



**MARYLAND DEPARTMENT OF THE ENVIRONMENT**  
2500 Broening Highway • Baltimore, Maryland 21224  
(410) 631-3000 • 1-800-633-6101 • <http://www.mde.state.md.us>

Parris N. Glendening  
Governor

Jane T. Nishida  
Secretary

April 8, 2002

02 APR 17 PM 2:52

STP

Ms. Josephine M. Piccone, Deputy Director  
Office of State and Tribal Programs  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

Dear Mr. Combs:

RE: Amendments to Maryland Regulations – Supplement 7

Enclosed please find a copy of the final “as published” Supplement 7 to Code of Maryland Regulations 26.12.01.01. Supplement 7 became effective April 1, 2002.

Two minor non-substantive changes were made to Supplement 7 as a result of public comment. A copy of the changes is attached.

We can supply a computer disk with Supplement 7 in Word format, or can e-mail Supplement 7 in Word format. If you wish us to do either, please contact Mr. Michael Kurman at (410) 631-3208 or at [mkurman@mde.state.md.us](mailto:mkurman@mde.state.md.us).

If further information is required, please advise.

Sincerely yours,

Roland G. Fletcher, Manager  
Radiological Health Program  
Air and Radiation Management Administration

Enclosures

RGF/MDK

cc: Michael Kurman  
Ray Manley

ALL PAGES ARE INCLUSIVE

Remove Pages From Permanent Binder

Cover Sheet  
v through xv  
A1 through A4  
A9 and A10  
C45 through C48  
C51 and C51-1  
D13 and D14  
E25  
G17 and G18  
G21 and G22

Insert Pages Into Permanent Binder

Cover Sheet  
v through xv  
A1 through A4  
A9 and A10  
C45 through C48  
C51 and C51-1  
D13 and D14  
D42-5 through D42-9  
E25 through E27  
G17 and G18  
G21 and G22

INQUIRIES TO: Ray Manley  
Radiological Health Program  
Maryland Department of the Environment  
2500 Broening Highway  
Baltimore, MD 21224  
(410) 631-3301

**\* CHANGES SHOWN \***

Sec. D.1404 Alternate Criteria for License termination.

(a) The Department may terminate a license using alternate criteria greater than the dose criterion of D.1402 if the licensee—

(1) Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 1 mSv/y (100 mrem/y) limit of subpart D, by submitting an analysis of possible sources of exposure;

(2) Has employed to the extent practical restrictions on site use according to the provisions of D.1403 in minimizing exposures at the site; and

(3) Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.

(4) Has submitted a decommissioning plan or License Termination Plan (LTP)] to the Department indicating the licensee's intent to decommission in accordance with Sec. D.32(~~d~~)(c) of this chapter, and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning. The scope of participation and persons representing community interests must be pre-approved by the Agency;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

(b) The use of alternate criteria to terminate a license requires the approval of the Department after consideration of the Agency staff's recommendations that will address any comments provided by the Environmental Protection Agency and any public comments submitted pursuant to Sec. D.1405.

Sec. D.1405 Public Notification and Public Participation.

Upon the receipt of an LTP or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to Sec. D.1404, D.1403 or whenever the Department deems such notice to be in the public interest, the Department shall:

(a) Notify and solicit comments from:

# Title 26 DEPARTMENT OF THE ENVIRONMENT

## Subtitle 12 RADIATION MANAGEMENT

### 26.12.01 Radiation Protection

Authority: Environment Article, §§8-106 and 8-301,  
Annotated Code of Maryland

#### Notice of Final Action (01-183-F-I)

On March 5, 2002, the Secretary of the Environment adopted amendments to Regulation .01 under COMAR 26.12.01 Radiation Protection. This action, which was proposed for adoption in 28:12 Md. R. 1183 — 1184 (June 15, 2001), has been adopted with the nonsubstantive changes shown below.

Effective Date: April 1, 2002.

#### Attorney General's Certification

In accordance with State Government Article, §10-113, Annotated Code of Maryland, the Attorney General certifies that the following changes do not differ substantively from the proposed text. The nature of the changes and the basis for this conclusion are as follows:

Sec. D.1404: This change corrects a typographical error in a cross-reference from D.32(d) to D.32(c).

Sec. D.1405: An omission was inadvertently made in a cross-reference. Section D.1403 has been added to the regulation to complete concurrence with the current federal regulations. The cross-reference assures that there will be notification of the public when alternative criteria of restricted release are used.

JANE T. NISHIDA  
Secretary of Environment

# Title 31 MARYLAND INSURANCE ADMINISTRATION

## Subtitle 10 HEALTH INSURANCE — GENERAL

### 31.10.06 Standards for Medicare Supplement Policies

Authority: Insurance Article, §§2-109 and 8-403(b), Title 15, Subtitle 9 and Title 27; Health-General Article, §§19-705 and 19-706;  
Annotated Code of Maryland

#### Notice of Final Action (01-381-F)

On February 5, 2002, the Insurance Commissioner amended Regulations .02, .08, and .09-1 and adopted new Regulations .23 and .24 under COMAR 31.10.06 Standards for Medicare Supplement Policies. This action,

which was proposed for adoption in 28:22 Md. R. 1971 — 1976 (November 2, 2001), has been adopted as proposed.  
Effective Date: April 1, 2002.

STEVEN B. LARSEN  
Insurance Commissioner

## Subtitle 10 HEALTH INSURANCE — GENERAL

### 31.10.27 Health Insurance — Notice of Substantial, Available, and Affordable Coverage

Authority: Insurance Article, §§2-109 and 15-606.1,  
Annotated Code of Maryland

#### Notice of Final Action (01-375-F)

On February 5, 2002, the Insurance Commissioner adopted new Regulations .01 — .06 under new chapter, COMAR 31.10.27 Health Insurance — Notice of Substantial, Available, and Affordable Coverage. This action, which was proposed for adoption in 28:22 Md. R. 1976 — 1977 (November 2, 2001), has been adopted as proposed.

Effective Date: April 1, 2002.

STEVEN B. LARSEN  
Insurance Commissioner

## Subtitle 14 LONG-TERM CARE

### 31.14.01 Long-Term Care Insurance

Authority: Insurance Article, §§2-109, 10-115, 10-116.1, 14-124, 14-126, 14-136, and 15-412;  
Title 18, Subtitle 1; and Title 27; Health-General Article, §19-705;  
Annotated Code of Maryland

#### Notice of Final Action (01-422-F)

On March 8, 2002, the Insurance Commissioner adopted amendments to Regulations .02, .04 — .07, .09, .11 — .13, .15, .16, .18, .19, and .21, and new Regulations .24 — .32 under COMAR 31.14.01 Long-Term Care Insurance. This action, which was proposed for adoption in 28:25 Md. R. 2221 — 2234 (December 14, 2001), has been adopted with the nonsubstantive changes shown below.

