10	0.1	Iodine-135	1	0.01
Cerium-143	10	0.1	Iridium-192	1	0.01
Cerium-144	0.1	0.001	Iridium-194	10	0.1
Cesium-131	100	1	Iron-55	10	0.1
Cesium-134m	100	1	Iron-59	1	0.01
Cesium-134	0.1	0.001	Krypton-85	100	1
Cesium-135	1	0.01	Krypton-87	10	0.1
Cesium-136	10	0.1	Lanthanum-140	1	0.01
Cesium-137	0.1	0.001	Lutetium-177	10	0.1
Chlorine-36	1	0.01	Manganese-52	1	0.01
Chlorine-38	100	1	Manganese-54	1	0.01
Chromium-51	100	1	Manganese-56	10	0.1
Cobalt-57	10	0.1	Mercury-197m	10	0.1
Cobalt-58m	100	1	Mercury-197	10	0.1
Cobalt-58	1	0.01	Mercury-203	1	0.01
Cobalt-60	0.1	0.001	Molybdenum-99	10	0.1
Copper-64	10	0.1	Neodymium-147	10	0.1
Dysprosium-165	100	1	Neodymium-149	10	0.1
Dysprosium-166	10	0.1	Nickel-59	10	0.1
Erbium-169	10	0.1	Nickel-63	1	0.01
Erbium-171	10	0.1	Nickel-65	10	0.1
Europium-152(9.2h	10	0.1	Niobium-93m	1	0.01
Europium-152(13y)	0.1	0.001	Niobium-95	1	0.01
Europium-154	0.1	0.001	Niobium-97	100	1
Europium-155	1	0.01	Osmium-185	1	0.01
Fluorine-18	100	1	Osmium-191m	100	1
Gadolinium-153	1	0.01	Osmium-191	10	0.1
Gadolinium-159	10	0.1	Osmium-193	10	0.1

* Type B Specific license ** Type C Specific license

Radioactive Material	Col I* Curies	Col II** Curies	Radioactive Material	Col I* Curies	Col II** Curies
Palladium-103	10	0.1	Technetium-96	10	0.1
Palladium-109	10	0.1	Technetium-97m	10	0.1
Phosphorus-32	1	0.01	Technetium-97	10	0.1
Platinum-191	10	0.1	Technetium-99m	100	1
Platinum-193m	100	1	Technetium-99	1	0.01
Platinum-193	10	0.1	Tellurium-125m	1	0.01
Platinum 197m	100	1	Tellurium-127m	1	0.01
Platinum-197	10	0.1	Tellurium-127	10	0.1
Polonium-210	0.01	0.0001	Tellurium-129m	1	0.01
Potassium-42	1	0.01	Tellurium-129	100	1
Praseodymium-142	10	0.1	Tellurium-131m	10	0.1
Praseodymium-143	10	0.1	Tellurium-132	1	0.01
Promethium-147	1	0.01	Terbium-160	1	0.01
Promethium-149	10	0.1	Thallium-200	10	0.1
Radium-226	0.01	0.0001	Thallium-201	10	0.1
Rhenium-186	10	0.1	Thallium-202	10	0.1
Rhenium-188	10	0.1	Thallium-204	1	0.01
Rhodium-103m	1,000	10	Thulium-170	1	0.01
Rhodium-105	10	0.1	Thulium-171	1	0.01
Rubidium-86	1	0.01	Tin-113	1	0.01
Rubidium-87	1	0.01	Tin-125	1	0.01
Ruthenium-97	100	1	Tungsten-181	1	0.01
Ruthenium-103	1	0.01	Tungsten-185	1	0.01
Ruthenium-105	10	0.1	Tungsten-187	10	0.1
Ruthenium-106	0.1	0.001	Vanadium-48	1	0.01
Samarium-151	1	0.01	Xenon-131m	1,000	10
Samarium-153	10	0.1	Xenon-133	100	1
Scandium-46	1	0.01	Xenon-135	100	1
Scandium-47	10	0.1	Ytterbium-175	10	0.1
Scandium-48	1	0.01	Yttrium-90	1	0.01
Selenium-75	1	0.01	Yttrium-91	1	0.01
Silicon-31	10	0.1	Yttrium-92	10	0.1
Silver-105	1	0.01	Yttrium-93	1	0.01
Silver-110m	0.1	0.001	Zinc-65	1	0.01
Silver-111	10	0.1	Zinc-69m	10	0.1
Sodium-22	0.1	0.001	Zinc-69	100	1
Sodium-24	1	0.01	Zirconium-93	1	0.01
Strontium-85m	1,000	10	Zirconium-95	1	0.01
Strontium-85	1	0.01	Zirconium-97	1	0.01
Strontium-89	1	0.01	Any radioactive material other than source material, special nuclear material or alpha emitting radioactive material not listed above.	0.1	0.001
Strontium-90	0.01	0.0001			
Strontium-91	10	0.1			
Strontium-92	10	0.1			
Sulphur-35	10	0.1			
Tantalum-182	1	0.01			

* Type B Specific license ** Type C Specific license

NOTE 1: To convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by 37.

SCHEDULE D

QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

Radioactive Material[1]	Release Fraction	Quantity (curies)	Radioactive Material	Release Fraction	Quantity (curies)
Actinium-228	0.001	4,000	Krypton-85	1	6,000,000
Americium-241	0.001	2	Lead-210	0.01	8
Americium-242	0.001	2	Manganese-56	0.01	60,000
Americium-243	0.001	2	Mercury-203	0.01	10,000
Antimony-124	0.01	4,000	Molybdenum-99	0.01	30,000
Antimony-126	0.01	6,000	Neptunium-237	0.001	2
Barium-133	0.01	10,000	Nickel-63	0.01	20,000
Barium-140	0.01	30,000	Niobium-94	0.01	300
Bismuth-207	0.01	5,000	Phosphorus-32	0.5	100
Bismuth-210	0.01	600	Phosphorus-33	0.5	1,000
Cadmium-109	0.01	1,000	Polonium-210	0.01	10
Cadmium-113	0.01	80	Potassium-42	0.01	9,000
Calcium-45	0.01	20,000	Promethium-145	0.01	4,000
Californium-252	0.001	9 (20 mg)	Promethium-147	0.01	4,000
Carbon-14 (NonCO_2)	0.01	50,000	Ruthenium-106	0.01	200
Cerium-141	0.01	10,000	Samarium-151	0.01	4,000
Cerium-144	0.01	300	Scandium-46	0.01	3,000
Cesium-134	0.01	2,000	Selenium-75	0.01	10,000
Cesium-137	0.01	3,000	Silver-110m	0.01	1,000
Chlorine-36	0.5	100	Sodium-22	0.01	9,000
Chromium-51	0.01	300,000	Sodium-24	0.01	10,000
Cobalt-60	0.001	5,000	Strontium-89	0.01	3,000
Copper-64	0.01	200,000	Strontium-90	0.01	90
Curium-242	0.001	60	Sulphur-35	0.5	900
Curium-243	0.001	3	Technetium-99	0.01	10,000
Curium-244	0.001	4	Technetium-99m	0.01	400,000
Curium-245	0.001	2	Tellurium-127m	0.01	5,000
Europium-152	0.01	500	Tellurium-129m	0.01	5,000
Europium-154	0.01	400	Terbium-160	0.01	4,000
Europium-155	0.01	3,000	Thulium-170	0.01	4,000
Gadolinium-153	0.01	5,000	Tin-113	0.01	10,000
Germanium-68	0.01	2,000	Tin-123	0.01	3,000
Gold-198	0.01	30,000	Tin-126	0.01	1,000
Hafnium-172	0.01	400	Titanium-44	0.01	100
Hafnium-181	0.01	7,000	Vanadium-48	0.01	7,000
Holmium-166m	0.01	100	Xenon-133	1	900,000
Hydrogen-3	0.5	20,000	Yttrium-91	0.01	2,000
Indium-114m	0.01	1,000	Zinc-65	0.01	5,000
Iodine-125	0.5	10	Zirconium-93	0.01	400
Iodine-131	0.5	10	Zirconium-95	0.01	5,000
Iridium-192	0.001	40,000			
Iron-55	0.01	40,000			
Iron-59	0.01	7,000			

Radioactive Material[1]	Release Fraction	Quantity (curies)	Radioactive Material	Release Fraction	Quantity (curies)
Any other beta-gamma emitter	0.01	10,000	Irradiated material, solid noncombustible	0.001	10,000
Mixed fission products	0.01	1,000	Mixed radioactive waste, beta-gamma[2]	0.01	1,000
Mixed corrosion products	0.01	10,000	Packaged mixed waste, beta-gamma	0.001	10,000
Contaminated equipment beta-gamma	0.001	10,000	Any other alpha emitter	0.001	2
			Contaminated equipment alpha	0.0001	20
Irradiated material, any form other than solid noncombustible	0.01	1,000	Packaged waste, alpha[2]/	0.0001	20
			Combinations of radioactive materials listed above[1]/		

1/ For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in schedule C exceeds one.

2/ Waste packaged in Type B containers does not require an emergency plan.

APPENDIX A

GENERAL PROVISIONS

A. Purpose.

The regulations in this part set out fees charged for licensing services rendered by the State of Maine, Radiation Control Program (the Agency), as authorized under 22 MRSA Section 690 of Maine's Radiation Protection Act.

B. Scope.

Except for persons who apply for or hold the permits, licenses, or approvals exempted in Part C, the regulations in this section apply to a person who is:

1. An applicant for or holder of a specific radioactive material license, NARM material, source material, or special nuclear material license issued pursuant to Part C of these rules;

2. An applicant for or holder of specific approval of shipping containers issued pursuant to Part L of these rules;

3. An applicant for or holder of a specific approval of sealed sources and devices containing radioactive material, NARM material, source material, or special nuclear material;

4. Required to have routine and non-routine safety and safeguards inspections of activities licensed pursuant to the requirements of these rules; or

5. An applicant for or holder of a license, approval, determination, or other authorization issued by the Agency pursuant to Parts D.22 and D.25 of these rules.

6. An applicant for or holder of a general license established by any of Parts C.5.E, C.6.B, or C.6.F of these rules.

C. Definitions. As used in this part:

1. **Materials license** means a radioactive, NARM, or a source material license issued pursuant to Part C of these rules.

2. **Sealed source** means any radioactive material, or NARM material that is encased in a capsule designed to prevent leakage or escape of the material.

3. **Inspection** means:

   a. Routine inspections designed to evaluate the licensee's activities within the context of the licensee having primary responsibility for protection of the public and environment.

   b. Non-routine inspections in response or reaction to an incident, allegation, follow-up to inspection deficiencies or inspections to determine implementation of safety issues. A non-routine or reactive inspection has the same purpose as the routine inspection.

4. **State agency** means any executive department, commission, independent establishment, corporation, wholly or partly owned by the State of Maine, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the State.

D. Exemptions.

1. No application fees, annual fees, amendment fees , or inspection fees shall be required for:

   a. A license authorizing the export only of a production or utilization facility.

   b. A license authorizing the export only or import only of radioactive material, source material or special nuclear material.

2. A license authorizing the use of source material as shielding only in devices and containers, provided, however, that all other licensed radioactive material, source material, or special nuclear material in the device or container will be subject to the fees prescribed in Table 1 of this appendix.

E. Payment of fees.

1. Application fees. Each application for which a fee is prescribed shall be accompanied by a remittance in the full amount of the fee. No application will be accepted for filing or processed prior to payment of the full amount specified. Applications for which no remittance is received may be returned to the applicant. All application fees will be charged irrespective of the Agency's disposition of the application or withdrawal of the application.

2. Full cost. For each application on which the review charges are based on full costs and the application has been pending with the Agency for six months or longer, the first bill for accumulated costs will be sent and will include all of the applicable review time and contractual costs expended. Thereafter, each applicant will be billed at six-month intervals or when the review is completed, whichever is earlier. Each bill will identify the applications and the costs related to each.

3. Non-routine inspection fees. Non-routine inspection fees are payable upon notification by the Agency. Inspection costs will include preparation time, time on site and documentation time and any associated contractual service costs but will exclude the time involved by the staff in the processing and issuance of a notice of violation or civil penalty.

4. Annual fees. A license fee based upon the type of license, number of sources and/or gauges shall be assessed on an annual basis. The licensee has sixty (60) days from the postmark date of the Radioactive Materials License Annual Fees Invoice notice to submit payment in full unless special arrangements are made with the Agency. Failure to pay the annual fee by the due date will result in a penalty not to exceed 9% of the unpaid fee compounded monthly. Failure to remit full payment within six (6) months could , at the Agency's discretion, result in the initiation of license termination procedures.

5. Method of payment. Fee payments shall be by check, draft, or money order made payable to the Treasurer, State of Maine.

F. Average cost per professional staff-hour. Fees for permits, licenses, amendments, renewals, special projects and inspections will be calculated based upon the full costs for the review.

TABLE 1 to Appendix A

RADIOACTIVE MATERIALS SPECIFIC LICENSE AND INSPECTION FEE SCHEDULE

LICENSE CATEGORY	APPLICATION	ANNUAL	NON-ROUTINE INSPECTION
1. SPECIAL NUCLEAR MATERIAL			
A. Sealed sources in devices	$500.00	$ 500.00[5]	$1,300.00
B. Pacemakers	$500.00	$350.00	$800.00
C. Other except critical	$690.00	$1,000.00	$800.00
D. Termination	$500.00	Full cost	
2. SOURCE MATERIAL			
A. Shielding	$110.00	$ 350.00	$350.00
B. Other	$790.00	$1,000.00	$1,500.00
C. Termination	$500.00	Full cost	
3. RADIOACTIVE MATERIAL, NATURALLY OCCURRING RADIOACTIVE MATERIAL OR ACCELERATOR PRODUCED MATERIAL			
A. Processing or manufacturing for commercial distribution			
1. Broad Scope A	$2,300.00	$3,000.00	$2,100.00
2. Broad Scope B	$2,300.00	$3,000.00	$2,100.00
3. Broad Scope C	$2,300.00	$3,000.00	$2,100.00
4. Other	$1,300.00	$1,750.00	$2,000.00
B. Radiopharmaceuticals, reagent kits, sources and devices.			
1. Processing, manufacturing and distribution. This category includes nuclear pharmacies.	$3,400.00	$2,000.00	$1,900.00
2. Distribution only	$1,100.00	$750.00	$1,200.00
C. Sealed sources for irradiation			
1. Fixed, self shielded	$500.00	$500.00	$690.00
2. Exposed source < 10,000 Ci.	$1,200.00	$1,500.00	$1,300.00
3. Exposed source > 10,000 Ci.	$4,600.00	$3,000.00	$1,400.00
D. Distribution to persons exempt (NARM)			
1. Device review required	$2,100.00	$750.00	$690.00
2. No device review required	$2,600.00	$750.00	$690.00
E. Distribution to persons generally licensed			
1. SSD review required	$2,500.00	$750.00	$690.00
2. No SSD review required	$1,900.00	$750.00	$690.00
F. Research and development, no commercial distribution			
1. Broad Scope A	$2,300.00	$1,250.00	$1,200.00
2. Broad Scope B	$2,300.00	$1,000.00	$1,200.00
3. Broad Scope C	$2,300.00	$750.00	$1,200.00
4. Other	$1,100.00	$750.00	$930.00
G. Services for other licensees	$1,400.00	$750.00	$690.00
H. Industrial radiography	$3,000.00	$2,000.00	$2,500.00
I. All other radioactive and NARM, except 4A through 8D			
1. Portable gauges	$500.00	500.00[5]	$1,200.00
2. Fixed gauges	$500.00	$500.00[5]	$1,200.00
3. X-ray Fluorescence	$500.00	$ 500.00[5]	$1,200.00
4. Laboratory services	$500.00	$350.00	$1,200.00
5. Storage only	$500.00	$350.00	$1,200.00
6. In-Vitro laboratories	$500.00	$500.00	$1,200.00

LICENSE CATEGORY	APPLICATION	ANNUAL	NON-ROUTINE INSPECTION
7. Gas Chromatographs	$500.00	$350.00	$1,200.00
8. Other	$500.00	$500.00	$1,200.00
4. WASTE DISPOSAL SERVICES			
A. Packaging or repackaging	$2,800.00	$2,500.00	$1,600.00
B. Transferal to another person	$1,900.00	$1,000.00	$2,100.00
C. Incineration or other treatment	$500.00 + full cost	Full cost	
5. WELL LOGGING			
A. Well logging and tracer studies	$3,400.00	$1,000.00	$800.00
B. Field flooding tracer studies	$500.00 + full cost	$1,750.00	$1,200.00
6. NUCLEAR LAUNDRIES	$1,400.00	$2,000.00	$1,900.00
7. HUMAN USE			
A. Teletherapy Devices	$3,400.00	$1,750.00	$1,900.00
B. . Broad Scope	$2,300.00	$2,500.00	$1,800.00
C. Other Medical Use			
1. G.100 – Unsealed radioactive material for uptake, dilution, and excretion studies - written directive not required	$710.00	$750.00	$1,500.00
2. G.200 – Unsealed radioactive material for imaging and localization studies - written directive not required	$710.00	$1,000.00[6]	$1,500.00
3. G.300 – Unsealed radioactive material - written directive required	$710.00	$1,000.00[6]	$1,500.00
4. G.400 – Manual brachytherapy	$710.00	$1,000.00[6]	$1,500.00
5. G.500 – Sealed sources for diagnosis	$710.00	$500.00	$1,500.00
6. Mobile Nuclear Van	$710.00	$1,200.00	$1,500.00
7. HDR Brachytherapy	$710.00	$1,750.00	$1,900.00
8. Gamma Knife Devices	$710.00	$1,750.00	$1,900.00
8. CIVIL DEFENSE ACTIVITIES	$580.00	$350.00	$690.00
9. DEVICE, PRODUCT OR SEALED SOURCE SAFETY EVALUATION			
A. Devices, for commercial dist.	$3,300.00		
B. Devices, single applicant	$2,000.00		
C. Sources, for commercial dist.	$750.00		
D. Sources, single applicant	$750.00		
10. GENERAL LICENSE REGISTRATION			
A. Submission of form HHE-860	$100.00	$100.00	$1200.00
B. Submission of form HHE-861	$25.00	$25.00	$1200.00
C. Submission of form HHE-862	$100.00	$100.00	$1200.00
D. Submission of form HHE-863	$100.00	$100.00	$1200.00
E. Submission of form HHE-867	$100.00	$100.00	$1200.00

1. Types of material license fees - Separate charges as shown in the schedule will be assessed for applications for new licenses and approvals, issuance of new licenses and approvals, and amendments to existing licenses and approvals. The following guidelines apply to these charges:

   a. Application fees - Applications for materials licenses and approvals must be accompanied by the prescribed application fee for each category, except that applications for licenses covering more than one fee category of special nuclear material or source material to be used at the same location, must be accompanied by the prescribed application fee for the highest fee category. When a license or approval has expired, the application fee for each category shall be due, except for licenses covering more than one fee category of special nuclear material or source material for use at the same location, in which case the application fee for the highest category applies.

   b. License/approval fees - For new licenses and approvals issued in fee Categories 1D, 2C, 4C, and 5B, the recipient shall pay the license or approval fee for each category, as determined by the Agency in accordance with Part E of this Appendix except that a license covering more than one fee category of special nuclear material in Categories 1A through 1D or source material in fee Categories 2A through 2C must pay a license fee for the highest fee category assigned to the license.

   c. Amendment fees - Applications for amendments must be accompanied by the minimum amendment fee of $50.00. The Agency will compute the final amendment fee based upon actual costs, but not more than $500.00, and the applicant will be billed at the completion of the licensing action.

2. Material license fees will not be charged for orders issued by the Agency pursuant to Part B.8 nor for amendments resulting specifically from such orders. However, fees will be charged for approvals issued pursuant to a specific exemption provision of the Agency's regulations regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. In addition to the fee shown, an applicant may be assessed an additional fee for sealed source and device evaluations as shown in Categories 9A through 9D.

3. Types of inspections - Separate charges as shown in this schedule will be the maximum amount assessed for each non-routine inspection, which is performed. The amount that will be charged to the licensee will be based on the staff time and contractual costs expended by the agency.

4. A licensee who is authorized to use licensed radioactive materials at multiple locations that are not immediately adjacent, or on the same campus, will be assessed an additional 25% of their annual fee. This does not apply to broad scope licensees.

5. The following scale of additional fees will be added to the stated annual fee as applicable from the licensed quantity. If a licensee is authorized for use under fee categories 1.A, 3.I.1, and/or 3.I.3 the total number of gauges authorized under all types are cumulative. If more than one of the remaining fee categories also applies to a licensee only the highest fee will be charged.

License Category	1 to 5 gauges	6 to 15 gauges	16 gauges plus
1.A.	0	$ 250.00	$ 500.00
3.I.1.	0	$ 250.00	$ 500.00
3.I.3.	0	$ 250.00	$ 500.00
License Category	**1 to 10 gauges**	**11 to 30 gauges**	**31 gauges plus**
3.I.2.	0	$ 250.00	$ 500.00

6. The license fee categories 7.C.1 through 7.C.5 will be charged the stated fee if any of the categories are authorized singly. If multiple categories are authorized an additional fee of $500.00 per category will be added to the annual fee of the highest fee category. If any of the categories 7.C.2 through 7.C.4 are authorized then authorization for 7.C.1 will not incur an additional fee.

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APPENDIX B

NATURALLY OCCURRING OR ACCELERATOR PRODUCED RADIOACTIVE MATERIAL (NARM)

Examples of Naturally Occurring Radioactive Materials. (Naturally occurring radioactive material is any material of natural origin that emits radiation spontaneously, excluding uranium, thorium, and the tailings produced in their extraction)

Hydrogen-3	Indium-115	Lead-210
Beryllium-7	Lanthanum-138	Lead-212
Beryllium-10	Cerium-142	Bismuth-210
Carbon-14	Neodymium-144	Bismuth-212
Sodium-22	Samarium-147	Polonium-210
Silicon-32	Samarium-148	Radon-220
Phosphorus-32	Samarium-149	Radon-222
Phosphorus-33	Gadolinium-152	Radium-224
Sulfur-35	Hafnium-174	Radium-226
Chlorine-36	Lutetium-176	Radium-228
Chlorine-39	Rhenium-187	Actinium-227
Potassium-40	Platinum-190	Actinium-228
Vanadium-50	Platinum-192	Protoactinium-231
Rubidium-87	Lead-204	

Examples of Accelerator-Produced Radioactive Materials. (Accelerator- produced radioactive material is any material made radioactive (emits radiation spontaneously) by a particle accelerator)

Carbon-11	Zinc-62	Iodine-124
Nitrogen-13	Gallium-66	Iodine-125*
Oxygen-15	Gallium--67	Iodine-126
Fluorine-18	Germanium-68	Xenon-127
Sodium-22	Arsenic-73	Cesium-131
Magnesium-28	Selenium-73	Promethium-145
Aluminum-28	Bromine-77	Dysprosium-157
Phosphorus-33	Krypton-77	Osmium-190
Argon-37	Krypton-81	Iridium-190
Potassium-43	Rubidium-81	Iridium-190ml
Scandium-49	Rubidium-82	Platinum-193m
Manganese-52	Rubidium-84	Gold-195
Iron-52	Strontium-82	Mercury-197
Cobalt-57	Strontium-87m	Thallium-199
Cobalt-58	Yttrium-87	Thallium-201
Copper-62	Technetium-97m	Lead-203
Copper-67	Indium-111	Bismuth-204
Zinc-62	Iodine-123	

* Excludes Iodine-125 as radioactive material, which requires licensing by either the U.S. Nuclear Regulatory Commission or an Agreement State.

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APPENDIX C

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND PARENT COMPANY GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

A. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

B. Financial Test

1. To pass the financial test, the parent company must meet the criteria of either paragraph 1.a or 2.a of this section:

   a. The parent company must have:

      (1) Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and

      (2) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof (Tangible net worth shall be calculated to exclude the net book value of the nuclear unit(s)); and

      (3) Tangible net worth of at least $10 million; and

      (4) Assets located in the United States amounting to at least 90 percent of the total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof.

   b. The parent company must have:

      (1) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or AAA, AA, A, or BAA as issued by Moody's; and

      (2) Tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof (Tangible net worth shall be calculated to exclude the net book value of the nuclear unit(s)); and

      (3) Tangible net worth of at least $10 million; and

      (4) Assets located in the United States amounting to at least 90 percent of the total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof.

2. The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform the Agency within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

3. a. After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

   b. If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the Agency of intent to establish alternate financial assurance as specified in the Agency's regulations. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

C. Parent Company Guarantee. The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

1. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Agency, as evidenced by the return receipts.

2. If the licensee fails to provide alternate financial assurance as specified in the Agency's regulations within 90 days after receipt by the licensee and Agency of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

3. The parent company guarantee and financial test provisions must remain in effect until the Agency has terminated the license.

4. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

APPENDIX D

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

A. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section B of this appendix. The terms of the self-guarantee are in Section C of this appendix. This appendix establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self-guarantee.

B. Financial Test

1. To pass the financial test, a company must meet all of the following criteria:

   a. Tangible net worth at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used), or, for a power reactor licensee, at least 10 times the amount of decommissioning funds being assured by a self guarantee, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all reactor units or parts thereof (Tangible net worth shall be calculated to exclude the net book value of the nuclear unit(s)).

   b. Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used), or, for a power reactor licensee, at least 10 times the amount of decommissioning funds being assured by a self guarantee, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all reactor units or parts thereof.

   c. A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.

2. To pass the financial test, a company must meet all of the following additional requirements:

   a. The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

   b. The company's independent certified public accountant must have compared the data used by the company in the financial test, which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

   c. After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

3. If the licensee no longer meets the requirements of Section B.2. of this appendix, the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in the Agency's regulations within 120 days of such notice.

C. Company Self-Guarantee. The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

1. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Agency, as evidenced by the return receipt.

2. The licensee shall provide alternative financial assurance as specified in the Agency's regulations within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

3. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

4. The licensee will promptly forward to the Agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

5. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of Section B.1. of this appendix.

6. The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

APPENDIX E

QUANTITIES FOR USE WITH DECOMMISSIONING

Material	Microcurie*	Material	Microcurie*
Americium-241	0.01	Germanium-71	100
Antimony-122	100	Gold-198	100
Antimony-124	10	Gold-199	100
Antimony-125	10	Hafnium-181	10
Arsenic-73	100	Holmium-166	100
Arsenic-74	10	Hydrogen-3	1,000
Arsenic-76	10	Indium-113m	100
Arsenic-77	100	Indium-114m	10
Barium-131	10	Indium-115m	100
Barium-133	10	Indium-115	10
Barium-140	10	Iodine-125	1
Bismuth-210	1	Iodine-126	1
Bromine-82	10	Iodine-129	0.1
Cadmium-109	10	Iodine-131	1
Cadmium-115m	10	Iodine-132	10
Cadmium-115	100	Iodine-133	1
Calcium-45	10	Iodine-134	10
Calcium-47	10	Iodine-135	10
Carbon-14	100	Iridium-192	10
Cerium-141	100	Iridium-194	100
Cerium-143	100	Iron-55	100
Cerium-144	1	Iron-59	10
Cesium-131	1,000	Krypton-85	100
Cesium-134m	100	Krypton-87	10
Cesium-134	1	Lanthanum-140	10
Cesium-135	10	Lutetium-177	100
Cesium-136	10	Manganese-52	10
Cesium-137	10	Manganese-54	10
Chlorine-36	10	Manganese-56	10
Chlorine-38	10	Mercury-197m	100
Chromium-51	1,000	Mercury-197	100
Cobalt-58m	10	Mercury-203	10
Cobalt-58	10	Molybdenum-99	100
Cobalt-60	1	Neodymium-147	100
Copper-64	100	Neodymium-149	100
Dysprosium-165	10	Nickel-59	100
Dysprosium-166	100	Nickel-63	10
Erbium-169	100	Nickel-65	100
Erbium-171	100	Niobium-93m	10
Europium-152 (9.2 h)	100	Niobium-95	10
Europium-152 (13 yr)	1	Niobium-97	10
Europium-154	1	Osmium-185	10
Europium-155	10	Osmium-191m	100
Florine-18	1,000	Osmium-191	100
Gadolinium-153	10	Osmium-193	100
Gadolinium-159	100	Palladium-103	100
Gallium-72	10	Palladium-109	100

* To convert µCi to kBq, multiply the µCi value by 37.

QUANTITIES FOR USE WITH DECOMMISSIONING

Material	Microcurie*	Material	Microcurie*
Phosphorus-32	10	Technetium-97m	100
Platinum-191	100	Technetium-97	100
Platinum-193m	100	Technetium-99m	100
Platinum-193	100	Technetium-99	10
Platinum-197m	100	Tellurium-125m	10
Platinum-197	100	Tellurium-127m	10
Plutonium-239	0.01	Tellurium-127	100
Polonium-210	0.1	Tellurium-129m	10
Potassium-42	10	Tellurium-129	100
Praseodymium-142	100	Tellurium-131m	10
Praseodymium-143	100	Tellurium-132	10
Promethium-147	10	Terbium-160	10
Promethium-149	10	Thallium-200	100
Radium-226	0.01	Thallium-201	100
Rhenium-186	100	Thallium-202	100
Rhenium-188	100	Thallium-204	10
Rhodium-103m	100	Thorium (natural)**	100
Rhodium-105	100	Thulium-170	10
Rubidium-86	10	Thulium-171	10
Rubidium-87	10	Tin-113	10
Ruthenium-97	100	Tin-125	10
Ruthenium-103	10	Tungsten-181	10
Ruthenium-105	10	Tungsten-185	10
Ruthenium-106	1	Tungsten-187	100
Samarium-153	100	Uranium (natural)***	100
Scandium-46	10	Uranium-233	0.01
Scandium-47	100	Uranium-234	0.01
Scandium-48	10	Uranium-235	0.01
Selenium-75	10	Vanadium-48	10
Silicon-31	100	Xenon-131m	1,000
Silver-105	10	Xenon-133	100
Silver-llOm	1	Xenon-135	100
Silver-111	100	Ytterbium-175	100
Sodium-22	1	Yttrium-90	10
Sodium-24	10	Yttrium-91	10
Strontium-85	10	Yttrium-92	100
Strontium-89	1	Yttrium-93	100
Strontium-90	0.1	Zinc-65	10
Strontium-91	10	Zinc-69m	100
Strontium-92	10	Zinc-69	1,000
Sulfur –35	100	Zirconium-93	10
Tantalum-182	10	Zirconium-95	10
Technetium-96	10	Zirconium-97	10

* To convert µCi to kBq, multiply the µCi value by 37.
** Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.
*** Based on alpha disintegration rate of U-238, U-234, and U-235.

QUANTITIES FOR USE WITH DECOMMISSIONING

Material	Microcurie*
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.01
Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1

* To convert µCi to kBq, multiply the µCi value by 37.

NOTE: Where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" -- that is, unity.

PART D

STANDARDS FOR PROTECTION AGAINST RADIATION

GENERAL PROVISIONS

1. **Purpose.**

   A. Part D establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Agency. These regulations are issued pursuant to the 22 MRSA, the Radiation Control Act.

   B. The requirements of Part D are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in Part D. However, nothing in Part D shall be construed as limiting actions that may be necessary to protect health and safety.

2. **Scope.** Except as specifically provided in other Parts of these regulations, Part D applies to persons licensed or registered by the Agency to receive, possess, use, transfer, or dispose of sources of radiation. The limits in Part D do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with Part G, or to voluntary participation in medical research programs.

3. **Definitions.** As used in this part, the following definitions apply:

   Annual limit on intake (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B.

   Class means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days , and for Class Y, Years, of greater than 100 days. For purposes of these regulations, "lung class" and "inhalation class" are equivalent terms.

   Declared pregnant woman means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

   Derived air concentration (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B.

   Derived air concentration-hour (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

Dosimetry processor means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

Inhalation class [see "Class"].

Lung class [see "Class"].

Nonstochastic effect means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation- induced cataract formation is an example of a nonstochastic effect. For purposes of these regulations, "deterministic effect" is an equivalent term.

Planned special exposure means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

Quarter means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

Reference Man means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the Reference Man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

Respiratory protection device means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

Sanitary sewerage means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

Stochastic effect means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these regulations, "probabilistic effect" is an equivalent term.

Very high radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rads) in 1 hour at 1 meter from a source of radiation or 1 meter from any surface that the radiation penetrates.[1]/

[1]/ At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.

Weighting factor w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS

Organ/Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[a]
Whole Body	**1.00[b]**

a 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

b For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, w_T = 1.0, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

4. Implementation.

A. Any existing license or registration condition that is more restrictive than Part D remains in force until there is an amendment or renewal of the license or registration.

B. If a license or registration condition exempts a licensee or registrant from a provision of Part D in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of Part D.

C. If a license or registration condition cites provisions of Part D in effect prior to January 1, 1994, which do not correspond to any provisions of Part D, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

RADIATION PROTECTION PROGRAMS

5. Radiation Protection Programs.

A. Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of Part D. See D.41 for record keeping requirements relating to these programs.

B. The licensee or registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

C. The licensee or registrant shall periodically (at least annually), review the radiation protection program content and implementation.

D. To implement the ALARA requirements of D.5. B and notwithstanding the requirements in D.14, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees other than those subject to 10 CFR Part 50.34a of the USNRC regulations, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 0.1mSv (10 mrem) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in D.53 and promptly take appropriate corrective action to ensure against recurrence.

OCCUPATIONAL DOSE LIMITS

6. Occupational Dose Limits for Adults.

A. The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to D.11, to the following dose limits:

(1) An annual limit, which is the more limiting of:

a. The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

b. The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem).

(2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

a. A lens dose equivalent of 0.15 Sv (15 rem), and

b. A shallow dose equivalent of 0.5 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.

B. Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See D.11.E.(1) and (2).

C. The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure determined as follows:

(1) The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep dose equivalent, lens dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable; or

(2) (*Reserved.*)

D. Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See D.46.

E. Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix B.

F. The licensee or registrant 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. See D.10.E.

7. Compliance with Requirements for Summation of External and Internal Doses.

A. If the licensee or registrant is required to monitor pursuant to both D.18.A and B, the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to D.18.A or only pursuant to D.18.B, then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to D.7.B, C and D. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

B. Intake by Inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(1) The sum of the fractions of the inhalation ALI for each radionuclide, or

(2) The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or

(3) The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

C. Intake by Oral Ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.

D. Intake through Wounds or Absorption through Skin. The licensee or registrant shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. Note the intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be further evaluated.

8. Determination of External Dose from Airborne Radioactive Material.

A. Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Appendix B, footnotes 1 and 2.

B. Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

9. Determination of Internal Exposure.

A. For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee or registrant shall, when required pursuant to D.18, take suitable and timely measurements of:

(1) Concentrations of radioactive materials in air in work areas; or

(2) Quantities of radionuclides in the body; or

(3) Quantities of radionuclides excreted from the body; or

(4) Combinations of these measurements.

B. Unless respiratory protective equipment is used, as provided in D.24, or the assessment of intake is based on bioassays, the licensee or registrant shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

C. When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee or registrant may:

(1) Use that information to calculate the committed effective dose equivalent, and, if used, the licensee or registrant shall document that information in the individual's record; and

(2) Upon prior approval of the Agency, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

(3) Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Appendix B.

D. If the licensee or registrant chooses to assess intakes of Class Y material using the measurements given in D.9.A.(2) or (3), the licensee or registrant may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by D.52 or D.53. This delay permits the licensee or registrant to make additional measurements basic to the assessments.

E. If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

(1) The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B for each radionuclide in the mixture; or

(2) The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

F. If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

G. When a mixture of radionuclides in air exists, a licensee or registrant may disregard certain radionuclides in the mixture if:

(1) The licensee or registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in D.6 and in complying with the monitoring requirements in D.18.B, and

(2) The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and

(4) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

H. When determining the committed effective dose equivalent, the following information may be considered:

(1) In order to calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(2) For an ALI and the associated DAC determined by the non-stochastic organ dose limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in D.6.A.(1)b. is met.

10. Determination of Prior Occupational Dose.

A. For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to D.18, the licensee or registrant shall:

(1) Determine the occupational radiation dose received during the current year; and

(2) Attempt to obtain the records of cumulative occupational radiation dose.

B. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

(1) The internal and external doses from all previous planned special exposures; and

(2) All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

(3) All cumulative occupational radiation dose.

C. In complying with the requirements of D.10.A, a licensee or registrant may:

(1) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and

(2) Accept, as the record of cumulative radiation dose, an up-to-date HHE 835 or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

(3) Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

D. The licensee or registrant shall record the exposure history, as required by D.10.A, on HHE 835, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure.

(1) For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing HHE 835 or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on HHE 835 or equivalent indicating the periods of time for which data are not available.

(2) Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the regulations in Part D in effect before January 1, 1994. Further, occupational exposure histories obtained and recorded on HHE 835 or equivalent before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

E. If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

(1) In establishing administrative controls pursuant to D.6.F. for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

(2) That the individual is not available for planned special exposures.

F. The licensee or registrant shall retain the records on HHE 835 or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing HHE 835 or equivalent for 3 years after the record is made.

11. Planned Special Exposures. A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in D.6 provided that each of the following conditions is satisfied:

A. The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

B. The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

C. Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

(1) Informed of the purpose of the planned operation; and

(2) Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

(3) Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

D. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by D.10.B during the lifetime of the individual for each individual involved.

E. Subject to D.6.B, the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

(1) The numerical values of any of the dose limits in D.6.A in any year; and

(2) Five times the annual dose limits in D.6.A during the individual's lifetime.

F. The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with D.45 and submits a written report in accordance with D.54.

G. The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to D.6.A but shall be included in evaluations required by D.11.D and E.

12. Occupational Dose Limits for Minors. The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in D.6.

13. Dose to an Embryo/Fetus.

A. The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). See D.46 for record keeping requirements.

B. The licensee or registrant shall make efforts to avoid substantial variation[2]/ above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in D.13.A.

C. The dose equivalent to an embryo/fetus shall be taken as the sum of:

(1) The deep dose equivalent to the declared pregnant woman; and

(2) The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

D. If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.5 mSv (0.05 rem) of this dose, by the time the woman declares her pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with paragraph A of this section if the additional dose equivalent does not exceed) 5mSv (0.05 rem) during the remainder of the pregnancy.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

14. Dose Limits for Individual Members of the Public.

A. Each licensee or registrant shall conduct operations so that:

(1) The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Part G, from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with D.35,[3]/ and

(2) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with Part G, does not exceed 0.02 mSv (0.002 rem) in any one hour.

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[2]/ The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.5 mSv (0.05 rem) to the embryo/fetus be received in any one month.

[3]/ Retrofit shall not be required for locations within facilities where only radiation machines existed prior to January 1, 1994 and met the previous requirements of 5 mSv (0.5 rem) in a year.

B. If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

C. Not withstanding paragraph A.(1) of this section, a licensee may permit visitors to an individual who can not be released in accordance with Part G, to receive a radiation dose greater than 1 mSv (0.1 rem) if:

(1) The radiation dose received does not exceed 5 mSv (0.5 rem); and

(2) The authorized user, as defined in Part G, has determined before the visit that it is appropriate.

D. A licensee, registrant, or an applicant for a license or registration may apply for prior Agency authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem). This application shall include the following information:

(1) Demonstration of the need for and the expected duration of operations in excess of the limit in D.14.A; and

(2) The licensee's or registrant's program to assess and control dose within the 5 mSv (0.5 rem) annual limit; and

(3) The procedures to be followed to maintain the dose ALARA.

E. In addition to the requirements of Part D, a licensee or registrant subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

F. The Agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

15. Compliance with Dose Limits for Individual Members of the Public.

A. The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in D.14.

B. A licensee or registrant shall show compliance with the annual dose limit in D.14 by:

(1) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

(2) Demonstrating that:

a. The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B; and

b. If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year.

C. Upon approval from the Agency, the licensee or registrant may adjust the effluent concentration values in Appendix B, Table II, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

16. Testing for Leakage or Contamination of Sealed Sources.

A. The licensee or registrant in possession of any sealed source shall assure that:

(1) Each sealed source, except as specified in D.16.B, is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee or registrant has a certificate from the transferor indicating that the sealed source was tested within 6 months before transfer to the licensee or registrant.

