

105 CMR 120.000: THE CONTROL OF RADIATION

Section

120.001: GENERAL PROVISIONS

- 120.002: Purpose and Scope
- 120.003: Regulatory Authority
- 120.004: Citation
- 120.005: Definitions
- 120.006: Exemptions
- 120.007: Prohibited Uses
- 120.008: Impounding
- 120.009: Records
- 120.010: Inspections
- 120.011: Tests
- 120.012: Additional Requirements
- 120.013: Communications
- 120.014: Units of Exposure and Dose
- 120.015: Units of Activity

ENFORCEMENT

- 120.016: Enforcement Policy and Procedures
- 120.017: Severability
- 120.018: Public Disclosure of Enforcement Actions
- 120.019: Appendix A -- Severity Categories

120.020: REGISTRATION OF RADIATION MACHINE FACILITIES AND SERVICES

- 120.021: Purpose and Scope
- 120.022: Definitions
- 120.023: Exemptions
- 120.024: Plan Review
- 120.025: Application for Registration
- 120.026: Application for Registration Services
- 120.027: Certificate of Registration
- 120.028: Expiration of Notice of Registration
- 120.029: Renewal of Notice of Registration
- 120.030: Report of Changes
- 120.031: Approval Not Implied
- 120.032: Assembler and/or Transfer Obligation
- 120.033: Out-of-state Radiation Machines
- 120.040: Notification to Fire Department

120.050: PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

- 120.051: Purpose
- 120.052: Scope
- 120.053: Definitions
- 120.054: Communications
- 120.055: Specific Exemptions
- 120.056: Personnel Access Authorization Requirements for Category 1 or Category 2 Quantities of Radioactive Materials
- 120.057: Access Authorization Program Requirements
- 120.058: Background Investigations
- 120.059: Requirements for Criminal History Records Checks of Individuals Granted Unescorted Access to Category 1 or Category 2 Quantities of Radioactive Material
- 120.060: Relief from Fingerprinting, Identification, and Criminal History Records Checks and Other Elements of Background Investigations for Designated Categories of Individuals Permitted Unescorted Access to Certain Radioactive Materials
- 120.061: Protection of Information
- 120.062: Access Authorization Program Review
- 120.063: Security Program
- 120.064: General Security Program Requirements

Section: continued

- 120.065: LLEA Coordination
- 120.066: Security Zones
- 120.067: Monitoring, Detection, and Assessment
- 120.068: Maintenance and Testing
- 120.069: Requirements for Mobile Devices
- 120.070: Security Program Review
- 120.071: Reporting of Events
- 120.072: Additional Requirements for Transfer of Category 1 and Category 2 Quantities of Radioactive Material
- 120.073: Applicability of Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Transit
- 120.074: Pre-planning and Coordination of Shipment of Category 1 or Category 2 Quantities of Radioactive Material
- 120.075: Advance Notification of Shipment of Category 1 Quantities of Radioactive Material
- 120.076: Requirements for Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Shipment
- 120.077: Reporting of Events
- 120.078: Form of Records
- 120.079: Record Retention
- 120.080: Appendix A - Category 1 and Category 2 Radioactive Materials
  
- 120.100: LICENSING OF RADIOACTIVE MATERIAL
- 120.101: Purpose and Scope
- 120.102: Definitions
- 120.103: Source Material
- 120.104: Radioactive Material Other than Source Material
- 120.120: Types of Licenses
- 120.121: General Licenses - Source Material
- 120.122: General Licenses - Radioactive Material Other Than Source Material
- 120.124: Filing Application for Specific Licenses
- 120.125: General Requirements for the Issuance of Specific Licenses
- 120.126: Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material
- 120.127: Special Requirements for Specific Licenses of Broad Scope
- 120.128: Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices which Contain Radioactive Material
- 120.130: Issuance of Specific Licenses
- 120.131: Specific Terms and Conditions of Licenses
- 120.132: Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas
- 120.133: Renewal of Licenses
- 120.134: Amendment of Licenses at Request of Licensee
- 120.135: Agency Action on Applications to Renew or Amend
- 120.136: Persons Possessing a License for Source, Byproduct, or Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass on March 21, 1997
- 120.137: Persons Possessing Naturally Occurring and Accelerator-produced Radioactive Material (NARM) on March 21, 1997
- 120.140: Transfer of Material
- 120.142: Reporting Requirements
- 120.146: Emergency Plan for Responding to a Release
- 120.150: Modification and Revocation of Licenses
- 120.190: Reciprocal Recognition of Licenses
- 120.195: Appendix A – Exempt Concentrations
- 120.196: Appendix B – Table 1 Exempt Quantities  
     Table II – Quantities for Use With 105 CMR 120.125(C)(1)  
     Table III – Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release
- 120.197: Appendix C – Limits for Broad Licenses
- 120.198: Appendix D – Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

Section: continued

- 120.198: Appendix E – Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning
- 120.198: Appendix F – Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have No Outstanding Rated Bonds
- 120.198: Appendix G – Criteria Relating to Use of Financial Tests and Self Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Nonprofit Colleges, Universities, and Hospitals

120.200: STANDARDS FOR PROTECTION AGAINST RADIATION

- 120.201: Purpose
- 120.202: Scope
- 120.203: Definitions
- 120.204: Implementation
- 120.210: Radiation Protection Programs
- 120.211: Occupational Dose Limits for Adults
- 120.212: Compliance with Requirements for Summation of External and Internal Doses
- 120.213: Determination of External Dose from Airborne Radioactive Material
- 120.214: Determination of Internal Exposure
- 120.216: Planned Special Exposures
- 120.217: Occupational Dose Limits for Minors
- 120.218: Dose Equivalent to an Embryo/Fetus

RADIATION DOSE LIMITS

- 120.221: Dose Limits for Individual Members of the Public
- 120.222: Compliance with Dose Limits for Individual Members of the Public
- 120.223: Testing for Leakage or Contamination of Sealed Sources

SURVEYS AND MONITORING

- 120.225: General
- 120.226: Conditions Requiring Individual Monitoring of External and Internal Occupational Dose
- 120.227: Control of Access to High Radiation Areas
- 120.228: Control of Access to Very High Radiation Areas
- 120.229: Control of Access to Very High Radiation Areas -- Irradiators
- 120.231: Use of Process or Other Engineering Controls
- 120.232: Use of Other Controls
- 120.233: Use of Individual Respiratory Protection Equipment
- 120.234: Further Restrictions on the Use of Respiratory Protection Equipment
- 120.235: Application for Use of Higher Assigned Protection Factors

NON-TEXT PAGE

Section: continued

- 120.236: Security and Control of Licensed or Registered Sources of Radiation
- 120.237: Caution Signs
- 120.238: Posting Requirements
- 120.239: Exceptions to Posting Requirements
- 120.240: Labeling Containers and Radiation Machines
- 120.241: Exemptions to Labeling Requirements
- 120.242: Procedures for Receiving and Opening Packages
- 120.243: Vacating Premises

#### RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

- 120.244: General Provisions and Scope
- 120.245: Radiological Criteria for Unrestricted Use
- 120.246: Criteria for License Termination Under Restricted Conditions
- 120.247: Alternate Criteria for License Termination
- 120.248: Public Notification and Public Participation
- 120.249: Minimization of Contamination
- 120.251: General Requirements
- 120.252: Method for Obtaining Approval of Proposed Disposal Procedures
- 120.253: Discharge by Release into Sanitary Sewerage
- 120.254: Treatment or Disposal by Incineration
- 120.255: Disposal of Specific Wastes
- 120.256: Transfer for Disposal and Manifests
- 120.257: Compliance with Environmental and Health Protection Regulations
- 120.258: Disposal of Certain Byproduct Material

#### RECORDS

- 120.261: General Provisions
- 120.262: Records of Radiation Protection Programs
- 120.263: Records of Surveys
- 120.264: Records of Tests for Leakage or Contamination of Sealed Sources
- 120.265: Determination and Records of Prior Occupational Dose
- 120.266: Records of Planned Special Exposures
- 120.267: Records of Individual Monitoring Results
- 120.268: Records of Dose to Individual Members of the Public
- 120.269: Records of Waste Transfers
- 120.270: Records of Testing Entry Control Devices for Very High Radiation Areas
- 120.271: Form of Records
- ~~120.273: Records of Tests for Leakage or Contamination of Sealed Sources~~

#### REPORTS

- 120.281: Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation
- 120.282: Notification of Incidents
- 120.283: Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or the Limits
- 120.284: Reports of Planned Special Exposures
- 120.285: Reports to Individuals of Exceeding Dose Limits
- 120.286: Reports of Individual Monitoring
- 120.287: Notifications and Reports to Individuals
- 120.288: Reports of Leaking or Contaminated Sealed Sources
- 120.290: Reports of Transactions Involving Nationally Tracked Sources
- 120.295: Appendix A – Assigned (APF) Protection Factors for Respirators<sup>a</sup>
- 120.296: 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
- 120.297: Appendix C -- Quantities<sup>1</sup> of Licensed Material Requiring Labeling
- 120.298: Appendix D – Nationally Tracked Source Thresholds
- 120.299: Appendix E -- Classification and Characteristics of Low-level Radioactive Waste

Section: continued

- 120.300: RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS
- 120.301: Purpose and Scope
- 120.302: Definitions
- 120.303: Exemptions
- 120.305: Licensing and Registration Requirements for Industrial Radiographic Operations
- 120.310: Records of Receipt, Transfer, and Disposal of Sources of Radiation
- 120.311: Limits on Levels of Radiation for Radiographic Exposure Devices, Source Changers, and Transport Containers
- 120.312: Locking of Sources of Radiation, Storage Containers and Source Changers
- 120.314: Radiation Survey Instruments
- 120.315: Performance Requirements for Industrial Radiography Equipment
- 120.316: Quarterly Inventory
- 120.317: Utilization Logs
- 120.318: Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments
- 120.319: Permanent Radiographic Installations

#### RADIATION SAFETY REQUIREMENTS

- 120.320: Training and Testing
- 120.321: Applications and Examinations
- 120.322: Revocation or Suspension of an I.D. Card
- 120.323: Personnel Monitoring
- 120.325: Operating and Emergency Procedures
- 120.326: Supervision of Radiographer Trainee
- 120.328: Conducting Industrial Radiographic Operations
- 120.331: Surveillance
- 120.332: Posting
- 120.333: Radiation Surveys and Survey Records
- 120.334: Records Required at Temporary Job Sites
- 120.337: Special Requirements and Exemptions for Enclosed Radiography
- 120.340: Underwater and Lay-barge Radiography
- 120.350: Prohibitions

#### RECORDKEEPING REQUIREMENTS

- 120.360: Records for Industrial Radiography
- 120.361: Records of Receipt, Transfer, and Disposal of Sources of Radiation
- 120.362: Records of Radiation Survey Instruments
- 120.363: Records of Leak Testing of Sealed Sources and Devices Containing DU
- 120.364: Records of Quarterly Inventory
- 120.365: Utilization Logs
- 120.366: Records of Inspections and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, associated Equipment, Source Changers, and Survey Instruments
- 120.367: Records of Alarm System and Entrance Control Tests at Permanent Radiographic Installations
- 120.368: Records of Training and Certification
- 120.369: Copies of Operating and Emergency Procedures
- 120.370: Records of Personnel Monitoring
- 120.371: Records of Radiation Surveys
- 120.372: Form of Records
- 120.373: Location of Documents and Records
- 120.380: Radiation Safety Officer
- 120.385: Notification of Incidents
- 120.390: Reciprocity

- 120.400: X-RAYS IN THE HEALING ARTS
- 120.401: Purpose and Scope
- 120.402: Definitions

## Section: continued

- 120.403: General Requirements
- 120.404: General Requirements for All Diagnostic X-ray Systems
- 120.405: Fluoroscopic X-ray Systems
- 120.406: Diagnostic X-ray Systems
- 120.407: Dental Radiographic Systems
- 120.408: Veterinary X-ray Systems
- 120.409: Computed Tomography (CT) X-ray Systems
- 120.410: Bone Densitometry
- 120.420: Appendix A -- Radiation Shielding and Safety Requirements
- 120.421: Appendix B -- Information to be Submitted by Persons Proposing to Conduct Healing Arts Screening
- 120.422: Appendix C -- Design Requirements for an Operator's Booth
- 120.423: Appendix D --Exemptions from Shielding for Certain Fluoroscopic Procedures
  
- 120.430: THERAPEUTIC RADIATION MACHINES IN THE HEALING ARTS
- 120.431: Purpose and Scope
- 120.432: Definitions
- 120.433: General Administrative Requirements for Facilities Using Therapeutic Radiation Machines
- 120.434: General Technical Requirements for Facilities Using Therapeutic Radiation Machines
- 120.435: Written Directives
- 120.436: Therapeutic Radiation Machines of Less than 500 kV
- 120.437: Therapeutic Radiation Machines - Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 keV and Above)
- 120.438: Calibration of Survey Instruments
- 120.439: Shielding and Safety Design Requirements
- 120.440: Appendix A: Information on Radiation Shielding Required for Plan Reviews
  
- 120.500: USE OF RADIONUCLIDES IN THE HEALING ARTS
- 120.501: Purpose and Scope
- 120.502: Definitions
- 120.503: Maintenance of Records
- 120.504: Provisions for Research Involving Human Subjects
- 120.505: Implementation
- 120.506: License Required
- 120.507: Application for License, Amendments, or Renewal
- 120.508: License Amendments
- 120.509: Notifications
- 120.510: Exemptions Regarding Type A Specific Licenses of Broad Scope
- 120.511: License Issuance
- 120.513: Specific Exemptions
- 120.515: Authority and Responsibilities for the Radiation Protection Program
- 120.517: Radiation Protection Program Changes
- 120.518: Duties of Authorized User and Authorized Medical Physicist
- 120.519: Supervision
- 120.520: Visiting Authorized User, Visiting Authorized Nuclear Pharmacist or Visiting Medical Physicist
- 120.521: Written Directives
- 120.522: Procedures for Administrations Requiring a Written Directive
- 120.523: Suppliers for Sealed Sources or Devices Containing Sealed Sources for Medical Use
- 120.524: Training for Radiation Safety Officer
- 120.525: Training for Authorized Medical Physicist
- 120.526: Training for an Authorized Nuclear Pharmacist
- 120.528: Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist
- 120.529: Recentness of Training
- 120.531: Quality Control of Diagnostic Equipment
- 120.532: Possession, Use, and Calibration of Instruments used to Measure the Activity of Unsealed Radioactive Material
- 120.533: Calibration of Survey Instruments
- 120.534: Determination of Dosages of Unsealed Radioactive Material for Medical Use
- 120.535: Authorization for Calibration, Transmission and Reference Sources
- 120.536: Requirements for Possession of Sealed Sources and Brachytherapy Sources

## Section: continued

- 120.537: Labeling of Vials and Syringes
- 120.539: Surveys for Ambient Radiation Dose Rate and Contamination
- 120.540: Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material
- 120.541: Provision of Mobile Medical Service
- 120.542: Storage of Volatiles and Gases
- 120.543: Decay-in-storage
- 120.544: Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for which a Written Directive is not Required
- 120.545: Possession of Survey Instrument
- 120.546: Training for Uptake, Dilution, and Excretion Studies
- 120.547: Use of Unsealed Byproduct Material for Imaging and Localization Studies for which a Written Directive is not Required
- 120.548: Radionuclide Contaminants
- 120.551: Training for Imaging and Localization Studies
- 120.552: Use of Unsealed Byproduct Material for which a Written Directive is Required
- 120.553: Safety Instruction
- 120.554: Safety Precautions
- 120.556: Training for Use of Unsealed Byproduct Material for which a Written directive is Required
- 120.557: Training for the Oral Administration of Sodium Iodide I-131 in Quantities Less than or Equal to 1.22 Gigabecquerels (33 millicurie) for which a Written Directive is Required
- 120.558: Training for the Oral Administration of Sodium Iodide I-131 in Quantities Greater than 1.22 Gigabecquerels (33 millicurie) for which a Written Directive is Required
- 120.558A: Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive
- 120.559: Use of Sealed Sources for Manual Brachytherapy
- 120.560: Surveys After Source Implant and Removal
- 120.561: Brachytherapy Sources Accountability
- 120.562: Safety Instruction
- 120.563: Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy
- 120.564: Calibration Measurement of Brachytherapy Sealed Sources
- 120.565: Therapy-related Computer Systems
- 120.566: Training for Use of Manual Brachytherapy Sources
- 120.567: Training for Ophthalmic Use of Strontium-90
- 120.568: Sealed Sources for Diagnosis
- 120.569: Training for Use of Sealed Sources for Diagnosis
- 120.570: Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit
- 120.571: Surveys of Patients and Human Research Subjects Treated with Remote Afterloader Unit
- 120.572: Installation, Maintenance, Adjustment, and Repair
- 120.573: Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
- 120.574: Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
- 120.575: Dosimetry Equipment
- 120.576: Full Calibration Measurements on Teletherapy Units
- 120.577: Full Calibration Measurements on Remote Afterloader Units
- 120.578: Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units
- 120.579: Periodic Spot-checks for Teletherapy Units
- 120.580: Periodic Spot-checks for Remote Afterloader Units
- 120.581: Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units
- 120.582: Additional Technical Requirements for Mobile Remote Afterloader Units
- 120.583: Radiation Surveys
- 120.584: Five Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units
- 120.585: Therapy-related Computer Systems
- 120.587: Training for Use of Remote Afterloader Units, Teletherapy units, and Gamma Stereotactic Radiosurgery Units
- 120.589: Other Medical Uses of Radioactive Material or Radiation from Radioactive Material
- 120.590: Requirements for Record Keeping
- 120.592: Requirements for Record Keeping Pertaining to the Use of Sealed Sources
- 120.594: Reports and Notifications



Section: continued

120.600: RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

- 120.601: Purpose and Scope
- 120.602: Definitions
- 120.603: Equipment Requirements
- 120.604: Area Requirements
- 120.605: Operating Requirements
- 120.606: Personnel Requirements

120.620: LICENSING AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

- 120.621: Purpose and Scope
- 120.622: Definitions
- 120.631: Application for a Specific License
- 120.633: Specific Licenses for Irradiators
- 120.635: Commencement of Construction
- 120.637: Applications for Exemptions
- 120.639: Request for Written Statements
- 120.641: Performance Criteria for Sealed Sources
- 120.643: Access Control
- 120.645: Shielding
- 120.647: Fire Protection
- 120.649: Radiation Monitors
- 120.651: Control of Source Movement
- 120.653: Irradiator Pools
- 120.655: Source Rack Protection
- 120.657: Power Failures
- 120.659: Design Requirements
- 120.661: Construction Monitoring and Acceptance Testing
- 120.671: Training
- 120.673: Operating, Safety, and Emergency Procedures
- 120.675: Personnel Monitoring
- 120.677: Radiation Surveys
- 120.679: Detection of Leaking Sources
- 120.681: Inspection and Maintenance
- 120.683: Pool Water Purity
- 120.685: Attendance During Operation
- 120.687: Entering and Leaving the Radiation Room
- 120.689: Irradiation of Explosive or Flammable Materials
- 120.691: Records and Retention Periods
- 120.693: Reports

120.700: RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

- 120.701: Purpose and Scope
- 120.702: Registration Requirements
- 120.703: General Requirements for the Issuance of a Registration for Particle Accelerators
- 120.704: Human Use of Particle Accelerators
- 120.705: Limitations
- 120.706: Shielding and Safety Design Requirements
- 120.707: Particle Accelerator Controls and Interlock Systems
- 120.708: Warning Devices
- 120.709: Operating Procedures
- 120.710: Radiation Monitoring Requirements
- 120.711: Ventilation Systems

120.750: NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

- 120.751: Purpose and Scope
- 120.752: Posting of Notices to Workers
- 120.753: Instructions to Workers
- 120.754: Notifications and Reports to Individuals
- 120.755: Presence of Representatives of Licensees or Registrants and Workers During Inspection

Section: continued

- 120.756: Consultation with Workers During Inspections
- 120.757: Requests by Workers for Inspections
- 120.758: Inspections not Warranted; Informal Review
- 120.760: Emergency Plans
  
- 120.770: TRANSPORTATION OF RADIOACTIVE MATERIAL
- 120.771: Purpose and Scope
- 120.772: Definitions
- 120.773: Requirement for License
- 120.774: Transportation of Licensed Material
- 120.775: Exemptions
- 120.776: General Licenses for Carriers
- 120.777: General License: Nuclear Regulatory Commission - Approved Packages
- 120.779: General License: U.S. Department of Transportation Specification Container
- 120.780: General License - Use of Foreign Approved Package
- 120.781: General License: Fissile Material, Limited Quantity per Package
- 120.782: General License: Plutonium Beryllium Special Form Material
- 120.783: External Radiation Standards for All Packages
- 120.784: Assumptions as to Unknown Properties of Fissile Material
- 120.785: Preliminary Determinations
- 120.786: Routine Determinations
- 120.787: Air Transport of Plutonium
- 120.788: Opening Instructions
- 120.789: Records**
- ~~120.789~~**90**: Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste
- ~~120.790~~**1**: Quality Assurance Requirements
- ~~120.791~~**2**: Quality Assurance Organization
- ~~120.792~~**3**: Quality Assurance Program
- 120.794: Changes to Quality Assurance Program**
- 120.795: Corrective Action**
- 120.796: Quality Assurance Records**
- 120.797: Audits**
- ~~120.798~~: Appendix A -- Determination of A<sub>1</sub> and A<sub>2</sub>
  
- 120.800: LICENSING AND OPERATIONAL REQUIREMENTS FOR LOW-LEVEL RADIOACTIVE WASTE FACILITIES
- 120.801: Purpose and Scope
- 120.802: Regulatory Authority
- 120.803: Definitions
- 120.810: General Requirements
- 120.811: Protection of the General Population from Releases of Radioactivity
- 120.812: Protection of Individuals from Inadvertent Intrusion
- 120.813: Protection of Individuals During Operations
- 120.814: Stability of the Facility After Closure
- 120.815: Facility Design
- 120.816: Facility Institutional Control
- 120.820: License Required
- 120.821: Licensing Process
- 120.822: Content of Application
- 120.823: General Information
- 120.824: Specific Technical Information
- 120.825: Technical Analyses
- 120.826: Institutional Information
- 120.827: Financial Information
- 120.828: Preoperational Environmental Monitoring
- 120.829: Standards for Issuance of a License
- 120.830: Conditions of Licenses
- 120.831: Environmental Monitoring
- 120.832: Facility Design
- 120.833: Facility Construction

105 CMR: DEPARTMENT OF PUBLIC HEALTH

- 120.834: Operating Budget Reimbursements
- 120.840: Facility Opening
- 120.841: Facility Operation
- 120.842: Receipt, Handling, and Inspection of Waste

Section: continued

- 120.843: Facility Boundaries and Markers
- 120.844: Contingency Plans for Facility Operations
- 120.845: Facility Maintenance
- 120.850: Funding for Facility Closure
- 120.851: Application for Renewal or Closure
- 120.852: Procedures for Review of Application for Facility Closure and Closure Plan
- 120.853: Facility Closure
- 120.860: Post-closure Observation and Maintenance
- 120.870: Transfer of License
- 120.871: Institutional Control
- 120.880: Maintenance of Records, Reports, and Transfers
- 120.881: Tests on Facilities
- 120.882: Department Inspection of Facilities
- 120.885: Waivers
  
- 120.890: LOW-LEVEL RADIOACTIVE WASTE MINIMIZATION REGULATIONS GENERAL PROVISIONS
- 120.891: Purpose and Scope
- 120.892: Regulatory Authority
- 120.893: Definitions
- 120.895: Objectives
- 120.896: Statement and Plan Requirements
- 120.897: Waste Minimization Plan Content
  
- 120.900: RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES
- 120.901: Purpose and Scope
- 120.902: Definitions
- 120.903: Licensing and Registration Requirements for Wireline Service Operations
- 120.904: Agreement with Well Owner or Operator
- 120.911: Labels, Security, and Transport Requirements
- 120.914: Radiation Survey Instruments
- 120.915: Leak Testing of Sealed Sources
- 120.916: Physical Inventory
- 120.917: Utilization Records
- 120.918: Design, Performance, and Certification Criteria for Sealed Sources Used in Downhole Operations
- 120.920: Inspection, Maintenance and Opening of a Source or Source Holder
- 120.922: Handling Tools
- 120.923: Subsurface Tracer Studies
- 120.924: Radioactive Markers
- 120.925: Uranium Sinker Bars
- 120.926: Use of a Sealed Source in a Well Without a Surface Casing
- 120.927: Energy Compensated Sources
- 120.928: Tritium Neutron Generator Target Source
- 120.929: Particle Accelerators
- 120.931: Training Requirements
- 120.932: Operating and Emergency Procedures
- 120.933: Personnel Monitoring
- 120.941: Radiation Surveys
- 120.951: Security
- 120.952: Documents and Records Required at Field Stations
- 120.953: Documents and Records Required at Temporary Jobsites
- 120.954: Notification of Incidents, Abandonment, and Lost Sources
- 120.960: Appendix A -- Subjects to be Included in Training Courses for Logging Supervisors
- 120.961: Appendix B -- Example of Plaque for Identifying Wells Containing Sealed Sources Containing Radioactive Material Abandoned Downhole

120.001: GENERAL PROVISIONS

120.002: Purpose and Scope

Except as otherwise specifically provided, 105 CMR 120.000 apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in 105 CMR 120.000 shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission (NRC). Regulation by the Commonwealth 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 NRC and to 10 CFR Part 150 of the NRC's regulations.

120.003: Regulatory Authority

The authority for the Department of Public Health to promulgate 105 CMR 120.000 is found in: M.G.L. c. 111, §§ 3, 5M, 5N, 5O, 5P.

120.004: Citation

105 CMR 120.000 shall be known and may be cited as the Massachusetts Regulations for the Control of Radiation (MRCR).

120.005: Definitions

As used in 105 CMR 120.000, these terms have the definitions set forth in 105 CMR 120.005. Additional definitions used only in a certain Section will be found in that Section.

105 CMR 120.000 means all Sections of the Massachusetts Regulations for the Control of Radiation.

~~A<sub>1</sub> means the maximum activity of special form radioactive material permitted in a Type A package. A<sub>2</sub> means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed in 120.795: *Table I*, or may be derived in accordance with the procedure prescribed in 120.795: *Appendix A*.~~

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. For purposes of this definition, "particle accelerator" is an equivalent term.

Accelerator-produced Material means any material made radioactive by a particle accelerator.

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 the Radiation Control Program of the Massachusetts Department of Public Health.

Agreement State means any State with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under § 274b of the Atomic Energy Act of 1954, as amended (St. 1973, c. 689).

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

120.005: continued

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

- (a) In excess of the derived air concentrations (DACs) specified in 105 CMR 120.200: *Appendix B*, Table I; or
- (b) 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% of the annual limit on intake (ALI) or 12 DAC- hours.

Airline Respirator (*see Supplied-air Respirator (SAR)*).

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.

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 105 CMR 120.000 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 ionizing radiation 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.

Background Radiation means radiation from cosmic sources; non-technologically enhanced naturally occurring radioactive material, 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 or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee or registrant. "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 one 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 105 CMR 120.000, Radiobioassay 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:

- (1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

120.005: continued

- (2) (a) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or
- (b) Any material that:
1. Has been made radioactive by use of a particle accelerator; and
  2. Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and
- (3) Any discrete source of naturally occurring radioactive material, other than source material, that:
- (a) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and
- (b) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

Calendar Quarter means not less than 12 consecutive weeks nor 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. The method observed by the licensee or registrant for determining calendar quarters shall only be changed at the beginning of a year.

Calibration means the determination of:

- (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or
- (2) 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.

CMR means Code of Massachusetts Regulations.

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.

Commissioner means the Commissioner, Massachusetts Department of Public Health.

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 ( $H_{E,50}$ ) means 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 ( $H_{E,50} = \sum w_T H_{T,50}$ ).

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

Consortium means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

120.005: continued

Constraint (Dose Constraint) means a value above which specified licensee actions are required.

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 activity. One curie (Ci) is that quantity of radioactive material which decays at the rate of  $3.7 \times 10^{10}$  disintegrations or transformations per second (dps or tps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) =  $1 \times 10^{-3}$  curie =  $3.7 \times 10^7$  tps. One microcurie ( $\mu$ Ci) =  $1 \times 10^{-6}$  curie =  $3.7 \times 10^4$  tps. One nanocurie (nCi) =  $1 \times 10^{-9}$  curie =  $3.7 \times 10^1$  tps. One picocurie (pCi) =  $1 \times 10^{-12}$  curie =  $10^{-2}$  tps.