Effective Date: April 1, 2002.

#### Attorney General's Certification

In accordance with State Government Article, §10-113, Annotated Code of Maryland, the Attorney General certifies that the following changes do not differ substantively from the proposed text. The nature of each change and the basis for this conclusion are as follows:

Regulation .02B(8): The change to correct a typographical error.

Regulation .04A(7): The change adds text that appears in the National Association of Insurance Commissioner's Long-Term Care Insurance Model Regulation that was inadvertently omitted. The insurance industry discovered the omission and requested that the omitted text be added. The change is not substantive because it could reasonably have been anticipated by participants in the adoption process and does not significantly decrease the benefits or increase the burdens under the regulation.

Code of Maryland Regulation 26.12.01.01

Adopted: September 9, 1995

Effective: October 9, 1995

Supplement 1 Effective: December 6, 1996

Supplement 2 Effective: November 3, 1997

Supplement 3 Effective: June 29, 1998

Supplement 4 Effective: December 28, 1998

Supplement 5 Effective: June 14, 1999

Supplement 6 Effective: February 7, 2000

Supplement 7 Effective: April 1, 2002

**REGULATIONS FOR THE CONTROL OF IONIZING RADIATION (1994)**

RADIOLOGICAL HEALTH PROGRAM  
AIR AND RADIATION MANAGEMENT ADMINISTRATION  
MARYLAND DEPARTMENT OF THE ENVIRONMENT

2500 BROENING HIGHWAY  
BALTIMORE, MARYLAND 21224

## Precautionary Procedures

Section D.901 Caution Signs.....	D24
Section D.902 Posting Requirements.....	D25
Section D.903 Exceptions to Posting Requirements .....	D25
Section D.904 Labeling Containers and Radiation Machines.....	D26
Section D.905 Exemptions to Labeling Requirements.....	D26
Section D.906 Procedures for Receiving and Opening Packages.....	D27

## Waste Disposal

Section D.1001 General Requirement .....	D29
Section D.1002 Method of Obtaining Approval of Proposed Disposal Procedures .....	D29
Section D.1003 Disposal by Release into Sanitary Sewerage.....	D29
Section D.1005 Treatment or Disposal by Incineration .....	D30
Section D.1006 Disposal of Specific Wastes.....	D30
Section D.1007 Transfer for Disposal and Manifests.....	D30
Section D.1008 Compliance with Environmental and Health Protection Regulations .....	D31

## Records

Section D.1101 General Provisions .....	D31
Section D.1102 Records of Radiation Protection Programs .....	D31
Section D.1103 Records of Surveys.....	D32
Section D.1104 Records of Tests for Leakage or Contamination of Sealed Sources.....	D32
Section D.1105 Records of Prior Occupational Dose .....	D32
Section D.1106 Records of Planned Special Exposures.....	D32
Section D.1107 Records of Individual Monitoring Results .....	D33
Section D.1108 Records of Dose to Individual Members of the Public .....	D33
Section D.1109 Records of Waste Disposal .....	D34
Section D.1110 Records of Testing Entry Control Devices for Very High Radiation Areas.....	D35
Section D.1111 Form of Records.....	D35

## Reports

Section D.1201 Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.....	D35
Section D.1202 Notification of Incidents.....	D35
Section D.1203 Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits .....	D37
Section D.1204 Reports of Planned Special Exposures .....	D38
Section D.1205 Notifications and Reports to Individuals .....	D38
Section D.1206 Reports of Leaking or Contaminated Sealed Sources.....	D38
Section D.1207 Annual Reports from General Licenses .....	D39
Section D.1208 Misadministration .....	D39
Section D.1209 Notifications, Records, and Reports of Misadministrations.,,,.....	D41
Section D.1210 Additional Reporting Requirements for Radioactive Materials .....	D42

## Additional Requirements

Section D.1220 Notification of Failure to Comply or Existence of a Defect and Its Evaluation.....	D42-2
Section D.1301 Vacating Premises.....	D42-4

## Radiological Criteria for License Termination

Section D.1401 General Provisions and Scope.....	D42-5
Section D.1402 Radiological Criteria for Unrestricted Use.....	D42.5
Section D.1403 Criteria for License Termination Under Restricted Conditions.....	D42-5
Section D.1404 Alternate Criteria for License Termination.....	D42-8
Section D.1405 Public Notification and Public Participation.....	D42-8
Section D.1406 Minimization of Contamination.....	D42-9

## Appendices

Appendix A Protection Factors for Respirators.....	D43
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.....	D47
Appendix C Quantities of Licensed Material Requiring Labeling .....	D102
Appendix D Requirements for Transfer of Low-Level Radioactive Waste for Disposal at Land Disposal Facilities and Manifests.....	D111
Appendix E Classification and Characteristics of Low Level Radioactive Waste.....	D112

## PART E – INDUSTRIAL RADIOGRAPHIC OPERATIONS

Section E.1 Purpose.....	E1
Section E.2 Scope .....	E1
Section E.4 Exemptions.....	E4
Section E.5 Special Requirements for Cabinet Radiography.....	E4
Section E.20 Performance Requirements for Industrial Radiography Equipment Using Sealed Sources of Radiation.....	E5
Section E.21 Limits on External Radiation Levels from Storage Containers and Source Changers.....	E7
Section E.23 Locking of Radiation Machines, Radiographic Exposure Devices, Storage Containers and Source Changers.....	E7
Section E.25 Radiation Survey Instruments .....	E8
Section E.27 Leak Testing and Replacement of Sealed Sources.....	E8
Section E.29 Quarterly Inventory.....	E9
Section E.31 Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.....	E10
Section E.33 Permanent Radiographic Installations.....	E10
Section E.35 Labeling, Storage, and Transportation.....	E11

Section E.41	Conducting Industrial Radiographic Operations.....	E12
Section E.42	Radiation Safety Officer for Industrial Radiography.....	E12
Section E.43	Training.....	E13
Section E.45	Operating and Emergency Procedures.....	E17
Section E.46	Supervision of Radiographers' Assistants.....	E18
Section E.47	Personnel Monitoring.....	E18
Section E.49	Radiation Surveys.....	E20
Section E.51	Surveillance.....	E20
Section E.53	Posting.....	E20
Section E.61	Records of the Specific License for Industrial Radiography.....	E20
Section E.63	Records of Receipt and Transfer of Sealed Sources.....	E20
Section E.65	Records of Radiation Survey Instruments.....	E21
Section E.67	Records of Leak Testing of Sealed Sources and Devices Containing Depleted Uranium.....	E21
Section E.69	Records of Quarterly Inventory.....	E21
Section E.71	Utilization Logs.....	E21
Section E.73	Records of Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.....	E22
Section E.75	Records of Alarm System and Entrance Control Checks at Permanent Radiographic Installations.....	E22
Section E.79	Records of Training and Certification.....	E22
Section E.81	Copies of Operating and Emergency Procedures.....	E22
Section E.82	Records of Personnel Monitoring Procedures.....	E23
Section E.85	Records of Radiation Surveys.....	E23
Section E.87	Form of Records.....	E23
Section E.89	Location of Documents and Records.....	E23
Section E.101	Notifications.....	E24

