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DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

6 CCR 1007-1

STATE BOARD OF HEALTH

RULES AND REGULATIONS PERTAINING TO RADIATION CONTROL

PART 3:

LICENSING OF RADIOACTIVE MATERIAL

3.1 Purpose and Scope

3.1.1 Authority.

3.1.1.1 Rules and regulations set forth herein are adopted pursuant to the provisions of sections 25-1-108, 25-1.5-101(1)(k) and (1)(l), and 25-11-104, CRS.

3.1.2 Basis and Purpose.

3.1.2.1 A statement of basis and purpose of these regulations is incorporated as part of these regulations; a copy may be obtained from the Department.

3.1.3 Scope.

3.1.3.1 This part, and Parts 5, 7, 14, 16, 17, 18, and 19 of these regulations, provide for the licensing of radioactive material.

3.1.3.2 No person shall receive, possess, own, acquire, process, use, store, transfer, or dispose radioactive material except as authorized pursuant to this part or Parts 5, 7, 14, 17, 18, or 19 of these regulations, or as otherwise provided in these parts.

3.1.4 Applicability.

3.1.4.1 In addition to the requirements of this part, all licensees are subject to the requirements of Parts 1, 4, 10, 12 and 17.

3.1.4.2 Furthermore:

- (1)** Licensees engaged in industrial radiographic operations are subject to the requirements of Part 5.
- (2)** Licensees using radionuclides in the healing arts are subject to the requirements of Part 7.
- (3)** Licensees engaged in land disposal of radioactive material are subject to the requirements of either Part 14 or Part 18, as appropriate.
- (4)** Licensees engaged in source material milling are subject to the requirements of Part 18.

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33 (5) Licensees engaged in wireline and subsurface tracer studies are subject to the
34 requirements of Part 16.

35 (6) Panoramic or underwater irradiator licensees are subject to the requirements of
36 Part 19.

37 3.1.5 The Department may engage the services of qualified persons in order to assist the Department
38 in meeting the requirements of these regulations, including, but not limited to, evaluating
39 information that may be required under 3.8.8.

40 3.1.5.1 Fees for these services may be charged by the Department as a part of fees charged for
41 radiation control services under Part 12.

42 EXEMPTIONS FROM THE REGULATORY REQUIREMENTS

43 3.2 EXEMPTION OF Source Material

44 3.2.1 Any person is exempt from this part to the extent that such person receives, possesses, uses,
45 owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which
46 the source material is by weight less than 1/20th of 1 percent (0.05 percent) of the mixture,
47 compound, solution, or alloy.

48 3.2.2 Any person is exempt from this part to the extent that such person receives, possesses, uses, or
49 transfers unrefined and unprocessed ore containing source material; provided that, except as
50 authorized in a specific license, such person shall not refine or process such ore.

51 3.2.3 Any person is exempt from this part to the extent that such person receives, possesses, uses, or
52 transfers an item containing uranium or thorium listed in Schedule 3C, Sections ~~3C-A, 3C-B,~~
53 ~~3C-C, 3C-D, 3C-E, 3C-F, 3C-G or 3C-H~~ **3C.1, 3C.2, 3C.3, 3C.4, 3C.5, 3C.6, 3C.7, 3C.8 or 3C.9.**

54 3.2.3.1 The exemptions listed in Schedule 3C do not authorize the manufacture of any of the
55 products described.

56 3.3 EXEMPTION OF Radioactive Material Other Than Source Material.

57 3.3.1 Exempt Concentrations.

58 3.3.1.1 Except as provided in 3.3.1.2, any person is exempt from this part to the extent that such
59 person receives, possesses, uses, transfers, or acquires products containing radioactive
60 material introduced in concentrations not in excess of those listed in Schedule 3A.

61 (1) **A MANUFACTURER, PROCESSOR OR PRODUCER THAT TRANSFERS A
62 PRODUCT OR MATERIAL IS EXEMPT SO LONG AS CONCENTRATIONS
63 LESS THAN THOSE LISTED IN SCHEDULE 3A WERE INTRODUCED UNDER
64 AN NRC LICENSE SO AUTHORIZING.**

65 (2) **TRANSFER OF RADIOACTIVE MATERIAL CONTAINED IN ANY FOOD,
66 BEVERAGE, COSMETIC, DRUG, OR OTHER COMMODITY OR PRODUCT
67 DESIGNED FOR INGESTION OR INHALATION BY, OR APPLICATION TO, A
68 HUMAN BEING, IS NOT EXEMPT UNDER 3.3.1.1(1).**

69 3.3.1.2 No person may introduce radioactive material into a product or material knowing or
70 having reason to believe that it will be transferred to persons exempt under 3.3.1.1 or
71 equivalent regulations of the ~~U.S. Nuclear Regulatory Commission, NRC~~ **OR** any

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72 Agreement State or Licensing State, except in accordance with a specific license issued
73 pursuant to ~~3.6.2~~ **CONSISTENT WITH** 3.12.1 or the general license provided in 3.24.

74 3.3.2 Exempt Quantities.

75 3.3.2.1 Except as provided in 3.3.2.3 and 3.3.2.4, any person is exempt from these regulations to
76 the extent that such person receives, possesses, uses, transfers, owns, or acquires
77 radioactive material in individual quantities each of which does not exceed the applicable
78 quantity set forth in Schedule 3B.

79 3.3.2.2 Any person who possesses radioactive material received or acquired under the general
80 license formerly provided in ~~3.6.2~~ **UNDER 10 CFR 31.4 BEFORE SEPTEMBER 25, 1971**
81 is exempt from the requirements for a license set forth in this part to the extent that such
82 person possesses, uses, transfers or owns such radioactive material. ~~Such exemption~~
83 ~~does not apply for radium-226.~~

84 3.3.2.3 **SECTION** This paragraph (3.3.2) does not authorize the production, packaging or
85 repackaging of radioactive material for purposes of commercial distribution, or the
86 incorporation of radioactive material into products intended for commercial distribution.

87 3.3.2.4 No person may, for purposes of commercial distribution, transfer radioactive material in
88 the individual quantities set forth in Schedule 3B, knowing or having reason to believe
89 that such quantities of radioactive material will be transferred to persons exempt under
90 3.3.2 or equivalent regulations of the ~~U.S. Nuclear Regulatory Commission, NRC OR~~ any
91 Agreement State or Licensing State, except in accordance with a specific license issued
92 by the ~~U.S. Nuclear Regulatory Commission-NRC~~ pursuant to Section 32.18 of 10 CFR
93 Part 32 (January 1, 20104) or by the Department pursuant to ~~3.12.2~~, which license states
94 that the radioactive material may be transferred by the licensee to persons exempt under
95 3.3.2 or the equivalent regulations of the ~~U.S. Nuclear Regulatory Commission, NRC OR~~
96 an Agreement State, or Licensing State.¹

97 ¹ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment,
98 device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and
99 disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear
100 Regulatory Commission, Washington, D.C. 20555.

101 **3.3.2.5 NO PERSON MAY, FOR PURPOSES OF PRODUCING AN INCREASED RADIATION**
102 **LEVEL, COMBINE QUANTITIES OF RADIOACTIVE MATERIAL COVERED BY THIS**
103 **EXEMPTION SO THAT THE AGGREGATE QUANTITY EXCEEDS THE LIMITS SET**
104 **FORTH IN SCHEDULE 3B, EXCEPT FOR A DEVICE PLACED IN USE BEFORE MAY**
105 **3, 1999, OR AS OTHERWISE PERMITTED BY THESE REGULATIONS.**

106 3.3.3 Exempt Items.

107 **3.3.3.1** Any person is exempt from this part to the extent that such person receives, possesses,
108 uses, or transfers an item containing radioactive material which is listed in Schedule 3C,
109 Sections ~~3C-I, 3C-J, 3C-K, 3C-L, 3C-M or 3C-N~~ **3C.10, 3C.11, 3C.12, OR 3C.13.**

110 LICENSES

111 **3.4 Types of Licenses.**

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

113 3.4.1 A general license is provided by regulation and grants authority to a person for certain activities
114 involving radioactive material.

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- 115 **3.4.1.1** A general license is effective without the filing of an application with the Department or
116 the issuance of a licensing document to a particular person.
- 117 **3.4.1.2** However, registration or filing of a certificate with the Department may be required by the
118 particular general license.
- 119 **3.4.1.3** The general licensee is subject to all other applicable portions of these regulations and
120 any limitations of the general license.
- 121 3.4.2 A specific license requires the submission of an application to the Department and the issuance
122 of a licensing document by the Department.
- 123 **3.4.2.1** The licensee is subject to all applicable portions of these regulations as well as any
124 limitations specified in the licensing document.

125 **GENERAL LICENSES**

126 **3.5 General Licenses - Source Material.**

- 127 3.5.1 A general license is hereby issued authorizing commercial and industrial firms, research,
128 educational and medical institutions, and State and local government agencies to use and
129 transfer not more than 6.82 kg (15 pounds) of source material at any one time for research,
130 development, educational, commercial, or operational purposes.
- 131 3.5.1.1 A person authorized to use or transfer source material, pursuant to this general license,
132 may not receive more than a total of 68.2 kg (150 pounds) of source material in any one
133 calendar year.
- 134 3.5.1.2 Persons who receive, possess, use or transfer source material pursuant to the general
135 license in 3.5.1 are prohibited from administering source material, or the radiation
136 therefrom, either externally or internally, to human beings except as may be authorized in
137 a specific license.
- 138 3.5.2 Persons who receive, possess, use, or transfer source material pursuant to the general license
139 issued in 3.5.1 are exempt from the provisions of Parts 4 and 10 to the extent that such receipt,
140 possession, use, or transfer is within the terms of such general license; provided, however, that
141 this exemption shall not be deemed to apply to any such person who is also in possession of
142 source material under a specific license issued pursuant to this part.
- 143 3.5.3 A general license is hereby issued authorizing the receipt of title to source material without regard
144 to quantity.
- 145 **3.5.3.1** This general license does not authorize any person to receive, possess, use, or transfer
146 source material.
- 147 3.5.4 A general license is hereby issued authorizing the possession of source material involved in
148 mining operations provided such operations meet the regulatory requirements of the Division of
149 ~~Minerals and Geology~~, **RECLAMATION, MINING AND SAFETY**, Colorado Department of Natural
150 Resources, or any successor thereto, and, except as authorized in a specific license, such mining
151 operations shall not refine or process such ore.
- 152 3.5.5 Depleted Uranium in Industrial Products and Devices.
- 153 3.5.5.1 A general license is hereby issued to receive, acquire, possess, use, or transfer, in
154 accordance with the provisions of 3.5.5.2, 3.5.5.3, 3.5.5.4, and 3.5.5.5, depleted uranium

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- 155 contained in industrial products or devices for the purpose of providing a concentrated
156 mass in a small volume of the product or device.
- 157 3.5.5.2 The general license in 3.5.5.1 applies only to industrial products or devices which have
158 been manufactured either in accordance with a specific license issued to the
159 manufacturer of the products or devices pursuant to 3.12.13 or in accordance with a
160 specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission
161 **NRC** or an Agreement State which authorizes manufacture of the products or devices for
162 distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission
163 **NRC** or an Agreement State.
- 164 (1) Persons who receive, acquire, possess, or use depleted uranium pursuant to the
165 general license established by 3.5.5.1 shall file Department Form R-52,
166 "Registration Certificate - Use of Depleted Uranium Under General License", with
167 the Department.
- 168 (a) The form shall be submitted within 30 days after the first receipt or
169 acquisition of such depleted uranium.
- 170 (b) The general licensee shall furnish on Department Form R-52 the
171 following information and such other information as may be required by
172 that form:
- 173 (ai) Name and address of the general licensee;
- 174 (bii) A statement that the general licensee has developed and will
175 maintain procedures designed to establish physical control over
176 the depleted uranium described in 3.5.5.1 and designed to
177 prevent transfer of such depleted uranium in any form, including
178 metal scrap, to persons not authorized to receive the depleted
179 uranium; and
- 180 (ciii) Name and title, address, and telephone number of the individual
181 duly authorized to act for and on behalf of the general licensee in
182 supervising the procedures identified in 3.5.5.3(1)(b)(ii).
- 183 (2) The general licensee possessing or using depleted uranium under the general
184 license established by 3.5.5.1 shall report in writing to the Department any
185 changes in information furnished by him in Department Form R-52, "Registration
186 Certificate - Use of Depleted Uranium Under General License". The report shall
187 be submitted within 30 days after the effective date of such change.

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- 188 3.5.5.4 A person who receives, acquires, possesses, or uses depleted uranium pursuant to the
189 general license established by 3.5.5.1:
- 190 (1) Shall not introduce such depleted uranium, in any form, into a chemical, physical,
191 or metallurgical treatment or process, except a treatment or process for repair or
192 restoration of any plating or other covering of the depleted uranium;
- 193 (2) Shall not abandon such depleted uranium;
- 194 (3) Shall transfer or dispose of such depleted uranium only by transfer in accordance
195 with the provisions of 3.22.
- 196 (a) In the case where the transferee receives the depleted uranium pursuant
197 to the general license established by 3.5.5.1, the transferor shall furnish
198 the transferee a copy of this regulation and a copy of Department Form
199 R-52.
- 200 (b) In the case where the transferee receives the depleted uranium pursuant
201 to a general license contained in ~~the U.S. Nuclear Regulatory~~
202 ~~Commission-NRC's~~ or Agreement State's regulation equivalent to
203 3.5.5.1, the transferor shall furnish the transferee a copy of this
204 regulation and a copy of Department Form R-52 accompanied by a note
205 explaining that use of the product or device is regulated by ~~the U.S.~~
206 ~~Nuclear Regulatory Commission-NRC~~ or Agreement State under
207 requirements substantially the same as those in this regulation;
- 208 (4) Within 30 days of any transfer, shall report in writing to the Department the name
209 and address of the person receiving the depleted uranium pursuant to such transfer, and
- 210 (5) Shall not export such depleted uranium except in accordance with a license
211 issued by ~~the U.S. Nuclear Regulatory Commission-NRC~~ pursuant to 10 CFR Part 110
212 (January 1, 20104).
- 213 3.5.5.5 Any person receiving, acquiring, possessing, using, or transferring depleted uranium
214 pursuant to the general license established by 3.5.5.1 is exempt from the requirements of
215 Parts 4 and 10 with respect to the depleted uranium covered by that general license.

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216 **3.6 General Licenses² - Radioactive Material Other Than Source Material.**

217 ² Different general licenses are issued in this section, each of which has its own specific conditions and
218 requirements.

219 3.6.1 Certain Devices and Equipment.

220 3.6.1.1 A general license is hereby issued to transfer, receive, acquire, own, possess, and use
221 radioactive material incorporated in the following devices or equipment which have been
222 manufactured, tested and labeled by the manufacturer in accordance with a specific
223 license issued to the manufacturer by the U.S. Nuclear Regulatory Commission-NRC for
224 use pursuant to Section 31.3 of 10 CFR Part 31 (January 1, 20104). This general license
225 is subject to the provisions of 1.4 through 1.9, 3.3.1.2, 3.15, 3.22, and 3.23, Part 4³, Part
226 10 and Part 17.

227 ³ Attention is directed particularly to the provisions of Part 4 which relate to the labeling of containers.

228 **(1)** ~~3.6.1.1 Static Elimination Device.~~ Devices designed for use as static eliminators
229 which contain, as a sealed source or sources, radioactive material consisting of a
230 total of not more than 18.5 MBq (500 µCi) of polonium-210 per device.

231 **(2)** ~~3.6.1.2 Ion Generating Tube.~~ Devices designed for ionization of air which
232 contain, as a sealed source or sources, radioactive material consisting of a total
233 of not more than 18.5 MBq (500 µCi) of polonium-210 per device or a total of not
234 more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

235 **3.6.1.2 THIS GENERAL LICENSE IS SUBJECT TO THE PROVISIONS OF 1.4 THROUGH 1.9,**
236 **3.3.1.2, 3.15, 3.22, AND 3.23, PART 4³, PART 10 AND PART 17.**

237 ³ Attention is directed particularly to the provisions of Part 4 which relate to the labeling of containers.

238 3.6.2 Reserved.

239 3.6.3 Reserved.

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240 3.6.4 Certain Measuring, Gauging or Controlling Devices.

241 3.6.4.1 A general license is hereby issued to commercial and industrial firms and to research,
242 educational and medical institutions, individuals in the conduct of their business, and
243 State or local government agencies to receive, acquire, possess, use or transfer, in
244 accordance with the provisions of 3.6.4.2, 3.6.4.3, and 3.6.4.4, radioactive material,
245 excluding special nuclear material, contained in devices designed and manufactured for
246 the purpose of detecting, measuring, gauging or controlling thickness, density, level,
247 interface location, radiation, leakage, or qualitative or quantitative chemical composition,
248 or for producing light or an ionized atmosphere.

249 3.6.4.2 The general license in 3.6.4.1 applies only to radioactive material contained in devices
250 which have been:

251 (1) Manufactured or initially transferred and labeled **FOR DISTRIBUTION TO**
252 **PERSONS GENERALLY LICENSED** in accordance with the specifications
253 contained in a specific license issued by:

254 (a) The Department pursuant to 3.12.4 or

255 (b) ~~in accordance with the specifications contained in a specific license~~
256 ~~issued by the U.S. Nuclear Regulatory Commission, BY NRC OR an~~
257 ~~Agreement State or a Licensing State⁴, or~~

258 ⁴ Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices
259 in food production require certain additional labeling thereon which is found in 21 CFR 179.21 (April 1, 20104).

260 (2) Received from one of the specific licensees described in 3.6.4.2(1) or through a
261 transfer made under 3.6.4.3(8).

262 3.6.4.3 Any person who owns, receives, acquires, possesses, uses, owns, or transfers
263 radioactive material in a device pursuant to the general license in 3.6.4.1:

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

267 (2) Shall assure that the device is tested for leakage of radioactive material and
268 proper operation of the "on-off" mechanism and indicator, if any, at no longer
269 than 6-month intervals or at such other intervals as are specified in the label,
270 however;

271 (a) Devices containing only krypton need not be tested for leakage of
272 radioactive material; and

273 (b) Devices containing only tritium or not more than 3.7 MBq (100 µCi) of
274 other beta- and/or gamma-emitting material or 0.37 MBq (10 µCi) of
275 alpha-emitting material and devices held in storage in the original
276 shipping container prior to initial installation need not be tested for any
277 purpose;

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- 278 (3) Shall assure that **THE TESTS REQUIRED BY 3.6.4.3(2) OF THIS SECTION**
279 **AND** other testing, installation, servicing, and removal from installation involving
280 the radioactive material, its shielding or containment, are performed:
- 281 (a) In accordance with the instructions provided by the labels; or
- 282 (b) By a person holding an applicable specific license from the Department,
283 ~~the U.S. Nuclear Regulatory Commission,~~**NRC OR** an Agreement State
284 ~~or a Licensing State~~ to perform such activities;
- 285 (4) Shall maintain records showing compliance with the requirements of 3.6.4.3(2)
286 and 3.6.4.3(3).
- 287 (a) The records shall show the results of tests.
- 288 (b) The records also shall show the dates of performance of, and the names
289 of persons performing, testing, installation, servicing, and removal from
290 installation concerning the radioactive material, its shielding or
291 containment.
- 292 (c) Records of tests for leakage of radioactive material required by 3.6.4.3(2)
293 shall be maintained for ~~13~~ **13** year**S** after the next required leak test is
294 performed or until the sealed source is transferred or disposed of.
- 295 (d) Records of tests of the "on-off" mechanism and indicator required by
296 3.6.4.3(2) shall be maintained for ~~13~~ **13** year**S** after the next required test of
297 the "on-off" mechanism and indicator is performed or until the sealed
298 source is transferred or disposed of.
- 299 (e) Records which are required by 3.6.4.3(3) shall be maintained for a period
300 of ~~23~~ **23** year**S** from the date of the recorded event or until the device is
301 transferred or disposed of;
- 302 (5) Upon the occurrence of a failure of or damage to, or any indication of a possible
303 failure of or damage to, the shielding of the radioactive material or the "on-off"
304 mechanism or indicator, or upon the detection of 185 Bq (0.005 µCi) or more
305 removable radioactive material, shall immediately suspend operation of the
306 device; and **SHALL:**
- 307 (a) ~~The device shall not be operate~~ **THE DEVICE** until it has been repaired
308 by the manufacturer or other person holding an applicable specific
309 license from the Department, ~~the U.S. Nuclear Regulatory~~
310 ~~Commission,~~**NRC OR** an Agreement State ~~or a Licensing State~~ to repair
311 such devices;
- 312 (b) **ENSURE THAT, IF DISPOSITIONED,** ~~t~~The device and any radioactive
313 material from the device ~~may only be is~~ disposed of by transfer to a
314 person authorized by an applicable specific license to receive the
315 radioactive material contained in the device;
- 316 (c) Within 30 days, ~~the general licensee shall~~ furnish to the Department a
317 report containing a brief description of the event and the remedial action
318 taken; and

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- (d) In the case of detection of 185 Bq (0.005 microcurie) or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, ~~the general licensee shall~~ furnish to the Director of the Hazardous Materials And Waste Management Division, within 30 days, a plan for ensuring that the premises and environs are acceptable for unrestricted use.
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- (i) Under these circumstances, the criteria set out in 4.61.2, "Radiological Criteria For Unrestricted Use," may be applicable, as determined by the division on a case by case basis;
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- (6) Shall not abandon the device containing radioactive material;
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- (7) Shall not export the device except in accordance with 10 CFR Part 110 (January 1, 2010~~4~~) and shall obtain written approval from ~~the U.S. Nuclear Regulatory Commission-NRC~~ before transferring the device to any other specific licensee not specifically identified in 3.6.4.3(8);
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- (8) Except as provided in 3.6.4.3(9), shall transfer or dispose of the device containing radioactive material:
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- (a) ~~e~~Only by transfer to a specific licensee of the Department, ~~the U.S. Nuclear Regulatory Commission,NRC~~ OR an Agreement State or a ~~Licensing State~~ whose specific license authorizes receipt of the device; and
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- (b) ~~w~~Within 30 days after transfer **OR EXPORT**, ~~of a device to a specific licensee~~ shall furnish to the Department a report containing:
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- (ai) Identification of the device by manufacturer's (or initial transferor's) name, model number and serial number;
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- (bii) The name, address and license number of the person receiving the device;
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- (eiii) The date of the transfer;
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- (div) The identity of the radionuclide(s) present and activity present, by assay or calculation;
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- (C) **COMPLY WITH 10 CFR 31.5(c)(8)(iii), AS APPLICABLE.**

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- 349 (9) Shall transfer the device to another general licensee only:
- 350 (a) Where the device remains in use at a particular location.
- 351 In such case the transferor shall give the transferee a copy of this
352 regulation and any safety documents identified in the label on the
353 device and within 30 days of the transfer, report to the
354 Department the manufacturer's (or initial transferor's) name and
355 model number and serial number of device transferred, the
356 identity of the radionuclide(s) present and assayed or calculated
357 activity present, the transferee's name and mailing address for
358 the location of use, and the name title, and phone number of the
359 responsible individual identified by the transferee in accordance
360 with 3.6.4.3(12) to have knowledge of and authority to take
361 actions to ensure compliance with the appropriate regulations
362 and requirements; or
- 363 (b) Where the device is held in storage by an intermediate person in the
364 original shipping container at its intended location of use prior to initial
365 use by a general licensee; and
- 366 (10) Shall comply with the provisions of 4.51 and 4.52 for reporting radiation incidents,
367 theft, or loss of licensed material, but shall be exempt from the other
368 requirements of Parts 4 and 10;
- 369 (11) Shall respond to written requests from the Department to provide information
370 relating to the general license within 30 calendar days of the date of the request,
371 or other time specified in the request.
- 372 (a) If the general licensee cannot provide the requested information within
373 the allotted time, it shall, within that same time period, request a longer
374 period to supply the information by providing the director of the
375 Hazardous Materials and Waste Management Division a written
376 justification for the request;
- 377 (12) Shall appoint an individual responsible for having knowledge of the appropriate
378 regulations and requirements and the authority for taking required actions to
379 comply with appropriate regulations and requirements.
- 380 (a) The general licensee, through this individual, shall ensure the day-to-day
381 compliance with appropriate regulations and requirements; this
382 appointment does not relieve the general licensee of any of its
383 responsibility in this regard;

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- (13) Shall register each device annually in accordance with 3.6.4.3(13)(a) and 3.6.4.3(13)(b), and shall pay the fee required by Part 12, if in possession of a device containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, or 37 MBq (1 mCi) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label;
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- (a) Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Department.
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- (i) The registration information must be submitted to the Department within 30 days of the date of the request for registration or as otherwise indicated in the request.
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- (b) In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Department:
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- (i) Name and mailing address of the general licensee;
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- (ii) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label);
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- (iii) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under 3.6.4.3(12);
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- (iv) Address or location at which the device(s) are used and/or stored; for portable devices, the address of the primary place of storage;
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- (v) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information; and
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- (vi) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.
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- (c) A general licensee holding devices meeting the criteria of 3.6.4.3(13) is subject to the bankruptcy notification requirement in 3.15.5.
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- (d) Persons generally licensed by an Agreement State with respect to devices meeting the criteria in paragraph 3.6.4.3(13) are not subject to U.S. Nuclear Regulatory Commission registration requirements if the devices are used in areas subject to NRC jurisdiction for a period less than 180 days in any calendar year. The Commission will not request registration information from such licensees.