(2) Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 6 months or at alternative intervals approved by the Agency, after evaluation of information specified by C.11.K.(4) and (5) of these regulations, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.

(3) Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 3 months or at alternative intervals approved by the Agency, after evaluation of information specified by C.11.K.(4) and (5) of these regulations, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission.

(4) For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee or registrant shall assure that the sealed source is tested for leakage or contamination before further use.

(5) Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005 μCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.

(6) The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 μCi) of radon-222 in a 24 hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time.

(7) Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq (0.005 μCi) of a radium daughter which has a half-life greater than 4 days.

B. A licensee or registrant need not perform test for leakage or contamination on the following sealed sources:

(1) Sealed sources containing only radioactive material with a half-life of less than 30 days;

(2) Sealed sources containing only radioactive material as a gas;

(3) Sealed sources containing 3.7 MBq (100 μCi) or less of beta or photon- emitting material or 370 kBq (10 μCi) or less of alpha-emitting material;

(4) Sealed sources containing only hydrogen-3;

(5) Seeds of iridium-192 encased in nylon ribbon; and

(6) Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee or registrant shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within 6 months before the date of use or transfer.

C. Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.

D. Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency.

E. The following shall be considered evidence that a sealed source is leaking:

(1) The presence of 185 Bq (0.005 μCi) or more of removable contamination on any test sample.

(2) Leakage of 37 Bq (0.001 μCi) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.

(3) The presence of removable contamination resulting from the decay of 185 Bq (0.005 μCi) or more of radium.

F. The licensee or registrant shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this Part.

G. Reports of test results for leaking or contaminated sealed sources shall be made pursuant to D.58.

SURVEYS AND MONITORING

17. General.

A. Each licensee or registrant shall make, or cause to be made, surveys that:

(1) Are necessary for the licensee or registrant to comply with Part D; and

(2) Are necessary under the circumstances to evaluate:

(a) The magnitude of radiation levels; and

(b) Concentrations or quantities of radioactive material; and

(c) The potential radiological hazards.

B. The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured.

C. All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with D.6, with other applicable provisions of these regulations, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

(1) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(2) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

D. The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

18. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.
Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Part D. As a minimum:

A. Each licensee or registrant shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by:

(1) Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in D.6.A; and

(2) Minors likely to receive, in 1 year from sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem), a lens dose equivalent in excess of 1.5 mSv (0.15 rem), or a shallow dose equivalent to the skin or to the extremities in excess of 5 mSv (0.5 rem; and

(3) Declared pregnant women likely to receive during the entire pregnancy, in 1 year from sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem; and

(4) Individuals entering a high or very high radiation area.

(5) *Reserved*

B. Each licensee or registrant shall monitor, to determine compliance with D.9, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(1) Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B; and

(2) Minors and declared pregnant women (during the entire pregnancy) likely to receive, in 1 year from radiation sources external to the body, a committed effective dose equivalent in excess of 1 mSv (0.1 rem).

CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

19. Control of Access to High Radiation Areas.

A. The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

(1) A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates; or

(2) A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(3) Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

B. In place of the controls required by D.19.A for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

C. The licensee or registrant may apply to the Agency for approval of alternative methods for controlling access to high radiation areas.

D. The licensee or registrant shall establish the controls required by D.19.A and C in a way that does not prevent individuals from leaving a high radiation area.

E. The licensee or registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation provided that:

(1) The packages do not remain in the area longer than 3 days; and

(2) The dose rate at 1 meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.

F. The licensee or registrant is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in Part D and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.

G. The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in D.19 if the registrant has met all the specific requirements for access and control specified in other applicable Parts of these regulations, such as, Part E for industrial radiography, Part F for x rays in the healing arts, and Part I for particle accelerators.

20. Control of Access to Very High Radiation Areas.

A. In addition to the requirements in D.19, the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 Gy (500 rad) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to non-self-shielded irradiators.

B. The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in D.20.A if the registrant has met all the specific requirements for access and control specified in other applicable Parts of these regulations, such as, Part E for industrial radiography, Part F for x rays in the healing arts, and Part I for particle accelerators.

21. Control of Access to Very High Radiation Areas -- Irradiators.

A. Section D.21 applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. Section D.21 does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

B. Each area in which there may exist radiation levels in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

(1) Each entrance or access point shall be equipped with entry control devices which:

a. Function automatically to prevent any individual from inadvertently entering a very high radiation area; and

b. Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

c. Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 1 mSv (0.1 rem) in 1 hour.

(2) Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by D.21.B(1):

a. The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

b. Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

(3) The licensee or registrant shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

a. The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

b. Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

(4) When the shield for stored sealed sources is a liquid, the licensee or registrant shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

(5) Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of D.21.B(3) and (4).

(6) Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.

(7) Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

(8) Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour.

(9) The entry control devices required in D.21.B(1) shall be tested for proper functioning. See D.49 for record keeping requirements.

(a) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and

(b) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

(c) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

(10) The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

(11) Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and automatically to prevent loose radioactive material from being carried out of the area.

C. Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of D.21.B which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of D.21.B, such as those for the automatic control of radiation levels, may apply to the Agency for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in D.21.B. At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

D. The entry control devices required by D.21.B and C shall be established in such a way that no individual will be prevented from leaving the area.

RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

22. Use of Process or Other Engineering Controls. The licensee or registrant shall use, to the extent practicable, process or other engineering controls, such as, containment, decontamination or ventilation, to control the concentrations of radioactive material in air.

23. Use of Other Controls.

A. When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee or registrant shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

(1) Control of access; or

(2) Limitation of exposure times; or

(3) Use of respiratory protection equipment; or

(4) Other controls.

B. If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

24. Use of Individual Respiratory Protection Equipment.

A. If the licensee or registrant assigns or permits the use respiratory protection equipment to limit the intake of radioactive material pursuant to D.23,

(1) Except as provided in D.24.A(2), the licensee or registrant shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH).

(2) If the licensee or registrant wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health, the licensee or registrant shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. This must be demonstrated either by licensee testing or on the basis of reliable test information.

(3) The licensee or registrant shall implement and maintain a respiratory protection program that includes:

a. Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses; Note: In those cases where air sampling is difficult or even impossible, the exposure can be calculated based upon the known chemicals and ventilation rates; and

b. Surveys and bioassays, as appropriate, to evaluate actual intakes; and

c. Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use; and

d. Written procedures regarding respirator selection, fit testing, storage, issuance, maintenance, repair, testing of respirators, including testing for operability immediately prior to each use; quality assurance of respiratory protection equipment supervision and training of respirator users; monitoring, including air sampling and bioassays; breathing air quality, inventory and control, and recordkeeping; and limitations on periods of respirator use and relief from respirator use; and

e. Determination by a physician that the individual user is medically fit to use the respiratory protection equipment; before.

(i) The initial fitting of a face sealing respirator;

(ii) Before the first field use of non-face sealing respirators, and

(iii) Either every 12 months thereafter, or periodically at a frequency determined by a physician.

f. Fit testing, with a fit factor ≥ 10 times the APF for negative pressure devices, and a fit factor ≥ 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face sealing respirators and periodically thereafter at a frequency not to exceed 1 year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

(5) The licensee or registrant shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(6) The licensee or registrant shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide for vision correction, adequate communication, low temperature work environments and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

(7) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

(8) Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed gas Association in publication G-7.1, "Commodity Specification for Air, " 1997 and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134(i)1(ii)(A) through (E). Grade D quality air criteria include:

a. Oxygen content (v/v) of 19.5-23.5%;

b. Hydrocarbon (condensed) content of 5 milligrams per cubic meter or air or less;

c. Carbon Monoxide (CO) content of 10 ppm or less;

d. Carbon Dioxide content of 1,000 ppm or less; and

e. Lack of noticeable odor

(9) The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face-facepiece seal or valve function, and that are under the control of the wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

(10) In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without the respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

B. The Agency may impose restrictions in addition to the provisions of D.23 and D.24, and Appendix A of this Part, in order to:

(1) Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

(2) Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

C. The licensee or registrant shall obtain authorization from the Agency before using assigned respiratory protection factors in excess of those specified in Appendix A. The Agency may authorize a licensee or registrant to use higher protection factors on receipt of an application that:

(1) Describes the situation for which a need exists for higher protection factors, and

(2) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

25. Security of Stored Sources of Radiation. The licensee or registrant shall secure from unauthorized removal or access licensed or registered sources of radiation that are stored in controlled or unrestricted areas.

26. Control of Sources of Radiation not in Storage

A. The licensee or registrant shall control and maintain constant surveillance of licensed or registered radioactive material that is in a controlled or unrestricted area and that is not in storage.

B. The registrant shall maintain control of radiation machines that are in a controlled or unrestricted area and that are not in storage.

PRECAUTIONARY PROCEDURES

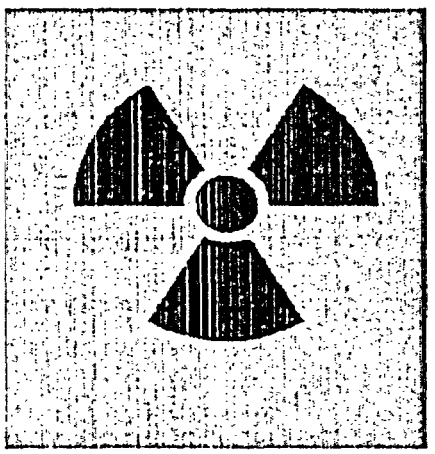
27. Caution Signs.

A. Standard Radiation Symbol. Unless otherwise authorized by the Agency, the symbol prescribed by D.27 shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

RADIATION SYMBOL

(1) Cross-hatched area is to be magenta, or purple, or black, and

(3) The background is to be yellow.



B Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of D.27.A, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

C. Additional Information on Signs and Labels. In addition to the contents of signs and labels prescribed in Part D, the licensee or registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

28. Posting Requirements

A. Posting of Radiation Areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

B. Posting of High Radiation Areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

C. Posting of Very High Radiation Areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

D. Posting of Airborne Radioactivity Areas. The licensee or registrant shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

E. Posting of Areas or Rooms in which Licensed or Registered Material is Used or Stored. The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding 10 times the quantity of such material specified in Appendix C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

29. Exceptions to Posting Requirements.

A. A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than 8 hours, if each of the following conditions is met:

(1) The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in Part D; and

(2) The area or room is subject to the licensee's or registrant's control.

B. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to D.28 provided that the patient could be released from confinement pursuant to G.27 of these regulations.

C. A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

D. Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under D.28 if:

(1) Access to the room is controlled pursuant to G.604; and

(2) Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this part.

E. A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

30. Labeling Containers and Radiation Machines.

A. The licensee or registrant shall ensure that each container of licensed or registered material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

B. Each licensee or registrant shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

C. Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner, which cautions individuals that radiation is produced when it is energized.

31. Exemptions to Labeling Requirements. A licensee or registrant is not required to label:

A. Containers holding licensed or registered material in quantities less than the quantities listed in Appendix C; or

B. Containers holding licensed or registered material in concentrations less than those specified in Table III of Appendix B; or

C. Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by Part D; or

D. Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation;[4]/ or

E. Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

F. Installed manufacturing or process equipment, such as piping and tanks.

32. Procedures for Receiving and Opening Packages.

A. Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in L.2 and Appendix A of Part L of these regulations, shall make arrangements to receive:

(1) The package when the carrier offers it for delivery; or

(2) The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

B. Each licensee or registrant shall:

(1) Monitor the external surfaces of a labeled[5]/ package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in A.2 of these regulations; and

(2) Monitor the external surfaces of a labeled[5]/ package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in L.2 and Appendix A to Part L of these regulations; and

(3) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

C. The licensee or registrant shall perform the monitoring required by D.32.B as soon as practicable after receipt of the package, but not later than 3 hours after the package is received at the licensee's or registrant's facility if it is received during the licensee's or registrant's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

D. The licensee or registrant shall immediately notify the final delivery carrier and the Agency by telephone and telegram, mailgram, or facsimile, when:

(1) Removable radioactive surface contamination exceeds the limits of L.15.H. of these regulations; or

(2) External radiation levels exceed the limits of L.15.I and J of these regulations.

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[4]/ Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421-424.

[5]/ Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 172.436-440.

E. Each licensee or registrant shall:

(1) Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(2) Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

F. Licensees or registrants transferring special form sources in vehicles owned or operated by the licensee or registrant to and from a work site are exempt from the contamination monitoring requirements of D.32.B, but are not exempt from the monitoring requirement in D.32.B for measuring radiation levels that ensures that the source is still properly lodged in its shield.

WASTE DISPOSAL

33. General Requirements.

A. A licensee or registrant shall dispose of licensed or registered material only:

(1) By transfer to an authorized recipient as provided in D.38, or in Parts C, M, or U[6]/ of these regulations, or to the U.S. Department of Energy; or

(2) By decay in storage; or

(3) By release in effluents within the limits in D.14; or

(4) As authorized pursuant to D.34, D.35, D.36, or D.37.

B. A person shall be specifically licensed or registered to receive waste containing licensed or registered material from other persons for:

(1) Treatment prior to disposal; or

(2) Treatment or disposal by incineration; or

(3) Decay in storage; or

(4) Disposal at a land disposal facility licensed pursuant to Part M; or

(5) Storage until transferred to a storage or disposal facility authorized to receive the waste.

34. Method for Obtaining Approval of Proposed Disposal Procedures. A licensee or registrant or applicant for a license or registration may apply to the Agency for approval of proposed procedures, not otherwise authorized in these regulations, to dispose of licensed or registered material generated in the licensee's or registrant's operations. Each application shall include:

A. A description of the waste containing licensed or registered material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal; and

B. An analysis and evaluation of pertinent information on the nature of the environment; and

[6]/ Part M and U are reserved.

C. The nature and location of other potentially affected facilities; and

D. Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in Part D.

35. Disposal by Release Into Sanitary Sewerage

A. A licensee or registrant may discharge licensed or registered material into sanitary sewerage if each of the following conditions is satisfied:

(1) The material is readily soluble, or is readily dispersible biological material, in water; and

(2) The quantity of licensed or registered radioactive material that the licensee or registrant releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee or registrant does not exceed the concentration listed in Table III of Appendix B; and

(3) If more than one radionuclide is released, the following conditions must also be satisfied:

a. The licensee or registrant shall determine the fraction of the limit in Table III of Appendix B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee or registrant into the sewer by the concentration of that radionuclide listed in Table III of Appendix B; and

b. The sum of the fractions for each radionuclide required by D.35.A(3)(a) does not exceed unity; and

(4) The total quantity of licensed or registered radioactive material that the licensee or registrant releases into the sanitary sewerage in a year does not exceed 185 GBq (5 Ci) of hydrogen-3, 37 GBq (1 Ci) of carbon-14, and 37 GBq (1 Ci) of all other radioactive materials combined.

B. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in D.35.A.

36. Treatment or Disposal by Incineration. A licensee or registrant may treat or dispose of licensed or registered material by incineration only in the amounts and forms specified in D.37 or as specifically approved by the Agency pursuant to D.34.

37. Disposal of Specific Wastes.

A. A licensee or registrant may dispose of the following licensed or registered material as if it were not radioactive:

(1) 1.85 kBq (0.05 μCi), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

(2) 1.85 kBq (0.05 μCi), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

B. A licensee or registrant shall not dispose of tissue pursuant to D.37.A(2) in a manner that would permit its use either as food for humans or as animal feed.

C. The licensee or registrant shall maintain records in accordance with D.48.

38. Transfer for Disposal and Manifests.

A. The requirements of D.38, Appendices D and G of this Part are designed to control transfers of low-level radioactive waste intended for disposal at a licensed low- level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and record keeping for those wastes.

B. Each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified in Section I of Appendix D.

C. Each shipment manifest shall include a certification by the waste generator as specified in Section II of Appendix D.

D. Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix D.

39. Compliance with Environmental and Health Protection Regulations. Nothing in D.33, D.34, D.35, D.36, D.37, or D.38 relieves the licensee or registrant from complying with other applicable Federal, State and local regulations governing any other toxic or hazardous properties of materials that may be disposed of to D.33, D.34, D.35, D.36, D.37, or D.38.

RECORDS

40. General Provisions.

A. Each licensee or registrant shall use the units (curie, rad, rem and roentgen) including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by Part D.

B. In the records required by this Part, the licensee may record quantities in the International System of Units (SI) in parentheses following each of the units specified in paragraph A. However, all quantities must be recorded as stated in paragraph A.

C. Not withstanding the requirements of paragraph A of this section, when recording information on shipment manifests, as required in D.38, information must be recorded in SI units or in SI units and units as specified in paragraph A above.

D. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by Part D, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

41. Records of Radiation Protection Programs.

A. Each licensee or registrant shall maintain records of the radiation protection program, including:

(1) The provisions of the program; and

(2) Audits and other reviews of program content and implementation.

B. The licensee or registrant shall retain the records required by D.41.A(1) until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by D.41.A(2) for 3 years after the record is made.

42. Records of Surveys.

A. Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by D.17 and D.32.B. The licensee or registrant shall retain these records for 3 years after the record is made.

B. The licensee or registrant shall retain each of the following records until the Agency terminates each pertinent license or registration requiring the record:

(1) Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

(2) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

(3) Records showing the results of air sampling, surveys, and bioassays required pursuant to D.24.A(3)(a) and (b); and

(4) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

C. Upon termination of the license or registration, the licensee or registrant shall permanently store records on HHE-835 or equivalent, or shall make provision with the Agency for transfer to the Agency.

43. Records of Tests for Leakage or Contamination of Sealed Sources. Records of tests for leakage or contamination of sealed sources required by D.16 shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency for 5 years after the records are made.

44. Records of Prior Occupational Dose.

A. The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in D.10 on HHE 835 or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing HHE 835 or equivalent for 3 years after the record is made.

B. Upon termination of the license or registration, the licensee or registrant shall permanently store records on HHE-835 or equivalent, or shall make provision with the Agency for transfer to the Agency.

45. Records of Planned Special Exposures.

A. For each use of the provisions of D.11 for planned special exposures, the licensee or registrant shall maintain records that describe:

(1) The exceptional circumstances requiring the use of a planned special exposure; and

(2) The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

(3) What actions were necessary; and

(4) Why the actions were necessary; and

(5) What precautions were taken to assure that doses were maintained ALARA; and

(6) What individual and collective doses were expected to result; and

(7) The doses actually received in the planned special exposure.

B. The licensee or registrant shall retain the records until the Agency terminates each pertinent license or registration requiring these records.

C. Upon termination of the license or registration, the licensee or registrant shall permanently store records on HHE-835 or equivalent, or shall make provision with the Agency for transfer to the Agency.

46. Records of Individual Monitoring Results.

A. Record keeping Requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to D.18, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994 need not be changed. These records shall include, when applicable:

(1) The deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and

(2) The estimated intake of radionuclides, see D.7; and

(3) The committed effective dose equivalent assigned to the intake of radionuclides; and

(4) The specific information used to calculate the committed effective dose equivalent pursuant to D.9.C.; and

(5) The total effective dose equivalent when required by D.7; and

(6) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

B. Record keeping Frequency. The licensee or registrant shall make entries of the records specified in D.46.A at intervals not to exceed 1 year.

C. Record keeping Format. The licensee or registrant shall maintain the records specified in D.46.A on HHE-840, in accordance with the instructions for HHE-840, or in clear and legible records containing all the information required by HHE-840.

D. The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

E. The licensee or registrant shall retain each required form or record until the Agency terminates each pertinent license or registration requiring the record.

F. Upon termination of the license or registration, the licensee or registrant shall permanently store records on HHE-835 or equivalent, or shall make provision with the Agency for transfer to the Agency.

47. Records of Dose to Individual Members of the Public.

A. Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See D.14.

B. The licensee or registrant shall retain the records required by D.47.A until the Agency terminates each pertinent license or registration requiring the record.

48. Records of Waste Disposal.

A. Each licensee or registrant shall maintain records of the disposal of licensed or registered materials made pursuant to D.34, D.35, D.36, D.37, of these regulations, and disposal by burial in soil, including burials authorized before January 28, 1981.[7]

B. The licensee or registrant shall retain the records required by D.48.A until the Agency terminates each pertinent license or registration requiring the record.

49. Records of Testing Entry Control Devices for Very High Radiation Areas.

A. Each licensee or registrant shall maintain records of tests made pursuant to D.21.B(9) on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

B. The licensee or registrant shall retain the records required by D.49.A for 3 years after the record is made.

50. Form of Records. Each record required by Part D shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

REPORTS

51. Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.

A. Telephone Reports. Each licensee or registrant shall report to the Agency by telephone as follows:

(1) Immediately after its occurrence becomes known to the licensee or registrant, stolen, lost, or missing licensed or registered radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas; or

(2) Within 30 days after its occurrence becomes known to the licensee or registrant, lost, stolen, or missing licensed or registered radioactive material in an aggregate quantity greater than 10 times the quantity specified in Appendix C that is still missing.

(3) Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

B. Written Reports. Each licensee or registrant required to make a report pursuant to D.51.A shall, within 30 days after making the telephone report, make a written report to the Agency setting forth the following information:

(1) A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

(2) A description of the circumstances under which the loss or theft occurred; and

[7] A previous U.S. Nuclear Regulatory Commission rule (10 CFR 20.304) authorized burial of small quantities of licensed materials in soil before January 28, 1981, without specific NRC authorization.

(3) A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

(4) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

(5) Actions that have been taken, or will be taken, to recover the source of radiation; and

(6) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

C. Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

D. The licensee or registrant shall prepare any report filed with the Agency pursuant to D.51 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

52. Notification of Incidents.

A. Immediate Notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(1) An individual to receive --

a. A total effective dose equivalent of 0.25 Sv (25 rem) or more; or

b. A lens dose equivalent of 0.75 Sv (75 rem) or more; or

c. A shallow-dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 Gy (250 rads) or more; or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).

B. Twenty-four hour Notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Agency each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

(1) An individual to receive, in a period of 24 hours:

a. A total effective dose equivalent exceeding 0.05 Sv (5 rem); or

b. A lens dose equivalent exceeding 0.15 Sv (15 rem); or

c. A shallow-dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. The provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

C. The licensee or registrant shall prepare each report filed with the Agency pursuant to D.52 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

D. Licensees or registrants shall make the reports required by D.52.A and B to the Agency by telephone, telegram, mailgram, or facsimile to the Agency.

E. The provisions of D.52 do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to D.54.

53. Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits.

A. Reportable Events. In addition to the notification required by D.52, each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

(1) Incidents for which notification is required by D.52; or

(2) Doses in excess of any of the following:

a. The occupational dose limits for adults in D.6; or

b. The occupational dose limits for a minor in D.12; or

c. The limits for an embryo/fetus of a declared pregnant woman in D.13; or

d. The limits for an individual member of the public in D.14; or

e. Any applicable limit in the license or registration; or

(3) Levels of radiation or concentrations of radioactive material in:

a. A restricted area in excess of applicable limits in the license or registration; or

b. An unrestricted area in excess of 10 times the applicable limit set forth in Part D or in the license or registration, whether or not involving exposure of any individual in excess of the limits in D.14; or

(4) For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

B. Contents of Reports.

(1) Each report required by D.53.A shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

a. Estimates of each individual's dose; and

b. The levels of radiation and concentrations of radioactive material involved; and

c. The cause of the elevated exposures, dose rates, or concentrations; and

d. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, generally applicable environmental standards, and associated license or registration conditions.

(2) Each report filed pursuant to D.53.A. shall include for each individual exposed: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in D.13, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

C. All licensees or registrants who make reports pursuant to D.53.A shall submit the report in writing to the Agency.

54. Reports of Planned Special Exposures. The licensee or registrant shall submit a written report to the Agency within 30 days following any planned special exposure conducted in accordance with D.11, informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by Sec. D.45.

55. Reports to Individuals of exceeding dose limits. When a licensee is required, pursuant to D.53, D.54, or D.56 to report to the Agency any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee shall also provide a copy of the report submitted to the Agency to the individual. This report must be transmitted at a time no later than the transmittal to the Agency.

56. Reports of Individual Monitoring.

A. This section applies to each person licensed or registered by the Agency to:

(1) Possess or use sources of radiation for purposes of industrial radiography pursuant to Parts C and E of these regulations; or

(2) Possess or use at any time, for processing or manufacturing for distribution pursuant to Part C or G of these regulations, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Activity[a]	
	Ci	GBq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium- 99m	1,000	37,000.

[a] The Agency may require as a license condition, or by rule, regulation, or order, reports from licensees or registrants who are licensed or registered to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

B. Each licensee or registrant in a category listed in D.56.A shall submit an annual report of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by D.18 during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required. The licensee or registrant shall use HHE-840 or equivalent or electronic media containing all the information required by HHE-840.

C. The licensee or registrant shall file the report required by D.56.B, covering the preceding year, on or before April 30 of each year. The licensee or registrant shall submit the report to the Agency.

57. Notifications and Reports to Individuals.

A. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in J.4 of these regulations.

B. When a licensee or registrant is required pursuant to D.53 to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Agency, and shall comply with the provisions of J.4.A of these regulations.

58. Reports of Leaking or Contaminated Sealed Sources. The licensee or registrant shall file a report within 5 days with the Agency if the test for leakage or contamination required pursuant to D.16. indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

ADDITIONAL REQUIREMENTS

59. Vacating Premises. Each specific licensee or registrant shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his activities, notify the Agency in writing of intent to vacate. When deemed necessary by the Agency, the licensee shall decontaminate the premises in such a manner as the Agency may specify.

RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

60. General Provisions and Scope. The criteria in this subpart apply to the decommissioning of facilities licensed under Parts C, E , G and K of these regulations.

A. The criteria in this subpart do not apply to sites, which have been decommissioned prior to the effective date of this rule.

B. After a site has been decommissioned and the license terminated in accordance with the criteria in this subpart, the Agency will require additional cleanup only if, based on new information, it determines that the criteria of this subpart were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

C. When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

D. Specific time limits for the completing the decommissioning process.

(1) Licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but not later than 24 months following the initiation of decommissioning.

(2) When decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but not later than 24 months following the initiation of decommissioning.

E. The Agency may approve a request for an alternative schedule for completion of the decommissioning of the site or separate building or outdoor area, and license termination is appropriate, if the Agency determines that the alternative is warranted.

61. **Radiological Criteria for Unrestricted Use.** A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that shall not exceed 10 mrem (0.10 mSv) per year, including that from groundwater sources of drinking water and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels, which are ALARA, must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

62. **Criteria for License Termination Under Restricted Conditions.** A site will be considered acceptable for license termination under restricted conditions if:

A. The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of D.61. would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels, which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal;

B. The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 10 mrem (0.10 mSv) per year;

C. The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

(1) Funds placed into an account segregated from the licensee's assets and outside the licensee's administrative control as described in Part C.8.F.

(2) Surety method, insurance, or other guarantee method as described in Part C.8.F.;

(3) A statement of intent in the case of State, or local Government licensees, as described in Part C.8.F.; or

(4) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

D. The licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the Agency indicating the licensee's intent to decommission in accordance with Parts C, D, and E, and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate , following analysis of that advice.

(1) Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

a. Whether provisions for institutional controls proposed by the licensee:

(i) Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 10 mrem (0.10 mSv) TEDE per year;

(ii) Will be enforceable; and

(iii) Will not impose undue burdens on the local community or other affected parties.

b. Whether the licensee has provided sufficient financial assurance to enable a third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site;

(2) In seeking advice on the issues identified in 62.D.(1), the licensee shall provide for:

a. Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

b. An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

c. A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

E. Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

(1) 1mSv (100 mrem) per year; or

(2) 5MsV (500 mrem) per year provided the licensee:

a. Demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem/yr (1 mSv/yr) value of paragraph E.(1) of this section are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

b. Makes provisions for durable institutional controls;

c. Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every 3 years to assure that the institutional controls remain in place as necessary to meet the criteria of D.62.B. and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in paragraph C. of this section.

63. Alternate Criteria for License Termination

A. The Agency may terminate a license using alternate criteria greater than the dose criterion of parts D.61., D.62.B., and D.62.D., if the licensee:

(1) Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 1 mSv/y (100 mrem/y) limit, by submitting an analysis of possible sources of exposure;

(2) Has employed to the extent practical restrictions on the site use according to the provisions of D.62. in minimizing exposures at the site; and

(3) Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.

(4) Has submitted a decommissioning plan or License Termination Plan (LTP) to the Agency indicating the licensee's intent to decommission in accordance with Parts C, D, and E., and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the license shall provide for:

a. Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

b. An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

c. A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues

B. The use of alternate criteria to terminate a license requires the approval of the Agency after consideration of the Agency's staff's recommendations that will address any comments by other appropriate agencies and any public comments submitted pursuant to D. 64.

64. Public Notification and Public Participation. Upon the receipt of an LTP or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to D.62. and D.63., or whenever the Agency deems such notice to be in the public interest, the Agency shall:

A. Notify and solicit comments from:

(1) Local governments in the vicinity of the site and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

(2) Other appropriate agencies for cases where the licensee proposes to release a site pursuant to D.63.

B. Publish a notice in a forum, such as local newspapers, letters to State or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

65. Minimization of Contamination. Applicants for licenses, after July 1, 1999, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste..

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APPENDIX A

ASSIGNED PROTECTION FACTORS FOR RESPIRATOR [A]

	Operating Mode	Assigned Protection Factors
I. Air purifying respirators (Particulate[b] only)[c]	Negative Pressure	([d])
Filtering faceplate disposable[d]	Negative Pressure	10
Facepiece, half[e]	Negative Pressure	100
Facepiece, full	Powered air-purifying	50
Facepiece, half	respirators-	1000
Facepiece, full	Powered air-purifying	1000
Helmet/hood	respirators-	25
Facepiece, loose fitting	Powered air-purifying respirators-	
	Powered air-purifying respirators-	
II. Atmosphere supplying respirators (Particulate, gases, and vapors[f])		
1: Air-line respirator:		
Facepiece, half	Demand	10
Facepiece, half[e]	Continuous Flow	50
Facepiece, half	Pressure Demand	50
Facepiece, full	Demand	100
Facepiece, full	Continuous Flow	1000
Facepiece, full	Pressure Demand	1000
Helmet/hood	Continuous Flow	1000
Facepiece, loose fitting	Continuous Flow	25
Suit	Continuous Flow	([g])
2: Self-contained breathing apparatus (SCBA):	Demand	[h]100
Facepiece, full	Pressure Demand	[i]10,000
Facepiece, full	Demand, recirculating	[h]100
Facepiece, full	Positive Pressure	[i]10,000
Facepiece, full	Recirculating	
Facepiece, full		
III. Combination respirators: Any combination of air-purifying and atmosphere-supplying respirators	Assigned protection factor for type and mode of operations as listed above	

See the following pages for footnotes.

a. These assigned protection factors apply only in respiratory protection program that meets the requirements of this Part. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances must also comply with Department of Labor regulations.

   Radioactive contaminants for which the concentration values in Table 1, column 3 of Appendix B to Part D are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

b. Air purifying respirators with APF <100 must be equipped with particulate filters that are at least 95 percent efficient. Air purifying respirators with APF =100 must be equipped with particulate filters that area t least 99 percent efficient. Air purifying respirators with APF >100 must be equipped with particulate filters that area t least 99.97 percent efficient.

c. The licensee may apply to the Agency for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).

d. Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in D.24 apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

e. Under-chin type only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95 percent efficient and all other requirements of this Part are met.

f. The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one0third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

g. No NIOSH approval schedule is currently available for atmospheric supplying units. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met (i.e., D.24).

h. The licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health (IDLH).

i. This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

APPENDIX B

ANNUAL LIMITS ON INTAKE (ALI) AND DERIVED AIR CONCENTRATIONS (DAC) OF RADIONUCLIDES FOR OCCUPATIONAL EXPOSURE; EFFLUENT CONCENTRATIONS; CONCENTRATIONS FOR RELEASE TO SANITARY SEWERAGE

1. Introduction

For each radionuclide, Table I indicates the chemical form which is to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1 mm, micron, and for three classes (D,W,Y) of radioactive material, which refer to their retention (approximately days, weeks or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times for D if less than 10 days, for W from 10 to 100 days, and for Y greater than 100 days. Table II provides concentration limits for airborne and liquid effluents released to the general environment. Table III provides concentration limits for discharges to sanitary sewerage.

Note: The values in Tables I, II, and III are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of 6 x 10^{-2} or 0.06, 6E+2 represents 6 x 10^{2} or 600, and 6E+0 represents 6 x 100 or 6.

2. Table I "Occupational Values"

Note that the columns in Table I of this appendix captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

The ALIs in this appendix are the annual intakes of given radionuclide by "Reference Man" which would result in either (1) a committed effective dose equivalent of 0.05 Sv (5 rem), stochastic ALI, or (2) a committed dose equivalent of 0.5 Sv (50 rem) to an organ or tissue, non-stochastic ALI. The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of 0.05 Sv (5 rem). The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor, w_T. This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of w_T are listed under the definition of weighting factor in D.3. The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.

A value of w_T = 0.06 is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following portions of the GI tract, stomach, small intestine, upper large intestine, and lower large intestine, are to be treated as four separate organs.

Note that the dose equivalents for an extremity, skin and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

When an ALI is defined by the stochastic dose limit, this value alone is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. Abbreviated organ or tissue designations are used:

LLI wall = lower large intestine wall;
St. wall = stomach wall;
Blad wall = bladder wall; and
Bone surf = bone surface.

The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the non-stochastic ALI is limiting, use of that non-stochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. However, the licensee shall also ensure that the 0.5 Sv (50 rem) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the non-stochastic ALIs (ALI_{ns}) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is, (intake (in □Ci) of each radionuclide/ALI_{ns}) $\leq$ 1.0. If there is an external deep dose equivalent contribution of H_d, then this sum must be less than 1 - (H_d/50), instead of $\leq$ 1.0.

Note that the dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

The derived air concentration (DAC) values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by:

DAC = ALI(in mCi)/(2000 hours per working year x 60 minutes/hour x 2 x 10^4 ml per minute) = [ALI/2.4 x 10^9] mCi/ml, where 2 x 10^4 ml is the volume of air breathed per minute at work by Reference Man under working conditions of light work.

The DAC values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. DACs based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

The ALI and DAC values include contributions to exposure by the single radionuclide named and any in-growth of daughter radionuclides produced in the body by decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.

The values of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation. See D.7. When an individual is exposed to radioactive materials, which fall under several of the translocation classifications of the same radionuclide, such as, Class D, Class W, or Class Y, the exposure may be evaluated as if it were a mixture of different radionuclides.

It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not take into account the radiological half-life of different radionuclides. For this reason, values are given for Class D, W, and Y compounds, even for very short-lived radionuclides.

3. Table II "Effluent Concentrations"

The columns in Table II of this appendix captioned "Effluents," "Air" and "Water" are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of D.15. The concentration values given in Columns 1 and 2 of Table II are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 0.5 mSv (0.05 rem).

Consideration of non-stochastic limits has not been included in deriving the air and water effluent concentration limits because non-stochastic effects are presumed not to occur at or below the dose levels established for individual members of the public. For radionuclides, where the non-stochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table II. For this reason, the DAC and airborne effluent limits are not always proportional.

The air concentration values listed in Table II, Column 1 were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by 2.4×10^9, relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of 300. The factor of 300 includes the following components: a factor of 50 to relate the 0.05 Sv (5 rem) annual occupational dose limit to the 1 mSv (0.1 rem) limit for members of the public, a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of 2 to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

For those radionuclides for which submersion, that is external dose, is limiting, the occupational DAC in Table I, Column 3 was divided by 219. The factor of 219 is composed of a factor of 50, as described above, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of 2 for age considerations is not warranted in the submersion case.

The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^7. The factor of 7.3×10^7 (ml) includes the following components: the factors of 50 and 2 described above and a factor of 7.3×10^5 (ml), which is the annual water intake of Reference Man.

Note 2 of this appendix provides groupings of radionuclides, which are applicable to unknown mixtures of radionuclides. These groupings, including occupational inhalation ALIs and DACs, air and water effluent concentrations and releases to sewer, require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitely excluded as being present either from knowledge of the radionuclide composition of the source or from actual measurements.

4. Table III "Releases to Sewers"

The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in D.35. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^6 (ml). The factor of 7.3×10^6 (ml) is composed of a factor of 7.3×10^5 (ml), the annual water intake by Reference Man, and a factor of 10, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a Reference Man during a year, would result in a committed effective dose equivalent of 5 mSv (0.5 rem).

