

1 **DRAFT 3 09/05/2023**

2 **DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

3 **Hazardous Materials and Waste Management Division**

4 **RADIATION CONTROL - LICENSING OF RADIOACTIVE MATERIAL**

5 **6 CCR 1007-1 PART 03**

6 *[Editor's Notes follow the text of the rules at the end of this CCR Document.]*

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8 **Adopted by the Board of Health on June 17, 2020October 18, 2023; effective August 14,**
9 **2020December 15, 2023.**

10 **LICENSING OF RADIOACTIVE MATERIAL**

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12 * * *
13 [* * * indicates unaffected sections of the rule]
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15 **Published material incorporated by reference.**

16 3.1.4.3 Throughout this Part 3, federal regulations, state regulations, and standards or guidelines
17 of outside organizations have been adopted and incorporated by reference. Unless a
18 prior version of the incorporated material is otherwise specifically indicated, the materials
19 incorporated by reference cited herein include only those versions that were in effect as
20 of the most recent effective date of this Part 3 (August 2020December 2023), and not
21 later amendments or editions of the incorporated material.

22 3.1.4.4 Materials incorporated by reference are available for public inspection, and copies
23 (including certified copies) can be obtained at reasonable cost, during normal business
24 hours from the Colorado Department of Public Health and Environment, Hazardous
25 Materials and Waste Management Division, 4300 Cherry Creek Drive South, Denver,
26 Colorado 80246. Additionally,
27 <https://www.colorado.gov/cdphe/radregs><https://cdphe.colorado.gov/hm/radregs>
28 identifies where the incorporated federal and state regulations are available to the public
29 on the internet at no cost. A copy of the materials incorporated in this Part is available for
30 public inspection at the state publications depository and distribution center.

31 3.1.4.5 Availability from Source Agencies or Organizations.

32 (1) All federal agency regulations incorporated by reference herein are available at
33 no cost in the online edition of the Code of Federal Regulations (CFR) hosted by
34 the U.S. Government Printing Office, online at www.govinfo.gov
35 <https://www.govinfo.gov/app/collection/cfr/>.

36 (2) All state regulations incorporated by reference herein are available at no cost in
37 the online edition of the Code of Colorado Regulations (CCR) hosted by the
38 Colorado Secretary of State's Office, online at
39 <https://www.sos.state.co.us/CCR/RegisterHome.de>[https://www.sos.state.co.us](https://www.sos.state.co.us/CCR/Welcome.do)
40 [/CCR/Welcome.do](https://www.sos.state.co.us/CCR/Welcome.do).
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Commented [JSJ1]: Editorial note 1: All comments (such as this one) shown in the right side margin of this draft document are for information purposes only to assist the reader in understanding the proposed rule change during the review and comment process. These side margin notes are **not** part of the rule and all comments will be deleted prior to publication of the final rule by the Colorado Secretary of State.

Editorial note 2: Alignment and formatting corrections and minor typographical adjustments may be made in the rule and may not be specifically identified with a side margin comment.

Editorial note 3: To maintain agreement state status, and be consistent with statute, Colorado's radiation regulations must be compatible with federal regulations of the U.S. Nuclear Regulatory Commission (NRC).

Editorial note 4: This is not a complete rule. Some unaffected sections or provisions have been removed from the rule for brevity and are not shown in this draft. Unaffected sections/provisions are denoted with a " * * * " and remain as-is in the current rule with no changes. Some sections of the rule are shown unchanged in the draft rule for context and understanding of sections and provisions being updated.

Commented [JSJ2]: The stated adoption and effective dates are tentative and subject to change, pending Board of Health meeting schedule, final adoption of the rule by the Board, and the Colorado Register publication dates.

The anticipated dates are based on the annual rulemaking schedule (regulatory agenda) for the Department which may be found [online](#).

Commented [JSJ3]: Unnumbered section header added for clarity and consistency with other radiation control regulations.

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44 3.3.2 Exempt Quantities.

45 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
 46 the extent that such person receives, possesses, uses, transfers, owns, or acquires
 47 radioactive material in individual quantities each of which does not exceed the applicable
 48 quantity set forth in Schedule 3B.

49 **3.3.2.2** Any person who possesses radioactive material received or acquired under the general
 50 license formerly provided under 10 CFR **Part** 31.4 before September 25, 1971 is exempt
 51 from the requirements for a license set forth in this part to the extent that such person
 52 possesses, uses, transfers or owns such radioactive material.

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55 3.5.2 Any person who receives, possesses, uses or transfers source material in accordance with the
 56 general license in 3.5.1:

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58 **3.5.2.1** Is prohibited from administering source material, or the radiation therefrom, either
 59 externally or internally, to human beings except as may be authorized by the
 60 **Department, NRC, or an Agreement State** in a specific license.

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64 3.5.8 Depleted Uranium in Industrial Products and Devices.

65 3.5.8.1 A general license is hereby issued to receive, acquire, possess, use, or transfer, in
 66 accordance with the provisions of 3.5.8.2, 3.5.8.3, and 3.5.8.4, depleted uranium
 67 contained in industrial products or devices for the purpose of providing a concentrated
 68 mass in a small volume of the product or device.

69 **3.5.8.2** The general license in 3.5.8.1 applies only to industrial products or devices which have
 70 been manufactured either in accordance with a specific license issued to the
 71 manufacturer of the products or devices pursuant to 3.12.13 or in accordance with a
 72 specific license issued to the manufacturer by **the** NRC or an Agreement State which
 73 authorizes manufacture of the products or devices for distribution to persons generally
 74 licensed by **the** NRC or an Agreement State.

75 (1) Persons who receive, acquire, possess, or use depleted uranium pursuant to the
 76 general license established by 3.5.8.1 shall file Department Form R-52,
 77 "Registration Certificate - Use of Depleted Uranium Under General License", with
 78 the Department.

79 (a) The form shall be submitted within 30 days after the first receipt or
 80 acquisition of such depleted uranium.

81 (b) The general licensee shall furnish on Department Form R-52 the
 82 following information and such other information as may be required by
 83 that form:

84 (i) Name and address of the general licensee;

Commented [JSJ4]:

Add "Part" - for consistency with format of other radiation control regulations.

Commented [JSJ5]: This provision is updated to add clarification that the Department or another Agreement State may also allow the described use when authorized by a specific license. The current language may incorrectly limit such authorization to (only) the NRC.