Cyclotron means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of ten megaelectron volts and is commonly used for production of short half-life radionuclides for medical use. (See 105 CMR 120.005: Accelerator).

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

Deep Dose Equivalent ( $H_d$ ) means the dose equivalent at a tissue depth of one centimeter ( $1000 \text{ mg/cm}^2$ ) and applies to external whole body exposure.

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

Department means the Department of Public Health.

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.

Discrete Source means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, industrial, or research activities.

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 105 CMR 120.000, 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 rem.

Dose Limits means the permissible upper bounds of radiation doses established in accordance with 105 CMR 120.000. For purposes of 105 CMR 120.000, Limits is an equivalent term.



120.005: continued

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 ( $H_E = \sum w_T H_T$ ).

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

Entrance or Access Point means any location through which 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 SI unit of exposure is the coulomb per kilogram (C/kg). See 105 CMR 120.014: *Units of Exposure and Dose* for the special unit.

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, arm below the elbow, foot, knee, and leg below the knee.

Filtering Facepiece (Dust Mask) means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

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 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.

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

Half-value layer (HVL) means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent that the air kerma rate, exposure rate, or absorbed dose rate is reduced to  $\frac{1}{2}$  of the value measured without the material at the same point.

120.005: continued

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

Healing Arts means any discipline which involves the diagnosis or treatment of persons by a practitioner or animals by a veterinarian, and who is licensed for that purpose by the Commonwealth of Massachusetts, and which discipline includes the intentional exposure of persons and animals to sources of radiation for diagnosis or treatment.

Healing Arts Radiologic Screening means the completion of a procedure that irradiates an individual, with no symptoms or other potential indicators of disease, to ionizing radiation for the purpose of diagnosing the presence or absence of disease within the individual.

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 could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in one hour at 30 centimeters from any source of radiation or 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.
  - (a) by the use of individual monitoring devices; or
  - (b) by the use of survey data; or
- (2) Committed effective dose equivalent.
  - (a) by bioassay; or
  - (b) 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 105 CMR 120.200).

Individual Monitoring Devices means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of 105 CMR 120.000, Personnel Dosimeter and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, optically stimulated luminescence (OSL) dosimeters, and personal (lapel) air sampling 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.

Instrument Traceability means the ability to show that an instrument has been calibrated at specified time intervals using a national standard or a transfer standard. If a transfer standard is used, the calibration must be at laboratory accredited by a program which requires continuing participation in measurement quality assurance with the National Institute of Standards and Technology or other equivalent national or international program.

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.

120.005: continued

Ionizing Radiation (*See Radiation*).

Irradiation means the exposure of a living being or matter to ionizing radiation.

Kilovolt (kV) [Kilo Electron Volt (keV)] means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1,000 volts in a vacuum. [*Note: current convention is to use kV for photons and keV for electrons.*]

Lead Equivalent means the thickness of the material in question affording the same attenuation, under specified conditions, as lead.

Leakage Radiation means radiation emanating from the diagnostic or therapeutic source assembly except for:

- (1) The useful beam; and,
- (2) Radiation produced when the exposure switch or timer is not activated.

Lens Dose Equivalent (LDE) means the external exposure to the lens of the eye as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm<sup>2</sup>).

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 105 CMR 120.000 and M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P.

Licensing State means any State which has been finally designated as such by the Conference of Radiation Control Program Directors, Inc., which reviews state regulations to establish equivalency with the Suggested State Regulations and ascertains whether a State has an effective program for control of naturally occurring or accelerator produced radioactive material (NARM). The Conference will designate as Licensing States those states with regulations for control of radiation relating to, and an effective program for, the regulatory control of NARM.

Limits (*See Dose limits*).

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

Lost or Missing Source of Radiation means licensed (or registered) source of radiation whose location is unknown. This definition includes, but is not limited to, 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 four 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 105 CMR 120.772.

Manifest means a detailed record of the characteristics and quantities of packaged waste as presented for transportation, treatment, storage, or disposal which usually accompanies waste transfers for these purposes.

Member of the Public means an individual except when that individual is receiving an occupational dose.

Minor means an individual less than 18 years of age.

120.005: continued

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 105 CMR 120.000, 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.

Nationally Tracked Source means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in 105 CMR 120.298: *Appendix D*. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

Natural Radioactivity means radioactivity of naturally occurring nuclides.

Negative Pressure Respirator (Tight Fitting) means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Non-ionizing Radiation (*See* Radiation).

NORM means any naturally occurring radioactive material. It does not include accelerator produced, byproduct, source, or special nuclear material.

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 assigned duties for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received: from background radiation, or from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 105 CMR 120.527, or from voluntary participation in medical research program, or as a member of the public.

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

Particle Accelerator (*See* Accelerator).

Patient means an individual subjected to healing arts examination, diagnosis, or treatment

Person means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency of the commonwealth other than the Department, any political subdivision of the commonwealth, 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).

Phantom means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

120.005: continued

Pharmacist means an individual certified as such under M.G.L. c. 112, § 24 to compound and dispense drugs, prescriptions, and poisons.

Physician means an individual certified as a physician under M.G.L. c. 112, § 2 or corresponding citation of earlier laws.

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

Positron Emission Tomography (PET) radionuclide production facility means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

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 facepiece when the positive pressure is reduced inside the facepiece by inhalation.

Principal Activities 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.

Protective Apron means an apron made of radiation-attenuating materials used to reduce exposure to radiation.

Protective Barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

- (1) Primary protective barrier means the material, excluding filters, placed in the useful beam.
- (2) Secondary protective barrier means the material which attenuates stray radiation.

Public Dose means the dose received by a member of the public from exposure to sources of radiation released by the licensee or registrant, or to any other source of radiation under the control of the licensee or registrant. Public dose does not include occupational dose, or 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 105 CMR 120.540, or from voluntary participation in medical research programs.

Pyrophoric Material means any liquid that ignites spontaneously in dry or moist air at or below 130°F (54.4°C) or 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.

Qualified Expert means an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, for example, individuals certified in the appropriate field by the American Board of Radiology, or the American Board of Health Physics, or the American Board of Medical Physics, or those having equivalent qualifications. 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, for example, individuals certified in Therapeutic Radiological Physics or X-ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications.

120.005: continued

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 105 CMR 120.014: *Tables I and II*, 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 gray).

Radiation means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of 105 CMR 120.000, ionizing radiation is an equivalent term. Radiation, as used in 105 CMR 120.000, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

Radiation Area means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

Radiation Dose (*See Dose*).

Radiation Detector means a device which, in the presence of radiation, provides by either direct or indirect means a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation Machine means any device capable of producing radiation except, those devices with radioactive material as the only source of radiation.

Radiation Safety Officer means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and programs and has been assigned such responsibility by the licensee or registrant.

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

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

Radiobioassay (*See Bioassay*).

Registrant means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to 105 CMR 120.000 and M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P.

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

Regulations of the U.S. Department of Transportation (U.S. DOT) means the regulations in 49 CFR Parts 100 through 189.

Rem means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (one rem = 0.01 Sv).

Research and Development means:

- (1) theoretical analysis, exploration, or experimentation; or

120.005: continued

(2) 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 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 105 CMR 120.200.

Restricted Area means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

Roentgen means the special unit of exposure. One roentgen (R) equals  $2.58 \times 10^{-4}$  coulombs/kilogram of air (*see* Exposure).

Scattered Primary Radiation means that scattered radiation that has been deviated in direction only by materials irradiated by the useful beam.

Scattered Radiation means ionizing radiation emitted by the interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation.

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

Sealed Source and Device Registry ~~(SSD)~~ means the national registry that contains the registration certificates, ~~maintained~~ **generated** by **both** the Nuclear Regulatory Commission (NRC) **and the Agreement States**, that summarize the radiation safety information for sealed sources and devices, and describe the licensing and use conditions approved for the product.

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 or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter ( $7 \text{ mg/cm}^2$ ).

Shutter means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

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 is equal to the absorbed dose in gray multiplied by the quality factor (one 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

120.005: continued

- (2) ores which contain by weight 1/20 of **one percent (0.05%)** 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 105 CMR 120.005: Byproduct Material(2).

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

Source Traceability means the ability to show that a radioactive source has been calibrated either by the national standards laboratory of the National Institute of Standards and Technology (NIST), or by a laboratory which participates in a continuing measurement quality assurance program with NIST or other equivalent national or international program.

Special Form Radioactive Material 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 five millimeters (0.2 inch); and
- (3) It satisfies the test requirements ~~specified by the Nuclear Regulatory Commission of 10 CFR 71.75~~. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements of 10 CFR 71.4 in effect on June 30, 1983 (**see 10 CFR part 71, revised as of January 1, 1983**), and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements of 10 CFR 71.4 in effect on March 31, 1996 (**see 10 CFR part 71, revised as of January 1, 1996**), and constructed prior to April 1, 1998, may continue to be used. **Special form material that was successfully tested before September 10, 2015 in accordance with the Nuclear Regulatory Commission requirements of 10 CFR 71.75(d) in effect before September 10, 2015 may continue to be used. Any other special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of 105 CMR 120.005: Special Form Radioactive Material applicable at the time of its design or construction **the specifications of this definition.****

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 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.

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 one. For example, the following quantities in combination would not exceed the limitation and are within the formula:



NON-TEXT PAGE

120.005: continued

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

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 sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

Test means the process of verifying compliance with an applicable regulation.

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

Total Effective Dose Equivalent (TEDE) means the sum of the effective 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 105 CMR 120.267(A)(6).

Traceable to National Standard (*See Instrument Traceability or Source Traceability*)

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 U.S. 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, 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).

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.

Unrefined and Unprocessed Ore means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining. **Processing does not include sieving or encapsulating of ore or preparation of samples for laboratory analysis.**

Unrestricted Area (Uncontrolled Area) means area access to which is neither limited nor controlled by the licensee or registrant. For purposes of 105 CMR 120.000, Uncontrolled Area is an equivalent term.

Vendor means a supplier of products or services to be used by a licensee or registrant or a licensed or registered facility or activity.

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 rad) in one hour at one meter from a source of radiation or one meter from any surface that the radiation penetrates [*Note: At very high doses rates, units of adsorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem*].

120.005: continued

Waste means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in 105 CMR 120.005: Byproduct Material(2) and (3).

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 seven 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 one 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 one 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 105 CMR 120.000. 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.

#### 120.006: Exemptions

(A) General Provision. The Agency may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of 105 CMR 120.000 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 Commonwealth is exempt from 105 CMR 120.000 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 Government-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 U.S. Nuclear Regulatory Commission jointly determine:

120.006: continued

- (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 thereunder can be accomplished without undue risk to the public health and safety.

120.007: Prohibited Uses

(A) A hand-held fluoroscopic screen shall not be used with x-ray equipment unless it has been listed in the Registry of Sealed Source and Devices or accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health.

(B) A Shoe-fitting fluoroscopic device shall not be used.

120.008: Impounding

Sources of radiation shall be subject to impounding pursuant to M.G.L. c. 111, §§ 50 and 5P.

120.009: Records

(A) 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 105 CMR 120.000.

(B) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the Agency:

- (1) Records of disposal of licensed material made under 105 CMR 120.252 (including burials authorized before January 28, 1981), 105 CMR 120.253, 120.254, 120.255; and,
- (2) Records required by 105 CMR 120.263(B)(4).

(C) If licensed activities are transferred or assigned in accordance with 105 CMR 120.131(B), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

- (1) Records of disposal of licensed material made under 105 CMR 120.252 (including burials authorized before January 28, 1981), 105 CMR 120.253, 120.254, 120.255; and,
- (2) Records required by 105 CMR 120.263(B)(4).

(D) Prior to license termination, each licensee shall forward the records required by 105 CMR 120.125(C)(1)(g) to the Agency.

120.010: 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 105 CMR 120.000.

120.011: 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) Sources of radiation;

120.011: continued

- (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.

120.012: Additional Requirements

- (A) The Agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in 105 CMR 120.000 as it deems appropriate or necessary to minimize danger to public health and safety or property.
- (B) Any person who finds or detects any source of radiation that is not under the physical or administrative control of a licensee or registrant, and that is not excluded, exempted or otherwise authorized under the provisions of 105 CMR 120.000, shall immediately report such source to the Radiation Control Program.

120.013: Communications

All correspondence in compliance with 105 CMR 120.000 shall be sent to the Department of Public Health, Radiation Control Program, at the programs' s current mailing address, as stated in the website <http://mass.gov.dph/rcp>.

120.014: Units of Exposure and Dose

- (A) As used in 105 CMR 120.000, the unit of Exposure is the coulomb per kilogram (C/kg) of air. One roentgen is equal to  $2.58 \times 10^{-4}$  coulomb per kilogram of air.
- (B) As used in 105 CMR 120.000, the units of dose are:
  - Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram or 0.01 joule per kilogram (0.01 gray).
  - Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rads).
  - Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).
  - Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 sievert = 100 rems).

120.014: continued

(C) As used in 105 CMR 120.000, 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*
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

(D) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in 105 CMR 120.014(C), 0.01 Sv (1 rem) of neutron radiation of unknown energies may, for purposes of 105 CMR 120.000, be assumed to result from a total fluence 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.

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\*Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

120.014: continued

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

Neutron Energy (MeV)	Quality Factor* (Q)	Fluence per Unit Dose Equivalent** (neutrons cm <sup>-2</sup> rem <sup>-1</sup> )	Fluence per Unit Dose Equivalent** (neutrons cm <sup>-2</sup> Sv <sup>-1</sup> )
1.0 x 10 <sup>-7</sup>	2	980 x 10 <sup>6</sup>	980 x 10 <sup>8</sup>
1.0 x 10 <sup>-6</sup>	2	810 x 10 <sup>6</sup>	810 x 10 <sup>8</sup>
1.0 x 10 <sup>-5</sup>	2	810 x 10 <sup>6</sup>	810 x 10 <sup>8</sup>
1.0 x 10 <sup>-4</sup>	2	840 x 10 <sup>6</sup>	840 x 10 <sup>8</sup>
1.0 x 10 <sup>-3</sup>	2	980 x 10 <sup>6</sup>	980 x 10 <sup>8</sup>
1.0 x 10 <sup>-2</sup>	2.5	1010 x 10 <sup>6</sup>	1010 x 10 <sup>8</sup>
1.0 x 10 <sup>-1</sup>	7.5	170 x 10 <sup>6</sup>	170 x 10 <sup>8</sup>
5.0 x 10 <sup>-1</sup>	11	39 x 10 <sup>6</sup>	39 x 10 <sup>8</sup>
1	11	27 x 10 <sup>6</sup>	27 x 10 <sup>8</sup>
2.5	9	29 x 10 <sup>6</sup>	29 x 10 <sup>8</sup>
5	8	23 x 10 <sup>6</sup>	23 x 10 <sup>8</sup>
7	7	24 x 10 <sup>6</sup>	24 x 10 <sup>8</sup>
10	6.5	24 x 10 <sup>6</sup>	24 x 10 <sup>8</sup>
14	7.5	17 x 10 <sup>6</sup>	17 x 10 <sup>8</sup>
20	8	16 x 10 <sup>6</sup>	16 x 10 <sup>8</sup>
40	7	14 x 10 <sup>6</sup>	14 x 10 <sup>8</sup>
60	5.5	16 x 10 <sup>6</sup>	16 x 10 <sup>8</sup>
1.0 x 10 <sup>2</sup>	4	20 x 10 <sup>6</sup>	20 x 10 <sup>8</sup>
2.0 x 10 <sup>2</sup>	3.5	19 x 10 <sup>6</sup>	19 x 10 <sup>8</sup>
3.0 x 10 <sup>2</sup>	3.5	16 x 10 <sup>6</sup>	16 x 10 <sup>8</sup>
4.0 x 10 <sup>2</sup>	3.5	14 x 10 <sup>6</sup>	14 x 10 <sup>8</sup>

120.015: Units of Activity

For purposes of 105 CMR 120.000, 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.

(A) One becquerel (Bq) = 1 disintegration or transformation per second (dps or tps).

(B) One curie (Ci) = 3.7 x 10<sup>10</sup> disintegrations or transformations per second (dps or tps) = 3.7 x 10<sup>10</sup> becquerel (Bq) = 2.22 x 10<sup>12</sup> disintegrations or transformations per minute (dpm or tpm).

## ENFORCEMENT

120.016: Enforcement Policy and Procedures

(A) Purpose. The purpose of the enforcement program of the Agency is to promote and protect the radiological health and safety of the public, including employees' health and safety, and the environment by:

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\* Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

\*\* Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

120.016: continued

- (1) Ensuring compliance with regulations and conditions of license;
- (2) Obtaining prompt correction of violations that may affect safety;
- (3) Deterring future violations; and
- (4) Encouraging improvement of licensee, registrant and vendor performance, and by example, that of industry, including the prompt identification and reporting of potential safety problems.

Consistent with the purpose of this program, prompt and vigorous enforcement action will be taken when dealing with all persons who do not comply with regulations. In no case will licensees who do not achieve and maintain adequate levels of protection be permitted to conduct licensed activities.

(B) Grounds for Immediate Suspension of a License or Certificate of Registration or Issuance of an Order to Immediately Cease Activity. In accordance with M.G.L. c. 111, § 5O, the Commissioner may summarily suspend a license or certificate of registration or order immediate cessation of an activity, without a prior hearing, whenever the Department finds that public health, safety or the environment would be threatened by delay in issuance of an order. A facility or person may not operate during the period of a suspension of his/its license or certificate of registration and may not conduct a prohibited activity after notification of an order requiring the immediate cessation of an activity. However, upon request by the licensee or registrant, a hearing shall be provided promptly after the issuance of such suspension or order.

(C) Grounds for Denial, Modification, Limitation, Revocation or Refusal to Renew a License or Certificate of Registration.

(1) Specific Grounds. The Department may issue an order denying, revoking, modifying, limiting, or refusing to renew a license or certificate of registration sought or issued under 105 CMR 120.000, or issue an order to cease an activity, for any one of the following reasons:

- (a) The applicant, licensee or registrant has failed to submit the information required for licensure or registration under 105 CMR 120.000.
- (b) The applicant failed to meet the requirements for licensure or registration as specified in 105 CMR 120.000.
- (c) The applicant, licensee or registrant is not suitable and responsible to operate a facility as required or provide the service as licensed or registered.
- (d) The applicant, licensee or registrant has obtained or attempted to obtain or maintain a certificate of registration or license by fraud, misrepresentation, or by the submission of incorrect, false or misleading information.
- (e) The applicant, licensee or registrant has failed to pay licensure and/or registration fees.
- (f) The applicant, licensee or registrant has failed to pay civil penalties or criminal fines levied in accordance with of M.G.L. c. 111, § 5O or 5P and/or 105 CMR 120.000.
- (g) The applicant, licensee or registrant has:
  1. failed to allow duly authorized agents of the Agency to conduct inspections; or
  2. attempted to impede the work of duly authorized representatives of the Agency or the enforcement of any provisions of M.G.L. c. 111 §§ 5N through 5P or 105 CMR 120.000.
- (h) The applicant, licensee or registrant has been convicted of, pleaded guilty to, or has, in a judicial proceeding, admitted facts sufficient for a finding that he/she is guilty of, any criminal violation relating directly or indirectly to his/her fitness to be licensed or registered under 105 CMR 120.000.
- (i) The applicant, licensee or registrant has been the subject of proceedings which resulted in the suspension, denial, modification, limitation, or revocation of a similar license or certificate of registration or refusal of renewal of a similar license.
- (j) The applicant, licensee or registrant has violated 105 CMR 120.000 or a license condition and has a history of non-compliance with the same or similar violation or has received a warning letter from the Department within the last five years for the same or similar violation.
- (k) The applicant, licensee or registrant has been disciplined in another jurisdiction in any way by a licensing authority for reasons substantially the same as those set forth in 105 CMR 120.016(C).



120.016: continued

- (l) The applicant or licensee operated a facility after the expiration of the license.
  - (m) The applicant, licensee or registrant has failed to remedy or correct a cited violation by the date specified in the written notice from the Department under M.G.L. c. 111, § 50 or by the date specified in the plan of correction accepted or modified by the Department, unless the applicant, licensee or registrant demonstrates to the satisfaction of the Department that such failure was not due to neglect of duty and occurred despite his/her good faith attempt to make corrections by the specified time.
  - (n) The applicant or licensee has engaged in or aided in the falsification of test results or any other records required to be maintained in accordance with 105 CMR 120.000.
  - (o) The applicant, licensee or registrant receives, possesses, uses, transfers, owns or operates or uses radioactive materials or machines which emit ionizing radiation in a manner which endangers public health, safety, or the environment.
- (2) Other Grounds. The Department reserves the right to deny, modify, limit revoke or refuse to renew a license or certificate of registration for any other sufficient reason not listed in 105 CMR 120.016(C)(1) if it reasonably considers such action necessary to protect the public health, safety or the environment. In addition, nothing in 105 CMR 120.000 shall be deemed to limit the Department's authority to establish or recognize further general or specific grounds for discipline through rulemaking, adjudication, the issuance of polices or advisories or other similar means.
- (D) Severity of Violations.
- (1) Violations of 105 CMR 120.000 are categorized in terms of five levels of severity to show their relative importance within each of the following five activity areas:
    - (a) Health Physics;
    - (b) Transportation;
    - (c) Materials Operations;
    - (d) Miscellaneous Matters; and,
    - (e) Emergency Preparedness.
  - (2) Within each activity area, Severity Level I has been assigned to violations that are the most significant and Severity Level V to those that 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.
  - (3) 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.
  - (4) While examples are provided in 105 CMR 120.019: *Appendix A* 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 of the examples is predicated on a violation of an existing regulatory requirement. Each is designed to illustrate the significance which the Department places on a particular type of violation of regulatory requirements.
  - (5) 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.

120.016: continued

(6) 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" includes, but is not limited to, the deliberate violation of any provision of M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P or careless disregard of the requirements of M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P. 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 Agency. 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.

(7) The Agency expects licensees to provide complete, timely, and accurate information and reports. Accordingly, unless otherwise categorized in 105 CMR 120.019: *Appendix A* 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 or should have been aware of the condition or event. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter.

(E) Enforcement Conference. 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 may schedule 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:

- (a) Discuss the violations or nonconformance, their significance and causes, and the licensee's or vendor's corrective actions;
- (b) Determine whether there are any aggravating or mitigating circumstances;
- (c) Obtain other information which will help determine the appropriate enforcement action; and
- (d) Provide an opportunity for the licensee to explain what corrective actions have been taken or will be taken in response to the Notice of Violation. (*See* 105 CMR 120.016(F)).

(F) Enforcement Procedures.

(1)(a) Notice of Violation. Whenever the Agency finds upon inspection, investigation of a complaint or through information in its possession that an applicant, licensee or registrant is not in compliance with provisions of M.G.L. c. 111, §§ 5N through 5P or a regulation promulgated thereunder, the Agency shall notify the applicant, licensee or registrant of such violation or deficiency. The notice shall include a statement of the violations or deficiencies found, the provision of the law relied upon, and a reasonable period of time for correction. A violation or deficiency may result in denial, suspension, revocation or refusal to renew a license or certificate of registration; a modification or limitation of a license or certificate of registration; a cease and desist order; and/or the imposition of a civil penalty and/or criminal sanctions.

(b) Confirmatory Action Letters. The Agency may issue Confirmatory Action Letters confirming a licensee's, registrant's, or vendor's agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.

(2) Plan of Correction.

(a) The applicant, licensee or registrant shall within ten days of receipt of the notice, file with the Agency a written plan of correction. The plan shall clearly identify the licensee or registrant, state the date, reference the violation(s) cited, state specific corrective action(s) and timetable(s) and date(s) for completion for each violation cited, and shall be signed by either the applicant, licensee or registrant or his/her designee.

120.016: continued

(b) The Agency may re-inspect a facility in order to determine whether the corrections have been made. If upon review of plan of correction and/or reinspection the Agency finds that the applicant, licensee or registrant is in compliance with 105 CMR 120.000 and that the applicant, licensee or registrant has submitted an acceptable plan of correction, the Agency shall notify the applicant, licensee or registrant of its findings of compliance and/or its acceptance or modification of the plan of correction.

(c) If upon review of plan of correction and/or reinspection the Agency finds the plan of correction is unacceptable, the Agency may request that the applicant, licensee or registrant amend and resubmit the plan of correction within five days of the date of notice of the required amendment to the plan of correction or such other time as the Agency may specify for resubmission.

(d) If upon review of the plan of correction and/or reinspection the Agency determines that an applicant, licensee or registrant remains non-compliant with applicable laws and regulations regarding licensure, or the Agency determines that further enforcement action is necessary to ensure compliance with regulatory requirements and deter future non-compliance the Department may initiate enforcement procedures as set forth in 105 CMR 120.016.

(3) Notice of Department's Intent to Issue an Order.

(a) Except as specified in 105 CMR 120.016(F)(4)(b), prior to the Department issuing an order to modify, limit, deny, revoke or refuse to renew a license, and/or to require a person to cease and desist any activity, and/or to impose civil penalties, the applicant, licensee or registrant shall be notified in writing of the Agency's Intent to Issue an Order. The Notice of Intent to Issue an Order shall include the grounds for the Department's action, the provision(s) of law relied upon, the amount of any civil penalty or the requirements of the proposed order, and a right to request an adjudicatory hearing.

(b) If a license or certificate of registration is to be denied, modified, limited, revoked or refused renewal or if an activity is to be ceased or a civil penalty imposed by the Department, then the aggrieved applicant, licensee or registrant may request an adjudicatory hearing within 21 days of receipt of notification of the Department's Intent to Issue an Order. Said request shall be filed in accordance with 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures*.

(4) Administrative Hearings: Procedure.

(a) Immediate Suspension of a License or Certificate of Registration or Issuance of an Order to Immediately Cease an Activity:

1. The Department shall give the licensee or registrant written notice stating the reason(s) for the immediate suspension or issuance of an order to immediately cease an activity and the provisions of law relied upon. The immediate suspension or order to immediately cease an activity shall take effect immediately upon issuance of the notice.

2. The Department shall provide for a hearing pursuant to 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures* promptly after the issuance of an order of immediate suspension or an order to immediately cease an activity.

3. In cases of immediate suspension of a license or certificate of registration or issuance of an order to immediately cease an activity, the Hearing Officer shall determine whether the Department has proved by a preponderance of the evidence that there existed, immediately prior to or at the time of the immediate suspension or cease and desist order, a threat to public health, safety or the environment.

4. In the event that the Department determines that the violation of state law or of 105 CMR 120.000 which posed a threat to public health, safety or the environment is corrected prior to the decision of the Hearing Officer, the Department may lift the immediate suspension by giving written notice to the licensee or registrant.

(b) Denial, Modification, Limitation, Revocation, or Refusal to Renew a License or Certificate of Registration Based on Failure to File Reports or Pay Fees or Maintain Insurance: In accordance with M.G.L. c. 30A, § 13, no Notice of Intent to Issue an Order shall be required and no hearing shall be offered where denial, modification, limitation, revocation, suspension or refusal to renew is based solely upon failure of the licensee or registrant to file timely reports, schedules or applications or to pay lawfully prescribed fees, or to maintain insurance coverage as required by any law or regulation.

120.016: continued

## (c) Denial, Modification, Limitation, Revocation or Refusal to Renew a License or Certificate of Registration; Orders to Cease an Activity; Civil Penalties:

1. All adjudicatory proceedings shall be conducted in accordance with M.G.L. c. 30A and 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures*.

2. Except for circumstances specified in 105 CMR 120.016(F)(4)(b), if the Department determines that a license or certificate of registration should be denied, modified, limited, revoked, or refused renewal, and/or that a facility should cease an activity, and/or that a civil penalty should be imposed, and if the Department notifies the applicant, licensee or registrant of its intended action, upon receipt of a Notice of Claim for an Adjudicatory Proceeding, the Department shall initiate a hearing pursuant to 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures*.

3. The Hearing Officer shall determine whether the Department has proved by a preponderance of the evidence that the license or certificate of registration should be denied, modified, limited, revoked or refused renewal; that an activity should be ceased; and/or that a civil penalty be imposed based on relevant facts as they existed at or prior to the time the Department initiated the hearing procedure.

4. If the Hearing Officer finds any single ground for denial, modification, limitation, revocation, suspension, or refusal to renew a license or certificate of registration; for a cessation of an activity; and/or for imposition of a civil penalty, then the Hearing Officer shall render a recommended decision affirming the issuance of the Department's Order.