**Appendix**

Appendix A--NRC 10 CFR Part 34 Radiographer Certification

**PART F - X RAYS IN THE HEALING ARTS**

Section F.1	Scope.....	F1
Section F.2	Definition.....	F1

**General Regulatory Requirements**

Section F.3	General Requirements.....	F10
-------------	---------------------------	-----

**Diagnostic X-Ray Systems**

Section F.4	General Requirements for All Diagnostic X-Ray Systems.....	F15
Section F.5	Fluoroscopic X-Ray Systems Except for Computed Tomography X-Ray Systems.....	F17

Section F.6 Radiographic Systems Other than Fluoroscopic, Dental Intraoral, Veterinarian, or Computed Tomography X-Ray Systems .....	F23
Section F.7 Intraoral Dental Radiographic Systems.....	F29

**Therapeutic X-Ray Systems**

Section F.8 Therapeutic X-Ray Systems of Less Than One MeV.....	F32
Section F.9 X-Ray and Electron Therapy Systems with Energies of One MeV and Above .....	F38

**Other Diagnostic X-Ray Systems**

Section F.10 Veterinary Medicine Radiographic Installations .....	F51
Section F.11 Computed Tomography X-Ray Systems .....	F52

**PART G - USE OF RADIONUCLIDES IN THE HEALING ARTS**

Section G.1 Purpose and Scope .....	G1
Section G.2 Definitions .....	G1

**General Regulatory Requirements**

Section G.3 License Required.....	G3
Section G.4 License Applications and Amendments .....	G4
Section G.5 Notifications .....	G5

**Additional Requirements**

Section G.6 Additional Programs Required .....	G5
Section G.7 Radiation Safety Officer .....	G9
Section G.8 Radiation Safety Committee .....	G10
Section G.9 Statement of Authorities and Responsibilities.....	G12
Section G.10 Supervision .....	G12
Section G.11 Reserved .....	G13
Section G.12 Mobile Nuclear Medicine Service Administrative Requirements .....	G13
Section G.13 Suppliers .....	G14

**Specific Requirements**

Section G.14 Possession, Use, Calibration, and Check of Instruments to Measure Dosages of Alpha- or Beta-Emitting Radionuclides.....	G14
Section G.15 Possession, Use, Calibration, and Check of Dose Calibrators.....	G14
Section G.16 Calibration and Check of Survey Instruments.....	G16
Section G.17 Measurement of Dosages of Unsealed Radioactive Material for Medical Use.....	G17

Section G.18 Authorization for Calibration and Reference Sources .....	G17
Section G.19 Requirements for Possession of Sealed Sources and Brachytherapy Sources .....	G18
Section G.20 Syringe Shields.....	G20
Section G.21 Syringe Labels.....	G20
Section G.22 Vial Shields .....	G20
Section G.23 Vial Shield Labels .....	G20
Section G.24 Surveys for Contamination and Ambient Radiation Dose Rate .....	G20
Section G.25 Release of Patients or Human Research Subjects Containing Radiopharmaceuticals or Permanent Implants .....	G21
Section G.26 Mobile Nuclear Medicine Service Technical Requirements .....	G22
Section G.27 Storage of Volatiles and Gases .....	G22
Section G.28 Reserved .....	G22

**Specific Requirements for the Use of Radiopharmaceuticals for Uptake, Dilution,  
Or Excretion Studies**

Section G.29 Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies .....	G23
Section G.30 Possession of Survey Instrument .....	G23

**Specific Requirements for the Use of Radiopharmaceuticals, Generators, and  
Reagent Kits for Imaging and Localization Studies**

Section G.31 Use of Unsealed Radioactive Material for Imaging and Localization Studies.....	G23
Section G.32 Permissible Molybdenum-99 Concentration.....	G24
Section G.33 Control of Aerosols and Gases .....	G24
Section G.34 Possession of Survey Instruments.....	G25

**Specific Requirements for the Use of Radiopharmaceuticals for Therapy**

Section G.35 Use of Unsealed Radioactive Material for Therapeutic Administration .....	G25
Section G.36 Safety Instruction .....	G25
Section G.37 Safety Precautions .....	G26
Section G.38 Possession of Survey Instruments.....	G27

**Specific Requirements for the Use of Sealed Sources for Diagnosis**

Section G.39 Use of Sealed Sources for Diagnosis.....	G27
Section G.40 Availability of Survey Instrument .....	G28

### **Specific Requirements for the Use of Sources of Brachytherapy**

Section G.41 Use of Sources for Brachytherapy .....	G28
Section G.42 Safety Instruction .....	G28
Section G.43 Safety Precautions .....	G29
Section G.44 Brachytherapy Sources Inventory .....	G30
Section G.45 Release of Patients and Human Research Subjects Treated with Temporary Implants.....	G31
Section G.46 Possession of Survey Instruments.....	G31

### **Specific Requirements for the Use of a Sealed Source in Teletherapy**

Section G.47 Use of a Sealed Source in a Teletherapy Unit.....	G31
Section G.48 Maintenance and Repair Restrictions .....	G31
Section G.49 Amendments.....	G32
Section G.50 Safety Instruction .....	G32
Section G.51 Doors, Interlocks, and Warning Systems .....	G33
Section G.52 Possession of Survey Instrument .....	G33
Section G.53 Radiation Monitoring Device .....	G33
Section G.54 Viewing System .....	G34
Section G.55 Dosimetry Equipment .....	G34
Section G.56 Full Calibration Measurements.....	G35
Section G.57 Periodic Spot Checks .....	G37
Section G.58 Radiation Surveys for Teletherapy Facilities .....	G38
Section G.59 Safety Spot Checks for Teletherapy Facilities .....	G39
Section G.60 Modification of Teletherapy Unit or Room Before Beginning a Treatment Program.....	G40
Section G.61 Reports of Teletherapy Surveys, Checks, Tests, and Measurements .....	G40
Section G.62 Five-Year Inspection.....	G40