Commented [JSJ6]:

Here and in subsequent sections of the rule, "by NRC" is modified to "by the NRC" for consistency with federal rule and [SSRCR Part C model rule \(2021\)](#).

- 85 (ii) A statement that the general licensee has developed and will
 86 maintain procedures designed to establish physical control over
 87 the depleted uranium described in 3.5.8.1 and designed to
 88 prevent transfer of such depleted uranium in any form, including
 89 metal scrap, to persons not authorized to receive the depleted
 90 uranium; and
- 91 (iii) Name and title, address, and telephone number of the individual
 92 duly authorized to act for and on behalf of the general licensee in
 93 supervising the procedures identified in 3.5.8.2(1)(b)(ii).
- 94 (2) The general licensee possessing or using depleted uranium under the general
 95 license established by 3.5.8.1 shall report in writing to the Department any
 96 changes in information furnished by him in previously furnished using
 97 Department Form R-52, "Registration Certificate - Use of Depleted Uranium
 98 Under General License". The report shall be submitted within 30 days after the
 99 effective date of such change.

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102 **3.6 General Licenses² - Radioactive Material Other Than Source Material.**

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

104 3.6.1 Reserved.

105 ³ Reserved

106 3.6.2 Reserved.

107 3.6.3 Reserved.

108 3.6.4 Certain Measuring, Gauging or Controlling Devices.

109 3.6.4.1 A general license is hereby issued to commercial and industrial firms and to research,
 110 educational and medical institutions, individuals in the conduct of their business, and
 111 State or local government agencies to receive, acquire, possess, use or transfer, in
 112 accordance with the provisions of 3.6.4.2, 3.6.4.3, and 3.6.4.4, radioactive material,
 113 excluding special nuclear material, contained in devices designed and manufactured for
 114 the purpose of detecting, measuring, gauging or controlling thickness, density, level,
 115 interface location, radiation, leakage, or qualitative or quantitative chemical composition,
 116 or for producing light or an ionized atmosphere.

117 3.6.4.2 The general license in 3.6.4.1 applies only to radioactive material contained in devices
 118 which have been:

119 (1) Manufactured or initially transferred and labeled for distribution to persons
 120 generally licensed in accordance with the specifications contained in a specific
 121 license issued by:

122 (a) The Department pursuant to 3.12.4 or

123 (b) ~~By The~~ NRC or an Agreement State⁴

124 ⁴ Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production
 125 require certain additional labeling thereon which is found in 21 CFR 179.21.

Commented [JSJ7]:

Wording change to make the rule gender neutral.

Commented [JSJ8]:

Sections 3.6.1 through 3.6.6 remain as is without changes. This section is shown in the draft rule for context and understanding only. There are no changes to this portion of the draft rule.

- 126 (2) Received from one of the specific licensees described in 3.6.4.2(1) or through a
127 transfer made under 3.6.4.3(8).
- 128 3.6.4.3 Any person who owns, receives, acquires, possesses, uses, owns, or transfers
129 radioactive material in a device pursuant to the general license in 3.6.4.1:
- 130 (1) Shall assure that all labels affixed to the device at the time of receipt, and bearing
131 a statement that removal of the label is prohibited, are maintained thereon and
132 shall comply with all instructions and precautions provided by such labels;
- 133 (2) Shall assure that the device is tested for leakage of radioactive material and
134 proper operation of the "on-off" mechanism and indicator, if any, at no longer
135 than 6-month intervals or at such other intervals as are specified in the label,
136 however;
- 137 (a) Devices containing only krypton need not be tested for leakage of
138 radioactive material; and
- 139 (b) Devices containing only tritium or not more than 3.7 MBq (100 µCi) of
140 other beta- and/or gamma-emitting material or 0.37 MBq (10 µCi) of
141 alpha-emitting material and devices held in storage in the original
142 shipping container prior to initial installation need not be tested for any
143 purpose.
- 144 (3) Shall assure that the tests required by 3.6.4.3(2) of this section and other testing,
145 installation, servicing, and removal from installation involving the radioactive
146 material, its shielding or containment, are performed:
- 147 (a) In accordance with the instructions provided by the labels; or
- 148 (b) By a person holding an applicable specific license from the Department,
149 NRC or an Agreement State to perform such activities;
- 150 (4) Shall maintain records showing compliance with the requirements of 3.6.4.3(2)
151 and 3.6.4.3(3).
- 152 (a) The records shall show the results of tests.
- 153 (b) The records also shall show the dates of performance of, and the names
154 of persons performing, testing, installation, servicing, and removal from
155 installation concerning the radioactive material, its shielding or
156 containment.
- 157 (c) Records of tests for leakage of radioactive material required by 3.6.4.3(2)
158 shall be maintained for 3 years after the next required leak test is
159 performed or until the sealed source is transferred or disposed of.
- 160 (d) Records of tests of the "on-off" mechanism and indicator required by
161 3.6.4.3(2) shall be maintained for 3 years after the next required test of
162 the "on-off" mechanism and indicator is performed or until the sealed
163 source is transferred or disposed of.
- 164 (e) Records which are required by 3.6.4.3(3) shall be maintained for a period
165 of 3 years from the date of the recorded event or until the device is
166 transferred or disposed of;

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- (5) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the "on-off" mechanism or indicator, or upon the detection of 185 Bq (0.005 μ Ci) or more removable radioactive material, shall immediately suspend operation of the device and shall:
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- (a) Not operate the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the Department, NRC or an Agreement State to repair such devices;
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- (b) Ensure that, if dispositioned, the device and any radioactive material from the device is disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device;
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- (c) Within 30 days, furnish to the Department a report containing a brief description of the event and the remedial action 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, 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 and shall obtain written approval from 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) Only by transfer to a specific licensee of the Department, NRC or an Agreement State whose specific license authorizes receipt of the device; and
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- (b) Within 30 days after transfer or export, shall furnish to the Department a report containing:
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- (i) Identification of the device by manufacturer's (or initial transferor's) name, model number and serial number;
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- (ii) The name, address and license number of the person receiving the device;
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- (iii) The date of the transfer;
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- (iv) The identity of the radionuclide(s) present and activity present, by assay or calculation;