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- 424 (14) Shall report changes to the mailing address for the location of use (including
425 change in name of general licensee) to the director of the hazardous materials
426 and waste management division within 30 days of the effective date of the
427 change.
- 428 (a) For a portable device, a report of address change is only required for a
429 change in the device's primary place of storage.
- 430 (15) May not hold a device that is not in use for longer than 2 years.
- 431 (a) If a device with shutters is not being used, the shutter must be locked in
432 the closed position.
- 433 (b) The testing required by 3.6.4.3(2) need not be performed during the
434 period of storage only.
- 435 (c) However, when a device is put back into service or transferred to another
436 person, and has not been tested within the required test interval, the
437 device must be tested for leakage before use or transfer and the shutter
438 tested before use.
- 439 (d) A device kept in standby for future use is excluded from the two-year
440 time limit if the general licensee performs quarterly physical inventories
441 of the device while the device is in standby.
- 442 3.6.4.4 The general license in 3.6.4.1 does not authorize the manufacture of devices containing
443 radioactive material.
- 444 3.6.4.5 The general license provided in 3.6.4.1 is subject to the provisions of 1.4 through 1.9,
445 3.15, 3.22, 3.23 and Part 17.
- 446 3.6.5 Luminous Safety Devices for Aircraft.
- 447 3.6.5.1 A general license is hereby issued to receive, acquire, possess, and use tritium or
448 promethium-147 contained in luminous safety devices for use in aircraft, provided:
- 449 (1) Each device contains not more than 370 GBq (10 Ci) of tritium or 11.1 GBq
450 (300 mCi) of promethium-147; and
- 451 (2) Each device has been manufactured, assembled or imported in accordance with
452 a specific license issued by ~~the U.S. Nuclear Regulatory Commission~~ **NRC** or
453 each device has been manufactured or assembled in accordance with the
454 specifications contained in a specific license issued by the Department or any
455 Agreement State to the manufacturer or assembler of such device pursuant to
456 licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32
457 (January 1, 20104).
- 458 3.6.5.2 Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to
459 the general license in 3.6.5.1 are exempt from the requirements of Parts 4 and 10 except
460 that they shall comply with the provisions of 4.51 and 4.52.
- 461 3.6.5.3 This general license does not authorize the manufacture, assembly, or repair of luminous
462 safety devices containing tritium or promethium-147.

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- 463 3.6.5.4 This general license does not authorize the ownership, receipt, acquisition, possession or
464 use of promethium-147 contained in instrument dials.
- 465 3.6.5.5 This general license is subject to the provisions of 1.4 through 1.9, 3.15, 3.22, 3.23, and
466 Part 17.
- 467 3.6.6 Ownership of Radioactive Material.
- 468 **3.6.6.1** A general license is hereby issued to own radioactive material without regard to quantity.
- 469 **3.6.6.2** Notwithstanding any other provisions of this part, this general license does not authorize
470 the manufacture, production, transfer, receipt, possession or use of radioactive material.
- 471 3.6.7 Calibration and Reference Sources.
- 472 3.6.7.1 A general license is hereby issued to those persons listed below to own, receive, acquire,
473 possess, use, and transfer, in accordance with the provisions of 3.6.7.4 and 3.6.7.5,
474 americium-241 in the form of calibration or reference sources:
- 475 (1) Any person who holds a specific license issued by the Department which
476 authorizes him to receive, possess, use, and transfer radioactive material; and
- 477 (2) Any person who holds a specific license issued by the ~~U.S. Nuclear Regulatory~~
478 ~~Commission~~ **NRC** which authorizes him to receive, possess, use, and transfer
479 special nuclear material.
- 480 3.6.7.2 A general license is hereby issued to receive, possess, use, and transfer plutonium in the
481 form of calibration or reference sources in accordance with the provisions of 3.6.7.4 and
482 3.6.7.5 to any person who holds a specific license issued by the Department which
483 authorizes him to receive, possess, use, and transfer radioactive material.
- 484 3.6.7.3 A general license is hereby issued to own, receive, possess, use, and transfer
485 radium-226 in the form of calibration or reference sources in accordance with the
486 provisions of 3.6.7.4 and 3.6.7.5 to any person who holds a specific license issued by the
487 Department which authorizes him to receive, possess, use, and transfer radioactive
488 material.
- 489 3.6.7.4 The general licenses in 3.6.7.1, 3.6.7.2, and 3.6.7.3 apply only to calibration or reference
490 sources which have been manufactured in accordance with the specifications contained
491 in a specific license issued to the manufacturer or importer of the sources by the ~~U.S.~~
492 ~~Nuclear Regulatory Commission~~ **NRC** pursuant to Section 32.57 of 10 CFR Part 32 or
493 Section 70.39 of 10 CFR Part 70 (January 1, 2010~~4~~) or which have been manufactured in
494 accordance with the specifications contained in a specific license issued to the
495 manufacturer by the Department, or any Agreement State or ~~Licensing State~~ pursuant to
496 licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32
497 or Section 70.39 of 10 CFR Part 70 (January 1, 2010~~4~~).

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498 3.6.7.5 The general licenses provided in 3.6.7.1, 3.6.7.2, and 3.6.7.3 are subject to the
499 provisions of 1.4 through 1.9, 3.15, 3.22, 3.23 and 3.24, and Parts 4 and 10. In addition,
500 persons who own, receive, acquire, possess, use, or transfer one or more calibration or
501 reference sources pursuant to these general licenses, shall:

502 (1) Not possess at any one time, at any one location of storage or use, more than
503 185 kBq (5 µCi) of americium-241, 185 kBq (5 µCi) of plutonium, or 185 kBq
504 (5 µCi) of radium-226 in such sources;

505 (2) Not receive, possess, use, or transfer such source unless the source, or the
506 storage container, bears a label which includes one of the following statements,
507 as appropriate, or a substantially similar statement which contains the
508 information called for in one of the following statements, as appropriate:

509 (a) The receipt, possession, use and transfer of this source, Model ____,
510 Serial No. ____ are subject to a general license and the regulations of the
511 U.S. Nuclear Regulatory Commission or of a **AN AGREEMENT** State with
512 which the Commission has entered into an agreement for the exercise of
513 regulatory authority. Do not remove this label.

514 CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS
515 (AMERICIUM-241). (PLUTONIUM) (RADIUM-226).⁵ DO NOT TOUCH
516 RADIOACTIVE PORTION OF THIS SOURCE.

517 ⁵ Showing only the name of the appropriate material.

518 _____

519 Name of manufacturer or importer

520 (b) ~~The receipt, possession, use and transfer of this source, Model ____,~~
521 ~~Serial No. ____ are subject to a general license and the regulations of a~~
522 ~~Licensing State. Do not remove this label.~~

523 CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS
524 RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS
525 SOURCE. _____

526 Name of manufacturer or importer

527 (3) Not transfer, abandon, or dispose of such source except by transfer to a person
528 authorized by a license from the Department, the U.S. Nuclear Regulatory
529 Commission, **NRC OR** an Agreement State or a Licensing State to receive the
530 source;

531 (4) Store such source, except when the source is being used, in a closed container
532 adequately designed and constructed to contain americium-241, plutonium, or
533 radium-226 which might otherwise escape during storage; and

534 (5) Not use such source for any purpose other than the calibration of radiation
535 detectors or the standardization of other sources.

536 3.6.7.6 These general licenses do not authorize the manufacture of calibration or reference
537 sources containing americium-241, plutonium or radium-226.

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538 3.6.8 Reserved.

539 3.6.9 General License for Use of Radioactive Material for Certain *In Vitro* Clinical or Laboratory
540 Testing.⁶

541 ⁶ The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of
542 any specific diagnostic drugs in interstate commerce.

543 3.6.9.1 A general license is hereby issued to any physician, veterinarian, clinical laboratory or
544 hospital to receive, acquire, possess, transfer or use, for any of the following stated tests,
545 in accordance with the provisions of 3.6.9.2, 3.6.9.3, 3.6.9.4, 3.6.9.5, and 3.6.9.6, the
546 following radioactive materials in prepackaged units for use in *in vitro* clinical or
547 laboratory tests not involving internal or external administration of radioactive material, or
548 the radiation therefrom, to human beings or animals:

549 (1) Carbon-14, in units not exceeding 370 kBq (10 µCi) each;

550 (2) Cobalt-57, in units not exceeding 370 kBq (10 µCi) each;

551 (3) Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 µCi) each;

552 (4) Iodine-125, in units not exceeding 370 kBq (10 µCi) each;

553 (5) Mock Iodine-125 reference or calibration sources, in units not exceeding
554 1.85 kBq (0.05 µCi) of iodine-129 and 185 Bq (0.005 µCi) of americium-241
555 each;

556 (6) Iodine-131, in units not exceeding 370 kBq (10 µCi) each;

557 (7) Iron-59, in units not exceeding 740 kBq (20 µCi) each; or

558 (8) Selenium-75, in units not exceeding 370 kBq (10 µCi) each.

559 3.6.9.2 No person shall receive, acquire, possess, use or transfer radioactive material pursuant
560 to the general license established by 3.6.9.1 until the person has filed Department Form
561 R-27, "Certificate - *In Vitro* Testing with Radioactive Material Under General License",
562 with the Department and received from the Department a validated copy of Department
563 Form R-27 with certification number assigned. The physician, veterinarian, clinical
564 laboratory or hospital shall furnish on Department Form R-27 the following information
565 and such other information as may be required by that form:

566 (1) Name and address of the physician, veterinarian, clinical laboratory or hospital;

567 (2) The location of use; and

568 (3) A statement that the physician, veterinarian, clinical laboratory or hospital has
569 appropriate radiation measuring instruments to carry out *in vitro* clinical or
570 laboratory tests with radioactive material as authorized under the general license
571 in 3.6.9.1 and that such tests will be performed only by personnel competent in
572 the use of such instruments and in the handling of the radioactive material.

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- 573 3.6.9.3 A person who receives, acquires, possesses or uses radioactive material pursuant to the
574 general license established by 3.6.9.1 shall comply with the following requirements.
- 575 (1) The general licensee shall not possess at any one time, pursuant to the general
576 license in 3.6.9.1, at any one location of storage or use, a total amount of
577 iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of
578 7.4 MBq (200 µCi).
- 579 (2) The general licensee shall store the radioactive material, until used, in the
580 original shipping container or in a container providing equivalent radiation
581 protection.
- 582 (3) The general licensee shall use the radioactive material only for the uses
583 authorized by 3.6.9.1.
- 584 (4) The general licensee shall not transfer the radioactive material to a person who is
585 not authorized to receive it pursuant to a license issued by the Department, the
586 U.S. Nuclear Regulatory Commission, **NRC OR** any Agreement State or
587 Licensing State, nor transfer the radioactive material in any manner other than in
588 the unopened, labeled shipping container as received from the supplier.
- 589 (5) The general licensee shall dispose of the Mock Iodine-125 reference or
590 calibration sources described in 3.6.9.1(5) as required by 4.33.
- 591 3.6.9.4 The general licensee shall not receive, acquire, possess, or use radioactive material
592 pursuant to 3.6.9.1:
- 593 (1) Except as prepackaged units which are labeled in accordance with the provisions
594 of an applicable specific license issued pursuant to 3.12.8 or in accordance with
595 the provisions of a specific license issued by the U.S. Nuclear Regulatory
596 Commission, **NRC OR** any Agreement State or Licensing State which authorizes
597 the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-
598 3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons
599 generally licensed under 3.6.9 or its equivalent; and
- 600 (2) Unless one of the following statements, as appropriate, or a substantially similar
601 statement which contains the information called for in one of the following
602 statements, appears on a label affixed to each prepackaged unit or appears in a
603 leaflet or brochure which accompanies the package:
- 604 (a) This radioactive material shall be received, acquired, possessed, and
605 used only by physicians, veterinarians, clinical laboratories or hospitals
606 and only for *in vitro* clinical or laboratory tests not involving internal or
607 external administration of the material, or the radiation therefrom, to
608 human beings or animals. Its receipt, acquisition, possession, use, and
609 transfer are subject to the regulations and a general license of the U.S.
610 Nuclear Regulatory Commission or of a **N AGREEMENT** State with which
611 the Commission has entered into an agreement for the exercise of
612 regulatory authority.
- 613 _____
614 Name of manufacturer
- 615 (b) ~~This radioactive material shall be received, acquired, possessed, and~~
616 ~~used only by physicians, veterinarians, clinical laboratories or hospitals~~

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617 and only for *in vitro* clinical or laboratory tests not involving internal or
618 external administration of the material, or the radiation therefrom, to
619 human beings or animals. Its receipt, acquisition, possession, use and
620 transfer are subject to the regulations and a general license of a
621 Licensing State. _____
622 Name of manufacturer

623 3.6.9.5 The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive
624 material under the general license of 3.6.9.1 shall report in writing to the Department, any
625 changes in the information furnished by him in the "Certificate - *In Vitro* Testing with
626 Radioactive Material Under General License", Department Form R-27. The report shall
627 be furnished within 30 days after the effective date of such change.

628 3.6.9.6 Any person using radioactive material pursuant to the general license of 3.6.9.1 is
629 exempt from the requirements of Part 4 and 10 with respect to radioactive material
630 covered by that general license, except that such persons using the Mock Iodine-125
631 described in 3.6.9.1(5) shall comply with the provisions of 4.33, 4.51 and 4.52.

632 3.6.10 Ice Detection Devices.

633 3.6.10.1 A general license is hereby issued to receive, acquire, possess, use, and transfer
634 strontium-90 contained in ice detection devices, provided each device contains not more
635 than 1.85 MBq (50 µCi) of strontium-90 and each device has been manufactured or
636 imported in accordance with a specific license issued by the ~~U.S. Nuclear Regulatory
637 Commission-NRC~~ or each device has been manufactured in accordance with the
638 specifications contained in a specific license issued by the Department or an Agreement
639 State to the manufacturer of such device pursuant to licensing requirements equivalent to
640 those in Section 32.61 of 10 CFR Part 32 (January 1, 20104).

641 3.6.10.2 Persons who own, receive, acquire, possess, use, or transfer strontium-90
642 contained in ice detection devices pursuant to the general license in 3.6.10.1:

643 (1) Shall, upon occurrence of visually observable damage, such as a bend or crack
644 or discoloration from overheating to the device, discontinue use of the device
645 until it has been inspected, tested for leakage and repaired by a person holding a
646 specific license from the ~~U.S. Nuclear Regulatory Commission-NRC~~ or an
647 Agreement State to manufacture or service such devices; or shall dispose of the
648 device pursuant to the provisions of 4.33;

649 (2) Shall assure that all labels affixed to the device at the time of receipt, and which
650 bear a statement which prohibits removal of the labels, are maintained thereon;
651 and

652 (3) Are exempt from the requirements of Parts 4 and 10 except that such persons
653 shall comply with the provisions of 4.33, 4.51, and 4.52.

654 3.6.10.3 This general license does not authorize the manufacture, assembly, disassembly
655 or repair of strontium-90 in ice detection devices.

656 3.6.10.4 This general license is subject to the provisions of 1.4 through 1.9, 3.15, 3.22,
657 3.23 and Part 17.

658 3.7 **Reserved.**

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659 **SPECIFIC LICENSES**

660 **3.8 Filing AN Application for A Specific Licenses.**

661 3.8.1 Applications for specific licenses shall be filed ~~in duplicate~~ on a form prescribed by the
662 Department.

663 3.8.2 The Department may at any time after the filing of the original application, and before the
664 expiration of the license, require further statements in order to enable the Department to
665 determine whether the application should be granted or denied or whether a license should be
666 modified or revoked.

667 3.8.3 Each application shall be signed by the applicant or licensee or a person duly authorized to act
668 for and on the applicant's or licensee's behalf.

669 3.8.4 An application for a license may include a request for a license authorizing one or more activities.

670 3.8.5 In the application, the applicant may incorporate by reference information contained in previous
671 applications, statements, or reports filed with the Department provided such references are clear
672 and specific.

673 3.8.6 Applications and documents submitted to the Department may be made available for public
674 inspection except that the Department may withhold any document or part thereof from public
675 inspection pursuant to 24-72-204, CRS.

676 3.8.7 Pre-licensing Construction

677 3.8.7.1 An application for a license, or to amend or renew an existing license, for (1) source
678 material milling, (2) commercial waste storage, treatment or disposal by incineration, (3)
679 transfer for disposal of wastes from treatment or incineration, (4) commercial waste
680 disposal by land burial or by underground injection, or the (5) conduct of any other activity
681 within the licensing authority of the Department which the Department determines will
682 significantly affect the radiological quality of the human environment, shall be filed with
683 the Department at least nine (9) months prior to the anticipated commencement of
684 construction of the plant or facility in which the activity will be conducted **OR IN**
685 **ACCORDANCE WITH THE REQUIREMENTS OF PART 18 IF APPLICABLE**, and shall be
686 accompanied by the environmental report required by 3.8.8, unless an exemption from
687 the requirement of furnishing such a report has been obtained from the Department.

688 3.8.7.2 No construction shall be commenced until the license has been issued.

689 3.8.7.3 For the purpose of 3.8.7 the term "commencement of construction" means any clearing of
690 land, excavation or other substantial action related to a proposed activity for specific
691 licensing that would adversely affect the natural environment of a site; this term does not
692 include changes desirable for the temporary use of the land for public recreational uses,
693 limited borings to determine site characteristics as necessary for environmental
694 assessment of other pre-construction monitoring to establish background information
695 related to the suitability of a site, or to the protection of environmental values.

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696 3.8.8 Environmental Impact Assessment.

697 3.8.8.1 In the case of an application for a license, or to amend or renew an existing license, for
698 (1) source material milling, (2) commercial waste storage, treatment or disposal by
699 incineration, (3) transfer for disposal of waste from incineration, (4) commercial waste
700 disposal by land burial or by underground injection, or for (5) the conduct of any other
701 activity which will affect the quality of the human environment by reason of exposure to
702 radiation, before "commencement of construction", as defined in 3.8.7.3, of the plant or
703 facility in or at which the activity will be conducted, or in case of a renewal of such a
704 license, the applicant shall submit all information required under these regulations and
705 such other material as the Department may deem necessary.

706 (1) Such information shall include the environmental report and other information
707 required by 3.8.8.2 to be submitted to assist the Department in the evaluation of
708 the short-term and long-range environmental impact of the project and activity so
709 that the Department may weigh environmental, economic, technical, and other
710 benefits against environmental costs, while considering available alternatives.

711 (2) In the event that an environmental report acceptable to the Department is on file
712 with the Department in regard to the specific licensed activity authorized under
713 an existing license, and upon request of the applicant to amend or renew an
714 existing license or at the initiation of the Department, the Department may grant
715 an exemption of the requirement to submit an additional environmental report or
716 require such amendment of the existing environmental report as will demonstrate
717 the environmental impact to result from the proposed activity.

718 (3) The request for exemption shall provide the Department with such information as
719 the Department requires of the applicant to demonstrate that no significant
720 environmental impact will result from the licensed activity.

721 3.8.8.2 An environmental report shall be required of the applicant and shall contain all
722 information deemed necessary by the Department as ~~REQUIRED~~ authorized by the Act.

723 (1) Upon receipt of the environmental report or any amendment thereto, and of any
724 other documents required, the Department shall determine the necessity to
725 transmit and, if appropriate, shall transmit the same for review and comment to
726 Federal, State, and local agencies having expertise in and jurisdiction over the
727 proposed project and activity.

728 (2) Written comments and reports of reviewing agencies shall be considered by the
729 Department in its decision-making review process on the license application
730 request.

731 (3) If an environmental impact statement (EIS) is required of a Federal agency
732 pursuant to the National Environment Policy Act of 1969 (NEPA) and is provided
733 by such Federal agency, it shall be used by the Department in its decision-
734 making review process on the license application request.

735 (4) The Department shall consider applicable regulations of Federal, State, and local
736 regulatory agencies and permit requirements thereof.

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737 **3.9 General Requirements for the Issuance of Specific Licenses.**

738 A license application will be approved if the Department determines that:

739 3.9.1 The applicant is qualified by reason of training and experience to use the material in question for
740 the purpose requested in accordance with these regulations in such a manner as to minimize
741 danger to public health and safety or property;

742 3.9.2 The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger
743 to public health and safety or property;

744 3.9.3 The issuance of the license will not be inimical to the health and safety of the public;

745 3.9.4 The applicant satisfies any applicable special requirements in 3.10, 3.11, or 3.12; and

746 3.9.5 The applicant has established Department-approved financial assurance warranties in
747 accordance with the following requirements.

748 3.9.5.1 A signed executed original copy of each warranty required by this part shall be furnished
749 to and approved by the Department prior to the issuance of a new license, or any
750 amendment or renewal of an existing license.

751 3.9.5.2 The Department may require any licensee to furnish a decommissioning warranty in a
752 dollar amount determined by the agency as necessary to protect public health and safety,
753 to ensure corrective action during operation, to ensure decontamination and
754 decommissioning of a facility and disposal of radioactive materials in the event of
755 abandonment, default or inability of the licensee to meet the requirements of the Act,
756 these regulations, or the license.

757 3.9.5.3 The following specific licensees are required to furnish decommissioning warranties:

758 (1) Each licensee authorized to possess and use greater than 370 MBq (10 mCi) of
759 source material in a readily dispersible form; and

760 (2) Each licensee authorized to possess and use radioactive material with a half-life
761 greater than 120 days, in quantities:

762 (a) Greater than 10^3 times the applicable quantity of Schedule 3B in
763 unsealed form. For a combination of isotopes if R divided by 10^3 is
764 greater than 1 (unity rule), where R is defined here as the sum of the
765 ratios of the quantity of each isotope to the applicable value in
766 Schedule 3B.

767 (b) Greater than 10^{10} times the applicable quantity of Schedule 3B in sealed
768 sources or plated foils. For a combination of isotopes if R divided by 10^{10}
769 is greater than 1 (unity rule), where R is defined in 3.9.5.3(2)(a).

770 (c) ~~Greater than 370 Bq (0.01 μCi)~~ **SHALL BE USED AS THE SCHEDULE 3B**
771 **VALUE** for any alpha emitting radionuclide not listed in Schedule 3B, or
772 mixtures of alpha emitters of unknown composition, for the purpose of
773 determining if the quantity of licensed radioactive material requires a
774 decommissioning warranty or a decommissioning funding plan as
775 defined in 3.9.6.