### **Specific Requirements for Training**

Section G.63 Radiation Safety Officer .....	G41
Section G.64 Training for Existing Radiation Safety Officer .....	G42
Section G.65 Training for Uptake, Dilution, or Excretion Studies.....	G42
Section G.66 Training for Imaging and Localization Studies.....	G43
Section G.67 Training for Therapeutic Use of Radiopharmaceuticals .....	G45
Section G.68 Training for Therapeutic Use of Brachytherapy Sources .....	G46
Section G.69 Training for Ophthalmic Use of Strontium-90 .....	G48
Section G.70 Training for Use of Sealed Sources for Diagnosis .....	G48
Section G.71 Training for Teletherapy .....	G49
Section G.72 Training for Teletherapy Physicist.....	G51
Section G.73 Training for Existing Authorized Users .....	G51
Section G.74 Physician Training in a Three-Month Program.....	G51

Section G.75 Training for an Authorized Nuclear Pharmacist .....	G51
Section G.75.1 Training for Existing Nuclear Pharmacist.....	G52
Section G.76 Recentness of Training.....	G53
Section G.77 Provisions for Research Involving Human Subjects Using Radioactive Material.....	G53

**PART H - RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT**

Section H.1 Purpose and Scope .....	H1
Section H.2 Definitions .....	H1

**General Regulatory Provisions and Specific Requirements**

Section H.3 Equipment Requirements.....	H1
Section H.4 Area Requirements.....	H3
Section H.5 Operating Requirements.....	H4
Section H.6 Personnel Requirements.....	H4

**PART I - RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS**

Section I.1 Purpose and Scope .....	I1
-------------------------------------	----

**Registration Procedure**

Section I.2 Registration Requirements.....	I1
Section I.3 General Requirements for the Issuance of a Registration for Particle Accelerators.....	I1
Section I.4 Human Use of Particle Accelerators .....	I2

**Radiation Safety Requirements for the Use of Particle Accelerators**

Section I.5 Reserved.....	I2
Section I.6 Limitations .....	I2
Section I.7 Shielding and Safety Design Requirements.....	I3
Section I.8 Particle Accelerator Controls and Interlock Systems .....	I3
Section I.9 Warning Devices.....	I3
Section I.10 Operating Procedures.....	I4
Section I.11 Radiation Monitoring Requirements.....	I4
Section I.12 Ventilation Systems .....	I5

**PART J - NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS**

Section J.1 Purpose and Scope.....	J1
------------------------------------	----

## **General Regulatory Provision and Specific Requirements**

Section J.11 Posting of Notices to Workers.....	J1
Section J.12 Instructions to Workers .....	J1
Section J.13 Notifications and Reports to Individuals .....	J2
Section J.14 Presence of Representatives of Licensees or Registrants and Workers During Inspection .....	J3
Section J.15 Consultation with Workers During Inspections.....	J4
Section J.16 Requests by Workers for Inspections.....	J4
Section J.17 Inspections Not Warranted; Informal Review .....	J4

## **PART T - TRANSPORTATION OF RADIOACTIVE MATERIAL**

Section T.1 Purpose and Scope .....	T1
Section T.2 Requirement for license.....	T1

### **General Regulatory Provisions**

Section T.3 Definitions.....	T1
Section T.5 Transportation of Licensed Material .....	T6

### **Exemptions**

Section T.10 Exemption for low-level materials.....	T7
---	----

### **General Licenses**

Section T.12 General License: Department Approved Package .....	T7
Section T.13 Previously Approved Packages .....	T8
Section T.14 General License: DOT Specification Container .....	T8
Section T.16 General License: Use of Foreign Approved Package.....	T9

### **Operating Controls and Procedures**

Section T.81 Applicability of Operating Controls and Procedures.....	T9
Section T.85 Preliminary Determination .....	T10
Section T.87 Routine Determinations.....	T10
Section T.88 Air Transport of Plutonium .....	T11
Section T.89 Opening Instructions.....	T11
Section T.91 Records.....	T11
Section T.93 Inspection and Tests .....	T12

Section T.95 Reports .....	T13
Section T.97 Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste .....	T13

**Quality Assurance**

Section T.101 Quality Assurance Requirements .....	T15
Section T.103 Quality Assurance Organization .....	T16
Section T.105 Quality Assurance Program.....	T17
Section T.107 Package Design Control .....	T18
Section T.109 Procurement Document Control .....	T19
Section T.111 Instructions, Procedures, and Drawings.....	T19
Section T.113 Document Control .....	T19
Section T.115 Control of Purchased Material, Equipment, and Supplies.....	T19
Section T.117 Identification and Control of Materials, Parts, and Components .....	T20
Section T.119 Control of Special Processes .....	T20
Section T.121 Internal Inspection .....	T20
Section T.123 Test Control .....	T20
Section T.125 Control of Measuring and Test Equipment.....	T20
Section T.127 Handling, Storage and Shipping Control .....	T21
Section T.129 Inspection, Test and Operating Status.....	T21
Section T.131 Nonconforming Materials, Parts, or Components .....	T21
Section T.133 Corrective Action.....	T21
Section T.135 Quality Assurance Records .....	T21
Section T.137 Audits .....	T21

**Appendix**

Appendix A Determination of A <sub>1</sub> and A <sub>2</sub> .....	T23
---	-----

**PART W - RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES**

Section W.1 Purpose .....	W1
Section W.2 Scope.....	W1
Section W.3 Definitions .....	W1

**Prohibition**

Section W.4 Prohibition .....	W2
-------------------------------	----

## Equipment Control

Section W.101 Limits on Levels of Radiation.....	W2
Section W.102 Storage Precautions.....	W2
Section W.103 Transport Precautions.....	W2
Section W.104 Radiation Survey Instruments.....	W3
Section W.105 Leak Testing of Sealed Sources.....	W3
Section W.106 Quarterly Inventory.....	W4
Section W.107 Utilization Records.....	W4
Section W.108 Use, Design, Performance, and Certification Criteria for Sealed Sources Used in Downhole Operations.....	W4
Section W.109 Labeling.....	W5
Section W.110 Inspection and Maintenance.....	W6

## Requirements for Personal Safety

Section W.201 Training Requirements.....	W6
Section W.202 Operating and Emergency Procedures.....	W7
Section W.203 Personnel Monitoring.....	W7

## Precautionary Procedures in Logging and Subsurface Tracer Studies

Section W.301 Security.....	W8
Section W.302 Handling Tools.....	W8
Section W.303 Subsurface Tracer Studies.....	W8
Section W.304 Particle Accelerators.....	W8
Section W.305 Uranium Sinker Bars.....	W8