LIST OF ELEMENTS

Name	Symbol	Atomic Number	Name	Symbol	Atomic Number
Actinium	Ac	89	Mercury	Hg	80
Aluminum	Al	13	Molybdenum	Mo	42
Americium	Am	95	Neodymium	Nd	60
Antimony	Sb	51	Neptunium	Np	93
Argon	Ar	18	Nickel	Ni	28
Arsenic	As	33	Niobium	Nb	41
Astatine	At	85	Osmium	Os	76
Barium	Ba	56	Palladium	Pd	46
Berkelium	Bk	97	Phosphorus	P	15
Beryllium	Be	4	Platinum	Pt	78
Bismuth	Bi	83	Plutonium	Pu	94
Bromine	Br	35	Polonium	Po	84
Cadmium	Cd	48	Potassium	K	19
Calcium	Ca	20	Praseodymium	Pr	59
Californium	Cf	98	Promethium	Pm	61
Carbon	C	6	Protactinium	Pa	91
Cerium	Ce	58	Radium	Ra	88
Cesium	Cs	55	Radon	Rn	86
Chlorine	Cl	17	Rhenium	Re	75
Chromium	Cr	24	Rhodium	Rh	45
Cobalt	Co	27	Rubidium	Rb	37
Copper	Cu	29	Ruthenium	Ru	44
Curium	Cm	96	Samarium	Sm	62
Dysprosium	Dy	66	Scandium	Sc	21
Einsteinium	Es	99	Selenium	Se	34
Erbium	Er	68	Silicon	Si	14
Europium	Eu	63	Silver	Ag	47
Fermium	Fm	100	Sodium	Na	11
Fluorine	F	9	Strontium	Sr	38
Francium	Fr	87	Sulfur	S	16
Gadolinium	Gd	64	Tantalum	Ta	73
Gallium	Ga	31	Technetium	Tc	43
Germanium	Ge	32	Tellurium	Te	52
Gold	Au	79	Terbium	Tb	65
Hafnium	Hf	72	Thallium	Tl	81
Holmium	Ho	67	Thorium	Th	90
Hydrogen	H	1	Thulium	Tm	69
Indium	In	49	Tin	Sn	50
Iodine	I	53	Titanium	Ti	22
Iridium	Ir	77	Tungsten	W	74
Iron	Fe	26	Uranium	U	92
Krypton	Kr	36	Vanadium	V	23
Lanthanum	La	57	Xenon	Xe	54
Lead	Pb	82	Ytterbium	Yb	70
Lutetium	Lu	71	Yttrium	Y	39
Magnesium	Mg	12	Zinc	Zn	30
Manganese	Mn	25	Zirconium	Zr	40
Mendelevium	Md	101			

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1	Hydrogen-3	Water, DAC includes skin absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
		Gas (HT or T2) Submersion1: Use above values as HT and T_2 oxidize in air and in the body to HTO.						
4	Beryllium-7	W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
		Y, oxides, halides, and nitrates	-	2E+4	8E-6	3E-8	-	-
4	Beryllium-10	W, see 7Be	1E+3	2E+2	6E-8	2E-10	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see 7Be	-	1E+1	6E-9	2E-11	-	-
6	Carbon-11[2]	Monoxide	-	1E+6	5E-4	2E-6	-	-
		Dioxide	-	6E+5	3E-4	9E-7	-	-
		Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
6	Carbon-14	Monoxide	-	2E+6	7E-4	2E-6	-	-
		Dioxide	-	2E+5	9E-5	3E-7	-	-
		Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
9	Fluorine-18[2]	D, fluorides of H, Li, Na, K, Rb, Cs, and Fr	5E+4	7E+4	3E-5	1E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		W, fluorides of Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Mn, Tc, and Re	-	9E+4	4E-5	1E-7	-	-
		Y, lanthanum fluoride	-	8E+4	3E-5	1E-7	-	-
11	Sodium-22	D, all compounds	4E+2	6E+2	3E-7	9E-10	6E-6	6E-5
11	Sodium-24	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
12	Magnesium-28	D, all compounds except those given for W	7E+2	2E+3	7E-7	2E-9	9E-6	9E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	1E+3	5E-7	2E-9	-	-
13	Aluminum-26	D, all compounds except those given for W	4E+2	6E+1	3E-8	9E-11	6E-6	6E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	9E+1	4E-8	1E-10	-	-
14	Silicon-31	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, oxides, hydroxides, carbides, and nitrates	-	3E+4	1E-5	5E-8	-	-
		Y, aluminosilicate glass	-	3E+4	1E-5	4E-8	-	-
14	Silicon-32	D, see 31Si	2E+3	2E+2	1E-7	3E-10	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		W, see 31Si	-	1E+2	5E-8	2E-10	-	-
		Y, see 31Si	-	5E+0	2E-9	7E-12	-	-
15	Phosphorus-32	D, all compounds except phosphates given for W	6E+2	9E+2	4E-7	1E-9	9E-6	9E-5
		W, phosphates of Zn2+, S3+, Mg2+, Fe3+, Bi3+, and lanthanides	-	4E+2	2E-7	5E-10	-	-
15	Phosphorus-33	D, see 32P	6E+3	8E+3	4E-6	1E-8	8E-5	8E-4
		W, see 32P	-	3E+3	1E-6	4E-9	-	-
16	Sulfur-35	Vapor	1E+4	6E-6	2E-8	-	-	
		D, sulfides and sulfates except those given for W	1E+4	2E+4	7E-6	2E-8	-	-
			LLI wall (8E+3)	-	-	-	1E-4	1E-3
		W, elemental sulfur, sulfides of Sr, Ba, Ge, Sn, Pb, As, Sb, Bi, Cu, Ag, Au, Zn, Cd, Hg, W, and Mo Sulfates of Ca, Sr, Ba, Ra, As, Sb, and Bi	6E+3 -	2E+3	9E-7	3E-9	-	-

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17	Chlorine-36	D, chlorides of H, Li, Na, K, Rb, Cs, and Fr	2E+3	2E+3	1E-6	3E-9	2E-5	2E-4
		W, chlorides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Cr, Mo, W, Mn, Tc, and Re	-	2E+2	1E-7	3E-10	-	-
17	Chlorine-38[2]	D, see 36Cl	2E+4	4E+4	2E-5	6E-8	-	-
			St wall (3E+4)	-	-	-	3E-4	3E-3
		W, see 36Cl	-	5E+4	2E-5	6E-8	-	-
17	Chlorine-39[2]	D, see 36Cl	2E+4	5E+4	2E-5	7E-8	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see 36Cl	-	6E+4	2E-5	8E-8	-	-
18	Argon-37	Submersion1	-	-	1E+0	6E-3	-	-
18	Argon-39	Submersion1	-	-	2E-4	8E-7	-	-
18	Argon-41	Submersion1	-	-	3E-6	1E-8	-	-
19	Potassium-40	D, all compounds	3E+2	4E+2	2E-7	6E-10	4E-6	4E-5
19	Potassium-42	D, all compounds	5E+3	5E+3	2E-6	7E-9	6E-5	6E-4
19	Potassium-43	D, all compounds	6E+3	9E+3	4E-6	1E-8	9E-5	9E-4
19	Potassium-44[2]	D, all compounds	2E+4	7E+4	3E-5	9E-8	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
19	Potassium-45[2]	D, all compounds	3E+4	1E+5	5E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
20	Calcium-41	W, all compounds	3E+3	4E+3	2E-6	-	-	-
			Bone surf (4E+3)	Bone surf (4E+3)	-	5E-9	6E-5	6E-4
20	Calcium-45	W, all compounds	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
20	Calcium-47	W, all compounds	8E+2	9E+2	4E-7	1E-9	1E-5	1E-4
21	Scandium-43	Y, all compounds	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
21	Scandium-44m	Y, all compounds	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
21	Scandium-44	Y, all compounds	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
21	Scandium-46	Y, all compounds	9E+2	2E+2	1E-7	3E-10	1E-5	1E-4
21	Scandium-47	Y, all compounds	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
21	Scandium-48	Y, all compounds	8E+2	1E+3	6E-7	2E-9	1E-5	1E-4
21	Scandium-49[2]	Y, all compounds	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
22	Titanium-44	D, all compounds except those given for W and Y	3E+2	1E+1	5E-9	2E-11	4E-6	4E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	3E+1	1E-8	4E-11	-	-
		Y, SrTi0	-	6E+0	2E-9	8E-12	-	-
22	Titanium-45	D, see 44Ti	9E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		W, see 44Ti	-	4E+4	1E-5	5E-8	-	-
		Y, see 44Ti	-	3E+4	1E-5	4E-8	-	-
23	Vanadium-47[2]	D, all compounds except those given for W	3E+4	8E+4	3E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, oxides, hydroxides, carbides, and halides	-	1E+5	4E-5	1E-7	-	-
23	Vanadium-48	D, see 47V	6E+2	1E+3	5E-7	2E-9	9E-6	9E-5
		W, see 47V	-	6E+2	3E-7	9E-10	-	-
23	Vanadium-49	D, see 47V	7E+4	3E+4	1E-5	-	-	-
			LLI wall (9E+4)	Bone surf (3E+4)	-	5E-8	1E-3	1E-2
		W, see 47V	-	2E+4	8E-6	2E-8	-	-
24	Chromium-48	D, all compounds except those given for W and Y	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, halides and nitrates	-	7E+3	3E-6	1E-8	-	-
		Y, oxides and hydroxides	-	7E+3	3E-6	1E-8	-	-
24	Chromium-49[2]	D, see 48Cr	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
		W, see 48Cr	-	1E+5	4E-5	1E-7	-	-
		Y, see 48Cr	-	9E+4	4E-5	1E-7	-	-
24	Chromium-51	D, see 48Cr	4E+4	5E+4	2E-5	6E-8	5E-4	5E-3
		W, see 48Cr	-	2E+4	1E-5	3E-8	-	-
		Y, see 48Cr	-	2E+4	8E-6	3E-8	-	-
25	Manganese-51[2]	D, all compounds except those given for W	2E+4	5E+4	2E-5	7E-8	3E-4	3E-3
		W, oxides, hydroxides, halides, and nitrates	-	6E+4	3E-5	8E-8	-	-

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25	Manganese-52m[2]	D, see 51Mn	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see 51Mn	-	1E+5	4E-5	1E-7	-	-
25	Manganese-52	D, see 51Mn	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
		W, see 51Mn	-	9E+2	4E-7	1E-9	-	-
25	Manganese-53	D, see 51Mn	5E+4	1E+4	5E-6	-	7E-4	7E-3
			-	Bone surf (2E+4)	-	3E-8	-	-
		W, see 51Mn	-	1E+4	5E-6	2E-8	-	-
25	Manganese-54	D, see 51Mn	2E+3	9E+2	4E-7	1E-9	3E-5	3E-4
		W, see 51Mn	-	8E+2	3E-7	1E-9	-	-
25	Manganese-56	D, see 51Mn	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see 51Mn	-	2E+4	9E-6	3E-8	-	-
26	Iron-52	D, all compounds except those given for W	9E+2	3E+3	1E-6	4E-9	1E-5	1E-4
		W, oxides, hydroxides, and halides	-	2E+3	1E-6	3E-9	-	-
26	Iron-55	D, see 52Fe	9E+3	2E+3	8E-7	3E-9	1E-4	1E-3
		W, see 52Fe	-	4E+3	2E-6	6E-9	-	-
26	Iron-59	D, see 52Fe	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		W, see 52Fe	-	5E+2	2E-7	7E-10	-	-
26	Iron-60	D, see 52Fe	3E+1	6E+0	3E-9	9E-12	4E-7	4E-6
		W, see 52Fe	-	2E+1	8E-9	3E-11	-	-
27	Cobalt-55	W, all compounds except those given for Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, oxides, hydroxides, halides, and nitrates	-	3E+3	1E-6	4E-9	-	-
27	Cobalt-56	W, see 55Co	5E+2	3E+2	1E-7	4E-10	6E-6	6E-5
		Y, see 55Co	4E+2	2E+2	8E-8	3E-10	-	-
27	Cobalt-57	W, see 55Co	8E+3	3E+3	1E-6	4E-9	6E-5	6E-4
		Y, see 55Co	4E+3	7E+2	3E-7	9E-10	-	-
27	Cobalt-58m	W, see 55Co	6E+4	9E+4	4E-5	1E-7	8E-4	8E-3
		Y, see 55Co	-	6E+4	3E-5	9E-8	-	-
27	Cobalt-58	W, see 55Co	2E+3	1E+3	5E-7	2E-9	2E-5	2E-4
		Y, see 55Co	1E+3	7E+2	3E-7	1E-9	-	-
27	Cobalt-60m[2]	W, see 55Co	1E+6	4E+6	2E-3	6E-6	-	-
			St wall (1E+6)	-	-	-	2E-2	2E-1
		Y, see 55Co	-	3E+6	1E-3	4E-6	-	-
27	Cobalt-60	W, see 55Co	5E+2	2E+2	7E-8	2E-10	3E-6	3E-5
		Y, see 55Co	2E+2	3E+1	1E-8	5E-11	-	-
27	Cobalt-612	W, see 55Co	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		Y, see 55Co	2E+4	6E+4	2E-5	8E-8	-	-
27	Cobalt-62m[2]	W, see 55Co	4E+4	2E+5	7E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		Y, see 55Co	-	2E+5	6E-5	2E-7	-	-
28	Nickel-56	D, all compounds except those given for W	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
		W, oxides, hydroxides, and carbides	-	1E+3	5E-7	2E-9	-	-
		Vapor	-	1E+3	5E-7	2E-9	-	-
28	Nickel-57	D, see 56Ni	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
		W, see 56Ni	-	3E+3	1E-6	4E-9	-	-
		Vapor	-	6E+3	3E-6	9E-9	-	-
28	Nickel-59	D, see 56Ni	2E+4	4E+3	2E-6	5E-9	3E-4	3E-3
		W, see 56Ni	-	7E+3	3E-6	1E-8	-	-
		Vapor	-	2E+3	8E-7	3E-9	-	-
28	Nickel-63	D, see 56Ni	9E+3	2E+3	7E-7	2E-9	1E-4	1E-3
		W, see 56Ni	-	3E+3	1E-6	4E-9	-	-
		Vapor	-	8E+2	3E-7	1E-9	-	-
28	Nickel-65	D, see 56Ni	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see 56Ni	-	3E+4	1E-5	4E-8	-	-
		Vapor	-	2E+4	7E-6	2E-8	-	-
28	Nickel-66	D, see 56Ni	4E+2	2E+3	7E-7	2E-9	-	-
			LLI wall (5E+2)	-	-	-	6E-6	6E-5
		W, see 56Ni	-	6E+2	3E-7	9E-10	-	-
		Vapor	-	3E+3	1E-6	4E-9	-	-
29	Copper-60[2]	D, all compounds except those given for W and Y	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, sulfides, halides, and nitrates	-	1E+5	5E-5	2E-7	-	-
		Y, oxides and hydroxides	-	1E+5	4E-5	1E-7	-	-
29	Copper-61	D, see 60Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see 60Cu	-	4E+4	2E-5	6E-8	-	-
		Y, see 60Cu	-	4E+4	1E-5	5E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
29	Copper-64	D, see 60Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see 60Cu	-	2E+4	1E-5	3E-8	-	-
		Y, see 60Cu	-	2E+4	9E-6	3E-8	-	-
29	Copper-67	D, see 60Cu	5E+3	8E+3	3E-6	1E-8	6E-5	6E-4
		W, see 60Cu	-	5E+3	2E-6	7E-9	-	-
		Y, see 60Cu	-	5E+3	2E-6	6E-9	-	-
30	Zinc-62	Y, all compounds	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
30	Zinc-63[2]	Y, all compounds	2E+4	7E+4	3E-5	9E-8	-	-
			St wall (3E+4)	-	-	-	3E-4	3E-3
30	Zinc-65	Y, all compounds	4E+2	3E+2	1E-7	4E-10	5E-6	5E-5
30	Zinc-69m	Y, all compounds	4E+3	7E+3	3E-6	1E-8	6E-5	6E-4
30	Zinc-69[2]	Y, all compounds	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
30	Zinc-71m	Y, all compounds	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
30	Zinc-72	Y, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
31	Gallium-65[2]	D, all compounds except those given for W	5E+4	2E+5	7E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	9E-4	9E-3
		W, oxides, hydroxides, carbides, halides, and nitrates	-	2E+5	8E-5	3E-7	-	-
31	Gallium-66	D, see 65Ga	1E+3	4E+3	1E-6	5E-9	1E-5	1E-4
		W, see 65Ga	-	3E+3	1E-6	4E-9	-	-
31	Gallium-67	D, see 65Ga	7E+3	1E+4	6E-6	2E-8	1E-4	1E-3
		W, see 65Ga	-	1E+4	4E-6	1E-8	-	-
31	Gallium-68[2]	D, see 65Ga	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see 65Ga	-	5E+4	2E-5	7E-8	-	-
31	Gallium-70[2]	D, see 65Ga	5E+4	2E+5	7E-5	2E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		W, see 65Ga	-	2E+5	8E-5	3E-7	-	-
31	Gallium-72	D, see 65Ga	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see 65Ga	-	3E+3	1E-6	4E-9	-	-
31	Gallium-73	D, see 65Ga	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see 65Ga	-	2E+4	6E-6	2E-8	-	-
32	Germanium-66	D, all compounds except those given for W	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
		W, oxides, sulfides, and halides	-	2E+4	8E-6	3E-8	-	-
32	Germanium-67[2]	D, see 66Ge	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		W, see 66Ge	-	1E+5	4E-5	1E-7	-	-
32	Germanium-68	D, see 66Ge	5E+3	4E+3	2E-6	5E-9	6E-5	6E-4
		W, see 66Ge	-	1E+2	4E-8	1E-10	-	-
32	Germanium-69	D, see 66Ge	1E+4	2E+4	6E-6	2E-8	2E-4	2E-3
		W, see 66Ge	-	8E+3	3E-6	1E-8	-	-
32	Germanium-71	D, see 66Ge	5E+5	4E+5	2E-4	6E-7	7E-3	7E-2
		W, see 66Ge	-	4E+4	2E-5	6E-8	-	-
32	Germanium-75[2]	D, see 66Ge	4E+4	8E+4	3E-5	1E-7	-	-
			St wall (7E+4)	-	-	-	9E-4	9E-3
		W, see 66Ge	-	8E+4	4E-5	1E-7	-	-
32	Germanium-77	D, see 66Ge	9E+3	1E+4	4E-6	1E-8	1E-4	1E-3
		W, see 66Ge	-	6E+3	2E-6	8E-9	-	-
32	Germanium-78[2]	D, see 66Ge	2E+4	2E+4	9E-6	3E-8	-	-
			St wall (2E+4)	-	-	-	3E-4	3E-3
		W, see 66Ge	-	2E+4	9E-6	3E-8	-	-
33	Arsenic-69[2]	W, all compounds	3E+4	1E+5	5E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
33	Arsenic-70[2]	W, all compounds	1E+4	5E+4	2E-5	7E-8	2E-4	2E-3
33	Arsenic-71	W, all compounds	4E+3	5E+3	2E-6	6E-9	5E-5	5E-4
33	Arsenic-72	W, all compounds	9E+2	1E+3	6E-7	2E-9	1E-5	1E-4
33	Arsenic-73	W, all compounds	8E+3	2E+3	7E-7	2E-9	1E-4	1E-3
33	Arsenic-74	W, all compounds	1E+3	8E+2	3E-7	1E-9	2E-5	2E-4
33	Arsenic-76	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
33	Arsenic-77	W, all compounds	4E+3	5E+3	2E-6	7E-9	-	-
			LLI wall (5E+3)	-	-	-	6E-5	6E-4
33	Arsenic-782	W, all compounds	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
34	Selenium-70[2]	D, all compounds except those given for W	2E+4	4E+4	2E-5	5E-8	1E-4	1E-3
		W, oxides, hydroxides, carbides, and elemental Se	1E+4	4E+4	2E-5	6E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
34	Selenium-73m[2]	D, see 70Se	6E+4	2E+5	6E-5	2E-7	4E-4	4E-3
		W, see 70Se	3E+4	1E+5	6E-5	2E-7	-	-
34	Selenium-73	D, see 70Se	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
		W, see 70Se	-	2E+4	7E-6	2E-8	-	-
34	Selenium-75	D, see 70Se	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
		W, see 70Se	-	6E+2	3E-7	8E-10	-	-
34	Selenium-79	D, see 70Se	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
		W, see 70Se	-	6E+2	2E-7	8E-10	-	-
34	Selenium-81m[2]	D, see 70Se	4E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		W, see 70Se	2E+4	7E+4	3E-5	1E-7	-	-
34	Selenium-81[2]	D, see 70Se	6E+4	2E+5	9E-5	3E-7	-	-
			St wall (8E+4)	-	-	-	1E-3	1E-2
		W, see 70Se	-	2E+5	1E-4	3E-7	-	-
34	Selenium-83[2]	D, see 70Se	4E+4	1E+5	5E-5	2E-7	4E-4	4E-3
		W, see 70Se	3E+4	1E+5	5E-5	2E-7	-	-
35	Bromine-74m[2]	D, bromides of H, Li, Na, K, Rb, Cs, and Fr	1E+4	4E+4	2E-5	5E-8	-	-
			St wall (2E+4)	-	-	-	3E-4	3E-3
		W, bromides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Mn, Tc, and Re	-	4E+4	2E-5	6E-8	-	-
35	Bromine-74[2]	D, see 74mBr	2E+4	7E+4	3E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see 74mBr	-	8E+4	4E-5	1E-7	-	-
35	Bromine-75[2]	D, see 74mBr	3E+4	5E+4	2E-5	7E-8	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see 74mBr	-	5E+4	2E-5	7E-8	-	-
35	Bromine-76	D, see 74mBr	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
		W, see 74mBr	-	4E+3	2E-6	6E-9	-	-
35	Bromine-77	D, see 74mBr	2E+4	2E+4	1E-5	3E-8	2E-4	2E-3
		W, see 74mBr	-	2E+4	8E-6	3E-8	-	-
35	Bromine-80m	D, see 74mBr	2E+4	2E+4	7E-6	2E-8	3E-4	3E-3
		W, see 74mBr	-	1E+4	6E-6	2E-8	-	-
35	Bromine-80[2]	D, see 74mBr	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see 74mBr	-	2E+5	9E-5	3E-7	-	-
35	Bromine-82	D, see 74mBr	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see 74mBr	-	4E+3	2E-6	5E-9	-	-
35	Bromine-83	D, see 74mBr	5E+4	6E+4	3E-5	9E-8	-	-
			St wall (7E+4)	-	-	-	9E-4	9E-3
		W, see 74mBr	-	6E+4	3E-5	9E-8	-	-
35	Bromine-84[2]	D, see 74mBr	2E+4	6E+4	2E-5	8E-8	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, see 74mBr	-	6E+4	3E-5	9E-8	-	-
36	Krypton-74[2]	Submersion1	-	-	3E-6	1E-8	-	-
36	Krypton-76	Submersion1	-	-	9E-6	4E-8	-	-
36	Krypton-77[2]	Submersion1	-	-	4E-6	2E-8	-	-
36	Krypton-79	Submersion1	-	-	2E-5	7E-8	-	-
36	Krypton-81	Submersion1	-	-	7E-4	3E-6	-	-
36	Krypton-83m[2]	Submersion1	-	-	1E-2	5E-5	-	-
36	Krypton-85m	Submersion1	-	-	2E-5	1E-7	-	-
36	Krypton-85	Submersion1	-	-	1E-4	7E-7	-	-
36	Krypton-87[2]	Submersion1	-	-	5E-6	2E-8	-	-
36	Krypton-88	Submersion1	-	-	2E-6	9E-9	-	-
37	Rubidium-79[2]	D, all compounds	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
37	Rubidium-81m[2]	D, all compounds	2E+5	3E+5	1E-4	5E-7	-	-
			St wall (3E+5)	-	-	-	4E-3	4E-2
37	Rubidium-81	D, all compounds	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
37	Rubidium-82m	D, all compounds	1E+4	2E+4	7E-6	2E-8	2E-4	2E-3
37	Rubidium-83	D, all compounds	6E+2	1E+3	4E-7	1E-9	9E-6	9E-5
37	Rubidium-84	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37	Rubidium-86	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37	Rubidium-87	D, all compounds	1E+3	2E+3	6E-7	2E-9	1E-5	1E-4
37	Rubidium-88[2]	D, all compounds	2E+4	6E+4	3E-5	9E-8	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
37	Rubidium-89[2]	D, all compounds	4E+4	1E+5	6E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	9E-4	9E-3
38	Strontium-80[2]	D, all soluble compounds except SrTiO	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		Y, all insoluble compounds and SrTi0	-	1E+4	5E-6	2E-8	-	-
38	Strontium-81[2]	D, see 80Sr	3E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see 80Sr	2E+4	8E+4	3E-5	1E-7	-	-
38	Strontium-82	D, see 80Sr	3E+2	4E+2	2E-7	6E-10	-	-
			LLI wall (2E+2)	-	-	-	3E-6	3E-5
		Y, see 80Sr	2E+2	9E+1	4E-8	1E-10	-	-
38	Strontium-83	D, see 80Sr	3E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, see 80Sr	2E+3	4E+3	1E-6	5E-9	-	-
38	Strontium-85m[2]	D, see 80Sr	2E+5	6E+5	3E-4	9E-7	3E-3	3E-2
		Y, see 80Sr	-	8E+5	4E-4	1E-6	-	-
38	Strontium-85	D, see 80Sr	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
		Y, see 80Sr	-	2E+3	6E-7	2E-9	-	-
38	Strontium-87m	D, see 80Sr	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		Y, see 80Sr	4E+4	2E+5	6E-5	2E-7	-	-
38	Strontium-89	D, see 80Sr	6E+2	8E+2	4E-7	1E-9	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		Y, see 80Sr	5E+2	1E+2	6E-8	2E-10	-	-
38	Strontium-90	D, see 80Sr	3E+1	2E+1	8E-9	-	-	-
			Bone surf (4E+1)	Bone surf (2E+1)	-	3E-11	5E-7	5E-6
		Y, see 80Sr	-	4E+0	2E-9	6E-12	-	-
38	Strontium-91	D, see 80Sr	2E+3	6E+3	2E-6	8E-9	2E-5	2E-4
		Y, see 80Sr	-	4E+3	1E-6	5E-9	-	-
38	Strontium-92	D, see 80Sr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see 80Sr	-	7E+3	3E-6	9E-9	-	-
39	Yttrium-86m[2]	W, all compounds except those given for Y	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		Y, oxides and hydroxides	-	5E+4	2E-5	8E-8	-	-
39	Yttrium-86	W, see 86mY	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
		Y, see 86mY	-	3E+3	1E-6	5E-9	-	-
39	Yttrium-87	W, see 86mY	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		Y, see 86mY	-	3E+3	1E-6	5E-9	-	-
39	Yttrium-88	W, see 86mY	1E+3	3E+2	1E-7	3E-10	1E-5	1E-4
		Y, see 86mY	-	2E+2	1E-7	3E-10	-	-
39	Yttrium-90m	W, see 86mY	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
		Y, see 86mY	-	1E+4	5E-6	2E-8	-	-
39	Yttrium-90	W, see 86mY	4E+2	7E+2	3E-7	9E-10	-	-
			LLI wall (5E+2)	-	-	-	7E-6	7E-5
		Y, see 86mY	-	6E+2	3E-7	9E-10	-	-
39	Yttrium-91m[2]	W, see 86mY	1E+5	2E+5	1E-4	3E-7	2E-3	2E-2
		Y, see 86mY	-	2E+5	7E-5	2E-7	-	-
39	Yttrium-91	W, see 86mY	5E+2	2E+2	7E-8	2E-10	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		Y, see 86mY	-	1E+2	5E-8	2E-10	-	-
39	Yttrium-92	W, see 86mY	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see 86mY	-	8E+3	3E-6	1E-8	-	-
39	Yttrium-93	W, see 86mY	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, see 86mY	-	2E+3	1E-6	3E-9	-	-
39	Yttrium-94[2]	W, see 86mY	2E+4	8E+4	3E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		Y, see 86mY	-	8E+4	3E-5	1E-7	-	-
39	Yttrium-95[2]	W, see 86mY	4E+4	2E+5	6E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		Y, see 86mY	-	1E+5	6E-5	2E-7	-	-
40	Zirconium-86	D, all compounds except those given for W and Y	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
		W, oxides, hydroxides, halides, and nitrates	-	3E+3	1E-6	4E-9	-	-
		Y, carbide	-	2E+3	1E-6	3E-9	-	-
40	Zirconium-88	D, see 86Zr	4E+3	2E+2	9E-8	3E-10	5E-5	5E-4
		W, see 86Zr	-	5E+2	2E-7	7E-10	-	-
		Y, see 86Zr	-	3E+2	1E-7	4E-10	-	-
40	Zirconium-89	D, see 86Zr	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see 86Zr	-	2E+3	1E-6	3E-9	-	-
		Y, see 86Zr	-	2E+3	1E-6	3E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
40	Zirconium-93	D, see 86Zr	1E+3	6E+0	3E-9	-	-	-
			Bone surf (3E+3)	Bone surf (2E+1)	-	2E-11	4E-5	4E-4
		W, see 86Zr	-	2E+1	1E-8	-	-	-
			-	Bone surf (6E+1)	-	9E-11	-	-
		Y, see 86Zr	-	6E+1	2E-8	-	-	-
			-	Bone surf (7E+1)	-	9E-11	-	-
40	Zirconium-95	D, see 86Zr	1E+3	1E+2	5E-8	-	2E-5	2E-4
			-	Bone surf (3E+2)	-	4E-10	-	-
		W, see 86Zr	-	4E+2	2E-7	5E-10	-	-
		Y, see 86Zr	-	3E+2	1E-7	4E-10	-	-
40	Zirconium-97	D, see 86Zr	6E+2	2E+3	8E-7	3E-9	9E-6	9E-5
		W, see 86Zr	-	1E+3	6E-7	2E-9	-	-
		Y, see 86Zr	-	1E+3	5E-7	2E-9	-	-
41	Niobium-88[2]	W, all compounds except those given for Y	5E+4	2E+5	9E-5	3E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		Y, oxides and hydroxides	-	2E+5	9E-5	3E-7	-	-
41	Niobium-89[2]	W, see 88Nb (66 min)	1E+4	4E+4	2E-5	6E-8	1E-4	1E-3
		Y, see 88Nb	-	4E+4	2E-5	5E-8	-	-
41	Niobium-89	W, see 88Nb (122 min)	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see 88Nb	-	2E+4	6E-6	2E-8	-	-
41	Niobium-90	W, see 88Nb	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		Y, see 88Nb	-	2E+3	1E-6	3E-9	-	-
41	Niobium-93m	W, see 88Nb	9E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (1E+4)	-	-	-	2E-4	2E-3
		Y, see 88Nb	-	2E+2	7E-8	2E-10	-	-
41	Niobium-94	W, see 88Nb	9E+2	2E+2	8E-8	3E-10	1E-5	1E-4
		Y, see 88Nb	-	2E+1	6E-9	2E-11	-	-
41	Niobium-95m	W, see 88Nb	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see 88Nb	-	2E+3	9E-7	3E-9	-	-
41	Niobium-95	W, see 88Nb	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
		Y, see 88Nb	-	1E+3	5E-7	2E-9	-	-
41	Niobium-96	W, see 88Nb	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, see 88Nb	-	2E+3	1E-6	3E-9	-	-
41	Niobium-97[2]	W, see 88Nb	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see 88Nb	-	7E+4	3E-5	1E-7	-	-
41	Niobium-98[2]	W, see 88Nb	1E+4	5E+4	2E-5	8E-8	2E-4	2E-3
		Y, see 88Nb	-	5E+4	2E-5	7E-8	-	-
42	Molybdenum-90	D, all compounds except those given for Y	4E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, oxides, hydroxides, and MoS	2E+3	5E+3	2E-6	6E-9	-	-
42	Molybdenum-93m	D, see 90Mo	9E+3	2E+4	7E-6	2E-8	6E-5	6E-4
		Y, see 90Mo	4E+3	1E+4	6E-6	2E-8	-	-
42	Molybdenum-93	D, see 90Mo	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
		Y, see 90Mo	2E+4	2E+2	8E-8	2E-10	-	-
42	Molybdenum-99	D, see 90Mo	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see 90Mo	1E+3	1E+3	6E-7	2E-9	-	-
42	Molybdenum-101[2]	D, see 90Mo	4E+4	1E+5	6E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		Y, see 90Mo	-	1E+5	6E-5	2E-7	-	-
43	Technetium-93m[2]	D, all compounds except those given for W	7E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, and nitrates	-	3E+5	1E-4	4E-7	-	-
43	Technetium-93	D, see 93mTc	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
		W, see 93mTc	-	1E+5	4E-5	1E-7	-	-
43	Technetium-94m[2]	D, see 93mTc	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
		W, see 93mTc	-	6E+4	2E-5	8E-8	-	-
43	Technetium-94	D, see 93mTc	9E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see 93mTc	-	2E+4	1E-5	3E-8	-	-
43	Technetium-95m	D, see 93mTc	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
		W, see 93mTc	-	2E+3	8E-7	3E-9	-	-
43	Technetium-95	D, see 93mTc	1E+4	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see 93mTc	-	2E+4	8E-6	3E-8	-	-
43	Technetium-96m[2]	D, see 93mTc	2E+5	3E+5	1E-4	4E-7	2E-3	2E-2
		W, see 93mTc	-	2E+5	1E-4	3E-7	-	-
43	Technetium-96	D, see 93mTc	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		W, see 93mTc	-	2E+3	9E-7	3E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
43	Technetium-97m	D, see 93mTc	5E+3	7E+3	3E-6	-	6E-5	6E-4
			-	St wall (7E+3)	-	1E-8	-	-
		W, see 93mTc	-	1E+3	5E-7	2E-9	-	-
43	Technetium-97	D, see 93mTc	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
		W, see 93mTc	-	6E+3	2E-6	8E-9	-	-
43	Technetium-98	D, see 93mTc	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
		W, see 93mTc	-	3E+2	1E-7	4E-10	-	-
43	Technetium-99m	D, see 93mTc	8E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, see 93mTc	-	2E+5	1E-4	3E-7	-	-
43	Technetium-99	D, see 93mTc	4E+3	5E+3	2E-6	-	6E-5	6E-4
			-	St wall (6E+3)	-	8E-9	-	-
		W, see 93mTc	-	7E+2	3E-7	9E-10	-	-
43	Technetium-101[2]	D, see 93mTc	9E+4	3E+5	1E-4	5E-7	-	-
			St wall (1E+5)	-	-	-	2E-3	2E-2
		W, see 93mTc	-	4E+5	2E-4	5E-7	-	-
43	Technetium-104[2]	D, see 93mTc	2E+4	7E+4	3E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, see 93mTc	-	9E+4	4E-5	1E-7	-	-
44	Ruthenium-94[2]	D, all compounds except those given for W and Y	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, halides	-	6E+4	3E-5	9E-8	-	-
		Y, oxides and hydroxides	-	6E+4	2E-5	8E-8	-	-
44	Ruthenium-97	D, see 94Ru	8E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see 94Ru	-	1E+4	5E-6	2E-8	-	-
		Y, see 94Ru	-	1E+4	5E-6	2E-8	-	-
44	Ruthenium-103	D, see 94Ru	2E+3	2E+3	7E-7	2E-9	3E-5	3E-4
		W, see 94Ru	-	1E+3	4E-7	1E-9	-	-
		Y, see 94Ru	-	6E+2	3E-7	9E-10	-	-
44	Ruthenium-105	D, see 94Ru	5E+3	1E+4	6E-6	2E-8	7E-5	7E-4
		W, see 94Ru	-	1E+4	6E-6	2E-8	-	-
		Y, see 94Ru	-	1E+4	5E-6	2E-8	-	-
44	Ruthenium-106	D, see 94Ru	2E+2	9E+1	4E-8	1E-10	-	-
			LLI wall (2E+2)	-	-	-	3E-6	3E-5
		W, see 94Ru	-	5E+1	2E-8	8E-11	-	-
		Y, see 94Ru	-	1E+1	5E-9	2E-11	-	-
45	Rhodium-99m	D, all compounds except those given for W and Y	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
		W, halides	-	8E+4	3E-5	1E-7	-	-
		Y, oxides and hydroxides	-	7E+4	3E-5	9E-8	-	-
45	Rhodium-99	D, see 99mRh	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see 99mRh	-	2E+3	9E-7	3E-9	-	-
		Y, see 99mRh	-	2E+3	8E-7	3E-9	-	-
45	Rhodium-100	D, see 99mRh	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
		W, see 99mRh	-	4E+3	2E-6	6E-9	-	-
		Y, see 99mRh	-	4E+3	2E-6	5E-9	-	-
45	Rhodium-101m	D, see 99mRh	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, see 99mRh	-	8E+3	4E-6	1E-8	-	-
		Y, see 99mRh	-	8E+3	3E-6	1E-8	-	-
45	Rhodium-101	D, see 99mRh	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
		W, see 99mRh	-	8E+2	3E-7	1E-9	-	-
		Y, see 99mRh	-	2E+2	6E-8	2E-10	-	-
45	Rhodium-102m	D, see 99mRh	1E+3	5E+2	2E-7	7E-10	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		W, see 99mRh	-	4E+2	2E-7	5E-10	-	-
		Y, see 99mRh	-	1E+2	5E-8	2E-10	-	-
45	Rhodium-102	D, see 99mRh	6E+2	9E+1	4E-8	1E-10	8E-6	8E-5
		W, see 99mRh	-	2E+2	7E-8	2E-10	-	-
		Y, see 99mRh	-	6E+1	2E-8	8E-11	-	-
45	Rhodium-103m[2]	D, see 99mRh	4E+5	1E+6	5E-4	2E-6	6E-3	6E-2
		W, see 99mRh	-	1E+6	5E-4	2E-6	-	-
		Y, see 99mRh	-	1E+6	5E-4	2E-6	-	-
45	Rhodium-105	D, see 99mRh	4E+3	1E+4	5E-6	2E-8	-	-
			LLI wall (4E+3)	-	-	-	5E-5	5E-4
		W, see 99mRh	-	6E+3	3E-6	9E-9	-	-
		Y, see 99mRh	-	6E+3	2E-6	8E-9	-	-
45	Rhodium-106m	D, see 99mRh	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, see 99mRh	-	4E+4	2E-5	5E-8	-	-
		Y, see 99mRh	-	4E+4	1E-5	5E-8	-	-
45	Rhodium-107[2]	D, see 99mRh	7E+4	2E+5	1E-4	3E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see 99mRh	-	3E+5	1E-4	4E-7	-	-
		Y, see 99mRh	-	3E+5	1E-4	3E-7	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
46	Palladium-100	D, all compounds except those given for W and Y	1E+3	1E+3	6E-7	2E-9	2E-5	2E-4
		W, nitrates	-	1E+3	5E-7	2E-9	-	-
		Y, oxides and hydroxides	-	1E+3	6E-7	2E-9	-	-
46	Palladium-101	D, see 100Pd	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see 100Pd	-	3E+4	1E-5	5E-8	-	-
		Y, see 100Pd	-	3E+4	1E-5	4E-8	-	-
46	Palladium-103	D, see 100Pd	6E+3	6E+3	3E-6	9E-9	-	-
			LLI wall (7E+3)	-	-	-	1E-4	1E-3
		W, see 100Pd	-	4E+3	2E-6	6E-9	-	-
		Y, see 100Pd	-	4E+3	1E-6	5E-9	-	-
46	Palladium-107	D, see 100Pd	3E+4	2E+4	9E-6	-	-	-
			LLI wall (4E+4)	Kidneys (2E+4)	-	3E-8	5E-4	5E-3
		W, see 100Pd	-	7E+3	3E-6	1E-8	-	-
		Y, see 100Pd	-	4E+2	2E-7	6E-10	-	-
46	Palladium-109	D, see 100Pd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
		W, see 100Pd	-	5E+3	2E-6	8E-9	-	-
		Y, see 100Pd	-	5E+3	2E-6	6E-9	-	-
47	Silver-102[2]	D, all compounds except those given for W and Y	5E+4	2E+5	8E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	9E-4	9E-3
		W, nitrates and sulfides	-	2E+5	9E-5	3E-7	-	-
		Y, oxides and hydroxides	-	2E+5	8E-5	3E-7	-	-
47	Silver-103[2]	D, see 102Ag	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
		W, see 102Ag	-	1E+5	5E-5	2E-7	-	-
		Y, see 102Ag	-	1E+5	5E-5	2E-7	-	-
47	Silver-104m[2]	D, see 102Ag	3E+4	9E+4	4E-5	1E-7	4E-4	4E-3
		W, see 102Ag	-	1E+5	5E-5	2E-7	-	-
		Y, see 102Ag	-	1E+5	5E-5	2E-7	-	-
47	Silver-104[2]	D, see 102Ag	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
		W, see 102Ag	-	1E+5	6E-5	2E-7	-	-
		Y, see 102Ag	-	1E+5	6E-5	2E-7	-	-
47	Silver-105	D, see 102Ag	3E+3	1E+3	4E-7	1E-9	4E-5	4E-4
		W, see 102Ag	-	2E+3	7E-7	2E-9	-	-
		Y, see 102Ag	-	2E+3	7E-7	2E-9	-	-
47	Silver-106m	D, see 102Ag	8E+2	7E+2	3E-7	1E-9	1E-5	1E-4
		W, see 102Ag	-	9E+2	4E-7	1E-9	-	-
		Y, see 102Ag	-	9E+2	4E-7	1E-9	-	-
47	Silver-106[2]	D, see 102Ag	6E+4	2E+5	8E-5	3E-7	-	-
			St. wall (6E+4)	-	-	-	9E-4	9E-3
		W, see 102Ag	-	2E+5	9E-5	3E-7	-	-
		Y, see 102Ag	-	2E+5	8E-5	3E-7	-	-
47	Silver-108m	D, see 102Ag	6E+2	2E+2	8E-8	3E-10	9E-6	9E-5
		W, see 102Ag	-	3E+2	1E-7	4E-10	-	-
		Y, see 102Ag	-	2E+1	1E-8	3E-11	-	-
47	Silver-110m	D, see 102Ag	5E+2	1E+2	5E-8	2E-10	6E-6	6E-5
		W, see 102Ag	-	2E+2	8E-8	3E-10	-	-
		Y, see 102Ag	-	9E+1	4E-8	1E-10	-	-
47	Silver-111	D, see 102Ag	9E+2	2E+3	6E-7	-	-	-
			LLI wall (1E+3)	Liver (2E+3)	-	2E-9	2E-5	2E-4
		W, see 102Ag	-	9E+2	4E-7	1E-9	-	-
		Y, see 102Ag	-	9E+2	4E-7	1E-9	-	-
47	Silver-112	D, see 102Ag	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see 102Ag	-	1E+4	4E-6	1E-8	-	-
		Y, see 102Ag	-	9E+3	4E-6	1E-8	-	-
47	Silver-115[2]	D, see 102Ag	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, see 102Ag	-	9E+4	4E-5	1E-7	-	-
		Y, see 102Ag	-	8E+4	3E-5	1E-7	-	-
48	Cadmium-104[2]	D, all compounds except those given for W and Y	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		W, sulfides, halides, and nitrates	-	1E+5	5E-5	2E-7	-	-
		Y, oxides and hydroxides	-	1E+5	5E-5	2E-7	-	-
48	Cadmium-107	D, see 104Cd	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
		W, see 104Cd	-	6E+4	2E-5	8E-8	-	-
		Y, see 104Cd	-	5E+4	2E-5	7E-8	-	-
48	Cadmium-109	D, see 104Cd	3E+2	4E+1	1E-8	-	-	-
			Kidneys (4E+2)	Kidneys (5E+1)	-	7E-11	6E-6	6E-5
		W, see 104Cd	-	1E+2	5E-8	-	-	-
			-	Kidneys (1E+2)	-	2E-10	-	-
		Y, see 104Cd	-	1E+2	5E-8	2E-10	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
48	Cadmium-113m	D, see 104Cd	2E+1	2E+0	1E-9	-	-	-
			Kidneys (4E+1)	Kidneys (4E+0)	-	5E-12	5E-7	5E-6
		W, see 104Cd	-	8E+0	4E-9	-	-	-
			-	Kidneys (1E+1)	-	2E-11	-	-
		Y, see 104Cd	-	1E+1	5E-9	2E-11	-	-
48	Cadmium-113	D, see 104Cd	2E+1	2E+0	9E-10	-	-	-
			Kidneys (3E+1)	Kidneys (3E+0)	-	5E-12	4E-7	4E-6
		W, see 104Cd	-	8E+0	3E-9	-	-	-
			-	Kidneys (1E+1)	-	2E-11	-	-
		Y, see 104Cd	-	1E+1	6E-9	2E-11	-	-
48	Cadmium-115m	D, see 104Cd	3E+2	5E+1	2E-8	-	4E-6	4E-5
			-	Kidneys (8E+1)	-	1E-10	-	-
		W, see 104Cd	-	1E+2	5E-8	2E-10	-	-
		Y, see 104Cd	-	1E+2	6E-8	2E-10	-	-
48	Cadmium-115	D, see 104Cd	9E+2	1E+3	6E-7	2E-9	-	-
			LLI wall (1E+3)	-	-	-	1E-5	1E-4
		W, see 104Cd	-	1E+3	5E-7	2E-9	-	-
		Y, see 104Cd	-	1E+3	6E-7	2E-9	-	-
48	Cadmium-117m	D, see 104Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		W, see 104Cd	-	2E+4	7E-6	2E-8	-	-
		Y, see 104Cd	-	1E+4	6E-6	2E-8	-	-
48	Cadmium-117	D, see 104Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		W, see 104Cd	-	2E+4	7E-6	2E-8	-	-
		Y, see 104Cd	-	1E+4	6E-6	2E-8	-	-
49	Indium-109	D, all compounds except those given for W	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
		W, oxides, hydroxides, halides, and nitrates	-	6E+4	3E-5	9E-8	-	-
49	Indium-110[2]	D, see 109In	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
(69 1 min)		W, see 109In	-	6E+4	2E-5	8E-8	-	-
49	Indium-110	D, see 109In	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
(4.9 h)		W, see 109In	-	2E+4	8E-6	3E-8	-	-
49	Indium-111	D, see 109In	4E+3	6E+3	3E-6	9E-9	6E-5	6E-4
		W, see 109In	-	6E+3	3E-6	9E-9	-	-
49	Indium-112[2]	D, see 109In	2E+5	6E+5	3E-4	9E-7	2E-3	2E-2
		W, see 109In	-	7E+5	3E-4	1E-6	-	-
49	Indium-113m[2]	D, see 109In	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		W, see 109In	-	2E+5	8E-5	3E-7	-	-
49	Indium-114m	D, see 109In	3E+2	6E+1	3E-8	9E-11	-	-
			LLI wall (4E+2)	-	-	-	5E-6	5E-5
		W, see 109In	-	1E+2	4E-8	1E-10	-	-
49	Indium-115m	D, see 109In	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see 109In	-	5E+4	2E-5	7E-8	-	-
49	Indium-115	D, see 109In	4E+1	1E+0	6E-10	2E-12	5E-7	5E-6
		W, see 109In	-	5E+0	2E-9	8E-12	-	-
49	Indium-116m[2]	D, see 109In	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		W, see 109In	-	1E+5	5E-5	2E-7	-	-
49	Indium-117m[2]	D, see 109In	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see 109In	-	4E+4	2E-5	6E-8	-	-
49	Indium-1172	D, see 109In	6E+4	2E+5	7E-5	2E-7	8E-4	8E-3
		W, see 109In	-	2E+5	9E-5	3E-7	-	-
49	Indium-119m[2]	D, see 109In	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		W, see 109In	-	1E+5	6E-5	2E-7	-	-
50	Tin-110	D, all compounds except those given for W	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
		W, sulfides, oxides, hydroxides, halides, nitrates, and stannic phosphate	-	1E+4	5E-6	2E-8	-	-
50	Tin-111[2]	D, see 110Sn	7E+4	2E+5	9E-5	3E-7	1E-3	1E-2
		W, see 110Sn	-	3E+5	1E-4	4E-7	-	-
50	Tin-113	D, see 110Sn	2E+3	1E+3	5E-7	2E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		W, see 110Sn	-	5E+2	2E-7	8E-10	-	-
50	Tin-117m	D, see 110Sn	2E+3	1E+3	5E-7	-	-	-
			LLI wall (2E+3)	Bone surf (2E+3)	-	3E-9	3E-5	3E-4
		W, see 110Sn	-	1E+3	6E-7	2E-9	-	-
50	Tin-119m	D, see 110Sn	3E+3	2E+3	1E-6	3E-9	-	-
			LLI wall (4E+3)	-	-	-	6E-5	6E-4
		W, see 110Sn	-	1E+3	4E-7	1E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
50	Tin-121m	D, see 110Sn	3E+3	9E+2	4E-7	1E-9	-	-
			LLI wall (4E+3)	-	-	-	5E-5	5E-4
		W, see 110Sn	-	5E+2	2E-7	8E-10	-	-
50	Tin-121	D, see 110Sn	6E+3	2E+4	6E-6	2E-8	-	-
			LLI wall (6E+3)	-	-	-	8E-5	8E-4
		W, see 110Sn	-	1E+4	5E-6	2E-8	-	-
50	Tin-123m[2]	D, see 110Sn	5E+4	1E+5	5E-5	2E-7	7E-4	7E-3
		W, see 110Sn	-	1E+5	6E-5	2E-7	-	-
50	Tin-123	D, see 110Sn	5E+2	6E+2	3E-7	9E-10	-	-
			LLI wall (6E+2)	-	-	-	9E-6	9E-5
		W, see 110Sn	-	2E+2	7E-8	2E-10	-	-
50	Tin-125	D, see 110Sn	4E+2	9E+2	4E-7	1E-9	-	-
			LLI wall (5E+2)	-	-	-	6E-6	6E-5
		W, see 110Sn	-	4E+2	1E-7	5E-10	-	-
50	Tin-126	D, see 110Sn	3E+2	6E+1	2E-8	8E-11	4E-6	4E-5
		W, see 110Sn	-	7E+1	3E-8	9E-11	-	-
50	Tin-127	D, see 110Sn	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		W, see 110Sn	-	2E+4	8E-6	3E-8	-	-
50	Tin-128[2]	D, see 110Sn	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, see 110Sn	-	4E+4	1E-5	5E-8	-	-
51	Antimony-115[2]	D, all compounds except those given for W	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, sulfides, sulfates, and nitrates	-	3E+5	1E-4	4E-7	-	-
51	Antimony-116m[2]	D, see 115Sb	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
		W, see 115Sb	-	1E+5	6E-5	2E-7	-	-
51	Antimony-116[2]	D, see 115Sb	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see 115Sb	-	3E+5	1E-4	5E-7	-	-
51	Antimony-117	D, see 115Sb	7E+4	2E+5	9E-5	3E-7	9E-4	9E-3
		W, see 115Sb	-	3E+5	1E-4	4E-7	-	-
51	Antimony-118m	D, see 115Sb	6E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		W, see 115Sb	5E+3	2E+4	9E-6	3E-8	-	-
51	Antimony-119	D, see 115Sb	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
		W, see 115Sb	2E+4	3E+4	1E-5	4E-8	-	-
51	Antimony-120 (16 min)	D, see 115Sb	1E+5	4E+5	2E-4	6E-7	-	-
			St wall (2E+5)	-	-	-	2E-3	2E-2
		W, see 115Sb	-	5E+5	2E-4	7E-7	-	-
51	Antimony-120 (5 76 d)	D, see 115Sb	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
		W, see 115Sb	9E+2	1E+3	5E-7	2E-9	-	-
51	Antimony-122	D, see 115Sb	8E+2	2E+3	1E-6	3E-9	-	-
			LLI wall (8E+2)	-	-	-	1E-5	1E-4
		W, see 115Sb	7E+2	1E+3	4E-7	2E-9	-	-
51	Antimony-124m[2]	D, see 115Sb	3E+5	8E+5	4E-4	1E-6	3E-3	3E-2
		W, see 115Sb	2E+5	6E+5	2E-4	8E-7	-	-
51	Antimony-124	D, see 115Sb	6E+2	9E+2	4E-7	1E-9	7E-6	7E-5
		W, see 115Sb	5E+2	2E+2	1E-7	3E-10	-	-
51	Antimony-125	D, see 115Sb	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
		W, see 115Sb	-	5E+2	2E-7	7E-10	-	-
51	Antimony-126m[2]	D, see 115Sb	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (7E+4)	-	-	-	9E-4	9E-3
		W, see 115Sb	-	2E+5	8E-5	3E-7	-	-
51	Antimony-126	D, see 115Sb	6E+2	1E+3	5E-7	2E-9	7E-6	7E-5
		W, see 115Sb	5E+2	5E+2	2E-7	7E-10	-	-
51	Antimony-127	D, see 115Sb	8E+2	2E+3	9E-7	3E-9	-	-
			LLI wall (8E+2)	-	-	-	1E-5	1E-4
		W, see 115Sb	7E+2	9E+2	4E-7	1E-9	-	-
51	Antimony-128[2] (10.4 min)	D, see 115Sb	8E+4	4E+5	2E-4	5E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
		W, see 115Sb	-	4E+5	2E-4	6E-7	-	-
51	Antimony-128 (9.01 h)	D, see 115Sb	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
		W, see 115Sb	-	3E+3	1E-6	5E-9	-	-
51	Antimony-129	D, see 115Sb	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		W, see 115Sb	-	9E+3	4E-6	1E-8	-	-
51	Antimony-130[2]	D, see 115Sb	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		W, see 115Sb	-	8E+4	3E-5	1E-7	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
51	Antimony-131[2]	D, see 115Sb	1E+4	2E+4	1E-5	-	-	-
			Thyroid (2E+4)	Thyroid (4E+4)	-	6E-8	2E-4	2E-3
		W, see 115Sb	-	2E+4	1E-5		-	-
			-	Thyroid (4E+4)	-	6E-8	-	-
52	Tellurium-116	D, all compounds except those given for W	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, oxides, hydroxides, and nitrates	-	3E+4	1E-5	4E-8	-	-
52	Tellurium-121m	D, see 116Te	5E+2	2E+2	8E-8	-	-	-
			Bone surf (7E+2)	Bone surf (4E+2)	-	5E-10	1E-5	1E-4
		W, see 116Te	-	4E+2	2E-7	6E-10	-	-
52	Tellurium-121	D, see 116Te	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see 116Te	-	3E+3	1E-6	4E-9	-	-
52	Tellurium-123m	D, see 116Te	6E+2	2E+2	9E-8	-	-	-
			Bone surf (1E+3)	Bone surf (5E+2)	-	8E-10	1E-5	1E-4
		W, see 116Te	-	5E+2	2E-7	8E-10	-	-
52	Tellurium-123	D, see 116Te	5E+2	2E+2	8E-8	-	-	-
			Bone surf (1E+3)	Bone surf (5E+2)	-	7E-10	2E-5	2E-4
		W, see 116Te	-	4E+2	2E-7	-	-	-
			-	Bone surf (1E+3)	-	2E-9	-	-
52	Tellurium-125m	D, see 116Te	1E+3	4E+2	2E-7	-	-	-
			Bone surf (1E+3)	Bone surf (1E+3)	-	1E-9	2E-5	2E-4
		W, see 116Te	-	7E+2	3E-7	1E-9	-	-
52	Tellurium-127m	D, see 116Te	6E+2	3E+2	1E-7	-	9E-6	9E-5
			-	Bone surf (4E+2)	-	6E-10	-	-
		W, see 116Te	-	3E+2	1E-7	4E-10	-	-
52	Tellurium-127	D, see 116Te	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see 116Te	-	2E+4	7E-6	2E-8	-	-
52	Tellurium-129m	D, see 116Te	5E+2	6E+2	3E-7	9E-10	7E-6	7E-5
		W, see 116Te	-	2E+2	1E-7	3E-10	-	-
52	Tellurium-129[2]	D, see 116Te	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see 116Te	-	7E+4	3E-5	1E-7	-	-
52	Tellurium-131m	D, see 116Te	3E+2	4E+2	2E-7	-	-	-
			Thyroid (6E+2)	Thyroid (1E+3)	-	2E-9	8E-6	8E-5
		W, see 116Te	-	4E+2	2E-7	-	-	-
			-	Thyroid (9E+2)	-	1E-9	-	-
52	Tellurium-131[2]	D, see 116Te	3E+3	5E+3	2E-6	-	-	-
			Thyroid (6E+3)	Thyroid (1E+4)	-	2E-8	8E-5	8E-4
		W, see 116Te	-	5E+3	2E-6	-	-	-
			-	Thyroid (1E+4)	-	2E-8	-	-
52	Tellurium-132	D, see 116Te	2E+2	2E+2	9E-8	-	-	-
			Thyroid (7E+2)	Thyroid (8E+2)	-	1E-9	9E-6	9E-5
		W, see 116Te	-	2E+2	9E-8	-	-	-
			-	Thyroid (6E+2)	-	9E-10	-	-
52	Tellurium-133m[2]	D, see 116Te	3E+3	5E+3	2E-6	-	-	-
			Thyroid (6E+3)	Thyroid (1E+4)	-	2E-8	9E-5	9E-4
		W, see 116Te	-	5E+3	2E-6	-	-	-
			-	Thyroid (1E+4)	-	2E-8	-	-
52	Tellurium-133[2]	D, see 116Te	1E+4	2E+4	9E-6	-	-	-
			Thyroid (3E+4)	Thyroid (6E+4)	-	8E-8	4E-4	4E-3
		W, see 116Te	-	2E+4	9E-6	-	-	-
			-	Thyroid (6E+4)	-	8E-8	-	-
52	Tellurium-134[2]	D, see 116Te	2E+4	2E+4	1E-5	-	-	-
			Thyroid (2E+4)	Thyroid (5E+4)	-	7E-8	3E-4	3E-3
		W, see 116Te	-	2E+4	1E-5	-	-	-
			-	Thyroid (5E+4)	-	7E-8	-	-
53	Iodine-120m[2]	D, all compounds	1E+4	2E+4	9E-6	3E-8	-	-
			Thyroid (1E+4)	-	-	-	2E-4	2E-3
53	Iodine-120[2]	D, all compounds	4E+3	9E+3	4E-6	-	-	-
			Thyroid (8E+3)	Thyroid (1E+4)	-	2E-8	1E-4	1E-3