- 208 (c) Shall obtain written Department approval before transferring the device
209 to any other specific licensee not specifically identified in 3.6.4.3(8).
210 However, a holder of a specific license may transfer a device for
211 possession and use under its own specific license without prior approval,
212 if, the holder:
- 213 (i) Verifies that the specific license authorizes the possession and
214 use, or applies for and obtains an amendment to the license
215 authorizing the possession and use;
- 216 (ii) Removes, alters, covers, or clearly and unambiguously
217 augments the existing label (otherwise required by 3.6.4.3(1) of
218 this part) so that the device is labeled in compliance with Part 4,
219 Section 4.30; however the manufacturer, model number, and
220 serial number must be retained;
- 221 (iii) Obtains the manufacturer's or initial transferor's information
222 concerning maintenance that would be applicable under the
223 specific license (such as leak testing procedures); and
- 224 (iv) Reports the transfer under 3.6.4.3(8)(b).
- 225 (9) Shall transfer the device to another general licensee only:
- 226 (a) Where the device remains in use at a particular location.
- 227 In such case the transferor shall give the transferee a copy of this
228 regulation and any safety documents identified in the label on the device
229 and within 30 days of the transfer, report to the Department the
230 manufacturer's (or initial transferor's) name and model number and serial
231 number of device transferred, the identity of the radionuclide(s) present
232 and assayed or calculated activity present, the transferee's name and
233 mailing address for the location of use, and the name, title, and phone
234 number of the responsible individual identified by the transferee in
235 accordance with 3.6.4.3(12) to have knowledge of and authority to take
236 actions to ensure compliance with the appropriate regulations and
237 requirements; or
- 238 (b) Where the device is held in storage by an intermediate person in the
239 original shipping container at its intended location of use prior to initial
240 use by a general licensee; and
- 241 (10) Shall comply with the provisions of 4.51 and 4.52 for reporting radiation incidents,
242 theft, or loss of licensed material, but shall be exempt from the other
243 requirements of Parts 4 and 10;
- 244 (11) Shall respond to written requests from the Department to provide information
245 relating to the general license within 30 calendar days of the date of the request,
246 or other time specified in the request.
- 247 (a) If the general licensee cannot provide the requested information within
248 the allotted time, it shall, within that same time period, request a longer
249 period to supply the information by providing the director of the
250 Hazardous Materials and Waste Management Division a written
251 justification for the request;

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- (12) Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements.
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- (a) The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements; this appointment does not relieve the general licensee of any of its responsibility in this regard;
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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, 3.7 MBq (0.1 mCi) of radium-226, or 37 MBq (1 mCi) of americium 241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described in 3.6.4.3(13)(b)(iv) of this section, represents a separate general licensee and requires a separate registration and fee.
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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.

- 294 (c) A general licensee holding devices meeting the criteria of 3.6.4.3(13) is
295 subject to the bankruptcy notification requirement in 3.15.5.
- 296 (d) Persons generally licensed by an Agreement State with respect to
297 devices meeting the criteria in paragraph 3.6.4.3(13) are not subject to
298 U.S. Nuclear Regulatory Commission registration requirements if the
299 devices are used in areas subject to NRC jurisdiction for a period less
300 than 180 days in any calendar year. The Commission will not request
301 registration information from such licensees.
- 302 (14) Shall report changes to the mailing address for the location of use (including
303 change in name of general licensee) to the director of the hazardous materials
304 and waste management division within 30 days of the effective date of the
305 change.
- 306 (a) For a portable device, a report of address change is only required for a
307 change in the device's primary place of storage.
- 308 (15) May not hold a device that is not in use for longer than 2 years.
- 309 (a) If a device with shutters is not being used, the shutter must be locked in
310 the closed position.
- 311 (b) The testing required by 3.6.4.3(2) need not be performed during the
312 period of storage only.
- 313 (c) However, when a device is put back into service or transferred to another
314 person, and has not been tested within the required test interval, the
315 device must be tested for leakage before use or transfer and the shutter
316 tested before use.
- 317 (d) A device kept in standby for future use is excluded from the two-year
318 time limit if the general licensee performs quarterly physical inventories
319 of the device while the device is in standby.
- 320 3.6.4.4 The general license in 3.6.4.1 does not authorize the manufacture of devices containing
321 radioactive material.
- 322 3.6.4.5 The general license provided in 3.6.4.1 is subject to the provisions of 1.4 through 1.9,
323 3.15, 3.22, 3.23 and Part 17.
- 324 3.6.5 Luminous Safety Devices for Aircraft.
- 325 3.6.5.1 A general license is hereby issued to receive, acquire, possess, and use tritium or
326 promethium-147 contained in luminous safety devices for use in aircraft, provided:
- 327 (1) Each device contains not more than 370 GBq (10 Ci) of tritium or 11.1 GBq (300
328 mCi) of promethium-147; and
- 329 (2) Each device has been manufactured, assembled or imported in accordance with
330 a specific license issued by the NRC or each device has been manufactured or
331 assembled in accordance with the specifications contained in a specific license
332 issued by the Department or any Agreement State to the manufacturer or
333 assembler of such device pursuant to licensing requirements equivalent to those
334 in Section 32.53 of 10 CFR Part 32.

335 3.6.5.2 Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to
 336 the general license in 3.6.5.1 are exempt from the requirements of Parts 4 and 10 except
 337 that they shall comply with the provisions of 4.51 and 4.52.

338 3.6.5.3 This general license does not authorize the manufacture, assembly, or repair of luminous
 339 safety devices containing tritium or promethium-147.

340 3.6.5.4 This general license does not authorize the ownership, receipt, acquisition, possession or
 341 use of promethium-147 contained in instrument dials.

342 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
 343 Part 17.

344 3.6.6 Ownership of Radioactive Material.

345 3.6.6.1 A general license is hereby issued to own radioactive material without regard to quantity.

346 3.6.6.2 Notwithstanding any other provisions of this part, this general license does not authorize
 347 the manufacture, production, transfer, receipt, possession or use of radioactive material.

348 3.6.7 Calibration and Reference Sources.

349 **3.6.7.1** A general license is hereby issued to those persons listed below to own, receive, acquire,
 350 possess, use, and transfer, in accordance with the provisions of 3.6.7.4 and 3.6.7.5,
 351 americium-241 in the form of calibration or reference sources:

352 (1) Any person who holds a specific license issued by the Department which
 353 authorizes ~~him to receive~~ receipt, ~~possess~~ possession, use, and transfer of
 354 radioactive material; and

355 (2) Any person who holds a specific license issued by **the** NRC which authorizes
 356 ~~him to receive~~ receipt, ~~possesses~~ possession, use, and transfer of special nuclear
 357 material.