776 (3) Former U.S. Atomic Energy Commission or NRC licensed facilities;

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- 777 (4) Radioactive waste collection and/or processing licensees;
- 778 (5) Radioactive waste disposal licensees;
- 779 (6) Source material milling licensees;
- 780 (7) Ore refineries; and
- 781 (8) Other persons with, or applicants for, a specific license as determined by the
782 agency.
- 783 3.9.5.4 Acceptable Financial Assurance Methods.
- 784 (1) Financial assurance warranties shall contain provisions which are acceptable to
785 the Department for:
- 786 (a) Defining the amount and term of the warranty;
- 787 (b) Providing written notification to the Department by the warrantor at least
788 ninety (90) days prior to cancellation, termination, or revocation of the
789 warranty; and
- 790 (c) Converting the warranty into cash upon forfeiture of the warranty, and
- 791 (2) Financial assurance warranties shall be in the form of a cash deposit,
792 prepayment of a trust, escrow account, government fund, certificate of deposit, or
793 deposit of government securities.
- 794 (a) Prepayment is the deposit prior to the start of operation into an account
795 segregated from licensee assets and outside the licensee's
796 administrative control of cash or liquid assets such that the amount of
797 funds would be sufficient to pay decommissioning costs; or
- 798 (3) Financial assurance warranties which involve a guarantee method to ensure that
799 costs will be paid should the licensee default shall be in a form as described
800 below:
- 801 (a) A bond issued by a fidelity or surety company consistent with the
802 provisions of Section 25-11-110(6)(b)(l), CRS;
- 803 (b) An irrevocable "letter of credit" or "line of credit" issued by a recognized
804 financial institution whose financial condition and commitment are
805 established to the satisfaction of the Department;

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- (c) For a decommissioning warranty, a guarantee of funds by the applicant, licensee, or parent company which satisfies the requirements listed below. However, this self-guarantee shall not apply to uranium or thorium milling licensees.
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- (i) The Department may accept a parent company guarantee of funds for decommissioning costs based upon a financial test of the parent company and a written guarantee as contained in Appendix 3A3F.
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- (ii) The Department may accept an applicant or licensee guarantee of funds for decommissioning costs based upon a financial test of the applicant or licensee and a written guarantee as contained in Appendix 3B3G.
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- (iii) A guarantee by the applicant, licensee, or parent company may not be used in combination with other financial methods to satisfy the requirements of this section.
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- (iv) A guarantee by the applicant or licensee may not be used in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company; or
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- (4) Financial assurance warranties which involve an external sinking fund shall be in a form 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.
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- (a) 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.
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- (b) An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities; or
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- (5) Financial assurance warranties previously provided to any State, Federal and/or local governing bodies concerning activities subject to license under these regulations, where the amount, terms, and conditions of such financial assurance warranties have been established to the satisfaction of the Department and in accordance with the requirements of 3.9.5; or
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- (6) Except for the guarantee of funds noted in 3.9.5.4(3), combinations of the above may be used to establish an acceptable financial assurance warranty.
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- (7) The term of the financial assurance warranty shall be open-ended or shall have provisions for automatic renewal until termination of the license by the Department, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance.
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- (8) The value of the financial assurance warranty must not be dependent upon the success, profitability, or continued operation of the licensed business or operation.

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- 850 3.9.5.5 The amount of funds to be provided by such decommissioning warranties shall be based
851 on Department-approved cost estimates and shall
- 852 (1) Include the disposal of radioactive materials;
- 853 (2) Include decontamination and decommissioning of buildings, facilities and the site
854 to levels which would allow unrestricted use of these areas upon
855 decommissioning;
- 856 (3) Include the reclamation of tailings and/or waste disposal areas in accordance
857 with technical criteria delineated in Parts 3, 4 and/or 18, as appropriate;
- 858 (4) Take into account total costs that would be incurred if an independent contractor
859 were hired to dispose of radioactive materials and perform decontamination,
860 decommissioning, and reclamation work, including:
- 861 (a) The cost of removal and/or disposal of radioactive material, or a
862 radioactivity-inducing machine, which is or would be generated, stored,
863 processed or otherwise present at the facility or site; and
- 864 (b) The probable extent of contamination through the possession or use of
865 radioactive material, at or adjacent to the facility or site, and the probable
866 cost of removal of such contamination; and
- 867 (5) Include reasonable administrative costs, including indirect costs, incurred by the
868 Department in conducting or overseeing the decontamination, decommissioning,
869 and disposal activities, and to cover the Department's reasonable attorney costs
870 that may be incurred in successfully revoking, foreclosing, or realizing the
871 decommissioning warranties established by the licensee in accordance with
872 Part 3.
- 873 3.9.5.6 The licensee shall provide in writing to the Department, no later than June 30th of each
874 calendar year, AN ANNUAL REPORT DEMONSTRATING PROOF OF THE VALUE OF EXISTING
875 FINANCIAL WARRANTIES AND any licensee-proposed changes to the financial assurance
876 warranties, including updated decommissioning funding plans, cost estimates, or the type
877 of warranty. THE ANNUAL REPORT SHALL DESCRIBE ANY CHANGES IN OPERATIONS, ESTIMATED
878 COSTS, OR ANY OTHER CIRCUMSTANCES THAT MAY AFFECT THE AMOUNT OF THE REQUIRED
879 FINANCIAL ASSURANCE WARRANTIES, INCLUDING ANY INCREASED OR DECREASED COSTS
880 ATTRIBUTABLE TO INFLATION.
- 881 3.9.5.7 Each licensee's financial assurance warranties shall be subject to review annually by the
882 Department to assure the continued adequacy of each warranty. PUBLIC NOTICE OF THE
883 SUBMITTAL OF THE LICENSEE'S ANNUAL REPORT SHALL BE POSTED ON THE DEPARTMENT'S
884 WEB SITE AND PUBLISHED BY THE LICENSEE IN THE LOCAL PAPER OF GENERAL CIRCULATION.
885 ANY PERSON MAY SUBMIT WRITTEN COMMENTS TO THE DEPARTMENT CONCERNING THE
886 ADEQUACY OF ANY FINANCIAL ASSURANCE WARRANTIES. THE ACT OF SUBMITTING SUCH
887 COMMENTS DOES NOT PROVIDE A RIGHT TO ADMINISTRATIVE APPEAL CONCERNING THE
888 FINANCIAL ASSURANCE WARRANTIES.
- 889 3.9.5.8 The Department will determine if the licensee must adjust the amount of the warranty to
890 account for increases or decreases in cost estimates resulting from inflation or deflation;
891 changes in engineering plans, activities performed, authorized quantities of radioactive
892 material; or changes in any other conditions affecting disposal, decontamination, and
893 decommissioning costs.

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894 (1) With the approval of the Department, a licensee may reduce the amount of a
895 decommissioning warranty as decommissioning activities are completed in
896 accordance with an approved decommissioning plan and/or to reflect current site
897 conditions and license authorizations.

898 (2) THE LICENSEE SHALL HAVE SIXTY DAYS AFTER THE DATE OF WRITTEN NOTIFICATION BY
899 THE DEPARTMENT OF A REQUIRED ADJUSTMENT TO ESTABLISH A WARRANTY
900 FULFILLING ALL NEW REQUIREMENTS UNLESS GRANTED AN EXTENSION BY THE
901 DEPARTMENT. IF THE LICENSEE DISPUTES THE AMOUNT OF THE REQUIRED FINANCIAL
902 ASSURANCE WARRANTIES, THE LICENSEE MAY REQUEST A HEARING TO BE CONDUCTED
903 IN ACCORDANCE WITH SECTION 24-4-105, CRS.

904 (3) IF THE LICENSEE REQUESTS A HEARING, NO NEW CLASSIFIED MATERIAL, AS THAT TERM
905 IS DEFINED IN 1.2.2, MAY BE BROUGHT ON SITE AND NO CLASSIFIED MATERIAL MAY BE
906 PROCESSED UNTIL THE LICENSEE'S DISPUTE OVER THE FINANCIAL ASSURANCE
907 WARRANTY IS RESOLVED, UNLESS THE LICENSEE POSTS A BOND IN A FORM APPROVED
908 BY THE DEPARTMENT EQUAL TO THE AMOUNT IN DISPUTE.

909 3.9.5.9 Regardless of whether the disposal, decontamination and decommissioning work is
910 phased through the life of the licensed operations or takes place at the end of the
911 operation, an appropriate and adequate decommissioning warranty shall be maintained
912 in good standing by the licensee until termination of the license or as otherwise
913 authorized by the Department.

914 3.9.5.10 In addition to the decommissioning warranty required by 3.9.5.2, the Department
915 may require any licensee to provide a long-term care warranty if the licensed facility will
916 remain a disposal site for radioactive materials subsequent to the termination of the
917 license, or the license will be terminated using criteria in 4.61.3 or 4.61.4.

918 (1) Except as provided in 3.9.5.10(2), the following specific licensees are required to
919 provide long-term care warranties:

- 920 (a) Radioactive waste disposal licensees;
- 921 (b) Commercial radioactive waste handling and/or packaging licensees;
- 922 (c) Source material milling licensees; and
- 923 (d) Formerly U.S. Atomic Energy Commission or U.S. Nuclear Regulatory
924 Commission-licensed facilities;

925 (2) A long-term care warranty is not required for a licensee identified in 3.9.5.10(1) if
926 the disposition of radioactive materials by the licensee is made in such a manner
927 as the Department determines does not require long-term monitoring and
928 maintenance of the site.

929 (3) The long-term care warranty shall be in a form as described in 3.9.5.4.

930 (4) The amount of funds to be provided by such long-term care warranties shall be
931 based on Department-approved cost estimates and shall be enough that with an
932 assumed six percent annual real interest rate, the annual interest earnings will be
933 sufficient to cover to the annual costs of site surveillance by the Department,
934 including reasonable administrative costs incurred by the Department, in
935 perpetuity, subsequent to the termination of the license.

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- 936 (a) For each source material mill licensee, the long-term care warranty must
937 have a minimum value equivalent to \$250,000 in 1978 dollars.
- 938 (i) The value of the long-term care warranty shall be adjusted
939 annually to recognize inflation.
- 940 (ii) The inflation rate to be used for this adjustment is that indicated
941 by the change in the consumer price index published by the U.S.
942 Department of Labor, Bureau of Labor Statistics.
- 943 (iii) The Department may use other indicators of the inflation rate if
944 reasonable; provided, however, that the license shall not
945 terminate unless the amount of the long-term care warranty is
946 acceptable to the licensing agency and site caretaker.
- 947 (b) Cost estimates for facilities and sites requiring long-term care
948 subsequent to license termination are to be based on the final disposition
949 of wastes such that ongoing active maintenance is not necessary to
950 preserve isolation.
- 951 (i) It is expected that, as a minimum, annual site inspections shall
952 be conducted to confirm the integrity of the stabilized waste
953 systems and to determine the need, if any, for maintenance
954 and/or monitoring.
- 955 (ii) Cost estimates shall be adjusted if more frequent site inspections
956 are required based on an evaluation of a particular site.
- 957 (c) For sites decommissioned in accordance with the provisions of 4.61.3 or
958 4.61.4, cost estimates for long-term care subsequent to license
959 termination must be sufficient to enable the Department, a responsible
960 government agency, or an independent third party to:
- 961 (i) Perform periodic site inspections no less frequently than each
962 five years;
- 963 (ii) Assure the continuation of institutional controls; and
- 964 (iii) Assume responsibilities and carry out any necessary control and
965 maintenance of the site. Cost estimates shall be adjusted if more
966 frequent site inspections are required based on an evaluation of
967 a particular site and the institutional controls established for that
968 site.
- 969 (5) Whenever the Department determines that a licensee's disposal,
970 decommissioning and decontamination requirements have been satisfied,
971 provisions shall be made for transferring custody of the site and the long-term
972 care warranty funds for that license in accordance with the act.
- 973 (a) If the value of the long-term care warranty funds exceeds the amount
974 required by the government agency overseeing the long-term care of the
975 site, then all such excess amounts shall be returned to the licensee.

976 3.9.6 Decommissioning Funding Plan Required.

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977 3.9.6.1 Each applicant for and holder of a license authorizing the possession and use unsealed
978 radioactive materials with half-life greater than 120 days and in quantities greater than
979 10^5 times the applicable quantity of Schedule 3B, shall establish a Department-approved
980 decommissioning funding plan to assure the availability of funds for decommissioning
981 activities conducted over the life of the licensed facility. 370 Bq (0.01 μ Ci) SHALL BE USED
982 AS THE SCHEDULE 3B VALUE FOR ANY ALPHA EMITTING RADIONUCLIDE NOT LISTED IN
983 SCHEDULE 3B, OR MIXTURES OF ALPHA EMITTERS OF UNKNOWN COMPOSITION.

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984 (1) A decommissioning funding plan is also required for licensees authorized a combination
985 of isotopes if R divided by 10^5 is greater than 1 (unity rule), where R is defined in
986 3.9.5.3(2)(a).

987 3.9.6.2 Each holder of, or applicant for, any specific license authorizing the possession and use
988 of sealed sources or plated foils of half-life greater than 120 days and in quantities
989 greater than 10^{12} times the applicable quantity in Schedule 3B shall establish a
990 Department-approved decommissioning funding plan to assure the availability of funds
991 for decommissioning activities conducted over the life of the licensed facility. 370 Bq
992 (0.01 μ Ci) SHALL BE USED AS THE SCHEDULE 3B VALUE FOR ANY ALPHA EMITTING
993 RADIONUCLIDE NOT LISTED IN SCHEDULE 3B, OR MIXTURES OF ALPHA EMITTERS OF UNKNOWN
994 COMPOSITION.

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995 (1) The decommissioning funding plan is also required for licensees authorized for a
996 combination of isotopes if R divided by 10^{12} is greater than 1 (unity rule), where R is
997 defined as in 3.9.5.3(2)(a).

998 (2) ~~The decommissioning funding plan must be submitted to the Department by June~~
999 ~~30, 2006.~~

1000 3.9.6.3 Waste collectors and waste processors, as defined in Part 4, Appendix D, shall establish
1001 an agency-approved decommissioning funding plan to assure the availability of funds for
1002 decommissioning activities conducted over the life of the licensed facility.

1003 (1) The decommissioning funding plan must include the cost of disposal of the
1004 maximum radioactivity (becquerel or curie) of radioactive material permitted by
1005 the license, and the cost of disposal of the maximum quantity, by volume, of
1006 radioactive material that could be present at the licensee's facility at any time, in
1007 addition to the cost to remediate the licensee's site to meet the license
1008 termination criteria of Part 4.

1009 (2) ~~The decommissioning funding plan must be submitted to the Department by~~
1010 ~~June 30, 2006.~~

1011 3.9.6.4 This plan shall contain a cost estimate for decommissioning, as required in this section,
1012 including means for adjusting cost estimates and associated funding levels periodically
1013 over the life of the facility. Cost estimates must be adjusted at intervals not to exceed
1014 three years.

1015 3.9.6.5 The decommissioning funding plan must also include a certification by the licensee that
1016 funding for decommissioning activities has been provided for in the amount of the cost
1017 estimate for decommissioning.

1018 (1) For an applicant, this certification may state that the appropriate assurance will
1019 be obtained after the application has been approved and the license issued, but
1020 prior to the receipt or possession of radioactive material.

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- 1021 (2) A signed original of the financial instrument shall be submitted to the Department.
- 1022 3.9.7 In the case of an application for a license for (1) source material milling, (2) commercial waste
1023 storage, treatment or disposal by incineration, (3) transfer for disposal of waste from incineration,
1024 (4) commercial waste disposal by land burial or by underground injection, or for (5) the conduct of
1025 any other activity which the Department determines will significantly affect the quality of the
1026 human environment, the Department has concluded that the action called for is the issuance of
1027 the proposed license with any appropriate conditions to protect environmental values.
- 1028 **3.9.7.1** Such determination shall be made before commencement of construction of the plant or
1029 facility in which the activity will be conducted and based on information filed and
1030 evaluation made pursuant to 3.8.8.
- 1031 3.9.8 Commencement of construction prior to the issuance of a license, or of an amendment or renewal
1032 thereof, or of an exemption under the requirements of 3.8.7, may be grounds for denial of such
1033 license, amendment or renewal; and
- 1034 3.9.9 Reserved.
- 1035 3.9.10 License Hearings.
- 1036 3.9.10.1 There shall be an opportunity for public hearings to be held in the following
1037 circumstances in accordance with the procedures in 24-4-104 and -105, C.R.S. and this
1038 paragraph:
- 1039 (1) Prior to the licensing or leasing of state-owned property for the concentration,
1040 storage or permanent disposal of radioactive materials.
- 1041 (2) FOR EACH PROPOSED LICENSE, FIVE-YEAR LICENSE RENEWAL, OR LICENSE
1042 AMENDMENT PERTAINING TO A URANIUM RECOVERY FACILITY'S RECEIPT OF CLASSIFIED
1043 MATERIAL AS SPECIFIED IN PART 18 OF THESE REGULATIONS.
- 1044 3.9.11 Contingency Plans
- 1045 3.9.11.1 Each application to possess radioactive materials in unsealed form, on foils or
1046 plated sources, or sealed in glass in excess of the quantities in Schedule 3E - "Quantities
1047 of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for
1048 Responding to a Release", must contain either:
- 1049 (1) An evaluation, as described in 3.9.11.2, showing that the projected dose to a
1050 person offsite due to a release of radioactive materials would not exceed 0.01 Sv
1051 (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or
- 1052 (2) A contingency plan for responding to a release of radioactive material.
- 1053 3.9.11.2 In evaluating the total effective dose equivalent to an individual pursuant to
1054 3.9.11.1(1):
- 1055 (1) The radioactive material is physically separated so that only a portion could be
1056 involved in an accident;
- 1057 (2) All or part of the radioactive material is not subject to release during an accident
1058 because of the way it is stored or packaged;

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- 1059
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- (3) The release fraction in the respirable size range is predicted to be lower than the release fraction shown in Schedule 3E due to the chemical or physical form of the material;
- 1062
- (4) The solubility of the radioactive material would reduce the dose received;
- 1063
1064
- (5) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Schedule 3E.
- 1065
1066
- (6) Operating restrictions or procedures would prevent a release fraction as large as that shown in Schedule 3E.
- 1067
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1069
- 3.9.11.3 A contingency plan for responding to a release of radioactive material submitted under 3.9.11.1(2) must include the following information, in separate sections having each page numbered and labeled with a revision date and revision number:
- 1070
1071
- (1) Facility description- **aA** brief description of the licensee's facility and surroundings.
- 1072
1073
1074
- (2) Types of accidents- **aA** n identification of each type of accident involving radioactive material for which actions by licensee staff or offsite response organizations will be needed to protect members of the public.
- 1075
1076
- (3) Classification of accidents- **aA** method for classifying and declaring each alert or site area emergency, as defined in Part 1.
- 1077
1078
- (4) Detection of accidents- **i**dentification of the means of detecting each type of accident in a timely manner.
- 1079
1080
1081
1082
- (5) Mitigation of consequences- **aA** brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.
- 1083
1084
- (6) Assessment of releases- **aA** brief description of the methods and equipment to assess releases of radioactive materials.
- 1085
1086
1087
1088
1089
- (7) Responsibilities- **aA** brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Department; also responsibilities for developing, maintaining, and updating the plan.
- 1090
- (8) Notification and coordination.
- 1091
1092
1093
1094
- (a)** A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate.
- 1095
- (b)** A control point must be established.
- 1096
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1098
- (c)** The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination.

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- 1109 (d) The licensee shall also commit to notify the Department immediately
1100 after notification of the appropriate offsite response organizations and not
1101 later than one hour after the licensee declares an emergency.
- 1102 (9) Information to be communicated: - aA brief description of the types of information
1103 on facility status, radioactive releases, and recommended protective actions, if
1104 necessary, to be given to offsite response organizations and to the Department.
- 1105 (10) Training.
- 1106 (a) A brief description of the frequency, performance objectives and plans
1107 for the training that the licensee will provide workers on how to respond
1108 to an emergency including any special instructions and orientation tours
1109 the licensee would offer to fire, police, medical and other emergency
1110 personnel.
- 1111 (b) The training shall familiarize personnel with site-specific emergency
1112 procedures.
- 1113 (c) Also, the training shall thoroughly prepare site personnel for their
1114 responsibilities in the event of accident scenarios postulated as most
1115 probable for the specific site, including the use of team training for such
1116 scenarios.
- 1117 (11) Safe shutdown- - aA brief description of the means of restoring the facility to a
1118 safe condition after an accident.
- 1119 (12) Exercises.
- 1120 (a) Provisions for conducting quarterly communications checks with offsite
1121 response organizations and biennial onsite exercises to test response to
1122 simulated emergencies.
- 1123 (b) Quarterly communications checks with offsite response organizations
1124 must include the check and update of all necessary telephone numbers.
- 1125 (c) The licensee shall invite offsite response organizations to participate in
1126 the biennial exercises.
- 1127 (d) Participation of offsite response organizations in biennial exercises
1128 although recommended is not required.
- 1129 (e) Exercises must use accident scenarios postulated as most probable for
1130 the specific site and the scenarios shall not be known to most exercise
1131 participants.
- 1132 (f) The licensee shall critique each exercise using individuals not having
1133 direct implementation responsibility for the plan.
- 1134 (g) Critiques of exercises must evaluate the appropriateness of the plan,
1135 emergency procedures, facilities, equipment, training of personnel, and
1136 overall effectiveness of the response.
- 1137 (h) Deficiencies found by the critiques must be corrected.

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- 1138 (13) Hazardous chemicals: - aA certification that the applicant has met its
1139 responsibilities under the Emergency Planning and Community Right-To-Know
1140 Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at
1141 the proposed place of use of the radioactive material.
- 1142 3.9.11.4 The licensee shall allow the offsite response organizations expected to respond
1143 in case of an accident 60 days to comment on the licensee's emergency plan before
1144 submitting it to the Department.
- 1145 (1) The licensee shall provide any comments received within 60 days to the
1146 Department with the emergency plan.
- 1147 **3.10 Additional Requirements for Issuance of Specific Licenses for Use of Unsealed**
1148 **Radioactive Material.**
- 1149 **3.10.1** In addition to the requirements set forth in 3.9, applicants for licenses authorizing the possession
1150 and use of unsealed radioactive materials shall include in the application a description of the
1151 facility and procedures for operation which
- 1152 3.10.1.1 Minimize to the extent practicable, contamination of the facility and environment;
- 1153 3.10.1.2 Facilitate eventual decommissioning; and
- 1154 3.10.1.3 Minimize, to the extent practicable, the generation of radioactive waste.
- 1155 **3.11 Special Requirements for Specific Licenses of Broad Scope.**
- 1156 **3.11.1** This section prescribes requirements for the issuance of specific licenses of broad scope for
1157 radioactive material and certain regulations governing holders of the types of broad licenses set
1158 forth below.⁷
- 1159 ⁷ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment,
1160 device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and
1161 disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear
1162 Regulatory Commission, Washington, D.C. 20555.
- 1163 ~~3.11.1 The different types of broad scope licenses are set forth below:~~
- 1164 3.11.1.1 A "Type A specific license of broad scope" is a specific license authorizing
1165 receipt, acquisition, ownership, possession, use and transfer of any chemical or physical
1166 form of the radioactive material specified in the license, but not exceeding quantities
1167 specified in the license, for any authorized purpose.
- 1168 (1) The quantities specified are usually in the multicurie range.
- 1169 3.11.1.2 A "Type B specific license of broad scope" is a specific license authorizing
1170 receipt, acquisition, possession, use and transfer of any chemical or physical form of
1171 radioactive material specified in Schedule 3D of this part, for any authorized purpose.
- 1172 (1) The possession limit for a Type B license of broad scope, if only one radionuclide
1173 is possessed thereunder, is the quantity specified for that radionuclide in
1174 Schedule 3D, Column I.
- 1175 (2) If two or more radionuclides are possessed thereunder, the possession limit for
1176 each is determined as follows: For each radionuclide, determine the ratio of the

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- 1177 quantity possessed to the applicable quantity specified in Schedule 3D, Column
1178 I, for that radionuclide.
- 1179 **(3)** The sum of the ratios for all radionuclides possessed under the license shall not
1180 exceed unity.
- 1181 3.11.1.3 A "Type C specific license of broad scope" is a specific license authorizing
1182 receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical
1183 form of radioactive material specified in Schedule 3D of this part, for any authorized
1184 purpose.
- 1185 **(1)** The possession limit for a Type C license of broad scope, if only one radionuclide
1186 is possessed thereunder, is the quantity specified for that radionuclide in
1187 Schedule 3D, Column II.
- 1188 **(2)** If two or more radionuclides are possessed thereunder, the possession limit is
1189 determined for each as follows: For each radionuclide, determine the ratio of the
1190 quantity possessed to the applicable quantity specified in Schedule 3D, Column
1191 II, for that radionuclide.
- 1192 **(3)** The sum of the ratios for all radionuclides possessed under the license shall not
1193 exceed unity.
- 1194 3.11.2 An application for a Type A specific license of broad scope will be approved if:
- 1195 3.11.2.1 The applicant satisfies the general requirements specified in 3.9;
- 1196 3.11.2.2 The applicant has engaged in a reasonable number of activities involving the use
1197 of radioactive material; and
- 1198 3.11.2.3 The applicant has established administrative controls and provisions relating to
1199 organization and management, procedures, record keeping, material control and
1200 accounting, and management review that are necessary to assure safe operations,
1201 including:
- 1202 **(1)** The establishment of a radiation safety committee composed of such persons as
1203 a radiation safety officer, a representative of management, and persons trained
1204 and experienced in the safe use of radioactive material;
- 1205 **(2)** The appointment of a radiation safety officer who is qualified by training and
1206 experience in radiation protection, and who is available for advice and assistance
1207 on radiation safety matters; and
- 1208 **(3)** The establishment of appropriate administrative procedures to assure:
- 1209 **(a)** Control of procurement and use of radioactive material;
- 1210 **(b)** Completion of safety evaluations of proposed uses of radioactive
1211 material which take into consideration such matters as the adequacy of
1212 facilities and equipment, training and experience of the user, the
1213 operating or handling procedures; and
- 1214 **(c)** Review, approval, and recording by the radiation safety committee of
1215 safety evaluations of proposed uses prepared in accordance with
1216 3.11.2.3(3)(b) prior to use of the radioactive material.