(d) Final Agency Decision and Judicial Review:

1. The recommended decision of a Hearing Officer in any adjudicatory proceeding conducted under 105 CMR 120.000 shall be reviewed by the Commissioner. The Commissioner's decision upon this review shall constitute a final agency decision in an adjudicatory proceeding subject to judicial review pursuant to M.G.L. c. 30A, § 14.

2. Any applicant, licensee or registrant that fails to exercise its right to an adjudicatory proceeding under 105 CMR 120.000 waives its right to an adjudicatory hearing, its right to administrative review by the Commissioner and its right to judicial review pursuant to M.G.L. c. 30A, § 14.

(G) Civil Penalties.

(1) If the Department determines, after a notice has been issued and an opportunity for a hearing has been provided, that a licensee, registrant or vendor has not complied with an order issued pursuant to M.G.L. c. 111, § 50 or with any provision of M.G.L. c. 111, §§ 5N through 5P or with any applicable rule, regulation, license or certificate of registration adopted or issued thereunder, the Department, in lieu of, or in addition to suspending, denying, modifying, limiting, revoking, or refusing renewal of a license or certificate of registration, may assess civil penalties in an amount not exceeding \$100,000 per violation. Such civil penalty may be assessed whether or not the violation was willful.

(2) The decision whether to issue a civil penalty and the amount of any civil penalty depends on the facts of each case. Generally, civil penalties are most likely to be 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 that occurred after the date of the last inspection or within two years, whichever period is greater for which the licensee did not take effective corrective action.

(3) Civil penalties may be assessed for known and conscious violations of the reporting requirements of 105 CMR 120.000 and for any willful violation of any Agency requirement including those at any severity level.

(4) Payment of civil penalties imposed under M.G.L. c. 111, § 50 shall be made by check, draft, or money order payable to the Commonwealth of Massachusetts, and mailed to the Radiation Control Program.

(5) Factors in Determining the Amount of Penalty. In determining the amount of the civil penalty, the Department shall consider the following:

- (a) The willfulness of the violation;
- (b) The actual and potential danger to the public health or the environment;
- (c) The actual or potential costs of such danger to the public health or the environment;

120.016: continued

- (d) The actual or potential damage or injury to the public health or environment;
- (e) The actual and potential cost of such damage or injury;
- (f) The actual or potential cost to the Commonwealth of enforcing provisions of 105 CMR 120.000;
- (g) Whether the person being assessed the civil penalty did everything reasonable to prevent failure to, to come into compliance promptly, and to remedy and mitigate whatever harm might have been done as a result of the failure to comply;
- (h) Whether the person being assessed the civil penalty has previously failed to comply with any order issued pursuant to M.G.L. c. 111, §§ 5N through 5P or any rule or regulation adopted hereunder;
- (i) Whether imposition of a civil penalty is likely to deter future non-compliance;
- (j) The financial condition of the person being assessed the civil penalty; and,
- (k) The public interest.

(H) Escalation of Enforcement Sanctions.

- (1) The Department considers violations of Severity Levels I, II or III to be of significant regulatory concern. When Severity Level I, II or III violations occur, the Department will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. The Department 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 105 CMR 120.016(D).
- (2) The progression of enforcement actions for similar violations will usually be based on similar violations at an individual facility and not on similar violations under the same license. However, 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 one division of a dual unit hospital that repeats an earlier violation of the other division might be considered similar.

(I) Criminal Enforcement. The Department may elect to enforce any section of 105 CMR 120.000 or provision of M.G.L. c. 111, § 5P by seeking to have criminal sanctions imposed. Any person who violates M.G.L. c. 111, § 5N or § 5O or any rule, regulation, license, registration, or order adopted or issued under said M.G.L. c. 111, § 5N or § 5O shall be fined not less than \$100 nor more than \$2,000, or be imprisoned for a period of not more than two years, or both. Any person who continues to violate the provisions of the aforementioned laws after due notice by the Department shall be fined not less than \$1,000 nor more than \$20,000 or be imprisoned for a period of not more than 20 years, or both. After due notice has been issued by the Department, each day of such violation shall constitute a separate offense.

(J) Judicial Enforcement. The Department may apply directly to the Supreme Judicial Court or Superior Court to enforce any provision of M.G.L. c. 111, §§ 5N through 5P and/or any rule or regulation, license, registration, or order adopted and issued thereunder by the Department. When a person is engaged in or about to engage in any act or practice which constitutes or will constitute a violation of such provision, rule, regulation, license, registration, or order, the Department may seek to restrain such act or practice or the use or occupation of premises or parts thereof or such other equitable relief as public health and safety requires.

(K) Nonexclusivity of Enforcement Procedures. None of the enforcement procedures contained in 105 CMR 120.000 are mutually exclusive. Any enforcement procedures may be invoked simultaneously if the situation so requires.

(L) Deliberate Misconduct.

- (1) Any licensee; certificate of registration holder; **quality assurance program approval holder;** applicant for a license or certificate of registration **or quality assurance program approval;** employee of a licensee, certificate of registration holder, **quality assurance program approval 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, **quality assurance program approval holder** or applicant for a license or certificate of registration **or quality assurance program approval**, who knowingly provides to any licensee, applicant, certificate holder, **quality assurance**

**program approval holder**, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's, **quality assurance program approval holder's** or applicant's activities in this part, may not:

## 120.016: continued

- (a) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, **quality assurance program approval holder** or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license **or certificate of registration or quality assurance program approval** issued by the Agency; or
  - (b) Deliberately submit to the Agency, a licensee, certificate of registration holder, **quality assurance program approval holder**, an applicant, or a licensee's, certificate holder's, **quality assurance program approval 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.
- (2) A person who violates 105 CMR 120.016(L)(1)(a) or (b) may be subject to enforcement action in accordance with the procedures in 105 CMR 120.016.
- (3) For the purposes of 105 CMR 120.016(L)(1)(a), deliberate misconduct by a person means an intentional act or omission that the person knows:
- (a) Would cause a licensee, certificate of registration holder, **quality assurance program approval 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
  - (b) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, **quality assurance program approval holder**, applicant, contractor, or subcontractor.

120.017: Severability

The provisions of 105 CMR 120.000 are severable. If any section, subsection, paragraph or provision is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining provisions shall not be so affected.

120.018: Public Disclosure of Enforcement Actions

In accordance with M.G.L. c. 30A, the Administrative Procedures Act, all enforcement actions and licensees' responses are publicly available for inspection. In addition, press releases may be issued for civil penalties related to violations at Severity Level I, II, or III.

120.019: Appendix A -- 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.

(A) Severity Level 1 -- Most Significant Violations.

- (1) Health Physics.
  - (a) 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;
  - (b) Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;
  - (c) Release of radioactive material to an unrestricted area in excess of ten times the limits of 105 CMR 120.253;
  - (d) Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 105 CMR 120.253;
  - (e) Exposure of a worker in restricted areas of ten times the limits of 105 CMR 120.212.
- (2) Transportation.
  - (a) Annual whole body radiation exposure of a member of the public in excess of 0.5 rems of radiation; or,
  - (b) Breach of package integrity resulting in surface contamination or external radiation levels in excess of ten times the Agency limits.
- (3) Materials Operations.
  - (a) Radiation levels, contamination levels, or releases that exceed ten times the limits specified in the license;
  - (b) A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function.

120.019: continued

- (4) Miscellaneous Matters.
- (a) A Material False Statement (MFS)<sup>1</sup> in which the statement made was deliberately false;
  - (b) 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,
  - (c) A knowing and intentional failure to provide any notice required by 105 CMR 120.000.
  - (d) Possession of licensable quantities of radioactive material without a license, or loss of control of a source of radiation.
  - (e) Refusing authorized Agency personnel access to facilities, records and/or equipment to conduct inspections or investigations.
- (5) 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).
- (B) Severity Level II -- Very Significant Violations.
- (1) Health Physics.
- (a) Single exposure of a worker in excess of 10 rems total effective dose equivalent, 30 rems to the lens of the eye or 100 rems to the skin of the whole body, or to the feet, ankles, hands or forearms or to any other organ or tissue;
  - (b) Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;
  - (c) Release of radioactive material to an unrestricted area in excess of five times the limits of 105 CMR 120.222;
  - (d) Failure to make an immediate notification as required by 105 CMR 120.282(A), and (B);
  - (e) Disposal of license material in quantities or concentrations in excess of five times the limits of 105 CMR 120.253;
  - (f) Exposure of a worker in restricted areas in excess of five times the limits of 105 CMR 120.212.
  - (g) 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.
  - (h) 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.
  - (i) A fluoroscopic system such that the entire x-ray beam is not intercepted by the primary protective barrier; or,
  - (j) Therapy systems which exhibit excessive leakage and/or inoperable door interlocks, shutters, timers, *etc.*
  - (k) Therapy system, with improper operator/patient communication/observation.

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<sup>1</sup> 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 severity 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 or deliberateness). The relative weight given to each of these factors will be dependent on the circumstances of the violation.



120.019: continued

- (2) Transportation.
    - (a) Breach of package integrity resulting in surface contamination or external radiation levels in excess of Agency requirements;
    - (b) Surface contamination or external radiation levels in excess of five times Agency limits that did not result from a breach of package integrity; or,
    - (c) Failure to make required initial notifications associated with Severity Level I or II violations.
  - (3) Material Operations.
    - (a) Radiation levels, contamination levels, or releases that exceed five times the limits specified in the license; or,
    - (b) A system designed to prevent or mitigate a serious safety event being inoperable.
  - (4) Miscellaneous Matters.
    - (a) 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;
    - (b) A MFS in which the false statement was made with careless disregard.
    - (c) Deliberate falsification of records which the Agency requires be kept involving significant information; or,
    - (d) A failure to provide the notice required.
    - (e) Failure to register sources of radiation or services as required by 105 CMR 120.000.
    - (f) Action by management to discriminate against an employee for attempting to communicate or for actually communicating with the Agency.
  - (5) Emergency Preparedness. Licensee failure to meet or implement more than one emergency planning standard involving assessment or notification.
- (C) Severity Level III --- Significant Violations.
- (1) Health Physics.
    - (a) A radiation exposure during any year of a worker in excess of 5 rems total effective dose equivalent, 15 rems to the lens of the eye, or 50 rems to the skin of the whole body or to the feet, ankles, hands or forearms, or to any other organ or tissue;
    - (b) A radiation level in an unrestricted area such that an individual could receive greater than 100 millirem in a one hour period or 500 millirem in a seven consecutive days;
    - (c) Failure to make a 24-hour notification as required by 105 CMR 120.281 or an immediate notification required by 105 CMR 120.282;
    - (d) Substantial potential for an exposure or release in excess of 105 CMR 120.200, 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);
    - (e) Release of radioactive material to an unrestricted area in excess of the limits of 105 CMR 120.222;
    - (f) Improper disposal of licensed material not covered in Severity Level I or II;
    - (g) Exposure of worker in restricted areas in excess of the limits of 105 CMR 120.212;
    - (h) 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;
    - (i) Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic, rather than an isolated weakness in radiation protection;
    - (j) Conduct of licensee activities by a technically unqualified person;
    - (k) Significant failure to control licensed material;
    - (l) Failure to use exposure reduction devices properly (*e.g.*, collimators, filtration);
    - (m) 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.

120.019: continued

- (n) 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% of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.
- (o) 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 nine centimeters or which exhibit a minimum SSD less than 16 centimeters.
- (p) Dental radiographic systems in which it is possible to produce x-rays with the timer in the zero or off position.
- (q) Mammographic x-ray systems in which the edge of the x-ray field at the chest wall extends beyond the edges of the image receptor by more than 5% of the source to image receptor distance.
- (r) Therapy systems which fail to maintain proper surveys, calibrations, spot checks or operating procedures.
- (2) Transportation.
  - (a) Breach of package integrity;
  - (b) 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;
  - (c) 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,
  - (d) Failure to make required initial notification associated with Severity Level III violations.
- (3) Materials Operations.
  - (a) Failure to control access to licensed materials for radiation purposes as specified by Agency requirements;
  - (b) Possession or use of unauthorized equipment or materials in the conduct of licensee activities which degrades safety;
  - (c) Use of radioactive material on humans where such use is not authorized;
  - (d) Conduct of licensed activities by a technically unqualified person;
  - (e) Radiation levels, contamination levels, or releases that exceed the limits specified in the license; or,
  - (f) Medical therapeutic misadministrations.
  - (g) Failure to obtain appropriate Agency approval before moving to a new use and/or storage location.
- (4) Miscellaneous Matters.
  - (a) An MFS not amounting to a Severity Level I or II violation; or,
  - (b) Deliberate falsification, or falsification by or with the knowledge of management of records which the Agency requires be kept that did not involve significant information.
- (5) Emergency Preparedness. Violations of lesser severity than Severity Level II violations.
- (D) Severity Level IV -- Violations.
  - (1) Health Physics.
    - (a) Exposures in excess of the limits of 105 CMR 120.211 not constituting Severity Level I, II, or III violations;
    - (b) A radiation level in an unrestricted area such that an individual could receive greater than two millirem in a one-hour period or 50 millirem in a year;
    - (c) Failure to make a 30-day notification required by 105 CMR 120.283;
    - (d) Failure to make a follow-up written report as required by 105 CMR 120.281, 120.287 and 120.750; or,
    - (e) Any other matter that has more than minor safety or environmental significance.
    - (f) A capacitor storage radiographic system such that the standby radiation is greater than 3.0 mR/hr, but less than 25 mR/hr.
    - (g) Systems equipped with positive beam limiting devices which do not allow the field size to be reduced to a size less than that of the image receptor.

120.019: continued

- (h) Systems equipped with positive beam limiting devices which do not provide for an automatic return to PBL from a reduced field size.
- (i) Mobile radiographic systems for which the minimum source to skin distance is less than 27.5 centimeters.
- (j) 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% of the SID.
- (2) Transportation.
  - (a) Package selection of 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,
  - (b) Other violations that have more than minor safety or environmental significance.
- (3) Material Operations.
  - (a) 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;
  - (b) Other violations that have more than minor safety or environmental significance; or,
  - (c) Failure to report medical diagnostic misadministrations.
- (4) Miscellaneous Matters.
  - (a) 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.
  - (b) 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,
- (5) Emergency Preparedness. Violations of lesser severity than Severity Level III violations.

120.020: REGISTRATION OF RADIATION MACHINE FACILITIES AND SERVICES120.021: Purpose and Scope

(A) 105 CMR 120.020 through 120.040 provides for the registration of radiation machine facilities and for the registration of persons providing radiation machine installation, servicing, and/or services to Department registrants or registrable facilities. For the purposes of 105 CMR 120.020, particle accelerators, whether used primarily for x-ray production or other purposes, shall be considered a radiation machine facility.

(B) In addition to the requirements of 105 CMR 120.020 through 120.040, all registrants are subject to the applicable provisions of other parts of 105 CMR 120.000.

120.022: Definitions

As used in 105 CMR 120.020 through 120.040, "facility" means the location at which one or more devices or sources are installed and/or located within one building, vehicle, or under one roof and are under the same administrative control.

120.023: Exemptions

(A) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of 105 CMR 120.020 through 120.040, providing dose equivalent rate averaged over an area of ten square centimeters does not exceed 0.5 millirem (5 $\mu$  Sv) per hour at five centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

(B) Radiation machines while in transit or storage incident thereto are exempt from the requirements of 105 CMR 120.020 through 120.040.

120.023: continued

(C) Domestic television receivers are exempt from the requirements of 105 CMR 120.020 through 120.040.

120.024: Plan Review

(A) Prior to construction, the floor plans and equipment arrangements of all new installations, or modifications of existing installations, utilizing ionizing radiation for diagnostics or therapeutic purposes shall be submitted to the Agency for review and approval. The installation shall meet the requirements of 105 CMR 120.420: *Appendix A* and 105 CMR 120.422: *Appendix C* unless specifically exempted. Additional shielding and design requirements are specified elsewhere in 105 CMR 120.000.

(B) The Agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

(C) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 105 CMR 120.211, 120.217, 120.218 and 120.221.

120.025: Application for Registration

Each person who owns or possess and administratively controls a facility, unless specifically exempted in 105 CMR 120.023 shall:

(A) Apply for registration of such facility with the Agency prior to the operation of a radiation machine facility. Application for registration shall be completed on forms furnished by the Agency and shall contain all the information required by the form and accompanying instructions.

(B) Designate on the application form an individual to be responsible for radiation protection.

(C) Each registrant shall prohibit any person from furnishing radiation machine servicing or services as described in 105 CMR 120.026(D) to his radiation machine facility until such person provides evidence that he has been registered with the Agency as a provider of services in accordance with 105 CMR 120.026.

120.026: Application for Registration Services

(A) Each person, prior to engaging in the business of installing or offering to install radiation machines or engaging in the business of furnishing or offering to furnish radiation machine servicing or services in this Commonwealth shall apply for and receive registration for such services with the Agency.

(B) Application for registration shall be completed on forms furnished by the Agency and shall contain all information required by the Agency as indicated on the forms and accompanying instructions.

(C) Each person applying for registration under 105 CMR 120.020 through 120.040 shall specify:

- (1) That he has read and understands the requirements of 105 CMR 120.020 through 120.040;
- (2) The services for which he is applying for registration; and,
- (3) The training and experience that qualify him to discharge the services for which he is applying for registration;

(D) For the purpose of 105 CMR 120.026, services may include but shall not be limited to:

- (1) Installation and/or servicing of radiation machines and associated radiation machine components;

120.026: continued

- (2) Calibration of radiation machines or radiation measurement instruments or devices;
- (3) Radiation protection or health physics consultations or surveys; and,
- (4) Personnel dosimetry services.

120.027: Certificate of Registration

(A) No person shall maintain a facility that is required by 105 CMR 120.000 to be registered unless such a person has obtained a valid certificate of registration for such facility.

(B) A person who applies for registration and whose application meets the requirements of 105 CMR 120.000, shall, upon payment of the required fee, be issued a certificate of registration effective on the date stated on such certificate.

(C) A current certificate of registration or a legible copy thereof shall be posted conspicuously at each registered facility.

(D) The Director of the Radiation Control Program may incorporate in the certificate of registration, at the time of issuance or thereafter, any such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of radiation machines as said Director finds appropriate and necessary for the protection of the general public or individuals against radiation hazards.

120.028: Expiration of Notice of Registration

Each certificate of registration shall expire at the end of the specified day in the month and year stated therein.

120.029: Renewal of Notice of Registration

(A) Application for renewal of registration shall be filed in accordance with 105 CMR 120.025 or 105 CMR 120.026.

(B) In any case in which a registrant not less than 30 days prior to the expiration of his existing notice of registration has filed an application in proper form for renewal, such existing notice of registration shall not expire until the application status has been finally determined by the Agency.

120.030: Report of Changes

The registrant shall notify the Agency in writing before making any change which would render the information contained in the application for registration and/or the certificate of registration no longer accurate. In the case of disposition of an x-ray system, such notification should specify the recipient of the system. In the case of modification involving a structural change, or the addition or relocation of an x-ray system, the Director of the Radiation Control Program may require the registrant to submit the information contained in 105 CMR 120.420: *Appendix A* and/or 105 CMR 120.421: *Appendix C*.

120.031: Approval Not Implied

No person, in any advertisement, shall refer to the fact that he or his facility is registered with the Agency pursuant to the provisions of 105 CMR 120.025 or 120.026, and no person shall state or imply that any activity under such registration has been approved by the Agency.

120.032: Assembler and/or Transfer Obligation

- (A) Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines in this Commonwealth shall notify the Agency within 15 days of:
- (1) The name and address of persons who have received these machines;
  - (2) The manufacturer, model, and serial number of each radiation machine transferred; and,
  - (3) The date of transfer of each radiation machine.

120.032: continued

(4) In the case of diagnostic x-ray system which contain certified components, a copy of the assembler's report prepared in compliance with requirements of the Federal Diagnostic X-Ray Standard (21 CFR 1020.30 (d)) shall be submitted to the Agency within 15 days following completion of the assembly. Such report shall suffice in *lieu* of any other by the assembler.

(B) No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and use shall meet the requirements of 105 CMR 120.000.

120.033: Out-of-state Radiation Machines

(A) Whenever any radiation machine is to be brought into the Commonwealth, for any temporary use, the person proposing to bring such machine into the Commonwealth shall give written notice to the Agency at least ten working days before such machine is to be used in the Commonwealth. The notice shall include:

- (1) The type of radiation machine;
- (2) The nature, duration, and scope of use;
- (3) The exact location(s) where the radiation machine is to be used; and,
- (4) States in which this machine is registered.

(B) The person referred to in 105 CMR 120.033 shall:

- (1) Comply with all applicable regulations of the Agency;
- (2) Register the radiation machine(s) with the Agency; and,
- (3) Submit payment of the required fee for registration.

(C) A pre-operational inspection may be required at the discretion of the Director of the Radiation Control Program.

(D) If, for a specific case, the ten working day period is not practical, notification to the Agency by telephone and hardcopy, permission to proceed sooner may be granted.

120.040: Notification to Fire Department

The user shall notify the local fire department of the presence on his premises of any radioactive material that may present special fire-fighting problems or require special precautionary measures in case of fire or other natural catastrophe, and he shall establish effective liaison with the fire department in regards to this matter.

120.050: PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

GENERAL PROVISIONS

120.051: Purpose

105 CMR 120.050 through 120.080 has been established to provide the requirements for the physical protection program for any licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material listed in 105 CMR 120.080: *Appendix A: Table 1*. 105 CMR 120.050 through 120.080 provide reasonable assurance of the security of category 1 or category 2 quantities of radioactive material by protecting these materials from theft or diversion. Specific requirements for access to material, use of material, transfer of material, and transport of material are included. No provision of 105 CMR 120.050 through 120.080 authorizes possession of licensed material.

120.052: Scope

(A) 105 CMR 120.056 through 120.071 applies to any person who, under the regulations in 105 CMR 120.000, possesses or uses at any site, an aggregated category 1 or category 2 quantity of radioactive material.

120.052: continued

- (B) 105 CMR 120.072 through 120.077 applies to any person who, under 105 CMR 120.000:
- (1) Transports or delivers to a carrier for transport in a single shipment, a category 1 or category 2 quantity of radioactive material; or
  - (2) Imports or exports a category 1 or category 2 quantity of radioactive material; the provisions only apply to the domestic portion of the transport.

120.053: Definitions

As used in 105 CMR 120.050 through 120.080, the following definitions apply:

Access Control means a system for allowing only approved individuals to have unescorted access to the security zone and for ensuring that all other individuals are subject to escorted access.

Aggregated means accessible by the breach of a single physical barrier that would allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a category 2 quantity of radioactive material.

Approved Individual means an individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with 105 CMR 120.056 through 120.062 and who has completed the training required by 105 CMR 120.064(C).

Background Investigation means the investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

Carrier means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

Category 1 Quantity of Radioactive Material means a quantity of radioactive material meeting or exceeding the category 1 threshold in 105 CMR 120.080: *Appendix A: Table 1*. This is determined by calculating the ratio of the total activity of each radionuclide to the category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

Category 2 Quantity of Radioactive Material means a quantity of radioactive material meeting or exceeding the category 2 threshold but less than the category 1 threshold in 105 CMR 120.080: *Appendix A: Table 1*. This is determined by calculating the ratio of the total activity of each radionuclide to the category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds one, the quantity would be considered a category 2 quantity. Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

Diversion means the unauthorized movement of radioactive material subject to 105 CMR 120.050 through 120.080 to a location different from the material's authorized destination inside or outside of the site at which the material is used or stored.

Escorted Access means accompaniment while in a security zone by an approved individual who maintains continuous direct visual surveillance at all times over an individual who is not approved for unescorted access.

Fingerprint Orders means the orders issued by the U.S. Nuclear Regulatory Commission or the legally binding requirements issued by Agreement States that require fingerprints and criminal history records checks for individuals with unescorted access to category 1 and category 2 quantities of radioactive material or safeguards information-modified handling.

120.053: continued

Government Agency means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

Local Law Enforcement Agency (LLEA) means a public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed category 1 or category 2 quantity of radioactive material is used, stored, or transported.

Mobile Device means a piece of equipment containing licensed radioactive material that is either mounted on wheels or casters, or otherwise equipped for moving without a need for disassembly or dismounting; or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.

Movement Control Center means an operations center that is remote from transport activity and that maintains position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies and can request and coordinate appropriate aid.

No-later-than Arrival Time means the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than arrival time may not be more than six hours after the estimated arrival time for shipments of category 2 quantities of radioactive material.

Reviewing Official means the individual who shall make the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to have, unescorted access to the category 1 or category 2 quantities of radioactive materials that are possessed by the licensee.

Sabotage means deliberate damage, with malevolent intent, to a category 1 or category 2 quantity of radioactive material, a device that contains a category 1 or category 2 quantity of radioactive material, or the components of the security system.

Safe Haven means a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law enforcement authorities.

Security Zone means any temporary or permanent area determined and established by the licensee for the physical protection of category 1 or category 2 quantities of radioactive material.

State means a State or Commonwealth of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Telemetric Position Monitoring System means a data transfer system that captures information by instrumentation and/or measuring devices about the location and status of a transport vehicle or package between the departure and destination locations.

Trustworthiness and Reliability are characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to category 1 or category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

Unescorted Access means solitary access to an aggregated category 1 or category 2 quantity of radioactive material or the devices that contain the material.



120.054: Communications

Except where otherwise specified or covered, all communications and reports concerning 105 CMR 120.050 through 120.080 may be sent as stated in 105 CMR 120.013.

120.055: Specific Exemptions

(A) The Agency may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of 105 CMR 120.050 through 120.080 as it determines are authorized by law and will not endanger life or property or the physical protection of agreement material, and are otherwise in the public interest.

(B) A licensee that possesses radioactive waste that contains category 1 or category 2 quantities of radioactive material is exempt from the requirements of 105 CMR 120.056 through 120.077. Except that any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements of 105 CMR 120.050 through 120.080. The licensee shall implement the following requirements to secure the radioactive waste:

- (1) Use continuous physical barriers that allow access to the radioactive waste only through established access control points;
- (2) Use a locked door or gate with monitored alarm at the access control point;
- (3) Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and
- (4) Immediately notify the LLEA and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains category 1 or category 2 quantities of radioactive material.

BACKGROUND INVESTIGATIONS AND ACCESS AUTHORIZATION PROGRAM

120.056: Personnel Access Authorization Requirements for Category 1 or Category 2 Quantities of Radioactive Materials

(A) General.

(1) Each licensee that possesses an aggregated quantity of radioactive material at or above the category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements of 105 CMR 120.056 through 120.062.

(2) An applicant for a new license and each licensee that would become newly subject to the requirements of 105 CMR 120.056 through 120.062 upon application for modification of its license shall implement the requirements of 105 CMR 120.056 through 120.062, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

(3) Any licensee that has not previously implemented the Security Orders or been subject to the provisions of 105 CMR 120.056 through 120.062 shall implement the provisions of 105 CMR 120.056 through 120.062 before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

(B) General Performance Objective. The licensee's access authorization program must ensure that the individuals specified in 105 CMR 120.056(C)(1) are trustworthy and reliable.

(C) Applicability.

(1) Licensees shall subject the following individuals to an access authorization program:

- (a) Any individual whose assigned duties require unescorted access to category 1 or category 2 quantities of radioactive material or to any device that contains the radioactive material; and
- (b) Reviewing officials.

(2) Licensees need not subject the categories of individuals listed in 105 CMR 120.060(A)(1) through (13) to the investigation elements of the access authorization program.

(3) Licensees shall approve for unescorted access to category 1 or category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to category 1 or category 2 quantities of radioactive material.

120.056: continued

(4) Licensees may include individuals needing access to safeguards information-modified handling under 10 CFR Part 73 in the access authorization program under 105 CMR 120.056 through 120.062.

120.057: Access Authorization Program Requirements

(A) Granting Unescorted Access Authorization.

(1) Licensees shall implement the requirements of 105 CMR 120.056 through 120.062 for granting initial or reinstated unescorted access authorization.

(2) Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by 105 CMR 120.064(C) before being allowed unescorted access to category 1 or category 2 quantities of radioactive material.

(B) Reviewing Officials.

(1) Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 quantities of radioactive materials possessed by the licensee.

(2) Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. The fingerprints of the named reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a State to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every ten years in accordance with 105 CMR 120.058(C).

(3) Reviewing officials must be permitted to have unescorted access to category 1 or category 2 quantities of radioactive materials or access to safeguards information or safeguards information-modified handling, if the licensee possesses safeguards information or safeguards information-modified handling.