358 **3.6.7.2** A general license is hereby issued to **own**, receive, possess, use, and transfer plutonium
 359 in the form of calibration or reference sources in accordance with the provisions of 3.6.7.4
 360 and 3.6.7.5 to any person who holds a specific license issued by the Department which
 361 authorizes ~~him~~ **the licensee** to receive, possess, use, and transfer radioactive material.

362 **3.6.7.3** A general license is hereby issued to own, receive, possess, use, and transfer radium
 363 226 in the form of calibration or reference sources in accordance with the provisions of
 364 3.6.7.4 and 3.6.7.5 to any person who holds a specific license issued by the Department
 365 which authorizes ~~him~~ **the licensee** to receive, possess, use, and transfer radioactive
 366 material.

367 **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
 368 sources which have been manufactured **or initially transferred** in accordance with the
 369 specifications contained in a specific license issued to the manufacturer or importer of the
 370 sources by **the** NRC pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10
 371 CFR Part 70 (~~January 1, 2015~~) or which have been manufactured in accordance with the
 372 specifications contained in a specific license issued to the manufacturer by the
 373 Department or any Agreement State pursuant to licensing requirements equivalent to
 374 those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70.

Commented [JSJ9]:

Minor changes are proposed to make the rule consistent with federal rule language and to make the wording gender neutral.

[10 CFR Part 31.8\(a\)](#)
[NRC Compatibility D](#)

Commented [JSJ10]: Minor changes are proposed to make the rule consistent with the phrasing of the CRCPD Part C model rule (Aug 2021) language and to make the wording gender neutral.

[CRCPD Model rule Part C, Section C.22h.ii.](#)

Commented [JSJ11]: Minor changes are proposed to make the rule consistent with the phrasing of the CRCPD Part C model rule (Aug 2021) language and to make the wording gender neutral.

[CRCPD Model rule Part C, Section C.22h.iii.](#)

Commented [JSJ12]:

Minor changes are proposed to make the rule consistent with federal rule language.

[10 CFR Part 31.8\(b\)](#)
[NRC Compatibility D](#)

375 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
 376 provisions of 1.4 through 1.9, 3.15, 3.22, 3.23 and 3.24, and Parts 4 and 10. In addition,
 377 persons who own, receive, acquire, possess, use, or transfer one or more calibration or
 378 reference sources pursuant to these general licenses, shall:

- 379 (1) Not possess at any one time, at any one location of storage or use, more than
 380 185 kBq (5 μ Ci) of americium-241, 185 kBq (5 μ Ci) of plutonium, or 185 kBq (5
 381 μ Ci) of radium-226 in such sources;
- 382 (2) Not receive, possess, use, or transfer such source unless the source, or the
 383 storage container, bears a label which includes one of the following statements,
 384 as appropriate, or a substantially similar statement which contains the
 385 information called for in one of the following statements, as appropriate:
- 386 (a) The receipt, possession, use and transfer of this source, Model ____,
 387 Serial No. __ are subject to a general license and the regulations of the
 388 U.S. Nuclear Regulatory Commission or an Agreement State. Do not
 389 remove this label.

390 CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS
 391 (AMERICIUM-241) (PLUTONIUM) (RADIUM-226).⁵ DO NOT TOUCH
 392 RADIOACTIVE PORTION OF THIS SOURCE.

393 ⁵ Showing only the name of the appropriate material.

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 Name of manufacturer or importer

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- 396 (3) Not transfer, abandon, or dispose of such source except by transfer to a person
 397 authorized by a license from the Department, NRC or an Agreement State to
 398 receive the source;
- 399 (4) Store such source, except when the source is being used, in a closed container
 400 adequately designed and constructed to contain americium-241, plutonium, or
 401 radium-226 which might otherwise escape during storage; and
- 402 (5) Not use such source for any purpose other than the calibration of radiation
 403 detectors or the standardization of other sources.

404 3.6.7.6 These general licenses do not authorize the manufacture, import, or export of
 405 calibration or reference sources containing americium-241, plutonium or radium-226.

406 3.6.8 ~~Reserved.~~ General license for certain items and self-luminous products containing radium-
 407 226.

408 3.6.8.1 A general license is hereby issued to any person to acquire, receive, possess, use,
 409 or transfer, in accordance with the provisions of 3.6.8.2 through 3.6.8.4.,
 410 radium-226 contained in the following products manufactured prior to November
 411 30, 2007.

- 412 (1) Antiquities originally intended for use by the general public.

413 For the purposes of 3.6.8.1(1), antiquities mean products originally
 414 intended for use by the general public and distributed in the late 19th and
 415 early 20th centuries, such as radium emanator jars, revigators, radium
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 417
 418
 419
 420
 421
 422

Commented [JSJ13]:

Language added for consistency with [10 CFR Part 31.8\(d\) and 31.8\(e\)](#).

NRC Compatibility D

Commented [JSJ14]:

This section is added for consistency with [10 CFR Part 31.12](#). The proposed section was omitted from the Part 3 rule during prior rule amendments.

The proposed new section will add a general license for low risk items – primarily antiquities - that contain radium-226 in small quantities. The general license (formally) allows individuals to receive and use specific items or products containing radium-226 (a radioactive material) that were manufactured prior to November 30, 2007. The general license for these items/products is implicit in the regulations and does not require application or registration with the Department.

NOTE: For additional background information regarding antiquities potentially containing radioactive materials see the NRC radium web page (<https://www.nrc.gov/materials/radium.html>) or the historical items catalog report at <https://www.nrc.gov/docs/ML1008/ML100840118.pdf>

NRC Compatibility C

423 water jars, radon generators, refrigerator cards, radium bath salts, and
424 healing pads.

425
426 (2) Intact timepieces containing greater than 0.037 MBq (1 μ Ci), nonintact
427 timepieces, and timepiece hands and dials no longer installed in
428 timepieces.

429
430 (3) Luminous items installed in air, marine, or land vehicles.

431
432 (4) All other luminous products, provided that no more than 100 items are
433 used or stored at the same location at any one time.