## Radiation Surveys and Records

Section W.401 Radiation Surveys.....	W8
Section W.402 Documents and Records Required at Field Stations.....	W9
Section W.403 Documents and Records Required at Temporary Jobsites.....	W9

## Notification

Section W.501 Notification of Incidents, Abandonment, and Lost Sources.....	W10
---	-----

## Appendices

Appendix A Subjects to be Included in Training Courses for Logging Supervisors.....	W13
Appendix B Example of Plaque for Identifying Wells Containing Sealed Sources Containing Radioactive Material Abandoned Downhole.....	W14

## **PART X - USE OF RADIOACTIVE MATERIALS IN IRRADIATORS**

### **General Provisions**

Section X.1 Purpose and Scope .....	X1
Section X.2 Definitions.....	X1

### **Design and Performance Requirements for Irradiators**

Section X.21 Performance Criteria for Sealed Sources.....	X2
Section X.23 Access Control .....	X3
Section X.25 Shielding .....	X4
Section X.27 Fire Protection.....	X4
Section X.29 Radiation Monitors .....	X4
Section X.31 Control of Source Movement .....	X5
Section X.33 Irradiator Pools.....	X5
Section X.35 Source Rack Protection.....	X6
Section X.37 Power Failures .....	X6
Section X.39 Design Requirements.....	X6
Section X.41 Construction Monitoring and Acceptance Testing.....	X7

### **Operation of Irradiators**

Section X.51 Training.....	X8
Section X.53 Operating and Emergency Procedures .....	X10
Section X.55 Personnel Monitoring .....	X11
Section X.57 Radiation Surveys.....	X11
Section X.59 Detection of Leaking Sources.....	X12
Section X.61 Inspection and Maintenance .....	X12
Section X.63 Pool Water Purity.....	X13
Section X.65 Attendance During Operation.....	X13
Section X.67 Entering and Leaving the Radiation Room .....	X14
Section X.69 Irradiation of Explosive or Flammable Materials.....	X14

### **Records**

Section X.81 Records and Retention Periods.....	X14
Section X.83 Reports .....	X15

## PART A

### GENERAL PROVISIONS

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

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

"A1" means the maximum activity of special form radioactive material permitted in a Type A package.  
"A2" 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 Appendix A of Part T of these regulations, Table I, or may be derived in accordance with the procedure prescribed in Appendix A of Part T of these regulations.

"Absorbed dose" [See "Dose"]

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

"Act" means the Annotated Code of Maryland, Environment Article, Title 8 "Radiation".

"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 Maryland Department of Environment, Radiological Health Program.

"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 subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

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

"Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive material exists in concentrations:

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

(2) To such a degree that an individual present in the area without respirator protective equipment

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

could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC hours.

"Annually" means either (1) at intervals not to exceed 1 year or (2) once per year, at about the same time per year (plus or minus 1 month).

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

"Authorized nuclear pharmacist" means a pharmacist who is:

- (1) Board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties;
- (2) Identified as an authorized nuclear pharmacist on a license issued by the Agency, the NRC, or any other Agreement State that authorizes the use of radioactive material in the practice of nuclear pharmacy; or
- (3) Identified as an authorized nuclear pharmacist on a permit issued by the Agency, NRC, or any other Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in the practice of nuclear pharmacy.

"Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include sources of radiation from radioactive materials or radiation producing machines regulated by the Agency.

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

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

"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 utilizing special nuclear material; and
- (2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

"Calendar quarter" means not less than 12 consecutive weeks 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. No licensee or registrant shall change the method observed by him of determining calendar quarters for purposes of these regulations except at the beginning of a calendar 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.

"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.

"COMAR" means Code of Maryland Regulations

"Committed dose equivalent" [See "Dose"]

"Committed effective dose equivalent" [See "Dose"]

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

"Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of  $3.7 \times 10^{10}$  transformations per second (tps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) = 0.001 curie =  $3.7 \times 10^7$  tps. One microcurie ( $\mu$ Ci) = 0.000001 curie =  $3.7 \times 10^4$  tps (See A.12 for SI equivalent becquerel).

"Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

- (1) Release of the property for unrestricted use and termination of the license; or
- (2) Release of the property under restricted conditions and termination of the license.

"Deep dose equivalent" [see "Dose"]

"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.

"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, committed dose equivalent, committed effective dose equivalent, deep dose equivalent, dose equivalent, effective dose equivalent, external dose, eye

dose equivalent, shallow dose equivalent, total effective dose equivalent, or total organ dose equivalent. For purposes of these regulations, "radiation dose" is an equivalent term.

- (1) "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.
- (2) "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.
- (3) "Committed effective dose equivalent" ( $H_{E,50}$ ) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ( $H_{E,50} = \sum w_T H_{T,50}$ ).
- (4) "Deep dose equivalent" ( $H_d$ ), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter ( $1000 \text{ mg/cm}^2$ ).
- (5) "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.
- (6) "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 ( $H_E = \sum w_T H_T$ ).
- (7) "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.
- (8) "Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter ( $300 \text{ mg/cm}^2$ ).
- (9) "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 ( $7 \text{ mg/cm}^2$ ) averaged over an area of 1 square centimeter.
- (10) "Total effective dose equivalent" (TEDE) means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.
- (11) "Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in D.1107 (a)(6) of these regulations.

"Dose equivalent" [see "Dose"]

"Public dose" means the dose received by a member of the public from exposure to radiation and/or to radioactive material released by a 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, dose received from background radiation, dose from any medical administration the individual has received, dose from exposure to individuals administered radioactive material and released in accordance with G.25, or dose from voluntary participation in medical research programs.

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

"Quality factor" (Q) means the modifying factor, listed in Tables 1 and 2 of A.13, that is used to derive dose equivalent from absorbed dose.

"Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg/gram or 0.01 joule/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 these regulations, ionizing radiation is an equivalent term. Radiation, as used in these regulations, 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 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

"Radiation machine" means any assemblage of components capable of producing radiation except those devices with radioactive material as the only source of radiation. This assemblage may include, as determined by the Agency:

- (1) Not more than one control panel;
- (2) The necessary supporting structures; and
- (3) Any additional components or auxiliary equipment that function with the assemblage to produce the result desired by using the machine.

"Radiation safety officer" means an individual, authorized by the agency under a specific license or a registration, who has the knowledge and responsibility to apply appropriate radiation protection regulations.

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

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

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

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

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

"Rem" means 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).

"Research and development" means (1) theoretical analysis, exploration, or experimentation; or (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 material at the site, and previous burials at the site, even if those burials were made in accordance with the provisions of Part D.

"Restricted area" means 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. A 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").

"Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

"Shallow dose equivalent" [See "Dose"]

"SI" means the abbreviation 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 (1 sv = 100 rem).