(4) Reviewing officials cannot approve other individuals to act as reviewing officials.

(5) A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

(a) The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

(b) The individual is subject to a category listed in 105 CMR 120.060(A).

(C) Informed Consent.

(1) Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals that meet the requirements of 105 CMR 120.058(B). A signed consent must be obtained prior to any reinvestigation.

(2) The subject individual may withdraw his or her consent at any time. Licensees shall inform the individual that:

(a) If an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the individual withdrew his or her consent; and

(b) The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

(D) Personal History Disclosure. Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by 105 CMR 120.056 through 120.062 is sufficient cause for denial or termination of unescorted access.

120.057: continued

(E) Determination Basis.

- (1) The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all of the information collected to meet the requirements of 105 CMR 120.056 through 120.062.
- (2) The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all of the information collected to meet the requirements of 105 CMR 120.056 through 120.062 and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.
- (3) The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.
- (4) The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access authorization.
- (5) Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

(F) Procedures. Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures must include provisions for the notification of individuals who are denied unescorted access. The procedures must include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures must contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

(G) Right to Correct and Complete Information.

- (1) Prior to any final adverse determination, licensees shall provide each individual subject to the requirements of 105 CMR 120.056 through 120.062 with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification must be maintained by the licensee for a period of one year from the date of the notification.
- (2) If, after reviewing his or her criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures include direct application by the individual challenging the record to the law enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in 28 CFR 16.30 through 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the data, and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. Licensees must provide at least ten days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his or her review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

(H) Records.

- (1) The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

120.057: continued

(2) The licensee shall retain a copy of the current access authorization program procedures as a record for three years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

(3) The licensee shall retain the list of persons approved for unescorted access authorization for three years after the list is superseded or replaced.

120.058: Background Investigations

(A) Initial Investigation. Before allowing an individual unescorted access to category 1 or category 2 quantities of radioactive material or to the devices that contain the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation must encompass at least the seven years preceding the date of the background investigation or since the individual's 18<sup>th</sup> birthday, whichever is shorter. The background investigation must include at a minimum:

(1) Fingerprinting and an FBI identification and criminal history records check in accordance with 105 CMR 120.059;

(2) Verification of True Identity. Licensees shall verify the true identity of the individual who is applying for unescorted access authorization to ensure that the applicant is who he or she claims to be. A licensee shall review official identification documents (*e.g.*, driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information. Licensees shall document the type, expiration, and identification number of the identification document, or maintain a photocopy of identifying documents on file in accordance with 105 CMR 120.061. Licensees shall certify in writing that the identification was properly reviewed, and shall maintain the certification and all related documents for review upon inspection;

(3) Employment History Verification. Licensees shall complete an employment history verification, including military history. Licensees shall verify the individual's employment with each previous employer for the most recent seven years before the date of application;

(4) Verification of Education. Licensees shall verify that the individual participated in the education process during the claimed period;

(5) Character and Reputation Determination. Licensees shall complete reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under 105 CMR 120.056 through 120.062 must be limited to whether the individual has been and continues to be trustworthy and reliable;

(6) The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the individual (*e.g.*, seek references not supplied by the individual); and

(7) If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at least after ten business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation; and attempt to obtain the information from an alternate source.

(B) Grandfathering.

(1) Individuals who have been determined to be trustworthy and reliable for unescorted access to category 1 or category 2 quantities of radioactive material under the Fingerprint Orders may continue to have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. These individuals shall be subject to the reinvestigation requirement.

120.058: continued

(2) Individuals who have been determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or the security orders for access to safeguards information, safeguards information-modified handling, or risk-significant material may have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. The licensee shall document that the individual was determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or a security order. Security order, in this context, refers to any order that was issued by the NRC that required fingerprints and an FBI criminal history records check for access to safeguards information, safeguards information-modified handling, or risk significant material such as special nuclear material or large quantities of uranium hexafluoride. These individuals shall be subject to the reinvestigation requirement.

(C) Reinvestigations. Licensees shall conduct a reinvestigation every ten years for any individual with unescorted access to category 1 or category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with 105 CMR 120.059. The reinvestigations must be completed within ten years of the date on which these elements were last completed.

120.059: Requirements for Criminal History Records Checks of Individuals Granted Unescorted Access to Category 1 or Category 2 Quantities of Radioactive Material

(A) General Performance Objective and Requirements.

(1) Except for those individuals listed in 105 CMR 120.060 and those individuals grandfathered under 105 CMR 120.058(B), each licensee subject to the provisions of 105 CMR 120.056 through 120.062 shall fingerprint each individual who is to be permitted unescorted access to category 1 or category 2 quantities of radioactive material. Licensees shall transmit all collected fingerprints to the U.S. Nuclear Regulatory Commission for transmission to the FBI. The licensee shall use the information received from the FBI as part of the required background investigation to determine whether to grant or deny further unescorted access to category 1 or category 2 quantities of radioactive materials for that individual.

(2) The licensee shall notify each affected individual that his or her fingerprints will be used to secure a review of his or her criminal history record, and shall inform him or her of the procedures for revising the record or adding explanations to the record.

(3) Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to category 1 or category 2 quantities of radioactive materials if:

(a) The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his or her unescorted access authorization; and

(b) The previous access was terminated under favorable conditions.

(4) Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to category 1 or category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee, based upon a background investigation conducted under 105 CMR 120.056 through 120.062, the Fingerprint Orders, or 10 CFR Part 73. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of 105 CMR 120.061(C).

(5) Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to category 1 or category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

(B) Prohibitions.

(1) Licensees may not base a final determination to deny an individual unescorted access authorization to category 1 or category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

(a) An arrest more than one year old for which there is no information of the disposition of the case; or

(b) An arrest that resulted in dismissal of the charge or an acquittal.

120.059: continued

(2) Licensees may not use information received from a criminal history records check obtained under 105 CMR 120.056 through 120.062 in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

(C) Procedures for Processing of Fingerprint Checks.

(1) For the purpose of complying with 105 CMR 120.056 through 120.062, licensees shall submit to the U.S. Nuclear Regulatory Commission, Director, Division of Facilities and Security, 11545 Rockville Pike, Rockville, Maryland 20852-2738, ATTN: Criminal History Program, Mail Stop T-03B46M, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 1-630-829-9565, or by email to FORMS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at <http://www.nrc.gov/site-help/e-submittals.html>.

(2) Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the Security Branch, Division of Facilities and Security at 301-415-7513.) Combined payment for multiple applications is acceptable. The U.S. Nuclear Regulatory Commission publishes the amount of the fingerprint check application fee on the NRC's public Web site. (To find the current fee amount, go to the Electronic Submittals page at <http://www.nrc.gov/site-help/e-submittals.html> and see the link for the Criminal History Program under Electronic Submission Systems.)

(3) The U.S. Nuclear Regulatory Commission will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

120.060: Relief from Fingerprinting, Identification, and Criminal History Records Checks and Other Elements of Background Investigations for Designated Categories of Individuals Permitted Unescorted Access to Certain Radioactive Materials

(A) Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, and other elements of the background investigation are not required for the following individuals prior to granting unescorted access to category 1 or category 2 quantities of radioactive materials:

- (1) An employee of the U.S. Nuclear Regulatory Commission or of the Executive Branch of the U.S. Government who has undergone fingerprinting for a prior U.S. Government criminal history records check;
- (2) A Member of Congress;
- (3) An employee of a member of Congress or Congressional committee who has undergone fingerprinting for a prior U.S. Government criminal history records check;
- (4) The Governor of a State or his or her designated State employee representative;
- (5) Federal, State, or local law enforcement personnel;
- (6) State Radiation Control Program Directors and State Homeland Security Advisors or their designated State employee representatives;
- (7) Agreement State employees conducting security inspections on behalf of the NRC under an agreement executed under section 274.i. of the Atomic Energy Act;
- (8) Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;
- (9) Emergency response personnel who are responding to an emergency;
- (10) Commercial vehicle drivers for road shipments of category 1 and category 2 quantities of radioactive material;
- (11) Package handlers at transportation facilities such as freight terminals and railroad yards;

120.060: continued

(12) Any individual who has an active Federal security clearance, provided that he or she makes available the appropriate documentation. Written confirmation from the agency/ employer that granted the Federal security clearance or reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material; and

(13) Any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to category 1 or category 2 quantities of radioactive material. Written verification from the service provider must be provided to the licensee. The licensee shall retain the documentation for a period of three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

(B) Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last five years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material. These programs include, but are not limited to:

- (1) National Agency Check;
- (2) Transportation Worker Identification Credentials (TWIC) under 49 CFR part 1572;
- (3) Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR part 555;
- (4) Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR part 73;
- (5) Hazardous Material security threat assessment for hazardous material endorsement to commercial driver's license under 49 CFR part 1572; and
- (6) Customs and Border Protection's Free and Secure Trade (FAST) Program.

#### 120.061: Protection of Information

(A) Each licensee who obtains background information on an individual under 105 CMR 120.056 through 120.062 shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

(B) The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his or her representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.

(C) The personal information obtained on an individual from a background investigation may be provided to another licensee:

- (1) Upon the individual's written request to the licensee holding the data to disseminate the information contained in his or her file; and
- (2) The recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.

(D) The licensee shall make background investigation records obtained under 105 CMR 120.056 through 120.062 available for examination by an authorized representative of the Agency to determine compliance with the regulations and laws.

120.061: continued

(E) The licensee shall retain all fingerprint and criminal history records (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, on an individual for three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

120.062: Access Authorization Program Review

(A) Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements of 105 CMR 120.056 through 120.062 and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. Each licensee shall periodically (at least annually) review the access program content and implementation.

(B) The results of the reviews, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the access authorization program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

(C) Review records must be maintained for three years.

#### PHYSICAL PROTECTION REQUIREMENTS DURING USE

120.063: Security Program

(A) Applicability.

(1) Each licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of 105 CMR 120.063 through 120.071.

(2) An applicant for a new license and each licensee that would become newly subject to the requirements of 105 CMR 120.063 through 120.071 upon application for modification of its license shall implement the requirements of 105 CMR 120.063 through 120.071, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

(3) Any licensee that has not previously implemented the Security Orders or been subject to 105 CMR 120.063 through 120.071 shall provide written notification to the Agency as specified in 105 CMR 120.054 at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

(B) General Performance Objective. Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive material.

(C) Program Features. Each licensee's security program must include the program features, as appropriate, described in 105 CMR 120.064 through 120.070.

120.064: General Security Program Requirements

(A) Security Plan.

(1) Each licensee identified in 105 CMR 120.063(A) shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by 105 CMR 120.063 through 120.071. The security plan must, at a minimum:



120.064: continued

- (a) Describe the measures and strategies used to implement the requirements of 105 CMR 120.063 through 120.071; and
  - (b) Identify the security resources, equipment, and technology used to satisfy the requirements of 105 CMR 120.063 through 120.071.
- (2) The security plan must be reviewed and approved by the individual with overall responsibility for the security program.
  - (3) A licensee shall revise its security plan as necessary to ensure the effective implementation of Agency requirements. The licensee shall ensure that:
    - (a) The revision has been reviewed and approved by the individual with overall responsibility for the security program; and
    - (b) The affected individuals are instructed on the revised plan before the changes are implemented.
  - (4) The licensee shall retain a copy of the current security plan as a record for three years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for three years after the record is superseded.
- (B) Implementing Procedures.
- (1) The licensee shall develop and maintain written procedures that document how the requirements of 105 CMR 120.063 through 120.071 and the security plan will be met.
  - (2) The implementing procedures and revisions to these procedures must be approved in writing by the individual with overall responsibility for the security program.
  - (3) The licensee shall retain a copy of the current procedure as a record for three years after the procedure is no longer needed. Superseded portions of the procedure must be retained for three years after the record is superseded.
- (C) Training.
- (1) Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training must include instruction in:
    - (a) The licensee's security program and procedures to secure category 1 or category 2 quantities of radioactive material, and in the purposes and functions of the security measures employed;
    - (b) The responsibility to report promptly to the licensee any condition that causes or may cause a violation of Agency requirements;
    - (c) The responsibility of the licensee to report promptly to the local law enforcement agency and licensee any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material; and
    - (d) The appropriate response to security alarms.
  - (2) In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of category 1 or category 2 quantities of radioactive material. The extent of the training must be commensurate with the individual's potential involvement in the security of category 1 or category 2 quantities of radioactive material.
  - (3) Refresher training must be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training must include:
    - (a) Review of the training requirements of 105 CMR 120.064(C) and any changes made to the security program since the last training;
    - (b) Reports on any relevant security issues, problems, and lessons learned;
    - (c) Relevant results of Agency inspections; and
    - (d) Relevant results of the licensee's program review and testing and maintenance.
  - (4) The licensee shall maintain records of the initial and refresher training for three years from the date of the training. The training records must include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.
- (D) Protection of Information.
- (1) Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

## 120.064: continued

- (2) Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan and implementing procedures.
- (3) Before granting an individual access to the security plan or implementing procedures, licensees shall:
- (a) Evaluate an individual's need to know the security plan or implementing procedures; and
  - (b) If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in 105 CMR 120.058(A)(2) through (7).
- (4) Licensees need not subject the following individuals to the background investigation elements for protection of information:
- (a) The categories of individuals listed in 105 CMR 120.060(A)(1) through (13); or
  - (b) Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in 105 CMR 120.058(A)(2) through (7), has been provided by the security service provider.
- (5) The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan or implementing procedures.
- (6) Licensees shall maintain a list of persons currently approved for access to the security plan or implementing procedures. When a licensee determines that a person no longer needs access to the security plan or implementing procedures or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to obtain the security plan or implementing procedures.
- (7) When not in use, the licensee shall store its security plan and implementing procedures in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.
- (8) The licensee shall retain as a record for three years after the document is no longer needed:
- (a) A copy of the information protection procedures; and
  - (b) The list of individuals approved for access to the security plan or implementing procedures.

120.065: LLEA Coordination

- (A) A licensee subject to 105 CMR 120.063 through 120.071 shall coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA must include:
- (1) A description of the facilities and the category 1 and category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with 105 CMR 120.063 through 120.071; and
  - (2) A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of material.
- (B) The licensee shall notify the Agency within three business days if:
- (1) The LLEA has not responded to the request for coordination within 60 days of the coordination request; or
  - (2) The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.
- (C) The licensee shall document its efforts to coordinate with the LLEA. The documentation must be kept for three years.

120.065: continued

(D) The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

120.066: Security Zones

(A) Licensees shall ensure that all aggregated category 1 and category 2 quantities of radioactive material are used or stored within licensee-established security zones. Security zones may be permanent or temporary.

(B) Temporary security zones must be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.

(C) Security zones must, at a minimum, allow unescorted access only to approved individuals through:

- (1) Isolation of category 1 and category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the category 1 or category 2 quantities of radioactive material within a security zone; or
- (2) Direct control of the security zone by approved individuals at all times; or
- (3) A combination of continuous physical barriers and direct control.

(D) For category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

(E) Individuals not approved for unescorted access to category 1 or category 2 quantities of radioactive material must be escorted by an approved individual when in a security zone.

120.067: Monitoring, Detection, and Assessment

(A) Monitoring and Detection.

(1) Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees shall provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

(2) Monitoring and detection must be performed by:

- (a) A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility; or
- (b) Electronic devices for intrusion detection alarms that will alert nearby facility personnel; or
- (c) A monitored video surveillance system; or
- (d) Direct visual surveillance by approved individuals located within the security zone; or
- (e) Direct visual surveillance by a licensee designated individual located outside the security zone.

(3) A licensee subject to 105 CMR 120.063 through 120.071 shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide:

- (a) For category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability must be provided by:
  1. Electronic sensors linked to an alarm; or
  2. Continuous monitored video surveillance; or
  3. Direct visual surveillance.

120.067: continued

- (b) For category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.
- (B) Assessment. Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.
- (C) Personnel Communications and Data Transmission. For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessment systems, licensees shall:
- (1) Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and
  - (2) Provide an alternative communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmission systems may not be subject to the same failure modes as the primary systems.
- (D) Response. Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.

120.068: Maintenance and Testing

- (A) Each licensee subject to 105 CMR 120.063 through 120.071 shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of 105 CMR 120.050 through 120.080 must be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no suggested manufacturer's suggested frequency, the testing must be performed at least annually, not to exceed 12 months.
- (B) The licensee shall maintain records on the maintenance and testing activities for three years.

120.069: Requirements for Mobile Devices

Each licensee that possesses mobile devices containing category 1 or category 2 quantities of radioactive material must:

- (A) Have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and
- (B) For devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, the licensee shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

120.070: Security Program Review

- (A) Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of 105 CMR 120.063 through 120.071 and that comprehensive actions are taken to correct any noncompliance that is identified. The review must include the radioactive material security program content and implementation. Each licensee shall periodically (at least annually) review the security program content and implementation.

120.070: continued

(B) The results of the review, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the security program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

(C) The licensee shall maintain the review documentation for three years.

120.071: Reporting of Events

(A) The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the Agency by telephone. In no case shall the notification to the Agency be later than four hours after the discovery of any attempted or actual theft, sabotage, or diversion.

(B) The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than four hours after notifying the LLEA, the licensee shall notify the Agency by telephone.

(C) The initial telephonic notification required by 105 CMR 120.071(A) must be followed within a period of 30 days by a written report submitted to the Agency by an appropriate method listed in 105 CMR 120.054. The report must include sufficient information for Agency analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

PHYSICAL PROTECTION IN TRANSIT

120.072: Additional Requirements for Transfer of Category 1 and Category 2 Quantities of Radioactive Material

A licensee transferring a category 1 or category 2 quantity of radioactive material to a licensee of the Agency, U.S. Nuclear Regulatory Commission, or an Agreement State shall meet the license verification provisions of 105 CMR 120.072(A) through (D) instead of those listed in 105 CMR 120.140(D):

(A) Any licensee transferring category 1 quantities of radioactive material to a licensee of the Agency, U.S. Nuclear Regulatory Commission, or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

(B) Any licensee transferring category 2 quantities of radioactive material to a licensee of the Agency, U.S. Nuclear Regulatory Commission, or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

120.072: continued

(C) In an emergency where the licensee cannot reach the license issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. The certification must include the license number, current revision number, issuing agency, expiration date, and for a category 1 shipment the authorized address. The licensee shall keep a copy of the certification. The certification must be confirmed by use of the NRC's license verification system or by contacting the license issuing authority by the end of the next business day.

(D) The transferor shall keep a copy of the verification documentation as a record for three years.

120.073: Applicability of Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Transit

(A) For shipments of category 1 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in 105 CMR 120.074(A) and (E); 120.075; 120.076(A)(1), (B)(1) and (C); and 120.077(A), (C), (E), (G), and (H).

(B) For shipments of category 2 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in 105 CMR 120.074(B) through (E); 120.076(A)(2) and (3) and (B)(2), and (C); and 120.077(B), (D), (F), (G), and (H). For those shipments of category 2 quantities of radioactive material that meet the criteria of 105 CMR 120.78990(B), the shipping licensee shall also comply with the advance notification provisions of 105 CMR 120.78990.

(C) The shipping licensee shall be responsible for meeting the requirements of 105 CMR 120.072 through 120.077 unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under 105 CMR 120.072 through 120.077.

(D) Each licensee that imports or exports category 1 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in 105 CMR 120.074(A)(2) and (E); 120.075; 120.076(A)(1), (B)(1), and (C); and 120.077(A), (C), (E), (G), and (H) for the domestic portion of the shipment.

(E) Each licensee that imports or exports category 2 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in 105 CMR 120.076(A)(2) and (3), and (B)(2); and 120.077(B), (D), (F), (G), and (H) for the domestic portion of the shipment.

120.074: Pre-planning and Coordination of Shipment of Category 1 or Category 2 Quantities of Radioactive Material

(A) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:

- (1) Pre-plan and coordinate shipment arrival and departure times with the receiving licensee;
- (2) Pre-plan and coordinate shipment information with the governor or the governor's designee of any State through which the shipment will pass to:
  - (a) Discuss the State's intention to provide law enforcement escorts; and
  - (b) Identify safe havens; and
- (3) Document the pre-planning and coordination activities.

(B) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

120.074: continued

(C) Each licensee who receives a shipment of a category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

(D) Each licensee, who transports or plans to transport a shipment of a category 2 quantity of radioactive material, and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to 105 CMR 120.074(B), shall promptly notify the receiving licensee of the new no-later-than arrival time.

(E) The licensee shall retain a copy of the documentation for pre-planning and coordination and any revision thereof, as a record for three years.

120.075: Advance Notification of Shipment of Category 1 Quantities of Radioactive Material

As specified in 105 CMR 120.075(A) and (B), each licensee shall provide advanced notification to the Agency and to the governor of a State, or the governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the State, before the transport, or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

(A) Procedures for Submitting Advance Notification.

(1) The notification must be made to the Agency and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governors' designees, is available on the U.S. Nuclear Regulatory Commission website at <https://scp.nrc.gov/special/designee.pdf>. A list of the contact information is also available upon request from the Director, Division of Material Safety, State, Tribal and Rulemaking programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Notifications to the Agency must be made in accordance with 105 CMR 120.054.

(2) A notification delivered by mail must be postmarked at least seven days before transport of the shipment commences at the shipping facility.

(3) A notification delivered by any means other than mail must reach the Agency at least four days before the transport of the shipment commences and must reach the office of the governor or the governor's designee at least four days before transport of a shipment within or through the State.

(B) Information to be Furnished in Advance Notification of Shipment. Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;

(2) The license numbers of the shipper and receiver;

(3) A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(4) The point of origin of the shipment and the estimated time and date that shipment will commence;

(5) The estimated time and date that the shipment is expected to enter each State along the route;

(6) The estimated time and date of arrival of the shipment at the destination; and

(7) A point of contact, with a telephone number, for current shipment information.

(C) Revision Notice.

(1) The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the State or the governor's designee and to the Agency by an appropriate method listed in 105 CMR 120.054.

(2) A licensee shall promptly notify the governor of the State or the governor's designee of any changes to the information provided in accordance with paragraphs 105 CMR 120.075(B) and (C)(1). The licensee shall also immediately notify the Agency of any such changes.

120.075: continued

(D) Cancellation Notice. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified and to the Agency. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

(E) Records. The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for three years.

(F) Protection of Information. State officials, State employees, and other individuals, whether or not licensees of the Agency, who receive schedule information of the kind specified in 105 CMR 120.075(B) shall protect that information against unauthorized disclosure as specified in 105 CMR 120.064(D).

120.076: Requirements for Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Shipment

(A) Shipments by Road.

(1) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(a) Ensure that movement control centers are established that maintain position information from a remote location. These control centers must monitor shipments 24 hours a day, seven days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies.

(b) Ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication.

(c) Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center must provide positive confirmation of the location, status, and control over the shipment. The movement control center must be prepared to promptly implement pre-planned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

(d) Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver.

(e) Develop written normal and contingency procedures to address:

1. Notifications to the communication center and law enforcement agencies;
2. Communication Protocols. Communication protocols must include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;
3. Loss of communications; and
4. Responses to an actual or attempted theft or diversion of a shipment.

(f) Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

(2) Each licensee that transports category 2 quantities of radioactive material shall maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

(3) Each licensee who delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:



## 120.076: continued

- (a) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.
  - (b) Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and
  - (c) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.
- (B) Shipments by Rail.
- (1) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:
    - (a) Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall implement pre-planned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.
    - (b) Ensure that periodic reports to the communications center are made at preset intervals.
  - (2) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:
    - (a) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.
    - (b) Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and
    - (c) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.
- (C) Investigations. Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall immediately conduct an investigation upon the discovery that a category 1 shipment is lost or missing. Each licensee who makes arrangements for the shipment of category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

120.077: Reporting of Events

- (A) The shipping licensee shall notify the appropriate LLEA and the Agency by telephone within one hour of its determination that a shipment of category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law enforcement agency in the area of the shipment's last confirmed location. During the investigation required by 105 CMR 120.076(C), the shipping licensee will provide agreed upon updates to the Agency on the status of the investigation.
- (B) The shipping licensee shall notify the Agency by telephone within four hours of its determination that a shipment of category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secured, the licensee shall immediately notify the Agency.

## 120.077: continued

(C) The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the Agency by telephone upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of category 1 radioactive material.

(D) The shipping licensee shall notify the Agency by telephone as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a category 2 quantity of radioactive material.

(E) The shipping licensee shall notify the Agency by telephone and the LLEA as soon as possible upon recovery of any lost or missing category 1 quantities of radioactive material.

(F) The shipping licensee shall notify the Agency by telephone as soon as possible upon recovery of any lost or missing category 2 quantities of radioactive material.

(G) The initial telephonic notification required by 105 CMR 120.077(A) through (D) must be followed within a period of 30 days by a written report submitted to the Agency by an appropriate method listed in 105 CMR 120.054. A written report is not required for notifications on suspicious activities required by 105 CMR 120.077(C) and (D). The report must set forth the following information:

- (1) A description of the licensed material involved, including kind, quantity, and chemical and physical form;
- (2) A description of the circumstances under which the loss or theft occurred;
- (3) A statement of disposition, or probable disposition, of the licensed material involved;
- (4) Actions that have been taken, or will be taken, to recover the material; and
- (5) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

(H) Subsequent to filing the written report, the licensee shall also report, by an appropriate method listed in 105 CMR 120.054, any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

## RECORDS

120.078: Form of Records

Each record required by 105 CMR 120.050 through 120.080 must be legible throughout the retention period specified by each Agency regulation. The record may 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. 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.

120.079: Record Retention

Licensees shall maintain the records that are required by the regulations in 105 CMR 120.050 through 120.080 for the period specified by the appropriate regulation. If a retention period is not otherwise specified, these records must be retained until the Agency terminates the facility's license. All records related to 105 CMR 120.050 through 120.080 may be destroyed upon Agency termination of the facility license.

120.080: Appendix A - Category 1 and Category 2 Radioactive Materials

Table 1 - Category 1 and Category 2 Threshold

The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Americium-241.....	60	1,620	0.6	16.2
Americium-241/Be.....	60	1,620	0.6	16.2
Californium-252.....	20	540	0.2	5.40
Cobalt-60.....	30	810	0.3	8.10
Curium-244.....	50	1,350	0.5	13.5
Cesium-137.....	100	2,700	1	27.0
Gadolinium-153.....	1,000	27,000	10	270
Iridium-192.....	80	2,160	0.8	21.6
Plutonium-238.....	60	1,620	0.6	16.2
Plutonium-239/Be.....	60	1,620	0.6	16.2
Promethium-147.....	40,000	1,080,000	400	10,800
Radium-226.....	40	1,080	0.4	10.8
Selenium-75.....	200	5,400	2	54.0
Strontium-90.....	1,000	27,000	10	270
Thulium-170.....	20,000	540,000	200	5,400
Ytterbium-169.....	300	8,100	3	81.0

Note: Calculations Concerning Multiple Sources or Multiple Radionuclides

The "sum of fractions" methodology for evaluating combinations of multiple sources or multiple radionuclides is to be used in determining whether a location meets or exceeds the threshold and is thus subject to the requirements of 105 CMR 120.050 through 120.080.

I. If multiple sources of the same radionuclide and/or multiple radionuclides are aggregated at a location, the sum of the ratios of the total activity of each of the radionuclides must be determined to verify whether the activity at the location is less than the category 1 or category 2 thresholds of Table 1, as appropriate. If the calculated sum of the ratios, using the equation below, is greater than or equal to 1.0, then the applicable requirements of 105 CMR 120.050 through 120.080 apply.

II. First determine the total activity for each radionuclide from Table 1. This is done by adding the activity of each individual source, material in any device, and any loose or bulk material that contains the radionuclide. Then use the equation below to calculate the sum of the ratios by inserting the total activity of the applicable radionuclides from Table 1 in the numerator of the equation and the corresponding threshold activity from Table 1 in the denominator of the equation. Calculations must be performed in metric values (*i.e.*, TBq) and the numerator and denominator values must be in the same units.

120.080: continued

R1 = total activity for radionuclide 1  
 R2 = total activity for radionuclide 2  
 Rn = total activity for radionuclide n  
 AR1 = activity threshold for radionuclide 1  
 AR2 = activity threshold for radionuclide 2  
 ARn = activity threshold for radionuclide n

$$\sum_1^n \left[ \frac{R_1}{AR_1} + \frac{R_2}{AR_2} + \frac{R_n}{AR_n} \right] \geq 1.0$$

## 120.100: LICENSING OF RADIOACTIVE MATERIAL

### 120.101: Purpose and Scope

(A) 105 CMR 120.100, 120.500 and 120.770, provide for the licensing of radioactive material. No person shall manufacture, produce, receive, possess, use, transfer, own, or acquire radioactive material except as authorized pursuant to 105 CMR 120.100, 120.500 or 120.770, or as otherwise provided in 105 CMR 120.000.