434
435 (5) Small radium sources containing no more than 0.037 MBq (1 μ Ci) of
436 radium-226.

437
438 For the purposes of 3.6.8.1(5), "small radium sources" means discrete
439 survey instrument check sources, sources contained in radiation
440 measuring instruments, sources used in educational demonstrations (such
441 as cloud chambers and spinthariscopes), electron tubes, lightning rods,
442 ionization sources, static eliminators, or as designated by the NRC.

443
444 **3.6.8.2 Persons who acquire, receive, possess, use, or transfer radioactive material under
445 the general license issued in 3.6.8.1 are exempt from the provisions of Parts 4 and 10 of
446 these regulations, to the extent that the receipt, possession, use, or transfer of radioactive
447 material is within the terms of the general license; provided, however, that this exemption
448 shall not be deemed to apply to any such person specifically licensed under this Part.**

449
450 **3.6.8.3 Any person who acquires, receives, possesses, uses, or transfers radioactive
451 material in accordance with the general license in 3.6.8.1 shall:**

452
453 (1) Notify the Department should there be any indication of possible damage to the
454 product so that it appears it could result in a loss of the radioactive material. A
455 report containing a brief description of the event, and the remedial action
456 taken, must be furnished to the Department within 30 days.

457
458 (2) Not abandon products containing radium-226. The product, and any
459 radioactive material from the product, may only be disposed of according to
460 Part 4, Section 4.39.2 of these regulations or by transfer to a person authorized
461 by a specific license to receive the radium-226 in the product or as otherwise
462 approved by the NRC or an Agreement State.

463
464 (3) Not export products containing radium-226 except in accordance with 10 CFR
465 Part 110.

466
467 (4) Dispose of products containing radium-226 at a disposal facility authorized to
468 dispose of radioactive material in accordance with any Federal or State solid or
469 hazardous waste law, including the Solid Waste Disposal Act, as authorized
470 under the Energy Policy Act of 2005, by transfer to a person authorized to
471 receive radium-226 by a specific license issued under this Part, or equivalent
472 regulations of the NRC or an Agreement State, or as otherwise approved by the
473 NRC or an Agreement State.

474
475 (5) Respond to written requests from the Department to provide information
476 relating to the general license within 30 calendar days of the date of the
477 request, or other time specified in the request. If the general licensee cannot
478 provide the requested information within the allotted time, it shall, within that

479 same time period, request a longer period to supply the information by
480 providing the Department, a written justification for the request.

481 **3.6.8.4. The general license in 3.6.8.1 does not authorize the manufacture, assembly,
482 disassembly, repair, or import of products containing radium-226, except that
483 timepieces may be disassembled and repaired.**
484

485 3.6.9 General License for Use of Radioactive Material for Certain *In Vitro* Clinical or Laboratory
486 Testing.⁶

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

489 3.6.9.1 A general license is hereby issued to any physician, veterinarian, clinical laboratory or
490 hospital to receive, acquire, possess, transfer or use, for any of the following stated tests,
491 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
492 following radioactive materials in prepackaged units for use in *in vitro* clinical or
493 laboratory tests not involving internal or external administration of radioactive material, or
494 the radiation therefrom, to human beings or animals:

- 495 (1) Carbon-14, in units not exceeding 370 kBq (10 µCi) each;
- 496 (2) Cobalt-57, in units not exceeding 370 kBq (10 µCi) each;
- 497 (3) Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 µCi) each;
- 498 (4) Iodine-125, in units not exceeding 370 kBq (10 µCi) each;
- 499 (5) Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85
500 kBq (0.05 µCi) of iodine-129 and 185 Bq (0.005 µCi) of americium-241 each;
- 501 (6) Iodine-131, in units not exceeding 370 kBq (10 µCi) each;
- 502 (7) Iron-59, in units not exceeding 740 kBq (20 µCi) each; or
- 503 (8) Selenium-75, in units not exceeding 370 kBq (10 µCi) each.

504 3.6.9.2 No person shall receive, acquire, possess, use or transfer radioactive material pursuant
505 to the general license established by 3.6.9.1 until the person has filed Department Form
506 R-27, "Certificate - *In Vitro* Testing with Radioactive Material Under General License",
507 with the Department and received from the Department a validated copy of Department
508 Form R-27 with certification number assigned. The physician, veterinarian, clinical
509 laboratory or hospital shall furnish on Department Form R-27 the following information
510 and such other information as may be required by that form:

- 511 (1) Name and address of the physician, veterinarian, clinical laboratory or hospital;
- 512 (2) The location of use; and
- 513 (3) A statement that the physician, veterinarian, clinical laboratory or hospital has
514 appropriate radiation measuring instruments to carry out *in vitro* clinical or
515 laboratory tests with radioactive material as authorized under the general license
516 in 3.6.9.1 and that such tests will be performed only by personnel competent in
517 the use of such instruments and in the handling of the radioactive material.

518 3.6.9.3 A person who receives, acquires, possesses or uses radioactive material pursuant to the
519 general license established by 3.6.9.1 shall comply with the following requirements.

520

- 521 (1) The general licensee shall not possess at any one time, pursuant to the general
522 license in 3.6.9.1, at any one location of storage or use, a total amount of iodine
523 125, iodine 131, selenium 75, iron 59, and/or cobalt 57 in excess of 7.4 MBq (200
524 μ Ci).
- 525 (2) The general licensee shall store the radioactive material, until used, in the
526 original shipping container or in a container providing equivalent radiation
527 protection.
- 528 (3) The general licensee shall use the radioactive material only for the uses
529 authorized by 3.6.9.1.
- 530 (4) The general licensee shall not transfer the radioactive material to a person who is
531 not authorized to receive it pursuant to a license issued by the Department, NRC
532 or any Agreement State nor transfer the radioactive material in any manner other
533 than in the unopened, labeled shipping container as received from the supplier.
- 534 (5) The general licensee shall dispose of the Mock Iodine 125 reference or
535 calibration sources described in 3.6.9.1(5) as required by 4.33.