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- 1217 3.11.3 An application for a Type B specific license of broad scope will be approved if:
- 1218 3.11.3.1 The applicant satisfies the general requirements specified in 3.9; and
- 1219 3.11.3.2 The applicant has established administrative controls and provisions relating to
1220 organization and management, procedures, record keeping, material control and
1221 accounting, and management review that are necessary to assure safe operations,
1222 including:
- 1223 (1) The appointment of a radiation safety officer who is qualified by training and
1224 experience in radiation protection, and who is available for advice and assistance
1225 on radiation safety matters; and
- 1226 (2) The establishment of appropriate administrative procedures to assure;
- 1227 (a) Control of procurement and use of radioactive material;
- 1228 (b) Completion of safety evaluations of proposed uses of radioactive
1229 material which take into consideration such matters as the adequacy of
1230 facilities and equipment, training and experience of the user, and the
1231 operating or handling procedures; and
- 1232 (c) Review, approval, and recording by the radiation safety officer of safety
1233 evaluations of proposed uses prepared in accordance with 3.11.3.2(2)(b)
1234 prior to use of the radioactive material.
- 1235 3.11.4 An application for a Type C specific license of broad scope will be approved if:
- 1236 3.11.4.1 The applicant satisfies the general requirements specified in 3.9;
- 1237 3.11.4.2 The applicant submits a statement that radioactive material will be used only by,
1238 or under the direct supervision of, individuals who have received:
- 1239 (1) A college degree at the bachelor level, or equivalent training and experience, in
1240 the physical or biological sciences or in engineering, and
- 1241 (2) At least 40 hours of training and experience in the safe handling of radioactive
1242 material, and in the characteristics of ionizing radiation, units of radiation dose
1243 and quantities, radiation detection instrumentation, and biological hazards of
1244 exposure to radiation appropriate to the type and forms of radioactive material to
1245 be used; and
- 1246 3.11.4.3 The applicant has established administrative controls and provisions relating to
1247 procurement of radioactive material, procedures, record keeping, material control and
1248 accounting, and management review necessary to assure safe operations.

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1249 3.11.5 Specific licenses of broad scope are subject to the following conditions:

1250 3.11.5.1 Unless specifically authorized, persons licensed pursuant to 3.11 shall not:

- 1251 (1) Conduct tracer studies in the environment involving direct release of radioactive
1252 material;
- 1253 (2) Receive, acquire, own, possess, use; or transfer devices containing 3.7 PBq
1254 (100 kCi) or more of radioactive material in sealed sources used for irradiation of
1255 materials;
- 1256 (3) Conduct activities for which a specific license issued by the Department under
1257 3.10, 3.12, or Parts 7, 14, and 18 is required; or
- 1258 (4) Add or cause the addition of radioactive material to any food, beverage,
1259 cosmetic, drug, or other product designed for ingestion or inhalation by, or
1260 application to, a human being.

1261 3.11.5.2 Each Type A specific license of broad scope issued under this part shall be
1262 subject to the condition that radioactive material possessed under the license may only
1263 be used by, or under the direct supervision of, individuals approved by the licensee's
1264 radiation safety committee.

1265 3.11.5.3 Each Type B specific license of broad scope issued under this part shall be
1266 subject to the condition that radioactive material possessed under the license may only
1267 be used by, or under the direct supervision of, individuals approved by the licensee's
1268 radiation safety officer.

1269 3.11.5.4 Each Type C specific license of broad scope issued under this part shall be
1270 subject to the condition that radioactive material possessed under the license may only
1271 be used by, or under the direct supervision of, individuals who satisfy the requirements of
1272 3.11.4.

1273 **3.12 Special Requirements for a Specific License to Manufacture, Assemble, Repair, or**
1274 **Distribute Commodities, Products, or Devices which Contain Radioactive Material.**

1275 3.12.1 Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations:
1276 **A LICENSEE AUTHORIZED TO INTRODUCE RADIOACTIVE MATERIAL INTO A PRODUCT**
1277 **OR MATERIAL OWNED BY OR IN THE POSSESSION OF THE LICENSEE OR ANOTHER TO**
1278 **BE TRANSFERRED TO PERSONS EXEMPT UNDER 3.3.1.1 SHALL MEET THE**
1279 **REQUIREMENTS OF 10 CFR 32.11 AND ANY OTHER APPLICABLE NRC REQUIREMENT.**

1280 ~~3.12.1.1 — In addition to the requirements set forth in 3.9, a specific license authorizing the~~
1281 ~~introduction of radioactive material into a product or material owned by or in the~~
1282 ~~possession of the licensee or another to be transferred to persons exempt under 3.3.1.1~~
1283 ~~will be issued if:~~

- 1284 (1) — The applicant submits a description of the product or material into which the
1285 radioactive material will be introduced, intended use of the radioactive material
1286 and the product or material into which it is introduced, method of introduction,
1287 initial concentration of the radioactive material in the product or material, control
1288 methods to assure that no more than the specified concentration is introduced
1289 into the product or material, estimated time interval between introduction and
1290 transfer of the product or material,; and estimated concentration of the
1291 radioactive material in the product or material at the time of transfer; and

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1292 (2) The applicant provides reasonable assurance that the concentrations of
1293 radioactive material at the time of transfer will not exceed the concentrations in
1294 Schedule 3A of this part; that reconcentration of the radioactive material in
1295 concentrations exceeding those in Schedule 3A is not likely, that use of lower
1296 concentrations is not feasible; and that the product or material is not likely to be
1297 incorporated in any food, beverage, cosmetic, drug, or other commodity or
1298 product designed for ingestion or inhalation by, or application to, a human being.

1299 3.12.1.2 Each person licensed under 3.12.1 shall file an annual report with the
1300 Department which shall identify the type and quantity of each product or material into
1301 which radioactive material has been introduced during the reporting period; name and
1302 address of the person who owned or possessed the product or material, into which
1303 radioactive material has been introduced, at the time of introduction; the type and
1304 quantity of radionuclide introduced into each such product or material; and the initial
1305 concentrations of the radionuclide in the product or material at time of transfer of the
1306 radioactive material by the licensee. If no transfers of radioactive material have been
1307 made pursuant to 3.12.1 during the reporting period, the report shall so indicate. The
1308 report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

1309 3.12.2 Licensing the Distribution of Radioactive Material in Exempt Quantities. **NO PERSON MAY**
1310 **INTRODUCE BYPRODUCT MATERIAL INTO A PRODUCT OR MATERIAL KNOWING OR**
1311 **HAVING REASON TO BELIEVE THAT IT WILL BE TRANSFERRED TO PERSONS**
1312 **EXEMPTED PURSUANT TO 3.3.2, UNDER 10 CFR 30.14 OR EQUIVALENT REGULATIONS**
1313 **OF AN AGREEMENT STATE, EXCEPT IN ACCORDANCE WITH A LICENSE ISSUED UNDER**
1314 **10 CFR 32.⁸**

1315 ⁸ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment,
1316 device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and
1317 disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear
1318 Regulatory Commission, Washington, D.C. 20555.

1319 3.12.2.1 An application for a specific license to distribute NARM to persons exempted
1320 from these regulations pursuant to 3.3.2 will be approved if:

1321 (1) The radioactive material is not contained in any food, beverage, cosmetic, drug,
1322 or other commodity designed for ingestion or inhalation by, or application to, a
1323 human being;

1324 (2) The radioactive material is in the form of processed chemical elements,
1325 compounds, or mixtures, tissue samples, bioassay samples, counting standards,
1326 plated or encapsulated sources, or similar substances, identified as radioactive
1327 and to be used for its radioactive properties, but is not incorporated into any
1328 manufactured or assembled commodity, product, or device intended for
1329 commercial distribution; and

1330 (3) The applicant submits copies of prototype labels and brochures and the
1331 Department approves such labels and brochures.

1332 3.12.2.2 The license issued under 3.12.2.1 is subject to the following conditions:

1333 (1) No more than 10 exempt quantities shall be sold or transferred in any single
1334 transaction. However, an exempt quantity may be composed of fractional parts of
1335 one or more of the exempt quantity provided the sum of the fractions shall not
1336 exceed unity.

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- 1337 (2) — Each exempt quantity shall be separately and individually packaged. No more
1338 than 10 such packaged exempt quantities shall be contained in any outer
1339 package for transfer to persons exempt pursuant to 3.3.2. The outer package
1340 shall be such that the dose rate at the external surface of the package does not
1341 exceed 5 microsievert (0.5 millirem) per hour.
- 1342 (3) — The immediate container of each quantity or separately packaged fractional
1343 quantity of radioactive material shall bear a durable, legible label which:
- 1344 (a) — Identifies the radionuclide and the quantity of radioactivity; and
- 1345 (b) — Bears the words "Radioactive Material".
- 1346 (4) — In addition to the labeling information required by 3.12.2.2(3), the label affixed to
1347 the immediate container, or an accompanying brochure, shall:
- 1348 (a) — State that the contents are exempt from Licensing State requirements;
- 1349 (b) — Bear the words "Radioactive Material-Not for Human Use-Introduction
1350 into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into
1351 Products Manufactured for Commercial Distribution is Prohibited-Exempt
1352 Quantities Should Not Be Combined"; and
- 1353 (c) — Set forth appropriate additional radiation safety precautions and
1354 instructions relating to the handling, use, storage, and disposal of the
1355 radioactive material.
- 1356 3.12.2.3 Each person licensed under 3.12.2 shall maintain records identifying, by name
1357 and address, each person to whom radioactive material is transferred for use under 3.3.2
1358 or the equivalent regulations of a Licensing State, and stating the kinds and quantities of
1359 radioactive material transferred. An annual summary report stating the total quantity of
1360 each radionuclide transferred under the specific license shall be filed with the
1361 Department. Each report shall cover the year ending June 30, and shall be filed within 30
1362 days thereafter. If no transfers of radioactive material have been made pursuant to 3.12.2
1363 during the reporting period, the report shall so indicate.
- 1364 3.12.3 Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material
1365 into Gas and Aerosol Detectors. **RESERVED.**
- 1366 An application for a specific license authorizing the incorporation of NARM into gas and aerosol
1367 detectors to be distributed to persons exempt under 3.3.3.3 will be approved if the application
1368 satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32
1369 (January 1, 2004). The maximum quantity of radium-226 in each device shall not exceed 3.7 kBq
1370 (0.1 μ Ci).

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- 1371 3.12.4 Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under
1372 3.6.4.
- 1373 3.12.4.1 An application for a specific license to manufacture or distribute devices
1374 containing radioactive material, excluding special nuclear material, to persons generally
1375 licensed under 3.6.4 or equivalent regulations of the U.S. Nuclear Regulatory
1376 Commission, **NRC OR** an Agreement State, or a Licensing State will be approved if:
- 1377 (1) The applicant satisfies the general requirements of 3.9;
- 1378 (2) The applicant submits sufficient information relating to the design, manufacture,
1379 prototype testing, quality control, labels, proposed uses, installation, servicing,
1380 leak testing, operating and safety instructions, and potential hazards of the
1381 device to provide reasonable assurance that:
- 1382 (a) The device can be safely operated by persons not having training in
1383 radiological protection;
- 1384 (b) Under ordinary conditions of handling, storage, and use of the device,
1385 the radioactive material contained in the device will not be released or
1386 inadvertently removed from the device, and it is unlikely that any person
1387 will receive in any period of 1 calendar quarter a dose in excess of
1388 10 percent of the limits specified in 4.6.1; and
- 1389 (c) Under accident conditions such as fire and explosion associated with
1390 handling, storage, and use of the device, it is unlikely that any person
1391 would receive an external radiation dose or dose commitment in excess
1392 of the following organ doses:
- 1393 (i) Whole body; head and trunk; active blood-forming organs;
1394 gonads; or lens of eye: 150 mSv (15 rem)
- 1395 (ii) Hands and forearms; feet and ankles; localized areas of skin
1396 averaged over areas no larger than 1 square centimeter: 2 Sv
1397 (200 rem)
- 1398 (iii) Other organs: 500 mSv (50 rem); and
- 1399 (3) Each device bears a durable, legible, clearly visible label or labels approved by
1400 the Department, which contain in a clearly identified and separate statement:
- 1401 (a) Instructions and precautions necessary to assure safe installation,
1402 operation, and servicing of the device; documents such as operating and
1403 service manuals may be identified in the label and used to provide this
1404 information;
- 1405 (b) The requirement, or lack of requirement, for leak testing, or for testing
1406 any "on-off" mechanism and indicator, including the maximum time
1407 interval for such testing, and the identification of radioactive material by
1408 isotope, quantity of radioactivity, and date of determination of the
1409 quantity; and
- 1410 (c) The information called for in one of the following statements, as
1411 appropriate, in the same or substantially similar form:

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1412 (i) The receipt, possession, use, and transfer of this device,
1413 Model ____, Serial No. ____⁹, are subject to a general license or
1414 the equivalent and the regulations of the U.S. Nuclear
1415 Regulatory Commission or an **AGREEMENT** State with which
1416 ~~the U.S. Nuclear Regulatory Commission has entered into an~~
1417 ~~agreement for the exercise of regulatory authority.~~ This label
1418 shall be maintained on the device in a legible condition. Removal
1419 of this label is prohibited.

1420 CAUTION - RADIOACTIVE MATERIAL

1421 _____
1422 Name of manufacturer or distributor

1423 ⁹ The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided
1424 the information is elsewhere specified in labeling affixed to the device.

1425 (ii) The receipt, possession, use, and transfer of this device,
1426 Model ____, Serial No. ____¹⁰, are subject to a general license or
1427 the equivalent, and the **RADIATION** regulations of a Licensing
1428 State. This label shall be maintained on the device in a legible
1429 condition. Removal of this label is prohibited.

1430 CAUTION - RADIOACTIVE MATERIAL

1431 _____
1432 Name of manufacturer or distributor

1433 ¹⁰ The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided
1434 the information is elsewhere specified in labeling affixed to the device.

1435 (4) Each device having a separable source housing that provides the primary
1436 shielding for the source also bears, on the source housing, a durable label containing the
1437 device model number and serial number, the isotope and quantity, the words, "Caution-
1438 Radioactive Material," the radiation symbol prescribed in 4.27 and the name of the
1439 manufacturer or initial distributor.

1440 3.12.4.2 In the event the applicant desires that the device be required to be tested at
1441 intervals longer than 6 months, either for proper operation of the "on-off" mechanism and
1442 indicator, if any, or for leakage of radioactive material or for both, the applicant shall
1443 include in the application sufficient information to demonstrate that such longer interval is
1444 justified by performance characteristics of the device or similar devices and by design
1445 features which have a significant bearing on the probability or consequences of leakage
1446 of radioactive material from the device or failure of the "on-off" mechanism and indicator.

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1447 **3.12.4.3** In determining the acceptable interval for the test for leakage of radioactive
1448 material, the Department will consider information which includes, but is not limited to:

- 1449 (1) Primary containment or source capsule;
- 1450 (2) Protection of primary containment;
- 1451 (3) Method of sealing containment;
- 1452 (4) Containment construction materials;
- 1453 (5) Form of contained radioactive material;
- 1454 (6) Maximum temperature withstood during prototype tests;
- 1455 (7) Maximum pressure withstood during prototype tests;
- 1456 (8) Maximum quantity of contained radioactive material;
- 1457 (9) Radiotoxicity of contained radioactive material; and
- 1458 (10) Operating experience with identical devices or similarly designed and
1459 constructed devices.

1460 **3.12.4.34** In the event the applicant desires that the general licensee under 3.6.4, or under
1461 equivalent regulations of the U.S. Nuclear Regulatory Commission, **NRC OR** an
1462 Agreement State, ~~or a Licensing State~~ be authorized to install the device, collect the
1463 sample to be analyzed by a specific licensee for leakage of radioactive material, service
1464 the device, test the "on-off" mechanism and indicator, or remove the device from
1465 installation, the applicant shall include in the application written instructions to be followed
1466 by the general licensee, estimated calendar quarter doses associated with such activity
1467 or activities, and bases for such estimates.

- 1468 (1) The submitted information shall demonstrate that performance of such activity or
1469 activities by an individual untrained in radiological protection, in addition to other
1470 handling, storage, and use of devices under the general license, is unlikely to
1471 cause that individual to receive a calendar quarter dose in excess of 10 percent
1472 of the limits specified in 4.6.1.

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- 1473 3.12.4.45 Each person licensed under 3.12.4 to distribute devices to generally licensed
1474 persons shall:
- 1475 (1) Before a device is transferred, furnish information specified in this paragraph to
1476 each person to whom a device is to be transferred, or in the case of a transfer
1477 through an intermediate person, to the intended user prior to initial transfer to the
1478 intermediate person, including:
- 1479 (a) A copy of the general license contained in 3.6.4 and a copy of the
1480 general license contained in the U.S. Nuclear Regulatory Commission's, **NRC**
1481 **OR** Agreement State's, Or Licensing State's regulation equivalent to 3.6.4;
- 1482 (i) ~~If a copy of the general license in 3.6.4 is furnished to such a~~
1483 ~~person as an alternative to that of the U.S. Nuclear Regulatory~~
1484 ~~Commission, Agreement State, or Licensing State, it shall be~~
1485 ~~accompanied by a note explaining that the use of the device is~~
1486 ~~regulated at transferee, and intermediate, locations by the U.S.~~
1487 ~~Nuclear Regulatory Commission, Agreement State, or Licensing~~
1488 ~~State under requirements substantially the same as those in~~
1489 ~~3.6.4;~~
- 1490 (b) A copy of sections 3.6 and 4.40 through 4.52;
- 1491 (c) A list of the services that can only be performed by a specific licensee;
- 1492 (d) Information on acceptable disposal options including estimated costs of
1493 disposal;
- 1494 (e) ~~, with a~~ An indication that federal policy is to issue high civil penalties for
1495 improper disposal; and
- 1496 (ef) The name or title, address, and phone number of the contact at the
1497 transferee's **NRC OR** Agreement State, ~~Licensing State,~~ or U.S. Nuclear
1498 ~~Regulatory Commission~~ location.
- 1499 (2) Report to the Department all transfers of such devices to persons for use under
1500 the general license in 3.6.4 and all receipts of such devices.
- 1501 (a) Such a report to the Department shall include:
- 1502 (i) The identity of each general licensee by name and mailing
1503 address for the location of use; if there is no mailing address for
1504 the location of use, an alternate address for the general licensee
1505 shall be submitted along with information on the actual location
1506 of use;
- 1507 (ii) The name, title, and phone number of the person identified by
1508 the general licensee as having knowledge of and authority to
1509 take required actions to ensure compliance with the appropriate
1510 regulations and requirements;
- 1511 (iii) The date of transfer;
- 1512 (iv) The type, model number, and serial number of the device
1513 transferred; and

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- 1514 (v) The quantity and type of radioactive material contained in the
1515 device.
- 1516 (b) If one or more intermediate persons will temporarily possess the device
1517 at the intended place of use before its possession by the user, the report
1518 must include the same information for both the intended user and each
1519 intermediate person, and clearly designate the intermediate person(s).
- 1520 (c) For devices received from a 3.6.4 general licensee, the report must
1521 include the identity of the general licensee by name and address, the
1522 type, model number, and serial number of the device received, the date
1523 of receipt, and, in the case of devices not initially transferred by the
1524 reporting licensee, the name of the manufacturer or initial transferor.
- 1525 (d) If the licensee makes changes to a device possessed by a 3.6.4 general
1526 licensee, such that the label must be changed to update required
1527 information, the report must identify the general licensee, the device, and
1528 the changes to information on the device label.
- 1529 (e) The report must cover each calendar quarter, must be filed within 30
1530 days of the end of the calendar quarter, and must clearly indicate the
1531 period covered by the report.
- 1532 (f) The report must clearly identify the specific licensee submitting the report
1533 and include the license number of the specific licensee.
- 1534 (g) If no transfers have been made to or from persons generally licensed
1535 under 3.6.4 during the reporting period, the report must so indicate.
- 1536 (3) Furnish clear and legible reports to other agencies, containing all of the data
1537 required by Form 653, "Transfers of Industrial Devices Report", including:
- 1538 (a) Report the information specified in 3.12.4.45(2) to the U.S. Nuclear
1539 Regulatory Commission **NRC** for all transfers of such devices to persons
1540 for use under the U.S. Nuclear Regulatory Commission **NRC** general
1541 license in Section 31.5 of 10 CFR Part 31 (January 1, 20104).
- 1542 (b) Report the information specified in 3.12.4.-45 (2) to the responsible State
1543 agency for all transfers of devices manufactured and distributed pursuant
1544 to 3.12.4 for use under a general license in that State's regulations
1545 equivalent to 3.6.4.
- 1546 (4) Maintain all information concerning transfers and receipts of devices that
1547 supports the reports required by this section for a period of 3 years following the
1548 date of the recorded event.

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- 1549 3.12.5 Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for
1550 Use in Aircraft.
- 1551 3.12.5.1 An application for a specific license to manufacture, assemble, or repair luminous
1552 safety devices containing tritium or promethium-147 for use in aircraft, for distribution to
1553 persons generally licensed under 3.6.5 will be approved if:
- 1554 ~~3.12.5.(1)~~ The applicant satisfies the general requirements specified in 3.9;and
- 1555 ~~3.12.5.(2)~~ The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55,
1556 32.56, and 32.101 of 10 CFR Part 32 (January 1, 20104), or their equivalent.
- 1557 3.12.6 Special Requirements for License to Manufacture Calibration Sources Containing
1558 Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under
1559 3.6.7.
- 1560 3.12.6.1 An application for a specific license to manufacture calibration and reference
1561 sources containing americium-241, plutonium or radium-226 to persons generally
1562 licensed under 3.6.7 will be approved if:
- 1563 ~~3.12.6.(1)~~ The applicant satisfies the general requirement of 3.9; and
- 1564 ~~3.12.6.(2)~~ The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59,
1565 and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 (January 1,
1566 20104) or their equivalent.
- 1567 3.12.7 Reserved.
- 1568 3.12.8 Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory
1569 Testing Under General License.
- 1570 3.12.8.1 An application for a specific license to manufacture or distribute radioactive material for
1571 use under the general license of 3.6.9 will be approved if:
- 1572 ~~3.12.8.(1)~~ The applicant satisfies the general requirements specified in 3.9.
- 1573 ~~3.12.8.(2)~~ The radioactive material is to be prepared for distribution in prepackaged
1574 units of:
- 1575 (1a) Carbon-14 in units not exceeding 370 kBq (10 µCi) each.
- 1576 (2b) Cobalt-57 in units not exceeding 370 kBq (10 µCi) each.
- 1577 (3c) Hydrogen-3 (tritium) in units not exceeding 1.85 MBq (50 µCi) each.
- 1578 (4d) Iodine-125 in units not exceeding 370 kBq (10 µCi) each.
- 1579 (5e) Mock Iodine-125 in units not exceeding 1.85 kBq (0.05 µCi) of iodine-129
1580 and 185 kBq (0.005 µCi) of americium-241 each.
- 1581 (6f) Iodine-131 in units not exceeding 370 kBq (10 µCi) each.
- 1582 (7g) Iron-59 in units not exceeding 740 kBq (20 µCi) each.
- 1583 (8h) Selenium-75 in units not exceeding 370 kBq (10 µCi) each.