(B) In addition to the requirements of 105 CMR 120.100, all licensees are subject to the requirements of 105 CMR 120.000, 120.200, 120.750, and 120.770. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of 105 CMR 120.300; licensees using radionuclides in the healing arts are subject to the requirements of 105 CMR 120.500, licensees engaged in land disposal of radioactive material are subject to the requirements of 105 CMR 120.801 through 120.885, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of 105 CMR 120.900.

### 120.102: Definitions

As used in 105 CMR 120.100, the following definitions apply:

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.

Commencement of Construction means taking any action defined as "construction" or any other activity at the site of a facility subject to 105 CMR 120.100 through 120.198 that has a reasonable nexus to radiological health and safety. Commencement of construction as defined in 105 CMR 120.102 may include non-construction activities if the activity has a reasonable nexus to radiological safety or security.

Construction means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to 105 CMR 120.100 through 120.198 that are related to radiological safety or security. The term "construction" does not include:

- (1) Changes for temporary use of the land for public recreational purposes;
- (2) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
- (3) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;
- (4) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to 105 CMR 120.100 through 120.198;
- (5) Excavation;
- (6) Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

120.102: continued

- (7) Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);
- (8) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or
- (9) Taking any other action that has no reasonable nexus to radiological health and safety.

Decommissioning Funding Plan means a written document that contains a cost estimate for decommissioning and a description of the method for assuring for decommissioning, including means of adjusting cost estimates and associated funding levels periodically over the life of the facility.

Facility means the location within one building, vehicle, or under one roof and under the same administrative control:

- (1) at which the possession, use, processing or storage of radioactive material is or was authorized; or
- (2) at which one or more radioactivity-inducing machines are installed or located.

Facility may also mean multiple such locations at a site or part of a site.

Financial Surety means the method of assuring that sufficient funds will be available at the time of license termination and decommissioning of the facility to cover all costs associated with the decommissioning.

Site means the area contained within the boundary of a location under the control of persons generating or storing radioactive materials.

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.

120.103: Source Material

(A) Any person is exempt from 105 CMR 120.100 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% (0.05%) of the mixture, compound, solution, or alloy.

(B) Any person is exempt from 105 CMR 120.100 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 105 CMR 120.100, **120.200 and 120.750** 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 two grams of thorium;
  - (f) rare earth metals and compounds, mixtures, and products containing not more than 0.25% by weight thorium, uranium, or any combination of these; or
  - (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 **manufactured before August 27, 2013**, provided that the glaze contains not more than 20% by weight source material;
  - (b) glassware containing not more than ~~10%~~ **2%** by weight source material **or, for glassware manufactured before August 27, 2013, 10% by weight source material;** but not including commercially manufactured glass brick, pane glass, ceramic tile, or

other glass or ceramic used in construction;

120.103: continued

- (c) glass enamel or glass enamel frit containing not more than 10% 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; or
- (d) piezoelectric ceramic containing not more than 2% 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% 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 (NRC), authorizing distribution by the licensee pursuant to 10 CFR Part 40;~~
  - (ba)** each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM";<sup>1</sup>
  - (eb)** each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED";<sup>1</sup> and
  - (ec)** 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 1/8 inch (3.2 mm);
- (7) thorium **or uranium** contained in **or on** finished optical lenses **and mirrors**, provided that each lens **or mirror** does not contain more than ~~30%~~ **10%** by weight of thorium **or uranium or, for lenses manufactured before August 27, 2013, 30% by weight of thorium;** and that this exemption shall not be deemed to authorize either:
  - (a) the shaping, grinding, or polishing of such lens **or mirror** or manufacturing processes other than the assembly of such lens **or mirror** into optical systems and devices without any alteration of the lens **or mirror**; or
  - (b) the receipt, possession, use, or transfer of thorium **or uranium** 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 microcurie of uranium; or~~
- (98)** 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% by weight.

(D) The exemptions in 105 CMR 120.103(C) do not authorize the manufacture of any of the products described.

**(E) No person may initially transfer for sale or distribution a product containing source material to persons exempt under 105 CMR 120.103(C), or equivalent regulations of the NRC or an Agreement State, unless authorized by a license issued by the NRC under 10 CFR 40.52 to initially transfer such products for sale or distribution. Persons authorized to manufacture, process, or produce these materials or products containing source material under a specific license issued by the Agency, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued by NRC under 10 CFR 40.52 for distribution only and are exempt from the requirements of 10 CFR 19, 20 and 40.32(b) and (c).**

<sup>1</sup> The requirements specified in 105 CMR 120.103(C)(5)(**ba**) and (**eb**) need not be met by

counterweights manufactured prior to December 31, 1969; provided, that such counterweights **were manufactured under a specific license issued by the Atomic Energy Commission and** are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by 105 CMR 120.000.



120.104: Radioactive Material Other than Source Material(A) Exempt Concentrations.

(1) Except as provided in 105 CMR 120.104(A)(3), and (4), any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing byproduct material introduced in concentrations not in excess of those listed in 105 CMR 120.195: *Appendix A*.

(2) 105 CMR 120.104(A) shall not be deemed to authorize the import of byproduct material or products containing byproduct material.

(3) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in 105 CMR 120.100 to the extent that this person transfers byproduct material contained in a product or material in concentrations not in excess of those specified in 105 CMR 120.195: *Appendix A* and introduced into the product or material by a licensee holding a specific license issued by NRC expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(4) No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 105 CMR 120.104(A) or equivalent regulations of the NRC, or an Agreement State except in accordance with a specific license issued pursuant to 10 CFR 32.11.

(B) Exempt Quantities.

(1) Except as provided in 105 CMR 120.104(B)(2), (3), and (5), any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in individual quantities each of which does not exceed the applicable quantity set forth in 105 CMR 120.196: *Appendix B* Table I provided they have been distributed pursuant to a license as described in 105 CMR 120.104(B)(3).

(2) 105 CMR 120.104(B) does not authorize the production, packaging or repackaging of byproduct material for purposes of commercial distribution, or the incorporation of byproduct material into products intended for commercial distribution.

(3) No person may, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in 105 CMR 120.196: *Appendix B*, Table 1, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under 105 CMR 120.104(B) or equivalent regulations of the NRC, an Agreement State except in accordance with a specific license issued by the NRC pursuant to 10 CFR Part 32, § 32.18 which license states that the byproduct material may be transferred by the licensee to persons exempt under 105 CMR 120.104(B) or the equivalent regulations of the NRC, an Agreement State.<sup>2</sup>

(4) Any person who possesses byproduct material received or acquired prior to September 25, 1971 under the general license then provided in 10 CFR 31.4 or similar general license of a State, is exempt from the requirements for a license set forth in 105 CMR 120.100 if such person possesses, uses, transfers, or owns such byproduct material.

(5) No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by the exemption in 105 CMR 120.104(B) so that the aggregate quantity exceeds the limits set forth in 105 CMR 120.196: *Appendix B* Table I, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by 105 CMR 120.100.

(C) Exempt Items.

(1) Certain Items Containing Byproduct Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, or persons who initially transfer for sale or distribution the following products containing byproduct materials, any person is exempt from 105 CMR 120.100 to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:

<sup>2</sup> Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the Nuclear Regulatory Commission (NRC), Washington, D.C.

## 120.104: continued

(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:

1. 25 millicuries (925 MBq) of tritium per timepiece.
2. five millicuries (185 MBq) of tritium per hand.
3. 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial).
4. 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece.
5. 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand.
6. 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).
7. The radiation dose rate 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 (1  $\mu$ Gy) per hour at ten centimeters from any surface.
  - b. For pocket watches, 0.1 millirad (1  $\mu$ Gy) per hour at one centimeter from any surface.
  - c. For any other timepiece, 0.2 millirad (2  $\mu$ Gy) per hour at ten centimeters from any surface.
8. One microcurie (37 kBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

(b) Precision balances containing not more than one millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before December 17, 2007.

(c) Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas manufactured before December 17, 2007.

(d) Ionization chamber smoke detectors containing not more than 1 microcurie ( $\mu$ Ci) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(e) Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of byproduct material:

1. 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube.
2. 1 microcurie (37 kBq) of cobalt-60.
3. 5 microcuries (185 kBq) of nickel-63.
4. 30 microcuries (1.11 MBq) of krypton-85.
5. 5 microcuries (185 kBq) of cesium-137.
6. 30 microcuries (1.11 MBq) of promethium-147.

And provided further, that the radiation dose rate from each electron tube containing byproduct material will not exceed one millirad (ten  $\mu$ Gy) per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber. For purposes of 105 CMR 120.104(C)(1)(e), "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.

(f) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:

1. Each source contains no more than one exempt quantity set forth in 105 CMR 120.196: *Appendix B, Table 1*; and

120.104: continued

2. Each instrument contains no more than ten 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 105 CMR 120.196: *Appendix B, Table 1*, provided that the sum of such fractions shall not exceed unity.
3. For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under 105 CMR 120.104(C)(1)(f).

- (g) 1. Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 µCi) of polonium-210 per device.**
- 2. Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 µCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.**
- 3. Such devices authorized before October 23, 2012 for use under the general license then provided in 105 CMR 120.122(A) and equivalent regulations of the U.S. Nuclear Regulatory Commission and Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission.**

**(gh)** Any person who desires to apply byproduct material to, or to incorporate byproduct material into, the products exempted in 105 CMR 120.104(C)(1), or who desires to initially transfer for sale or distribution such products containing byproduct material, should apply to the Nuclear Regulatory Commission for a specific license pursuant to 10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to 105 CMR 120.104(C)(1) or equivalent regulations of the Nuclear Regulatory Commission, 10 CFR 30.15(a).

**(2) Self-luminous Products Containing Radioactive Material.**

**(a) Tritium, Krypton-85, or Promethium-147.** Except for persons who manufacture, process, or produce, **or initially transfer for sale or distribution** self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from 105 CMR 120.100 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 **initially** transferred in accordance with a specific license issued by the NRC pursuant to 10 CFR Part 32, § 32.22 which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. **Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under 105 CMR 120.104(C)(2), should apply to the NRC for a license under 10 CFR 32.22 and for a certificate of registration in accordance with 105 CMR 120.128(N).** The exemption in 105 CMR 120.104(C)(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

**(b) Radium-226.** Any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium-226 which were acquired prior to March 11, 1994.

**(3) Gas and Aerosol Detectors Containing Radioactive Material.**

**(a)** Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirement of a license set forth in 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect ~~life~~ **health, safety,** or property ~~from fires and airborne hazards~~ provided that detectors containing byproduct material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 32, § 32.26, which license authorizes the initial transfer of the product for use under 105 CMR 120.104(C)(3). 105 CMR 120.104(C)(3) also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a State under comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

**(b)** Any person who desires to manufacture, process, or produce gas and aerosol

detectors containing byproduct material, or to initially transfer such products for use pursuant 105 CMR 120.104(C)(3)(a), should apply **to the NRC** for a license pursuant to 10 CFR 32.26; **and for a certificate of registration in accordance with 105 CMR 120.128(N)**. ~~which license states that the product may be initially transferred by the licensee to persons exempt from the regulations pursuant to 105 CMR 120.104(C)(3)(a) or equivalent regulations of an Agreement State.~~

(4) Radioactive Drug: Capsules Containing Carbon-14 Urea for *In Vivo* Diagnostic Use for Humans.

(a) Except as provided in 105 CMR 120.104(C)(4)(b) and (c), any person is exempt from the requirements for a license set forth in M.G.L. c. 111, § 5P and from 105 CMR 120.100 and 120.500 provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 $\mu$  Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for *in vivo* diagnostic use for humans.

(b) Any persons who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to 105 CMR 120.500.

(c) Any person who desires to manufacture, prepare, process, produce, package, or transfer for commercial distribution such capsules shall apply, to NRC, for and receive a specific license pursuant to 10 CFR 32.21.

## 120.104: continued

(d) Nothing in 105 CMR 120.104(C)(4) relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

**(5) Certain Industrial Devices.**

**(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material 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 an ionized atmosphere, any person is exempt from the requirement of a license set forth in 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the NRC under 10 CFR 32.30, which license authorizes the initial transfer of the device for use under 105 CMR 120.104(C)(5). This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.**

**(b) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use pursuant 105 CMR 120.104(C)(5), should apply to the NRC for a license under 10 CFR 32.30 and for a certificate of registration in accordance with 105 CMR 120.128(N).**

120.120: Types of Licenses

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

(A) The Agency issues a specific license to a named person who has filed an application for the license under the provisions of 105 CMR 120.124.

(B) A general license is provided by regulation, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the Agency or the issuance of a licensing document to a particular person. However, registration with the Agency may be required by the particular general license.

120.121: 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 **receive, possess, use, and transfer not more than 15 pounds (6.82 kg) of source material at any one time uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium**, for research, development, educational, commercial, or operational purposes **in the following forms and quantities:** ~~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.~~

**(1) No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under 105 CMR 120.121(A)(1) may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year; and**

**(2) No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under 105 CMR 120.121(A)(2) may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under 105 CMR 120.121(A)(2) unless it is accounted for under the limits of 105 CMR 120.121(A)(1); or**

**(3) No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under 105 CMR 120.121(A)(3); or**

**(4) No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under 105 CMR 120.121(A)(4) may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.**

~~(B) Persons~~ **Any person** who receives, possesses, uses, or transfers source material pursuant to the general license issued in 105 CMR 120.121(A): ~~are exempt from the provisions of 105 CMR 120.200 and 120.750 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 105 CMR 120.100.~~

**(1) Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Agency in a specific license.**

**(2) Shall not abandon such source material. Source material may be disposed of as follows:**

**(a) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of 105 CMR 120.121(B)(2)(a) is exempt from the requirements to obtain a license under 105 CMR 120.100 to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under 105 CMR 120.100; or**

**(b) In accordance with 105 CMR 120.251.**

**(3) Is subject to the provisions in 105 CMR 120.001 through 120.019, 120.101(A), 120.131(A) through (C), 120.140, 120.142, and 120.150.**

**(4) 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 person cannot provide the requested information within the allotted time, the person shall, within that same time period, request a longer period to supply the information by providing the Agency, using an appropriate method listed in 105 CMR 120.013, a written justification for the request;**

**(5) Shall not export such source material except in accordance with 10 CFR Part 110.**

~~(C) Persons who receive, possess, use, or transfer source material pursuant to the general license in 105 CMR 120.121(A) are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Agency in a specific license.~~

**(C) Any person who receives, possesses, uses, or transfers source material in accordance with 105 CMR 120.121(A) shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Agency by an appropriate method listed in 105 CMR 120.013 about such contamination and may consult with the Agency as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in 105 CMR 120.245.**

(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 105 CMR 120.121(E)(2) through (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 105 CMR 120.121(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 105 CMR 120.128(M) 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 105 CMR 120.121(E)(1) shall file form MRCP 120.100-1 "Certificate - Use of Depleted Uranium Under General License", with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The general licensee shall furnish on form MRCP 120.100-1 the following information and such other information as may be required by that form:
1. name and address of the general licensee;

120.121: continued

2. a statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 105 CMR 120.121(E)(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
  3. name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in 105 CMR 120.121(E)(3)(a)2.
- (b) The general licensee possessing or using depleted uranium under the general license established by 105 CMR 120.121(E)(1) shall report in writing to the Agency any changes in information furnished by him in form MRCP 120.100-1 "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 105 CMR 120.121(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;



NON-TEXT PAGE

120.121: continued

- (c) shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 105 CMR 120.140. In the case where the transferee receives the depleted uranium pursuant to the general license established by 105 CMR 120.121(E)(1), the transferor shall furnish the transferee a copy of 105 CMR 120.100 and a copy of form MRCP 120.100-1. 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 regulation equivalent to 105 CMR 120.121(E)(1), the transferor shall furnish the transferee a copy of 105 CMR 120.100 and a copy of form MRCP 120.100-1 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 105 CMR 120.100;
- (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; and,
- (e) shall not export such depleted uranium except in accordance with a 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 105 CMR 120.121(E)(1) is exempt from the requirements of 105 CMR 120.200 and 120.750 with respect to the depleted uranium covered by that general license.

**(F) Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in 105 CMR 120.121(A) is exempt from the provisions of 105 CMR 120.200 and 120.750 to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of 105 CMR 120.245 and 120.251 to the extent necessary to meet the provisions of 105 CMR 120.121(B)(2) and 120.121(C). However, this exemption does not apply to any person who also holds a specific license issued under 105 CMR 120.100.**

**(G) No person may initially transfer or distribute source material to persons generally licensed under 105 CMR 120.121(A)(1) or (2), or equivalent regulations of the NRC or an Agreement State, unless authorized by a specific license issued in accordance with 105 CMR 120.128(B) or equivalent provisions of the NRC or an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample.**

#### 120.122: General Licenses - Radioactive Material Other Than Source Material

(A) **Requirements for Other General Licenses (Reserved).** ~~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 10 CFR Part 31, § 31.3. This general license is subject to the provisions of 105 CMR 120.001 through 120.016, 120.104(A)(2), 120.131, 120.140, 120.150 and 120.200, 120.750, and 120.770. Attention is directed particularly to the provisions of 105 CMR 120.200 which relate to the labeling of containers:~~

~~(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 (18.5 MBq) 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 (18.5 MBq) of polonium-210 per device or a total of not more than 50 millicuries (1.85 GBq) of hydrogen-3 (tritium) per device:~~

(B) 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 (370 GBq) of tritium or 300 millicuries (11.1 GBq) 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

105 CMR: DEPARTMENT OF PUBLIC HEALTH

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 10 CFR Part 32, § 32.53.

(2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 105 CMR 120.122(B)(1) are exempt from the requirements of 105 CMR 120.200 through 120.299 and 120.750 through 120.760 except that they shall comply with the provisions of 105 CMR 120.281 and 120.282.

(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 105 CMR 120.005 through 120.016, 120.131, 120.140, 120.150, and 120.770 through 120.795~~8~~.

(C) Requirements for Other General Licenses (Reserved).

120.122: continued

(D) 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 research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to acquire, receive, possess, use or transfer in accordance with the provisions of 105 CMR 120.122(D)(2) through (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)(a) The general license in 105 CMR 120.122(D)(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:
1. a specific license issued by the Agency pursuant to 105 CMR 120.128(D); or
  2. an equivalent specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or an equivalent specific license issued by a State with provisions comparable to 105 CMR 120.128(D).
- (b) The devices must have been received from one of the specific licensees described in 105 CMR 120.122(D)(2)(a) or through a transfer made under 105 CMR 120.122(D)(3)(i).
- (3) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in 105 CMR 120.122(D)(1):
- (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,
    1. devices containing only krypton need not be tested for leakage of radioactive material; and
    2. devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta and/or gamma-emitting material or ten microcuries (0.37 MBq) 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 the tests required under 105 CMR 120.122(D)(3)(b) and other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:
    1. in accordance with the instructions provided by the labels; or
    2. by a person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform such activities;
  - (d) shall maintain records showing compliance with the requirements of 105 CMR 120.122(D)(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. The licensee shall retain these records as follows:
    1. each record of a test for leakage of radioactive material required by 105 CMR 120.122(D)(3)(b) shall be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of;
    2. each record of a test of the "on-off" mechanism and indicator required by 105 CMR 120.122(D)(3)(b) shall be retained for three years after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of; and
    3. each record that is required by 105 CMR 120.122(D)(3)(c) shall be maintained for a period of three years from the date of the recorded event or until the device is transferred or disposed of;

120.122: continued

- (e) shall immediately suspend operation of the device if there is 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 185 Bq (0.005 microcurie) or more removable radioactive material. The device shall not be operated 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, or an Agreement State to repair such devices. The device and any radioactive material from the device shall only be disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device or as otherwise approved by 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 radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Agency within 30 days. Under these circumstances, the criteria set out in 105 CMR 120.243: *Vacating Premises*, may be applicable, as determined by the Agency on a case-by-case basis;
- (f) shall not abandon the device containing radioactive material;
- (g) shall not export the device containing radioactive material except in accordance with 10 CFR110;
- (h) 1. shall transfer or dispose of the device containing radioactive material only by export as provided in 105 CMR 120.122(D)(3)(g), by transfer to another general licensee as authorized in 105 CMR 120.122(D)(3)(i), or to a person authorized to receive the device by a specific license issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State that authorizes waste collection or as otherwise approved under 105 CMR 120.122(D)(3)(h)3.
2. shall furnish a report to the Agency within 30 days after the transfer of a device to a specific licensee or export. The report shall contain:
- the identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;
  - the name, address, and license number of the person receiving the device (license number not applicable if exported); and
  - the date of the transfer.
3. shall obtain written Agency approval before transferring the device to any other specific licensee not specifically identified in 105 CMR 120.122(D)(3)(h)1.; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:
- Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;
  - Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by 105 CMR 120.122(D)(3)(a)) so that the device is labeled in compliance with 105 CMR 120.240; however the manufacturer, model number, and serial number must be retained;
  - Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and
  - Reports the transfer under 105 CMR 120.122(D)(3)(h)2.
- (i) shall transfer the device to another general licensee only if:
- the device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of 105 CMR 120.122(D), a copy of 120.122, 120.009, 120.281, and 120.282, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Agency:
    - the manufacturer's (or initial transferor's) name;
    - the model number and the serial number of the device transferred;
    - the transferee's name and mailing address for the location of use; and
    - the name, title, and phone number of the responsible individual identified by the transferee in accordance with 105 CMR 120.122(D)(3)(l) to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or
  - 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;

120.122: continued

- (j) shall comply with the provisions of 105 CMR 120.281 and 120.282 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of 105 CMR 120.200 and 120.750;
- (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 Director, Radiation Control Program, Massachusetts Department of Public Health, 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) 1. shall register, in accordance with 105 CMR 120.122(D)(3)(m)2. and 3., devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 MBq (0.1 mCi) radium-226, or 37 MBq (1 mCi) of americium-241 or any other transuranic (*i.e.*, element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under 105 CMR 120.122(D)(3)(m)3.d. represents a separate general licensee and requires a separate registration and fee;
2. if in possession of a device meeting the criteria of 105 CMR 120.122(D)(3)(m)1., shall register these devices annually with the Agency and shall pay any prescribed fee. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Agency. The registration information must be submitted to the Agency within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of 105 CMR 120.122(D)(3)(m)1. is subject to the bankruptcy notification requirement in 105 CMR 120.131(E);
3. in registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Agency:
- name and mailing address of the general licensee;
  - information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label);
  - name, title, and telephone number of the responsible person designated as a representative of the general licensee under 105 CMR 120.122(D)(3)(l);
  - address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage;
  - certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information;
  - certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.
4. persons generally licensed by an Agreement State, or NRC with respect to devices meeting the criteria in 105 CMR 120.122(D)(3)(m)1. are not subject to registration requirements if the devices are used in areas subject to Agency jurisdiction for a period less than 180 days in any calendar year. The Agency will not request registration information from such licensees.
- (n) shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Director, Radiation Control Program, Massachusetts Department of Public Health, 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;

120.122: continued

- (o) may not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by 105 CMR 120.122(D)(3)(b) 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 105 CMR 120.122(D)(1) does not authorize the manufacture or import of devices containing radioactive material.

[*Note:* Persons possessing radioactive material in devices under a general license in 10 CFR 31.5 before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of 10 CFR 31.5 in effect on January 14, 1975.]

- (E) General License for Certain Items and Self-luminous Products Containing Radium-226.
- (1) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of 105 CMR 120.122(E)(2), (3), and (4), radium-226 contained in the following products manufactured prior to November 30, 2007.
- (a) Antiquities originally intended for use by the general public. For the purposes of 105 CMR 120.122(E)(1)(a), antiquities mean products originally intended for use by the general public and distributed in the late 19<sup>th</sup> and early 20<sup>th</sup> centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.
- (b) Intact timepieces containing greater than 0.037 megabecquerel (one microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.
- (c) Luminous items installed in air, marine, or land vehicles.
- (d) All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.
- (e) Small radium sources containing no more than 0.037 megabecquerel (one microcurie) of radium-226. For the purposes of 105 CMR 120.122(E)(1)(e), "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC.
- (2) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in 105 CMR 120.122(E)(1) are exempt from the provisions of 105 CMR 120.750, 120.200, and 120.142 and 120.009, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under 105 CMR 120.100.
- (3) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in 105 CMR 120.122(E)(1):
- (a) Shall notify the Agency should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director of the Agency within 30 days.
- (b) Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 105 CMR 120.256 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the Agency
- (c) Shall not export products containing radium-226 except in accordance with 10 CFR 110.
- (d) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued by the Agency, Nuclear Regulatory Commission, or an Agreement State, or as otherwise approved by the Agency.

120.122: continued

- (e) 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 providing the Director of the Agency, a written justification for the request.
- (4) The general license in 105 CMR 120.122(E)(1) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.
- (F) Ownership of Radioactive Material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of 105 CMR 120.122, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.
- (G) 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 105 CMR 120.122(G)(4) and (5), americium-241 in the form of calibration or reference sources:
- any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material; and
  - 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 105 CMR 120.122(G)(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 105 CMR 120.122(G)(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 105 CMR 120.122(G)(1) through (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 10 CFR Part 32, § 32.57 or 10 CFR Part 70, § 70.39 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 10 CFR Part 32, § 32.57 or 10 CFR Part 70, § 70.39.
- (5) The general licenses provided in 105 CMR 120.122(G)(1) through (3) are subject to the provisions of 105 CMR 120.005 through 120.016, 120.131, 120.140, 120.150, and 120.770. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:
- shall not possess at any one time, at any one location of storage or use, more than five microcuries (185 kBq) of americium-241, five microcuries (185 kBq) of plutonium, or five microcuries (185 kBq) of radium-226 in such sources;
  - 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:
    - 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 U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.



120.122: continued

CAUTION - RADIOACTIVE MATERIAL  
THIS SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM)<sup>3</sup>.  
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

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Name of Manufacturer or Importer

2. The receipt, possession, use and transfer of this source, Model \_\_\_\_\_, Serial No. \_\_\_\_\_, are subject to a general license and the regulations of a Licensing State. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL  
THIS SOURCE CONTAINS RADIUM-226.  
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

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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,
  - (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.

(H) Requirements for Other General Licenses (Reserved).

(I) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.<sup>4</sup>

- (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 105 CMR 120.122(I)(2) through (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 therefrom, to human beings or animals:
- (a) Carbon-14, in units not exceeding ten microcuries (370 kBq) each.
  - (b) Cobalt-57, in units not exceeding ten microcuries (370 kBq) each.
  - (c) Hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each.
  - (d) Iodine-125, in units not exceeding ten microcuries (370 kBq) each.
  - (e) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.
  - (f) Iodine-131, in units not exceeding ten microcuries (370 kBq) each.
  - (g) Iron-59, in units not exceeding 20 microcuries (740 kBq) each.
  - (h) Selenium-75, in units not exceeding ten microcuries (370 kBq) each.
- (2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 105 CMR 120.122(I)(1) until he has filed form MRCP 120.100-2, "Certificate - *In Vitro* Testing with Radioactive Material Under General License", with the Agency and received from the Agency a validated copy of form MRCP 120.100-2 with certification number assigned, or, has a license that authorizes the medical use of radioactive material that was issued under 105 CMR 120.500. The physician, veterinarian, clinical laboratory or hospital shall furnish on form MRCP 120.100-2 the following information and such other information as may be required by that form:

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<sup>3</sup> Showing only the name of the appropriate material.

<sup>4</sup> The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

120.122: continued

- (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 105 CMR 120.122(I)(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 105 CMR 120.122(I)(1) shall comply with the following:
- (a) The general licensee shall not possess at any one time, pursuant to the general license in 105 CMR 120.122(I)(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 (7.4 MBq).
  - (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 105 CMR 120.122(I)(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 105 CMR 120.122(I)(1)(e) as required by 105 CMR 120.251.
- (4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 105 CMR 120.122(I)(1):
- (a) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 105 CMR 120.128(H) 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 105 CMR 120.122(I) 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:
    - 1. 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 therefrom, 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.

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Name of Manufacturer

- 2. 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 therefrom, 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.

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Name of Manufacturer

## 120.122: continued

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 105 CMR 120.122(I)(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", form MRCP 120.100-2. 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 105 CMR 120.122(I)(1) is exempt from the requirements of 105 CMR 120.200 and 120.750 with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 105 CMR 120.122(I)(1)(e) shall comply with the provisions of 105 CMR 120.251, 120.281 and 120.282.