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

"Source material" means:

- (1) Uranium or thorium, or any combination thereof, in any physical or chemical form; or
- (2) Ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

(d) Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from paragraph (e) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility. 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 paragraph (e) of this section.

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

(1) 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 be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

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

(i) 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.

(ii) The surety method or insurance must be payable to a trust established for decommissioning cost. The trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate State and federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or State agency.

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

(3) 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 be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in paragraph (e)(2) of this section.

(4) In the case of federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on Table 2 of this section, and indicating that funds for decommissioning will be obtained when necessary.

(f) Each person licensed under Part C shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with C31(b), licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for certifying that all the received records are complete and accurate and will be responsible for maintaining these records until the license is terminated. 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:

(1) Records of spills or other occurrences involving the spread of radioactive material in and around the facility, equipment, or site. These records may be limited to instances when radioactive material remains after any cleanup procedures or when there is reasonable likelihood that radioactive material 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;

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

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

(i) All areas designated and formerly designated restricted areas as defined in Part A, Section 2;

(ii) All areas outside of restricted areas that require documentation under D.1202;

(iii) All areas outside of restricted areas where current and previous wastes have been buried; and

(iv) 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 meet the criteria for decommissioning in §§ D.1401-1406 or apply for approval for disposal under D.1002.

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

(g) Approval of decommissioning funding plans and certifications.

(1) Upon a determination that an application under this section meets the requirements of this section, the Agency shall approve such decommissioning funding plan or certification.

(2) No person shall receive, possess, use, transfer, own or acquire radioactive material of a type described in paragraph (a) or (b) of this section for more than 180 days following the dates prescribed in this section for submittal of a decommissioning funding plan or certification, if that decommissioning funding plan or certification has not been approved by the Agency.

(h) Financial assurance for decommissioning pursuant to termination under restricted conditions as described in Section D.1403 of Part D shall not be considered a potential financial mechanism until such time as the licensee has submitted its intent to decommission in accordance with C.32 and has submitted a License Termination Plan (LTP) in accordance with Section D.1403 (d).

#### Sec. C.30 Issuance of Specific Licenses.

(a) Upon a determination that an application meets the requirements of the Act and the regulations of the Agency, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(b) The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:

(1) minimize danger to public health and safety or property;

(2) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) prevent loss or theft of material subject to this part.

#### Sec. C.31 Specific Terms and Conditions of Licenses.

(a) Each license issued pursuant to this part shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

(b) No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations, and orders of the Agency, and shall give its consent in writing.

(c) Each person licensed by the Agency pursuant to this part shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

(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(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(3) an affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(f) The notification specified in C.31(e) shall indicate the bankruptcy court in which the petition for bankruptcy was filed, a copy of the bankruptcy petition, and the date of the filing of the petition.

Sec. C.32 Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas. (See also D.1301 "Vacating Premises.")

(a) Except as provided in Md. Code Ann., State Gov't Sec. 10-226 (1996), and provided that the licensee is applying for the same activities as allowed in the current license, each specific license expires at the end of the day, in the month and year stated in the license.

(b) No less than 30 days before expiration of a license, the licensee shall notify the Agency promptly, in writing, and request termination of the license when the licensee decides to terminate all activities involving materials authorized under the license.

(c) Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the Agency in writing, as specified in subsections (d) and (f)(1)(i)-(iv) or by license conditions, 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 subsection (f)(1) of this section, and begin decommissioning upon approval of that plan if:

(1) The license has expired pursuant to subsection (a) of this section; or

(2) The licensee has decided to permanently cease principal activities, as defined in this part, 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.

(5) The licensee's right to operate has been terminated either by court action or by action of law or regulation.

(d) Coincident with the notification required by paragraph (c) of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to C.29 in conjunction with a license issuance or renewal or as required by this section. 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 paragraph (f)(4)(v) of this section.

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so on or before the effective date of this regulation.

(i) As the final step in decommissioning, the licensee shall--

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed MDE Form or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in §§ D.1401-1406. The licensee shall, as appropriate--

(i) Report levels of gamma radiation in units of millisieverts (microroentgens) 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

(ii) Specify the survey instruments(s) used and certify that each instrument is properly calibrated and tested.

(3) Forward all records required by Sec.C.38 to the Agency.

(j) 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 of;

(2) Reasonable effort (as determined by the Agency) has been made to eliminate residual radioactive contamination if present; and

(3) (i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in-§§ D.1401-1406; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in-§§ D.1401-1406.

Sec. C.33 Application for Renewal of Licenses. Subject to C.32(a), an application for renewal of a specific license must be filed on a form prescribed by the Agency, in accordance with C.24.

Sec. C.34 Amendment of Licenses at Request of Licensee. Applications for amendment of a license shall be filed in accordance with C.24 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

Sec. C.35 Agency Action on Applications to Renew or Amend. In considering an application by a licensee to renew or amend the license, the Agency will apply the criteria set forth in C.25, C.26, C.27, and C.28 and in Parts E, G, or W of these regulations, as applicable.

Sec. C. 36 Person Possessing a License for Medical Use of Radioactive Material on Effective Date of These Regulations. Any person or institution possessing a specific license for the medical use of radioactive material issued prior to October 9, 1995 when the licensee was authorized according to Groups I through VI of Schedule C, Part C, shall be deemed to possess a license issued under the revised regulations, according to Part G. The existing license will be valid until its stated expiration date and the renewal will be issued in accordance with the regulations dated October 9, 1995.

Sec. C.37 Registration of Sources or Devices Containing Radioactive Materials.

- (a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific or general license may submit a request to the Agency for evaluation of radiation safety information about its product and for its registration.
- (b) 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.
- (c) The Agency normally evaluates a sealed source or a device using radiation safety criteria in accordance with 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.
- (d) After completion of the evaluation, the Agency may 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.
- (e) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:
  - (1) The statements and representation, including quality control program, contained in the request; and
  - (2) The provisions of the registration certificate.

Sec.C.38 Records.

- (a) Each person who receives radioactive material through a license issued pursuant to the regulations in this Part shall keep records showing the receipt, transfer, and disposal of the radioactive material as follows:
  - (1) The licensee shall retain each record of receipt of radioactive material as long as the material is possessed and for three years following transfer or disposal of the material.