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- 1584 3-12.8-(3) Each prepackaged unit bears a durable, clearly visible label:
- 1585 (1a) Identifying the radioactive contents as to chemical form and radionuclide,
1586 and indicating that the amount of radioactivity does not exceed 370 kBq
1587 (10 µCi) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75;
1588 1.85 MBq (50 µCi) of hydrogen-3 (tritium); 740 kBq (20 µCi) of iron-59; or
1589 Mock Iodine-125 in units not exceeding 1.85 kBq (0.05 µCi) of iodine-129
1590 and 185 Bq (0.005 µCi) of americium-241 each; and
- 1591 (2b) Displaying the radiation caution symbol described in 4.27.1 and the
1592 words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or
1593 External Use in Humans or Animals".
- 1594 3-12.8-(4) One of the following statements, as appropriate, or a substantially similar
1595 statement which contains the information called for in one of the following
1596 statements, appears on a label affixed to each prepackaged unit or appears in a
1597 leaflet or brochure which accompanies the package:
- 1598 (1a) This radioactive material may be received, acquired, possessed, and
1599 used only by physicians, veterinarians, clinical laboratories or hospitals
1600 and only for *in vitro* clinical or laboratory tests not involving internal or
1601 external administration of the material, or the radiation therefrom, to
1602 human beings or animals. Its receipt, acquisition, possession, use, and
1603 transfer are subject to the regulations and a general license of the U.S.
1604 Nuclear Regulatory Commission NRC or of a **AGREEMENT** State with
1605 which the Commission has entered into an agreement for the exercise of
1606 regulatory authority. _____
1607 Name of manufacturer
- 1608 (2) ~~This radioactive material may be received, acquired, possessed, and~~
1609 ~~used only by physicians, veterinarians, clinical laboratories or hospitals~~
1610 ~~and only for *in vitro* clinical or laboratory tests not involving internal or~~
1611 ~~external administration of the material, or the radiation therefrom, to~~
1612 ~~human beings or animals. Its receipt, acquisition, possession, use, and~~
1613 ~~transfer are subject to the regulations and a general license of a~~
1614 ~~Licensing State.~~ _____
1615 Name of manufacturer
- 1616 3-12.8-(5) The label affixed to the unit, or the leaflet or brochure which
1617 accompanies the package, contains adequate information as to the precautions
1618 to be observed in handling and storing such radioactive material. In the case of
1619 the Mock Iodine-125 reference or calibration source, the information
1620 accompanying the source must also contain directions to the licensee regarding
1621 the waste disposal requirements set out in 4.33.
- 1622 3.12.9 Licensing the Manufacture and Distribution of Ice Detection Devices.
- 1623 3.12.9.1 An application for a specific license to manufacture and distribute ice detection
1624 devices to persons generally licensed under 3.6.10 will be approved if:
- 1625 3-12.9-(1) The applicant satisfies the general requirements of 3.9; and
- 1626 3.12.9-(2) The criteria of Sections 32.61, 32.62, and 32.103 of 10 CFR Part 32
1627 (January 1, 20104) are met.

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- 1628 3.12.10 Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs for
1629 Medical Use.
- 1630 3.12.10.1 An application for a specific license to manufacture, prepare, or transfer for
1631 commercial distribution radioactive drugs for medical use will be approved if:
- 1632 (1) The applicant satisfies the general requirements specified in 3.9 of this part;
- 1633 (2) The applicant submits evidence that the applicant is at least one of the following:
- 1634 (a) Registered or licensed with the U.S. Food and Drug Administration
1635 (FDA) as a drug manufacturer;
- 1636 (b) Registered or licensed with the State Board of Pharmacy as a drug
1637 manufacturer;
- 1638 (c) Licensed as a pharmacy by the State Board of Pharmacy;
- 1639 (3) The applicant submits information on the radionuclide, chemical and physical
1640 form, packaging including maximum activity per package, and shielding provided
1641 by the packaging of the radioactive material which is appropriate for safe
1642 handling and storage of radioactive drugs by medical use licensees; and
- 1643 (4) The applicant has procedures to assure the following labeling requirements:
- 1644 (a) A label shall be affixed to each transport radiation shield (whether it is
1645 constructed of lead, glass, plastic, or other material) of a radioactive drug
1646 to be transferred for commercial distribution.
- 1647 (i) The label ~~must~~ **SHALL** include the radiation symbol prescribed
1648 in 4.27 and the words "CAUTION, RADIOACTIVE MATERIAL" or
1649 "DANGER, RADIOACTIVE MATERIAL"; the name of the
1650 radioactive drug or its abbreviation; and the quantity of
1651 radioactivity at a specified date and time.
- 1652 (ii) For radioactive drugs with a half-life greater than 100 days, the
1653 time may be omitted.
- 1654 (b) A label shall be affixed to each syringe, vial, or other container used to
1655 hold a radioactive drug to be transferred for commercial distribution. ~~The~~
1656 ~~label must~~ **AND SHALL** include:
- 1657 (i) ~~†~~The radiation symbol prescribed in 4.27 and the words
1658 "CAUTION, RADIOACTIVE MATERIAL" or "DANGER,
1659 RADIOACTIVE MATERIAL"; and
- 1660 (ii) ~~a~~An identifier that ensures that the syringe, vial or other
1661 container can be correlated with the information on the transport
1662 radiation shield label.
- 1663 3.12.10.2 A radioactive materials licensee who is also licensed by the State Board of
1664 Pharmacy:
- 1665 (1) May prepare radioactive drugs for medical use, as defined in 1.42 **AND PART 7**,
1666 provided that the radioactive drug is prepared by either:

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- (a) ~~a~~An authorized nuclear pharmacist, as specified in 3.12.10.2(2) of this section, or
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- (b) ~~a~~An individual under the direct supervision of an authorized nuclear pharmacist as specified in 7.10;
- 1671
- (2) May allow a pharmacist to work as an authorized nuclear pharmacist if:
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1673
- (a) ~~This individual qualifies as an authorized nuclear pharmacist as defined in 1.4;~~
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- (b) ~~—~~This individual meets the **PART 7, APPENDIX 7C**, requirements **FOR AN AUTHORIZED NUCLEAR PHARMACIST**; specified in 7.74, 7.76, and 7.78 and
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- (b) ~~t~~The licensee has received an approved **DEPARTMENT** license amendment identifying this individual as an authorized nuclear pharmacist; ~~or~~
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- (c) ~~—~~This individual is identified on July 1, 1998 as an "authorized user" on a nuclear pharmacy license issued by the Department under this part, or by the NRC, an Agreement State or a Licensing State under regulations similar to this part.
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- (3) Shall, within 30 days after the date the licensee allows an individual to work as an authorized nuclear pharmacist pursuant to 3.12.10.2(2), ~~(a) and 3.12.10.2(2)(c)~~ provide to the Department **DOCUMENTATION OF AUTHORIZATION**:
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- (a) A copy of each individual's certification by the Board of Pharmaceutical Specialties; or
- 1690
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- (bi) The Department, ~~the~~ NRC or Agreement State license **THAT ALLOWS SUCH WORK**; or
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1693
- (ii) ~~t~~The permit issued by a licensee of broad scope **THAT ALLOWS SUCH WORK**; and
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- (eb) A copy of **RADIOACTIVE MATERIAL LICENSEE'S** State Ppharmacy licensure or registration.

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- 1696 3.12.10.3 A licensee shall possess and use instrumentation to measure the radioactivity of
1697 radioactive drugs.
- 1698 (1) The licensee shall have procedures for use of the instrumentation.
- 1699 (2) The licensee shall measure, by direct measurement or by combination of
1700 measurements and calculations, the amount of radioactivity in dosages of alpha-,
1701 beta- or photon-emitting radioactive drugs prior to transfer for commercial
1702 distribution.
- 1703 (3) In addition, the licensee shall:
- 1704 (4a) Perform tests before initial use, periodically, and following repair, on
1705 each instrument for accuracy, linearity and geometry dependence, as
1706 appropriate for the use of the instrument; and make adjustments when
1707 necessary; and
- 1708 (2b) Check each instrument for constancy and proper operation at the
1709 beginning of each day of use.
- 1710 3.12.10.4 Nothing in this section relieves the licensee from complying with applicable FDA,
1711 Federal, and state requirements governing radioactive drugs.
- 1712 3.12.11 Reserved.
- 1713 3.12.12 Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical
1714 Use.
- 1715 **3.12.12.1** An application for a specific license to manufacture and distribute sources and
1716 devices containing radioactive material to persons licensed pursuant to Part 7 for use as
1717 a calibration or reference source or for the uses listed in **7.19, 7.40, and 7.42, 7.48 AND**
1718 **7.62 will** be approved if:
- 1719 ~~3.12.12.(1)~~ The applicant satisfies the general requirements in 3.9 of this part;
- 1720 ~~3.12.12.(2)~~ The applicant submits sufficient information regarding each type of
1721 source or device pertinent to an evaluation of its radiation safety, including:
- 1722 (4a) The radioactive material contained, its chemical and physical form, and
1723 amount,
- 1724 (2b) Details of design and construction of the source or device,
- 1725 (3c) Procedures for, and results of, prototype tests to demonstrate that the
1726 source or device will maintain its integrity under stresses likely to be
1727 encountered in normal use and accidents,
- 1728 (4d) For devices containing radioactive material, the radiation profile of a
1729 prototype device,
- 1730 (5e) Details of quality control procedures to assure that production sources
1731 and devices meet the standards of the design and prototype tests,
- 1732 (6f) Procedures and standards for calibrating sources and devices,

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- 1733 (7g) Legend and methods for labeling sources and devices as to their
1734 radioactive content, and
- 1735 (8h) Instructions for handling and storing the source or device from the
1736 radiation safety standpoint; these instructions are to be included on a
1737 durable label attached to the source or device or attached to a
1738 permanent storage container for the source or device; provided, that
1739 instructions which are too lengthy for such label may be summarized on
1740 the label and printed in detail on a brochure which is referenced on the
1741 label;
- 1742 ~~3.12.12.(3)~~ The label affixed to the source or device, or to the permanent storage
1743 container for the source or device, contains information on the radionuclide,
1744 quantity, and date of assay, and a statement that the source or device is licensed
1745 by the Department for distribution to persons licensed pursuant to 7.40 and 7.42
1746 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, NRC
1747 OR an Agreement State, or a Licensing State, provided that such labeling for
1748 sources which do not require long term storage may be on a leaflet or brochure
1749 which accompanies the source;
- 1750 3.12.12.42 In the event the applicant desires that the source or device be required to be
1751 tested for leakage of radioactive material at intervals longer than 6 months, the applicant
1752 shall include in the application sufficient information to demonstrate that such longer
1753 interval is justified by performance characteristics of the source or device or similar
1754 sources or devices and by design features that have a significant bearing on the
1755 probability or consequences of leakage of radioactive material from the source; and
- 1756 3.12.12.53 In determining the acceptable interval for test of leakage of radioactive material,
1757 the Department will consider information that includes, but is not limited to:
- 1758 (1) Primary containment or source capsule,
1759 (2) Protection of primary containment,
1760 (3) Method of sealing containment,
1761 (4) Containment construction materials,
1762 (5) Form of contained radioactive material,
1763 (6) Maximum temperature withstood during prototype tests,
1764 (7) Maximum pressure withstood during prototype tests,
1765 (8) Maximum quantity of contained radioactive material,
1766 (9) Radiotoxicity of contained radioactive material, and
1767 (10) Operating experience with identical sources or devices or similarly designed and
1768 constructed sources or devices.

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- 1769 3.12.13 Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted
1770 Uranium for Mass-Volume Applications.
- 1771 3.12.13.1 An application for a specific license to manufacture industrial products and
1772 devices containing depleted uranium for use pursuant to 3.5.5 or equivalent regulations
1773 of the U.S. Nuclear Regulatory Commission ~~NRC~~ or an Agreement State will be
1774 approved if:
- 1775 (1) The applicant satisfies the general requirements specified in 3.9;
- 1776 (2) The applicant submits sufficient information relating to the design, manufacture,
1777 prototype testing, quality control procedures, labeling or marking, proposed uses,
1778 and potential hazards of the industrial product or device to provide reasonable
1779 assurance that possession, use, or transfer of the depleted uranium in the
1780 product or device is not likely to cause any individual to receive in any period of 1
1781 calendar quarter a radiation dose in excess of 10 percent of the limits specified in
1782 4.6.1; and
- 1783 (3) The applicant submits sufficient information regarding the industrial product or
1784 device and the presence of depleted uranium for a mass-volume application in
1785 the product or device to provide reasonable assurance that unique benefits will
1786 accrue to the public because of the usefulness of the product or device.
- 1787 3.12.13.2 In the case of an industrial product or device whose unique benefits are
1788 questionable, the Department will approve an application for a specific license under
1789 3.12.13 only if the product or device is found to combine a high degree of utility and low
1790 probability of uncontrolled disposal and dispersal of significant quantities of depleted
1791 uranium into the environment.
- 1792 3.12.13.3 The Department may deny any application for a specific license under 3.12.13 if
1793 the end use(s) of the industrial product or device cannot be reasonably foreseen.
- 1794 3.12.13.4 Each person licensed pursuant to 3.12.13.1 shall:
- 1795 (1) Maintain the level of quality control required by the license in the manufacture of
1796 the industrial product or device, and in the installation of the depleted uranium
1797 into the product or device;
- 1798 (2) Label or mark each unit to:
- 1799 (a) Identify the manufacturer of the product or device and the number of the
1800 license under which the product or device was manufactured, the fact
1801 that the product or device contains depleted uranium, and the quantity of
1802 depleted uranium in each product or device; and
- 1803 (b) State that the receipt, possession, use, and transfer of the product or
1804 device are subject to a general license or the equivalent and the
1805 regulations of the U.S. Nuclear Regulatory Commission ~~NRC~~ or an
1806 Agreement State;
- 1807 (3) Assure that the depleted uranium before being installed in each product or device
1808 has been impressed with the following legend clearly legible through any plating
1809 or other covering: "Depleted Uranium";

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- 1810 (4) Furnish a copy of the general license:
- 1811 (a) Contained in 3.5.5 and a copy of Department Form R-52 to each person
1812 to whom the specific licensee transfers depleted uranium in a product or
1813 device for use pursuant to the general license contained in 3.5.5, or
- 1814 (b) Contained in ~~the U.S. Nuclear Regulatory Commission's~~ **AN NRC** or
1815 Agreement State's regulation equivalent to 3.5.5 and a copy of ~~the U.S.~~
1816 ~~Nuclear Regulatory Commission's~~ **AN NRC** or Agreement State's
1817 certificate, or alternatively, furnish a copy of the general license
1818 contained in 3.5.5 and a copy of Department Form R-52 to each person
1819 to whom the specific licensee transfers depleted uranium in a product or
1820 device for use pursuant to the general license of ~~the U.S. Nuclear~~
1821 ~~Regulatory Commission~~ **NRC** or an Agreement State, with a note
1822 explaining that use of the product or device is regulated by ~~the U.S.~~
1823 ~~Nuclear Regulatory Commission~~ **NRC** or an Agreement State under
1824 requirements substantially the same as those in 3.5.5;
- 1825 (5) Report to the Department all transfers of industrial products or devices to
1826 persons for use under the general license in 3.5.5.
- 1827 (a) Such report shall identify each general licensee by name and address,
1828 an individual by name and/or position who may constitute a point of
1829 contact between the Department and the general licensee, the type and
1830 model number of device transferred, and the quantity of depleted
1831 uranium contained in the product or device.
- 1832 (b) The report shall be submitted within 30 days after the end of each
1833 calendar quarter in which such a product or device is transferred to the
1834 generally licensed person.
- 1835 (c) If no transfers have been made to persons generally licensed under
1836 3.5.5 during the reporting period, the report shall so indicate;
- 1837 (6) Report to ~~the U.S. Nuclear Regulatory Commission~~ **NRC** all transfers of industrial
1838 products or devices to persons for use under ~~the U.S. Nuclear Regulatory~~
1839 ~~Commission~~ **NRC** general license in Section 40.25 of 10 CFR Part 40 (January
1840 1, 20104).
- 1841 (a) Such report shall identify each general licensee by name and address,
1842 an individual by name and/or position who may constitute a point of
1843 contact between the agency and the general licensee, the type and
1844 model number of device transferred, and the quantity of depleted
1845 uranium contained in the product or device.
- 1846 (b) The report shall be submitted within 30 days after the end of each
1847 calendar quarter in which such a product or device is transferred to the
1848 generally licensed person.
- 1849 (c) If no transfers have been made to U.S. Nuclear Regulatory Commission
1850 licensees during the reporting period, this information shall be reported to
1851 ~~the U.S. Nuclear Regulatory Commission~~ **NRC**;

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- (7) Report to the responsible State agency all transfers of devices manufactured and distributed pursuant to 3.12.13 for use under a general license in that State's regulations equivalent to 3.5.5,
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- (a) Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device.
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- (b) The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person.
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- (c) If no transfers have been made general licensees within a particular agreement state during the reporting period, this information shall be reported to the responsible Agreement State agency upon the request of that agency;
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- (8) Keep records showing the name, address, and point of contact for each general licensee to whom the specific licensee transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 3.5.5 or equivalent regulations of the U.S. Nuclear Regulatory Commission-NRC or an Agreement State.
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- (a) The records shall be maintained for a period of 2 years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.
- 1876 3.12.14 Registration of Product Information.
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- 3.12.14.1 Any manufacturer or initial distributor of a sealed source, or of a device containing a sealed source, whose product is intended for use under a specific license may submit a request to the Department for evaluation of radiation safety information about the product and for the product registration.
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- 3.12.14.2 The request for review must be made in duplicate and sent to the Director, Hazardous Materials And Waste Management Division, Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive South, Denver, Colorado 80246-1530.
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- 3.12.14.3 The request for review of a sealed source or 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.

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- 1891 3.12.14.4 The Department normally evaluates a sealed source or device using radiation
1892 safety criteria in accepted industry standards.
- 1893 (1) If these standards and criteria do not readily apply to a particular case, the
1894 Department formulates reasonable standards and criteria with the help of the
1895 manufacturer or distributor.
- 1896 (2) The Department shall use criteria and standards sufficient to ensure that the
1897 radiation safety properties of the device or sealed source are adequate to protect
1898 health and minimize danger to life and property.
- 1899 3.12.14.5 After completion of the evaluation, the Department issues a certificate of
1900 registration to the person making the request. The certificate of registration
1901 acknowledges the availability of the submitted information for inclusion in an application
1902 for specific license proposing use of the product.
- 1903 3.12.14.6 The person submitting the request for evaluation and registration of safety
1904 information about the product shall manufacture and distribute the product in accordance
1905 with:
- 1906 (1) The statements and representations, including quality control program, contained
1907 in the request; and
- 1908 (2) The provisions of the certificate of registration.
- 1909 **3.13 Third-Party Method.**
- 1910 **3.13.1** If the applicant consents, the Department may enter into third party agreements for the applicant
1911 to engage and pay for the services of a third party contractor to prepare the environmental impact
1912 analysis required under 18.4 and/or to furnish an opinion of independent experts, satisfactory to
1913 the Department, in respect to the completeness and adequacy of any information or data
1914 furnished by the applicant and on any aspect of the applicant's project or effects thereof.
- 1915 ~~3.13.1 When the license applicant pays for a third party agreement, the monies paid for the consultant
1916 shall not be charged as part of the fees required under Part 12.~~
- 1917 3.13.2 In proceeding under the third party agreement, the Department shall carry out the following
1918 practices:
- 1919 3.13.2.1 Such contractor shall be chosen solely by the Department.
- 1920 3.13.2.2 The Department shall manage the contract.
- 1921 3.13.2.3 The consultant shall be selected based on the consultant's ability relevant and
1922 applicable work experience and an absence of conflict of interest. Third party contractors
1923 will be required to execute a disclosure statement signifying they have no financial or
1924 other conflicting interest in the outcome of the project.
- 1925 3.13.2.4 The Department shall specify the information to be developed and supervise the
1926 gathering, analysis and presentation of the information.
- 1927 3.13.2.5 The Department shall have sole authority for approval and modification of the
1928 statement, analysis, and conclusions included in third party's report.

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1929 **3.13.3 WHEN THE LICENSE APPLICANT PAYS FOR A THIRD PARTY AGREEMENT, THE MONIES**
1930 **PAID FOR THE CONSULTANT SHALL NOT BE CHARGED AS PART OF THE FEES**
1931 **REQUIRED UNDER PART 12.**

1932 **3.14 Issuance of A Specific Licenses.**

1933 3.14.1 Upon a determination that an application meets the requirements of the Act and the regulations of
1934 the Department, the Department will issue a specific license authorizing the proposed activity in
1935 such form and containing such conditions and limitations as it deems appropriate or necessary.

1936 3.14.2 The Department may incorporate in any license at the time of issuance, or thereafter by
1937 appropriate rule, regulation, or order, such additional requirements and conditions with respect to
1938 the licensee's receipt, possession, use, and transfer of radioactive material subject to this part, as
1939 it deems appropriate or necessary in order to:

1940 3.14.2.1 Minimize danger to public health and safety or property;

1941 3.14.2.2 Require such reports and the keeping of such records, and to provide for such
1942 inspections of activities under the license as may be appropriate or necessary; and

1943 3.14.2.3 Prevent loss or theft of material subject to this part.

1944 3.14.3 Whenever the Department denies an application for a new license or a license renewal, the
1945 Department will notify the applicant in writing stating the grounds for denial

1946 **3.14.3.1** Upon denial, the applicant may request a hearing pursuant to Sections 24-4-104
1947 and 24-4-105, CRS.

1948 **3.15 Specific Terms and Conditions of License.**

1949 3.15.1 Each license issued pursuant to this part shall be subject to all the provisions of the Act, now or
1950 hereafter in effect, and to all rules, regulations, and orders of the Department.

1951 3.15.2 No license issued or granted under this part and no right to possess or utilize radioactive material
1952 granted by any license issued pursuant to this part shall be transferred, assigned, or in any
1953 manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of
1954 control of any license to any person unless the Department shall, after securing full information,
1955 find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect,
1956 and to all valid rules, regulations, and orders of the Department, and shall give its consent in
1957 writing.

1958 3.15.3 Each person licensed by the Department pursuant to this part shall confine use and possession
1959 of the material licensed to the locations and purposes authorized in the license.

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- 1960 3.15.4 Notice and Disposition of Records Prior to License Termination.
- 1961 3.15.4.1 Each licensee shall notify the Department in writing when the licensee decides to
1962 permanently discontinue all activities involving materials authorized under the license.
- 1963 3.15.4.12 Prior to license termination, each licensee authorized to possess radioactive
1964 material with a half-life greater than 120 days, in an unsealed form, shall forward the
1965 following records to the Department.
- 1966 (1) Records of disposal required by 4.48; and
- 1967 (2) Records of surveys required by 4.42.
- 1968 3.15.4.23 If licensed activities are transferred or assigned in accordance with 3.15.2, each
1969 licensee authorized to possess radioactive material, with a half-life greater than 120 days,
1970 in an unsealed form, shall transfer the records required in 3.15.4.12 to the new licensee
1971 and the new licensee will be responsible for maintaining these records until the license is
1972 terminated.
- 1973 3.15.4.34 Prior to license termination, each licensee shall forward the records required by
1974 3.16.5 to the Department.
- 1975 3.15.5 Bankruptcy.
- 1976 3.15.5.1 Each specific licensee and each general license that is required to register by
1977 3.6.4.3 of this part shall notify the Department in writing immediately following the filing of
1978 a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11
1979 (Bankruptcy) of the United States Code by or against:
- 1980 (1) The licensee;
- 1981 (2) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or
1982 listing the license or licensee as property of the estate; or
- 1983 (3) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.
- 1984 3.15.5.2 The notification specified in 3.15.5.1 shall include the bankruptcy court in which
1985 the petition for bankruptcy was filed and the date of the filing of the petition.
- 1986 **3.16 Expiration, Decommissioning and Termination of Licenses.**
- 1987 3.16.1 Definition of "principal activity".:
- 1988 **3.16.1.1** As used in this regulation, "principal activity" means an activity authorized by the
1989 license which is essential to achieving the purpose(s) for which the license was issued or
1990 amended.
- 1991 **3.16.1.2** Not included as principal activities are:
- 1992 (1) ~~Radioactive material storage while no licensed material is accessed for use or~~
1993 disposal; and
- 1994 (2) **ANY** activity incidental to decontamination or decommissioning.