(J) 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 (1.85 MBq) 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 an Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in 10 CFR Part 32, § 32.61.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 105 CMR 120.122(J)(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 105 CMR 120.251;

(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 105 CMR 120.200 and 120.750 except that such persons shall comply with the provisions of 105 CMR 120.251, 120.281 and 120.282.

(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 105 CMR 120.001 through 120.019, 120.131, 120.140, 120.150, and 120.770.

120.124: Filing Application for Specific Licenses

(A) Applications for specific licenses shall be filed in duplicate on form MRCP 120.100-4 as 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 application should be granted or denied or whether a 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 his or her behalf.

(D) An application for a license may include a request for a license authorizing one or more activities. The Agency will not grant the request if the proposed activities are not under the control of the same facility, administrator and radiation safety officer. In addition, when evaluating the request, the Agency will consider complexity, similarity and proximity of the proposed activities.

## 120.124: continued

(E) In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Agency provided such references are clear and specific.

(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)(1) Except as provided in 105 CMR 120.124(G)(2), (3), and (4),** An application for a specific license to authorize receipt, possession or use of radioactive material in the form of a sealed source or in a device that contains a sealed source shall either:

~~(1a)~~ identify the sealed source or device that contains a sealed source by manufacturer and model number as registered in the U.S. Nuclear Regulatory Commission "Registry of Radioactive Sealed Sources and Devices" **with the Agency** under ~~10 CFR 32.210~~ **105 CMR 120.128(N)**, with **the NRC** or an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to 105 CMR 120.128(N); **or**

~~(2b)~~ contain the information identified in 105 CMR 120.128(N)~~(3)~~;

~~(32)~~ for sources or devices ~~containing naturally occurring or accelerator-produced radioactive material~~ manufactured prior to ~~November 30, 2007~~ **October 23, 2012** that are not registered with ~~NRC~~ **the Agency** under ~~10 CFR 32.210~~ **105 CMR 120.128(N)** or with **the NRC** or an Agreement State, and for which the applicant is unable to provide all categories of information specified in 105 CMR 120.128(N)~~(3)(2)(b) or (c)~~ as applicable, the applicant must provide:

(a) All available information identified in 105 CMR 120.128(N)~~(3)(2)(b) or (c)~~ concerning the source, and, if applicable, the device; and,

(b) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

**(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 105 CMR 120.128(N)(7)(a), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.**

**(4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.**

120.125: General Requirements for the Issuance of Specific Licenses

(A) A license application will be approved only if the Agency determines that:

(1) the applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with 105 CMR 120.000 in such a manner as to minimize danger to public health and safety or property;

(2) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

(3) the issuance of the license will not be inimical to the health and safety of the public; and,

(4) the applicant satisfies any applicable special requirements in 105 CMR 120.050 through 120.080, 120.126, 120.127, 120.128, 120.300, 120.500, 120.620 120.800, 120.890 and 120.900.

(B) Environmental Report, Commencement of Construction.

(1) In the case of an application for a license to receive and possess radioactive material for commercial waste disposal, or for the conduct of any other activity which the Agency determines will significantly affect the quality of the environment, a license application shall be reviewed and approved by the Agency before commencement of construction of the plant or facility in which the activity will be conducted. Issuance of the license shall be based upon a consideration by the Agency of the environmental, economic, technical and other

benefits in comparison with the environmental costs and available alternatives and a determination that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values;

(2) 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.

120.125: continued

(C) Financial Surety Arrangements and Recordkeeping for Decommissioning.

(1) Unless exempted by 105 CMR 120.125(C)(3), issuance, renewal or amendment of a license shall be dependent upon satisfactory financial surety arrangements to ensure the protection of the public health and safety in the event of abandonment, default or other inability of the licensee to meet the requirements of M.G.L. c. 111H, § 9 and 105 CMR 120.000.

(2) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material with a half-life greater than 120 days and in quantities exceeding  $10^5$  times the applicable quantities set forth in 105 CMR 120.196: *Appendix B*, Table II shall submit a decommissioning funding plan as described in 105 CMR 120.125(C)(6). 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 as the sum of the ratios of the quantity of each isotope to the applicable value in 105 CMR 120.196: *Appendix B*, Table II.

(3) Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in 105 CMR 120.125(C)(5) shall either:

(a) submit a decommissioning funding plan as described in 105 CMR 120.125(C)(6); or

(b) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 105 CMR 120.125(C)(5) using one of the methods described in 105 120.125(C)(7). 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. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of 105 CMR 120.125(C)(7) is to be submitted to the Agency.

(4) (a) Each holder of a specific license issued on or after March 11, 1994, which is of a type described in 105 CMR 120.125(C)(2) or (3), shall provide financial assurance for decommissioning in accordance with the criteria set forth in 105 CMR 120.125(C)(1) through (8).

(b) Each holder of a specific license issued before March 11, 1994, and of a type described in 105 CMR 120.125(C)(2) shall submit, on or before March 11, 1995, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to \$1,125,000, in accordance with the criteria set forth in this part. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

(c) Each holder of a specific license issued before March 11, 1994, and of a type described in 105 CMR 120.125(C)(3) shall submit, on or before March 11, 1995, a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in 105 CMR 120.125(C)(1) through (8).

(d) Waste collectors and waste processors, as defined in 10 CFR part 20, Appendix G must establish an Agency-approved decommissioning funding plan to assure the availability of funds for decommissioning activities conducted over the life of the licensed facility. The decommissioning funding plan must include the cost of disposal of the maximum radioactivity (curies) of radioactive material permitted by the license, and the cost of disposal of the maximum quantity, by volume, of radioactive material that could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of 105 CMR 120.200. The decommissioning funding plan must be submitted by April 6, 2007.

**(e) If, in surveys made under 105 CMR 120.225(A), residual radioactivity in the facility and environment, including the subsurface, is detected at levels that would, if left uncorrected, prevent the site from meeting the 105 CMR 120.245 criteria for unrestricted use, the licensee must submit a decommissioning funding plan within one year of when the survey is completed.**

120.125: continued

(5) Table of Required Amounts of Financial Assurance for Decommissioning by Quantity of Material:

-1	Greater than $10^4$ but less than or equal to $10^5$ times the applicable quantities in 105 CMR 120.196: <i>Appendix B</i> , Table II in unsealed form. (For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2), divided by $10^4$ is greater than 1 but R divided by $10^5$ is less than or equal to 1.)	\$1,125,000
-2a	Greater than $10^3$ but less than or equal to $10^4$ times the applicable quantities in 105 CMR 120.196: <i>Appendix B</i> , Table II in unsealed form. (For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2), divided by $10^3$ is greater than 1 but R divided by $10^4$ is less than or equal to 1.)	\$225,000
-2b	Greater than 10 mCi but less than 100 mCi of source material	\$225,000
-3	Greater than $10^{10}$ times the applicable quantities in 105 CMR 120.196: <i>Appendix B</i> , Table II in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2), divided by $10^{10}$ is greater than 1.)	\$113,000

(a) Licensees required to submit the \$1,125,000 amount must do so by October 6, 2006.

(b) Licensees required to submit the \$113,000 or \$225,000 amount must do so by April 6, 2007.

~~(6) Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from 105 CMR 120.125(C)(7), including means of adjusting cost estimates and associated funding levels periodically over the life of the facility. Cost estimates must be adjusted at intervals not to exceed three years. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of 105 CMR 120.125(C)(7).~~

**(6) (a) Each decommissioning funding plan must be submitted for review and approval and must contain:**

- 1. A detailed cost estimate for decommissioning, in an amount reflecting:**
  - a. The cost of an independent contractor to perform all decommissioning activities;**
  - b. The cost of meeting the 105 CMR 120.245 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 105 CMR 120.246, the cost estimate may be based on meeting the 105 CMR 120.246 criteria;**
  - c. The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and**
  - d. An adequate contingency factor.**
- 2. Identification of and justification for using the key assumptions contained in the cost estimate for decommissioning;**
- 3. A description of the method of assuring funds for decommissioning from 105 CMR 120.125(C)(7), including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;**
- 4. A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and**
- 5. A signed original of the financial instrument obtained to satisfy the requirements of 105 CMR 120.125(C)(7) (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).**

**(b) At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. The decommissioning funding**

**plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:**

- 1. Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;**
- 2. Waste inventory increasing above the amount previously estimated;**
- 3. Waste disposal costs increasing above the amount previously estimated;**
- 4. Facility modifications;**
- 5. Changes in authorized possession limits;**
- 6. Actual remediation costs that exceed the previous cost estimate;**
- 7. Onsite disposal; and**
- 8. Use of a settling pond.**

**(7) The financial instrument must include the licensee's name, license number, and docket number, and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. The financial instrument submitted must be a signed original or signed original duplicate, except where a copy of the signed original is specifically permitted.** Financial assurance for decommissioning 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 such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment ~~may~~ **must** be in the form of **made into** a trust **account**, ~~escrow account, government fund, certificate of deposit, or deposit of government securities~~ **and the trust must be acceptable to the Agency.**

(b) A Surety Method, Insurance or other Guarantee Method. ~~A surety method, insurance or other guarantee method.~~ These methods guarantee that decommissioning costs will be paid should the licensee default.

1. A surety method may be in the form of a surety bond, issued by a corporate surety company authorized to transact business in the commonwealth; or **an irrevocable letter of credit.**

~~2. An irrevocable letter of credit, or line of credit; or~~

~~3. A parent company guarantee of funds for decommissioning costs may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix D*. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of 105 CMR 120.125(C).~~

~~a~~**3.** For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix E*.

~~b~~**4.** For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix F*.

~~e~~**5.** For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix G*.



120.125: continued

**46.** Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

- a. The surety method 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 method or insurance must also provide that the full face amount be paid to the beneficiary automatically 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.
- b. The surety method or insurance must be payable to a trust 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 that has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.
- c. The surety method or insurance must remain in effect until the Agency has terminated the license.

(c) An External Sinking Fund. 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 setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund ~~may~~ **must** be in the form of a trust, ~~escrow account, government fund, certificate of deposit, or deposit of government securities.~~ **If the other guarantee method is used, no surety or insurance may be combined with the external sinking fund.** The surety or insurance provisions must be as stated in 105 CMR 120.125(C)(7)(b).

(d) Statement of Intent. In the case of federal, state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount pursuant to 105 CMR 120.125(C)(5), and indicating that funds for decommissioning will be obtained when necessary.

(8) Each person licensed under 105 CMR 120.100 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. 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:

- (a) 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.
- (b) 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 that 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.
- (c) 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 two years, of the following:
  1. all areas designated and formerly designated restricted areas as defined in 105 CMR 120.005;
  2. all areas outside of restricted areas that require documentation under 105 CMR 120.125(C)(8)(a);
  3. all areas outside of restricted areas where current and previous wastes have been buried as documented under 105 CMR 120.269; and,

## 120.125: continued

4. all areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under 105 CMR 120.252.
- (d) 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) The following specific licensees are required to make financial surety arrangements:
  - (a) major processors;
  - (b) waste handling licensees;
  - (c) former U.S. Atomic Energy Commission or NRC licensed facilities; and,
  - (d) all others except persons exempt pursuant to 105 CMR 120.125(C)(10).
- (10) The following persons are exempt from the requirements of 105 CMR 120.125(C)(1):
  - (a) persons authorized to possess no more than 1,000 times the quantity specified in 105 CMR 120.196: *Appendix B, Table 1* or combination of radioactive material listed therein as given in 105 CMR 120.196: *Appendix B, Table 1, Note 1*;
  - (b) persons authorized to possess radioactive noble gases in sealed sources with no radioactive daughter product with half-life greater than 30 days.

120.126: Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material

Uses of Sealed Sources in Industrial Radiography. In addition to the requirements set forth in 105 CMR 120.125, 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 radiographic personnel 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; and,
  - (d) means to be used by the licensee to determine the radiographic personnel's knowledge and understanding of and ability to comply with Agency regulations and licensing requirements, and 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 105 CMR ~~120.360~~ **120.325**;
- (3) the applicant will have an internal inspection system adequate to assure that 105 CMR 120.001, 120.020, 120.200, 120.300, 120.750, 120.770, license provisions, and the applicant's operating and emergency procedures are followed by radiographic personnel; the inspection system shall include the performance of internal inspections at intervals not to exceed three months and the retention of records of such inspections for five years;
- (4) the applicant submits to the Agency a description of the 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 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; and,
  - (c) pertinent experience of the individual 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.

120.127: Special Requirements for Specific Licenses of Broad Scope

105 CMR 120.127 prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of such licenses.

120.127: continued

- (A) The different types of broad scope licenses are set forth in 105 CMR 120.127(A):
- (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 multicurie range.
  - (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 105 CMR 120.197: *Appendix C*, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 105 CMR 120.197: *Appendix C*, Column I. If two or more radionuclides are possessed thereunder, 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 105 CMR 120.197: *Appendix 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 105 CMR 120.197: *Appendix C*, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 105 CMR 120.197: *Appendix C*, Column II. If two or more radionuclides are possessed thereunder, 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 105 CMR 120.197: *Appendix 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 105 CMR 120.125;
  - (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:
      1. control of procurement and use of radioactive material;
      2. 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,
      3. review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 105 CMR 120.127(B)(3)(c)2. 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 105 CMR 120.125; 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

120.127: continued

- (b) the establishment of appropriate administrative procedures to assure;
  1. control of procurement and use of radioactive material;
  2. 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,
  3. review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with 105 CMR 120.127(C)(2)(b)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 105 CMR 120.125;
  - (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 105 CMR 120.127 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 (3.7 PBq) 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 105 CMR 120.126, 120.128 or 120.500, and 120.800 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 105 CMR 120.127 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 105 CMR 120.127 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 105 CMR 120.127(D).

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

- (A) Licensing Requirements to Produce for Noncommercial Transfer Positron Emission Tomography (PET) Radioactive Drugs. An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under 105 CMR 120.500, or equivalent Nuclear Regulatory Commission, or Agreement State requirements shall include:

120.128: continued

- (1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under 105 CMR 120.100 or equivalent Nuclear Regulatory Commission, or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.
- (2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 105 CMR 120.128(J)(1)(b).
- (3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in 105 CMR 120.128(J)(2)(b).
- (4) Information identified in 105 CMR 120.128(J)(1)(c) on the PET drugs to be noncommercially transferred to members of its consortium.

**(B) Licensing Requirements to Initially Transfer Source Material to Persons Generally Licensed Under 105 CMR 120.121(A).**

- (1) An application for a specific license to initially transfer source material for use under 105 CMR 120.121(A), or equivalent regulations of the NRC or an Agreement State, will be approved if:
  - (a) The applicant satisfies the general requirements specified in 105 CMR 120.125; and
  - (b) The applicant submits adequate information on, and the Agency approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.
- (2) Each person licensed under 105 CMR 120.128(B) shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, “radioactive material.”
- (3) Each person licensed under 105 CMR 120.128(B) shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.
- (4) Each person licensed under 105 CMR 120.128(B) shall provide the information specified in 105 CMR 120.128(B)(4) to each person to whom source material is transferred for use under 105 CMR 120.121(A) or equivalent provisions in the NRC or Agreement State regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:
  - (a) A copy of 105 CMR 120.121(A) through (C), (F), and (G) and 105 CMR 120.140, or relevant equivalent regulations of the NRC or Agreement State.
  - (b) Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.
- (5) Each person licensed under 105 CMR 120.128(B) shall report transfers as follows:
  - (a) File a report with the Agency by an appropriate method listed in 105 CMR 120.013. The report shall include the following information:
    1. The name, address, and license number of the person who transferred the source material;
    2. For each general licensee under 105 CMR 120.121(A) or equivalent NRC or Agreement State provisions to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and
    3. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.
  - (b) File a report with each responsible NRC or Agreement State agency that identifies all persons, operating under provisions equivalent to 105 CMR 120.121(A), to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the NRC or Agreement State being reported to:
    1. The name, address, and license number of the person who transferred the source material; and
    2. The name and address of the general licensee to whom source material was

**distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred.**

**3. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the NRC's jurisdiction or the Agreement State.**

**(c) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under 105 CMR 120.121(A) or equivalent NRC or Agreement State provisions during the current period, a report shall be submitted to the Agency indicating so. 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 upon request of that agency. If no transfers have been made to NRC general licensees during the reporting period, this information shall be reported to the NRC.**

**(6) Each person licensed under 105 CMR 120.128(B) shall maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of 1 year after the event is included in a report to the NRC or to an Agreement State agency.**

**(C) Requirements for Other Specific Licenses (Reserved).**

**(D) Licensing Requirements to Manufacture or Initially Transfer Devices Containing Radioactive Material to Persons Generally Licensed Under 105 CMR 120.122(D).**

(1) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 105 CMR 120.122(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 105 CMR 120.125;
- (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:

- 1. the device can be safely operated by persons not having training in radiological protection,
- 2. 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% of the annual limits specified in 105 CMR 120.211(A), and
- 3. 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:

- a. Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye. . . . . 15 rems (150 mSv)
- b. Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter. . . . . 200 rems (2 Sv)
- c. Other organs. . . . . 50 rems (500 mSv); and,

(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:

- 1. 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;
- 2. 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,
- 3. the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

The receipt, possession, use, and transfer of this device, Model \_\_\_\_\_, Serial No. \_\_\_\_\_, 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. [The model, serial number, and name of the manufacturer or distributor may be omitted from the label provided the information is elsewhere specified in labeling affixed to the device.]

120.128: continued

## CAUTION - RADIOACTIVE MATERIAL

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 Name of Manufacturer or Distributor

[Note: Devices licensed under 10 CFR 32.53 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.]

(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 105 CMR 120.237, and the name of the manufacturer or initial distributor.

(e) each device meeting the criteria of 105 CMR 120.122(D)(3)(m)1., 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 105 CMR 120.237.

**(f) the device has been registered in the Sealed Source and Device Registry.**

(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, the applicant shall include in the 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 or 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.

(3) In the event the applicant desires that the general licensee under 105 CMR 120.122(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, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and basis 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 a dose in excess of 10% of the annual limits specified in 105 CMR 120.211(A).

(4) Each person licensed under 105 CMR 120.128(D) to initially transfer devices to generally licensed persons shall:

- (a) if a device containing radioactive material is to be transferred for use under the general license contained in 105 CMR 120.122(D), each person that is licensed under 105 CMR 120.128(D) shall provide the information specified in 120.128(D)(4) 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:



120.128: continued

1. a copy of the general license contained in 105 CMR 120.122(D); if 105 CMR 120.122(D)(3)(b) through (d) do not apply to the particular device, those paragraphs may be omitted;
  2. a copy of 105 CMR 120.122, 120.009(A), 120.281, and 120.282;
  3. a list of the services that can only be performed by a specific licensee; and,
  4. information on acceptable disposal options including estimated costs of disposal;
- (b) if radioactive material is to be transferred in a device for use under an equivalent general license of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State each person that is licensed under 105 CMR 120.128(D) shall provide the information specified in 105 CMR 120.128(D)(4)(b) 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:
1. a copy of NRC or Agreement State regulations equivalent to 105 CMR 120.122(D), 120.009(A), 120.281, and 120.282. If a copy of the 105 CMR 120.000 is provided to a prospective general licensee in lieu of the U.S. Nuclear Regulatory Commission's, Agreement State's, or Licensing State's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the U.S. Nuclear Regulatory Commission, the Agreement State; or Licensing State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;
  2. a list of the services that can only be performed by a specific licensee;
  3. information on acceptable disposal options including estimated costs of disposal; and,
  4. the name or title, address, and phone number of the contact at the U.S. Nuclear Regulatory Commission, the Agreement State, or Licensing State from which additional information may be obtained;
- (c) an alternative approach to informing customers may be proposed by the licensee for approval by the Agency;
- (d) each device that is transferred after February 19, 2002 must meet the labeling requirements in 105 CMR 120.128(D)(1)(c) through (e);
- (e) if a notification of bankruptcy has been made under 105 CMR 120.131(E) or the license is to be terminated, each person licensed under 105 CMR 120.128(D) shall provide, upon request, to the Agency and to any appropriate Agreement State or NRC, records of final disposition required under 105 CMR 120.128(D)(5)(c).
- (5) Each person licensed under 105 CMR 120.128(D) to initially transfer devices to generally licensed persons shall comply with the requirements of 105 CMR 120.128(D)(5).
- (a) The person shall report to the Agency all transfers of devices to persons for use under the general license in 105 CMR 120.122(D) and all receipts of devices from persons licensed under 105 CMR 120.122(D). The report must be submitted on a quarterly basis on NRC Form 653 - "Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.
    1. The required information for transfers to general licensees includes:
      - a. the identity of each general licensee by name and mailing 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;
      - b. 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;
      - c. the date of transfer;
      - d. the type, model number, and serial number of the device transferred; and,
      - e. the quantity and type of byproduct material contained in the device.
    2. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

120.128: continued

3. For devices received from a 105 CMR 120.122(D) 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 105 CMR 120.122(D) 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 U.S. Nuclear Regulatory Commission Licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.
  8. 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 that agency.
- (b) The person shall report all transfers of devices to persons for use under a general license in the U.S. Nuclear Regulatory Commission's, an Agreement State's, or a Licensing State's regulations that are equivalent to 105 CMR 120.122(D) and all receipts of devices from general licensees in the U.S. Nuclear Regulatory Commission's, an Agreement State's, or a Licensing State's jurisdiction to the responsible agency. The report must be submitted on Form 653 - "Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.
1. The required information for transfers to general licensees includes:
    - a. the identity of each general licensee by name and mailing 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;
    - b. 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;
    - c. the date of transfer;
    - d. the type, model number, and serial number of the device transferred; and,
    - e. the quantity and type of byproduct material contained in the device.
  2. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).
  3. For devices received from a 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 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 must include the license number of the specific licensee.
  7. 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.

120.128: continued

8. 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 that agency.

(c) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by 105 CMR 120.128(D)(5). Records required by 105 CMR 120.128(D)(5)(c) must be maintained for a period of three years following the date of the recorded event.

(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 105 CMR 120.122(B) will be approved if:

- (1) the applicant satisfies the general requirements specified in 105 CMR 120.125; and,
- (2) the applicant satisfies the requirements of 10 CFR Part 32 §§ 32.53 through 32.56, ~~and 32.101, or their equivalent.~~

(F) Special Requirements for License to Manufacture or Initially Transfer Calibration or Reference Sources Containing Americium-241, or Radium-226 for Distribution to Persons Generally Licensed Under 105 CMR 120.122(G). An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241; or radium-226, **for distribution** to persons generally licensed under 105 CMR 120.122(G), will be approved if:

- (1) the applicant satisfies the general requirement of 105 CMR 120.125; and,
- (2) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:
  - (a) Chemical and physical form and maximum quantity of americium 241 or radium-226 in the source;
  - (b) Details of construction and design;
  - (c) Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;
  - (d) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;
  - (e) Details of quality control procedures to be followed in manufacture of the source;
  - (f) Description of labeling to be affixed to the source or the storage container for the source;
  - (g) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source.
- (3) Each source will contain no more than 5 microcuries of americium-241 or radium-226.
- (4) The Agency determines, with respect to any type of source containing more than 0.005 microcurie of americium-241 or radium-226, that:
  - (a) The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and
  - (b) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by **10 CFR 32.57(e)**. ~~10 CFR 32.102, Schedule C.~~
- (5) Each person licensed under 105 CMR 120.128(F) shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:

120.128: continued

The receipt, possession, use, and transfer of this source, Model \_\_\_\_\_, Serial No. \_\_\_\_\_, 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. Do not remove this label

CAUTION - RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS AMERICIUM-241 (OR RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE

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Name of manufacturer or initial transferor

(6) Each person licensed under 105 CMR 120.128(F) shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under 105 CMR 120.122(G) **or under equivalent regulations of NRC or an Agreement State**. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the **filter** paper shall be measured by using ~~radiation detection instrumentation~~ **methods** capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If ~~this test discloses a source has been shown to be leaking or losing~~ more than 0.185 kilobecquerel (0.005 microcurie) of ~~radioactive material~~ **americium-241 or radium-226 by the methods described in 105 CMR 120.128(F)(6)**, the source shall be ~~deemed to be leaking or losing americium-241 or radium-226~~ **rejected** and shall not be transferred to a general licensee under 105 CMR 120.122(G) or equivalent regulations of NRC or an Agreement State.

(G) Requirements for Other Specific Licenses (Reserved).

(H) 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 105 CMR 120.122(I) will be approved if:

- (1) the applicant satisfies the general requirements specified in 105 CMR 120.125.
- (2) the radioactive material is to be prepared for distribution in prepackaged units of:
  - (a) carbon-14 in units not exceeding ten microcuries (370 kBq) each.
  - (b) cobalt-57 in units not exceeding ten microcuries (370 kBq) each.
  - (c) hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.
  - (d) iodine-125 in units not exceeding ten microcuries (370 kBq) each.
  - (e) 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.
  - (f) iodine-131 in units not exceeding ten microcuries (370 kBq) each.
  - (g) iron-59 in units not exceeding 20 microcuries (740 kBq) each.
  - (h) selenium-75 in units not exceeding ten microcuries (370 kBq) 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 ten 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 microcurie (185 Bq) of americium-241 each; or cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) and
  - (b) displaying the radiation caution symbol described in 105 CMR 120.237(A) and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".
- (4) The following statement or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

120.128: continued

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 therefrom, 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 U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.

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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 105 CMR 120.251.

(I) 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 105 CMR 120.122(J) will be approved if:

- (1) the applicant satisfies the general requirements of 105 CMR 120.125; and,
- (2) the criteria of 10 CFR Part 32, §§ 32.61; **and** 32.62; ~~and 32.103~~ are met.

(J) Manufacture, Preparation, or Transfer for Commercial Distribution of Drugs Containing Radioactive Material for Medical Use Under 105 CMR 120.500.

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to 105 CMR 120.500 will be approved if:

- (a) the applicant satisfies the general requirements specified in 105 CMR 120.125;
- (b) the applicant submits evidence that the applicant is at least one of the following:
  1. registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a); or
  2. registered or licensed with a state agency as a drug manufacturer; or,
  3. licensed as a pharmacy by a State Board of Pharmacy; or,
  4. operating as a nuclear pharmacy pursuant to 247 CMR 13.00: *Registration Requirements and Minimal Professional Standards for Nuclear Pharmacies*; or
  5. operating as a nuclear pharmacy within a Federal medical institution; or
  6. a Positron Emission Tomography (PET) drug production facility registered with a State agency.
- (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 safe handling and storage of the radioactive drugs by medical use licensees; and,
- (d) the applicant satisfies the following labeling requirements:
  1. 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", 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.
  2. 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.

120.128: continued

- (2) A licensee pursuant to 105 CMR 120.128(J)(1)(b)3. or (b)4. or (b)5.:
- (a) may prepare radioactive drugs for medical use, as defined 105 CMR 120.502, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 105 CMR 120.128(J)(2)(b) and (d), or an individual under the supervision of an authorized nuclear pharmacist as specified in 105 CMR 120.519.
  - (b) may allow a pharmacist to work as an authorized nuclear pharmacist if:
    - 1. if this individual qualifies as an authorized nuclear pharmacist as defined in 105 CMR 120.502; or,
    - 2. this individual meets the requirements specified in 105 CMR 120.526(B) and 120.529 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or,
    - 3. this individual is designated as an authorized nuclear pharmacist in accordance with 105 CMR 120.128(J)(2)(d).
  - (c) the actions authorized in 105 CMR 120.128(J)(2)(a) and (b) are permitted in spite of more restrictive language in license conditions.
  - (d) may designate a pharmacist, as defined in 105 CMR 120.005, as an authorized nuclear pharmacist if:
    - 1. The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and
    - 2. The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.
  - (e) shall provide to the Agency:
    - 1. A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in 105 CMR 120.526(A) with the written attestation signed by a preceptor as required by 105 CMR 120.526(B); or
    - 2. Agreement State or Nuclear Regulatory Commission license; or
    - 3. Nuclear Regulatory Commission master materials licensee permit; or
    - 4. The permit issued by a licensee or Nuclear Regulatory Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or
    - 5. Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and
    - 6. A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under 105 CMR 120.128(J)(2)(b)1. and 3. of 105 CMR 120.128(J), 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 105 CMR 120.128(J) relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

120.128: continued

(K) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material.<sup>5</sup> 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 105 CMR 120.100 for the uses listed in 105 CMR 120.547 will be approved if:

- (1) the applicant satisfies the general requirements specified in 105 CMR 120.125;
- (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 105 CMR 120.533~~47~~ 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 105 CMR 120.128(K) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(L) 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 105 CMR 120.500 for use as a calibration, transmission, or reference source or for the uses listed in 105 CMR 120.559, 120.568, 120.570 and 120.589 will be approved if:

- (1) the applicant satisfies the general requirements in 105 CMR 120.125;
- (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;

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<sup>5</sup> 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 105 CMR 120.547 may submit the pertinent information specified in 105 CMR 120.128(K).