536 3.6.9.4 The general licensee shall not receive, acquire, possess, or use radioactive material
537 pursuant to 3.6.9.1:

- 538 (1) Except as prepackaged units which are labeled in accordance with the provisions
539 of an applicable specific license issued pursuant to 3.12.8 or in accordance with
540 the provisions of a specific license issued by the NRC or any Agreement State
541 which authorizes the manufacture and distribution of iodine-125, iodine-131,
542 carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-
543 125 to persons generally licensed under 3.6.9 or its equivalent; and
- 544 (2) Unless one of the following statements, as appropriate, or a substantially similar
545 statement which contains the information called for in one of the following
546 statements, appears on a label affixed to each prepackaged unit or appears in a
547 leaflet or brochure which accompanies the package:
- 548 (a) This radioactive material shall be received, acquired, possessed, and
549 used only by physicians, veterinarians, clinical laboratories or hospitals
550 and only for *in vitro* clinical or laboratory tests not involving internal or
551 external administration of the material, or the radiation therefrom, to
552 human beings or animals. Its receipt, acquisition, possession, use, and
553 transfer are subject to the regulations and a general license of the U.S.
554 Nuclear Regulatory Commission or an Agreement State.

555

Name of manufacturer

557 **3.6.9.5** The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive
558 material under the general license of 3.6.9.1 shall report in writing to the Department, any
559 changes in the information ~~furnished by him~~ **previously furnished using** the

Commented [JSJ15]: Wording change to make the rule gender neutral.

560 "Certificate - *In Vitro* Testing with Radioactive Material Under General License",
561 Department Form R-27. The report shall be furnished within 30 days after the effective
562 date of such change.

563 * * *
564

565 **3.8.9** Except as provided in 3.8.9.3, 3.8.9.4, and 3.8.9.5, an application for a specific license to use
566 radioactive material in the form of a sealed source or in a device that contains the sealed source
567 must either:

Commented [JSJ16]:
Add "Part" - for consistency with format of other radiation control regulations.

568 3.8.9.1 Identify the source or device by manufacturer and model number as registered with the
569 NRC under 10 CFR **Part** 32.210 or with an Agreement State, or for a source or a device
570 containing radium-226 or accelerator produced radioactive material with an Agreement
571 State under provisions comparable to 10 CFR **Part** 32.210; or

572 3.8.9.2 Contain the information identified in 3.12.14.3; or

573 3.8.9.3 For sources or devices manufactured before October 23, 2012 that are not registered
574 with the NRC under 10 CFR **Part** 32.210 or with an Agreement State, and for which the
575 applicant is unable to provide all categories of information specified in 3.12.14.3, the
576 application must include:

577 * * *
578

579 **3.8.10** An application from a medical facility, educational institution, or Federal facility to produce
580 Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees
581 in its consortium authorized for medical use under Part 7 of these regulations or equivalent
582 Agreement State requirements shall include:

Commented [JSJ17]: Section 3.8.10 formatted for alignment.

There are no changes to the text or requirements of this section.

583 3.8.10.1 A request for authorization for the production of PET radionuclides or evidence of
584 an existing license issued under this Part or Agreement State requirements for a
585 PET radionuclide production facility within its consortium from which it receives
586 PET radionuclides.

587 3.8.10.2 Evidence that the applicant is qualified to produce radioactive drugs for medical
588 use by meeting one of the criteria in 3.12.10.1(2).

589 3.8.10.3 Identification of individual(s) authorized to prepare the PET radioactive drugs if
590 the applicant is a pharmacy, and documentation that each individual meets the
591 requirements of an authorized nuclear pharmacist as specified in 3.12.10.2(2).

592 3.8.10.4 Information identified in 3.12.10.1(3) on the PET drugs to be noncommercially
593 transferred to members of its consortium.

594 * * *
595

596 **3.9.6.3** Waste collectors and waste processors, as defined in Part 4, Appendix D, shall establish
597 ~~ana~~ Department-approved decommissioning funding plan to assure the availability of
598 funds for decommissioning activities conducted over the life of the licensed facility.

Commented [JSJ18]: Grammar correction.

599 * * *
600

601 **3.12** **Special Requirements for a Specific License to Manufacture, Assemble, Repair, or**
602 **Distribute Commodities, Products, or Devices which Contain Radioactive Material.**

Commented [JSJ19]:
Add "Part" - for consistency with format of other radiation control regulations.

603 3.12.1 A licensee authorized to introduce radioactive material into a product or material owned by or in
 604 the possession of the licensee or another to be transferred to persons exempt under 3.3.1.1 shall
 605 meet the requirements of 10 CFR **Part** 32.11 and any other applicable NRC requirement.

606 3.12.2 No person may introduce byproduct material into a product or material knowing or having reason
 607 to believe that it will be transferred to persons exempted pursuant to 3.3.2, under 10 CFR **Part**
 608 30.14 or equivalent regulations of an Agreement State, except in accordance with a license
 609 issued under 10 CFR **Part** 32.⁸

610 ⁸ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or
 611 other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are
 612 exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C.
 613 20555.

614 3.12.2.3 Each person licensed under 3.12.2 shall maintain records identifying, by name
 615 and address, each person to whom radioactive material is transferred for use under
 616 3.3.2, and stating the kinds and quantities of radioactive material transferred. An annual
 617 summary report stating the total quantity of each radionuclide transferred under the
 618 specific license shall be filed with the Department. Each report shall cover the year
 619 ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive
 620 material have been made pursuant to 3.12.2 during the reporting period, the report shall
 621 so indicate.
 622
 623 * * *

624 3.12.10 Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs for
 625 Medical Use.

626 3.12.10.1 An application for a specific license to manufacture, prepare, or transfer for
 627 commercial distribution radioactive drugs containing radioactive material for use by
 628 persons authorized under Part 7 will be approved if:

- 629 (1) The applicant satisfies the general requirements specified in 3.9;
- 630 (2) The applicant submits evidence that the applicant is at least one of the following:

- 631 (a) Registered or licensed with the U.S. Food and Drug Administration
 632 (FDA) as the owner or operator of a drug establishment that engages in
 633 the manufacture, preparation, propagation, compounding, or processing
 634 of a drug under 21 CFR Part ~~207.20(a)~~207.17(a);
 635
 636
 637
 638 * * *

639 3.13.2 In proceeding under the third party agreement, the Department shall carry out the following
 640 practices:

- 641 3.13.2.1 Such contractor shall be chosen solely by the Department.
- 642 3.13.2.2 The Department shall manage the contract.
- 643 3.13.2.3 The consultant shall be selected based on the consultant's ability relevant and
 644 applicable work experience and an absence of conflict of interest. Third party
 645 contractors will be required to execute a disclosure statement signifying they
 646 have no financial or other conflicting interest in the outcome of the project.