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1995 3.16.2 Expiration.

1996 3.16.2.1 Except as provided in 3.17.2, each specific license shall expire at the end of the
1997 specified day in the month and year stated therein.

1998 3.16.2.2 Each specific license revoked by the Department expires at the end of the day on
1999 the date of final determination to revoke the license, or on the expiration date stated in
2000 the determination, or as otherwise provided by order.

2001 3.16.2.3 With respect to possession of radioactive material and residual radioactive
2002 contamination, each specific license continues in effect beyond the expiration date until
2003 the Department notifies the licensee in writing that the license is terminated, even if:

- 2004 (1) The licensee decides not to renew the license;
- 2005 (2) No application for license renewal is submitted;
- 2006 (3) An application for renewal is denied; or
- 2007 (4) The Department modifies or suspends a license.

2008 3.16.2.4 No less than 30 days before the expiration date specified in the license, the
2009 licensee shall either:

- 2010 (1) Submit an application for license renewal under 3.17; or
- 2011 (2) Notify the Department, in writing, that the licensee has decided not to renew the
2012 license.

2013 3.16.2.5 If a licensee does not submit an application for license renewal under 3.17, the
2014 licensee shall, on or before the expiration date specified in the license:

- 2015 (1) Terminate use of radioactive material;
- 2016 (2) Transfer radioactive materials to an authorized recipient and/or properly dispose
2017 of radioactive material;
- 2018 (3) Reduce residual radioactive contamination to levels which are as low as
2019 reasonably achievable (ALARA); and
- 2020 (4) Submit a completed Department Form R-23, *Request for Termination of a*
2021 *Radioactive Materials License*, or equivalent information requesting license
2022 termination, including survey results, leak tests, disposal records, and/or other
2023 documentation which demonstrates acceptable conditions for license termination
2024 as specified in 3.16.6.

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- 3.16.2.6 Each licensee who possesses radioactive material, including residual radioactive material attributable to licensed activities, following the expiration date specified in the license shall:
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- (1) Limit actions involving radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and
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- (2) Continue to control entry to restricted areas until they are suitable for release for unrestricted use or the Department notifies the licensee in writing that the license is terminated.
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- 3.16.2.7 Each licensee or person responsible for a facility or site which includes a non-exempt source of radiation or which may be contaminated by residual radioactivity shall, no less than 30 days before vacating or relinquishing possession or control of the facility or site, notify the agency, in writing, of the intent to vacate.
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- 3.16.3 Timely Decommissioning.
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- 3.16.3.1 Each licensee or person in possession of a non-exempt source of radiation who decides to terminate all activities involving that source of radiation shall notify the hazardous materials and waste management division immediately, in writing.
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- 3.16.3.2 The licensee shall notify the Hazardous Materials And Waste Management Division in writing within 60 days of the occurrence of any of the following:
- 2043
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- (1) 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 unrestricted use in accordance with 4.61; or
- 2047
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- (2) No principal activities under the license have been conducted for a period of 24 months; or
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- (3) 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 unrestricted use in accordance with these regulations.
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- 3.16.3.3 Concurrent with the notification of the Hazardous Materials And Waste Management Division required in 3.16.3.1 and 3.16.3.2, the licensee shall either:
- 2055
- (1) Begin decommissioning activities; or,
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- (2) Within 12 months of notification, submit a decommissioning plan if required by 3.16.4, and begin decommissioning upon approval of that plan.
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- 3.16.3.4 Licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning, unless an alternate schedule addressing the factors in 3.16.4 is requested and approved by the Department.
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- 3.16.3.5 When decommissioning involves the entire site, the licensee shall request license termination upon completion of decommissioning activities.

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2064 3.16.3.6 The Department may approve alternate schedules for the submission of plans
2065 and for the completion of decommissioning as required pursuant to 3.16.3.3 and 3.16.3.4
2066 if the Department determines that the alternate schedule:

- 2067 (1) Is necessary to effectively conduct decommissioning;
- 2068 (2) Presents no undue risks to public health and safety; and
- 2069 (3) Is otherwise in the public interest.

2070 3.16.4 Decommissioning Plan.

2071 3.16.4.1 A licensee must submit a decommissioning plan:

- 2072 (1) If the licensee intends to terminate the license using radiological criteria specified
2073 in 4.61.3 or 4.61.4 (the exemption of 4.61.1.1 applies);
- 2074 (2) If required otherwise by these regulations;
- 2075 (3) If required by license condition; or
- 2076 (4) If the procedures and activities necessary to carry out decommissioning of the
2077 site or separate building or outdoor area have not been previously approved by
2078 the Department and these procedures could increase potential health and safety
2079 impacts to workers or to the public, such as in any of the following cases:
 - 2080 (a) Procedures would involve techniques not applied routinely during
2081 cleanup or maintenance operations;
 - 2082 (b) Workers would be entering areas not normally occupied where surface
2083 contamination and radiation levels are significantly higher than routinely
2084 encountered during operation;
 - 2085 (c) Procedures could result in significantly greater airborne concentrations of
2086 radioactive materials than are present during operation; or
 - 2087 (d) Procedures could result in significantly greater releases of radioactive
2088 material to the environment than those associated with operation.

2089 3.16.4.2 Procedures such as those listed in 3.16.4.1 of this section with potential health
2090 and safety impacts may not be carried out prior to Department approval of the
2091 decommissioning plan.

2092 3.16.4.3 The decommissioning plan for the site or separate building or outdoor area must
2093 include:

- 2094 (1) A description of the conditions of the site, separate buildings, and/or outdoor
2095 areas sufficient to evaluate the acceptability of the plan;
- 2096 (2) A description of planned decommissioning activities and a schedule for
2097 completion;
- 2098 (3) A description of methods used to ensure protection of workers and the
2099 environment against radiation hazards during decommissioning;

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- 2100 (4) A description of the planned final radiation survey;
- 2101 (5) A current detailed cost estimate for decommissioning, comparison of that
2102 estimate with present funds set aside for decommissioning, and a plan for
2103 assuring the availability of adequate funds for completion of decommissioning;
2104 and
- 2105 (6) A description of the intended final condition of the site, separate buildings, and/or
2106 outdoor areas upon completion of decommissioning activities.
- 2107 (7) Decommissioning plans proposing the use of radiological criteria specified in
2108 4.61.3 or 4.61.4, must also include:
- 2109 (a) An analysis demonstrating that reductions in residual radioactivity
2110 necessary to comply with the provisions of 4.61.2 would result in net
2111 public or environmental harm or were not being made because the
2112 residual levels of contamination associated with restricted conditions are
2113 ALARA.
- 2114 (i) Determination of dose and residual radioactivity levels which are
2115 ALARA must take into account consideration of any detriments,
2116 such as deaths from transportation accidents, expected to
2117 potentially result from decontamination and waste disposal;
- 2118 (b) A description of the institutional controls necessary to satisfy the
2119 requirements of 4.61.3.2, including a description of how the controls will
2120 be enforced and an analysis showing that the controls will not impose
2121 undue burdens on the local community or other affected parties;
- 2122 (c) An analysis demonstrating that if institutional controls were no longer in
2123 effect then the dose criteria of 4.61.3.3 will be met;
- 2124 (d) A detailed cost estimate for a long-term care warranty, and a plan for
2125 establishing a Department approved warranty prior to completion of
2126 decommissioning activities;
- 2127 (e) A description of how the licensee will seek advice from representatives of
2128 a broad cross section of community interests who may be affected by the
2129 decommissioning and how the licensee will provide participants an
2130 opportunity for a comprehensive, collective discussion on key
2131 decommissioning issues, including: the adequacy and enforceability of
2132 institutional controls, burdens/impacts to local communities and affected
2133 parties, and the adequacy of financial assurance; and
- 2134 (f) A description of how the licensee will make publicly available a summary
2135 of the results of all such discussions, including: a description of the
2136 individual viewpoints of the participants on the issues, the extent of
2137 agreement and disagreement among the participants on the issues, and
2138 a description of how key issues in disagreement will be addressed during
2139 decommissioning.

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- 2140 3.16.4.4 For decommissioning plans calling for completion of decommissioning later than
2141 24 months after plan approval, the plan shall include a justification for the
2142 decommissioning schedule which addresses the following:
- 2143 (1) Whether it is technically feasible to complete decommissioning within a 24-month
2144 period;
- 2145 (2) Whether sufficient waste disposal capacity is available to allow completion of
2146 decommissioning with a 24-month period;
- 2147 (3) Whether a significant volume reduction in wastes requiring disposal will be
2148 achieved by allowing short-lived radionuclides to decay;
- 2149 (4) Whether a significant reduction in radiation exposure to workers can be achieved
2150 by allowing short-lived radionuclides to decay; and
- 2151 (5) Other site-specific factors which the Department may consider appropriate on a
2152 case-by-case basis, such as the regulatory requirements of other government
2153 agencies, lawsuits, ground-water treatment activities, monitored natural ground-
2154 water restoration, actions that could result in more environmental harm than
2155 deferred cleanup, and other factors beyond the control of the licensee.
- 2156 3.16.4.5 Upon the receipt of a decommissioning plan or proposal by the licensee for
2157 release of a site pursuant to 4.61.3 or 4.61.4, or whenever the Department deems such
2158 notice to be in the public interest, the Department shall:
- 2159 (1) Notify and solicit comments from:
- 2160 (a) Local and state governments in the vicinity of the site and any Indian
2161 nation or other indigenous people that have treaty or statutory rights that
2162 could be affected by the decommissioning; and
- 2163 (b) The environmental protection agency for cases where the licensee
2164 proposes to release a site pursuant to 4.61.4.
- 2165 (2) Publish a notice in a forum, such as local newspapers, letters to state or local
2166 organizations, or other appropriate forum, that is readily accessible to individuals
2167 in the vicinity of the site, and solicit comments from affected parties.
- 2168 3.16.4.6 The proposed decommissioning plan will be approved by the Department if the
2169 information therein demonstrates that the decommissioning will be in accordance with the
2170 requirements of 3.9.5.10, 3.16, and 4.61 (the exemption of 4.61.1.1 applies), completed
2171 as soon as practicable, and that the health and safety of workers and the public will be
2172 adequately protected.

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2173 3.16.5 Decommissioning Record Keeping.

2174 3.16.5.1 The licensee shall keep records of information important to the decommissioning
2175 of a facility in an identified location until authorized by the Department.

2176 (1) Before licensed activities are transferred or assigned in accordance with 3.15.2,
2177 licensees shall transfer all records described in this paragraph to the new
2178 licensee.

2179 (2) In this case, the new licensee will be responsible for maintaining these records
2180 until the license is terminated. If records important to the decommissioning of a
2181 facility are kept for other purposes, reference to these records and their locations
2182 may be used.

2183 3.16.5.2 Information considered important to decommissioning includes:

2184 (1) Records of spills or other unusual occurrences involving the spread of
2185 contamination in and around the facility, equipment, or site.

2186 (a) These records may be limited to instances when contamination remains
2187 after any cleanup procedures or when there is reasonable likelihood that
2188 contaminants may have spread to inaccessible areas as in the case of
2189 possible seepage into porous materials such as concrete.

2190 (b) These records must include any known information on identification of
2191 involved nuclides, quantities, forms and concentrations.

2192 (2) As-built drawings and modifications of structures and equipment in restricted
2193 areas where radioactive materials are used and/or stored, and of locations of
2194 possible inaccessible contamination such as buried pipes which may be subject
2195 to contamination.

2196 (a) If required drawings are referenced, each relevant document needs to be
2197 indexed individually. If drawings are not available, the licensee shall
2198 substitute appropriate records of available information concerning these
2199 areas and locations.

2200 (3) A list contained in a single document and updated every 2 years -- except for
2201 areas containing only sealed sources (provided the sources have not leaked or
2202 no contamination remains after any leak), radioactive materials having only half-
2203 lives of less than 65 days, or areas containing depleted uranium used only for
2204 shielding or as penetrators in unused munitions, -- of the following:

2205 (a) All areas designated and formerly designated restricted areas as defined
2206 in 1.4;

2207 (b) All areas outside of restricted areas that require documentation under
2208 3.16.5.2(1);

2209 (c) All areas outside of restricted areas where current and previous wastes
2210 have been buried as documented under 4.48; and

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- 2211 (d) All areas outside of restricted areas which contain material such that, if
2212 the license expired, the licensee would be required to either
2213 decontaminate the area to unrestricted release levels or apply for
2214 approval for disposal under 4.34.
- 2215 (e) A list containing the location and description of all equipment to remain
2216 onsite after license termination that was contaminated when final
2217 decommissioning was initiated; and
- 2218 (f) Any other information not required by 3.16.5.3 that is considered
2219 necessary to support the adequacy of the decommissioning plan for
2220 approval.
- 2221 (4) Records of the cost estimate performed for the decommissioning funding plan or
2222 of the amount certified for decommissioning, and records of the funding method
2223 used for assuring funds if either a funding plan or certification is used.
- 2224 (5) For licenses decommissioned in accordance with the requirements of 4.61.3 or
2225 4.61.4, the licensee shall maintain documentation of public meetings held to
2226 discuss decommissioning activities.
- 2227 (a) This documentation is to include the dates and locations of the meetings,
2228 participants, topics of discussion, a description of the individual
2229 viewpoints of the participants on the issues, the extent of agreement and
2230 disagreement among the participants on the issues, and a description of
2231 how key issues in disagreement were addressed during
2232 decommissioning.
- 2233 3.16.6 Demonstrating Acceptable Conditions for License Termination.
- 2234 3.16.6.1 The Department will address comments provided by the U.S. Environmental
2235 Protection Agency and public comments submitted pursuant to 3.16.4.5 prior to the use
2236 of the alternate criteria, authorized in 4.61.4, to terminate a license.
- 2237 3.16.6.2 The licensee shall conduct a radiation survey of the licensee's site to confirm the
2238 absence of radioactive material and/or to establish levels of residual radioactive
2239 contamination, unless the licensee can demonstrate that the site is suitable for release in
2240 some other manner.
- 2241 (1) As appropriate, the licensee shall also conduct radiation surveys in any separate
2242 building or outdoor area that contains residual radioactivity resulting from the
2243 licensee's activities.
- 2244 3.16.6.3 The licensee shall submit a report of the results of this survey and/or other
2245 documentation to the Department which demonstrates compliance with the radiological
2246 criteria for license termination specified in Part 4 of the regulations.

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- 2247 3.16.6.4 The licensee's **REPORT REQUIRED BY 16.6.6.3** shall **SPECIFY**, as
2248 appropriate:
- 2249 (1) ~~Report~~ Levels of gamma radiation in units of microsievert per hour ($\mu\text{Sv/hr}$ or
2250 $\mu\text{rem/hr}$) at one meter from surfaces;
- 2251 (2) ~~Report~~ Levels of radioactive surface contamination, including alpha and beta
2252 emitting radioactive materials, in units of disintegrations per minute per 100
2253 square centimeters ($\text{dpm}/100\text{cm}^2$ or $\text{Bq}/100\text{cm}^2$), specifying levels for both
2254 removable and fixed contamination;
- 2255 (3) ~~Report~~ Levels of radioactivity in units of becquerel per liter (Bq/l or pCi/l) for
2256 water, and becquerel per gram (Bq/g or pCi/g) for solids such as soils or
2257 concrete; and
- 2258 (4) ~~Specify the survey instrument(s) used including and certify~~ **ACTION** that each
2259 instrument is properly calibrated and tested.
- 2260 3.16.7 License Termination.
- 2261 3.16.7.1 Specific licenses, including expired licenses, will be terminated by written notice
2262 to the licensee when the Department determines that:
- 2263 ~~3.16.7.(1)~~ Radioactive materials have been properly disposed and records of
2264 disposal required by 4.48 to be maintained and retained have been forwarded to
2265 the Department as required by 3.15.4.3;
- 2266 ~~3.16.7.(2)~~ The licensee has demonstrated, by radiation survey results and/or other
2267 appropriate methods, that the license termination will be in compliance with these
2268 regulations;
- 2269 ~~3.16.7.(3)~~ The licensee has established a Department approved long term care
2270 warranty, if required;
- 2271 ~~3.16.7.(4)~~ Department approved institutional controls have been implemented to
2272 limit public doses, if required; and
- 2273 ~~3.16.7.(5)~~ All records required by 3.16.5 have been transferred to the Department.
- 2274 3.16.8 Additional Cleanup.
- 2275 3.16.8.1 Except for facilities exempted under 4.61.1.1, after a site has been
2276 decommissioned and the license terminated in accordance with 3.16 and 4.61, the
2277 Department may reinstate the terminated license or issue a new license and require
2278 additional cleanup only if, based on new or previously unknown information, it determines
2279 that the criteria of 4.61 were not met and residual radioactivity remaining at the site could
2280 result in significant threat to public health and safety.
- 2281 **3.17 Renewal of Licenses.**
- 2282 3.17.1 Applications for renewal of specific licenses shall be filed in accordance with 3.8.
- 2283 3.17.2 In any case in which a licensee, not less than 30 days prior to expiration of his existing license,
2284 has filed an application in proper form for renewal or for a new license authorizing the same
2285 activities, such existing license shall not expire until final action by the Department.

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2286 **3.18 Amendment of Licenses at Request of Licensee.**

2287 3.18.1 Applications for amendment of a license shall be filed in accordance with 3.8 and shall specify the
2288 respects in which the licensee desires the license to be amended and the grounds for such
2289 amendment.

2290 **3.19 Agency Action on Applications to Renew and Amend.**

2291 3.19.1 In considering an application by a licensee to renew or amend the license, the Department will
2292 apply the criteria set forth in 3.9 and 3.10, 3.11, 3.12, and in Parts 5, 7, 14, 16, 18 and 19, as
2293 applicable.

2294 **3.20 Reserved.**

2295 **3.21 Reserved.**

2296 **TRANSFER OF MATERIALS**

2297 **3.22 Transfer of Material.**

2298 3.22.1 No licensee shall transfer radioactive material except as authorized pursuant to 3.22.

2299 3.22.2 Except as otherwise provided in his license and subject to the provisions of 3.22.3 and 3.22.4,
2300 any licensee may transfer radioactive material:

2301 3.22.2.1 To the Department¹⁴⁰;

2302 ¹⁴⁰ A licensee may transfer material to the Department only after receiving prior approval from the Department.

2303 3.22.2.2 To the U.S. Department of Energy;

2304 3.22.2.3 To any person exempt from the regulations in this part to the extent permitted
2305 under such exemption;

2306 3.22.2.4 To any person authorized to receive such material under terms of a general
2307 license or its equivalent, or a specific license or equivalent licensing document, issued by
2308 the Department, ~~the U.S. Nuclear Regulatory Commission,~~ **NRC OR** any Agreement
2309 State ~~or any Licensing State~~, or to any person otherwise authorized to receive such
2310 material by the Federal Government or any agency thereof, the Department, **OR** an
2311 Agreement State, ~~or a Licensing State~~; or

2312 3.22.2.5 As otherwise authorized by the Department in writing.

2313 3.22.3 Before transferring radioactive material to a specific licensee of the Department, ~~the U.S. Nuclear~~
2314 ~~Regulatory Commission,~~ **NRC OR** an Agreement State ~~or a Licensing State~~, or to a general
2315 licensee who is required to register with the Department, ~~the U.S. Nuclear Regulatory~~
2316 ~~Commission,~~ **NRC OR** an Agreement State ~~or a Licensing State~~ prior to receipt of the radioactive
2317 material, the licensee transferring the material shall verify that the transferee's license authorizes
2318 the receipt of the type, form, and quantity of radioactive material to be transferred.

2319 3.22.4 Any of the following methods for the verification required by 3.22.3 is acceptable:

2320 3.22.4.1 The transferor may possess and read a current copy of the transferee's specific
2321 license or registration certificate.

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2322 3.22.4.2 The transferor may possess a written certification by the transferee that the
2323 transferee is authorized by license or registration certificate to receive the type, form, and
2324 quantity of radioactive material to be transferred, specifying the license or registration
2325 certificate number, issuing agency, and expiration date.

2326 3.22.4.3 For emergency shipments, the transferor may accept oral certification by the
2327 transferee that the transferee is authorized by license or registration certificate to receive
2328 the type, form, and quantity of radioactive material to be transferred, specifying the
2329 license or registration certificate number, issuing agency, and expiration date; provided,
2330 that the oral certification is confirmed in writing within 10 days.

2331 3.22.4.4 The transferor may obtain other information compiled by a reporting service from
2332 official records of the Department, ~~the U.S. Nuclear Regulatory Commission, NRC OR an~~
2333 ~~Agreement State, or a Licensing State~~ regarding the identity of licensees and the scope
2334 and expiration dates of licenses and registration.

2335 3.22.4.5 When none of the methods of verification described in 3.22.4.1 through 3.22.4.4
2336 are readily available or when a transferor desires to verify that information received by
2337 one of such methods is correct or up-to-date, the transferor may obtain and record
2338 confirmation from the Department, ~~the U.S. Nuclear Regulatory Commission~~ **NRC**, or an
2339 ~~Agreement State, or a Licensing State~~ that the transferee is licensed to receive the
2340 radioactive material.

2341 3.22.5 Shipment and transport of radioactive material shall be in accordance with the provisions of
2342 Part 17.

2343 **MODIFICATION AND REVOCATION OF LICENSES**

2344 **3.23 Modification and Revocation of Licenses.**

2345 3.23.1 The terms and conditions of all licenses shall be subject to amendment, revision, or modification
2346 or the license may be suspended or revoked by reason of amendments to the Act, or by reason
2347 of rules, regulations, and orders issued by the Department.

2348 3.23.2 Any license may be revoked, suspended, or modified, in whole or in part, for any material false
2349 statement in the application or any statement of fact required under provisions of the Act, or
2350 because of conditions revealed by such application or statement of fact or any report, record, or
2351 inspection or other means which would warrant the Department to refuse to grant a license on an
2352 original application, or for violation of, or failure to observe any of the terms and conditions of the
2353 Act, or of the license, or of any rule, regulation, or order of the Department.

2354 3.23.3 Except in cases of willfulness or those in which the public health, interest or safety requires
2355 otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of
2356 proceedings therefor, facts or conduct which may warrant such action shall have been called to
2357 the attention of the licensee in writing and the licensee shall have been accorded an opportunity
2358 to demonstrate or achieve compliance with all lawful requirements.

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2359 **RECIPROCITY**

2360 **3.24 Reciprocal Recognition of Licenses.**

2361 3.24.1 Radioactive Material in Quantities Not Sufficient to Form a Critical Mass.

2362 3.24.1.1 Subject to these regulations, any person who holds a specific license from the
2363 ~~U.S. Nuclear Regulatory Commission, NRC OR~~ an Agreement State or a Licensing State,
2364 and issued by the agency having jurisdiction where the licensee maintains an office for
2365 directing the licensed activity and at which radiation safety records are normally
2366 maintained, is hereby granted a general license to conduct the activities authorized in
2367 such licensing document within this State for a period not in excess of 180 days in any
2368 calendar year, provided that:

- 2369 (1) The licensing document does not limit the activity authorized by such document
2370 to specified installations or locations;
- 2371 (2) The out-of-state licensee notifies the Department in writing at least 3 days prior to
2372 engaging in such activity.
- 2373 (a) Such notification shall indicate the location, period, and type of proposed
2374 possession and use within the State, and shall be accompanied by a
2375 copy of the pertinent licensing document.
- 2376 (b) Based upon an application which includes documentation of why it is not
2377 possible or is an undue hardship to provide 3 days notice, the
2378 Department may grant permission to proceed sooner.
- 2379 (c) The Department may waive the requirement for filing additional written
2380 notifications during the remainder of the calendar year following the
2381 receipt of the initial notification from a person engaging in activities under
2382 the general license provided in 3.24.1.1;
- 2383 (3) The out-of-state licensee complies with all applicable regulations of the
2384 Department and with all the terms and conditions of the licensing document,
2385 except any such terms and conditions which may be inconsistent with applicable
2386 regulations of the Department;
- 2387 (4) The out-of-state licensee supplies such other information as the Department may
2388 request; and
- 2389 (5) The out-of-state licensee shall not transfer or dispose of radioactive material
2390 possessed or used under the general license provided in 3.24.1.1 except by
2391 transfer to a person:
- 2392 (a) Specifically licensed by the Department, ~~or by the U. S. Nuclear~~
2393 ~~Regulatory Commission NRC, OR~~ an Agreement State or a Licensing
2394 State, to receive such material; or
- 2395 (b) Exempt from the requirements for a license for such material under
2396 3.3.1.