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
53	Iodine-121	D, all compounds	1E+4	2E+4	8E-6	-	-	-
			Thyroid (3E+4)	Thyroid (5E+4)	-	7E-8	4E-4	4E-3
53	Iodine-123	D, all compounds	3E+3	6E+3	3E-6	-	-	-
			Thyroid (1E+4)	Thyroid (2E+4)	-	2E-8	1E-4	1E-3
53	Iodine-124	D, all compounds	5E+1	8E+1	3E-8	-	-	-
			Thyroid (2E+2)	Thyroid (3E+2)	-	4E-10	2E-6	2E-5
53	Iodine-125	D, all compounds	4E+1	6E+1	3E-8	-	-	-
			Thyroid (1E+2)	Thyroid (2E+2)	-	3E-10	2E-6	2E-5
53	Iodine-126	D, all compounds	2E+1	4E+1	1E-8	-	-	-
			Thyroid (7E+1)	Thyroid (1E+2)	-	2E-10	1E-6	1E-5
53	Iodine-128[2]	D, all compounds	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
53	Iodine-129	D, all compounds	5E+0	9E+0	4E-9	-	-	-
			Thyroid (2E+1)	Thyroid (3E+1)	-	4E-11	2E-7	2E-6
53	Iodine-130	D, all compounds	4E+2	7E+2	3E-7	-	-	-
			Thyroid (1E+3)	Thyroid (2E+3)	-	3E-9	2E-5	2E-4
53	Iodine-131	D, all compounds	3E+1	5E+1	2E-8	-	-	-
			Thyroid (9E+1)	Thyroid (2E+2)	-	2E-10	1E-6	1E-5
53	Iodine-132m[2]	D, all compounds	4E+3	8E+3	4E-6	-	-	-
			Thyroid (1E+4)	Thyroid (2E+4)	-	3E-8	1E-4	1E-3
53	Iodine-132	D, all compounds	4E+3	8E+3	3E-6	-	-	-
			Thyroid (9E+3)	Thyroid (1E+4)	-	2E-8	1E-4	1E-3
53	Iodine-133	D, all compounds	1E+2	3E+2	1E-7	-	-	-
			Thyroid (5E+2)	Thyroid (9E+2)	-	1E-9	7E-6	7E-5
53	Iodine-134[2]	D, all compounds	2E+4	5E+4	2E-5	6E-8	-	-
			Thyroid (3E+4)	-	-	-	4E-4	4E-3
53	Iodine-135	D, all compounds	8E+2	2E+3	7E-7	-	-	-
			Thyroid (3E+3)	Thyroid (4E+3)	-	6E-9	3E-5	3E-4
54	Xenon-120[2]	Submersion1	-	-	1E-5	4E-8	-	-
54	Xenon-121[2]	Submersion1	-	-	2E-6	1E-8	-	-
54	Xenon-122	Submersion1	-	-	7E-5	3E-7	-	-
54	Xenon-123	Submersion1	-	-	6E-6	3E-8	-	-
54	Xenon-125	Submersion1	-	-	2E-5	7E-8	-	-
54	Xenon-127	Submersion1	-	-	1E-5	6E-8	-	-
54	Xenon-129m	Submersion1	-	-	2E-4	9E-7	-	-
54	Xenon-131m	Submersion1	-	-	4E-4	2E-6	-	-
54	Xenon-133m	Submersion1	-	-	1E-4	6E-7	-	-
54	Xenon-133	Submersion1	-	-	1E-4	5E-7	-	-
54	Xenon-135m[2]	Submersion1	-	-	9E-6	4E-8	-	-
54	Xenon-135	Submersion1	-	-	1E-5	7E-8	-	-
54	Xenon-138[2]	Submersion1	-	-	4E-6	2E-8	-	-
55	Cesium-125[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
55	Cesium-127	D, all compounds	6E+4	9E+4	4E-5	1E-7	9E-4	9E-3
55	Cesium-129	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
55	Cesium-130[2]	D, all compounds	6E+4	2E+5	8E-5	3E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
55	Cesium-131	D, all compoinds	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
55	Cesium-132	D, all compounds	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
55	Cesium-134m	D, all compounds	1E+5	1E+5	6E-5	2E-7	-	-
			St wall (1E+5)	-	-	-	2E-3	2E-2
55	Cesium-134	D, all compounds	7E+1	1E+2	4E-8	2E-10	9E-7	9E-6
55	Cesium-135m[2]	D, all compounds	1E+5	2E+5	8E-5	3E-7	1E-3	1E-2
55	Cesium-135	D, all compounds	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
55	Cesium-136	D, all compounds	4E+2	7E+2	3E-7	9E-10	6E-6	6E-5
55	Cesium-137	D, all compounds	1E+2	2E+2	6E-8	2E-10	1E-6	1E-5
55	Cesium-138[2]	D, all compounds	2E+4	6E+4	2E-5	8E-8	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
56	Barium-1262	D, all compounds	6E+3	2E+4	6E-6	2E-8	8E-5	8E-4
56	Barium-128	D, all compounds	5E+2	2E+3	7E-7	2E-9	7E-6	7E-5
56	Barium-131m[2]	D, all compounds	4E+5	1E+6	6E-4	2E-6	-	-
			St wall (5E+5)	-	-	-	7E-3	7E-2

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
56	Barium-131	D, all compounds	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
56	Barium-133m	D, all compounds	2E+3	9E+3	4E-6	1E-8	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
56	Barium-133	D, all compounds	2E+3	7E+2	3E-7	9E-10	2E-5	2E-4
56	Barium-135m	D, all compounds	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
56	Barium-139[2]	D, all compounds	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
56	Barium-140	D, all compounds	5E+2	1E+3	6E-7	2E-9	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
56	Barium-141[2]	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
56	Barium-142[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
57	Lanthanum-131[2]	D, all compounds except those given for W	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		W, oxides and hydroxides	-	2E+5	7E-5	2E-7	-	-
57	Lanthanum-132	D, see 131La	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
		W, see 131La	-	1E+4	5E-6	2E-8	-	-
57	Lanthanum-135	D, see 131La	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
		W, see 131La	-	9E+4	4E-5	1E-7	-	-
57	Lanthanum-137	D, see 131La	1E+4	6E+1	3E-8	-	2E-4	2E-3
			-	Liver (7E+1)	-	1E-10	-	-
		W, see 131La	-	3E+2	1E-7	-	-	-
			-	Liver (3E+2)	-	4E-10	-	-
57	Lanthanum-138	D, see 131La	9E+2	4E+0	1E-9	5E-12	1E-5	1E-4
		W, see 131La	-	1E+1	6E-9	2E-11	-	-
57	Lanthanum-140	D, see 131La	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
		W, see 131La	-	1E+3	5E-7	2E-9	-	-
57	Lanthanum-141	D, see 131La	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
		W, see 131La	-	1E+4	5E-6	2E-8	-	-
57	Lanthanum-142[2]	D, see 131La	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see 131La	-	3E+4	1E-5	5E-8	-	-
57	Lanthanum-143[2]	D, see 131La	4E+4	1E+5	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see 131La	-	9E+4	4E-5	1E-7	-	-
58	Cerium-134	W, all compounds except those given for Y	5E+2	7E+2	3E-7	1E-9	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		Y, oxides, hydroxides, and fluorides	-	7E+2	3E-7	9E-10	-	-
58	Cerium-135	W, see 134Ce	2E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		Y, see 134Ce	-	4E+3	1E-6	5E-9	-	-
58	Cerium-137m	W, see 134Ce	2E+3	4E+3	2E-6	6E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see 134Ce	-	4E+3	2E-6	5E-9	-	-
58	Cerium-137	W, see 134Ce	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		Y, see 134Ce	-	1E+5	5E-5	2E-7	-	-
58	Cerium-139	W, see 134Ce	5E+3	8E+2	3E-7	1E-9	7E-5	7E-4
		Y, see 134Ce	-	7E+2	3E-7	9E-10	-	-
58	Cerium-141	W, see 134Ce	2E+3	7E+2	3E-7	1E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see 134Ce	-	6E+2	2E-7	8E-10	-	-
58	Cerium-143	W, see 134Ce	1E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see 134Ce	-	2E+3	7E-7	2E-9	-	-
58	Cerium-144	W, see 134Ce	2E+2	3E+1	1E-8	4E-11	-	-
			LLI wall (3E+2)	-	-	-	3E-6	3E-5
		Y, see 134Ce	-	1E+1	6E-9	2E-11	-	-
59	Praseodymium-136[2]	W, all compounds except those given for Y	5E+4	2E+5	1E-4	3E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		Y, oxides, hydroxides, carbides, and fluorides	-	2E+5	9E-5	3E-7	-	-
59	Praseodymium-137[2]	W, see 136Pr	4E+4	2E+5	6E-5	2E-7	5E-4	5E-3
		Y, see 136Pr	-	1E+5	6E-5	2E-7	-	-
59	Praseodymium-138m	W, see 136Pr	1E+4	5E+4	2E-5	8E-8	1E-4	1E-3
		Y, see 136Pr	-	4E+4	2E-5	6E-8	-	-
59	Praseodymium-139	W, see 136Pr	4E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		Y, see 136Pr	-	1E+5	5E-5	2E-7	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
59	Praseodymium-142m[2]	W, see 136Pr	8E+4	2E+5	7E-5	2E-7	1E-3	1E-2
		Y, see 136Pr	-	1E+5	6E-5	2E-7	-	-
59	Praseodymium-142	W, see 136Pr	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
		Y, see 136Pr	-	2E+3	8E-7	3E-9	-	-
59	Praseodymium-143	W, see 136Pr	9E+2	8E+2	3E-7	1E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see 136Pr	-	7E+2	3E-7	9E-10	-	-
59	Praseodymium-144[2]	W, see 136Pr	3E+4	1E+5	5E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		Y, see 136Pr	-	1E+5	5E-5	2E-7	-	-
59	Praseodymium-145	W, see 136Pr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see 136Pr	-	8E+3	3E-6	1E-8	-	-
59	Praseodymium-147[2]	W, see 136Pr	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (8E+4)	-	-	-	1E-3	1E-2
		Y, see 136Pr	-	2E+5	8E-5	3E-7	-	-
60	Neodymium-136[2]	W, all compounds except those given for Y	1E+4	6E+4	2E-5	8E-8	2E-4	2E-3
		Y, oxides, hydroxides, carbides, and fluorides	-	5E+4	2E-5	8E-8	-	-
60	Neodymium-138	W, see 136Nd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
		Y, see 136Nd	-	5E+3	2E-6	7E-9	-	-
60	Neodymium-139m	W, see 136Nd	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
		Y, see 136Nd	-	1E+4	6E-6	2E-8	-	-
60	Neodymium-139[2]	W, see 136Nd	9E+4	3E+5	1E-4	5E-7	1E-3	1E-2
		Y, see 136Nd	-	3E+5	1E-4	4E-7	-	-
60	Neodymium-141	W, see 136Nd	2E+5	7E+5	3E-4	1E-6	2E-3	2E-2
		Y, see 136Nd	-	6E+5	3E-4	9E-7	-	-
60	Neodymium-147	W, see 136Nd	1E+3	9E+2	4E-7	1E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see 136Nd	-	8E+2	4E-7	1E-9	-	-
60	Neodymium-149[2]	W, see 136Nd	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
		Y, see 136Nd	-	2E+4	1E-5	3E-8	-	-
60	Neodymium-151[2]	W, see 136Nd	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
		Y, see 136Nd	-	2E+5	8E-5	3E-7	-	-
61	Promethium-141[2]	W, all compounds except those given for Y	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
		Y, oxides, hydroxides, carbides, and fluorides	-	2E+5	7E-5	2E-7	-	-
61	Promethium-143	W, see 141Pm	5E+3	6E+2	2E-7	8E-10	7E-5	7E-4
		Y, see 141Pm	-	7E+2	3E-7	1E-9	-	-
61	Promethium-144	W, see 141Pm	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		Y, see 141Pm	-	1E+2	5E-8	2E-10	-	-
61	Promethium-145	W, see 141Pm	1E+4	2E+2	7E-8	-	1E-4	1E-3
			-	Bone surf (2E+2)	-	3E-10	-	-
		Y, see 141Pm	-	2E+2	8E-8	3E-10	-	-
61	Promethium-146	W, see 141Pm	2E+3	5E+1	2E-8	7E-11	2E-5	2E-4
		Y, see 141Pm	-	4E+1	2E-8	6E-11	-	-
61	Promethium-147	W, see 141Pm	4E+3	1E+2	5E-8	-	-	-
			LLI wall (5E+3)	Bone surf (2E+2)	-	3E-10	7E-5	7E-4
		Y, see 141Pm	-	1E+2	6E-8	2E-10	-	-
61	Promethium-148m	W, see 141Pm	7E+2	3E+2	1E-7	4E-10	1E-5	1E-4
		Y, see 141Pm	-	3E+2	1E-7	5E-10	-	-
61	Promethium-148	W, see 141Pm	4E+2	5E+2	2E-7	8E-10	-	-
			LLI wall (5E+2)	-	-	-	7E-6	7E-5
		Y, see 141Pm	-	5E+2	2E-7	7E-10	-	-
61	Promethium-149	W, see 141Pm	1E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see 141Pm	-	2E+3	8E-7	2E-9	-	-
61	Promethium-150	W, see 141Pm	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see 141Pm	-	2E+4	7E-6	2E-8	-	-
61	Promethium-151	W, see 141Pm	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		Y, see 141Pm	-	3E+3	1E-6	4E-9	-	-
62	Samarium-141m[2]	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
62	Samarium-1412	W, all compounds	5E+4	2E+5	8E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
62	Samarium-142[2]	W, all compounds	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
62	Samarium-145	W, all compounds	6E+3	5E+2	2E-7	7E-10	8E-5	8E-4
62	Samarium-146	W, all compounds	1E+1	4E2	1E-11	-	-	-
			Bone surf (3E+1)	Bone surf (6E-2)	-	9E-14	3E-7	3E-6
62	Samarium-147	W, all compounds	2E+1	4E2	2E-11	-	-	-
			Bone surf (3E+1)	Bone surf (7E-2)	-	1E-13	4E-7	4E-6
62	Samarium-151	W, all compounds	1E+4	1E+2	4E-8	-	-	-
			LLI wall (1E+4)	Bone surf (2E+2)	-	2E-10	2E-4	2E-3
62	Samarium-153	W, all compounds	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
62	Samarium-155[2]	W, all compounds	6E+4	2E+5	9E-5	3E-7	-	-
			St wall (8E+4)	-	-	-	1E-3	1E-2
62	Samarium-156	W, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
63	Europium-145	W, all compounds	2E+3	2E+3	8E-7	3E-9	2E-5	2E-4
63	Europium-146	W, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
63	Europium-147	W, all compounds	3E+3	2E+3	7E-7	2E-9	4E-5	4E-4
63	Europium-148	W, all compounds	1E+3	4E+2	1E-7	5E-10	1E-5	1E-4
63	Europium-149	W, all compounds	1E+4	3E+3	1E-6	4E-9	2E-4	2E-3
63	Europium-150 (12.62 h)	W, all compounds	3E+3	8E+3	4E-6	1E-8	4E-5	4E-4
63	Europium-150 (34.2 y)	W, all compounds	8E+2	2E+1	8E-9	3E-11	1E-5	1E-4
63	Europium-152m	W, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
63	Europium-152	W, all compounds	8E+2	2E+1	1E-8	3E-11	1E-5	1E-4
63	Europium-154	W, all compounds	5E+2	2E+1	8E-9	3E-11	7E-6	7E-5
63	Europium-155	W, all compounds	4E+3	9E+1	4E-8	-	5E-5	5E-4
			-	Bone surf (1E+2)	-	2E-10	-	-
63	Europium-156	W, all compounds	6E+2	5E+2	2E-7	6E-10	8E-6	8E-5
63	Europium-157	W, all compounds	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
63	Europium-158[2]	W, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
64	Gadolinium-145[2]	D, all compounds except those given for W	5E+4	2E+5	6E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	6E-4	6E-3
		W, oxides, hydroxides, and fluorides	-	2E+5	7E-5	2E-7	-	-
64	Gadolinium-146	D, see 145Gd	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		W, see 145Gd	-	3E+2	1E-7	4E-10	-	-
64	Gadolinium-147	D, see 145Gd	2E+3	4E+3	2E-6	6E-9	3E-5	3E-4
		W, see 145Gd	-	4E+3	1E-6	5E-9	-	-
64	Gadolinium-148	D, see 145Gd	1E+1	8E+3	3E-12	-	-	-
			Bone surf (2E+1)	Bone surf (2E+2)	-	2E-14	3E-7	3E-6
		W, see 145Gd	-	3E-2	1E-11	-	-	-
			-	Bone surf (6E-2)	-	8E-14	-	-
64	Gadolinium-149	D, see 145Gd	3E+3	2E+3	9E-7	3E-9	4E-5	4E-4
		W, see 145Gd	-	2E+3	1E-6	3E-9	-	-
64	Gadolinium-151	D, see 145Gd	6E+3	4E+2	2E-7	-	9E-5	9E-4
			-	Bone surf (6E+2)	-	9E-10	-	-
		W, see 145Gd	-	1E+3	5E-7	2E-9	-	-
64	Gadolinium-152	D, see 145Gd	2E+1	1E-2	4E-12	-	-	-
			Bone surf (3E+1)	Bone surf (2E-2)	-	3E-14	4E-7	4E-6
		W, see 145Gd	-	4E-2	2E-11	-	-	-
64	Gadolinium-153	D, see 145Gd	5E+3	Bone surf 1E+2	6E-8	-	6E-5	6E-4
			-	Bone surf (2E+2)	-	3E-10	-	-
		W, see 145Gd	-	6E+2	2E-7	8E-10	-	-
64	Gadolinium-159	D, see 145Gd	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see 145Gd	-	6E+3	2E-6	8E-9	-	-
65	Terbium-147[2]	W, all compounds	9E+3	3E+4	1E-5	5E-8	1E-4	1E-3
65	Terbium-149	W, all compounds	5E+3	7E+2	3E-7	1E-9	7E-5	7E-4
65	Terbium-150	W, all compounds	5E+3	2E+4	9E-6	3E-8	7E-5	7E-4
65	Terbium-151	W, all compounds	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
65	Terbium-153	W, all compounds	5E+3	7E+3	3E-6	1E-8	7E-5	7E-4
65	Terbium-154	W, all compounds	2E+3	4E+3	2E-6	6E-9	2E-5	2E-4
65	Terbium-155	W, all compounds	6E+3	8E+3	3E-6	1E-8	8E-5	8E-4