120.128: continued

- (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, that 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 Agency has approved the distribution of the (name of source or device) to persons licensed to use radioactive material identified in 105 CMR 120.532~~35~~**35**, 120.559, 120.568, and 120.570 or under equivalent licenses of the U.S. Nuclear Regulatory Commission; **or** an Agreement State;
- (4) the source or device has been registered in the Sealed Source and Device Registry;**
- (45)** 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; and
- (56)** 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 or 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.

**(M) Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-volume Applications.**

- (1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 105 CMR 120.121(E) 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 105 CMR 120.125;
  - (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 a radiation dose in excess of 10% of the annual limits specified in 105 CMR 120.211(A); 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 105 CMR 120.128(M) 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 105 CMR 120.128(M) if the end use(s) of the industrial product or device cannot be reasonably foreseen.



120.128: continued

- (4) Each person licensed pursuant to 105 CMR 120.128(M)(1) 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:
    - 1. 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
    - 2. 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 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)
    - 1. furnish a copy of the general license contained in 105 CMR 120.121(E) and a copy of form MRCP 120.100-1 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in 105 CMR 120.121(E); or,
    - 2. furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 105 CMR 120.121(E) 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 105 CMR 120.121(E) and a copy of form MRCP 120.100-1 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 105 CMR 120.121(E);
  - (e) report to the Agency all transfers of industrial products or devices to persons for use under the general license in 105 CMR 120.121(E). 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 105 CMR 120.121(E) during the reporting period, the report shall so indicate;
  - (f)
    - 1. 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 10 CFR Part 40, § 40.25.
    - 2. report to the responsible State agency all transfers of devices manufactured and distributed pursuant to 105 CMR 120.128(M) for use under a general license in that State's regulations equivalent to 105 CMR 120.121(E);
    - 3. 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;
    - 4. 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; and
    - 5. 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 upon the request of that agency; and

120.128: continued

(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 105 CMR 120.121(E) 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 105 CMR 120.100.

(N) ~~Special Requirements for License to Manufacture, Import or Initially Distribute Sealed Sources or Devices Containing Sealed Sources to Persons Having a Specific License.~~ **Sealed Source and Device Registration - Registration of Product Information and Inactivation of Certificates of Registration of Sealed Sources and Devices.**

~~(1) An application for license to manufacture, import (NARM only) or initially distribute sealed sources or devices containing sealed sources for initial transfer to persons having a specific license to receive such sealed sources or devices will be approved subject to the following conditions:~~

~~(a) the applicant satisfies the general requirements specified in 105 CMR 120.125;~~

~~(b) the licensee subject to 105 CMR 120.128(N) shall not transfer a sealed source or device containing a sealed source to any person except in accordance with the requirements of 105 CMR 120.140.~~

~~(2) Any manufacturer, importer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to the Agency for evaluation of radiation safety information about its product and for **its registration**, filing an evaluation sheet in the U.S. Nuclear Regulatory Commission "Registry of Radioactive Sealed Sources and Devices".~~

~~(a) A request for evaluation of a sealed source or device containing a sealed source shall be submitted in duplicate and shall include information required by 105 CMR 120.128(N)(2)(b) or (c), as applicable, demonstrating that the radiation safety properties of such source or device will not endanger public health and safety or property.~~

~~(b) A request for evaluation of a sealed source shall include the following radiation safety information:~~

~~1. proposed uses for the sealed source;~~

~~2. chemical and physical form and maximum quantity of radioactive material in the sealed source;~~

~~3. details of design of the sealed source, radiation and its shielding including blueprints, engineering drawings or annotated drawings;~~

~~4. details of construction of the sealed source including a description of materials used in construction;~~

~~5. radiation profile of a prototype sealed source;~~

~~6. procedures for and results of prototype testing;~~

~~7. details of quality control procedures to be followed in manufacture;~~

~~8. a description or facsimile of labeling to be affixed to the sealed source;~~

~~9. leak testing procedures; and,~~

~~10. any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the sealed source, as required by 105 CMR 120.125.~~

~~(c) A request for evaluation of a device containing a sealed source shall include the following radiation safety information:~~

~~1. proposed uses for the device;~~

~~2. manufacturer, model number, chemical and physical form and maximum quantity of radioactivity in the sealed source or sources to be used in the device;~~

~~3. details of design of the sealed source, including blueprints, engineering drawings or annotated drawings;~~

~~4. details of construction of the sealed source including a description of materials used in construction;~~

~~5. radiation profile of a prototype device;~~

~~6. procedures for and results of prototype testing;~~

~~7. details of quality control procedures to be followed in manufacture;~~

~~8. a description or facsimile of labeling to be affixed to the device;~~

~~9. leak testing procedures;~~

120.128: continued

- ~~10. a description of potential hazards in installation, service, maintenance, handling, use and operation of the device;~~
- ~~11. information about installation, service and maintenance procedures;~~
- ~~12. handling, operating and safety instructions; and~~
- ~~13. any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the device as required by 105 CMR 120.125.~~

~~(d) When evaluating a sealed source or device, the Agency will apply the radiation safety criteria described in 10 CFR 32.210(d), published January 1, 1993, exclusive of subsequent amendments or editions.~~

~~(e) The person submitting a request for evaluation of a product shall manufacture and distribute the product in accordance with:~~

- ~~1. the statements and representations, including the quality control program, described in the request; and~~
- ~~2. the provisions of the evaluation sheet prepared by the Agency and submitted to the U.S. Nuclear Regulatory Commission, for filing in the "Registry of Radioactive Sealed Sources and Devices".~~

**(2) The request for review must be sent to the Agency in duplicate by an appropriate method listed in 105 CMR 120.013.**

**(3) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.**

**(4) The Agency normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the Agency formulates reasonable standards and criteria with the help of the manufacturer or distributor. The Agency shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.**

**(5) After completing the evaluation and determining that requirements for registration have been met, the Agency shall issue a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.**

**(6) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:**

**(a) The statements and representations, including quality control program, contained in the request; and**

**(b) The provisions of the registration certificate.**

**(7) Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:**

**(a) Calibration and reference sources containing no more than:**

- 1. 37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or**
- 2. 0.37 MBq (10 µCi), for alpha emitting radionuclides; or**

**(b) The intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and**

- 1. The intended recipients are licensed under 105 CMR 120.127 or comparable provisions of NRC or an Agreement State; or**
- 2. The recipients are authorized for research and development; or**
- 3. The sources and devices are to be built to the unique specifications of the**

**particular recipient and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide.**

**(8) After the certificate is issued, the Agency may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the Agency will complete its evaluation in accordance with criteria specified in this section. The Agency may request such additional information as it considers necessary to conduct its review and the certificate holder shall provide the information as requested.**

**(9) A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the Agency shall request inactivation of the registration certificate. Such a request must be made to the Agency by an appropriate method listed in 105 CMR 120.013 and must normally be made no later than two years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the certificate holder shall request inactivation of the certificate within 90 days of this determination and briefly describe the circumstances of the delay.**

**(10) If a distribution license is to be terminated in accordance with 105 CMR 120.132, the licensee shall request inactivation of its registration certificates associated with that distribution license before the Agency will terminate the license. Such a request for inactivation of certificate(s) must indicate that the license is being terminated and include the associated specific license number.**

**(11) A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.**

#### 120.130: Issuance of Specific Licenses

(A)(1) Upon a determination that an application meets the requirements of M.G.L. c. 111, §§ 3, 5M through 5P and 105 CMR 120.000 and upon payment of the required fee as specified in 105 CMR 120.130(A)(2), 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.

(2) Each initial application for a license or a certificate of registration for which a fee is established by the Executive Office for Administration and Finance in 801 CMR 4.00 shall be accompanied by a non-refundable fee, payable to the Commonwealth of Massachusetts, in the amount specified for the corresponding annual fee. Thereafter, the Radiation Control Program will issue an annual fee invoice based on the applicable annual fee specified in 801 CMR 4.00. Fees are payable within 30 days after receipt of a fee invoice.

(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 105 CMR 120.100 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 105 CMR 120.100.

#### 120.131: Specific Terms and Conditions of Licenses

(A) Each license issued pursuant to 105 CMR 120.000 shall be subject to all the provisions of M.G.L. c. 111, §§ 3, 5M through 5P, and to all rules, regulations, orders of the Agency and license conditions as provided for in 105 CMR 120.130(B).

(B) **(1)** No license issued or granted under 105 CMR 120.000 and no right to possess or utilize radioactive material granted by any license issued pursuant to 105 CMR 120.131 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 M.G.L. c. 111, §§ 3, 5M through 5P, and to all valid rules, regulations, and

orders of the Agency, and shall give its consent in writing.

**(2) An application for transfer of license must include:**

- 1. The identity, technical and financial qualifications of the proposed transferee; and**
- 2. Financial assurance for decommissioning information required by 105 CMR 120.125(C), as applicable.**

(C) Each person licensed by the Agency pursuant to 105 CMR 120.100 shall confine use and possession of the material licensed to the locations and purposes authorized in the license. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of 10 CFR part 71 and 105 CMR 120.770.

120.131: continued

(D) Each licensee shall notify the Agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

(E) Each licensee 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(15)) 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.

(F) The notification specified in 105 CMR 120.131(E) shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

(G) Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(H) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 105 CMR 120.548. The licensee shall record the results of each test and retain each record for three years after the record is made.

(I) (1) Authorization under 105 CMR 120.128(A) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(2) Each licensee authorized under 105 CMR 120.128(A) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

1. Satisfy the labeling requirements in 105 CMR 120.128(J)(1)(d) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.
2. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 105 CMR 120.128(J)(3).

(3) A licensee that is a pharmacy authorized under 105 CMR 120.128(A) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

1. an authorized nuclear pharmacist that meets the requirements in 105 CMR 120.128(J)(2)(b); or
2. an individual under the supervision of an authorized nuclear pharmacist as specified in 105 CMR 120.519.

(4) A pharmacy, authorized under 105 CMR 120.128(A) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of 105 CMR 120.128(J)(2)(e).

120.132: Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas

(A) Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under 105 CMR 120.133 not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the Agency makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(B) Each specific license revoked by the Agency expires at the end of the day on the date of the Agency's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Agency Order.

(C) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Agency notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

- (1) Limit actions involving radioactive material to those related to decommissioning; and,
- (2) Continue to control entry to restricted areas until they are suitable for release in accordance with Agency requirements.

(D) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in 105 CMR 120.013, each licensee shall provide notification to the Agency in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Agency requirements, or submit within 12 months of notification a decommissioning plan, if required by 105 CMR 120.132(G)(1) and begin decommissioning upon approval of that plan if:

- (1) The license has expired pursuant to 105 CMR 120.132(A) or (B); or
- (2) The licensee has decided to permanently cease principal activities, as defined in 105 CMR 120.005, at the entire site or 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; or
- (3) No principal activities under the license have been conducted for a period of 24 months; or
- (4) 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.

(E) Coincident with the notification required by 105 CMR 120.132(D), the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to 105 CMR 120.125(C) in conjunction with a license issuance or renewal or as required by 105 CMR 120.132. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to 105 CMR 120.132(G)(4)(e).

- (1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so.
- (2) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Agency.

(F) The Agency may grant a request to extend the time periods established in 105 CMR 120.132(D) if the Agency determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to 105 CMR 120.132(D). The schedule for decommissioning set forth in 105 CMR 120.132(D) may not commence until the Agency has made a determination on the request.

120.132: continued

- (G) (1) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor have not been previously approved by the Agency and these procedures could increase potential health and Safety impacts to workers or to the public, such as in any of the following cases:
- (a) procedures would involve techniques not applied routinely during cleanup or maintenance operations;
  - (b) workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;
  - (c) procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or,
  - (d) procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.
- (2) The Agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to 105 CMR 120.132(D) if the Agency determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.
- (3) Procedures such as those listed in 105 CMR 120.132(G)(1) with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.
- (4) The proposed decommissioning plan for the site or separate building or outdoor area must include:
- (a) a description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;
  - (b) a description of planned decommissioning activities;
  - (c) a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;
  - (d) a description of the planned final radiation survey; and,
  - (e) an updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.
  - (f) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in 105 CMR 120.132(H).
- (5) The proposed decommissioning plan will be approved by the Agency if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.
- (H) (1) Except as provided in 105 CMR 120.132(I), licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.
- (2) Except as provided in 105 CMR 120.132(I), when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.
- (I) The Agency may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Agency determines that the alternative is warranted by consideration of the following:
- (1) whether it is technically feasible to complete decommissioning within the allotted 24-month period;
  - (2) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;
  - (3) whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;
  - (4) whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and,



## 120.132: continued

(5) other site-specific factors which the Agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(J) As the final step in decommissioning, the licensee shall:

(1) Certify the disposition of all licensed material including accumulated wastes, by submitting a completed Agency Form MRCP 120.100-3 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 that the premises are suitable for release in some other manner. The licensee shall, as appropriate-

(a) Report levels of gamma radiation in units of millisieverts (microrentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters -removable and fixed - for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (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.

(K) 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 Agency requirements; or,

(b) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with Agency requirements.

120.133: Renewal of Licenses

(A) Applications for renewal of specific licenses shall be filed in accordance with 105 CMR 120.124.

(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 final action by the Agency.

120.134: Amendment of Licenses **and Registration Certificates** at Request of Licensee

(A) Applications for amendment of a license shall be filed in accordance with 105 CMR 120.124 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment. **Applications for amendment of sealed source and device registration certificates must be filed in accordance with 105 CMR 120.128(N) and any other applicable provisions and must specify the respects in which the certificate holder desires its certificate to be amended and the grounds for the amendment.**

(B) An invoice for an amendment fee will be issued on receipt of a request to amend a license. The amendment will not be issued until after the invoiced amount has been paid.

120.135: Agency Action on Applications to Renew or Amend

In considering an application by a licensee to renew or amend the license **or to amend a sealed source or device registration certificate**, the Agency will apply the criteria set forth in 105 CMR 120.125, 120.126, 120.127, and 120.128 and in 120.300, 120.500, 120.800 or 120.900, as applicable.

120.136: Persons Possessing a License for Source, Byproduct, or Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass on March 21, 1997

Any person who, on March 21, 1997, date of the Agreement between the Commonwealth and the NRC pursuant to section 274b of the Atomic Energy Act of 1954, as amended (42 USC 2021), possesses a general or specific license for source, byproduct, 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 105 CMR 120.136 and M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P, such license to expire either 90 days after receipt from the Agency of a notice of expiration of such license, or on the date or expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier.

120.137: Persons Possessing Naturally Occurring and Accelerator-produced Radioactive Material (NARM) on March 21, 1997

Any person who, on October 6, 2006, possesses NARM for which a specific license is required by M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P or 105 CMR 120.137 shall be deemed to possess such a license issued under M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P and 105 CMR 120.137. Such license shall expire on January 6, 2007; 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.

120.140: Transfer of Material

(A) No licensee shall transfer radioactive material except as authorized pursuant to 105 CMR 120.140.

(B) Except as otherwise provided in his license and subject to the provisions of 105 CMR 120.140(C) and (D), any licensee may transfer radioactive material:

- (1) to the Agency (Only after receiving prior approval from the Agency.);
- (2) to the U.S. Department of Energy;
- (3) to any person exempt from 105 CMR 120.000 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, an Agreement State, or a 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) Any of the following methods for the verification required by 105 CMR 120.140(C) is acceptable:

- (1) The transferor may possess and read a current copy of the transferee's specific license or registration certificate.
- (2) The transferor may possess a written certification by the transferee that the transferee 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 the transferee 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 ten days.

## 120.140: continued

(4) The transferor may obtain other information compiled by a reporting service from official records of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State regarding the identity of licensees and the scope and expiration dates of licenses and registration.

(5) When none of the methods of verification described in 105 CMR 120.140(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 and record confirmation from the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State, or a Licensing State that the transferee is licensed to receive the radioactive material.

(E) Shipment and transport of radioactive material shall be in accordance with the provisions of 105 CMR 120.770.

120.142: Reporting Requirements

(A) Immediate Report. Each licensee shall notify the Agency as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, *etc.*).

(B) 24 Hour Report. Each licensee shall notify the Agency within 24 hours after the discovery of any of the following events involving licensed material:

(1) An unplanned contamination event that:

(a) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(b) Involves a quantity of material greater than five times the lowest annual limit on intake specified in 105 CMR 120.296: *Appendix B* for the material; and,

(c) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(2) An event in which equipment is disabled or fails to function as designed when:

(a) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(b) The equipment is required to be available and operable when it is disabled or fails to function; and,

(c) No redundant equipment is available and operable to perform the required safety function.

(3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(4) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(a) The quantity of material involved is greater than five times the lowest annual limit on intake specified in 105 CMR 120 296: *Appendix B* for the material; and,

(b) The damage affects the integrity of the licensed material or its container.

(C) Preparation and Submission of Reports. Reports made by licensees in response to the requirements of 105 CMR 120.142 must be made as follows:

(1) Licensees shall make reports required by 105 CMR 120.142(A) and (B) by telephone to the Agency during normal working hours or the Nuclear Incident Advisory Team (NIAT) at all other times. To the extent that the information is available at the time of notification, the information provided in these reports must include:

(a) The caller's name and call back telephone number;

(b) A description of the event, including date and time;

(c) The exact location of the event;

(d) The isotopes, quantities, and chemical and physical form of the licensed material involved; and,

(e) Any personnel radiation exposure data available.

120.142: continued

(2) Written Report. Each licensee who makes a report required by 105 CMR 120.142(A) or (B) shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the Massachusetts Department of Public Health, Radiation Control Program. The report must include the following:

- (a) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
- (b) The exact location of the event;
- (c) The isotopes, quantities, and chemical and physical form of the licensed material involved;
- (d) Date and time of the event;
- (e) Corrective actions taken or planned and the results of any evaluations or assessments; and,
- (f) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

120.146: Emergency Plan for Responding to a Release

(A) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 105 CMR 120.196: *Appendix B*, Table III must contain either:

- (1) 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 rems to the thyroid; or
- (2) An emergency plan for responding to a release of radioactive material.

(B) One or more of the following factors may be used to support an evaluation submitted pursuant to 105 CMR 120.146 and 120.760:

- (1) The radioactive material is physically separated so that only a portion could be involved in an accident;
- (2) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;
- (3) The release fraction in the respirable size range would be lower than the release fraction shown in 105 CMR 120.196: *Appendix B*, Table III due to the chemical or physical form of the material;
- (4) The solubility of the radioactive material would reduce the dose received;
- (5) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in 105 CMR 120.196: *Appendix B*, Table III;
- (6) Operating restrictions or procedures would prevent a release fraction as large as that shown in 105 CMR 120.196: *Appendix B*, Table III; or
- (7) Other factors appropriate for the specific facility.

(C) An emergency plan for responding to a release of radioactive material submitted pursuant to 105 CMR 120.146 and 120.760 must include the following information:

- (1) Facility Description. A brief description of the licensee's facility and area near the site.
- (2) Types of Accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.
- (3) Classification of Accidents. A classification system for classifying accidents as alerts or site area emergencies.
- (4) Detection of Accidents. Identification of the means of detecting each type of accident in a timely manner.
- (5) 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.
- (6) Assessment of Releases. A brief description of the methods and equipment to assess releases of radioactive materials.

120.146: continued

(7) 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.

(8) 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 the Agency immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.\*\*\*

(9) 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.

(10) 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.

(11) Safe Shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(12) 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.

(13) 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.

(D) The license 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 to the Agency. The licensee shall provide any comments received within the 60 days to the Agency with the emergency plan.

#### 120.150: Modification and Revocation 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 M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P, or by reason of rules, regulations, and orders issued by the Agency.

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\*\*\* These reporting requirements do not supersede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499 or other state or federal reporting requirements.

120.150: continued

(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 M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P, 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 M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P, 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 therefor, facts or 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.

120.190: Reciprocal Recognition of Licenses

(A) Licenses of Byproduct, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

(1) Subject to 105 CMR 120.000, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an 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 for a period not in excess of 180 days in any calendar year 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 three days prior to engaging in such activity. 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. If, for a specific case, the three day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency may 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 105 CMR 120.190(A)(1);
- (c) the out-of-state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of the 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 105 CMR 120.190(A)(1) except by transfer to a person:
  - 1. specifically licensed by the Agency or by the U.S. Nuclear Regulatory Commission to receive such material; or,
  - 2. exempt from the requirements for a license for such material under 105 CMR 120.104(A).

(2) Notwithstanding the provisions of 105 CMR 120.190(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 105 CMR 120.122(D)(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) Filing a report with the Agency (Reserved);
- (b) 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;

120.190: continued

- (c) 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,
  - (d) the holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in 105 CMR 120.122(D) or in equivalent regulations of the Agency having jurisdiction over the manufacture and distribution of the device.
- (3) The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by 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) Exceptions to the General License.
- (1) The general license granted in 105 CMR 120.190(A) to conduct activities in the State does not include activities in areas of exclusive Federal jurisdiction within the State or offshore waters.
  - (2) Authorization for use of radioactive materials in areas of exclusive Federal jurisdiction within the State or offshore waters may be obtained from the U.S. Nuclear Regulatory Commission as provided for in 10 CFR 150.20.
  - (3) Before radioactive material can be used at a temporary job site in another State, authorization shall be obtained from the State if it is an Agreement State, or from the NRC for any non-Agreement State, either by filing for reciprocity or applying for a specific license.

NON-TEXT PAGE



## 105 CMR: DEPARTMENT OF PUBLIC HEALTH

## 120.195: Appendix A -- Exempt Concentrations

Element (Atomic Number)	Isotope	Column I Gas Concentration $\mu\text{Ci/ml}$ <u>1/</u>	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2/</u>
Antimony (51)	Sb-122 Sb-124 Sb-125		$3 \times 10^{-4}$ $2 \times 10^{-4}$ $1 \times 10^{-3}$
Argon (18)	Ar-37 Ar-41	$1 \times 10^{-3}$ $4 \times 10^{-7}$	
Arsenic (33)	As-73 As-74 As-76 As-77		$5 \times 10^{-3}$ $5 \times 10^{-4}$ $2 \times 10^{-4}$ $8 \times 10^{-4}$
Barium (56)	Ba-131 Ba-140		$2 \times 10^{-3}$ $3 \times 10^{-4}$
Beryllium (4)	Be-7		$2 \times 10^{-2}$
Bismuth (83)	Bi-206		$4 \times 10^{-4}$
Bromine (35)	Br-82	$4 \times 10^{-7}$	$3 \times 10^{-3}$
Cadmium (48)	Cd-109 Cd-115m Cd-115		$2 \times 10^{-3}$ $3 \times 10^{-4}$ $3 \times 10^{-4}$
Calcium (20)	Ca-45 Ca-47		$9 \times 10^{-5}$ $5 \times 10^{-4}$
Carbon (6)	C-14	$1 \times 10^{-6}$	$8 \times 10^{-3}$
Cerium (58)	Ce-141 Ce-143 Ce-144		$9 \times 10^{-4}$ $4 \times 10^{-4}$ $1 \times 10^{-4}$
Cesium (55)	Cs-131 Cs-134m Cs-134		$2 \times 10^{-2}$ $6 \times 10^{-2}$ $9 \times 10^{-5}$
Chlorine (17)	Cl-38	$9 \times 10^{-7}$	$4 \times 10^{-3}$
Chromium (24)	Cr-51		$2 \times 10^{-2}$
Cobalt (27)	Co-57 Co-58 Co-60		$5 \times 10^{-3}$ $1 \times 10^{-3}$ $5 \times 10^{-4}$
Copper (29)	Cu-64		$3 \times 10^{-3}$
Dysprosium (66)	Dy-165 Dy-166		$4 \times 10^{-3}$ $4 \times 10^{-4}$
Erbium (68)	Er-169 Er-171		$9 \times 10^{-4}$ $1 \times 10^{-3}$

## 105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.195: continued

Element (Atomic Number)	Isotope	Column I Gas Concentration $\mu\text{Ci/ml}$ <u>1/</u>	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2/</u>
Europium (63)	Eu-152/ (9.2h)		$6 \times 10^{-4}$
	Eu-155		$2 \times 10^{-3}$
Fluorine (9)	F-18	$2 \times 10^{-6}$	$8 \times 10^{-3}$
Gadolinium (64)	Gd-153		$2 \times 10^{-3}$
	Gd-159		$8 \times 10^{-4}$
Gallium (31)	Ga-72		$4 \times 10^{-4}$
Germanium (32)	Ge-71		$2 \times 10^{-2}$
Gold (79)	Au-196		$2 \times 10^{-3}$
	Au-198		$5 \times 10^{-4}$
	Au-199		$2 \times 10^{-3}$
Hafnium (72)	Hf-181		$7 \times 10^{-4}$
Hydrogen (1)	H-3	$5 \times 10^{-6}$	$3 \times 10^{-2}$
Indium (49)	In-113m		$1 \times 10^{-2}$
	In-114m		$2 \times 10^{-4}$
Iodine (53)	I-126	$3 \times 10^{-9}$	$2 \times 10^{-5}$
	I-131	$3 \times 10^{-9}$	$2 \times 10^{-5}$
	I-132	$8 \times 10^{-8}$	$6 \times 10^{-4}$
	I-133	$1 \times 10^{-8}$	$7 \times 10^{-5}$
	I-134	$2 \times 10^{-7}$	$1 \times 10^{-3}$
Iridium (77)	Ir-190		$2 \times 10^{-3}$
	Ir-192		$4 \times 10^{-4}$
	Ir-194		$3 \times 10^{-4}$
Iron (26)	Fe-55		$8 \times 10^{-3}$
	Fe-59		$6 \times 10^{-4}$
Krypton (36)	Kr-85m	$1 \times 10^{-6}$	
	Kr-85	$3 \times 10^{-6}$	
Lanthanum (57)	La-140		$2 \times 10^{-4}$
Lead (82)	Pb-203		$4 \times 10^{-3}$
Lutetium (71)	Lu-177		$1 \times 10^{-3}$
Manganese (25)	Mn-52		$3 \times 10^{-4}$
	Mn-54		$1 \times 10^{-3}$
	Mn-56		$1 \times 10^{-3}$
Mercury (80)	Hg-197m		$2 \times 10^{-3}$
	Hg-197		$3 \times 10^{-3}$
	Hg-203		$2 \times 10^{-4}$
Molybdenum (42)	Mo-99		$2 \times 10^{-3}$
Neodymium (60)	Nd-147		$6 \times 10^{-4}$
	Nd-149		$3 \times 10^{-3}$
Nickel (28)	Ni-65		$1 \times 10^{-3}$
Niobium (Columbium) (41)	Nb-95		$1 \times 10^{-3}$
	Nb-97		$9 \times 10^{-3}$

120.195: continued

Element (Atomic Number)	Isotope	Column I Gas Concentration $\mu\text{Ci/ml}$ <u>1/</u>	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2/</u>
Osmium (76)	Os-185 Os-191m Os-191 Os-193		$7 \times 10^{-4}$ $3 \times 10^{-2}$ $2 \times 10^{-3}$ $6 \times 10^{-4}$
Palladium (46)	Pd-103 Pd-109		$3 \times 10^{-3}$ $9 \times 10^{-4}$
Phosphorus (15)	P-32 P-33		$2 \times 10^{-4}$ $1 \times 10^{-3}$
Platinum (78)	Pt-191 Pt-193m Pt-197m Pt-197		$1 \times 10^{-3}$ $1 \times 10^{-2}$ $1 \times 10^{-2}$ $1 \times 10^{-3}$
Potassium (19)	K-42		$3 \times 10^{-3}$
Praseodymium (59)	Pr-142 Pr-143		$3 \times 10^{-4}$ $5 \times 10^{-4}$
Promethium (61)	Pm-147 Pm-149		$2 \times 10^{-3}$ $4 \times 10^{-4}$
Rhenium (75)	Re-183 Re-186 Re-188		$6 \times 10^{-3}$ $9 \times 10^{-4}$ $6 \times 10^{-4}$
Rhodium (45)	Rh-103m Rh-105		$1 \times 10^{-1}$ $1 \times 10^{-3}$
Rubidium (37)	Rb-86		$7 \times 10^{-4}$
Ruthenium (44)	Ru-97 Ru-103 Ru-105 Ru-106		$4 \times 10^{-3}$ $8 \times 10^{-4}$ $1 \times 10^{-3}$ $1 \times 10^{-4}$
Samarium (62)	Sm-153		$8 \times 10^{-4}$
Scandium (21)	Sc-46 Sc-47 Sc-48		$4 \times 10^{-4}$ $9 \times 10^{-4}$ $3 \times 10^{-4}$
Selenium (34)	Se-75		$3 \times 10^{-3}$
Silicon (14)	Si-31		$9 \times 10^{-3}$
Silver (47)	Ag-105 Ag-110m Ag-111		$1 \times 10^{-3}$ $3 \times 10^{-4}$ $4 \times 10^{-4}$
Sodium (11)	Na-24		$2 \times 10^{-3}$
Strontium (38)	Sr-85 Sr-89 Sr-91 Sr-92		$1 \times 10^{-3}$ $1 \times 10^{-4}$ $7 \times 10^{-4}$ $7 \times 10^{-4}$
Sulfur (16)	S-35	$9 \times 10^{-8}$	$6 \times 10^{-4}$
Tantalum (73)	Ta-182		$4 \times 10^{-4}$

## 105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.195: continued

Element (Atomic Number)	Isotope	Column I Gas Concentration $\mu\text{Ci/ml}$ <u>1/</u>	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2/</u>
Technetium (43)	Tc-96m Tc-96		$1 \times 10^{-1}$ $1 \times 10^{-3}$
Tellurium (52)	Te-125m Te-127m Te-127 Te-129m Te-131m Te-132		$2 \times 10^{-3}$ $6 \times 10^{-4}$ $3 \times 10^{-3}$ $3 \times 10^{-4}$ $6 \times 10^{-4}$ $3 \times 10^{-4}$
Terbium (65)	Tb-160		$4 \times 10^{-4}$
Thallium (81)	Tl-200 Tl-201 Tl-202 Tl-204		$4 \times 10^{-3}$ $3 \times 10^{-3}$ $1 \times 10^{-3}$ $1 \times 10^{-3}$
Thulium (69)	Tm-170 Tm-171		$5 \times 10^{-4}$ $5 \times 10^{-3}$
Tin (50)	Sn-113 Sn-125		$9 \times 10^{-4}$ $2 \times 10^{-4}$
Tungsten (Wolfram) (74)	W-181 W-187		$4 \times 10^{-3}$ $7 \times 10^{-4}$
Vanadium (23)	V-48		$3 \times 10^{-4}$
Xenon (54)	Xe-131m Xe-133 Xe-135	$4 \times 10^{-6}$ $3 \times 10^{-6}$ $1 \times 10^{-6}$	
Ytterbium (70)	Yb-175		$1 \times 10^{-3}$
Yttrium (39)	Y-90 Y-91m Y-91 Y-92 Y-93		$2 \times 10^{-4}$ $3 \times 10^{-2}$ $3 \times 10^{-4}$ $6 \times 10^{-4}$ $3 \times 10^{-4}$
Zinc (30)	Zn-65 Zn-69m Zn-69		$1 \times 10^{-3}$ $7 \times 10^{-4}$ $2 \times 10^{-2}$
Zirconium (40)	Zr-95 Zr-97		$6 \times 10^{-4}$ $2 \times 10^{-4}$
Beta and/or gamma emitting radioactive material not listed above with half-life of less than three years.		$1 \times 10^{-10}$	$1 \times 10^{-6}$

120.195: continued

Note 1: Many radioisotopes transform into isotopes which are also radioactive. In expressing the concentrations in 105 CMR 120.195: *Appendix A*, the activity stated is that of the parent isotope and takes into account the daughters.