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- (6) The out-of-state licensee shall at all times during work at any work location within the state have available:
- 2399 (a) ~~t~~The pertinent licensing document;
- 2400 (b) ~~t~~The applicable sections of the state radiation regulations;
- 2401 (c) ~~a~~A complete source inventory;
- 2402 (d) ~~p~~Pertinent U.S. ~~DO~~Department of Transportation documentation;
- 2403 (e) ~~l~~Leak test records;
- 2404 (f) ~~i~~nstrument calibration records;
- 2405 (g) ~~p~~Personnel training records; and
- 2406 (h) ~~n~~Necessary documentation required by applicable special requirements
2407 of these regulations.
- 2408 (7) While working in Colorado, the out-of-state licensee shall notify the Department
2409 (in writing, indicating date and court) immediately following the filing of a
2410 voluntary or involuntary petition for bankruptcy under any Chapter of Title 11
2411 (Bankruptcy) of the United States code by or against:
- 2412 (a) The licensee;
- 2413 (b) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the
2414 licensee or listing the license or licensee as property of the estate; or
- 2415 (c) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the license.
- 2416 (8) The out-of-state licensee shall notify the Department within 1 hour after arrival at
2417 the actual work location within the state and notification within 1 hour after any
2418 change of work location within the state.
- 2419 (9) If multiple persons work concurrently at more than one work location under a
2420 general license granted pursuant to this 3.24.1, each day worked per location
2421 shall be counted separately toward the limit of 180 days per calendar year.
- 2422 3.24.1.2 Notwithstanding the provisions of 3.24.1.1, any person who holds a specific
2423 license issued by the U. S. Nuclear Regulatory Commission ~~NRC~~; ~~OR~~ an Agreement
2424 State ~~or a Licensing State~~ authorizing the holder to manufacture, transfer, install, or
2425 service a device described in 3.6.4.1 within areas subject to the jurisdiction of the
2426 licensing body is hereby granted a general license to install, transfer, demonstrate, or
2427 service such a device in this State provided that:
- 2428 (1) Such person shall file a report with the Department within 30 days after the end
2429 of each calendar quarter in which any device is transferred to or installed in this
2430 State.
- 2431 (a) Each such report shall identify each general licensee to whom such
2432 device is transferred by name and address, the type of device
2433 transferred, and the quantity and type of radioactive material contained in
2434 the device;

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- 2435 (2) The device has been manufactured, labeled, installed, and serviced in
2436 accordance with applicable provisions of the specific license issued to such
2437 person by ~~the U. S. Nuclear Regulatory Commission, an Agreement State or~~
2438 **NRCa Licensing State;**
- 2439 (3) Such person shall assure that any labels required to be affixed to the device
2440 under regulations of the authority which licensed manufacture of the device bear
2441 a statement that "Removal of This Label Is Prohibited"; and
- 2442 (4) The holder of the specific license shall furnish to each general licensee to whom
2443 the specific licensee transfers such device or on whose premises the specific
2444 licensee installs such device a copy of the general license contained in 3.6.4 or in
2445 equivalent regulations of the agency having jurisdiction over the manufacture and
2446 distribution of the device.
- 2447 3.24.1.3 The Department may withdraw, limit, or qualify its acceptance of any specific
2448 license or equivalent licensing document issued by ~~the U. S. Nuclear Regulatory~~
2449 ~~Commission, NRC OR an Agreement State or a Licensing State,~~ or any product
2450 distributed pursuant to such licensing document, upon determining that such action is
2451 necessary in order to prevent undue hazard to public health and safety or property.
- 2452 3.24.2 Each general licensee granted authorization to conduct activities within this state pursuant to
2453 3.24.1 based upon an acceptable licensing document will receive acknowledgment from the
2454 Department. This acknowledgment shall be kept at the site of use.
- 2455 3.24.3 Each general licensee granted authorization to conduct activities within this state pursuant to
2456 3.24.1 based upon an acceptable licensing document may be inspected by the Department and
2457 subject to a fee for the inspection. The fee for a routine inspection shall:
- 2458 3.24.3.1 Be as provided by Part 12; and
- 2459 3.24.3.2 Shall not be charged more often than once during each calendar year, except
2460 that for a licensee authorizing use of material at more than one address, a separate fee
2461 will be assessed for inspection of each location. If multiple installations are inspected
2462 during a single visit, a single inspection fee will be assessed.
- 2463 3.24.4 Each general licensee operating within the state under reciprocity in areas of exclusive federal
2464 jurisdiction shall comply with the applicable provisions of 10 CFR 150.20 (January 1, 20104).
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2466 PART 3, SCHEDULE 3A:

2467 EXEMPT CONCENTRATIONS (3.3.1)

Element (atomic number)	Isotope	Column I Gas Concentration ¹² µCi/ml	Column II Liquid and Solid Concentration ¹³ µCi/ml
Antimony (51)	Sb-122		3×10^{-4}
	Sb-124		2×10^{-4}
	Sb-125		1×10^{-3}
Argon (18)	Ar-37	1×10^{-3}	
	Ar-41	4×10^{-7}	
Arsenic (33)	As-73		5×10^{-3}
	As-74		5×10^{-4}
	As-76		2×10^{-4}
	As-77		8×10^{-4}
Barium (56)	Ba-131		2×10^{-3}
	Ba-140		3×10^{-4}
Beryllium (4)	Be-7		2×10^{-2}
Bismuth (83)	Bi-206		4×10^{-4}
Bromine (35)	Br-82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd-109		2×10^{-3}
	Cd-115m		3×10^{-4}
	Cd-115		3×10^{-4}
Calcium (20)	Ca-45		9×10^{-5}
	Ca-47		5×10^{-4}
Carbon (6)	C-14	1×10^{-6}	8×10^{-3}

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Element (atomic number)	Isotope	Column I Gas Concentration ¹² μCi/ml	Column II Liquid and Solid Concentration ¹³ μCi/ml
Cerium (58)	Ce-141		9×10^{-4}
	Ce-143		4×10^{-4}
	Ce-144		1×10^{-4}
Cesium (55)	Cs-131		2×10^{-2}
	Cs-134m		6×10^{-2}
	Cs-134		9×10^{-5}
Chlorine (17)	Cl-38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr-51		2×10^{-2}
Cobalt (27)	Co-57		5×10^{-3}
	Co-58		1×10^{-3}
	Co-60		5×10^{-4}
Copper (29)	Cu-64		3×10^{-3}
Dysprosium (66)	Dy-165		4×10^{-3}
	Dy-166		4×10^{-4}
Erbium (68)	Er-169		9×10^{-4}
	Er-171		1×10^{-3}
Europium (63)	Eu-152 (9.2 h)		6×10^{-4}
	Eu-155		2×10^{-3}
Fluorine (9)	F-18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd-153		2×10^{-3}
	Gd-159		8×10^{-4}

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Element (atomic number)	Isotope	Column I Gas Concentration ¹² μCi/ml	Column II Liquid and Solid Concentration ¹³ μCi/ml
Gallium (31)	Ga-72		4×10 ⁻⁴
Germanium (32)	Ge-71		2×10 ⁻²
Gold (79)	Au-196		2×10 ⁻³
	Au-198		5×10 ⁻⁴
	Au-199		2×10 ⁻³
Hafnium (72)	Hf-181		7×10 ⁻⁴
Hydrogen (1)	H-3	5×10 ⁻⁶	3×10 ⁻²
Indium (49)	In-113m		1×10 ⁻²
	In-114m		2×10 ⁻⁴
Iodine (53)	I-126	3×10 ⁻⁹	2×10 ⁻⁵
	I-131	3×10 ⁻⁹	2×10 ⁻⁵
	I-132	8×10 ⁻⁸	6×10 ⁻⁴
	I-133	1×10 ⁻⁸	7×10 ⁻⁵
	I-134	2×10 ⁻⁷	1×10 ⁻³
Iridium (77)	Ir-190		2×10 ⁻³
	Ir-192		4×10 ⁻⁴
	Ir-194		3×10 ⁻⁴
Iron (26)	Fe-55		8×10 ⁻³
	Fe-59		6×10 ⁻⁴
Krypton (36)	Kr-85m	1×10 ⁻⁶	
	Kr-85	3×10 ⁻⁶	
Lanthanum (57)	La-140		2×10 ⁻⁴

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Element (atomic number)	Isotope	Column I Gas Concentration¹² μCi/ml	Column II Liquid and Solid Concentration¹³ μCi/ml
Lead (82)	Pb-203		4×10^{-3}
Lutetium (71)	Lu-177		1×10^{-3}
Manganese (25)	Mn-52		3×10^{-4}
	Mn-54		1×10^{-3}
	Mn-56		1×10^{-3}
Mercury (80)	Hg-197m		2×10^{-3}
	Hg-197		3×10^{-3}
	Hg-203		2×10^{-4}
Molybdenum (42)	Mo-99		2×10^{-3}
Neodymium (60)	Nd-147		6×10^{-4}
	Nd-149		3×10^{-3}
Nickel (28)	Ni-65		1×10^{-3}
Niobium (Columbium) (41)	Nb-95		1×10^{-3}
	Nb-97		9×10^{-3}
Osmium (76)	Os-185		7×10^{-4}
	Os-191m		3×10^{-2}
	Os-191		2×10^{-3}
	Os-193		6×10^{-4}
Palladium (46)	Pd-103		3×10^{-3}
Phosphorus (15)	P-32		2×10^{-4}
Platinum (78)	Pt-191		1×10^{-3}
	Pt-193m		1×10^{-2}

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Element (atomic number)	Isotope	Column I Gas Concentration ¹² μCi/ml	Column II Liquid and Solid Concentration ¹³ μCi/ml
	Pt-197m		1×10 ⁻²
	Pt-197		1×10 ⁻³
Potassium (19)	K-42		3×10 ⁻³
Praseodymium (59)	Pr-142		3×10 ⁻⁴
	Pr-143		5×10 ⁻⁴
Promethium (61)	Pm-147		2×10 ⁻³
	Pm-149		4×10 ⁻⁴
Rhenium (75)	Re-183		6×10 ⁻³
	Re-186		9×10 ⁻⁴
	Re-188		6×10 ⁻⁴
Rhodium (45)	Rh-103m		1×10 ⁻¹
	Rh-105		1×10 ⁻³
Rubidium (37)	Rb-86		7×10 ⁻⁴
Ruthenium (44)	Ru-97		4×10 ⁻³
	Ru-103		8×10 ⁻⁴
	Ru-105		1×10 ⁻³
	Ru-106		1×10 ⁻⁴
Samarium (62)	Sm-153		8×10 ⁻⁴
Scandium (21)	Sc-46		4×10 ⁻⁴
	Sc-47		9×10 ⁻⁴
	Sc-48		3×10 ⁻⁴
Selenium (34)	Se-75		3×10 ⁻³

RQ

Element (atomic number)	Isotope	Column I Gas Concentration ¹² μCi/ml	Column II Liquid and Solid Concentration ¹³ μCi/ml
Silicon (14)	Si-31		9×10^{-3}
Silver (47)	Ag-105		1×10^{-3}
	Ag-110m		3×10^{-4}
	Ag-111		4×10^{-4}
Sodium (11)	Na-24		2×10^{-3}
Strontium (38)	Sr-85		1×10^{-3}
	Sr-89		1×10^{-4}
	Sr-91		7×10^{-4}
	Sr-92		7×10^{-4}
Sulfur (16)	S-35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta-182		4×10^{-4}
Technetium (43)	Tc-96m		1×10^{-1}
	Tc-96		1×10^{-3}
Tellurium (52)	Te-125m		2×10^{-3}
	Te-127m		6×10^{-4}
	Te-127		3×10^{-3}
	Te-129m		3×10^{-4}
	Te-131m		6×10^{-4}
	Te-132		3×10^{-4}
Terbium (65)	Tb-160		4×10^{-4}
Thallium (81)	Tl-200		4×10^{-3}
	Tl-201		3×10^{-3}

RQ

Element (atomic number)	Isotope	Column I Gas Concentration ¹² μCi/ml	Column II Liquid and Solid Concentration ¹³ μCi/ml
	Tl-202		1×10 ⁻³
	Tl-204		1×10 ⁻³
Thulium (69)	Tm-170		5×10 ⁻⁴
	Tm-171		5×10 ⁻³
Tin (50)	Sn-113		9×10 ⁻⁴
	Sn-125		2×10 ⁻⁴
Tungsten (Wolfram) (74)	W-181		4×10 ⁻³
	W-187		7×10 ⁻⁴
Vanadium (23)	V-48		3×10 ⁻⁴
Xenon (54)	Xe-131m	4×10 ⁻⁶	
	Xe-133	3×10 ⁻⁶	
	Xe-135	1×10 ⁻⁶	
Ytterbium (70)	Yb-175		1×10 ⁻³
Yttrium (39)	Y-90		2×10 ⁻⁴
	Y-91m		3×10 ⁻²
	Y-91		3×10 ⁻⁴
	Y-92		6×10 ⁻⁴
	Y-93		3×10 ⁻⁴
Zinc (30)	Zn-65		1×10 ⁻³
	Zn-69m		7×10 ⁻⁴
	Zn-69		2×10 ⁻²
Zirconium (40)	Zr-95		6×10 ⁻⁴

RQ

Element (atomic number)	Isotope	Column I Gas Concentration ¹² µCi/ml	Column II Liquid and Solid Concentration ¹³ µCi/ml
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	Zr-97		2×10 ⁻⁴
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Beta- and/or gamma-emitting radioactive material not listed above with half-life of less than 3 years.

		1×10 ⁻¹⁰	1×10 ⁻⁶
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2468 ¹² Values are given in Column I only for those materials normally used as gases.

2469 ¹³ µCi/g for solids.

2470 Note 1: Many radionuclides transform into other radionuclides. In expressing the concentrations in
2471 Schedule 3A, the activity stated is that of the parent radionuclide and takes into account the radioactive
2472 decay products.

2473 Note 2: For purposes of Section 3.3 where there is involved a combination of radionuclides, the limit for
2474 the combination should be derived as follows:

2475 Determine for each radionuclide in the product the ratio between the radioactivity concentration present in
2476 the product and the exempt radioactivity concentration established in Schedule 3A for the specific
2477 radionuclide when not in combination. The sum of such ratios may not exceed "1".

2478 Example:

$$\frac{\text{Concentration of Radionuclide A in Product}}{\text{Exempt concentration of Radionuclide A}} + \frac{\text{Concentration of Radionuclide B in Product}}{\text{Exempt concentration of Radionuclide B}} \leq 1$$

2479 Note 3: To convert µCi/ml to SI units of megabecquerels per liter multiply the above values by 37.

2480 Example: Zirconium (40), Zr-97 (2×10⁻⁴ µCi/ml multiplied by 37 is equivalent to 74 × 10⁻⁴ MBq/l)
2481

RQ

2482 **PART 3, SCHEDULE 3B:**

2483 **EXEMPT QUANTITIES (3.3.2)**

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1

RQ

Radioactive Material	Microcuries
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152) 9.2h	100
Europium-152 (Eu 152) 13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10

RQ

Radioactive Material	Microcuries
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-68 (Ge 68)	10
Germanium-71 (Ge 71)	100
Gold-195 (Au 195)	10
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1
Iodine-131 (I 131)	1

RQ

Radioactive Material	Microcuries
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100

RQ

Radioactive Material	Microcuries
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium-147 (Pm 147)	10

RQ

Radioactive Material	Microcuries
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (103m)	100
Rhodium-105 (105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10

RQ

Radioactive Material	Microcuries
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131 m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-.201 (Tl 201)	100

RQ

Radioactive Material	Microcuries
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131 m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000

RQ

Radioactive Material	Microcuries
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha-emitting radioactive material	0.1

2484

2485 Note 1: For purposes of 3.9.5.3(5)(a) and 3.9.5.3(5)(b) where there is involved a combination of
2486 radionuclides, the limit for the combination should be derived as follows:

2487 Determine the amount of each radionuclide possessed and 1,000 times the amount in Schedule 3B for
2488 each of those radionuclides when not in combination. The sum of the ratios of those quantities may not
2489 exceed 1.

2490 Example:

$$\frac{\text{Amount of Radionuclide A possessed}}{1000 \times \text{Schedule 3B quantity for Radionuclide A}} + \frac{\text{Amount of Radionuclide B possessed}}{1000 \times \text{Schedule 3B quantity for Radionuclide B}} \leq 1$$

2491 Note 2: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

2492 Example: Zirconium-97 (10 μCi multiplied by 37 is equivalent to 370 kBq).

2493

RQ

2494 **PART 3, SCHEDULE 3C:**

2495 **EXEMPT ITEMS (3.2.3 AND 3.3.3)**

2496 **3C Any person is exempt from this part to the extent that such person receives, possesses,**
2497 **uses, or transfers an item listed below:**

2498 **3C.1A-** Any quantities of thorium contained in:

2499 **3C.1.1-** Incandescent gas mantles;

2500 **3C.1.2-** Vacuum tubes;

2501 **3C.1.3-** Welding rods;

2502 **3C.1.4-** Electric lamps for illuminating purposes provided that each lamp does not contain more
2503 than 50 milligrams of thorium;

2504 **3C.1.5-** Germicidal lamps, sunlamps, and lamps for outdoors or industrial lighting provided that
2505 each lamp does not contain more than 2 grams of thorium;

2506 **3C.1.6-** Rare earth metals and compounds, mixtures, and products containing not more than 0.25
2507 percent by weight thorium, uranium, or any combination of these; or

2508 **3C.1.7-** Personnel neutron dosimeters provided that each dosimeter does not contain more than
2509 50 milligrams of thorium;

2510 **3C.2B-** Source material contained in the following products:

2511 **3C.2.1-** Glazed ceramic tableware, provided that the glaze contains not more than 20 percent by
2512 weight source material;

2513 **3C.2.2-** Glassware containing not more than 10 percent by weight source material, but not
2514 including commercially manufactured glass brick, pane glass, ceramic tile or other glass
2515 or ceramic used in construction;

2516 **3C.2.3-** Glass enamel or glass enamel frit containing not more than 10 percent by weight source
2517 material imported or ordered for importation into the United States, or initially distributed
2518 by manufacturers in the United States, before July 25, 1983; or

2519 **3C.2.4-** Piezoelectric ceramic containing not more than 2 percent by weight source material;

2520 **3C.3C-** Photographic film, negatives, and prints containing uranium or thorium;

2521 **3C.4D-** Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium
2522 alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and
2523 that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical
2524 treatment or processing of any such product or part;

2525 **3C.5E-** Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or
2526 stored or handled in connection with installation or removal of such counterweights, provided that:

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- 2527 **3C.5.1-** The counterweights are manufactured in accordance with a specific license issued by the
2528 ~~U.S. Nuclear Regulatory Commission-NRC~~, authorizing distribution by the licensee
2529 pursuant to 10 CFR Part 40 (January 1, 2010);;
- 2530 **3C.5.2-** Each counterweight has been impressed with the following legend clearly legible through
2531 any plating or other covering: "Depleted Uranium";¹⁴
- 2532 ¹⁴ The requirement specified in ~~E3C.5.2~~ need not be met by counterweights manufactured prior to December 31,
2533 1969; provided, that such counterweights are impressed with the legend, "CAUTION – RADIOACTIVE MATERIAL –
2534 URANIUM", as previously required by the regulations.
- 2535 **3C.5.3-** Each counterweight is durably and legibly labeled or marked with the identification of the
2536 manufacturer and the statement: "Unauthorized Alterations Prohibited"¹⁵; and
- 2537 ¹⁵ The requirement specified in ~~E3C.5.3~~ need not be met by counterweights manufactured prior to December 31,
2538 1969; provided, that such counterweights are impressed with the legend, "CAUTION – RADIOACTIVE MATERIAL –
2539 URANIUM", as previously required by the regulations.
- 2540 **3C.5.4-** This exemption shall not be deemed to authorize the chemical, physical, or metallurgical
2541 treatment or processing of any such counterweights other than repair or restoration of
2542 any plating or other covering;.
- 2543 **3C.6F-** Natural or depleted uranium used as shielding constituting part of any shipping container,
2544 provided that:
- 2545 **3C.6.1-** The shipping container is conspicuously and legibly impressed with the legend "Caution -
2546 Radioactive Shielding - Uranium"; and
- 2547 **3C.6.2-** The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall
2548 thickness of 1/8 inch (3.2 mm).
- 2549 ~~**3C.7G-**~~ Thorium contained in finished optical lenses, provided that each lens does not contain more than
2550 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either
- 2551 **3C.7.1-** The shaping, grinding, or polishing of such lens or manufacturing processes other than
2552 the assembly of such lens into optical systems and devices without any alteration of the
2553 lens; or
- 2554 **3C.7.2-** The receipt, possession, use, or transfer of thorium contained in contact lenses, or in
2555 spectacles, or in eyepieces in binoculars or other optical instruments;.
- 2556 ~~**3C.8H-**~~ Uranium contained in detector heads for use in fire detection units, provided that each detector
2557 head contains not more than 185 Bq (0.005 µCi) of uranium; or
- 2558 ~~**3C.9I-**~~ Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that
- 2559 **3C.9.1-** The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria
2560 (thorium dioxide); and
- 2561 **3C.9.2-** The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

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2562 ~~3C.10J. Certain items containing radioactive material. Except for persons who apply radioactive material~~
2563 ~~to, or persons who incorporate radioactive material into, the following products, any person is~~
2564 ~~exempt from these regulations to the extent that the person receives, possesses, uses, transfers,~~
2565 ~~owns, or acquires the following products¹⁶:~~

2566 ¹⁶ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment,
2567 device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and
2568 disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear
2569 Regulatory Commission, Washington, D.C. 20555.