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
			-	(8E-2)	-	1E-13	-	-
65	Terbium-156m (5.0 h)	W, all compounds	2E+4	3E+4	1E-5	4E-8	2E-4	2E-3
65	Terbium-156m (24.4 h)	W, all compounds	7E+3	8E+3	3E-6	1E-8	1E-4	1E-3
65	Terbium-156	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
65	Terbium-157	W, all compounds	5E+4	3E+2	1E-7	-	-	-
			LLI wall (5E+4)	Bone surf (6E+2)	-	8E-10	7E-4	7E-3
65	Terbium-158	W, all compounds	1E+3	2E+1	8E-9	3E-11	2E-5	2E-4
65	Terbium-160	W, all compounds	8E+2	2E+2	9E-8	3E-10	1E-5	1E-4
65	Terbium-161	W, all compounds	2E+3	2E+3	7E-7	2E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
66	Dysprosium-155	W, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
66	Dysprosium-157	W, all compounds	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
66	Dysprosium-159	W, all compounds	1E+4	2E+3	1E-6	3E-9	2E-4	2E-3
66	Dysprosium-165	W, all compounds	1E+4	5E+4	2E-5	6E-8	2E-4	2E-3
66	Dysprosium-166	W, all compounds	6E+2	7E+2	3E-7	1E-9	-	-
			LLI wall (8E+2)	-	-	-	1E-5	1E-4
67	Holmium-155[2]	W, all compounds	4E+4	2E+5	6E-5	2E-7	6E-4	6E-3
67	Holmium-157[2]	W, all compounds	3E+5	1E+6	6E-4	2E-6	4E-3	4E-2
67	Holmium-159[2]	W, all compounds	2E+5	1E+6	4E-4	1E-6	3E-3	3E-2
67	Holmium-161	W, all compounds	1E+5	4E+5	2E-4	6E-7	1E-3	1E-2
67	Holmium-162m[2]	W, all compounds	5E+4	3E+5	1E-4	4E-7	7E-4	7E-3
67	Holmium-162[2]	W, all compounds	5E+5	2E+6	1E-3	3E-6	-	-
			St wall (8E+5)	-	-	-	1E-2	1E-1
67	Holmium-164m[2]	W, all compounds	1E+5	3E+5	1E-4	4E-7	1E-3	1E-2
67	Holmium-1642	W, all compounds	2E+5	6E+5	3E-4	9E-7	-	-
			St wall (2E+5)	-	-	-	3E-3	3E-2
67	Holmium-166m	W, all compounds	6E+2	7E+0	3E-9	9E-12	9E-6	9E-5
67	Holmium-166	W, all compounds	9E+2	2E+3	7E-7	2E-9	-	-
			LLI wall (9E+2)	-	-	-	1E-5	1E-4
67	Holmium-167	W, all compounds	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
68	Erbium-161	W, all compounds	2E+4	6E+4	3E-5	9E-8	2E-4	2E-3
68	Erbium-165	W, all compounds	6E+4	2E+5	8E-5	3E-7	9E-4	9E-3
68	Erbium-169	W, all compounds	3E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (4E+3)	-	-	-	5E-5	5E-4
68	Erbium-171	W, all compounds	4E+3	1E+4	4E-6	1E-8	5E-5	5E-4
68	Erbium-172	W, all compounds	1E+3	1E+3	6E-7	2E-9	-	-
			LLI wall (E+3)	-	-	-	2E-5	2E-4
69	Thulium-162[2]	W, all compounds	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
69	Thulium-166	W, all compounds	4E+3	1E+4	6E-6	2E-8	6E-5	6E-4
69	Thulium-167	W, all compounds	2E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (2E+3)-	-	-	3E-5	3E-4	
69	Thulium-170	W, all compounds	8E+2	2E+2	9E-8	3E-10	-	-
			LLI wall (1E+3)	-	-	-	1E-5	1E-4
69	Thulium-171	W, all compounds	1E+4	3E+2	1E-7	-	-	-
			LLI wall (1E+4)	Bone surf (6E+2)	-	8E-10	2E-4	2E-3
69	Thulium-172	W, all compounds	7E+2	1E+3	5E-7	2E-9	-	-
			LLI wall (8E+2)	-	-	-	1E-5	1E-4
69	Thulium-173	W, all compounds	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
69	Thulium-175[2]	W, all compounds	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
70	Ytterbium-162[2]	W, all compounds except those given for Y	7E+4	3E+5	1E-4	4E-7	1E-3	1E-2
		Y, oxides, hydroxides, and fluorides	-	3E+5	1E-4	4E-7	-	-
70	Ytterbium-166	W, see 162Yb	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
		Y, see 162Yb	-	2E+3	8E-7	3E-9	-	-
70	Ytterbium-167[2]	W, see 162Yb	3E+5	8E+5	3E-4	1E-6	4E-3	4E-2
		Y, see 162Yb	-	7E+5	3E-4	1E-6	-	-
70	Ytterbium-169	W, see 162Yb	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
		Y, see 162Yb	-	7E+2	3E-7	1E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
70	Ytterbium-175	W, see 162Yb	3E+3	4E+3	1E-6	5E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		Y, see 162Yb	-	3E+3	1E-6	5E-9	-	-
70	Ytterbium-177[2]	W, see 162Yb	2E+4	5E+4	2E-5	7E-8	2E-4	2E-3
		Y, see 162Yb	-	5E+4	2E-5	6E-8	-	-
70	Ytterbium-178[2]	W, see 162Yb	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		Y, see 162Yb	-	4E+4	2E-5	5E-8	-	-
71	Lutetium-169	W, all compounds except those given for Y	3E+3	4E+3	2E-6	6E-9	3E-5	3E-4
		Y, oxides, hydroxides, and fluorides	-	4E+3	2E-6	6E-9	-	-
71	Lutetium-170	W, see 169Lu	1E+3	2E+3	9E-7	3E-9	2E-5	2E-4
		Y, see 169Lu	-	2E+3	8E-7	3E-9	-	-
71	Lutetium-171	W, see 169Lu	2E+3	2E+3	8E-7	3E-9	3E-5	3E-4
		Y, see 169Lu	-	2E+3	8E-7	3E-9	-	-
71	Lutetium-172	W, see 169Lu	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
		Y, see 169Lu	-	1E+3	5E-7	2E-9	-	-
71	Lutetium-173	W, see 169Lu	5E+3	3E+2	1E-7	-	7E-5	7E-4
			-	Bone surf (5E+2)	-	6E-10	-	-
		Y, see 169Lu	-	3E+2	1E-7	4E-10	-	-
71	Lutetium-174m	W, see 169Lu	2E+3	2E+2	1E-7	-	-	-
			LLI wall (3E+3)	Bone surf (3E+2)	-	5E-10	4E-5	4E-4
		Y, see 169Lu	-	2E+2	9E-8	3E-10	-	-
71	Lutetium-174	W, see 169Lu	5E+3	1E+2	5E-8	-	7E-5	7E-4
			-	Bone surf (2E+2)	-	3E-10	-	-
		Y, see 169Lu	-	2E+2	6E-8	2E-10	-	-
71	Lutetium-176m	W, see 169Lu	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		Y, see 169Lu	-	2E+4	9E-6	3E-8	-	-
71	Lutetium-176	W, see 169Lu	7E+2	5E+0	2E-9	-	1E-5	1E-4
			-	Bone surf (1E+1)	-	2E-11	-	-
		Y, see 169Lu	-	8E+0	3E-9	1E-11	-	-
71	Lutetium-177m	W, see 169Lu	7E+2	1E+2	5E-8	-	1E-5	1E-4
			-	Bone surf (1E+2)	-	2E-10	-	-
		Y, see 169Lu	-	8E+1	3E-8	1E-10	-	-
71	Lutetium-177	W, see 169Lu	2E+3	2E+3	9E-7	3E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		Y, see 169Lu	-	2E+3	9E-7	3E-9	-	-
71	Lutetium-178m2	W, see 169Lu	5E+4	2E+5	8E-5	3E-7	-	-
			St. wall (6E+4)	-	-	-	8E-4	8E-3
		Y, see 169Lu	-	2E+5	7E-5	2E-7	-	-
71	Lutetium-178[2]	W, see 169Lu	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		Y, see 169Lu	-	1E+5	5E-5	2E-7	-	-
71	Lutetium-179	W, see 169Lu	6E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see 169Lu	-	2E+4	6E-6	3E-8	-	-
72	Hafnium-170	D, all compounds except those given for W	3E+3	6E+3	2E-6	8E-9	4E-5	4E-4
		W, oxides, hydroxides, carbides, and nitrates	-	5E+3	2E-6	6E-9	-	-
72	Hafnium-172	D, see 170Hf	1E+3	9E+0	4E-9	-	2E-5	2E-4
			-	Bone surf (2E+1)	-	3E-11	-	-
		W, see 170Hf	-	4E+1	2E-8	-	-	-
			-	Bone surf (6E+1)	-	8E-11	-	-
72	Hafnium-173	D, see 170Hf	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see 170Hf	-	1E+4	5E-6	2E-8	-	-
72	Hafnium-175	D, see 170Hf	3E+3	9E+2	4E-7	-	4E-5	4E-4
			-	Bone surf (1E+3)	-	1E-9	-	-
		W, see 170Hf	-	1E+3	5E-7	2E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
72	Hafnium-177m[2]	D, see 170Hf	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		W, see 170Hf	-	9E+4	4E-5	1E-7	-	-
72	Hafnium-178m	D, see 170Hf	3E+2	1E+0	5E-10	-	3E-6	3E-5
			-	Bone surf (2E+0)	-	3E-12	-	-
		W, see 170Hf	-	5E+0	2E-9	-	-	-
			-	Bone surf (9E+0)	-	1E-11	-	-
72	Hafnium-179m	D, see 170Hf	1E+3	3E+2	1E-7	-	1E-5	1E-4
			-	Bone surf (6E+2)	-	8E-10	-	-
		W, see 170Hf	-	6E+2	3E-7	8E-10	-	-
72	Hafnium-180m	D, see 170Hf	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see 170Hf	-	3E+4	1E-5	4E-8	-	-
72	Hafnium-181	D, see 170Hf	1E+3	2E+2	7E-8	-	2E-5	2E-4
			-	Bone surf (4E+2)	-	6E-10	-	-
		W, see 170Hf	-	4E+2	2E-7	6E-10	-	-
72	Hafnium-182m[2]	D, see 170Hf	4E+4	9E+4	4E-5	1E-7	5E-4	5E-3
		W, see 170Hf	-	1E+5	6E-5	2E-7	-	-
72	Hafnium-182	D, see 170Hf	2E+2	8E-1	3E-10	-	-	-
			Bone surf (4E+2)	Bone surf (2E+0)	-	2E-12	5E-6	5E-5
		W, see 170Hf	-	3E+0	1E-9	-	-	-
			-	Bone surf (7E+0)	-	1E-11	-	-
72	Hafnium-183[2]	D, see 170Hf	2E+4	5E+4	2E-5	6E-8	3E-4	3E-3
		W, see 170Hf	-	6E+4	2E-5	8E-8	-	-
72	Hafnium-184	D, see 170Hf	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		W, see 170Hf	-	6E+3	3E-6	9E-9	-	-
73	Tantalum-172[2]	W, all compounds except those given for Y	4E+4	1E+5	5E-5	2E-7	5E-4	5E-3
		Y, elemental Ta, oxides, hydroxides, halides, carbides, nitrates, and nitrides	-	1E+5	4E-5	1E-7	-	-
73	Tantalum-173	W, see 172Ta	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see 172Ta	-	2E+4	7E-6	2E-8	-	-
73	Tantalum-174[2]	W, see 172Ta	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
		Y, see 172Ta	-	9E+4	4E-5	1E-7	-	-
73	Tantalum-175	W, see 172Ta	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
		Y, see 172Ta	-	1E+4	6E-6	2E-8	-	-
73	Tantalum-176	W, see 172Ta	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
		Y, see 172Ta	-	1E+4	5E-6	2E-8	-	-
73	Tantalum-177	W, see 172Ta	1E+4	2E+4	8E-6	3E-8	2E-4	2E-3
		Y, see 172Ta	-	2E+4	7E-6	2E-8	-	-
73	Tantalum-178	W, see 172Ta	2E+4	9E+4	4E-5	1E-7	2E-4	2E-3
		Y, see 172Ta	-	7E+4	3E-5	1E-7	-	-
73	Tantalum-179	W, see 172Ta	2E+4	5E+3	2E-6	8E-9	3E-4	3E-3
		Y, see 172Ta	-	9E+2	4E-7	1E-9	-	-
73	Tantalum-180m	W, see 172Ta	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		Y, see 172Ta	-	6E+4	2E-5	8E-8	-	-
73	Tantalum-180	W, see 172Ta	1E+3	4E+2	2E-7	6E-10	2E-5	2E-4
		Y, see 172Ta	-	2E+1	1E-8	3E-11	-	-
73	Tantalum-182m[2]	W, see 172Ta	2E+5	5E+5	2E-4	8E-7	-	-
			St wall (2E+5)	-	-	-	3E-3	3E-2
		Y, see 172Ta	-	4E+5	2E-4	6E-7	-	-
73	Tantalum-182	W, see 172Ta	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		Y, see 172Ta	-	1E+2	6E-8	2E-10	-	-
73	Tantalum-183	W, see 172Ta	9E+2	1E+3	5E-7	2E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see 172Ta	-	1E+3	4E-7	1E-9	-	-
73	Tantalum-184	W, see 172Ta	2E+3	5E+3	2E-6	8E-9	3E-5	3E-4
		Y, see 172Ta	-	5E+3	2E-6	7E-9	-	-
73	Tantalum-185[2]	W, see 172Ta	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
		Y, see 172Ta	-	6E+4	3E-5	9E-8	-	-
73	Tantalum-186[2]	W, see 172Ta	5E+4	2E+5	1E-4	3E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		Y, see 172Ta	-	2E+5	9E-5	3E-7	-	-
74	Tungsten-176	D, all compounds	1E+4	5E+4	2E-5	7E-8	1E-4	1E-3
74	Tungsten-177	D, all compounds	2E+4	9E+4	4E-5	1E-7	3E-4	3E-3
74	Tungsten-178	D, all compounds	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
74	Tungsten-179[2]	D, all compounds	5E+5	2E+6	7E-4	2E-6	7E-3	7E-2
74	Tungsten-181	D, all compounds	2E+4	3E+4	1E-5	5E-8	2E-4	2E-3
74	Tungsten-185	D, all compounds	2E+3	7E+3	3E-6	9E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
74	Tungsten-187	D, all compounds	2E+3	9E+3	4E-6	1E-8	3E-5	3E-4
74	Tungsten-188	D, all compounds	4E+2	1E+3	5E-7	2E-9	-	-
			LLI wall (5E+2)	-	-	-	7E-6	7E-5
75	Rhenium-177[2]	D, all compounds except those given for W	9E+4	3E+5	1E-4	4E-7	-	-
			St wall (1E+5)	-	-	-	2E-3	2E-2
		W, oxides, hydroxides, and nitrates	-	4E+5	1E-4	5E-7	-	-
75	Rhenium-178[2]	D, see 177Re	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
		W, see 177Re	-	3E+5	1E-4	4E-7	-	-
75	Rhenium-181	D, see 177Re	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
		W, see 177Re	-	9E+3	4E-6	1E-8	-	-
75	Rhenium-182 (12.7 h)	D, see 177Re	7E+3	1E+4	5E-6	2E-8	9E-5	9E-4
		W, see 177Re	-	2E+4	6E-6	2E-8	-	-
75	Rhenium-182 (64 0 h)	D, see 177Re	1E+3	2E+3	1E-6	3E-9	2E-5	2E-4
		W, see 177Re	-	2E+3	9E-7	3E-9	-	-
75	Rhenium-184m	D, see 177Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see 177Re	-	4E+2	2E-7	6E-10	-	-
75	Rhenium-184	D, see 177Re	2E+3	4E+3	1E-6	5E-9	3E-5	3E-4
		W, see 177Re	-	1E+3	6E-7	2E-9	-	-
75	Rhenium-186m	D, see 177Re	1E+3	2E+3	7E-7	-	-	-
			St wall (2E+3)	St wall (2E+3)	-	3E-9	2E-5	2E-4
		W, see 177Re	-	2E+2	6E-8	2E-10	-	-
75	Rhenium-186	D, see 177Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see 177Re	-	2E+3	7E-7	2E-9	-	-
75	Rhenium-187	D, see 177Re	6E+5	8E+5	4E-4	-	8E-3	8E-2
			-	St wall (9E+5)	-	1E-6	-	-
		W, see 177Re	-	1E+5	4E-5	1E-7	-	-
75	Rhenium-188m[2]	D, see 177Re	8E+4	1E+5	6E-5	2E-7	1E-3	1E-2
		W, see 177Re	-	1E+5	6E-5	2E-7	-	-
75	Rhenium-188	D, see 177Re	2E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		W, see 177Re	-	3E+3	1E-6	4E-9	-	-
75	Rhenium-189	D, see 177Re	3E+3	5E+3	2E-6	7E-9	4E-5	4E-4
		W, see 177Re	-	4E+3	2E-6	6E-9	-	-
76	Osmium-180[2]	D, all compounds except those given for W and Y	1E+5	4E+5	2E-4	5E-7	1E-3	1E-2
		W, halides and nitrates	-	5E+5	2E-4	7E-7	-	-
		Y, oxides and hydroxides	-	5E+5	2E-4	6E-7	-	-
76	Osmium-181[2]	D, see 180Os	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see 180Os	-	5E+4	2E-5	6E-8	-	-
		Y, see 180Os	-	4E+4	2E-5	6E-8	-	-
76	Osmium-182	D, see 180Os	2E+3	6E+3	2E-6	8E-9	3E-5	3E-4
		W, see 180Os	-	4E+3	2E-6	6E-9	-	-
		Y, see 180Os	-	4E+3	2E-6	6E-9	-	-
76	Osmium-185	D, see 180Os	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
		W, see 180Os	-	8E+2	3E-7	1E-9	-	-
		Y, see 180Os	-	8E+2	3E-7	1E-9	-	-
76	Osmium-189m	D, see 180Os	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
		W, see 180Os	-	2E+5	9E-5	3E-7	-	-
		Y, see 180Os	-	2E+5	7E-5	2E-7	-	-
76	Osmium-191m	D, see 180Os	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see 180Os	-	2E+4	8E-6	3E-8	-	-
		Y, see 180Os	-	2E+4	7E-6	2E-8	-	-
76	Osmium-191	D, see 180Os	2E+3	2E+3	9E-7	3E-9	-	-
			LLI wall (3E+3)	-	-	-	3E-5	3E-4
		W, see 180Os	-	2E+3	7E-7	2E-9	-	-
		Y, see 180Os	-	1E+3	6E-7	2E-9	-	-
76	Osmium-193	D, see 180Os	2E+3	5E+3	2E-6	6E-9	-	-
			LLI wall (2E+3)	-	-	-	2E-5	2E-4
		W, see 180Os	-	3E+3	1E-6	4E-9	-	-
		Y, see 180Os	-	3E+3	1E-6	4E-9	-	-
76	Osmium-194	D, see 180Os	4E+2	4E+1	2E-8	6E-11	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		W, see 180Os	-	6E+1	2E-8	8E-11	-	-
		Y, see 180Os	-	8E+0	3E-9	1E-11	-	-
77	Iridium-182[2]	D, all compounds except those given for W and Y	4E+4	1E+5	6E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		W, halides, nitrates, and metallic iridium	-	2E+5	6E-5	2E-7	-	-
		Y, oxides and hydroxides	-	1E+5	5E-5	2E-7	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
77	Iridium-184	D, see 182Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see 182Ir	-	3E+4	1E-5	5E-8	-	-
		Y, see 182Ir	-	3E+4	1E-5	4E-8	-	-
77	Iridium-185	D, see 182Ir	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see 182Ir	-	1E+4	5E-6	2E-8	-	-
		Y, see 182Ir	-	1E+4	4E-6	1E-8	-	-
77	Iridium-186	D, see 182Ir	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		W, see 182Ir	-	6E+3	3E-6	9E-9	-	-
		Y, see 182Ir	-	6E+3	2E-6	8E-9	-	-
77	Iridium-187	D, see 182Ir	1E+4	3E+4	1E-5	5E-8	1E-4	1E-3
		W, see 182Ir	-	3E+4	1E-5	4E-8	-	-
		Y, see 182Ir	-	3E+4	1E-5	4E-8	-	-
77	Iridium-188	D, see 182Ir	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
		W, see 182Ir	-	4E+3	1E-6	5E-9	-	-
		Y, see 182Ir	-	3E+3	1E-6	5E-9	-	-
77	Iridium-189	D, see 182Ir	5E+3	5E+3	2E-6	7E-9	-	-
			LLI wall (5E+3)	-	-	-	7E-5	7E-4
		W, see 182Ir	-	4E+3	2E-6	5E-9	-	-
		Y, see 182Ir	-	4E+3	1E-6	5E-9	-	-
77	Iridium-190m[2]	D, see 182Ir	2E+5	2E+5	8E-5	3E-7	2E-3	2E-2
		W, see 182Ir	-	2E+5	9E-5	3E-7	-	-
		Y, see 182Ir	-	2E+5	8E-5	3E-7	-	-
77	Iridium-190	D, see 182Ir	1E+3	9E+2	4E-7	1E-9	1E-5	1E-4
		W, see 182Ir	-	1E+3	4E-7	1E-9	-	-
		Y, see 182Ir	-	9E+2	4E-7	1E-9	-	-
77	Iridium-192m	D, see 182Ir	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
		W, see 182Ir	-	2E+2	9E-8	3E-10	-	-
		Y, see 182Ir	-	2E+1	6E-9	2E-11	-	-
77	Iridium-192	D, see 182Ir	9E+2	3E+2	1E-7	4E-10	1E-5	1E-4
		W, see 182Ir	-	4E+2	2E-7	6E-10	-	-
		Y, see 182Ir	-	2E+2	9E-8	3E-10	-	-
77	Iridium-194m	D, see 182Ir	6E+2	9E+1	4E-8	1E-10	9E-6	9E-5
		W, see 182Ir	-	2E+2	7E-8	2E-10	-	-
		Y, see 182Ir	-	1E+2	4E-8	1E-10	-	-
77	Iridium-194	D, see 182Ir	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		W, see 182Ir	-	2E+3	9E-7	3E-9	-	-
		Y, see 182Ir	-	2E+3	8E-7	3E-9	-	-
77	Iridium-195m	D, see 182Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see 182Ir	-	3E+4	1E-5	4E-8	-	-
		Y, see 182Ir	-	2E+4	9E-6	3E-8	-	-
77	Iridium-195	D, see 182Ir	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see 182Ir	-	5E+4	2E-5	7E-8	-	-
		Y, see 182Ir	-	4E+4	2E-5	6E-8	-	-
78	Platinum-186	D, all compounds	1E+4	4E+4	2E-5	5E-8	2E-4	2E-3
78	Platinum-188	D, all compounds	2E+3	2E+3	7E-7	2E-9	2E-5	2E-4
78	Platinum-189	D, all compounds	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
78	Platinum-191	D, all compounds	4E+3	8E+3	4E-6	1E-8	5E-5	5E-4
78	Platinum-193m	D, all compounds	3E+3	6E+3	3E-6	8E-9	-	-
			LLI wall (3E+4)	-	-	-	4E-5	4E-4
78	Platinum-193	D, all compounds	4E+4	2E+4	1E-5	3E-8	-	-
			LLI wall (5E+4)	-	-	-	6E-4	6E-3
78	Platinum-195m	D, all compounds	2E+3	4E+3	2E-6	6E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
78	Platinum-197m[2]	D, all compounds	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
78	Platinum-197	D, all compounds	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
78	Platinum-199[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
78	Platinum-200	D, all compounds	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
79	Gold-193	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, halides and nitrates	-	2E+4	9E-6	3E-8	-	-
		Y, oxides and hydroxides	-	2E+4	8E-6	3E-8	-	-
79	Gold-194	D, see 193Au	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see 193Au	-	5E+3	2E-6	8E-9	-	-
		Y, see 193Au	-	5E+3	2E-6	7E-9	-	-
79	Gold-195	D, see 193Au	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see 193Au	-	1E+3	6E-7	2E-9	-	-
		Y, see 193Au	-	4E+2	2E-7	6E-10	-	-
79	Gold-198m	D, see 193Au	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		W, see 193Au	-	1E+3	5E-7	2E-9	-	-
		Y, see 193Au	-	1E+3	5E-7	2E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
79	Gold-198	D, see 193Au	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		W, see 193Au	-	2E+3	8E-7	3E-9	-	-
		Y, see 193Au	-	2E+3	7E-7	2E-9	-	-
79	Gold-199	D, see 193Au	3E+3	9E+3	4E-6	1E-8	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		W, see 193Au	-	4E+3	2E-6	6E-9	-	-
		Y, see 193Au	-	4E+3	2E-6	5E-9	-	-
79	Gold-200m	D, see 193Au	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see 193Au	-	3E+3	1E-6	4E-9	-	-
		Y, see 193Au	-	2E+4	1E-6	3E-9	-	-
79	Gold-200[2]	D, see 193Au	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see 193Au	-	8E+4	3E-5	1E-7	-	-
		Y, see 193Au	-	7E+4	3E-5	1E-7	-	-
79	Gold-201[2]	D, see 193Au	7E+4	2E+5	9E-5	3E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see 193Au	-	2E+5	1E-4	3E-7	-	-
		Y, see 193Au	-	2E+5	9E-5	3E-7	-	-
80	Mercury-193m	Vapor	-	8E+3	4E-6	1E-8	-	-
		Organic D	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		D, sulfates	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		W, oxides, hydroxides, halides, nitrates, and sulfides	-	8E+3	3E-6	1E-8	-	-
80	Mercury-193	Vapor	-	3E+4	1E-5	4E-8	-	-
		Organic D	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		D, see 193mHg	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see 193mHg	-	4E+4	2E-5	6E-8	-	-
80	Mercury-194	Vapor	-	3E+1	1E-8	4E-11	-	-
		Organic D	2E+1	3E+1	1E-8	4E-11	2E-7	2E-6
		D, see 193mHg	8E+2	4E+1	2E-8	6E-11	1E-5	1E-4
		W, see 193mHg	-	1E+2	5E-8	2E-10	-	-
80	Mercury-195m	Vapor	-	4E+3	2E-6	6E-9	-	-
		Organic D	3E+3	6E+3	3E-6	8E-9	4E-5	4E-4
		D, see 193mHg	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
		W, see 193mHg	-	4E+3	2E-6	5E-9	-	-
80	Mercury-195	Vapor	-	3E+4	1E-5	4E-8	-	-
		Organic D	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
		D, see 193mHg	1E+4	4E+4	1E-5	5E-8	2E-4	2E-3
		W, see 193mHg	-	3E+4	1E-5	5E-8	-	-
80	Mercury-197m	Vapor	-	5E+3	2E-6	7E-9	-	-
		Organic D	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
		D, see 193mHg	3E+3	7E+3	3E-6	1E-8	4E-5	4E-4
		W, see 193mHg	-	5E+3	2E-6	7E-9	-	-
80	Mercury-197	Vapor	-	8E+3	4E-6	1E-8	-	-
		Organic D	7E+3	1E+4	6E-6	2E-8	9E-5	9E-4
		D, see 193mHg	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, see 193mHg	-	9E+3	4E-6	1E-8	-	-
80	Mercury-199m[2]	Vapor	-	8E+4	3E-5	1E-7	-	-
		Organic D	6E+4	2E+5	7E-5	2E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
		D, see 193mHg	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
		W, see 193mHg	-	2E+5	7E-5	2E-7	-	-
80	Mercury-203	Vapor	-	8E+2	4E-7	1E-9	-	-
		Organic D	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
		D, see 193mHg	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
		W, see 193mHg	-	1E+3	5E-7	2E-9	-	-
81	Thallium-194m[2]	D, all compounds	5E+4	2E+5	6E-5	2E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
81	Thallium-194[2]	D, all compounds	3E+5	6E+5	2E-4	8E-7	-	-
			St wall (3E+5)	-	-	-	4E-3	4E-2
81	Thallium-195[2]	D, all compounds	6E+4	1E+5	5E-5	2E-7	9E-4	9E-3
81	Thallium-197	D, all compounds	7E+4	1E+5	5E-5	2E-7	1E-3	1E-2
81	Thallium-198m[2]	D, all compounds	3E+4	5E+4	2E-5	8E-8	4E-4	4E-3
81	Thallium-198	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
81	Thallium-199	D, all compounds	6E+4	8E+4	4E-5	1E-7	9E-4	9E-3
81	Thallium-200	D, all compounds	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
81	Thallium-201	D, all compounds	2E+4	2E+4	9E-6	3E-8	2E-4	2E-3
81	Thallium-202	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
81	Thallium-204	D, all compounds	2E+3	2E+3	9E-7	3E-9	2E-5	2E-4
82	Lead-195m[2]	D, all compounds	6E+4	2E+5	8E-5	3E-7	8E-4	8E-3
82	Lead-198	D, all compounds	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
82	Lead-1992	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
82	Lead-200	D, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
82	Lead-201	D, all compounds	7E+3	2E+4	8E-6	3E-8	1E-4	1E-3
82	Lead-202m	D, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
82	Lead-202	D, all compounds	1E+2	5E+1	2E-8	7E-11	2E-6	2E-5
82	Lead-203	D, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
82	Lead-205	D, all compounds	4E+3	1E+3	6E-7	2E-9	5E-5	5E-4
82	Lead-209	D, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
82	Lead-210	D, all compounds	6E1	2E1	1E-10	-	-	-
			Bone surf (1E+0)	Bone surf (4E-1)	-	6E-13	1E-8	1E-7
82	Lead-211[2]	D, all compounds	1E+4	6E+2	3E-7	9E-10	2E-4	2E-3
82	Lead-212	D, all compounds	8E+1	3E+1	1E-8	5E-11	-	-
			Bone surf (1E+2)	-	-	-	2E-6	2E-5
82	Lead-2142	D, all compounds	9E+3	8E+2	3E-7	1E-9	1E-4	1E-3
83	Bismuth-200[2]	D, nitrates	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
		W, all other compounds	-	1E+5	4E-5	1E-7	-	-
83	Bismuth-201[2]	D, see 200Bi	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see 200Bi	-	4E+4	2E-5	5E-8	-	-
83	Bismuth-202[2]	D, see 200Bi	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see 200Bi	-	8E+4	3E-5	1E-7	-	-
83	Bismuth-203	D, see 200Bi	2E+3	7E+3	3E-6	9E-9	3E-5	3E-4
		W, see 200Bi	-	6E+3	3E-6	9E-9	-	-
83	Bismuth-205	D, see 200Bi	1E+3	3E+3	1E-6	3E-9	2E-5	2E-4
		W, see 200Bi	-	1E+3	5E-7	2E-9	-	-
83	Bismuth-206	D, see 200Bi	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
		W, see 200Bi	-	9E+2	4E-7	1E-9	-	-
83	Bismuth-207	D, see 200Bi	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
		W, see 200Bi	-	4E+2	1E-7	5E-10	-	-
83	Bismuth-210m	D, see 200Bi	4E+1	5E+0	2E-9	-	-	-
			Kidneys (6E+1)	Kidneys (6E+0)	-	9E-12	8E-7	8E-6
		W, see 200Bi	-	7E-1	3E-10	9E-13	-	-
83	Bismuth-210	D, see 200Bi	8E+2	2E+2	1E-7	-	1E-5	1E-4
			-	Kidneys (4E+2)	-	5E-10	-	-
		W, see 200Bi	-	3E+1	1E-8	4E-11	-	-
83	Bismuth-212[2]	D, see 200Bi	5E+3	2E+2	1E-7	3E-10	7E-5	7E-4
		W, see 200Bi	-	3E+2	1E-7	4E-10	-	-
83	Bismuth-213[2]	D, see 200Bi	7E+3	3E+2	1E-7	4E-10	1E-4	1E-3
		W, see 200Bi	-	4E+2	1E-7	5E-10	-	-
83	Bismuth-214[2]	D, see 200Bi	2E+4	8E+2	3E-7	1E-9	-	-
			St wall (2E+4)	-	-	-	3E-4	3E-3
		W, see 200Bi	-	9E-2	4E-7	1E-9	-	-
84	Polonium-203[2]	D, all compounds except those given for W	3E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		W, oxides, hydroxides, and nitrates	-	9E+4	4E-5	1E-7	-	-
84	Polonium-205[2]	D, see 203Po	2E+4	4E+4	2E-5	5E-8	3E-4	3E-3
		W, see 203Po	-	7E+4	3E-5	1E-7	-	-
84	Polonium-207	D, see 203Po	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		W, see 203Po	-	3E+4	1E-5	4E-8	-	-
84	Polonium-210	D, see 203Po	3E+0	6E-1	3E-10	9E-13	4E-8	4E-7
		W, see 203Po	-	6E-1	3E-10	9E-13	-	-
85	Astatine-207[2]	D, halides	6E+3	3E+3	1E-6	4E-9	8E-5	8E-4
		W	-	2E+3	9E-7	3E-9	-	-
85	Astatine-211	D, halides	1E+2	8E+1	3E-8	1E-10	2E-6	2E-5
		W	-	5E+1	2E-8	8E-11	-	-
86	Radon-220	With daughters removed	-	2E+4	7E-6	2E-8	-	-
		With daughters present	-	2E+1 (or 12 WLM)	9E-9 (or 1.0 WL)	3E-11	-	-
86	Radon-222	With daughters removed	-	1E+4	4E-6	1E-8	-	-
		With daughters present	-	1E+2 (or 4 WLM)	3E-8 (or 0.33 WL)	1E-10	-	-
87	Francium-222[2]	D, all compounds	2E+3	5E+2	2E-7	6E-10	3E-5	3E-4
87	Francium-223[2]	D, all compounds	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
88	Radium-223	W, all compounds	5E+0	7E-1	3E-10	9E-13	-	-
			Bone surf (9E+0)	-	-	-	1E-7	1E-6
88	Radium-224	W, all compounds	8E+0	2E+0	7E-10	2E-12	-	-
			Bone surf (2E+1)	-	-	-	2E-7	2E-6
88	Radium-225	W, all compounds	8E+0	7E-1	3E-10	9E-13	-	-
			Bone surf (2E+1)	-	-	-	2E-7	2E-6

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88	Radium-226	W, all compounds	2E+0	6E-1	3E-10	9E-13	-	-
			Bone surf (5E+0)	-	-	-	6E-8	6E-7
88	Radium-227[2]	W, all compounds	2E+4	1E+4	6E-6	-	-	-
			Bone surf (2E+4)	Bone surf (2E+4)	-	3E-8	3E-4	3E-3
88	Radium-228	W, all compounds	2E+0	1E+0	5E-10	2E-12	-	-
			Bone surf (4E+0)	-	-	-	6E-8	6E-7
89	Actinium-224	D, all compounds except those given for W and Y	2E+3	3E+1	1E-8	-	-	-
			LLI wall (2E+3)	Bone surf (4E+1)	-	5E-11	3E-5	3E-4
		W, halides and nitrates	-	5E+1	2E-8	7E-11	-	-
		Y, oxides and hydroxides	-	5E+1	2E-8	6E-11	-	-
89	Actinium-225	D, see 224Ac	5E+1	3E-1	1E-10	-	-	-
			LLI wall (5E+1)	Bone surf (5E-1)	-	7E-13	7E-7	7E-6
		W, see 224Ac	-	6E-1	3E-10	9E-13	-	-
		Y, see 224Ac	-	6E-1	3E-10	9E-13	-	-
89	Actinium-226	D, see 224Ac	1E+2	3E+0	1E-9	-	-	-
			LLI wall (1E+2)	Bone surf (4E+0)	-	5E-12	2E-6	2E-5
		W, see 224Ac	-	5E+0	2E-9	7E-12	-	-
		Y, see 224Ac	-	5E+0	2E-9	6E-12	-	-
89	Actinium-227	D, see 224Ac	2E-1	4E-4	2E-13	-	-	-
			Bone surf (4E-1)	Bone surf (8E-4)	-	1E-15	5E-9	5E-8
		W, see 224Ac	-	2E-3	7E-13	-	-	-
			Bone surf -	(3E-3)	-	4E-15	-	-
		Y, see 224Ac	-	4E-3	2E-12	6E-15	-	-
89	Actinium-228	D, see 224Ac	2E+3	9E+0	4E-9	-	3E-5	3E-4
			-	Bone surf (2E+1)	-	2E-11	-	-
		W, see 224Ac	-	4E+1	2E-8	-	-	-
			-	Bone surf (6E+1)	-	8E-11	-	-
		Y, see 224Ac	-	4E+1	2E-8	6E-11	-	-
90	Thorium-2262	W, all compounds except those given for Y	5E+3	2E+2	6E-8	2E-10	-	-
			St wall (5E+3)	-	-	-	7E-5	7E-4
		Y, oxides and hydroxides	-	1E+2	6E-8	2E-10	-	-
90	Thorium-227	W, see 226Th	1E+2	3E-1	1E-10	5E-13	2E-6	2E-5
		Y, see 226Th	-	3E-1	1E-10	5E-13	-	-
90	Thorium-228	W, see 226Th	6E+0	1E-2	4E-12	-	-	-
			Bone surf (1E+1)	Bone surf (2E-2)	-	3E-14	2E-7	2E-6
		Y, see 226Th	-	2E-2	7E-12	2E-14	-	-
90	Thorium-229	W, see 226Th	6E-1	9E-4	4E-13	-	-	-
			Bone surf (1E+0)	Bone surf (2E-3)	-	3E-15	2E-8	2E-7
		Y, see 226Th	-	2E-3	1E-12	-	-	-
			-	Bone surf (3E-3)	-	4E-15	-	-
90	Thorium-230	W, see 226Th	4E+0	6E-3	3E-12	-	-	-
			Bone surf (9E+0)	Bone surf (2E-2)	-	2E-14	1E-7	1E-6
		Y, see 226Th	-	2E-2	6E-12	-	-	-
			-	Bone surf (2E-2)	-	3E-14	-	-
90	Thorium-231	W, see 226Th	4E+3	6E+3	3E-6	9E-9	5E-5	5E-4
		Y, see 226Th	-	6E+3	3E-6	9E-9	-	-
90	Thorium-232	W, see 226Th	7E-1	1E-3	5E-13	-	-	-
			Bone surf (2E+0)	Bone surf (3E-3)	-	4E-15	3E-8	3E-7
		Y, see 226Th	-	3E-3	1E-12	-	-	-
			-	Bone surf (4E-3)	-	6E-15	-	-
90	Thorium-234	W, see 226Th	3E+2	2E+2	8E-8	3E-10	-	-
			LLI wall (4E+2)	-	-	-	5E-6	5E-5
		Y, see 226Th	-	2E+2	6E-8	2E-10	-	-
91	Protactinium-227[2]	W, all compounds except those given for Y	4E+3	1E+2	5E-8	2E-10	5E-5	5E-4
		Y, oxides and hydroxides	-	1E+2	4E-8	1E-10	-	-

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91	Protactinium-228	W, see 227Pa	1E+3	1E+1	5E-9	-	2E-5	2E-4
			-	Bone surf (2E+1)	-	3E-11	-	-
		Y, see 227Pa	-	1E+1	5E-9	2E-11	-	-
91	Protactinium-230	W, see 227Pa	6E+2	5E+0	2E-9	7E-12	-	-
			Bone surf (9E+2)	-	-	-	1E-5	1E-4
		Y, see 227Pa	-	4E+0	1E-9	5E-12	-	-
91	Protactinium-231	W, see 227Pa	2E-1	2E-3	6E-13	-	-	-
			Bone surf (5E-1)	Bone surf (4E-3)	-	6E-15	6E-9	6E-8
		Y, see 227Pa	-	4E-3	2E-12	-	-	-
			-	Bone surf (6E-3)	-	8E-15	-	-
91	Protactinium-232	W, see 227Pa	1E+3	2E+1	9E-9	-	2E-5	2E-4
			-	Bone surf (6E+1)	-	8E-11	-	-
		Y, see 227Pa	-	6E+1	2E-8	-	-	-
			-	Bone surf (7E+1)	-	1E-10	-	-
91	Protactinium-233	W, see 227Pa	1E+3	7E+2	3E-7	1E-9	-	-
			LLI wall (2E+3)	-	-	-	2E-5	2E-4
		Y, see 227Pa	-	6E+2	2E-7	8E-10	-	-
91	Protactinium-234	W, see 227Pa	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		Y, see 227Pa	-	7E+3	3E-6	9E-9	-	-
92	Uranium-230	D, UF, UOF, UO(NO)	4E+0	4E-1	2E-10	-	-	-
			Bone surf (6E+0)	Bone surf (6E-1)	-	8E-13	8E-8	8E-7
		W, UO, UF, UCl	-	4E-1	1E-10	5E-13	-	-
		Y, UO, UO	-	3E-1	1E-10	4E-13	-	-
92	Uranium-231	D, see 230U	5E+3	8E+3	3E-6	1E-8	-	-
			LLI wall (4E+3)	-	-	-	6E-5	6E-4
		W, see 230U	-	6E+3	2E-6	8E-9	-	-
		Y, see 230U	-	5E+3	2E-6	6E-9	-	-
92	Uranium-232	D, see 230U	2E+0	2E-1	9E-11	-	-	-
			Bone surf (4E+0)	Bone surf (4E-1)	-	6E-13	6E-8	6E-7
		W, see 230U	-	4E-1	2E-10	5E-13	-	-
		Y, see 230U	-	8E-3	3E-12	1E-14	-	-
92	Uranium-233	D, see 230U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see 230U	-	7E-1	3E-10	1E-12	-	-
		Y, see 230U	-	4E-2	2E-11	5E-14	-	-
92	Uranium-234[3]	D, see 230U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see 230U	-	7E-1	3E-10	1E-12	-	-
		Y, see 230U	-	4E-2	2E-11	5E-14	-	-
92	Uranium-235[3]	D, see 230U	1E+1	1E+0	6E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see 230U	-	8E-1	3E-10	1E-12	-	-
		Y, see 230U	-	4E-2	2E-11	6E-14	-	-
92	Uranium-236	D, see 230U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see 230U	-	8E-1	3E-10	1E-12	-	-
		Y, see 230U	-	4E-2	2E-11	6E-14	-	-
92	Uranium-237	D, see 230U	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		W, see 230U	-	2E+3	7E-7	2E-9	-	-
		Y, see 230U	-	2E+3	6E-7	2E-9	-	-
92	Uranium-238[3]	D, see 230U	1E+1	1E+0	6E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see 230U	-	8E-1	3E-10	1E-12	-	-
		Y, see 230U	-	4E-2	2E-11	6E-14	-	-
92	Uranium-239[2]	D, see 230U	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
		W, see 230U	-	2E+5	7E-5	2E-7	-	-
		Y, see 230U	-	2E+5	6E-5	2E-7	-	-
92	Uranium-240	D, see 230U	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		W, see 230U	-	3E+3	1E-6	4E-9	-	-
		Y, see 230U	-	2E+3	1E-6	3E-9	-	-