Commented [JSJ20]:
 A cross-reference is corrected based on a recent [August 2023 change to federal rule \(10 CFR Part 32\)](#). The current cross-reference to 207.20 does not exist in federal rule. This does not change the intent of the rule or requirements.

NRC Compatibility B.
[NRC RATS 2023-1](#)

Commented [JSJ21]: Section 3.13.2 formatted for alignment.

There are no changes to the text or requirements of this section.

647 3.13.2.4 The Department shall specify the information to be developed and supervise the
648 gathering, analysis and presentation of the information.

649 3.13.2.5 The Department shall have sole authority for approval and modification of the
650 statement, analysis, and conclusions included in third party's report.
651
652

* * *

653 3.14.3 Whenever the Department denies an application for a new license or a license renewal, the
654 Department will notify the applicant in writing stating the grounds for denial

Commented [JSJ22]: Section 3.14.3 formatted for alignment.

655 3.14.3.1 Upon denial, the applicant may request a hearing pursuant to Sections 24-4-104
656 and 24-4-105, CRS.
657
658

There are no changes to the text or requirements of this section.

* * *

659 **3.17 Renewal of Licenses.**

660 3.17.1 Applications for renewal of specific licenses shall be filed in accordance with 3.8.

661 3.17.2 In any case in which a licensee, not less than 30 days prior to expiration of ~~his~~the existing
662 license, has filed an application in proper form for renewal or for a new license authorizing the
663 same activities, such existing license shall not expire until final action by the Department.
664
665

Commented [JSJ23]:
Wording is modified to make the rule more gender neutral.

* * *

666 **TRANSFER OF MATERIALS**

667 **3.22 Transfer of Material.**

668 3.22.1 No licensee shall transfer radioactive material except as authorized pursuant to 3.22.

669 3.22.2 Except as otherwise provided in ~~his~~the license and subject to the provisions of 3.22.3 and 3.22.4,
670 any licensee may transfer radioactive material:
671
672

Commented [JSJ24]:
Wording is modified to make the rule more gender neutral.

* * *

673 **PART 3, SCHEDULE 3C: UNIMPORTANT QUANTITIES OF SOURCE MATERIAL AND EXEMPT**
674 **ITEMS (3.2)**

Commented [JSJ25]: Prior to final publication, ensure Schedule 3C begins at the top of the page.

675 3C Any person is exempt from the requirements for a license set forth in section 62 of the Atomic
676 Energy Act and from the regulations in this part 3, and parts 4 and 10, to the extent that such
677 person receives, possesses, uses, or transfers:
678
679

* * *

680 3C.10 No person may initially transfer for sale or distribution a product containing source material to
681 persons exempt under 3C.1 through 3C.10, or equivalent regulations of the NRC or an
682 Agreement State, unless authorized by a license issued ~~by NRC~~ under 10 CFR Part 40.52 **by the**
683 **NRC** to initially transfer such products for sale or distribution.

Commented [JSJ26]:
Minor wording updates for consistency and alignment with wording of [10 CFR Part 40.13\(c\)\(10\)\(ii\)](#) and [SSRCR Part C model rule \(2021\)](#) Section C.3.c.ix.

684 3C.10.1 Persons authorized to manufacture, process, or produce these materials or products
685 containing source material by **the Department**, an Agreement State, and persons who
686 import finished products or parts, for sale or distribution **must be authorized by a**

687 license issued under 10 CFR Part 40.52 by the NRC for distribution only and are
 688 exempt from the requirements of parts 4, ~~and part~~ 10, and 3.9.1 and 3.9.2.

689 **3C.11** Except for persons who apply radioactive material to, or persons who incorporate radioactive
 690 material into, the following products, any person is exempt from these regulations to the extent
 691 that the person receives, possesses, uses, transfers, owns, or acquires the following products¹⁶:

Commented [JSJ27]:
 Section 3C.11 is formatted for alignment of text.

692 ¹⁶ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or
 693 other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are
 694 exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C.
 695 20555.

696 3C.11.1 Timepieces or hands or dials containing not more than the following specified
 697 quantities of radioactive material and not exceeding the following specified
 698 radiation dose rate:

699 3C.11.1.1 925 MBq (25 mCi) of tritium per timepiece.

700 3C.11.1.2 185 MBq (5 mCi) of tritium per hand.

701 3C.11.1.3 555 MBq (15 mCi) of tritium per dial (bezels when used shall be
 702 considered as part of the dial).

703 3C.11.1.4 3.7 MBq (100 µCi) of promethium-147 per watch or 7.4 MBq (200 µCi) of
 704 promethium-147 per any other timepiece.

705 3C.11.1.5 0.74 MBq (20 µCi) of promethium-147 per watch hand or 1.48 MBq (40
 706 µCi of promethium-147 per other timepiece hand.

707 3C.11.1.6 2.22 MBq (60 µCi) of promethium-147 per watch dial or 4.44 MBq (120
 708 µCi) of promethium-147 per other timepiece dial (bezels when used shall
 709 be considered as part of the dial).

710 3C.11.1.7 The radiation dose rate from hands and dials containing promethium-147
 711 will not exceed, when measured through 50 milligrams per square
 712 centimeter of absorber:

713 (1) For wristwatches, 1 µGy (0.1 mrad) per hour at 10 centimeters from any
 714 surface.

715 (2) For pocket watches, 1 µGy (0.1 mrad) per hour at 1 centimeter from any
 716 surface.

717 (3) For any other timepiece, 2 µGy (0.2 mrad) per hour at 10 centimeters
 718 from any surface.

719 **3C.11.1.8** 37 kBq (1 µCi) of radium-226 per timepiece in **intact** timepieces
 720 **manufactured prior to November 30, 2007**~~acquired prior to the~~
 721 ~~effective date of this regulation;~~

Commented [JSJ28]:
 Provision 3C.11.1.8 is revised for consistency with
 current federal rule in [10 CFR Part 30.15\(a\)\(1\)\(viii\)](#).
 The November 30, 2007 date is used in federal rule.

* * *

724 3C.13 Gas and aerosol detectors containing radioactive material.