Note 2: For purposes of 105 CMR 120.104(A) 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 120.195: *Appendix A* for the specific isotope when not in combination. The sum of such ratios may not exceed "1".

Example: 
$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} +$$

$$\frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} \leq 1$$

Note 3: To convert  $\mu\text{Ci/ml}$  to SI units of megabecquerels per liter multiply the above values by 37.

Example: Zirconium (40) Zr-97 ( $2 \times 10^{-4} \mu\text{Ci/ml}$  multiplied by 37 is equivalent to  $74 \times 10^{-4} \text{MBq/l}$ )

120.196: Appendix B -- Table I Exempt Quantities

Radioactive Material	Micro- curies
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152)9.2h	100
Europium-152 (Eu 152)13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-68 (Ge 68)	10
Germanium-71 (Ge 71)	100
Gold-195 (Au 195)	10
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100

## 105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.196 Table 1: continued

Radioactive Material	Micro- curies
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Phosphorus-33 (P 33)	100
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100

## 105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.196 Table 1: continued

Radioactive Material	Micro- curies
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10



120.196 Table 1: continued

Radioactive Material	Micro-curies
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha-emitting radioactive material	0.1

Note 1: For purposes of 105 CMR 100.125(C)(3) where there is involved a combination of isotopes, the limit for the combination should be derived as follows:

Determine the amount of each isotope possessed and 1,000 times the amount in 105 CMR 120.196: *Appendix B, Table 1* for each of those isotopes when not in combination. The sum of the ratios of those quantities may not exceed 1.

Example:

$$\frac{\text{Amt. of Isotope A possessed}}{1000 \times \text{Appendix B Table 1 quantity for Isotope A}} + \frac{\text{Amt. of Isotope B possessed}}{1000 \times \text{Appendix B Table 1 quantity for Isotope B}} < 1$$

Note 2: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

Example: Zirconium-97 (10 μCi multiplied by 37 is equivalent to 370 kBq).

105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.196: Table II -- Quantities For Use With 105 CMR 120.125(C)(1)

Material	Microcuries
Americium-241	0.01
Antimony-122	100.00
Antimony-124	10.00
Antimony-125	10.00
Arsenic-73	100.00
Arsenic-74	10.00
Arsenic-76	10.00
Arsenic-77	100.00
Barium-131	10.00
Barium-133	10.00
Barium-140	10.00
Bismuth-210	1.00
Bromine-82	10.00
Cadmium-109	10.00
Cadmium-115m	10.00
Cadmium-115	100.00
Calcium-45	10.00
Calcium-47	10.00
Carbon-14	100.00
Cerium-141	100.00
Cerium-143	100.00
Cerium-144	1.00
Cesium-131	1,000.00
Cesium-134m	100.00
Cesium-134	1.0
Cesium-135	10.00
Cesium-136	10.00
Cesium-137	10.00
Chlorine-36	10.00
Chlorine-38	10.00
Cobalt-57	10.00
Chromium-51	1,000.00
Cobalt-58m	10.00
Cobalt-58	10.00
Cobalt-60	1.00
Copper-64	100.00
Dysprosium-165	10.00
Dysprosium-166	100.00
Erbium-169	100.00
Erbium-171	100.00
Europium-152 (9.2 h)	100.00
Europium-152 (13 yr)	1.00
Europium-154	1.00
Europium-155	10.00
Fluorine-18	1,000.00
Gadolinium-153	10.00
Gadolinium-159	100.00
Gallium-72	10.00
Germanium-71	100.00
Gold-198	100.00
Gold-199	100.00
Hafnium-181	10.00
Holmium-166	100.00
Hydrogen-3	1,000.00
Indium-113m	100.00
Indium-114m	10.00
Indium-115m	100.00
Indium-115	10.00
Iodine-125	1.00

## 105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.196 Table II: continued

Material	Microcuries
Iodine-126	1.00
Iodine-129	0.1
Iodine-131	1.0
Iodine-132	10.00
Iodine-133	1.00
Iodine-134	10.00
Iodine-135	10.00
Iridium-192	10.00
Iridium-194	100.00
Iron-55	100.00
Iron-59	10.00
Krypton-85	100.00
Krypton-87	10.00
Lanthanum-140	10.00
Lutetium-177	100.00
Manganese-52	10.00
Manganese-54	10.00
Manganese-56	10.00
Mercury-197m	100.00
Mercury-197	100.00
Mercury-203	10.00
Molybdenum-99	100.00
Neodymium-147	100.00
Neodymium-149	100.00
Nickel-59	100.00
Nickel-63	10.00
Nickel-65	100.00
Niobium-93m	10.00
Niobium-95	10.00
Niobium-97	10.00
Osmium-185	10.00
Osmium-191m	100.00
Osmium-191	100.00
Osmium-193	100.00
Palladium-103	100.00
Palladium-109	100.00
Phosphorus-32	10.00
Phosphorus-33	100.00
Platinum-191	100.00
Platinum-193m	100.00
Platinum-193	100.00
Platinum-197m	100.00
Platinum-197	100.00
Plutonium-239	0.01
Polonium-210	0.1
Potassium-42	10.00
Praseodymium-142	100.00
Praseodymium-143	100.00
Promethium-147	10.00
Promethium-149	10.00
Radium-226	0.01
Rhenium-186	100.00
Rhenium-188	100.00
Rhodium-103m	100.00
Rhodium-105	100.00
Rubidium-86	10.00
Rubidium-87	10.00
Ruthenium-97	100.00

## 105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.196 Table II: continued

<u>Material</u>	<u>Microcuries</u>
Ruthenium-103	10.00
Ruthenium-105	10.00
Ruthenium-106	1.00
Samarium-151	10.00
Samarium-153	100.00
Scandium-46	10.00
Scandium-47	100.00
Scandium-48	10.00
Selenium-75	10.00
Silicon-31	100.00
Silver-105	10.00
Silver-110m	1.00
Silver-111	100.00
Sodium-22	1.0
Sodium-24	10.00
Strontium-85	10.00
Strontium-89	1.00
Strontium-90	0.1
Strontium-91	10.00
Strontium-92	10.00
Sulphur-35	100.00
Tantalum-182	10.00
Technetium-96	10.00
Technetium-97m	100.00
Technetium-97	100.00
Technetium-99m	100.00
Technetium-99	10.00
Tellurium-125m	10.00
Tellurium-127m	10.00
Tellurium-127	100.00
Tellurium-129m	10.00
Tellurium-129	100.00
Tellurium-131m	10.00
Tellurium-132	10.00
Terbium-160	10.00
Thallium-200	100.00
Thallium-201	100.00
Thallium-202	100.00
Thallium-204	10.00
Thorium (natural)	100.00
Thulium-170	10.00
Thulium-171	10.00
Tin-113	10.00
Tin-125	10.00
Tungsten-181	10.00
Tungsten-185	10.00
Tungsten-187	100.00
Uranium (natural)	100.00
Uranium-233	0.01
Uranium-234/235	0.01
Vanadium-48	10.00
Xenon-131m	1,000.00
Xenon-133	100.00
Xenon-135	100.00
Ytterbium-175	100.00
Yttrium-90	10.00
Yttrium-91	10.00
Yttrium-92	100.00

120.196 Table II: continued

Material	Microcuries
Yttrium-93	100.00
Zinc-65	10.00
Zinc-69m	100.00
Zinc-69	1,000.00
Zirconium-93	10.00
Zirconium-95	10.00
Zirconium-97	10.00
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

Note: For purposes of 105 CMR 120.125(C)(1), where there is involved a combination of radionuclides in known amounts, the limit for the combination should 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 the radionuclides in the combination is R.

Note: To convert microcuries ( $\mu\text{Ci}$ ) to SI units of kilobecquerels (kBq), multiply the above values by 37.

Example: Zirconium-97 (10  $\mu\text{Ci}$ ) (37) = 370 kBq.  
(10  $\mu\text{Ci}$  multiplied by 37 is equivalent to 370 kBq)

120.196: Table III Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release

Radioactive Material <sup>1</sup>	Release fraction	Quantity(Ci)
Actinium-228	0.001	4,000
Americium-241	0.001	2
Americium-242	0.001	2
Americium-243	0.001	2
Antimony-124	0.01	4,000
Antimony-126	0.01	6,000
Barium-133	0.01	10,000
Barium-140	0.01	30,000
Bismuth-207	0.01	5,000
Bismuth-210	0.01	600
Cadmium-109	0.01	1,000
Cadmium-113	0.01	80
Calcium-45	0.01	20,000
Californium-252	0.001	9 (20mg)
Carbon-14	0.01	50,000
	Non CO	
Cerium-141	0.01	10,000
Cerium-144	0.01	300
Cesium-134	0.01	2,000
Cesium-137	0.01	3,000
Chlorine-36	0.5	100
Chromium-51	0.01	300,000
Cobalt-60	0.001	5,000
Copper-64	0.01	200,000
Curium-242	0.001	60
Curium-243	0.001	3
Curium-244	0.001	4
Curium-245	0.001	2
Europium-152	0.01	500
Europium-154	0.01	400
Europium-155	0.01	3,000
Germanium-68	0.01	2,000
Gadolinium-153	0.01	5,000
Gold-198	0.01	30,000
Hafnium-172	0.01	400
Hafnium-181	0.01	7,000
Holmium-166m	0.01	100
Hydrogen-3	0.5	20,000
Indium-114m	0.01	1,000
Iodine-125	0.5	10
Iodine-131	0.5	10
Iridium-192	0.001	40,000
Iron-55	0.01	40,000
Iron-59	0.01	7,000
Krypton-85	1.0	6000000
Lead-210	0.01	8
Manganese-56	0.01	60,000
Mercury-203	0.01	10,000
Molybdenum-99	0.01	30,000
Neptunium-237	0.001	2
Nickel-63	0.01	20,000
Niobium-94	0.01	300
Phosphorus-32	0.5	100

<sup>1</sup> 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 Table III exceeds one.

120.196 Table III: continued

Radioactive Material <sup>1</sup>	Release fraction	Quantity(Ci)
Phosphorus-33	0.5	1,000
Polonium-210	0.01	10
Potassium-42	0.01	9,000
Promethium-145	0.01	4,000
Promethium-147	0.01	4,000
Radium-226	0.001	100
Ruthenium-106	0.01	200
Samarium-151	0.01	4,000
Scandium-46	0.01	3,000
Selenium-75	0.01	10,000
Silver-110m	0.01	1,000
Sodium-22	0.01	9,000
Sodium-24	0.01	10,000
Strontium-89	0.01	3,000
Strontium-90	0.01	90
Sulphur-35	0.5	900
Technetium-99	0.01	10,000
Technetium-99m	0.01	400,000
Tellurium-127m	0.01	5,000
Tellurium-129m	0.01	5,000
Terbium-160	0.01	4,000
Thulium-170	0.01	4,000
Tin-113	0.01	10,000
Tin-123	0.01	3,000
Tin-126	0.01	1,000
Titanium-44	0.01	100
Vanadium-48	0.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	0.01	2,000
Zinc-65	0.01	5,000
Zirconium-93	0.01	400
Zirconium-95	0.01	5,000
Any other beta-gamma emitter	0.01	10,000
Mixed fission products	0.01	1,000
Mixed corrosion products	0.01	10,000
Contaminated equipment $\beta$ - $\gamma$	0.001	10,000
Irradiated material, any form other than solid noncombustible	0.01	1,000
Irradiated material, solid noncombustible	0.001	10,000
Mixed radioactive waste, $\beta$ - $\gamma$	0.01	1,000
Packaged mixed waste <sup>3</sup>	0.001	10,000
Contaminated equipment, alpha	0.0001	20
Any other alph emitter	0.001	2
Packaged waste alpha <sup>2</sup>	0.0001	20
Combinations of radioactive materials listed <sup>1</sup>	-----	----

<sup>1</sup> 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 Table III exceeds one.

<sup>2</sup> 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 the material in Table III exceeds one.

<sup>3</sup> Waste packaged in Type B containers does not require an emergency plan.

## 105 CMR: DEPARTMENT OF PUBLIC HEALTH

## 120.197: Appendix C -- Limits for Broad Licenses

RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Antimony-122	1.0	0.01
Antimony-124	1.0	0.01
Antimony-125	1.0	0.01
Arsenic-73	10.0	0.1
Arsenic-74	1.0	0.01
Arsenic-76	1.0	0.01
Arsenic-77	10.0	0.1
Barium-131	10.0	0.1
Barium-140	1.0	0.01
Beryllium-7	10.0	0.1
Bismuth-210	0.1	0.001
Bromine-82	10.0	0.1
Cadmium-109	1.0	0.01
Cadmium-115m	1.0	0.01
Cadmium-115	10.0	0.1
Calcium-45	1.0	0.01
Calcium-47	10.0	0.1
Carbon-14	100.0	1.0
Cerium-141	10.0	0.1
Cerium-143	10.0	0.1
Cerium-144	0.1	0.001
Cesium-131	100.0	1.0
Cesium-134m	100.0	1.0
Cesium-134	0.1	0.001
Cesium-135	1.0	0.01
Cesium-136	10.0	0.1
Cesium-137	0.1	0.001
Chlorine-36	1.0	0.01
Chlorine-38	100.0	1.0
Chromium-51	100.0	1.0
Cobalt-57	10.0	0.1
Cobalt-58m	100.0	1.0
Cobalt-58	1.0	0.01
Cobalt-60	0.1	0.001
Copper-64	10.0	0.1
Dysprosium-165	100.0	1.0



## 105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.197: continued

RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Dysprosium-166	10.0	0.1
Erbium-169	10.0	0.1
Erbium-171	10.0	0.1
Europium-152 (9.2 h)	10.0	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1.0	0.01
Fluorine-18	100.0	1.0
Gadolinium-153	1.0	0.01
Gadolinium-159	10.0	0.1
Gallium-72	10.0	0.1
Germanium-71	100.0	1.0
Gold-198	10.0	0.1
Gold-199	10.0	0.1
Hafnium-181	1.0	0.01
Holmium-166	10.0	0.1
Hydrogen-3	100.0	1.0
Indium-113m	100.0	1.0
Indium-114m	1.0	0.01
Indium-115m	100.0	1.0
Indium-115	1.0	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10.0	0.1
Iodine-133	1.0	0.01
Iodine-134	10.0	0.1
Iodine-135	1.0	0.01
Iridium-192	1.0	0.01
Iridium-194	10.0	0.1
Iron-55	10.0	0.1
Iron-59	1.0	0.01
Krypton-85	100.0	1.0
Krypton-87	10.0	0.1
Lanthanum-140	1.0	0.01

## 105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.197: continued

RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Lutetium-177	10.0	0.1
Manganese-52	1.0	0.01
Manganese-54	1.0	0.01
Manganese-56	10.0	0.1
Mercury-197m	10.0	0.1
Mercury-197	10.0	0.1
Mercury-203	1.0	0.01
Molybdenum-99	10.0	0.1
Neodymium-147	10.0	0.1
Neodymium-149	10.0	0.1
Nickel-59	10.0	0.1
Nickel-63	1.0	0.01
Nickel-65	10.0	0.1
Niobium-93m	1.0	0.01
Niobium-95	1.0	0.01
Niobium-97	100.0	1.0
Osmium-185	1.0	0.01
Osmium-191m	100.0	1.0
Osmium-191	10.0	0.1
Osmium-193	10.0	0.1
Palladium-103	10.0	0.1
Palladium-109	10.0	0.1
Phosphorus-32	1.0	0.01
Phosphorus-33	10.0	0.1
Platinum-191	10.0	0.1
Platinum-193m	100.0	1.0
Platinum-193	10.0	0.1
Platinum-197m	100.0	1.0
Platinum-197	10.0	0.1
Polonium-210	0.01	0.0001
Potassium-42	1.0	0.01
Praseodymium-142	10.0	0.1
Praseodymium-143	10.0	0.1
Promethium-147	1.0	0.01
Promethium-149	10.0	0.1
Radium-226	0.01	0.0001

## 105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.197: continued

RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Rhenium-186	10.0	0.1
Rhenium-188	10.0	0.1
Rhodium-103m	1,000.0	10.0
Rhodium-105	10.0	0.1
Rubidium-86	1.0	0.01
Rubidium-87	1.0	0.01
Ruthenium-97	100.0	1.0
Ruthenium-103	1.0	0.01
Ruthenium-105	10.0	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1.0	0.01
Samarium-153	10.0	0.1
Scandium-46	1.0	0.01
Scandium-47	10.0	0.1
Scandium-48	1.0	0.01
Selenium-75	1.0	0.01
Silicon-31	10.0	0.1
Silver-105	1.0	0.01
Silver-110m	0.1	0.001
Silver-111	10.0	0.1
Sodium-22	0.1	0.001
Sodium-24	1.0	0.01
Strontium-85m	1,000.0	10.0
Strontium-85	1.0	0.01
Strontium-89	1.0	0.01
Strontium-90	0.01	0.0001
Strontium-91	10.0	0.1
Strontium-92	10.0	0.1
Sulphur-35	10.0	0.1
Tantalum-182	1.0	0.01
Technetium-96	10.0	0.1
Technetium-97m	10.0	0.1
Technetium-97	10.0	0.1
Technetium-99m	100.0	1.0
Technetium-99	1.0	0.01
Tellurium-125m	1.0	0.01

## 105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.197: continued

RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Tellurium-127m	1.0	0.01
Tellurium-127	10.0	0.1
Tellurium-129m	1.0	0.01
Tellurium-129	100.0	1.0
Tellurium-131m	10.0	0.1
Tellurium-132	1.0	0.01
Terbium-160	1.0	0.01
Thallium-200	10.0	0.1
Thallium-201	10.0	0.1
Thallium-202	10.0	0.1
Thallium-204	1.0	0.01
Thulium-170	1.0	0.01
Thulium-171	1.0	0.01
Tin-113	1.0	0.01
Tin-125	1.0	0.01
Tungsten-181	1.0	0.01
Tungsten-185	1.0	0.01
Tungsten-187	10.0	0.1
Vanadium-48	1.0	0.01
Xenon-131m	1,000.0	10.0
Xenon-133	100.0	1.0
Xenon-135	100.0	1.0
Ytterbium-175	10.0	0.1
Yttrium-90	1.0	0.01
Yttrium-91	1.0	0.01
Yttrium-92	10.0	0.1
Yttrium-93	1.0	0.01
Zinc-65	1.0	0.01
Zinc-69m	10.0	0.1
Zinc-69	100.0	1.0
Zirconium-93	1.0	0.01
Zirconium-95	1.0	0.01

120.197: continued

RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Zirconium-97	1.0	0.01
Any Radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above.	0.1	0.001

Note 1: To convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by 37.

Example: Zirconium-97 (Col. II) (0.01 Ci multiplied by 37 is equivalent to 0.37 GBq)

120.198: Appendix D: Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

I. 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.

II. Financial Test.

(A) To pass the financial test, the parent company must meet the criteria of either II.A.1 or II.A.2:

(1) The parent company must have:

(a) 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,

(b) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used); and,

(c) Tangible net worth of at least ~~\$10~~ **\$21** million; and,

(d) Assets located in the United States amounting to at least 90% of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

(2) The parent company must have:

(a) A current rating for its most recent **uninsured, uncollateralized, and unencumbered** bond issuance of AAA, AA, A, or BBB **(including adjustments of + and -)** as issued by Standard and Poor's or Aaa, Aa, A, or Baa **(including adjustments of 1, 2, or 3)** as issued by Moody's; and,

(b) Tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used); and,

(c) Tangible net worth of at least ~~\$10~~ **\$21** million; and,

(d) Assets located in the United States amounting to at least 90% of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if certification is used).

(B) 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 statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the auditor's attention 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) (1) 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.

(2) If the parent company no longer meets the requirements of II.A, the licensee must send notice to the Agency of intent to establish alternate financial assurance as specified in the ~~Commission's~~ **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.

120.198: continued

III. Parent Company Guarantee. The terms of a parent company guarantee that an applicant or licensee obtains must provide that:

(A) 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.

(B) 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 the 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.

(C) The parent company guarantee and financial test provisions must remain in effect until the Agency has terminated the license.

(D) 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 that has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

120.198: Appendix E: Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

I. 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 105 CMR 120.198: *Appendix E*, Section II. The terms of the self-guarantee are in 105 CMR 120.198: *Appendix E*, Section III. 105 CMR 120.198: *Appendix E* establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test.

(A) To pass the financial test, a company must meet all of the following criteria:

(1) Tangible net worth **of at least \$21 million, and** at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(2) Assets located in the United States amounting to at least 90% of total assets or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(3) A current rating for its most recent **uninsured, uncollateralized, and unencumbered** bond issuance of AAA, AA, or A (**including adjustments of + and -**) as issued by Standard and Poors (S&P), Aaa, Aaa, or A (**including adjustments of 1, 2, or 3**) as issued by Moody's.

(B) To pass the financial test, a company must meet all of the following additional requirements:

(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(2) 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, 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 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.

(3) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(C) If the licensee no longer meets the requirements of 105 CMR 120.198: *Appendix E*, Section II.(A), 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.

III. Company Self-Guarantee. The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

(A) The ~~parent company~~ 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 receipts.

(B) 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.



120.198: continued

(C) 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.

(D) 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.

(E) 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 105 CMR 120 198: *Appendix E*, Section II.(A).

(F) 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.

120.198: Appendix F: Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have No Outstanding Rated Bonds

I. 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 105 CMR 120.198: *Appendix F*, Section II. The terms of the self-guarantee are in 105 CMR 120.198: *Appendix F*, Section III. 105 CMR 120.198: *Appendix F* establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test.

(A) To pass the financial test, a company must meet all of the following criteria:

(1) Tangible net worth greater than ~~\$10~~ **\$21** million, or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(2) Assets located in the United States amounting to at least 90% of total assets or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(3) A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

(B) In addition, to pass the financial test, a company must meet all of the following additional requirements:

(1) The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited year end financial statement based on United States generally accepted accounting practices 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 that may 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.

(2) 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 105 CMR 120.198: *Appendix F*, Section II.(A), the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in 105 CMR 120.125(C). The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. Company Self-guarantee. The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

(A) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the Agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

(B) 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.

120.198: continued

(C) 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.

(D) 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.

120.198: Appendix G: Criteria Relating to Use of Financial Tests and Self Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Nonprofit Colleges, Universities, and Hospitals

I. 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 applicant or licensee passes the financial test of 105 CMR 120.198: *Appendix G*, Section II. The terms of the self-guarantee are in 105 CMR 120.198: *Appendix G*, Section III. 105 CMR 120.198: *Appendix G* establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test.

(A) For colleges and universities, to pass the financial test a college or university must meet either the criteria in 105 CMR 120.198: *Appendix G*, Section II.(A)(1) or the criteria in 105 CMR 120.198: *Appendix G*, Section II.(A)(2).

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A **(including adjustments of + or -)** as issued by Standard and Poor's (S&P) or Aaa, Aa, or A **(including adjustments of 1, 2, or 3)** as issued by Moody's.

(2) For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least \$50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

(B) For hospitals, to pass the financial test a hospital must meet either the criteria in 105 CMR 120.198: *Appendix G*, Section II.(B)(1) or the criteria in 105 CMR 120.198: *Appendix G*, Section II.(B)(2):

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A **(including adjustments of + or -)** as issued by Standard and Poor's (S&P) or Aaa, Aa, or A **(including adjustments of 1, 2, or 3)** as issued by Moody's.

(2) For applicants or licensees that do not issue bonds, all the following tests must be met:

(a) (Total Revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

(b) Long term debt divided by net fixed assets must be less than or equal to 0.67.

(c) (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

(d) Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing licensee.

(C) In addition, to pass the financial test, a licensee must meet the following requirements: (for institutions using 105 CMR 120.198: *Appendix G*: Section II, (A)(2) method of qualifying; for a self-guarantee 105 CMR 120.198: *Appendix G*: Sections II(C)(1) and II(C)(2) will apply.

(1) The licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the independently audited year end financial statements, based on United States generally accepted accounting practices, 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 licensee no longer passes the test.

120.198: continued

(2) After the initial financial test, the licensee 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 105 CMR 120.198: *Appendix G*: Section I, the licensee must send notice to the Agency of its intent to establish alternative financial assurance as specified in Agency regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Self-guarantee. The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

(A) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, and/or return receipt requested, to the Agency. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

(B) The licensee shall provide alternative financial assurance as specified in 105 CMR 120.125(C) within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

(C) 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.

(D) The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer or officer of the institution) 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.

~~(DE)~~ 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 Poor's or Moody's, the licensee shall provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service.

~~(E)~~ 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.

~~(D)~~ 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.

~~(EF)~~ 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 Poor's or Moody's, 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 Poor's and Moody's, the licensee no longer meets the requirements of 105 CMR 120 199: *Appendix E*, Section II.(A).

~~(F)~~ 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.