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92	Uranium-natural[3]	D, see 230U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see 230U	-	8E-1	3E-10	9E-13	-	-
		Y, see 230U	-	5E-2	2E-11	9E-14	-	-
93	Neptunium-232[2]	W, all compounds	1E+5	2E+3	7E-7	-	2E-3	2E-2
			-	Bone surf (5E+2)	-	6E-9	-	-
93	Neptunium-233[2]	W, all compounds	8E+5	3E+6	1E-3	4E-6	1E-2	1E-1
93	Neptunium-234	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
93	Neptunium-235	W, all compounds	2E+4	8E+2	3E-7	-	-	-
			LLI wall (2E+4)	Bone surf (1E+3)	-	2E-9	3E-4	3E-3
93	Neptunium-236 (1.15E+5 y)	W, all compounds	3E+0	2E-2	9E-12	-	-	-
			Bone surf (6E+0)	Bone surf (5E-2)	-	8E-14	9E-8	9E-7
93	Neptunium-236 (22.5 h)	W, all compounds	3E+3	3E+1	1E-8	-	-	-
			Bone surf (4E+3)	Bone surf (7E+1)	-	1E-10	5E-5	5E-4
93	Neptunium-237	W, all compounds	5E-1	4E-3	2E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	1E-14	2E-8	2E-7
93	Neptunium-238	W, all compounds	1E+3	6E+1	3E-8	-	2E-5	2E-4
			-	Bone surf (2E+2)	-	2E-10	-	-
93	Neptunium-239	W, all compounds	2E+3	2E+3	9E-7	3E-9	-	-
			LLI wall (2E+3)	-	-	-	2E-5	2E-4
93	Neptunium-240[2]	W, all compounds	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
94	Plutonium-234	W, all compounds except PuO	8E+3	2E+2	9E-8	3E-10	1E-4	1E-3
		Y, PuO	-	2E+2	8E-8	3E-10	-	-
94	Plutonium-235[2]	W, see 234Pu	9E+5	3E+6	1E-3	4E-6	1E-2	1E-1
		Y, see 234Pu	-	3E+6	1E-3	3E-6	-	-
94	Plutonium-236	W, see 234Pu	2E+0	2E-2	8E-12	-	-	-
			Bone surf (4E+0)	Bone surf (4E-2)	-	5E-14	6E-8	6E-7
		Y, see 234Pu	-	4E-2	2E-11	6E-14	-	-
94	Plutonium-237	W, see 234Pu	1E+4	3E+3	1E-6	5E-9	2E-4	2E-3
		Y, see 234Pu	-	3E+3	1E-6	4E-9	-	-
94	Plutonium-238	W, see 234Pu	9E-1	7E-3	3E-12	-	-	-
			Bone surf (2E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
		Y, see 234Pu	-	2E-2	8E-12	2E-14	-	-
94	Plutonium-239	W, see 234Pu	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
		Y, see 234Pu	-	2E-2	7E-12	-	-	-
			-	Bone surf (2E-2)	-	2E-14	-	-
94	Plutonium-240	W, see 234Pu	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
		Y, see 234Pu	-	2E-2	7E-12	-	-	-
			-	Bone surf (2E-2)	-	2E-14	-	-
94	Plutonium-241	W, see 234Pu	4E+1	3E-1	1E-10	-	-	-
			Bone surf (7E+1)	Bone surf (6E-1)	-	8E-13	1E-6	1E-5
		Y, see 234Pu	-	8E-1	3E-10	-	-	-
			-	Bone surf (1E+0)	-	1E-12	-	-
94	Plutonium-242	W, see 234Pu	8E-1	7E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
		Y, see 234Pu	-	2E-2	7E-12	-	-	-
			-	Bone surf (2E-2)	-	2E-14	-	-
94	Plutonium-243	W, see 234Pu	2E+4	4E+4	2E-5	5E-8	2E-4	2E-3
		Y, see 234Pu	-	4E+4	2E-5	5E-8	-	-
94	Plutonium-244	W, see 234Pu	8E-1	7E-3	3E-12	-	-	-
			Bone surf (2E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
		Y, see 234Pu	-	2E-2	7E-12	-	-	-
			-	Bone surf (2E-2)	-	2E-14	-	-
94	Plutonium-245	W, see 234Pu	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
		Y, see 234Pu	-	4E+3	2E-6	6E-9	-	-
94	Plutonium-246	W, see 234Pu	4E+2	3E+2	1E-7	4E-10	-	-
			LLI wall (4E+2)	-	-	-	6E-6	6E-5
		Y, see 234Pu	-	3E+2	1E-7	4E-10	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
95	Americium-237[2]	W, all compounds	8E+4	3E+5	1E-4	4E-7	1E-3	1E-2
95	Americium-238[2]	W, all compounds	4E+4	3E+3	1E-6	-	5E-4	5E-3
			-	Bone surf (6E+3)	-	9E-9	-	-
95	Americium-239	W, all compounds	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
95	Americium-240	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
95	Americium-241	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
95	Americium-242m	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
95	Americium-242	W, all compounds	4E+3	8E+1	4E-8	-	5E-5	5E-4
			-	Bone surf (9E+1)	-	1E-10	-	-
95	Americium-243	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
95	Americium-244m[2]	W, all compounds	6E+4	4E+3	2E-6	-	-	-
			St wall (8E+4)	Bone surf (7E+3)	-	1E-8	1E-3	1E-2
95	Americium-244	W, all compounds	3E+3	2E+2	8E-8	-	4E-5	4E-4
			-	Bone surf (3E+2)	-	4E-10	-	-
95	Americium-245	W, all compounds	3E+4	8E+4	3E-5	1E-7	4E-4	4E-3
95	Americium-246m[2]	W, all compounds	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
95	Americium-246[2]	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
96	Curium-238	W, all compounds	2E+4	1E+3	5E-7	2E-9	2E-4	2E-3
96	Curium-240	W, all compounds	6E+1	6E-1	2E-10	-	-	-
			Bone surf (8E+1)	Bone surf (6E-1)	-	9E-13	1E-6	1E-5
96	Curium-241	W, all compounds	1E+3	3E+1	1E-8	-	2E-5	2E-4
			-	Bone surf (4E+1)	-	5E-11	-	-
96	Curium-242	W, all compounds	3E+1	3E-1	1E-10	-	-	-
			Bone surf (5E+1)	Bone surf (3E-1)	-	4E-13	7E-7	7E-6
96	Curium-243	W, all compounds	1E+0	9E-3	4E-12	-	-	-
			Bone surf (2E+0)	Bone surf (2E-2)	-	2E-14	3E-8	3E-7
96	Curium-244	W, all compounds	1E+0	1E-2	5E-12	-	-	-
			Bone surf (3E+0)	Bone surf (2E-2)	-	3E-14	3E-8	3E-7
96	Curium-245	W, all compounds	7E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
96	Curium-246	W, all compounds	7E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
96	Curium-247	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
96	Curium-248	W, all compounds	2E-1	2E-3	7E-13	-	-	-
			Bone surf (4E-1)	Bone surf (3E-3)	-	4E-15	5E-9	5E-8
96	Curium-2492	W, all compounds	5E+4	2E+4	7E-6	-	7E-4	7E-3
			-	Bone surf (3E+4)	-	4E-8	-	-
96	Curium-250	W, all compounds	4E-2	3E-4	1E-13	-	-	-
			Bone surf (6E-2)	Bone surf (5E-4)	-	8E-16	9E-10	9E-9
97	Berkelium-245	W, all compounds	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
97	Berkelium-246	W, all compounds	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
97	Berkelium-247	W, all compounds	5E-1	4E-3	2E-12	-	-	-
			Bone surf (1E+0)	Bone surf (9E-3)	-	1E-14	2E-8	2E-7
97	Berkelium-249	W, all compounds	2E+2	2E+0	7E-10	-	-	-
			Bone surf (5E+2)	Bone surf (4E+0)	-	5E-12	6E-6	6E-5
97	Berkelium-250	W, all compounds	9E+3	3E+2	1E-7	-	1E-4	1E-3
			Bone surf -	(7E+2)	-	1E-9	-	-
98	Californium-244[2]	W, all compounds except those given for Y	3E+4	6E+2	2E-7	8E-10	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		Y, oxides and hydroxides	-	6E+2	2E-7	8E-10	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
98	Californium-246	W, see 244Cf	4E+2	9E+0	4E-9	1E-11	5E-6	5E-5
		Y, see 244Cf	-	9E+0	4E-9	1E-11	-	-
98	Californium-248	W, see 244Cf	8E+0	6E-2	3E-11	-	-	-
			Bone surf (2E+1)	Bone surf (1E-1)	-	2E-13	2E-7	2E-6
		Y, see 244Cf	-	1E-1	4E-11	1E-13	-	-
98	Californium-249	W, see 244Cf	5E-1	4E-3	2E-12	-	-	-
			Bone surf (1E+0)	Bone surf (9E-3)	-	1E-14	2E-8	2E-7
		Y, see 244Cf	-	1E-2	4E-12	-	-	-
			Bone surf -	(1E-2)	-	2E-14	-	-
98	Californium-250	W, see 244Cf	1E+0	9E-3	4E-12	-	-	-
			Bone surf (2E+0)	Bone surf (2E-2)	-	3E-14	3E-8	3E-7
		Y, see 244Cf	-	3E-2	1E-11	4E-14	-	-
98	Californium-251	W, see 244Cf	5E-1	4E-3	2E-12	-	-	-
			Bone surf (1E+0)	Bone surf (9E-3)	-	1E-14	2E-8	2E-7
		Y, see 244Cf	-	1E-2	4E-12	-	-	-
			Bone surf -	(1E-2)	-	2E-14	-	-
98	Californium-252	W, see 244Cf	2E+0	2E-2	8E-12	-	-	-
			Bone surf (5E+0)	Bone surf (4E-2)	-	5E-14	7E-8	7E-7
		Y, see 244Cf	-	3E-2	1E-11	5E-14	-	-
98	Californium-253	W, see 244Cf	2E+2	2E+0	8E-10	3E-12	-	-
			Bone surf (4E+2)	-	-	-	5E-6	5E-5
		Y, see 244Cf	-	2E+0	7E-10	2E-12	-	-
98	Californium-254	W, see 244Cf	2E+0	2E-2	9E-12	3E-14	3E-8	3E-7
		Y, see 244Cf	-	2E-2	7E-12	2E-14	-	-
99	Einsteinium-250	W, all compounds	4E+4	5E+2	2E-7	-	6E-4	6E-3
			-	Bone surf (1E+3)	-	2E-9	-	-
99	Einsteinium-251	W, all compounds	7E+3	9E+2	4E-7	-	1E-4	1E-3
			-	Bone surf (1E+3)	-	2E-9	-	-
99	Einsteinium-253	W, all compounds	2E+2	1E+0	6E-10	2E-12	2E-6	2E-5
99	Einsteinium-254m	W, all compounds	3E+2	1E+1	4E-9	1E-11	-	-
			LLI wall (3E+2)	-	-	-	4E-6	4E-5
99	Einsteinium-254	W, all compounds	8E+0	7E-2	3E-11	-	-	-
			Bone surf (2E+1)	Bone surf (1E-1)	-	2E-13	2E-7	2E-6
100	Fermium-252	W, all compounds	5E+2	1E+1	5E-9	2E-11	6E-6	6E-5
100	Fermium-253	W, all compounds	1E+3	1E+1	4E-9	1E-11	1E-5	1E-4
100	Fermium-254	W, all compounds	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
100	Fermium-255	W, all compounds	5E+2	2E+1	9E-9	3E-11	7E-6	7E-5
100	Fermium-257	W, all compounds	2E+1	2E-1	7E-11	-	-	-
			Bone surf (4E+1)	Bone surf (2E-1)	-	3E-13	5E-7	5E-6
101	Mendelevium-257	W, all compounds	7E+3	8E+1	4E-8	-	1E-4	1E-3
			-	Bone surf (9E+1)	-	1E-10	-	-
101	Mendelevium-258	W, all compounds	3E+1	2E-1	1E-10	-	-	-
			Bone surf (5E+1)	Bone surf (3E-1)	-	5E-13	6E-7	6E-6
-Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours		Submersion[1]	-	2E+2	1E-7	1E-9	-	-
-Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life greater than 2 hours		...	-	2E-1	1E-10	1E-12	1E-8	1E-7
-Any single radionuclide not listed above that decays by alpha emission or spontaneous fission, or any mixture for which either the identity or the concentration of any radionuclide in the mixture is not known		..	-	4E-4	2E-13	1E-15	2E-9	2E-8

FOOTNOTES:

1 "Submersion" means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.

2 These radionuclides have radiological half-lives of less than 2 hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class "Submersion," are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do NOT include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7 μCi/ml for the listed DAC to account for the submersion dose prospectively, but should use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits. (See 20.1203.)

3 For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor (see 20.1201(e)). If the percent by weight (enrichment) of U-235 is not greater than 5, the concentration value for a 40-hour workweek is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour workweek shall not exceed 8E-3 (SA) μCi-hr/ml, where SA is the specific activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7 curies per gram U. The specific activity for other mixtures of U-238, U-235, and U-234, if not known, shall be:

SA = 3.6E-7 curies/gram U U-depleted
SA = [0.4 + 0.38 (enrichment) + 0.0034 (enrichment)2] E-6 , enrichment $\geq$ 0.72
where enrichment is the percentage by weight of U-235, expressed as percent.

NOTES:

1. If the identity of each radionuclide in a mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

2. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in this appendix are not present in the mixture, the inhalation ALI, DAC, and effluent and sewage concentrations for the mixture are the lowest values specified in this appendix for any radionuclide that is not known to be absent from the mixture; or

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				Monthly Average
Atomic No.	Radionuclide	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
If it is known that Ac-227-D and Cm-250-W are not present			-	7E-4	3E-13	-	-	-
If, in addition, it is known that Ac-227-W,Y, Th-229-W,Y, Th-230-W, Th-232-W,Y, Pa-231-W,Y, Np-237-W, Pu-239-W, Pu-240-W, Pu-242-W, Am-241-W, Am-242m-W, Am-243-W, Cm-245-W, Cm-246-W, Cm-247-W, Cm-248-W, Bk-247-W, Cf-249-W, and Cf-251-W are not present			-	7E-3	3E-12	-	-	-
If, in addition, it is known that Sm-146-W, Sm-147-W, Gd-148-D,W, Gd-152-D,W, Th-228-W,Y, Th-230-Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, Np-236-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-Y, Pu-240-Y, Pu-242-Y, Pu-244-W,Y, Cm-243-W, Cm-244-W, Cf-248-W, Cf-249-Y, Cf-250-W,Y, Cf-251-Y, Cf-252-W,Y, and Cf-254-W,Y are not present			-	7E-2	3E-11	-	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
	If, in addition, it is known that Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-Y, Es-254-W, Fm-257-W, and Md-258-W are not present		-	7E-1	3E-10	-	-	-
	If, in addition, it is known that Si-32-Y, Ti-44-Y, Fe-60-D, Sr-90-Y, Zr-93-D, Cd-113m-D, Cd-113-D, In-115-D,W, La-138-D, Lu-176-W, Hf-178m-D,W, Hf-182-D,W, Bi-210m-D, Ra-224-W, Ra-228-W, Ac-226-D,W,Y, Pa-230-W,Y, U-233-D,W, U-234-D,W, U-235-D,W, U-236-D,W, U-238-D,W, Pu-241-Y, Bk-249-W, Cf-253-W,Y, and Es-253-W are not present		-	7E+0	3E-9	-	-	-
	If it is known that Ac-227-D,W,Y, Th-229-W,Y, Th-232-W,Y, Pa-231-W,Y, Cm-248-W, and Cm-250-W are not present		-	-	-	1E-14	-	-
	If, in addition, it is known that Sm-146-W, Gd-148-D,W, Gd-152-D, Th-228-W,Y, Th-230-W,Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, U-Nat-Y, Np-236-W, Np-237-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-W,Y, Pu-240-W,Y, Pu-242-W,Y, Pu-244-W,Y, Am-241-W, Am-242m-W, Am-243-W, Cm-243-W, Cm-244-W, Cm-245-W, Cm-246-W, Cm-247-W, Bk-247-W, Cf-249-W,Y, Cf-250-W,Y, Cf-251-W,Y, Cf-252-W,Y, and Cf-254-W,Y are not present		-	-	-	1E-13	-	-
	If, in addition, it is known that Sm-147-W, Gd-152-W, Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, U-Nat-W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-W,Y, Es-254-W, Fm-257-W, and Md-258-W are not present		-	-	-	1E-12	-	-
	If, in addition it is known that Fe-60, Sr-90, Cd-113m, Cd-113, In-115, I-129, Cs-134, Sm-145, Sm-147, Gd-148, Gd-152, Hg-194 (organic), Bi-210m, Ra-223, Ra-224, Ra-225, Ac-225, Th-228, Th-230, U-233, U-234, U-235, U-236, U-238, U-Nat, Cm-242, Cf-248, Es-254, Fm-257, and Md-258 are not present		-	-	-	-	1E-6	1E-5

NOTES:

3. If a mixture of radionuclides consists of uranium and its daughters in ore dust (10 µm AMAD particle distribution assumed) prior to chemical separation of the uranium from the ore, the following values may be used for the DAC of the mixture: 6E-11 µCi of gross alpha activity from uranium-238, uranium-234, thorium-230, and radium-226 per milliliter of air; 3E-11 µCi of natural uranium per milliliter of air; or 45 micrograms of natural uranium per cubic meter of air.

4. If the identity and concentration of each radionuclide in a mixture are known, the limiting values should be derived as follows: determine, for each radionuclide in the mixture, the ratio between the concentration present in the mixture and the concentration otherwise established in Appendix B for the specific radionuclide when not in a mixture. The sum of such ratios for all of the radionuclides in the mixture may not exceed "1" (i.e., "unity").

   Example: If radionuclides "A," "B," and "C" are present in concentrations CA, CB, and CC, and if the applicable DACs are DACA, DACB, and DACC, respectively, then the concentrations shall be limited so that the following relationship exists:

$$\frac{C_A}{DAC_A} + \frac{C_B}{DAC_B} + \frac{C_C}{DAC_C} \leq 1$$

APPENDIX C

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Hydrogen-3	1,000	Chromium-48	1,000
Beryllium-7	1,000	Chromium-49	1,000
Beryllium-10	1	Chromium-51	1,000
Carbon-11	1,000	Manganese-51	1,000
Carbon-14	100	Manganese-52m	1,000
Fluorine-18	1,000	Manganese-52	100
Sodium-22	10	Manganese-53	1,000
Sodium-24	100	Manganese-54	100
Magnesium-28	100	Manganese-56	1,000
Aluminum-26	10	Iron-52	100
Silicon-31	1,000	Iron-55	100
Silicon-32	1	Iron-59	10
Phosphorus-32	10	Iron-60	1
Phosphorus-33	100	Cobalt-55	100
Sulfur-35	100	Cobalt-56	10
Chlorine-36	10	Cobalt-57	100
Chlorine-38	1,000	Cobalt-58m	1,000
Chlorine-39	1,000	Cobalt-58	100
Argon-39	1,000	Cobalt-60m	1,000
Argon-41	1,000	Cobalt-60	1
Potassium-40	100	Cobalt-61	1,000
Potassium-42	1,000	Cobalt-62m	1,000
Potassium-43	1,000	Nickel-56	100
Potassium-44	1,000	Nickel-57	100
Potassium-45	1,000	Nickel-59	100
Calcium-41	100	Nickel-63	100
Calcium-45	100	Nickel-65	1,000
Calcium-47	100	Nickel-66	10
Scandium-43	1,000	Copper-60	1,000
Scandium-44m	100	Copper-61	1,000
Scandium-44	100	Copper-64	1,000
Scandium-46	10	Copper-67	1,000
Scandium-47	100	Zinc-62	100
Scandium-48	100	Zinc-63	1,000
Scandium-49	1,000	Zinc-65	10
Titanium-44	1	Zinc-69m	100
Titanium-45	1,000	Zinc-69	1,000
Vanadium-47	1,000	Zinc-71m	1,000
Vanadium-48	100	Zinc-72	100
Vanadium-49	1,000	Gallium-65	1,000

* To convert µCi to kBq, multiply the µCi value by 37.

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Gallium-66	100	Krypton-81	1,000
Gallium-67	1,000	Krypton-83m	1,000
Gallium-68	1,000	Krypton-85m	1,000
Gallium-70	1,000	Krypton-85	1,000
Gallium-72	100	Krypton-87	1,000
Gallium-73	1,000	Krypton-88	1,000
Germanium-66	1,000	Rubidium-79	1,000
Germanium-67	1,000	Rubidium-81m	1,000
Germanium-68	10	Rubidium-81	1,000
Germanium-69	1,000	Rubidium-82m	1,000
Germanium-71	1,000	Rubidium-83	100
Germanium-75	1,000	Rubidium-84	100
Germanium-77	1,000	Rubidium-86	100
Germanium-78	1,000	Rubidium-87	100
Arsenic-69	1,000	Rubidium-88	1,000
Arsenic-70	1,000	Rubidium-89	1,000
Arsenic-71	100	Strontium-80	100
Arsenic-72	100	Strontium-81	1,000
Arsenic-73	100	Strontium-83	100
Arsenic-74	100	Strontium-85m	1,000
Arsenic-76	100	Strontium-85	100
Arsenic-77	100	Strontium-87m	1,000
Arsenic-78	1,000	Strontium-89	10
Selenium-70	1,000	Strontium-90	0.1
Selenium-73m	1,000	Strontium-91	100
Selenium-73	100	Strontium-92	100
Selenium-75	100	Yttrium-86m	1,000
Selenium-79	100	Yttrium-86	100
Selenium-81m	1,000	Yttrium-87	100
Selenium-81	1,000	Yttrium-88	10
Selenium-83	1,000	Yttrium-90m	1,000
Bromine-74m	1,000	Yttrium-90	10
Bromine-74	1,000	Yttrium-91m	1,000
Bromine-75	1,000	Yttrium-91	10
Bromine-76	100	Yttrium-92	100
Bromine-77	1,000	Yttrium-93	100
Bromine-80m	1,000	Yttrium-94	1,000
Bromine-80	1,000	Yttrium-95	1,000
Bromine-82	100	Zirconium-86	100
Bromine-83	1,000	Zirconium-88	10
Bromine-84	1,000	Zirconium-89	100
Krypton-74	1,000	Zirconium-93	1
Krypton-76	1,000	Zirconium-95	10
Krypton-77	1,000	Zirconium-97	100
Krypton-79	1,000	Niobium-88	1,000

* To convert µCi to kBq, multiply the µCi value by 37.

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Niobium-89m (66 min)	1,000	Palladium-101	1,000
Niobium-89 (122 min)	1,000	Palladium-103	100
Niobium-90	100	Palladium-107	10
Niobium-93m	10	Palladium-109	100
Niobium-94	1	Silver-102	1,000
Niobium-95m	100	Silver-103	1,000
Niobium-95	100	Silver-104m	1,000
Niobium-96	100	Silver-104	1,000
Niobium-97	1,000	Silver-105	100
Niobium-98	1,000	Silver-106m	100
Molybdenum-90	100	Silver-106	1,000
Molybdenum-93m	100	Silver-108m	1
Molybdenum-93	10	Silver-110m	10
Molybdenum-99	100	Silver-111	100
Molybdenum-101	1,000	Silver-112	100
Technetium-93m	1,000	Silver-115	1,000
Technetium-93	1,000	Cadmium-104	1,000
Technetium-94m	1,000	Cadmium-107	1,000
Technetium-94	1,000	Cadmium-109	1
Technetium-96m	1,000	Cadmium-113m	0.1
Technetium-96	100	Cadmium-113	100
Technetium-97m	100	Cadmium-115m	10
Technetium-97	1,000	Cadmium-115	100
Technetium-98	10	Cadmium-117m	1,000
Technetium-99m	1,000	Cadmium-117	1,000
Technetium-99	100	Indium-109	1,000
Technetium-101	1,000	Indium-110m(69.1m)	1,000
Technetium-104	1,000	Indium-110 (4.9h)	1,000
Ruthenium-94	1,000	Indium-111	100
Ruthenium-97	1,000	Indium-112	1,000
Ruthenium-103	100	Indium-113m	1,000
Ruthenium-105	1,000	Indium-114m	10
Ruthenium-106	1	Indium-115m	1,000
Rhodium-99m	1,000	Indium-115	100
Rhodium-99	100	Indium-116m	1,000
Rhodium-100	100	Indium-117m	1,000
Rhodium-101m	1,000	Indium-117	1,000
Rhodium-101	10	Indium-119m	1,000
Rhodium-102m	10	Tin-110	100
Rhodium-102	10	Tin-111	1,000
Rhodium-103m	1,000	Tin-113	100
Rhodium-105	100	Tin-117m	100
Rhodium-106m	1,000	Tin-119m	100
Rhodium-107	1,000	Tin-121m	100
Palladium-100	100	Tin-121	1,000

* To convert µCi to kBq, multiply the µCi value by 37.

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Tin-123m	1,000	Iodine-120m	1,000
Tin-123	10	Iodine-120	100
Tin-125	10	Iodine-121	1,000
Tin-126	10	Iodine-123	100
Tin-127	1,000	Iodine-124	10
Tin-128	1,000	Iodine-125	1
Antimony-115	1,000	Iodine-126	1
Antimony-116m	1,000	Iodine-128	1,000
Antimony-116	1,000	Iodine-129	1
Antimony-117	1,000	Iodine-130	10
Antimony-118m	1,000	Iodine-131	1
Antimony-119	1,000	Iodine-132m	100
Antimony-120 (16m)	1,000	Iodine-132	100
Antimony-120 (5.76d)	100	Iodine-133	10
Antimony-122	100	Iodine-134	1,000
Antimony-124m	1,000	Iodine-135	100
Antimony-124	10	Xenon-120	1,000
Antimony-125	100	Xenon-121	1,000
Antimony-126m	1,000	Xenon-122	1,000
Antimony-126	100	Xenon-123	1,000
Antimony-127	100	Xenon-125	1,000
Antimony-128 (10.4m)	1,000	Xenon-127	1,000
Antimony-128 (9.O1h)	100	Xenon-129m	1,000
Antimony-129	100	Xenon-131m	1,000
Antimony-130	1,000	Xenon-133m	1,000
Antimony-131	1,000	Xenon-133	1,000
Tellurium-116	1,000	Xenon-135m	1,000
Tellurium-121m	10	Xenon-135	1,000
Tellurium-121	100	Xenon-138	1,000
Tellurium-123m	10	Cesium-125	1,000
Tellurium-123	100	Cesium-127	1,000
Tellurium-125m	10	Cesium-129	1,000
Tellurium-127m	10	Cesium-130	1,000
Tellurium-127	1,000	Cesium-131	1,000
Tellurium-129m	10	Cesium-132	100
Tellurium-129	1,000	Cesium-134m	1,000
Tellurium-131m	10	Cesium-134	10
Tellurium-131	100	Cesium-135m	1,000
Tellurium-132	10	Cesium-135	100
Tellurium-133m	100	Cesium-136	10
Tellurium-133	1,000	Cesium-137	10
Tellurium-134	1,000	Cesium-138	1,000

* To convert µCi to kBq, multiply the µCi value by 37.

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Barium-126	1,000	Promethium-141	1,000
Barium-128	100	Promethium-143	100
Barium-131m	1,000	Promethium-144	10
Barium-131	100	Promethium-145	10
Barium-133m	100	Promethium-146	1
Barium-133	100	Promethium-147	10
Barium-135m	100	Promethium-148m	10
Barium-139	1,000	Promethium-148	10
Barium-140	100	Promethium-149	100
Barium-141	1,000	Promethium-150	1,000
Barium-142	1,000	Promethium-151	100
Lanthanum-131	1,000	Samarium-141m	1,000
Lanthanum-132	100	Samarium-141	1,000
Lanthanum-135	1,000	Samarium-142	1,000
Lanthanum-137	10	Samarium-145	100
Lanthanum-138	100	Samarium-146	1
Lanthanum-140	100	Samarium-147	100
Lanthanum-141	100	Samarium-151	10
Lanthanum-142	1,000	Samarium-153	100
Lanthanum-143	1,000	Samarium-155	1,000
Cerium-134	100	Samarium-156	1,000
Cerium-135	100	Europium-145	100
Cerium-137m	100	Europium-146	100
Cerium-137	1,000	Europium-147	100
Cerium-139	100	Europium-148	10
Cerium-141	100	Europium-149	100
Cerium-143	100	Europium-150 (12.62h)	100
Cerium-144	1	Europium-150 (34.2y)	1
Praseodymium-136	1,000	Europium-152m	100
Praseodymium-137	1,000	Europium-152	1
Praseodymium-138m	1,000	Europium-154	1
Praseodymium-139	1,000	Europium-155	10
Praseodymium-142m	1,000	Europium-156	100
Praseodymium-142	100	Europium-157	100
Praseodymium-143	100	Europium-158	1,000
Praseodymium-144	1,000	Gadolinium-145	1,000
Praseodymium-145	100	Gadolinium-146	10
Praseodymium-147	1,000	Gadolinium-147	100
Neodymium-136	1,000	Gadolinium-148	0.001
Neodymium-138	100	Gadolinium-149	100
Neodymium-139m	1,000	Gadolinium-151	10
Neodymium-139	1,000	Gadolinium-152	100
Neodymium-141	1,000	Gadolinium-153	10
Neodymium-147	100	Gadolinium-159	100
Neodymium-149	1,000		
Neodymium-151	1,000		

* To convert µCi to kBq, multiply the µCi value by 37.

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Terbium-147	1,000	Ytterbium-167	1,000
Terbium-149	100	Ytterbium-169	100
Terbium-150	1,000	Ytterbium-175	100
Terbium-151	100	Ytterbium-177	1,000
Terbium-153	1,000	Ytterbium-178	1,000
Terbium-154	100	Lutetium-169	100
Terbium-155	1,000	Lutetium-170	100
Terbium-156m (5.0h)	1,000	Lutetium-171	100
Terbium-156m (24.4h)	1,000	Lutetium-172	100
Terbium-156	100	Lutetium-173	10
Terbium-157	10	Lutetium-174m	10
Terbium-158	1	Lutetium-174	10
Terbium-160	10	Lutetium-176m	1,000
Terbium-161	100	Lutetium-176	100
Dysprosium-155	1,000	Lutetium-177m	10
Dysprosium-157	1,000	Lutetium-177	100
Dysprosium-159	100	Lutetium-178m	1,000
Dysprosium-165	1,000	Lutetium-178	1,000
Dysprosium-166	100	Lutetium-179	1,000
Holmium-155	1,000	Hafnium-170	100
Holmium-157	1,000	Hafnium-172	1
Holmium-159	1,000	Hafnium-173	1,000
Holmium-161	1,000	Hafnium-175	100
Holmium-162m	1,000	Hafnium-177m	1,000
Holmium-162	1,000	Hafnium-178m	0.1
Holmium-164m	1,000	Hafnium-179m	10
Holmium-164	1,000	Hafnium-180m	1,000
Holmium-166m	1	Hafnium-181	10
Holmium-166	100	Hafnium-182m	1,000
Holmium-167	1,000	Hafnium-182	0.1
Erbium-161	1,000	Hafnium-183	1,000
Erbium-165	1,000	Hafnium-184	100
Erbium-169	100	Tantalum-172	1,000
Erbium-171	100	Tantalum-173	1,000
Erbium-172	100	Tantalum-174	1,000
Thulium-162	1,000	Tantalum-175	1,000
Thulium-166	100	Tantalum-176	100
Thulium-167	100	Tantalum-177	1,000
Thulium-170	10	Tantalum-178	1,000
Thulium-171	10	Tantalum-179	100
Thulium-172	100	Tantalum-180m	1,000
Thulium-173	100	Tantalum-180	100
Thulium-175	1,000	Tantalum-182m	1,000
Ytterbium-162	1,000	Tantalum-182	10
Ytterbium-166	100	Tantalum-183	100
		Tantalum-184	100
		Tantalum-185	1,000

* To convert µCi to kBq, multiply the µCi value by 37.

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Tantalum-186	1,000	Iridium-195m	1,000
Tungsten-176	1,000	Iridium-195	1,000
Tungsten-177	1,000	Platinum-186	1,000
Tungsten-178	1,000	Platinum-188	100
Tungsten-179	1,000	Platinum-189	1,000
Tungsten-181	1,000	Platinum-191	100
Tungsten-185	100	Platinum-193m	100
Tungsten-187	100	Platinum-193	1,000
Tungsten-188	10	Platinum-195m	100
Rhenium-177	1,000	Platinum-197m	1,000
Rhenium-178	1,000	Platinum-197	100
Rhenium-181	1,000	Platinum-199	1,000
Rhenium-182 (12.7h)	1,000	Platinum-200	100
Rhenium-182 (64.Oh)	100	Gold-193	1,000
Rhenium-184m	10	Gold-194	100
Rhenium-184	100	Gold-195	10
Rhenium-186m	10	Gold-198m	100
Rhenium-186	100	Gold-198	100
Rhenium-187	1,000	Gold-199	100
Rhenium-188m	1,000	Gold-200m	100
Rhenium-188	100	Gold-200	1,000
Rhenium-189	100	Gold-201	1,000
Osmium-180	1,000	Mercury-193m	100
Osmium-181	1,000	Mercury-193	1,000
Osmium-182	100	Mercury-194	1
Osmium-185	100	Mercury-195m	100
Osmium-189m	1,000	Mercury-195	1,000
Osmium-191m	1,000	Mercury-197m	100
Osmium-191	100	Mercury-197	1,000
Osmium-193	100	Mercury-199m	1,000
Osmium-194	1	Mercury-203	100
Iridium-182	1,000	Thallium-194m	1,000
Iridium-184	1,000	Thallium-194	1,000
Iridium-185	1,000	Thallium-195	1,000
Iridium-186	100	Thallium-197	1,000
Iridium-187	1,000	Thallium-198m	1,000
Iridium-188	100	Thallium-198	1,000
Iridium-189	100	Thallium-199	1,000
Iridium-190m	1,000	Thallium-200	1,000
Iridium-190	100	Thallium-201	1,000
Iridium-192 (73.8d)	1	Thallium-202	100
Iridium-192m (1.4m)	10	Thallium-204	100
Iridium-194m	10	Lead-195m	1,000
Iridium-194	100	Lead-198	1,000

* To convert µCi to kBq, multiply the µCi value by 37.

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Lead-199	1,000	Thorium-226	10
Lead-200	100	Thorium-227	0.01
Lead-201	1,000	Thorium-228	0.001
Lead-202m	1,000	Thorium-229	0.001
Lead-202	10	Thorium-230	0.001
Lead-203	1,000	Thorium-231	100
Lead-205	100	Thorium-232	100
Lead-209	1,000	Thorium-234	10
Lead-210	0.01	Thorium-natural	100
Lead-211	100	Protactinium-227	10
Lead-212	1	Protactinium-228	1
Lead-214	100	Protactinium-230	0.1
Bismuth-200	1,000	Protactinium-231	0.001
Bismuth-201	1,000	Protactinium-232	1
Bismuth-202	1,000	Protactinium-233	100
Bismuth-203	100	Protactinium-234	100
Bismuth-205	100	Uranium-230	0.01
Bismuth-206	100	Uranium-231	100
Bismuth-207	10	Uranium-232	0.001
Bismuth-210m	0.1	Uranium-233	0.001
Bismuth-210	1	Uranium-234	0.001
Bismuth-212	10	Uranium-235	0.001
Bismuth-213	10	Uranium-236	0.001
Bismuth-214	100	Uranium-237	100
Polonium-203	1,000	Uranium-238	100
Polonium-205	1,000	Uranium-239	1,000
Polonium-207	1,000	Uranium-240	100
Polonium-210	0.1	Uranium-natural	100
Astatine-207	100	Neptunium-232	100
Astatine-211	10	Neptunium-233	1,000
Radon-220	1	Neptunium-234	100
Radon-222	1	Neptunium-235	100
Francium-222	100	Neptunium-236 (1.15E+5)	0.001
Francium-223	100	Neptunium-236 (22.5h)	1
Radium-223	0.1	Neptunium-237	0.001
Radium-224	0.1	Neptunium-238	10
Radium-225	0.1	Neptunium-239	100
Radium-226	0.1	Neptunium-240	1,000
Radium-227	1,000	Plutonium-234	10
Radium-228	0.1	Plutonium-235	1,000
Actinium-224	1	Plutonium-236	0.001
Actinium-225	0.01	Plutonium-237	100
Actinium-226	0.1		
Actinium-227	0.001		
Actinium-228	1		

* To convert µCi to kBq, multiply the µCi value by 37.

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Plutonium-238	0.001	Curium-247	0.001
Plutonium-239	0.001	Curium-248	0.001
Plutonium-240	0.001	Curium-249	1,000
Plutonium-241	0.01	Berkelium-245	100
Plutonium-242	0.001	Berkelium-246	100
Plutonium-243	1,000	Berkelium-247	0.001
Plutonium-244	0.001	Berkelium-249	0.1
Plutonium-245	100	Berkelium-250	10
Americium-237	1,000	Californium-244	100
Americium-238	100	Californium-246	1
Americium-239	1,000	Californium-248	0.01
Americium-240	100	Californium-249	0.001
Americium-241	0.001	Californium-250	0.001
Americium-242m	0.001	Californium-251	0.001
Americium-242	10	Californium-252	0.001
Americium-243	0.001	Californium-253	0.1
Americium-244m	100	Californium-254	0.001
Americium-244	10	Einsteinium-250	100
Americium-245	1,000	Einsteinium-251	100
Americium-246m	1,000	Einsteinium-253	0.1
Americium-246	1,000	Einsteinium-254m	1
Curium-238	100	Einsteinium-254	0.01
Curium-240	0.1	Fermium-252	1
Curium-241	1	Fermium-253	1
Curium-242	0.01	Fermium-254	10
Curium-243	0.001	Fermium-255	1
Curium-244	0.001	Fermium-257	0.01
Curium-245	0.001	Mendelevium-257	10
Curium-246	0.001	Mendelevium-258	0.01
Any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.001	Any radionuclide other than alpha-emitting radionuclides not listed above, or mixtures of beta emitters of unknown composition	0.01

* To convert µCi to kBq, multiply the µCi value by 37.

NOTE: For purposes of D.28.E, D.31.A, and D.51.A where there is involved a combination of radionuclides in known amounts, the limit for the combination shall be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" – that is, unity.

[1]The quantities listed above were derived by taking 1/10th of the most restrictive ALI listed in Table I, Columns 1 and 2, of Appendix B to Part D, rounding to the nearest factor of 10, and constraining the values listed between 37 Bq and 37 MBq (0.001 and 1,000 µCi). Values of 3.7 MBq (100 µCi) have been assigned for radionuclides having a radioactive half- life in excess of E+9 years, except rhenium, 37 MBq (1,000 µCi), to take into account their low specific activity.

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APPENDIX D

Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests

I. Manifest

A. A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a Manifest reflecting information requested on applicable Agency Forms (or other equivalent NRC, Licensing State or Agreement State approved forms) HHE-846 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and HHE-847 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable Agency Form HHE-848 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)). Agency Forms HHE-846 and HHE-846A must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, Agency Forms HHE-847, HHE-847A, HHE-848 and HHE-848A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by Agency to comply with the manifesting requirements of this part when they ship:

1. LLW for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;

2. LLW that is being returned to the licensee who is the "waste generator" or "generator," as defined in this part; or

3. Radioactively contaminated material to a "waste processor" that becomes the processor's "residual waste."

B. For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

C. Agency Forms HHE-846, HHE-846A, HHE-847, HHE-847A, HHE-848 and HHE-848A, and the accompanying instructions, in hard copy, may be obtained from the Maine Radiation Control Program, 11 State House Station, Augusta, Maine 04333-0011

D. This appendix includes information requirements of the Department of Transportation, as codified in 49 CFR part 172. Information on hazardous, medical, or other waste, required to meet Environmental Protection Agency regulations, as codified in 40 CFR parts 259, 261 or elsewhere, is not addressed in this section, and must be provided on the required EPA forms. However, the required EPA forms must accompany the Uniform Low-Level Radioactive Waste Manifest required by this appendix.

E. As used in this appendix, the following definitions apply:

1. **Agency Forms HHE-846, HHE-846A, HHE-847, HHE-847A, HHE-848 and HHE-848A** are official Agency Forms referenced in this appendix. Licensees need not use originals of these Agency Forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, Agency Forms HHE-847 (and HHE-847A) and Agency Forms HHE-848 (and HHE-848A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

2. **Chemical description** means a description of the principal chemical characteristics of a low-level radioactive waste.

3. **Computer-readable medium** means that the regulatory agency's computer can transfer the information from the medium into its memory.

4. **Consignee** means the designated receiver of the shipment of low-level radioactive waste.

5. **Decontamination facility** means a facility operating under a Commission or Agreement State license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this part, is not considered to be a consignee for LLW shipments.

6. **Disposal container** means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

7. **EPA identification number** means the number received by a transporter following application to the Administrator of EPA as required by 40 CFR part 263.

8. **Generator** means a licensee operating under a Commission or Agreement State license who:

   (a) is a waste generator as defined in this part, or

   (b) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

9. **High integrity container (HIC)** means a container commonly designed to meet the structural stability requirements of section V of this appendix, and to meet Department of Transportation requirements for a Type A package.

10. **Land disposal facility** means the land, buildings and structures, and equipment, which are intended to be used for the disposal of radioactive wastes. For purposes of this chapter, a "geologic repository" is not considered a "land disposal facility.

11. **Package** means the assembly of components necessary to ensure compliance with the packaging requirements of DOT regulations, together with its radioactive contents, as presented for transport.

12. **Physical description** means the items called for on Agency Form HHE-847 to describe a low-level radioactive waste.

13. **Residual waste** means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

14. **Shipper** means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

15. **Shipping paper** means Agency Form HHE-846 and, if required, Agency Form HHE-846A, which includes the information, required by DOT in 49 CFR part 172.

16. **Uniform Low-Level Radioactive Waste Manifest *or* uniform manifest** means the combination of Agency Forms HHE-846, HHE-847, and, if necessary, HHE-848, and their respective continuation sheets as needed, or equivalent.

17. **Waste collector** means an entity, operating under a Commission or Agreement State license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

18. **Waste description** means the physical, chemical and radiological description of a low-level radioactive waste as called for on Agency Form HHE-847.

19. **Waste generator** means an entity, operating under a Commission or Agreement State license, who

    (a) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and

    (b) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste."

20. **Waste processor** means an entity, operating under a Commission or Agreement State license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

21. **Waste type** means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

II. Information Requirements

A. General Information: The shipper of the radioactive waste, shall provide the following information on the uniform manifest:

1. The name, facility address, and telephone number of the licensee shipping the waste;

2. An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

3. The name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste.

B. Shipment Information: The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;

2. The total number of packages/disposal containers;

3. The total disposal volume and disposal weight in the shipment;

4. The total radionuclide activity in the shipment;

5. The activity of each of the radionuclides H-3, C-14, Tc-99, and I-129 contained in the shipment; and

6. The total masses of U-233, U-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

C. Disposal Container and Waste Information: The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

2. A physical description of the disposal container, including the manufacturer and model of any high integrity container;

3. The volume displaced by the disposal container;

4. The gross weight of the disposal container, including the waste;

5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

6. A physical and chemical description of the waste;

7. The total weight percentage of chelating agent for any waste containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

8. The approximate volume of waste within a container;

9. The absorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

10. The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container shall be reported;

11. The total radioactivity within each container; and

12. For wastes consigned to a disposal facility, the classification of the waste pursuant to section V of this appendix. Waste not meeting the structural stability requirements of section VI.B. of this appendix must be identified.

D. Uncontainerized Waste Information: The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;

2. A physical and chemical description of the waste;

3. The total weight percentage of chelating agent if the chelating agent exceeds 0.1% by weight, plus the identity of the principal chelating agent;

4. For waste consigned to a disposal facility, the classification of the waste pursuant to section V. of this appendix. Waste not meeting the structural stability requirements of section VI.B. of this appendix must be identified;

5. The identities and activities of individual radionuclides contained in the waste, the masses of U - 233, U - 235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

E. Multi-Generator Disposal Container Information: This section applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLW resulting from a processor's activities may be attributable to one or more "generators" (including "waste generators") as defined in this part). It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

1. For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

2. For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide the following:

(a) The volume of waste within the disposal container;

(b) A physical and chemical description of the waste, including the solidification agent, if any;

(c) The total weight percentage of chelating agents for any disposal container containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

(d) The absorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in section VI.B. of this appendix; and

(e) Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

III. Certification: An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation and the Agency. A collector in signing the certification is certifying that nothing has been done to the collected waste, which would invalidate the waste generator's certification.