- ii. The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.
- d. If by the time the woman declares pregnancy to the licensee or registrant, the dose to the embryo/fetus has exceeded 4.5 mSv (0.45 rem), the licensee or registrant shall be deemed to be in compliance with D.208a. if the additional dose to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

## **RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC**

### Sec. D.301 Dose Limits for Individual Members of the Public.

- a. Each licensee or registrant shall conduct operations so that:
  - i. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with G.25, from voluntary participation in medical research programs, and the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with D.1003, and
  - ii. The dose in any unrestricted area from external sources exclusive of the dose contributions from patients administered radioactive material and released in accordance with Sec. G.25 does not exceed 0.02 mSv (0.002 rem) in any one hour.
- b. The Agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.
- c. If the licensee or registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

### Sec. D.302 Compliance with Dose Limits for Individual Members of the Public.

- a. The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in D.301.

- b. A licensee or registrant shall show compliance with the annual dose limit in D.301(a)(i) by:
  - i. Demonstrating compliance with D.101 a; and
  - ii. (1) Demonstrating by measurement, or calculation, or appropriate simulation model that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered source of radiation does not exceed the annual dose limit of D.301; or
    - (2) Demonstrating that:
      - (a) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B; and
      - (b) If an individual were continually present in an unrestricted area, at the point of highest potential exposure from the licensed or registered source of radiation, the dose to that individual would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in any year.

#### **TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES**

##### Sec. D.401 Testing for Leakage or Contamination of Sealed Sources.

- a. Each sealed source, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas, shall be tested for leakage or contamination prior to initial use and, unless otherwise authorized by the Agency, at intervals not to exceed 6 months. If, at any other time, there is reason to suspect that a sealed source might have been damaged or might be leaking, it shall be tested for leakage before further use. In the absence of a certificate from a transferor indicating that a test for leakage has been made within 6 months prior to the transfer, the sealed source shall not be put into use until tested and the results received.
  - i. Tests for leakage for all sealed sources, except those manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005  $\mu$ Ci) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate.

## RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

### Sec. D.1401 General Provisions and Scope.

(a) The criteria in this subpart apply to the decommissioning of facilities licensed under Part C of this regulation, as well as other facilities subject to the Department's jurisdiction. For low-level waste disposal facilities (COMAR 26.13.05 through .10), the criteria apply only to ancillary surface facilities that support radioactive waste disposal activities.

(b) The criteria in this subpart do not apply to sites which:

- (1) Have been decommissioned prior to the effective date of this regulation in accordance with criteria identified in the Site Decommissioning Management Plan (SDMP) Action Plan of April 16, 1992 (57 FR 13389);
- (2) Have previously submitted and received Agency approval on a license termination plan (LTP)] or decommissioning plan that is compatible with the SDMP Action Plan criteria; or
- (3) Submit a sufficient LTP or decommissioning plan prior to the [effective date of this regulation] and such LTP or decommissioning plan is approved by the Department before March 1, 2001 and in accordance with the criteria identified in the SDMP Action Plan, except that if an EIS is required in the submittal, there will be a provision for day-for-day extension.

(c) After a site has been decommissioned and the license terminated in accordance with the criteria in this subpart, the Department will require additional cleanup only if, based on new information, it determines that the criteria of this subpart were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

(d) When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

### Sec. D.1402 Radiological Criteria for Unrestricted Use.

A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

Sec. D.1403 Criteria for License Termination Under Restricted Conditions. A site will be considered acceptable for license termination under restricted conditions if:

(a) The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of C.1402 would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

(b) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) per year;

(c) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are--

- (1) Funds placed into an account segregated from the licensee's assets and outside the licensee's administrative control as described in Sec. C.29(e)(1) of this chapter;
- (2) Surety method, insurance, or other guarantee method as described in Sec. C.29(e)(2) of this chapter;
- (3) A statement of intent in the case of Federal, State, or local Government licensees, as described in Sec. C.29(e)(4) of this chapter; or
- (4) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(d) The licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the Department indicating the licensee's intent to decommission in accordance with Sec.C.32 and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

- (1) Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning--
  - (i) Whether provisions for institutional controls proposed by the licensee;
    - (A) Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) TEDE per year;
    - (B) Will be enforceable; and
    - (C) Will not impose undue burdens on the local community or other affected parties.

(ii) Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site;

(2) In seeking advice on the issues identified in Sec. 20.1403(d)(1), the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning. The scope of participation and persons representing community interests must be pre-approved by the Agency;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

(e) Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either--

(1) 100 mrem (1 mSv) per year; or

(2) 500 mrem (5 mSv) per year provided the licensee--

(i) Demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem/y (1 mSv/y) value of paragraph (e)(1) of this section are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(ii) Makes provisions for durable institutional controls;

(iii) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every 5 years to assure that the institutional controls remain in place as necessary to meet the criteria of Sec. D.1403(b) and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in paragraph (c) of this section.

Sec. D.1404 Alternate Criteria for License termination.

(a) The Department may terminate a license using alternate criteria greater than the dose criterion of D.1402 if the licensee—

- (1) Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 1 mSv/y (100 mrem/y) limit of subpart D, by submitting an analysis of possible sources of exposure;
- (2) Has employed to the extent practical restrictions on site use according to the provisions of D.1403 in minimizing exposures at the site; and
- (3) Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.
- (4) Has submitted a decommissioning plan or License Termination Plan (LTP)] to the Department indicating the licensee's intent to decommission in accordance with Sec. D.32(c) of this chapter, and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:
  - (i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning. The scope of participation and persons representing community interests must be pre-approved by the Agency;
  - (ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and
  - (iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

(b) The use of alternate criteria to terminate a license requires the approval of the Department after consideration of the Agency staff's recommendations that will address any comments provided by the Environmental Protection Agency and any public comments submitted pursuant to Sec. D.1405.

Sec. D.1405 Public Notification and Public Participation.

Upon the receipt of an LTP or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to Sec. D.1404, D.1403 or whenever the Department deems such notice to be in the public interest, the Department shall:

(a) Notify and solicit comments from:

- (1) Local and State governments in the vicinity of the site and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and
- (2) The Environmental Protection Agency for cases where the licensee proposes to release a site pursuant to Sec. D.1404.

(b) Publish a notice in the Maryland Register and in a forum, such as local newspapers, letters to State or local organizations, posting of the site or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

Sec. D.1406 Minimization of Contamination.

Applicants for licenses, other than renewals, after [the effective date of this regulation], shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

Baltimore, MD 21224 within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

- (1) Unintentional disconnection of the source assembly from the control cable;
- (2) Inability to retract the source assembly to its fully shielded position and secure it in this position;  
or
- (3) Failure of any component (critical to safe operation of the device) to properly perform its intended function;

(b) The licensee shall include the following information in each report submitted under paragraph (a) of this section, and in each report of overexposure submitted under D.1203 which involves failure of safety components of radiography equipment:

- (1) A description of the equipment problem;
- (2) Cause of each incident, if known;
- (3) Name of the manufacturer and model number of equipment involved in the incident;
- (4) Place, date, and time of the incident;
- (5) Actions taken to establish normal operations;
- (6) Corrective actions taken or planned to prevent recurrence; and
- (7) Qualifications of personnel involved in the incident.