2570 **3C.10.1-** Timepieces or hands or dials containing not more than the following specified
2571 quantities of radioactive material and not exceeding the following specified radiation dose
2572 rate:

2573 **3C.10.1a.1** 925 MBq (25 mCi) of tritium per timepiece;

2574 **3C.10.1b.2** 185 MBq (5 mCi) of tritium per hand;

2575 **3C.10.1e.3** 555 MBq (15 mCi) of tritium per dial (bezels when used shall be
2576 considered as part of the dial);

2577 **3C.10.1d.4** 3.7 MBq (100 µCi) of promethium-147 per watch or 7.4 MBq (200 mCi) of
2578 promethium-147 per any other timepiece;

2579 **3C.10.1e.5** 0.74 MBq (20 µCi) of promethium-147 per watch hand or 1.48 MBq
2580 (40 mCi of promethium-147 per other timepiece hand);

2581 **3C.10.1f.6** 2.22 MBq (60 µCi) of promethium-147 per watch dial or 4.44 MBq
2582 (120 µCi) of promethium-147 per other timepiece dial (bezels when used shall be
2583 considered as part of the dial);

2584 **3C.10.1g.7** The radiation dose rate from hands and dials containing promethium-147
2585 will not exceed, when measured through 50 milligrams per square centimeter of
2586 absorber:

2587 (i1) For wristwatches, 1 µGy (0.1 mrad) per hour at 10 centimeters from any
2588 surface;

2589 (ii2) For pocket watches, 1 µGy (0.1 mrad) per hour at 1 centimeter from any
2590 surface;

2591 (iii3) For any other timepiece, 2 µGy (0.2 mrad) per hour at 10 centimeters
2592 from any surface;

2593 **3C.10.1h.8** 37 kBq (1 µCi) of radium-226 per timepiece in timepieces acquired prior
2594 to the effective date of this regulation;

2595 ~~2. Lock illuminators containing not more than 555 MBq (15 mCi) of tritium or not more than~~
2596 ~~74 MBq (2 mCi) of promethium-147 installed in automobile locks. The radiation dose rate~~
2597 ~~from each lock illuminator containing promethium-147 will not exceed 10 µGy (1 mrad)~~
2598 ~~per hour at 1 centimeter from any surface when measured through 50 milligrams per~~
2599 ~~square centimeter of absorber.~~

2600 **3C.10.23-** Precision balances containing not more than 37 MBq (1 mCi) of tritium per
2601 balance or not more than 18.5 MBq (0.5 mCi) of tritium per balance part
2602 **MANUFACTURED BEFORE DECEMBER 17, 2007-;**

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- 2603 4. ~~Automobile shift quadrants containing not more than 925 MBq (25 mCi) of tritium.~~
- 2604 **3C.10.35.** Marine compasses containing not more than 27.8 GBq (750 mCi) of tritium gas
2605 and other marine navigational instruments **MANUFACTURED BEFORE DECEMBER 17,**
2606 **2007** containing not more than 9.25 GBq (250 mCi) of tritium gas;
- 2607 6. ~~Thermostat dials and pointers containing not more than 925 MBq (25 mCi) of tritium per~~
2608 ~~thermostat.~~
- 2609 **3C.10.4 IONIZATION CHAMBER SMOKE DETECTORS CONTAINING NOT MORE THAN**
2610 **1 MICROCURIE (μCi) OF AMERICIUM-241 PER DETECTOR IN THE FORM OF A**
2611 **FOIL AND DESIGNED TO PROTECT LIFE AND PROPERTY FROM FIRES.**
- 2612 **3C.10.57.** Electron tubes, provided, that:
- 2613 **3C.10.5.1** Each tube does not contain more than one of the following specified
2614 quantities of radioactive material:
- 2615 a.(1) 0.55 GBq (150 mCi) of tritium per microwave receiver protector tube or
2616 370 MBq (10 mCi) of tritium per any other electron tube;
- 2617 b.(2) 37 kBq (1 μCi) of cobalt-60;
- 2618 e.(3) 185 kBq (5 μCi) of nickel-63;
- 2619 d.(4) 1.11 MBq (30 μCi) of krypton-85;
- 2620 e.(5) 185 kBq (5 μCi) of cesium-137;
- 2621 f.(6) 1.11 MBq (30 μCi) of promethium-147; and ~~provided further, that~~
- 2622 **3C.10.5.2** ~~†~~The radiation dose rate from each electron tube containing radioactive
2623 material will not exceed 10 μGy (1 mrad) per hour at 1 centimeter from any
2624 surface when measured through 7 milligrams per square centimeter of
2625 absorber;¹⁷
- 2626 ¹⁷ For purposes of ~~3C.10.57~~, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow
2627 lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other
2628 completely sealed tube that is designed to conduct or control electrical currents.
- 2629 **3C.10.68.** Ionizing radiation measuring instruments containing, for purposes of internal
2630 calibration or standardization, one or more sources of radioactive material, provided that:
- 2631 **3C.10.6a.1** Each source contains no more than one exempt quantity set forth in
2632 Schedule 3B of this part; and
- 2633 **3C.10.6b.2** Each instrument contains no more than 10 exempt quantities. For
2634 purposes of this requirement, an instrument's source(s) may contain either one or
2635 different types of radionuclides and an individual exempt quantity may be
2636 composed of fractional parts of one or more of the exempt quantities in
2637 Schedule 3B of this part, provided that the sum of such fractions shall not exceed
2638 unity.
- 2639 **3C.10.6e.3** For americium-241, 1.85 kBq (0.05 μCi) is considered an exempt
2640 quantity under ~~3C.10.68~~;

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2641 9. ~~Spark gap irradiators containing not more than 37 kBq (1 µCi) of cobalt-60 per spark gap~~
2642 ~~irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3~~
2643 ~~gallons (11.4 l) per hour.~~

2644 **3C.11K.** Self-luminous products containing radioactive material **CONTAINING** Tritium, krypton-
2645 85, or promethium-147.

2646 **3C.11.1** Except for persons who manufacture, process, or produce self-luminous products
2647 containing tritium, krypton-85, or promethium-147, any person is exempt from these
2648 regulations to the extent that such person receives, possesses, uses, transfers, owns, or
2649 acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured,
2650 processed, produced, imported, or transferred in accordance with a specific license
2651 issued by the U.S. Nuclear Regulatory Commission **NRC** pursuant to section 32.22 of 10
2652 CFR Part 32 (January 1, 20104), which license authorizes the transfer of the product to
2653 persons who are exempt from regulatory requirements.

2654 **3C.11.2** The exemption in this section does not apply to tritium, krypton-85, or promethium-147
2655 used in products for frivolous purposes or in toys or adornments.

2656 2. ~~Radium-226. Any person is exempt from these regulations to the extent that such person~~
2657 ~~receives, possesses, uses, transfers, or owns articles containing less than 3.7 kBq~~
2658 ~~(0.1 µCi) of radium-226 which were acquired prior to the effective date of this regulation.~~

2659 **3C.12L.** Gas and aerosol detectors containing radioactive material.

2660 **3C.12.1:** Except for persons who manufacture, process, or produce gas and aerosol
2661 detectors containing radioactive material, any person is exempt from these regulations to
2662 the extent that such person receives, possesses, uses, transfers, owns, or acquires
2663 radioactive material in gas and aerosol detectors designed to protect life or property from
2664 fires and airborne hazards provided that detectors containing radioactive material shall
2665 have been manufactured, imported, or transferred in accordance with a specific license
2666 issued by the U.S. Nuclear Regulatory Commission **NRC**¹⁸ pursuant to section 32.26 of
2667 10 CFR Part 32 (January 1, 20104); or a Licensing State pursuant to 3.12.3, which
2668 authorizes the transfer of the detectors to persons who are exempt from regulatory
2669 requirements.

2670 ¹⁸ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment,
2671 device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and
2672 disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear
2673 Regulatory Commission, Washington, D.C. 20555.

2674 **3C.12.2:** Gas and aerosol detectors previously manufactured and distributed to general
2675 licensees in accordance with a specific license issued by an agreement state shall be
2676 considered exempt under **3C.12.1**, provided that the device is labeled in accordance
2677 with the specific license authorizing distribution of the generally licensed device, and
2678 provided further that they meet the requirements of 3.12.3.

2679 3. ~~Gas and aerosol detectors containing NARM previously manufactured and distributed in~~
2680 ~~accordance with a specific license issued by a licensing state shall be considered exempt~~
2681 ~~under L.1, provided that the device is labeled in accordance with the specific license~~
2682 ~~authorizing distribution, and provided further that they meet the requirements of 3.12.3.~~

RQ

- 2683 ~~M.~~ Resins containing scandium-46 and designed for sand consolidation in oil wells.
- 2684 1. Any person is exempt from these regulations to the extent that such person receives,
2685 possesses, uses, transfers, owns or acquires synthetic plastic resins containing
2686 scandium-46 which are designed for sand consolidation in oil wells.
- 2687 2. Such resins shall have been manufactured or imported in accordance with a specific
2688 license issued by the U.S. Nuclear Regulatory Commission, or shall have been
2689 manufactured in accordance with the specifications contained in a specific license issued
2690 by the Department or any agreement state to the manufacturer of such resins pursuant to
2691 licensing requirements equivalent to those in sections 32.16 and 32.17 of 10 CFR Part 32
2692 (January 1, 2004).
- 2693 3. This exemption does not authorize the manufacture of any resins containing
2694 scandium-46.
- 2695 ~~3C.13N.~~ Radioactive drug capsules containing carbon-14 urea for "in vivo" diagnostic use for
2696 humans.
- 2697 ~~3C.13.1.~~ Except as provided in paragraphs ~~N3C.13.2~~ and ~~N3C.13.3~~ of this section, any
2698 person is exempt from the regulations in this part provided that such person receives,
2699 possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 µCi)
2700 carbon-14 urea (allowing for nominal variation that may occur during the manufacturing
2701 process) each, for "in vivo" diagnostic use for humans.
- 2702 ~~3C.13.2.~~ Any person who desires to use the capsules for research involving human
2703 subjects shall apply for and receive a specific license pursuant to Part 7.
- 2704 ~~3C.13.3.~~ Nothing in this section relieves persons from complying with applicable FDA,
2705 federal, and state requirements governing receipt, administration, and use of drugs.
2706

RQ

2707 **PART 3, SCHEDULE 3D:**

2708 **LIMITS FOR BROAD LICENSES (3.11)**

Radioactive Material	Col. 1 curies	Col. 2 curies
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76		0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1.
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001

RQ

Radioactive Material	Col. 1 curies	Col. 2 curies
Cesium-131	100	1.
Cesium-134m	100	1.
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.
Chromium-51	100	1.
Cobalt-57	10	0.1
Cobalt-58m	100	1.
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2 h)	10	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1.

RQ

Radioactive Material	Col. 1 curies	Col. 2 curies
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1.
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1.
Indium-113m	100	1.
Indium-114m	1	0.01
Indium-115m	100	1.
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1

RQ

Radioactive Material	Col. 1 curies	Col. 2 curies
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1.
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1.
Osmium-185	1	0.01
Osmium-191m	100	1.

RQ

Radioactive Material	Col. 1 curies	Col. 2 curies
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1.
Platinum-193	10	0.1
Platinum-197m	100	1.
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10.
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01

RQ

Radioactive Material	Col. 1 curies	Col. 2 curies
Ruthenium-97	100	1.
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10.
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1

RQ

Radioactive Material	Col. 1 curies	Col. 2 curies
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01

RQ

Radioactive Material	Col. 1 curies	Col. 2 curies
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10.
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1.
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha-emitting radioactive material not listed above.	0.1	0.001

2709 Note 1: To convert Ci to SI units of gigabecquerel (GBq) per liter, multiply the above values by 37.

2710 Example: Zirconium-97 (Col. II) (0.01 Ci multiplied by 37 is equivalent to 0.37 GBq)
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2712 **PART 3, SCHEDULE 3E:**

2713 **QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN**
2714 **EMERGENCY PLAN FOR RESPONDING TO A RELEASE (3.9.11)**

Radioactive material ¹⁹	Release fraction	Quantity	
		TBq	Ci
Actinium-228	.001	148	(4,000)
Americium-241	.001	0.074	(2)
Americium-242	.001	0.074	(2)
Americium-243	.001	0.074	(2)
Antimony-124	.01	148	(4,000)
Antimony-126	.01	222	(6,000)
Barium-133	.01	370	(10,000)
Barium-140	.01	1,100	(30,000)
Bismuth-207	.01	185	(5,000)
Bismuth-210	.01	22.2	(600)
Cadmium-109	.01	37	(1,000)
Cadmium-113	.01	2.96	(80)
Calcium-45	.01	740	(20,000)
Californium-252	.001	0.333	(9)(20 mg)
Carbon-14 (non CO)	.01	1,850	(50,000)
Cerium-141	.01	370	(10,000)
Cerium-144	.01	11.1	(300)
Cesium-134	.01	74	(2,000)
Cesium-137	.01	111	(3,000)
Chlorine-36	.5	3.7	(100)

RQ

Radioactive material ¹⁹	Release fraction	Quantity	
		TBq	Ci
Chromium-51	.01	11,100	(300,000)
Cobalt-60	.001	185	(5,000)
Copper-64	.01	7,400	(200,000)
Curium-242	.001	2.22	(60)
Curium-243	.001	0.111	(3)
Curium-244	.001	0.148	(4)
Curium-245	.001	0.074	(2)
Europium-152	.01	18.5	(500)
Europium-154	.01	14.8	(400)
Europium-155	.01	111	(3,000)
Germanium-68	.01	74	(2,000)
Gadolinium-153	.01	185	(5,000)
Gold-198	.01	1,110	(30,000)
Hafnium-172	.01	14.8	(400)
Hafnium-181	.01	259	(7,000)
Holmium-166m	.01	3.7	(100)
Hydrogen-3	.5	740	(20,000)
Iodine-125	.5	0.37	(10)
Iodine-131	.5	0.37	(10)
Indium-114m	.01	37	(1,000)
Iridium-192	.001	1,480	(40,000)
Iron-55	.01	1,480	(40,000)

RQ

Radioactive material ¹⁹	Release fraction	Quantity	
		TBq	Ci
Iron-59	.01	259	(7,000)
Krypton-85	1.0	222,000	(6,000,000)
Lead-210	.01	0.296	(8)
Manganese-56	.01	2,200	(60,000)
Mercury-203	.01	370	(10,000)
Molybdenum-99	.01	1,100	(30,000)
Neptunium-237	.001	0.074	(2)
Nickel-63	.01	740	(20,000)
Niobium-94	.01	11.1	(300)
Phosphorus-32	.5	3.7	(100)
Phosphorus-33	.5	37	(1,000)
Polonium-210	.01	0.37	(10)
Potassium-42	.01	333	(9,000)
Promethium-145	.01	148	(4,000)
Promethium-147	.01	148	(4,000)
Ruthenium-106	.01	7.4	(200)
Samarium-151	.01	148	(4,000)
Scandium-46	.01	111	(3,000)
Selenium-75	.01	370	(10,000)
Silver-110m	.01	37	(1,000)
Sodium-22	.01	333	(9,000)
Sodium-24	.01	370	(10,000)

RQ

Radioactive material ¹⁹	Release fraction	Quantity	
		TBq	Ci
Strontium-89	.01	111	(3,000)
Strontium-90	.01	3.33	(90)
Sulfur-35	.5	33.3	(900)
Technetium-99	.01	370	(10,000)
Technetium-99m	.01	14,800	(400,000)
Tellurium-127m	.01	185	(5,000)
Tellurium-129m	.01	185	(5,000)
Terbium-160	.01	148	(4,000)
Thulium-170	.01	148	(4,000)
Tin-113	.01	370	(10,000)
Tin-123	.01	111	(3,000)
Tin-126	.01	37	(1,000)
Titanium-44	.01	3.7	(100)
Vanadium-48	.01	259	(7,000)
Xenon-133	1.0	33,300	(900,000)
Yttrium-91	.01	74	(2,000)
Zinc-65	.01	185	(5,000)
Zirconium-93	.01	14.8	(400)
Zirconium-95	.01	185	(5,000)
Any other beta-gamma emitter	.01	370	(10,000)
Mixed fission products	.01	37	(1,000)
Mixed corrosion products	.01	370	(10,000)

RQ

Radioactive material ¹⁹	Release fraction	Quantity	
		TBq	Ci
Contaminated equipment beta-gamma	.001	370	(10,000)
Irradiated material, any form other than solid noncombustible	.01	37	(1,000)
Irradiated material, solid noncombustible	.001	370	(10,000)
Mixed radioactive waste, beta-gamma	.01	37	(1,000)
Packaged mixed waste, beta-gamma ¹⁹	.001	370	(10,000)
Any other alpha emitter	.001	0.074	(2)
Contaminated equipment, alpha	.0001	0.74	(20)
Packaged waste, alpha ²⁰	.0001	0.74	(20)
Combinations of radioactive materials listed above ¹⁹			

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¹⁹ For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive materials authorized to the quantity listed for that material in Schedule 3E exceeds one.

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2719

²⁰ Waste packaged in Type B containers does not require an emergency plan.

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2720 **PART 3, APPENDIX 3AF:**

2721 **CRITERIA RELATING TO USE OF FINANCIAL TESTS AND PARENT COMPANY GUARANTEES**
2722 **FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING**

2723 **I-3F.1 Introduction**

2724 **3F.1.1** An applicant or licensee may provide reasonable assurance of the availability of funds for
2725 decommissioning based on obtaining a parent company guarantee that funds will be available for
2726 decommissioning costs and on a demonstration that the parent company passes a financial test.
2727 This Appendix establishes criteria for passing the financial test and for obtaining the parent
2728 company guarantee.

2729 **II-3F.2 Financial Test**

2730 **A-3F.2.1** To pass the financial test, the parent company must meet the criteria of either paragraph
2731 A.1 or A.2 of this Appendix:

2732 **3F.2.1.1** The parent company must have:

2733 **a-(1)** Two of the following three ratios: a ratio of total liabilities to net worth less than
2734 2.0; a ratio of the sum of net income plus depreciation, depletion, and
2735 amortization to total liabilities greater than 0.1; and ratio of current assets to
2736 current liabilities greater than 1.5; and

2737 **b-(2)** Net working capital and tangible net worth each at least ten times the current
2738 decommissioning cost estimates (or prescribed amount if a certification is used);
2739 and

2740 **c-(3)** Tangible net worth of at least \$10 million; and

2741 **d-(4)** Assets located in the United States amounting to at least 90 percent of total
2742 assets or at least ten times the current decommissioning cost estimates (or
2743 prescribed amount if a certification is used).

2744 **3F.2.1.2** The parent company must have:

2745 **a-(1)** A current rating for its most recent bond issuance of AAA, AA, A, or BBB as
2746 issued by Standard and Poor's or AAA, AA, A, or BAA as issued by Moody's; and

2747 **b-(2)** Tangible net worth at least ten times the current decommissioning cost
2748 estimate (or prescribed amount if a certification is used); and

2749 **c-(3)** Tangible net worth of at least \$10 million; and

2750 **d-(4)** Assets located in the United States amounting to at least 90 percent of total
2751 assets or at least ten times the current decommissioning cost estimates (or
2752 prescribed amount if certification is used).

RQ

2753 **B-3F.2.2** The parent company's independent certified public accountant must have compared the
2754 data used by the parent company in the financial test, which is derived from independently
2755 audited, year end financial statements for the latest fiscal year, with the amounts in such financial
2756 statement. In connection with that procedure the licensee shall inform the Department within 90
2757 days of any matters coming to the auditor's attention which cause the auditor to believe that the
2758 data specified in the financial test should be adjusted and that the company no longer passes the
2759 test.

2760 **C-3F.2.3** Follow-up

2761 **3F.2.3.1.** After the initial financial test, the parent company must repeat the passage of the
2762 test within 90 days after the close of each succeeding fiscal year.

2763 **3F.2.3.2** If the parent company no longer meets the requirements of Paragraph A of this
2764 section, the licensee must send notice to the Department of intent to establish alternate
2765 financial assurance as specified in the Department's regulations.

2766 **(1)** The notice must be sent by certified mail within 90 days after the end of the fiscal
2767 year for which the year-end financial data show that the parent company no
2768 longer meets the financial test requirements.

2769 **(2)** The licensee must provide alternate financial assurance within 120 days after the
2770 end of such fiscal year.

2771 **III.3F.3 Parent Company Guarantee**

2772 **3F.3.1** The terms of a parent company guarantee which an applicant or licensee obtains must provide
2773 that:

2774 **3F.3.A1.1.** The parent company guarantee will remain in force unless the guarantor sends
2775 notice of cancellation by certified mail to the licensee and the Department. Cancellation
2776 may not occur, however, during the 120 days beginning on the date of receipt of the
2777 notice of cancellation by both the licensee and the Department, as evidenced by the
2778 return receipts.

2779 **3F.3.B1.2** If the licensee fails to provide alternate financial assurance as specified in the
2780 Department's regulations within 90 days after receipt by the licensee and Department of
2781 a notice of cancellation of the parent company guarantee from the guarantor, the
2782 guarantor will provide such alternative financial assurance in the name of the licensee.

2783 **3F.3.C1.3** The parent company guarantee and financial test provisions must remain in
2784 effect until the Department has terminated the license or until another financial assurance
2785 method acceptable to the Department has been put in effect by the licensee.

2786 **3F.3.D1.4** If a trust is established for decommissioning costs, the trustee and trust must be
2787 acceptable to the Department. An acceptable trustee includes the following: an
2788 appropriate state or federal government agency or an entity which has the authority to act
2789 as a trustee and whose trust operations are regulated and examined by a state or federal
2790 agency.
2791

RQ

2792 **PART 3, APPENDIX 3BG:**

2793 **CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEES FOR PROVIDING**
2794 **REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING**

2795 **I.3G.1 Introduction**

2796 **3G.1.1** An applicant or licensee may provide reasonable assurance of the availability of funds for
2797 decommissioning, based on furnishing its own guarantee that funds will be available for
2798 decommissioning costs, and on a demonstration that the company passes the financial test
2799 Section II of this Appendix.

2800 **3G.1.1.1** The terms of this self-guarantee are in Section III of this Appendix.

2801 **3G.1.1.2** This Appendix establishes criteria for passing the financial test for the self-
2802 guarantee and establishes the terms for a self-guarantee.

2803 **II.3G.2 Financial Test**

2804 **3G.2.1A-** To pass the financial test, a company must meet the all of the following criteria:

2805 **3G.2.1.1** A tangible net worth of at least ten times the total current decommissioning cost
2806 estimate (or the current amount required if certification is used) for all decommissioning
2807 activities for which the company is responsible as self-guaranteeing licensee and as
2808 parent-guarantor.

2809 **3G.2.1.2** Assets located in the United States amounting to at least 90 percent of total
2810 assets or at least ten times the current decommissioning cost estimates (or the current
2811 amount required if certification is used) for all decommissioning activities for which the
2812 company is responsible as self-guaranteeing licensee and as parent-guarantor.

2813 **3G.2.1.3-** A current rating for its most recent bond issuance of AAA, AA, or A as issued by
2814 Standard and Poor's or AAA, AA, or A as issued by Moody's; and

2815 **3G.2B.2** To pass the financial test, a company must meet all of the following additional
2816 requirements:

2817 **3G.2.2.1-** The company must have at least one class of equity securities registered under
2818 the Securities Exchange Act of 1934.

2819 **3G.2.2.2** The company's independent certified public accountant must have compared the
2820 data used by the company in the financial test which is derived from the independently
2821 audited, year end financial statements for the latest fiscal year, with the amounts in such
2822 financial statement.

2823 **(1)** In connection with that procedure, the licensee shall inform the Department
2824 within 90 days of any matters coming to the attention of the auditor that cause
2825 the auditor to believe that the data specified in the financial test should be
2826 adjusted and that the company no longer passes the test.

2827 **3G.2.2.3-** After the initial financial test, the company must repeat passage of the test within
2828 90 days after the close of each succeeding fiscal year.

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2829 **3G.2G.3** If the licensee no longer meets the requirements of ~~Section 3G.2.1H.A of this Appendix,~~
2830 the licensee must send immediate notice to the Department of its intent to establish alternate
2831 financial assurance as specified in the Department's regulations within 120 days of such notice.

2832 **III.3G.3 Company Self-Guarantee**

2833 **3G.3.1** The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

2834 **3G.3.1A.1** The guarantee will remain in force unless the licensee sends notice of
2835 cancellation by certified mail to the Department.

2836 (1) Cancellation may not occur, however, during the 120 days beginning on the date
2837 of receipt of the notice of cancellation by the Department, as evidenced by the
2838 return receipt.

2839 **3G.3.1B.2** The licensee shall provide alternative financial assurance as specified in the
2840 Department's regulations within 90 days following receipt by the Department of a notice
2841 of cancellation of the guarantee.

2842 **3G.3.1C.3** The guarantee and financial test provisions must remain in effect until the
2843 Department has terminated the license or until another financial assurance method
2844 acceptable to the Department has been put in effect by the licensee.

2845 **3G.3.1D.4** The licensee will promptly forward to the Department and the licensee's
2846 independent auditor all reports covering the latest fiscal year filed by the licensee with the
2847 Securities and Exchange Commission pursuant to the requirements of Section 13 of the
2848 Securities and Exchange Act of 1934.

2849 **3G.3.1E.5** If, at any time, the licensee's most recent bond issuance ceases to be rated in
2850 any category of "A" or above by either Standard and Poors and Moodys, the licensee will
2851 provide notice in writing of such fact to the Department within 20 days after publication of
2852 the change by the rating service.

2853 (1) If the licensee's most recent bond issuance ceases to be rated in any category of
2854 A or above by both Standard and Poors and Moodys, the licensee no longer
2855 meets the requirements of ~~Section 3G.2.1H.A of this Appendix.~~

2856 **3G.3.1F.6** The applicant or licensee must provide to the Department a written guarantee (a
2857 written commitment by a corporate officer) which states that the licensee will fund and
2858 carry out the required decommissioning activities or, upon issuance of an order by the
2859 Department, the licensee will set up and fund a trust in the amount of the current cost
2860 estimates for decommissioning.