IV. Control and Tracking:

A. Any licensee or registrant who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in paragraphs A.1 through 9 of this section. Any licensee or registrant who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of paragraphs A.4 through 9 of this appendix. A licensee shall:

1. Prepare all wastes so that the waste is classified according to section V. of this appendix and meets the waste characteristics requirements in section VI. of this appendix;

2. Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater then Class C waste, in accordance with section V. of this appendix;

3. Conduct a quality assurance program to assure compliance with sections V. and VI. of this appendix (the program must include management evaluation of audits);

4. Prepare the Agency Uniform Low-Level Radioactive Waste Manifest as required by this appendix;

5. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either

   (a) receipt of the manifest precedes the LLW shipment or

   (b) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (a) and (b) is also acceptable;

6. Include Agency Form HHE-846 (and Agency Form HHE-846A, if required) with the shipment regardless of the option chosen in paragraph A.5 of this section;

7. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of Agency Form HHE-846;

8. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by these regulations; and

9. For any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix.

B. Any waste collector licensee who handles only prepackaged waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of Agency Form HHE-846;

2. Prepare a new manifest to reflect consolidated shipments that meet the requirements of this appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

3. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either:

   (a) Receipt of the manifest precedes the LLW shipment or

   (b) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (a) and (b) is also acceptable;

4. Include Agency Form HHE-846 (and Agency Form HHE-846A, if required) with the shipment regardless of the option chosen in paragraph B.3 of this section;

5. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of Agency Form HHE-846;

6. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by these regulations;

7. For any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this section; and

8. Notify the shipper and the Agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

C. Any licensed waste processor who treats or repackages waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of Agency Form HHE-846;

2. Prepare a new manifest that meets the requirements of this appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in paragraph I.E. of this appendix;

3. Prepare all wastes so that the waste is classified according to section V. of this appendix and meets the waste characteristics requirements in section VI. of this appendix;

4. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with sections V. and VI. of this appendix;

5. Conduct a quality assurance program to assure compliance with sections V. and VI. of this appendix (the program shall include management evaluation of audits);

6. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either:

   (a) Receipt of the manifest precedes the LLW shipment or

   (b) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (a) and (b) is also acceptable;

7. Include Agency Forms HHE-846 (and Agency Forms HHE-846A, if required) with the shipment regardless of the option chosen in paragraph C.6 of this section;

8. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of Agency Forms HHE-846;

9. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by these regulations;

10. For any shipment or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this section; and

11. Notify the shipper and the Agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

D. The land disposal facility operator shall:

1. Acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of Agency Forms HHE-846 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the Uniform Low-Level Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

2. Maintain copies of all completed manifests and electronically store the information required by this Appendix until the Agency terminates the license; and

3. Notify the shipper and the Agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

E. Any shipment or part of a shipment for which acknowledgement is not received within the times set forth in this section must:

1. Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

2. Be traced and reported. The investigation shall include tracing the shipment and filing a report with the Agency. Each licensee who conducts a trace investigation shall file a written report with the Agency within 2 weeks of completion of the investigation.

V. Classification of Waste

A. Classification of waste for near surface disposal.

1. **Considerations:** Determination of the classification of radioactive waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

2. **Classes of waste.**

(a) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in VI.A. of this appendix. If Class A waste also meets the stability requirements set forth in VI.B. of this appendix, it is not necessary to segregate the waste for disposal.

(b) Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in section VI of this appendix.

(c) Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in section VI of this appendix.

(d) Waste that is not generally acceptable for near-surface disposal is waste for which form and disposal methods must be different, and in general more stringent, than those specified for Class C waste. In the absence of specific requirements in this part, such waste must be disposed of in a geologic repository as defined in 10 CFR part 60 unless proposals for disposal of such waste in a disposal site licensed pursuant to 10 CFR Part 61 are approved by the Nuclear Regulatory Commission.

3. **Classification determined by long-lived radionuclides.** If radioactive waste contains only radionuclides listed in Table 1, classification shall be determined as follows:

(a) If the concentration does not exceed 0.1 times the value in Table 1, the waste is Class A.

(b) If the concentration exceeds 0.1 times the value in Table 1 but does not exceed the value in Table 1, the waste is Class C.

(c) If the concentration exceeds the value in Table 1, the waste is not generally acceptable for near-surface disposal.

(d) For wastes containing mixtures of radionuclides listed in Table 1, the total concentration shall be determined by the sum of fractions.

Table 1	
Radionuclide	**Concentration curies per cubic meter**
C-14	8
C-14 in activated metal	80
Ni-59 in activated metal	220
Nb-94 in activated metal	0.2
Tc-99	3
I-129	0.08
Alpha emitting transuranic nuclides with half-life greater than 5 years	[1]100
Pu-241	[1]3,500
Cm-242	[1]20,000

[1]Units are nanocuries per gram.

4. **Classification determined by short-lived radionuclides.** If radioactive waste does not contain any of the radionuclides listed in Table 1, classification shall be determined based on the concentrations shown in Table 2. However, as specified in paragraph A.6. of this section, if radioactive waste does not contain any nuclides listed in either Table 1 or 2, it is Class A.

(a) If the concentration does not exceed the value in Column 1, the waste is Class A.

(b) If the concentration exceeds the value in Column 1, but does not exceed the value in Column 2, the waste is Class B.

(c) If the concentration exceeds the value in Column 2, but does not exceed the value in Column 3, the waste is Class C.

(d) If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.

(e) For wastes containing mixtures of the nuclides listed in Table 2, the total concentration shall be determined by the sum of fractions rule

Table 2			
Radionuclide	Concentration, curies per cubic meter		
	Col. 1	Col. 2	Col. 3
Total of all nuclides with less than 5 year half-life	700	([1])	([1])
H-3	40	([1])	([1])
Co-60	700	([1])	([1])
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137	1	44	4600

[1] There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other nuclides in Table 2 determine the waste to the Class C independent of these nuclides.

5. **Classification determined by both long- and short-lived radionuclides.** If radioactive waste contains a mixture of radionuclides, some of which are listed in Table 1, and some of which are listed in Table 2, classification shall be determined as follows:

   (a) If the concentration of a nuclide listed in Table 1 does not exceed 0.1 times the value listed in Table 1, the class shall be that determined by the concentration of nuclides listed in Table 2.

   (b) If the concentration of a nuclide listed in Table 1 exceeds 0.1 times the value listed in Table 1 but does not exceed the value in Table 1, the waste shall be Class C, provided the concentration of nuclides listed in Table 2 does not exceed the value shown in Column 3 of Table 2.

6. **Classification of wastes with radionuclides other than those listed in Tables 1 and 2.** If radioactive waste does not contain any nuclides listed in either Table 1 or 2, it is Class A.

7. **The sum of the fractions rule for mixtures of radionuclides.** For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each nuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 50 Ci/m^3. and Cs-137 in a concentration of 22 Ci/m^3. Since the concentrations both exceed the values in Column 1, Table 2, they must be compared to Column 2 values. For Sr-90 fraction 50/150=0.33; for Cs-137 fraction, 22/44=0.5; the sum of the fractions=0.83. Since the sum is less than 1.0, the waste is Class B.

8. **Determination of concentrations in wastes.** The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as nanocuries per gram.

VI. Waste characteristics.

A. The following requirements are minimum requirements for all classes of waste and are intended to facilitate handling at the disposal site and provide protection of health and safety of personnel at the disposal site.

1. Waste must not be packaged for disposal in cardboard or fiberboard boxes.

2. Liquid waste must be solidified or packaged in sufficient absorbent material to absorb twice the volume of the liquid.

3. Solid waste containing liquid shall contain as little free standing and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume.

4. Waste must not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

5. Waste must not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with paragraph A.7. of this section.

6. Waste must not be pyrophoric. Pyrophoric materials contained in waste shall be treated, prepared, and packaged to be nonflammable.

7. Waste in a gaseous form must be packaged at a pressure that does not exceed 1.5 atmospheres at 20°C. Total activity must not exceed 100 curies per container.

8. Waste containing hazardous, biological, pathogenic, or infectious material must be treated to reduce to the maximum extent practicable the potential hazard from the non-radiological materials.

B. The requirements in this section are intended to provide stability of the waste. Stability is intended to ensure that the waste does not structurally degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

1. Waste must have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

2. Notwithstanding the provisions in VI.A.2 and 3, liquid wastes, or wastes containing liquid, must be converted into a form that contains as little free standing and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.

3. Void spaces within the waste and between the waste and its package must be reduced to the extent practicable.

VII. Labeling. Each package of waste must be clearly labeled to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with section V of this appendix.

VIII. Maintenance of records, reports, and transfers.

A. Each licensee shall maintain any records and make any reports in connection with the licensed activities as may be required by the conditions of the license or by the rules, regulations, and orders of the Agency.

B. Records which are required by the regulations in this part or by license conditions must be maintained for a period specified by the appropriate regulations in this chapter or by license condition. If a retention period is not otherwise specified, these records must be maintained and transferred to the officials specified in paragraph E of this section as a condition of license termination unless the Agency otherwise authorizes their disposition.

C. Records which must be maintained pursuant to this part may be the original or a reproduced copy or a microform if this reproduced copy or microform is capable of producing copy that is clear and legible at the end of the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

D. If there is a conflict between the Agency's regulations in this part, license condition, or other written Agency approval or authorization pertaining to the retention period for the same type of record, the longest retention period specified takes precedence.

E. Notwithstanding paragraphs A through D of this section, the licensee shall record the location and the quantity of radioactive wastes contained in the disposal site and transfer these records upon license termination to the chief executive of the nearest municipality, the chief executive of the county in which the facility is located, the county zoning board or land development and planning agency, the State governor and other State, local, and Federal governmental agencies as designated by the Agency at the time of license termination.

F. Following receipt and acceptance of a shipment of radioactive waste, the licensee shall record the date of disposal of the waste, the location in the disposal site, the condition of the waste packages as received, any discrepancies between materials listed on the manifest and those received, and any evidence of leaking or damaged packages or radiation or contamination levels in excess of limits specified in Department of Transportation and Agency regulations. The licensee shall briefly describe any repackaging operations of any of the waste packages included in the shipment, plus any other information required by the Agency as a license condition. The licensee shall retain these records until the Agency transfers or terminates the license that authorizes the activities described in this section.

G. Each licensee shall comply with the safeguards reporting requirements of Part C of these regulations if the quantities or activities of materials received or transferred exceed the limits of these sections. Inventory reports required by these sections are not required for materials after disposal.

H. Each licensee authorized to dispose of radioactive waste received from other persons shall file a copy of its financial report or a certified financial statement annually with the Agency in order to update the information base for determining financial qualifications.

I. 1. Each licensee authorized to dispose of waste materials received from other persons, pursuant to this part, shall submit annual reports to the Agency. Reports must be submitted by the end of the first calendar quarter of each year for the preceding year.

2. The reports shall include:

   (a) specification of the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in airborne effluents during the preceding year,

   (b) the results of the environmental monitoring program,

   (c) a summary of licensee disposal unit survey and maintenance activities,

   (d) a summary, by waste class, of activities and quantities of radionuclides disposed of,

   (e) any instances in which observed site characteristics were significantly different from those described in the application for a license; and

   (f) any other information the Agency may require. If the quantities of radioactive materials released during the reporting period, monitoring results, or maintenance performed are significantly different from those expected in the materials previously reviewed as part of the licensing action, the report must cover this specifically.

J. Each licensee shall report in accordance with the requirements of Part C.

K. Any transfer of radioactive materials by the licensee is subject to the requirements in Part C.

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APPENDIX E

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Appendix F

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APPENDIX G

SPECIAL REQUIREMENTS INVOLVING LOW-LEVEL RADIOACTIVE WASTE

1. Definitions

A. As used in this Part D Appendix G, the following definitions apply:

(1) **Activity** as it applies to reporting the radioactivity of waste requiring disposal refers to the radioactivity of the waste at the time of disposal. If the state did not have access to a disposal facility for that year, the radioactivity of waste placed in storage for that year shall apply (this radioactivity may be calculated to December 31 of the appropriate calendar year).

(2) **Generators of low-level radioactive waste** or **generators** means any persons who produce or process waste, as defined in part A, whether or not that waste is shipped off site.

(3) **Minimization plan** means the plan required of each licensee who generates waste requiring disposal, which identifies actions to allow for "storage for decay" of short-lived radioisotopes and actions to achieve source and volume minimization.

(3) **Mixed waste** means waste that also contain a hazardous component, regulated under subtitle C of the Resource Conservation and Recovery Act (RCRA).

(4) **Source minimization** means minimizing the volume and curie content of waste prior to its generation by such methods as: (1) avoiding unnecessary contamination of items during the use of radioactive materials; (2) carefully segregating waste from non-radioactive trash; (3) substituting non-radioactive isotopes or radioisotopes with shorter half-lives where practicable.

(5) **Storage** means the holding of waste for treatment or disposal.

(6) **Storage for decay** means a procedure in which waste that is authorized by the United States Nuclear Regulatory Commission to be stored at the site of generation for decay and ultimate disposal without regard to radioactivity.

(7) **Volume** as it applies to reporting volumes of waste requiring disposal refers to the required space for ultimate disposal at a waste disposal facility. If the state did not have access to a disposal facility for that year, the volume of waste to be disposed of that was placed in storage for that year shall apply.

(8) **Volume minimization** means treatment of waste after its generation in order to minimize the physical dimensions of the waste and the space required for disposal.

2. Low-Level Radioactive Waste Fund

A. An annual service fee and a compact fee assessment shall be billed by the agency. These fees are pro-rated such that fifty percent of the fees is based on volume of waste generated and fifty percent is based on the activity of waste generated.

B. Exempted from the annual service fee of Part D. Appendix G.2.A. are the following:

(1) Waste that is authorized by the United States Nuclear Regulatory Commission for disposal without regard to radioactivity;

(2) Waste that is stored for decay;

(3) Radioactive waste or other material that is returned to vendor, including, but not limited to, sealed sources.

C. The annual service fee and compact fee assessment, as specified in Part D. Appendix G.2.A, are determined by data collected on the Low-Level Radioactive Waste surveys. These fees will be based on a pro-rata share of the previous years' waste generation.

D. Generators are subject to service fee assessments the year following a termination of their radioactive materials license.

3. Annual Surveys of the Low-Level Radioactive Waste Stream

A. Generators of low-level radioactive waste must annually file a Low-Level Radioactive Waste Survey with the agency.

B. The Low-Level Radioactive Waste survey will require information concerning the volume, activity, isotopic content, chemical form, physical state, packaging, storage for decay, and interim storage capacity of waste and mixed wastes.

C. Completed survey forms must be returned to the agency within sixty days of the postmarked date.

D. Generators shall maintain copies of their survey forms for the preceding three calendar years.

4. Advance Notification of Transportation of Low-Level Radioactive Waste

A. The following reporting requirements are made in addition to the requirements of Parts D.38 and L.19.

B. Three working days prior to the transport of waste outside the confines of the generators' facility or other place of use or storage, or three working days prior to the delivery of any waste to a carrier for transport, each generator shall provide advance notification of such transport to the agency.

C. Advance notification is required only for:

(1) Waste that is being shipped to a disposal facility.

D. The notification required by Part D Appendix G.4.C. shall contain the following information:

(1) The name, address, and telephone number of the shipper, carrier and receiver of the shipment;

(2) A description of the waste contained in the shipment as required by the regulations of the U. S. Department of Transportation, 49 CFR 172.202 and 172.203;

(3) The point of origin of the shipment;

(4) The destination of the shipment and the 7-day period during which arrival of the shipment is estimated to occur;

(5) A point of contact with a telephone number for current shipment information

E. The notification required by Part D Appendix G.4. shall be made in writing to the agency. A notification delivered by mail must be postmarked 7 days prior to the date that the shipment is scheduled to occur. A notification delivered by telephone facsimile or messenger, must be delivered to the agency at least three working days prior to the date that the shipment is scheduled to occur. A copy of the notification shall be retained by the licensee for 1 year.

5. Waste Minimization

A. Generators who generate waste requiring disposal at a rate in excess of 100 cubic feet per calendar year, must submit a waste minimization plan to the agency on a biennial basis. The plan must include:

(1) A description of the facility and the process or service that generates the waste.

(2) Identification and characterization of the waste streams that result from the process or service.

(3) Analysis of the technical characterization of the waste stream to determine the practicability of source minimization and volume minimization.

(4) Declaration of goals for waste minimization efforts and an analysis of the successfulness of the current waste minimization effort.

B. A detailed existing waste minimization plan may be submitted for agency approval to meet the requirements of Part D Appendix G.5.A.

6. Packaging and Waste Form

A. Packaging and waste form of waste for disposal will comply with the requirements of the licensed or registered receiving Radioactive Waste Site or Authority.

PART G

MEDICAL USE OF RADIOACTIVE MATERIAL

SUBPART A – GENERAL INFORMATION

1. **Purpose And Scope.** This part contains the requirements and provisions for the medical use of radioactive material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in these regulations. The requirements and provisions of these regulations apply to applicants and licensees subject to this part unless specifically exempted.

2. **Definitions.** As used in this part, the following definitions apply:

Address of Use means the building or buildings that are identified on the license and where radioactive material may be received, prepared, used, or stored.

Agreement State means any State with which the U.S. Nuclear Regulatory Commission (NRC) or the U.S. Atomic Energy Commission has entered into effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

Area of Use means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing radioactive material.

Authorized Medical Physicist means an individual who –

(1) Meets the requirements in G.19.A and G.22; or

(2) Is identified as an authorized medical physicist or teletherapy physicist on –

a. A specific medical use license issued by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State;

b. A medical use permit issued by a Nuclear Regulatory Commission master material licensee;

c. A permit issued by an Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State broad scope medical use licensee; or

d. A permit issued by a Nuclear Regulatory Commission master medical license broad scope medical use permittee.

Authorized Nuclear Pharmacist means a pharmacist who –

(1) Meets the requirements in G.20.A and G.22; or

(2) Is identified as an authorized nuclear pharmacist on –

a. A specific license issued by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State that authorizes medical use or the practice of nuclear pharmacy;

b. A permit issued by a Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

c. A permit issued by an Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

d. A permit issued by a Nuclear Regulatory Commission master medical license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

(3) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(4) Is designated as an authorized nuclear pharmacist in accordance with Part C.11.I(2)(d).

Authorized User means a physician, dentist, or podiatrist who --

(1) Meets the requirements in G.22 and G.190, G.290, G.390, G.392.A., G.394.A, G.490, G.590, G.690 or G.790; or

(2) Is identified as an authorized user on --

a. An Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State license that authorizes the medical use of radioactive material;

b. A permit issued by a Nuclear Regulatory Commission master material licensee that is authorized to permit the use of radioactive material;

c. A permit issued by an Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

d. A permit issued by a Nuclear Regulatory Commission master material licensee broad scope permittee that is authorized to permit the medical use of radioactive material.

Black Box means the radiopharmaceutical production purification system used in a Cyclotron / PET facility.

Brachytherapy means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

Brachytherapy Source means a radioactive source or a manufacturer-assembled source train or combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters .

Client's Address means the area of use or a temporary job site for the purpose of providing mobile nuclear medicine services in accordance with G.31.

Cyclotron means a type of particle accelerator that is used for the production of radioactive material.

Cyclotron / PET Facility means a facility comprised of a cyclotron and a nuclear pharmacy that specializes in the preparation of Positron Emission Tomography (PET) radiopharmaceuticals.

Dedicated Check Source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

Dentist means an individual duly registered and licensed to practice dentistry or dental surgery or any branch thereof under 32 MRSA §1082.

High Dose-Rate Remote Afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Low Dose-Rate Remote Afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

Management means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

Manual Brachytherapy as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

Medical Event means an event that meets the criteria in G.3001.

Medical Institution means an organization in which more than one medical discipline is practiced.

Medical Use means the intentional internal or external administration of radioactive material, or the radiation there from, to patients or human research subjects under the supervision of an authorized user.

Medium Dose-Rate Remote Afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Mobile Nuclear Medicine Service means the transportation of radioactive material to and its medical use at the client's address.

Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

Patient Intervention means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

Pharmacist means an individual licensed by this State to compound and dispense drugs, prescriptions, and poisons.

Physician means an individual duly registered and licensed to practice medicine or surgery or any branch thereof under 32 MRSA §3270.

Podiatrist means an individual duly registered and licensed to practice podiatry or any branch thereof under 32 MRSA §3552.

Preceptor means an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

Prescribed Dosage means the specified activity or range of activity of unsealed radioactive material as documented --

(1) In a written directive; or

(2) In accordance with the directions of the authorized user for procedures performed pursuant to G.100 and G.200.

Prescribed Dose means –

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(3) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

Pulsed Dose-Rate Remote Afterloader, as used in this part, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but –

(1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(2) Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer means an individual who –

(1) Meets the requirements in G.18.A and G.22; or

(2) Is identified as a Radiation Safety Officer on –

a. A specific medical use license issued by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

b. A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

Stereotactic Radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

Structured Educational Program means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

Teletherapy, as used in this part, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

Therapeutic Dosage means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Therapeutic Dose means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

Treatment Site means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Type of Use means use of radioactive material under G.100, G.200, G.300, G.400, G.500, G.600, G.700 or G.1000.

Unit Dosage means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

Written Directive means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in G.15.

3. **Maintenance of Records.** Each record required by this part must be legible throughout the specified retention period. The record may be the original, a reproduced copy, or a microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

4. **Provisions for the Protection of Human Research Subjects.**

   A. A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.

   B. If the research is conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research --

      (1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

      (2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

   C. If the research will not be conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy, the license shall, before conducting research, apply for and receive a specific amendment to its medical use license. The amendment request must include a written commitment that the licensee will, before conducting research --

      (1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

      (2) Obtain "informed consent", as defined and described in the Federal Policy, from the human research subject.

   D. Nothing in this section relieves licensees from complying with the other requirements in this part.

5. **License Required.**

   A. A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive material for medical use only in accordance with a specific license issued pursuant to these regulations.

   B. A specific license is not needed for an individual who --

      (1) Receives, possesses, uses, or transfer radioactive material in accordance with the regulations in this part under the supervision of an authorized user as provided in G.14, unless prohibited by license condition; or

      (2) Prepares unsealed radioactive material for medical use in accordance with these regulations under the supervision of an authorized nuclear pharmacist or authorized user as provided in G.14, unless prohibited by license condition.

6. Application for License, Amendment, or Renewal.

A. An application must be signed by the applicant's or licensee's management.

B. An application for a license for medical use of radioactive material as described in G.100, G.200, G.300, G.400, G.500, G.600, G.700 and G.1000 must be made by --

(1) Filing the appropriate HHE Form 850, "Application for Radioactive Material License" that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s); and

(2) Submitting procedures required by G.603, G.609, G.610 and G.611, as applicable.

C. A request for a license amendment must be made by --

(1) Submitting either the appropriate HHE Form 850, "Application for a Radioactive Material License" or a letter requesting the amendment; and

(2) Submitting procedures required by G.603, G.609, G.610, and G.611, as applicable.

D. A request for a license renewal must be made by --

(1) Submitting the appropriate HHE Form 850, "Application for a Radioactive Material License"; and

(2) Submitting procedures required by G.603, G.609, G.610 and G.611, as applicable.

E. In addition to the requirements in G.6.A, G.6.B and G.6.C, an application for a license or amendment for medical use of radioactive material as described in G.1000 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of Part G.

(1) The applicant shall also provide specific information on --

a. Radiation safety precautions and instructions;

b. Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

c. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(2) The applicant or licensee shall also provide any other information requested by the Agency in its review of the application.

F. An applicant that satisfies the requirements specified in Part C.10.B may apply for a Type A specific license of broad scope.

7. License Amendments. A licensee shall apply for and must receive a license amendment --

A. Before it receives, prepares, or uses radioactive material for a type of use that is permitted under this part, but is not authorized on the licensee's current license under this part;

B. Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except --

(1) For an authorized user, an individual who meets the requirements in G.190.A, G.290.A, G.390.A, G.392.A, G.394.A, G.490.A, G.590.A, G.690.A, and G.22;

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in G.20.A and G.22;

(3) For an authorized medical physicist, an individual who meets the requirements in G.19.A and G.22;

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist --

a. On an Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State license or other equivalent permit or license recognized by the Agency that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

b. On a permit issued by an Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State specific license of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

c. On a permit issued by a Nuclear Regulatory Commission master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

d. By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

C. Before it changes Radiation Safety Officers, except as provided in G.12.C;

D. Before it receives radioactive material in excess of the amount, or in a different form, or receives a different radionuclide than is authorized on the license;

E. Before it adds to or changes the areas of use identified in the application or on the license, except for areas of use where radioactive material is used only in accordance with either G.100 or G.200;

F. Before it changes the address(es) of use identified in the application or on the license; and

G. Before it revises procedures required by G.603, G.609, G.610, and G.611, as applicable, where such revision reduces radiation safety.

8. Notifications.

A. A licensee shall provide the Agency a copy of the board certification and the Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State license for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under G.7.B.(1) through G.7.B.(4).

B. A licensee shall notify the Agency by letter no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist, permanently discontinues performance of duties under the license or has a name change;

(2) The licensee's mailing address changes;

(3) The licensee's name changes, but the name change does not constitute a transfer of control of the license; or

(4) The licensee has added to or changed the areas of use as identified in the application or on the license.

C. The licensee shall mail the documents required in this section to: Radiation Control Program, Division of Health Engineering, 11 State House Station, Augusta, ME, 04333-0011.

9. **Exemptions Regarding Type A Specific Licenses of Broad Scope.** A licensee possessing a Type A specific license of broad scope for medical use is exempt from --

A. The provisions of G.6.C regarding the need to file an amendment to the license for medical use of radioactive material, as described in G.1000;

B. The provisions of G.7.B;

C. The provisions of G.7.E regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

D. The provisions of G.8.A;

E. The provisions of G.8.B.1 for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

F. The provisions of G.8.B.4 regarding additions to or changes in the areas of use identified in the application or on the license where radioactive material is used in accordance with G.100 or G.200; and

G. The provisions of G.17.A.

10. **License Issuance.**

A. The Agency shall issue a license for the medical use of radioactive material if --

(1) The applicant has filed HHE Form 850 "Application for a Radioactive Material License" in accordance with the instructions in G.6;

(2) The applicant has paid any applicable fee as provided in Part C;

(3) The Agency finds the applicant equipped and committed to observe the safety standards established by the Agency in these regulations for the protection of the public health and safety; and

(4) The applicant meets the requirements of Part C.

B. The Agency shall issue a license for mobile nuclear medicine service if the applicant:

(1) Meets the requirements in G.10.A; and

(2) Assures that individuals or human research subjects to whom unsealed radioactive material or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with G.30.

11. **Specific Exemptions.** The Agency may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

SUBPART B -- GENERAL ADMINISTRATIVE REQUIREMENTS

12. Authority and Responsibilities for the Radiation Protection Program

A. In addition to the radiation protection program requirements of Part D, a licensee's management shall approve in writing --

(1) Requests for a license application, renewal, or amendment before submittal to the Agency;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under G.13.

B. A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

C. For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer, under G.18 and G.22, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in G.12.G, if the licensee takes the actions required in G.12.B, G.12.E, G.12.G and G.12.H and notifies the Agency in accordance with G.18.B.

D. A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with G.12.C, if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of radioactive material permitted by the license.

E. A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

F. Licensees that are authorized for two or more different types of uses of radioactive material under Subparts E, F, and H of Part G, or two or more types of units under Subpart H of Part G, shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

G. A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to --

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

H. A licensee shall retain a record of actions taken under G.12.A, G.12.B, and G.12.E in accordance with G.2012.

13. Radiation Protection Program Changes.

A. A licensee may revise its radiation protection program without Agency approval if --

(1) The revision does not require a license amendment under G.7;

(2) The revision is in compliance with the regulations and the license;

(3) The revision has been reviewed and approved by the Radiation Safety Officer and licensee management; and

(4) The affected individuals are instructed on the revised program before the changes are implemented.

B. A licensee shall retain a record of each change in accordance with G.2013.

14. Supervision.

A. A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by G.5.B.(1) shall --

(1) In addition to the requirements in Part J, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of radioactive material.

B. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by G.5.B.(2), shall --

(1) In addition to the requirements in Part J, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, these regulations, and license conditions.

C. A licensee that permits supervised activities under G.14.A and G.14.B is responsible for the acts and omissions of the supervised individual.

15. Written Directives.

A. A written directive must be dated and signed by an authorized user before the administration of sodium iodide I-131 greater than 1.11 Megabequerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed radioactive material, or any therapeutic dose of radiation from radioactive material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

B. The written directive must contain the patient or human research subject's name and the following information –

(1) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

a. Before implantation: treatment site, the radionuclide, and dose; and

b. After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

C. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

1. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

D. The licensee shall retain a copy of the written directive in accordance with G.2015.

16. Procedures for Administrations Requiring a Written Directive.

A. For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(1) The patient's or human research subject's identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

B. At a minimum, the procedures required by G.16.A must address the following items that are applicable to the licensee's use of radioactive material –

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations; and

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by G.600.

C. A licensee shall retain a copy of the procedures required under G.16.A in accordance with G.2016.

17. Suppliers for Radioactive Material, Sealed Sources or Devices for Medical Use. For medical use, a licensee may only use --

A. Radioactive material, sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to these regulations or the equivalent regulations of the NRC, an Agreement State, or a Licensing State.

B. Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Department of Health and Human Services, Food and Drug Administration.

C. Sealed sources or devices noncommercially transferred from a Part G licensee; or

D. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to these regulations, or the equivalent regulations of the NRC, an Agreement State, or a Licensing State.

18. Training for Radiation Safety Officer. Except as provided in G.21, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in G.12 to be an individual who --

A. Is certified by a specialty board whose certification process includes all of the requirements in G.18.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. (1) Has completed a structured educational program consisting of both:

a. 200 hours of didactic training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiation biology; and

(v) Radiation dosimetry; and

b. One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on an Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State license that authorizes similar type(s) of use(s) of radioactive material involving the following --

(1) Shipping, receiving, and performing related radiation surveys;

(2) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(3) Securing and controlling radioactive material;

(4) Using administrative controls to avoid mistakes in the administration of radioactive material;

(5) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(6) Using emergency procedures to control radioactive material; and

(7) Disposing of radioactive material; and

2. Has obtained written certification, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in G.18.B and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; or

C. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities.

19. Training for an Authorized Medical Physicist. Except as provided in G.21, the licensee shall require the authorized medical physicist to be an individual who –

A Is certified by a specialty board whose certification process includes all of the training and experience requirements in G.19.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. (1) Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics and has completed 1 year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist at a medical institution that includes the tasks listed in G.27, G.406, G.606, G.607, G.608, G.609, G.610, G.611 and G.613, as applicable; and

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in G.19.B.(1) and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in G.19 or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

20. Training for an Authorized Nuclear Pharmacist. Except as provided in G.21, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who –

A. Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in G.20.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. (1) Has completed 700 hours in a structured educational program consisting of both:

a. Didactic training in the following areas –

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

b. Supervised practical experience in a nuclear pharmacy involving --

(i) Shipping, receiving, and performing related radiation surveys;

(ii) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(iii) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(iv) Using administrative controls to avoid medical events in the administration of radioactive material; and

(v) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in G.20.B.(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

21. Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and Nuclear Pharmacist.

A. An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on an Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State license or a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before December 1, 2003 need not comply with the training requirements of G.18, G.19, or G.20, respectively.

B. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee before December 1, 2003, who perform only those medical uses for which they were authorized on that date, need not comply with the training requirements of Subparts D through H of Part G.

22. Recentness of Training. The training and experience specified in Subparts B, D, E, F, G, H, I and J of Part G must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

SUBPART C -- GENERAL TECHNICAL REQUIREMENTS

23. Possession, Use, and Calibration of Instruments Used To Measure the Activity of Unsealed Radioactive Material.

A. For direct measurements performed in accordance with G.25, a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

B. A licensee shall calibrate the instrumentation required in G.23.A 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 G.2023.

24. Calibration of Survey Instruments.

A. A licensee shall calibrate the survey instruments used to show compliance with this part and Part D before first use, annually, and following a repair that affects the calibration. A licensee shall --

(1) Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;

(2) Calibrate two separated readings on each scale or decade that will be used to show compliance; and

(3) Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

B. A licensee may not use survey instruments if the difference between the indicated exposure rate and the calibrated exposure rater is more than 20 percent

C. The licensee shall retain a record of each survey instrument calibration in accordance with G.2024

25. Determination of Dosages of Unsealed Radioactive Material for Medical Use.

A. A licensee shall determine and record the activity of each dosage before medical use.

B. For a unit dosage, this determination must be made by --

(1) Direct measurement of radioactivity; or

(2) A decay correction, based on the activity or activity concentration determined by --

a. A manufacturer or preparer licensed under Part C or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements; or

b. An Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA.

C. For other than unit dosages, this determination must be made by --

(1) Direct measurement of radioactivity;

(2) Combination of measurement of radioactivity and mathematical calculations; or

(3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under Part C or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements.

D. Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

E. A licensee shall retain a record of the dosage determination required by this section in accordance with G.2025.

26. Authorization for Calibration, Transmission, and Reference Sources. Any person authorized by G.5 for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use:

A. Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by persons licensed pursuant to Part C of these regulations or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State regulations.

B. Sealed sources, not exceeding 1.11 GBq (30mCi) each, redistributed by a person licensed under Part C.11.K, provided the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

C. Any radioactive material with a half- life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).

D. Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 μCi) or 1000 times the quantities in Appendix C of Part D of these regulations.

E. Technetium-99m in amounts as needed.

27. Requirements for Possession of Sealed Sources and Brachytherapy Sources.

A. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

B. A licensee in possession of a sealed source shall --

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State in the Sealed Source and Device Registry.

C. To satisfy the leak test requirements of G.27.B. the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 μCi) of radioactive material in the sample.

D. A licensee shall retain leak test records in accordance with G.2027.A.

E. If the leak test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination, the licensee shall --

(1) Immediately withdraw the sealed source from use and store, dispose of, or cause it to be repaired in accordance with the requirements of these regulations; and

(2) File a report with the Agency within 5 days of the leak test in accordance with G.3003.

F. A licensee need not perform a leak test on the following sources:

(1) Sources containing only radioactive material with a half-life of less than 30 days;

(2) Sources containing only radioactive material as a gas;

(3) Sources containing 3.7 MBq (100 μCi) or less of beta or gamma-emitting material or 0.37 MBq (10 μCi) or less of alpha-emitting material;

(4) Seeds of iridium-192 encased in nylon ribbon; and

(5) Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.

G. A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with G.2027.B.

28. Labeling of Vials and Syringes. Each syringe and vial that contains unsealed radioactive material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

29. Surveys for Ambient Radiation Dose Rate.

A. In addition to the surveys required by Part D, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed radioactive material was prepared for use or administered.

B. A licensee does not need to perform the surveys required by G.29.A in an area(s) where patients or human research subjects are confined when they cannot be released under G. 30.

C. A licensee shall retain a record of each survey in accordance with G.2029.

30. Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material

A. A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).[D]

B. The licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem) . If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include --

(1) Guidance on the interruption or discontinuation of breast-feeding; and

[D] U.S. Nuclear Regulatory Commission Regulatory Guide NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

(2) Information on the potential consequences, if any, of failure to follow guidance.

C. The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with G.2030.A.

D. The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with G.2030.B.

31. Provision of Mobile Nuclear Medicine Service

A. A licensee providing mobile nuclear medicine service shal --

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(2) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check;

(3) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(4) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in Part D of these regulations.

B. A mobile nuclear medicine service shall have all radioactive material delivered directly from the manufacturer or the distributor to the mobile nuclear medicine facility. At no time may the client take receipt of any radioactive material intended for the mobile nuclear medicine service's use.

C. A licensee providing mobile medical services shall retain the letter required in G.31.A.(1) and the record of each survey required in G.31.A.(4) in accordance with G.2031.A and G.2031.B, respectively.

32. Decay-In-Storage.

A. A licensee may hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee --

(1) Monitors radioactive material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding; and

(2) Removes or obliterates all radiation labels except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

B. A licensee shall retain a record for each disposal permitted under G.32.A in accordance with G.2032.

SUBPART D – UNSEALED RADIOACTIVE MATERIAL WRITTEN DIRECTIVE NOT REQUIRED

100. Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive Is Not Required. Except for quantities that require a written directive under G.15. a licensee may use any unsealed radioactive material, prepared for medical use for uptake, dilution, or excretion studies that is --

A. Obtained from a manufacturer or preparer licensed pursuant to Part C or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements; or

B. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Part G, or an individual under the supervision of either as specified in Part G.14; or

C. Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration (FDA); or

D. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration (FDA).

190. Training for Uptake, Dilution, and Excretion Studies. Except as provided in G.21, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.100 to be a physician who --

A. Is certified by a medical specialty board whose certification process includes all of the requirements in G.190.C and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. Is an authorized user under G.290 or G.390 or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements; or

C. (1) Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include --

a. Classroom and laboratory training in the following areas --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

b. Work experience, under the supervision of an authorized user who meets the requirements in G.190, G.290, or G.390 or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements, involving --

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages of radioactive drugs to patients or human research subjects; and

2. Has obtained written certification, signed by a preceptor authorized user who meets the requirements in G.190, G.290, or G.390 or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements, that the individual has satisfactorily completed the requirements in G.190.C.(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G.100.

200. Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive Is Not Required. Except for quantities that require a written directive under G.15, a licensee may use for any unsealed radioactive material prepared for medical use for imaging and localization studies that is --

A. Obtained from a manufacturer or preparer licensed pursuant to Part C or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements; or

B. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in G.290 or G.390, or an individual under the supervision of either as specified in G.14;

C. Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration (FDA); or

D. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration (FDA).

201. Permissible Molybdenum-99 Concentration.

A. A licensee may not administer to humans a radiopharmaceutical containing more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m).

B. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with G.201.A.

C. If a licensee is required to measure the molybdenum-99 concentration, the licensee shall retain a record of each measurement in accordance with G.2201.

290. Training for imaging and localization studies. Except as provided in G.21, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.200 to be a physician who –

A. Is certified by a medical specialty board whose certification process includes all of the requirements in G.290.C and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. Is an authorized user under G.390 or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements; or

C. (1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

c. Classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use;

(v) Radiation biology; and

b. Work experience, under the supervision of an authorized user, who meets the requirements in G.290 or G.390 or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements, involving:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(v) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(vi) Administering dosages of radioactive drugs to patients or human research subjects; and

(vii) 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; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in G.290 or G.390 or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements, that the individual has satisfactorily completed the requirements in G.290.C.(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G.100 and G.200.

SUBPART E – UNSEALED RADIOACTIVE MATERIAL WRITTEN DIRECTIVE REQUIRED

300. Use of Unsealed Radioactive Material For Which A Written Directive Is Required.

A. A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is --

(1) Obtained from a manufacturer or preparer licensed pursuant to Part C or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements; or

(2) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in G.290 or G.390, or an individual under the supervision of either as specified in G.14; or

(3) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration (FDA); or

(4) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration (FDA).

301. Safety Instruction. In addition to the requirements of Part J.3.

A. A licensee shall provide radiation safety instruction initially and at least annually, to l personnel caring for patients or human research subjects who cannot be released under G.30. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include --

(1) Patient or human research subject control;

(2) Visitor control, including --

a. Routine visitation to hospitalized individuals in accordance with Part D.14.A.(1), and

d. Visitation authorized in accordance with Part D.14.C;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer or his or her designee, and the authorized user if the patient or human research subject has a medical emergency or dies.

B. A licensee shall retain a record of individuals receiving instruction in accordance with G.2301.

302. Safety Precautions.

A. For each patient or human research subject who cannot be released under G.30, a licensee shall --

(1) Quarter the patient or human research subject either in:

a. A private room with a private sanitary facility; or

b. A room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under G.30.

(2) Visibly post the patient's or human research subject's room with a " Radioactive Materials" sign.