(c) Any person conducting radiographic operations or storing radiation machines or radioactive material at any location not listed on the registration or license for a period in excess of 180 days in a calendar year, shall notify the Agency prior to exceeding the 180 days.

## Appendix A –NRC 10 CFR Part 34 Radiographer Certification

### I. Requirements for an Independent Certifying Organization

An independent certifying organization shall:

1. Be an organization such as a society or association, whose members participate in, or have an interest in, the fields of industrial radiography;
2. Make its membership available to the general public nationwide that is not restricted because of race, color, religion, sex, age, national origin or disability;
3. Have a certification program open to nonmembers, as well as members;
4. Be an incorporated, nationally recognized organization that is involved in setting national standards of practice within its fields of expertise;
5. Have an adequate staff, a viable system for financing its operations, and a policy- and decision-making review board;
6. Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;
7. Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;
8. Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;
9. Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;
10. Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;
11. Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;
12. Exchange information about certified individuals with the NRC and other independent certifying organizations and/or Agreement States and allow periodic review of its certification program and related records; and
13. Provide a description to the NRC of its procedures for choosing examination sites and

for providing an appropriate examination environment.

## II. Requirements for Certification Programs

All certification programs must:

1. Require applicants for certification to (a) receive training in the topics set forth in Sec. E.43(g) or equivalent Agreement State regulations, and (b) satisfactorily complete a written examination covering these topics;
2. Require applicants for certification to provide documentation that demonstrates that the applicant has:
  - (a) received training in the topics set forth in Sec. E.43(g) or equivalent Agreement State regulations;
  - (b) satisfactorily completed a minimum period of on-the-job training; and
  - (c) has received verification by an Agreement State or a NRC licensee that the applicant has demonstrated the capability of independently working as a radiographer;
3. Include procedures to ensure that all examination questions are protected from disclosure;
4. Include procedures for denying an application, revoking, suspending, and reinstating a certificate;
5. Provide a certification period of not less than 3 years nor more than 5 years;
6. Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training.
7. Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

## III. Requirements for Written Examinations

All examinations must be:

1. Designed to test an individual's knowledge and understanding of the topics listed in Sec. E.43(g) or equivalent Agreement State requirements;
2. Written in a multiple-choice format;
3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in Sec. E.43(g).

the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

(f) To meet the requirements of G.16(a), (b), and (c), the licensee may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by G.16(e) shall be maintained by the licensee.

Sec. G.17 Measurement of dosages of unsealed radioactive material for medical use. A licensee shall:

(a) Measure the activity of each dosage of a photon-emitting radionuclide prior to medical use;

(b) Measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or beta- emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed by the Agency pursuant to C.28(j), or licensed by the NRC or any other Agreement State pursuant to provisions equivalent to C.28(j); and

(c) Retain a record of the measurements required by this section for three years. To satisfy this requirement, the record must contain the:

(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates, and the radionuclide;

(2) Patient's or human research subject's name, and identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 1.1 megabecquerels (30 microcuries);

(4) Date and time of the measurement; and

(5) Initials of the individual who made the record.

Sec. G.18 Authorization for Calibration and Reference Sources. Any person authorized by G.3 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

- (a) Sealed sources manufactured and distributed by persons specifically licensed pursuant to Part C of these regulations or equivalent provisions of the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State and that do not exceed 15 millicuries (555 MBq) each;
- (b) Any radioactive material listed in G.29 or G.31 with a half-life of 100 days or less in individual amounts not to exceed 15 millicuries (555 MBq);
- (c) Any radioactive material listed in G.29 or G.31 with a half life greater than 100 days in individual amounts not to exceed 200 microcuries (7.4 MBq) each; and
- (d) Technetium-99m in individual amounts not to exceed 50 millicuries (1.85 GBq).

Sec. G.19 Requirements for Possession of Sealed Sources and Brachytherapy Sources.

- (a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Agency and shall maintain the instructions for the duration of source use in a legible form convenient to users.
- (b) A licensee in possession of a sealed source shall assure that:
  - (1) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and
  - (2) The source is tested for leakage at intervals not to exceed 6 months or at intervals approved by the Agency, another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission.
- (c) To satisfy the leak test requirements of G.19(b), the licensee shall assure that:
  - (1) Leak tests are capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) per 24 hours;
  - (2) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and
  - (3) Test samples are taken when the source is in the "off" position.
- (d) A licensee shall retain leak test records for 5 years. The records shall

Safety Officer if a dose rate exceeds an action level.

(e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.

(f) A licensee shall conduct the surveys required by G.24(e) so as to be able to detect contamination on each wipe sample of 200 disintegrations per minute (33.3 Bq).

(g) A licensee shall establish removable contamination action levels for the surveys required by G.24(e) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(h) A licensee shall retain a record of each survey required by G.24 (a), (b), and (e) for 2 years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

#### Sec. G.25 Release of Individuals Containing Radiopharmaceuticals or Permanent Implants.

(a) The licensee may authorize release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).<sup>3</sup>

(b) The licensee shall provide the released individual with written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

- (1) Guidance on the interruption or discontinuation of breast-feeding; and

---

<sup>3</sup> NRC Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 millisieverts (0.5 rem).

- (2) Information on the consequences of failure to follow the guidance.
- (c) The licensee shall maintain a record of the basis for authorizing the release of an individual, for 3 years after the date of release, if the total effective dose equivalent is calculated by:
  - (1) Using the retained activity rather than the activity administered;
  - (2) Using an occupancy factor less than 0.25 at one meter;
  - (3) Using the biological or effective half-life; or
  - (4) Considering the shielding by tissue.
- (d) The licensee shall maintain a record, for 3 years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem).

Sec. G.26 Mobile Nuclear Medicine Service Technical Requirements. A licensee providing mobile nuclear medicine service shall:

- (a) Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;
- (b) Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;
- (c) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use;
- (d) Check survey instruments and dose calibrators as required in G.15(b)(1), G.15(d), G.15(e) and G.16(d), and check all other transported equipment for proper function before medical use at each location of use;
- (e) Carry two calibrated survey meters in each vehicle that is being used to transport radioactive material, and, before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed; and
- (f) Retain a record of each survey required by G.26(e) for 2 years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirems (microsieverts) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.

Sec. G.27 Storage of Volatiles and Gases.

- (a) A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.
- (b) A licensee shall store and use a multidose container in a properly functioning fume hood.

Sect. G.28 Reserved.