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room; and

(4) Either monitor material and items removed from the patient's or human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste;

B. A licensee shall notify the Radiation Safety Officer or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

390. Training for use of Unsealed Radioactive Material for Which a Written Directive Is Required. Except as provided in G.21, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.300 to be a physician who --

A. Is certified by a medical specialty board whose certification process includes all of the requirements in G.390.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. (1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

a. Classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

b. Work experience under the supervision of an authorized user who meets the requirements in G.390.A, G.390.B or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements. A supervising authorized user who meets the requirements in G.390.B must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status. The work experience must involve --

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(vi) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(vii) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

(a) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

(b) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131[1];

(c) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or

(d) Parenteral administration of any other radionuclide; and

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in G.390.B.(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G.300. The written certification must be signed by a preceptor authorized user who meets the requirements in G.390.A, G.390.B, or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements. The preceptor authorized user, who meets the requirements in G.390B, must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

.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). Except as provided in G.21, the licensee shall require an authorized user 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), to be a physician who –

A. Is certified by a medical specialty board whose certification process includes all of the requirements in G.392.C and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. Is an authorized user under G.390.A and G.390.B, for uses listed in G.390.B.(1)b(vii)(a) or (b), G.394 or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements; or

C. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include –

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use; and

[1] Experience with at least 3 cases in Category (vii)(2) also satisfies the requirement in Category (G)(1).

e. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in G.390.A, G.390.B, G.392, G.394 or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements. A supervising authorized user who meets the requirements in G.390.B, must have experience in administering dosages as specified in G.390.B.(1)b(vii)(a) or (b). The work experience must involve --

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Calibrating 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;

d. Using administrative controls to prevent a medical event involving the use of radioactive material;

e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

f. Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in G.392.C.(1) and G.392.C.(2) and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under G.300. The written certification must be signed by a preceptor authorized user who meets the requirements in G.390.A, G.390.B, G.392, G.394, or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements. A preceptor authorized user who meets the requirement in G.390.B, must have experience in administering dosages as specified in G.390.B.(1)a.(vii)(a) or (b).

394. Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive In Quantities Greater Than 1.22 Gigabecquerels (33 Millicuries). Except as provided in G.21, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who:

A. Is certified by a medical specialty board whose certification process includes all of the requirements in G.394.C and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. Is an authorized user under G.390.A and G.390.B for uses listed in G.390 B.(1)b((vii)(b), or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements; or

C. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use; and

e. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in G.390.A, G.390.B, G.394, or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements. A supervising authorized user, who meets the requirements in G.390.B must have experience in administering dosages as specified in G.390 B.(1)b(vii)(b). The work experience must involve --

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

c. Calculating, measuring, and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent a medical event involving the use of radioactive material;

e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

f. Administering dosages to patients or human research subjects, including at least 3 cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in G.394.C.(1) and G.394.C.(2) and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under G.300. The written certification must be signed by a preceptor authorized user who meets the requirements in G.390.A, G.390.B, G.394, or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements. A preceptor authorized user who meets the requirements in G.390.B must have experience in administering dosages as specified in G.390.B.(1)b(vii)(b).

SUBPART F – MANUAL BRACHYTHERAPY

400. Use of Sources For Manual Brachytherapy. A licensee shall use only brachytherapy sources for therapeutic medical uses:

A. As approved in the Sealed Source and Device Registry; or

B. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA, provided the requirements of G.17 are met.

401. Surveys After Source Implant And Removal.

A. Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

B. Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

C. A licensee shall retain a record of the surveys required by G.401.A and G.401.B in accordance with G.2401.

402. Brachytherapy Sources Accountability.

A. A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

B. As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

C. A licensee shall maintain a record of the brachytherapy source accountability in accordance with G.2402.

403. Safety Instruction. In addition to the requirements of Part J.

A. The licensee shall provide radiation safety instruction initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under G.30. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include --

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Patient and human research subject control;

(4) Visitor control, including both:

a. Routine visitation of hospitalized individuals in accordance with Part D.14.A(1); and

b. Visitation authorized in accordance with Part D.14.C; and

(2) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or human research subject has a medical emergency or dies.

B. A licensee shall retain a record of individuals receiving instruction in accordance with G.2301.

404. Safety Precautions.

A. For each patient or human research subject who is receiving brachytherapy and cannot be release under G.30, a licensee shall --

(1) Not quarter the patient or human research subject in the same room as an individual who is not receiving brachytherapy;

(2) Visibly post the patient's or human research subject's room with a " Radioactive Materials" sign; and

(3) Note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

B. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source --

(1) Dislodged from the patient or human research subject; and

(2) Lodged within the patient or human research subject following removal of the source applicators.

C. A licensee shall notify the Radiation Safety Officer or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

405. Calibration Measurements Of Brachytherapy Sources.

A. Before the first medical use of a brachytherapy source on or after December 1, 2003, a licensee shall have --

(1) Determined the source output or activity using a dosimetry system that meets the requirements of G.605.A;

(2) Determined source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of G.405.A.(1) and G.405. A.(2).

B. A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with G.405.A.

C. A licensee shall mathematically correct the outputs or activities determined in G.405.A for physical decay at intervals consistent with 1 percent physical decay.

D. A licensee shall retain a record of each calibration in accordance with G.2405.

406. Decay Of Strontium-90 Sources For Ophthalmic Treatments.

A. Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under G.405.

B. A licensee shall retain a record of the activity of each strontium-90 source in accordance with G.2406.

407. Therapy-Related Computer Systems. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

A. The source-specific input parameters required by the dose calculation algorithm;

B. The accuracy of dose, dwell time, and treatment time calculations at representative points;

C. The accuracy of isodose plots and graphic displays; and

D. The accuracy of the software used to determine sealed source positions from radiographic images.

490. Training For Use Of Manual Brachytherapy Sources. Except as provided in G.21, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under G.400 to be a physician who --

A. Is certified by a medical specialty board whose certification process includes all of the requirements in G.490.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. (1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes --

a. 200 hours of classroom and laboratory training in the following areas --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

b. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.490 or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements at a medical institution, involving:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Checking survey meters for proper operation;

(iii) Preparing, implanting, and removing brachytherapy sources;

(iv) Maintaining running inventories of material on hand;

(v) Using administrative controls to prevent a medical event involving the use of radioactive material;

(vi) Using emergency procedures to control radioactive material; and

(2) Has obtained 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in G.490 or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by G.490.B.(1)b.; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in G.490 or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements, that the individual has satisfactorily completed the requirements in G.490.B.(1) and G.490.B.(2) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under G.400.

491. Training For Ophthalmic Use Of Strontium-90. Except as provided in G.21, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who –

A. Is an authorized user under G.490 or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements; or

B. (1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include –

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology; and

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve –

a. Examination of each individual to be treated;

b. Calculation of the dose to be administered;

c. Administration of the dose; and

d. Follow up and review of each individual's case history; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in G.490, G.491, or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements, that the individual has satisfactorily completed the requirements in G.491.A and G.491.B and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

SUBPART G - SEALED SOURCES FOR DIAGNOSIS

500. Use of Sealed Sources for Diagnosis. A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

590. Training for Use of Sealed Sources for Diagnosis. Except as provided in G.21, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under G.500 to be a physician, dentist, or podiatrist who --

A. Is certified by a specialty board whose certification process includes all of the requirements in G.590.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include --

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiation biology; and

(5) Training in the use of the device for the uses requested.

SUBPART H – PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

600. Use of a Sealed Source In a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit. A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

A. As approved in the Sealed Source and Device Registry; or

B. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the Food and Drug Administration (FDA), provided the requirements of G.17 are met.

601. Surveys of Patients and Human Research Subjects Treated With a Remote Afterloader Unit.

A. Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

B. A licensee shall retain a record of these surveys in accordance with G.2401.

602. Installation, Maintenance, Adjustment and Repair.

A. Only a person specifically licensed by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

B. Except for low dose-rate remote afterloader units, only a person specifically licensed by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

C. For a low dose-rate remote afterloader unit, only a person specifically licensed by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

D. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with G.2602.

603. Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

A. A licensee shall –

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include --

a. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

b. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

c. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

B. A copy of the procedures required by G.603.A.(4) must be physically located at the unit console.

C. A licensee shall post instructions at the unit console to inform the operator of --

(1) The location of the procedures required by G.603.A.(4); and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

D. A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

(1) The procedures identified in G.603.A.(4); and

(2) The operating procedures for the unit.

E. A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

F. A licensee shall retain a record of individuals receiving instruction required by G.603.D, in accordance with G.2301.

G. A licensee shall retain a copy of the procedures required by G.603.A.(4) and G.603.D.(2) in accordance with G.2603.

604. Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

A. A licensee shall control access to the treatment room by a door at each entrance.

B. A licensee shall equip each entrance to the treatment room with an electrical interlock system that will --

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the source(s) to be shielded when an entrance door is opened; and

(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

C. A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

D. Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

E. For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

F. In addition to the requirements specified in G.604.A through G.604.E, a licensee shall --

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require --

a. An authorized medical physicist and either an authorized user or a physician under the supervision of an authorized user who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

b. An authorized medical physicist and either an authorized user or an individual under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require --

a. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

b. An authorized medical physicist and either an authorized user or a physician under the supervision of an authorized user who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(4) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

G. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source --

(1) Remaining in the unshielded position;

(2) Lodged within the patient following completion of the treatment.

605. Dosimetry Equipment.

A. Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may I not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

B. The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with G.605.A.. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system shall be the same system used to meet the requirement in G.605.A

B. The licensee shall maintain a record of each calibration, intercomparison, and comparison in accordance with G.2605.

606. Full Calibration Measurements on Teletherapy Units.

A. A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit --

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

a. Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

b. Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

c. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 year.

B. To satisfy the requirement of G.606.A, full calibration measurements must include determination of --

(1) The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy and linearity over the range of use;

(5) "On-off" error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

C. A licensee shall use the dosimetry system described in G.605.A to measure the output for one set of exposure conditions. The remaining radiation measurements required in G.605.B.(1) may be made using a dosimetry system that indicates relative dose rates.

D. A licensee shall make full calibration measurements required by G.606.A . in accordance with published protocols accepted by nationally recognized bodies.

E. A licensee shall mathematically correct the outputs determined in G.606.B.(1) for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides..

F. Full calibration measurements required by G.606.A . and physical decay corrections required by G.606.E must be performed by a the authorized medical physicist.

G. A licensee shall retain a record of each calibration in accordance with G.2606.

607. Full Calibration Measurements on Remote Afterloader Units.

A. A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit --

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

a. Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

b. Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(4) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

B. To satisfy the requirement of G.607.A, full calibration measurements must include, as applicable, determination of:

(1) The output within +/- 5 percent;

(2) Source positioning accuracy to within +/- 1 millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of the applicators; and

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

C. A licensee shall use the dosimetry system described in G.605.A to measure the output.

D. A licensee shall make full calibration measurements required by G.607.A in accordance with published protocols accepted by nationally recognized bodies.

E. In addition to the requirements for full calibrations for low dose-rate remote afterloader units in G.607.B, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

F. For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with G.607.A through G.607.E.

G. A licensee shall mathematically correct the outputs determined in G.607.B.(1) for physical decay at intervals consistent with 1 percent physical decay.

H. Full calibration measurements required by G.607.A and physical decay corrections required by G.607.G must be performed by the authorized medical physicist.

I. A licensee shall retain a record of each calibration in accordance with G.2606.

608. Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.

A. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit --

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions --

a. Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

b. Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

c. Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(3) At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

B. To satisfy the requirement of G.608.A, full calibration measurements must include determination of --

(1) The output within +/-3 percent;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error;

(6) Trunnion centricity;

(7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(8) Helmet microswitches;

(9) Emergency timing circuits; and

(10) Stereotactic frames and localizing devices (trunnions).

C. A licensee shall use the dosimetry system described in G.605.A to measure the output for one set of exposure conditions. The remaining radiation measurements required in G.608.B.(1) may be made using a dosimetry system that indicates relative dose rates.

D. A licensee shall make full calibration measurements required by G.608.A in accordance with published protocols accepted by nationally recognized bodies.

E. A licensee shall mathematically correct the outputs determined in G.608.B.(1) at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

F. Full calibration measurements required by G.608.A and physical decay corrections required by G.608.E must be performed by the authorized medical physicist.

G. A licensee shall retain a record of each calibration in accordance with G.2606.

609. Periodic Spot Checks for Teletherapy Units.

A. A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit once in each calendar month that include determination of –

(1) Timer accuracy, and timer linearity over the range of use;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in G.605.A; and

(6) The difference between the measurement made in G.609.B.(5) and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

B. A licensee shall perform measurements required by G.609.A. in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

C. A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

D. A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of –

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing and intercom systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

E. If the results of the checks required in G.609.D indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

F. A licensee shall retain a record of each spot- check required by G.609.A . and G.609.D, and a copy of the procedures required by G.609.B, in accordance with G.2609.

610. Periodic Spot-Checks for Remote Afterloader Units.

A. A licensee authorized to use a remote afterloader unit for medical use shall perform spot- checks of each remote afterloader facility and on each unit --

(1) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(2) Before each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

B. A licensee shall perform the measurements required by G.610.A in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

C. A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

D. To satisfy the requirements of G.610.A, spot-checks must, at a minimum, assure proper operation of --

(1) Electrical interlocks at each remote afterloader unit room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(4) Emergency response equipment;

(5) Radiation monitors used to indicate the source position;

(6) Timer accuracy;

(7) Clock (date and time) in the unit's computer; and

(8) Decayed source(s) activity in the unit's computer.

E. If the results of the checks required in G.610.D indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

F. A licensee shall retain a record of each check required by G.610.D and a copy of the procedures required by G.610.B in accordance with G.2610.

611. Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

A. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit --

(1) Monthly;

(2) Before the first use of the unit on a given day; and

(3) After each source installation.

B. A licensee shall --

(1) Perform the measurements required by G.611.A in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(2) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

C. To satisfy the requirements G.611.A.(1), spot-checks must, at a minimum --

(1) Assure proper operation of --

a. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

b. Helmet microswitches;

c. Emergency timing circuits; and

d. Stereotactic frames and localizing devices (trunnions).

(2) Determine --

a. The output for one typical set of operating conditions measured with the dosimetry system described in G.605.A;

b. The difference between the measurement made in G.611.C.2.a and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

c. Source output against computer calculation;

d. Timer accuracy and linearity over the range of use;

e. On-off error; and

f. Trunnion centricity.

D. To satisfy the requirements of G.611.A.(2) and G.611.(3), spot-checks must assure proper operation of --

(1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Timer termination;

(5) Radiation monitors used to indicate room exposures; and

(6) Emergency off buttons.

E. A licensee shall arrange for the repair of any system identified in G.611.C that is not operating properly as soon as possible.

F. If the results of the checks required in G.611.D indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

G. A licensee shall retain a record of each check required by G.611.C and G.611.D and a copy of the procedures required by G.611.B in accordance with G.2611.

612. Additional Technical Requirements for Mobile Remote Afterloader Units.

A. A licensee providing mobile remote afterloader service shall --

(1) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(2) Account for all sources before departure from a client's address of use.

B. In addition to the periodic spot-checks required by G.610, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the proper operation of --

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and

(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

C. In addition to the requirements for checks in G.612.B, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

D. If the results of the checks required in G.612.B indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

E. A licensee shall retain a record of each check required by G.612.B in accordance with G.2612.

613. Radiation Surveys.

A. In addition to the survey requirement in Part D.17, a person licensed under Part G shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

B. The licensee shall make the survey required by G.613.A at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

C. A licensee shall retain a record of the radiation surveys required by G.613.A in accordance with G.2613.

614. Five Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

A. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

B. This inspection and servicing may only be performed by persons specifically licensed to do so by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

C. A licensee shall keep a record of the inspection and servicing in accordance with G.2614.

615. Therapy-Related Computer Systems. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

A. The source-specific input parameters required by the dose calculation algorithm;

B. The accuracy of dose, dwell time, and treatment time calculations at representative points;

C. The accuracy of isodose plots and graphic displays;

D. The accuracy of the software used to determine sealed source positions from radiographic images; and

E. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

690. Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. Except as provided in G.21, the licensee shall require an authorized user of a sealed source for a use authorized under G.600 to be a physician who –

A. Is certified by a medical specialty board whose certification process includes all of the requirements in G.690.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. (1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes –

a. 200 hours of classroom and laboratory training in the following areas –

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

b. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.690 or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements, at a medical institution, involving –

(i) Reviewing full calibration measurements and periodic spot-checks;

(ii) Preparing treatment plans and calculating treatment doses and times;

(iii) Using administrative controls to prevent a medical event involving the use of radioactive material;

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(v) Checking and using survey meters; and

(vi) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in G.690 or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required byG.690.B.(1)a; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in G.690.B.(1) and G.609.B.(2) and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in G.690 or equivalent Nuclear Regulatory Commission, Agreement State, or Licensing State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

SUBPART I – CYCLOTRON / PET FACILITIES

700. Licensing and Registration of Cyclotron / PET Facilities

A. The cyclotron / PET facility components shall be licensed pursuant to the following criteria:

(1) The accelerator shall be registered pursuant to Part I.

(2) The processing, manufacturing, and distribution of radioactive material shall be licensed pursuant to Part C.

(3) The nuclear pharmacy shall be licensed pursuant to Part C.

(4) The PET medical use shall be licensed pursuant to Part C, but may be approved under an existing specific license for radioactive material for human use (nuclear medicine) via the amendment process.

B. The licensee or registrant shall receive applicable agency authorization prior to the production of any accelerator-produced radioactive material or any change in accelerator configuration, shielding, location, room shielding or configuration, nuclide production method, ventilation systems, rabbit or other delivery systems, operating or emergency procedures, radiation safety personnel, authorized users or operators, or other applicable provisions authorized pursuant to these rules.

701. Supervision of Cyclotron / PET Facilities

A. Management shall ensure that there is a qualified Radiation Safety Officer (RSO) who shall oversee the radiation safety aspects of the cyclotron / PET facility and be responsible for radiation safety of the cyclotron accelerator and the nuclear pharmacy.

(1) In the case of a nuclear medicine service associated with the cyclotron / PET facility, there shall be a cooperative consortium of management and radiation safety personnel that acts as directors for the both the facility and the clinic;

(2) Management, whether singular or in consortium, shall write a statement of authority and responsibility for all staff handling or controlling the production and use of cyclotron produced radioactive material and PET isotopes.

B. The RSO shall be assisted by personnel specifically trained and designated for the area of concern, whether cyclotron accelerator operation or radiopharmaceutical production.

702. Other Applicable Requirements

A. The licensee shall ensure that any radiopharmaceutical for which an Investigational New Drug (IND) status does not exist, or which shall be used for research purposes in humans, is reviewed by an Institutional Review Board (IRB) or Human Subjects Review Board or Committee. The licensee shall establish procedures, reviews, quality assurance, and emergency procedures for all procedures reviewed by the IRB. The IRB, and the Radiation Safety Officer shall review and approve any and all PET procedures, unless otherwise authorized in a radioactive materials license pursuant to Part C.7.

B. Transfers of radioisotopes shall be in accordance with requirements in Part C.21.

C. Cyclotron / PET facility radiation protection programs, occupational dose limits, radiation dose limits for the public, surveys and monitoring, restricted area control, storage of radioactive materials, internal exposure control, precautionary procedures, waste disposal, records, and reports shall meet all applicable requirements of Part D.

703. Cyclotron / PET Facility Accelerator Requirements. Accelerators shall meet all requirements of Part I in shall also meet the following additional requirements:

A. Shielded-room accelerators shall be equipped with interlocks and personnel control; self-shielded accelerators shall be shielded such that personnel access is prevented during operation.

B. Target maintenance and repair, contamination control, and emergency actions shall be conducted pursuant to Part D.

C. There shall be an Understanding of Transfer (UOT) when isotopes are transferred from one licensee or entity to another for processing, specifying at what point control is transferred to personnel handling radiochemical production or nuclear pharmacy operation.

D. Radiation surveys shall be made prior to any accelerator operation or isotope production with a radiation survey instrument calibrated in accordance with requirements in G.23. Periodic surveys shall be done throughout times of operation to ensure that radiation levels meet all applicable requirements in Part D.

E. Ventilation controls shall be implemented to ensure compliance with all applicable local, state, and federal requirements. Controls shall include monitoring of stacks and computer modeling of air emissions to confirm compliance with standards.

F. Real-time (integrating) monitors shall be used to confirm requirements in Parts D.6., D.12., D.13,, and D.14.

G. Dosimetry must address both gamma and beta doses in all areas of the facility. Licensees and registrants must monitor extremities to ensure compliance with Part D.. Bioassays, as defined in Part A.2.(19), are not required, but there must be evaluation of internal exposures, pursuant to Part D.9., based on calculated releases and monitoring.

704. Safety Considerations for Cyclotron / PET Facilities

A. Area monitors must be visible and audible to accelerator operators. Monitors must be checked for proper operation daily.

B. Wasted targets shall be treated as radioactive waste and must be properly dismantled, shielded, stored, and disposed.

C. Accelerator shielding design and safety shall meet requirements of Part I.7.

D. Shielding around guide-bends, targets, hot-cells, purification manifolds, etc. shall ensure that limits in Parts D.14. and D.15. have been met in all areas of beam and nuclide production.

E. Security provisions for unauthorized access, janitorial services, maintenance, visitors, tours, and personnel-in-training shall conform to requirements in Parts D.14., D.25, and D.26.

705. Cyclotron / PET Facility Nuclear Pharmacy and Radiochemical Production

A. All preparations used in humans shall meet the State of Maine Board of Pharmacy standards, as well as applicable federal Food and Drug Administration (FDA) requirements.

(1) All research products to be used in humans shall be reviewed and approved by the licensee's or consortium Institutional Review Board (IRB) or Radioactive Drug Research Committee (RDRC).

(2) No research radiopharmaceutical shall be used in a human being until its pyrogenicity and purity have been shown to meet applicable standards.

B. Cyclotron facility staff shall work directly under the supervision of a cyclotron / PET Facility authorized user as per G.990.

C. There shall be no transfers between or among licensees unless there is a signed Memorandum or Understanding of Transfer. Such memorandum shall preclude any transfers from one licensee entity to another if there is incomplete information, purity questions, or non-approval from the IRB or RDRC.

D. There shall be a detailed description of the shielding and operation of the "black box" (hot cell).

E. There shall be operating and emergency, training, and survey procedures for ease of movement of the product within the pharmacy production area. Emergency procedures must address potential high dose rate emergencies such as stuck rabbit (transport container), pneumatic tube contamination, manifold leak or spill, hot cell emergency, or other incident.

F. Equipment and procedures shall include --

(1) Air processing system (e.g. hood with stack monitoring) with continuous effluent monitoring to assure compliance with air emission standards;

(2) Remote handling equipment for very high dose rates (all handling must be done remotely);

(3) Dose calibration, system validation, and calibration standards, for all individual doses;

(4) Ba-133 shall not be used as a calibration source;

(5) Dose calibrator linearity check using a positron emitter (beta shield must be evaluated to prevent interference with annihilation measurement);

(6) Product delivery system design, shielding, carrier, and emergency procedures;

(7) Leak tests (hermeticity) of delivery container;

(8) Labeling requirements, transportation manifests, and packaging for outside deliveries;

(9) Transportation requirements pursuant to Part L of these rules;

(10) Inventory control, "cradle to grave" tracking, and communication with PET clinic; and

(11) Waste disposal procedures.

706. Rubidium-82 Generator. Rubidium-82 generators require quality assurance procedures for equipment, patient injection, waiting area, imaging, and post-imaging care. There also must be a procedure for spills, and a handling procedure for liquid quality assurance sources for early model PET cameras. Dose calibration procedures are the same as in G. 705.F.

790. Training for Cyclotron / PET Facility Authorized Users The licensee shall require that the authorized user who will operate the cyclotron or process cyclotron products without direct supervision be an Authorized Nuclear Pharmacist as per G.20 or have equivalent professional training and experience as deemed appropriate by the Agency, as well as specific training and experience relevant to work in a cyclotron/PET facility. This should include --

A. Additional training in cyclotron physics and radiation safety, targetry, radiochemistry, use of automated and semi-automated chemical synthesis devices, quality control, airborne emissions verification and evaluation, and the regulatory standards and

B. Cyclotron manufacturer's training.

791. Training for Cyclotron / PET Facility Staff. The licensee shall require that staff who will participate in operation of the cyclotron or processing of cyclotron products under the supervision of authorized users have appropriate training and experience. This should include --

A. Certified in nuclear medicine technology by the State of Maine Radiologic Technology Board of Examiners, or

B. Certified in Pharmacy Technology by the State of Maine Board of Pharmacy, or

C. Have equivalent professional training and experience as deemed appropriate by the Agency, and

C. Additional instruction in radiation safety precautions and procedures, regulatory and license requirements, operating and emergency procedures, cyclotron operation, use of related equipment and of survey and monitoring equipment as appropriate to their assigned tasks.

SUBPART J - TRAINING AND EXPERIENCE REQUIREMENTS

(May be used in the lieu of training requirements listed in G.18, G.19, G.20, G.190, G.290, G.390, G.490, G.590, G.690 until June 1, 2005)

900. **Radiation Safety Officer.** Except as provided in G.21, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in G.12 to be an individual who --

A. Is certified by a specialty board whose certification process includes all of the requirements in G.900.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. Has had classroom and laboratory training and experience as follows --

(1) 200 hours of classroom and laboratory training that includes --

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Radiation biology; and

e. Radiopharmaceutical chemistry; and

(2) One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on an Agency, Agreement State, Licensing State, or Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or

C. Is an authorized user identified on the licensee's license.

910. **Training for Uptake, Dilution, or Excretion Studies.** Except as provided in G.970 and G.971, the licensee shall require the authorized user of a radiopharmaceutical listed in G.100 to be a physician who --

A. Is certified by a specialty board whose certification process includes all of the training and experience requirements in G.910.B. and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows --

(1) 40 hours of classroom and laboratory instruction that includes --

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Radiation biology; and

e. Radiopharmaceutical chemistry; and

(2) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes –

a. Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

b. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

c. Administering dosages to patients or human research subjects and using syringe radiation shields;

d. Collaborating with the authorized user in the interpretation of radioisotope test results; and

e. Patient or human research subject follow up; or

C. Has successfully completed a 6-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in G.910.B.

920. **Training for Imaging and Localization Studies.** Except as provided in G.970 or G.971, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in G.200 to be a physician who –

A. Is certified by a specialty board whose certification process includes all of the training and experience requirements in G.920.B. and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows –

(1) 200 hours of classroom and laboratory training that includes –

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Radiopharmaceutical chemistry; and

e. Radiation biology; and

(2) 500 hours of supervised work experience under the supervision of an authorized user that includes –

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

c. Calculating and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent the medical event of radioactive material;

e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

f. Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(3) 500 hours of supervised clinical experience shall be under the supervision of an authorized user that includes --

a. Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

b. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

c. Administering dosages to patients or human research subjects and using syringe radiation shields;

d. Collaborating with the authorized user in the interpretation of radioisotope test results; and

e. Patient or human research subject follow-up; or

C. Has successfully completed a 6-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in G.920.B.

930. **Training for Therapeutic Use of Unsealed Radioactive Material.** Except as provided in G.970, the licensee shall require the authorized user of a radiopharmaceuticals in G.300 to be a physician who --

A. Is certified by a specialty board whose certification process includes all of the training and experience requirements in G.930.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows --

(1) 80 hours of classroom and laboratory training that includes --

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user at a medical institution that includes --

a. Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and

b. Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals.

932. Training for Treatment of Hyperthyroidism. Except as provided in G.21, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows –

A. 80 hours of classroom and laboratory training that includes –

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

B. Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in 10 individuals

934. Training for Treatment of Thyroid Carcinoma. Except as provided in G.21, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma and supervised clinical experience as follows –

A. 80 hours of classroom and laboratory training that includes –

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

B. Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in 3 individuals

940. Training for Use of Brachytherapy Sources. Except as provided in G.970, the licensee shall require the authorized user using a brachytherapy source listed in G.400 for therapy to be a physician who –

A. Is certified by a specialty board whose certification process includes all of the training and experience requirements in G.940.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. Is in the active practice of therapeutic radiology, has had classroom and laboratory training radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows –

(1) 200 hours of classroom and laboratory training that include –

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology.

(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes --

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Checking survey meters for proper operation;

c. Preparing, implanting, and removing sealed sources;

d. Maintaining running inventories of material on hand;

e. Using administrative controls to prevent a medical event involving radioactive material; and

f. Using emergency procedures to control radioactive material; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes --

a. Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

b. Selecting the proper brachytherapy sources and dose and method of administration;

c. Calculating the dose; and

d. Post-administration follow-up and review of case histories in collaboration with the authorized user.

941. **Training for Ophthalmic Use of Strontium-90.** Except as provided in G.21, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows --

A. 24 hours of classroom and laboratory training that include's--

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology.

B. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution and that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes --

(1) Examination of each individual to be treated;

(2) Calculation of the dose to be administered;

(3) Administration of the dose; and

(4) Follow-up and review of each individual's case history.

950. Training for Use of Sealed Sources for Diagnosis. Except as provided in G.21, the licensee shall require the authorized user of a sealed source in a device listed in G.500 to be a physician, dentist, or podiatrist who –

A. Is certified by a specialty board whose certification process includes all of the training and experience requirements in G.950.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. Had 8 hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes –

(1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

(2) Radiation biology;

(3) Radiation protection; and

(4) Training in the use of the device for the uses requested.

960. Training for Use of Therapeutic Medical Devices. Except as provided in G.21, the licensee shall require the authorized user of a sealed source listed in G.600 to be a physician who –

A. Is certified by a specialty board whose certification process includes all of the training and experience requirements in G.960.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a therapeutic medical device, supervised work experience, and supervised clinical experience as follows –

(1) 200 hours of classroom and laboratory training that includes –

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology.

(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes –

a. Review of the full calibration measurements and periodic spot checks;

b. Preparing treatment plans and calculating treatment times;

c. Using administrative controls to prevent medical events;

d. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical device or console; and

e. Checking and using survey meters; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes --

a. Examining individuals and reviewing their case histories to determine their suitability for teletherapy, remote afterloader, or gamma stereotactic radiosurgery treatment, and any limitations or contraindications;

b. Selecting the proper dose and how it is to be administered;

c. Calculating the doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and

d. Post-administration follow-up and review of case histories.

961. Training for Authorized Medical Physicist. The licensee shall require the authorized medical physicist to be an individual who --

A. Is certified by a specialty board whose certification process includes all of the training and experience requirements in G.961.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed 1 year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in G.27, G.606, G.607, G.608, G.609, G.610, G.611 and G.613, as applicable.

980. Training for an Authorized Nuclear Pharmacist. The licensee shall require the authorized nuclear pharmacist to be a pharmacist who --

A. Is certified by a specialty board whose certification process includes all of the training and experience requirements in G.980.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

B. (1) Has completed 700 hours in a structured educational program consisting of both --

a. Didactic training in the following areas --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

b. Supervised experience in a nuclear pharmacy involving the following –

(i) Shipping, receiving, and performing related radiation surveys;

(ii) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(iii) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(iv) Using administrative controls to avoid mistakes in the administration of radioactive material;

(v) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

981. **Training for Experienced Nuclear Pharmacists.** A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in G.980.B.1 before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement (G.980.B.(2)) and recentness of training (G.22) to qualify as an authorized nuclear pharmacist.

SUBPART K--OTHER MEDICAL USES OF RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL

1000. Other Medical Uses of Radioactive Material or Radiation from Radioactive Material. A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of Part G if --

A. The applicant or licensee has submitted the information required by G.6.B through G.6.D; and

B. The applicant or licensee has received written approval from the Agency in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Agency considers necessary for the medical use of the material.

C. There are three modalities currently authorized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State:

(1) Yttrium 90 (Y-90) Microspheres. (e.g., MDS Nordion Y-90 TheraSphere®)

(2) Liquid Brachytherapy. (e.g., Proxima Therapeutics' GilaSite ® Radiation Therapy System)

(3) Intravascular Brachytherapy. (e.g., Cordis Checkmate™ System, Novoste Beta-Cath™ System, and Guidant Galileo™ Intravascular Radiotherapy System).

SUBPART L-- RECORDS

2012. Records of Authority and Responsibilities for Radiation Protection Programs.

A. A licensee shall retain a record of actions taken by the licensee's management in accordance with G.12.A for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

B. The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by G.12.E, and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by G.12.B, for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

2013. Records of Radiation Protection Program Changes. A licensee shall retain a record of each radiation protection program change made in accordance with G.13.A for 5 years. The record must include a copy of the old and new procedures, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

2015. Records of Written Directives. A licensee shall retain a copy of each written directive as required by G.15 for 3 years.

2016. Records for Procedures for Administrations Requiring a Written Directive. A licensee shall retain a copy of the procedures required by G.16.A for the duration of the license.

2023. Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material. A licensee shall maintain a record of instrument calibrations required by G.23 for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

2024. Records of Radiation Survey Instrument Calibrations. A licensee shall maintain a record of radiation survey instrument calibrations required by G.24 for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

2025. Records of Dosages of Unsealed Radioactive Material for Medical Use.

A. A licensee shall maintain a record of dosage determinations required by G.25 for 3 years.

B. The record must contain --

(1) The radiopharmaceutical;

(2) The patient's or human research subject's name, or identification number if one has been assigned;

(3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 µCi);

(4) The date and time of the dosage determination; and

(5) The name of the individual who determined the dosage.

2027. Records of Leaks Tests and Inventory of Sealed Sources and Brachytherapy Sources.

A. A licensee shall retain records of leak tests required by G.27.B for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested, the identity of each source by radionuclide and its estimated activity, the results of the test, the date of the test, and the name of the individual who performed the test.

B. A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by G.27.G for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

2029. Records of Surveys for Ambient Radiation Exposure Rate. A licensee shall retain a record of each survey required by G.29 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

2030. Records of the Release Of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material.

A. A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with G.30, if the total effective dose equivalent is calculated by --

(1) Using the retained activity rather than the activity administered;

(2) Using an occupancy factor less than 0.25 at 1 meter;

(3) Using the biological or effective half-life; or

(4) Considering the shielding by tissue.

B. A licensee shall retain a record that the instructions required by G.30.B were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

C. The records required by G.2030.A and G2030.B must be retained for 3 years after the date of release of the individual.

2031. Records of Mobile Nuclear Medicine Services.

A. A licensee shall retain a copy of each letter that permits the use of radioactive material at a client's address, as required by G.31.A.(1) Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for 3 years after the last provision of service.

B. A licensee shall retain the record of each survey required by G.31.A.4 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

2032. Records of Decay-In-Storage. A licensee shall maintain records of the disposal of licensed materials, as required by G.32, for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

2201. Records of Molybdenum-99 Concentrations. A licensee shall maintain a record of the molybdenum-99 concentration tests required by G.201.B for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement.

2301. Records of Safety Instruction. A licensee shall maintain a record of safety instructions required by G.301, G.403, and G.603 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

2401. Records of Surveys After Source Implant and Removal. A licensee shall maintain a record of the surveys required by G.401 and G.601 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

2402. Records of Brachytherapy Source Accountability.

A. A licensee shall maintain a record of brachytherapy source accountability required by G.402 for 3 years

B. For temporary implants, the record must include --

(1) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(2) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

C. For permanent implants, the record must include:

(1) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(2) The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

(3) The number and activity of sources permanently implanted in the patient or human research subject.

2405. Records of Calibration Measurements of Brachytherapy Sources.

A. A licensee shall maintain a record of the calibrations of brachytherapy sources required by G.405 for 3 years after the last use of the source.

B. The record must include --

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The signature of the authorized medical physicist.

2406. Records of Decay of Strontium-90 Sources for Ophthalmic Treatments.

A. A licensee shall maintain a record of the activity of a strontium-90 source required by G.406 for the life of the source.

B. The record must include --

(1) The date and initial activity of the source as determined under G.405; and

(2) For each decay calculation, the date and the source activity as determined under G.406.

2602. Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by G.602 for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

2603. Records of Safety Procedures. A licensee shall retain a copy of the procedures required by G.603.A.(4) and G.603.D.(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

2605. Records of Dosimetry Equipment Used With Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

A. A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with G.605 for the duration of the license.

B. For each calibration, intercomparison, or comparison, the record must include --

(1) The date;

(2) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by G.605.A and G.605.B;

(3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(4) The names of the individuals who performed the calibration, intercomparison, or comparison.

2606. Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations.

A. A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by G.606, G.607, and G.608 for 3 years.

B. The record must include --

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrate the unit(s);

(3) The results and an assessment of the full calibrations;

(4) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(5) The signature of the authorized medical physicist who performed the full calibration.

2609. Records of Periodic Spot-Checks for Teletherapy Units.

A. A licensee shall retain a record of each periodic spot-check for teletherapy units required by G.609 for 3 years.

B. The record must include --

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number of the teletherapy unit, source, and instrument used to measure the output of the teletherapy unit;

(3) An assessment of timer linearity and constancy;

(4) The calculated on-off error;

(5) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(6) The determined accuracy of each distance measuring and localization device;

(7) The difference between the anticipated output and the measured output;

(8) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

C. A licensee shall retain a copy of the procedures required by G.609.B until the licensee no longer possesses the teletherapy unit.

2610. Records of Periodic Spot-Checks for Remote Afterloader Units.

A. A licensee shall retain a record of each spot-check for remote afterloader units required by G.610 for 3 years.

B. The record must include, as applicable --

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(3) An assessment of timer accuracy;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

(5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

C. A licensee shall retain a copy of the procedures required by G.610.B until the licensee no longer possesses the remote afterloader unit.

2611. Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

A. A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by G.611 for 3 years.

B. The record must include –

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(3) An assessment of timer linearity and accuracy;

(4) The calculated on-off error;

(5) A determination of trunnion centricity;

(6) The difference between the anticipated output and the measured output;

(7) An assessment of source output against computer calculations;

(8) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

C. A licensee shall retain a copy of the procedures required by G.611.B until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

2612. Records of Additional Technical Requirements for Mobile Remote Afterloader Units.

A. A licensee shall retain a record of each check for mobile remote afterloader units required by G.612 for 3 years.

B. The record must include –

(1) The date of the check;

(2) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(3) Notations accounting for all sources before the licensee departs from a facility;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

(5) The signature of the individual who performed the check.

2613. Records of Surveys of Therapeutic Treatment Units.

A. A licensee shall maintain a record of radiation surveys of treatment units made in accordance with G.613 for the duration of use of the unit.

B. The record must include --

(1) The date of the measurements;

(2) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(4) The signature of the individual who performed the test.

2614. Records of 5-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

A. A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by G.614 for the duration of use of the unit.

B. The record must contain --

(1) The inspector's radioactive materials license number;

(2) The date of inspection;

(3) The manufacturer's name and model number and serial number of both the treatment unit and source;

(4) A list of components inspected and serviced, and the type of service; and

(5) The signature of the inspector.

SUBPART M--REPORTS

3001. Report and Notification of a Medical Event.

A. A licensee shall report any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in --

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

a. The total dose delivered differs from the prescribed dose by 20 percent or more;

b. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following --

a. An administration of a wrong radioactive drug containing radioactive material;

b. An administration of a radioactive drug containing radioactive material by the wrong route of administration;

c. An administration of a dose or dosage to the wrong individual or human research subject;

d. An administration of a dose or dosage delivered by the wrong mode of treatment; or

e. A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

B. A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

C. The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of the medical event.

D. The licensee shall submit a written report to the Agency within 15 days after discovery of the medical event.

(5) The written report must include --

a. The licensee's name;

b. The name of the prescribing physician;

c. A brief description of the event;

d. Why the event occurred;

e. The effect, if any, on the individual(s) who received the administration;

f. What actions, if any, have been taken or are planned to prevent recurrence; and

g. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

E. The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of G.3001.E, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

F. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

G. A licensee shall:

(1) Annotate a copy of the report provided to the Agency with the:

a. Name of the individual who is the subject of the event; and

b. Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

3002. Report and Notification of a Dose to An Embryo/Fetus or a Nursing Child.

A. A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

C. A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

(1) Is greater than 50 mSv (5 rem) total effective dose equivalent; or

(2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

C. The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in G.3002.A or G.3002.B.

D. The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in G.3002.A or G.3002.B.

(1) The written report must include --

a. The licensee's name;

b. The name of the prescribing physician;

c. A brief description of the event;

d. Why the event occurred;

e. The effect, if any, on the embryo/fetus or the nursing child;

f. What actions, if any, have been taken or are planned to prevent recurrence; and

g. Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(2) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

E. The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under G.3002.A or G.3002.B, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

F. A licensee shall:

(1) Annotate a copy of the report provided to the U.S. Nuclear Regulatory Commission with the:

a. Name of the pregnant individual or the nursing child who is the subject of the event; and

b. Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

3003. Report of a Leaking Source. A licensee shall file a report within 5 days if a leak test required by G.27 reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination. The report must be filed with the Agency. The written report must include the model number and serial number, if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.