725 3C.13.1 Except for persons who manufacture, process, produce, or initially transfer for sale or
 726 distribution gas and aerosol detectors containing radioactive material, any person is

Additionally, rule language is modified to clarify that the
 exemption for timepieces containing up to 1 uCi of
 radium-226 applies only to those timepieces that are
 intact rather than all timepieces. NRC reports have
 indicated that most timepieces typically contain less
 than 1 uCi.

727 exempt from the requirements for a license set forth in the Act and from the regulations in
 728 3, 4, 5, 7, 10, 16, and 19 to the extent that such person receives, possesses, uses,
 729 transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to
 730 protect health, safety, or property and manufactured, processed, produced, or initially
 731 transferred in accordance with a specific license issued by **the NRC**¹⁸ pursuant to
 732 section 32.26 of 10 CFR Part 32, which license authorizes the initial transfer of the
 733 detectors to persons who are exempt from regulatory requirements. This exemption also
 734 covers gas and aerosol detectors manufactured or distributed before November 30,
 735 2007, in accordance with a specific license issued by **the NRC** or an Agreement State
 736 under comparable provisions to 10 CFR Part 32.26 authorizing distribution to persons
 737 exempt from regulatory requirements.

Commented [JSJ29]:
 Due to an error at the time of publication of the final rule during a 2020 amendment, the "18" is displayed as standard font in the current rule rather than a superscript. For final publication of this amended rule in 2023, "18" should be shown as a superscript as the redline indicates to properly reference the footnote found on the next page.

738 ¹⁸ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or
 739 other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are
 740 exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C.
 741 20555.
 742 * * *

743 **3C.15** Certain industrial devices

Commented [JSJ30]:
 Minor changes are incorporated to this section for consistency in formatting with other regulatory parts.

744 3C.15.1 Except for persons who manufacture, process, produce, or initially transfer for sale or
 745 distribution industrial devices containing byproduct material designed and manufactured
 746 for the purpose of detecting, measuring, gauging or controlling thickness, density, level,
 747 interface location, radiation, leakage, or qualitative or quantitative chemical composition,
 748 or for producing an ionized atmosphere, any person is exempt from the requirements for
 749 a license set forth in the Act and from the regulations in parts 3, 4, 5, 7, 10, 16, and 19 to
 750 the extent that such person receives, possesses, uses, transfers, owns, or acquires
 751 byproduct material, in these certain detecting, measuring, gauging, or controlling devices
 752 and certain devices for producing an ionized atmosphere, and manufactured, processed,
 753 produced, or initially transferred in accordance with a specific license issued by **the NRC**
 754 under 10 CFR **Part** 32.30, which license authorizes the initial transfer of the device for
 755 use under this section. This exemption does not cover sources not incorporated into a
 756 device, such as calibration and reference sources.

757 3C.15.2 Any person who desires to manufacture, process, produce, or initially transfer for sale or
 758 distribution industrial devices containing byproduct material for use under 3C.15.1, should
 759 apply for an NRC license under 10 CFR **Part** 32.30 and for a certificate of registration in
 760 accordance with 10 CFR **Part** 32.210.
 761 * * *
 762

763 **3F.2** Financial Test

764 **3F.2.1** To pass the financial test, the parent company must meet the criteria of either ~~paragraph~~
 765 ~~A.43F.2.1.1~~ or ~~A.23F.2.1.2~~ of this Appendix:

Commented [JSJ31]:
 The proposed change corrects a cross reference error that occurred during a past revision to Appendix 3F. A prior amendment to Part 3 revised the format and numbering of Appendix 3F, but the indicated changes in 3F.2.1 were not included at that time.

 This does not change the requirements or intent of the rule as 3F.2.1.1 and 3F.2.1.2 are equivalent to paragraphs A.1, and A.2 in the prior rule, respectively.

- 766 3F.2.1.1 The parent company must have:
- 767 (1) Two of the following three ratios: a ratio of total liabilities to net worth less than
 768 2.0; a ratio of the sum of net income plus depreciation, depletion, and
 769 amortization to total liabilities greater than 0.1; and ratio of current assets to
 770 current liabilities greater than 1.5; and
 - 771 (2) Net working capital and tangible net worth each at least ten times the current
 772 decommissioning cost estimates (or prescribed amount if a certification is used);
 773 and

- 774 (3) Tangible net worth of at least \$10 million; and
- 775 (4) Assets located in the United States amounting to at least 90 percent of total
- 776 assets or at least ten times the current decommissioning cost estimates (or
- 777 prescribed amount if a certification is used).
- 778 3F.2.1.2 The parent company must have:
- 779 (1) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as
- 780 issued by Standard and Poor's or AAA, AA, A, or BAA as issued by Moody's; and
- 781 (2) Tangible net worth at least ten times the current decommissioning cost estimate
- 782 (or prescribed amount if a certification is used); and
- 783 (3) Tangible net worth of at least \$10 million; and
- 784 (4) Assets located in the United States amounting to at least 90 percent of total
- 785 assets or at least ten times the current decommissioning cost estimates (or
- 786 prescribed amount if certification is used).

787 3F.2.2 The parent company's independent certified public accountant must have compared the data
 788 used by the parent company in the financial test, which is derived from independently audited,
 789 year end financial statements for the latest fiscal year, with the amounts in such financial
 790 statement. In connection with that procedure the licensee shall inform the Department within 90
 791 days of any matters coming to the auditor's attention which cause the auditor to believe that the
 792 data specified in the financial test should be adjusted and that the company no longer passes the
 793 test.

794 3F.2.3 Follow-up

795 3F.2.3.1. After the initial financial test, the parent company must repeat the passage of the
 796 test within 90 days after the close of each succeeding fiscal year.

797 3F.2.3.2 If the parent company no longer meets the requirements of Paragraph A3F.2.1 of
 798 this section, the licensee must send notice to the Department of intent to
 799 establish alternate financial assurance as specified in the Department's
 800 regulations.

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

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

806 * * *

808 **PART 3, APPENDIX 3G: CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-**
 809 **GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR**
 810 **DECOMMISSIONING**

811 **3G.1 Introduction**

812 3G.1.1 An applicant or licensee may provide reasonable assurance of the availability of funds for
 813 decommissioning, based on furnishing its own guarantee that funds will be available for

Commented [JSJ32]:
 The proposed change corrects a cross reference error that occurred during a past revision to Appendix 3F. A prior amendment to Part 3 revised the format and numbering of Appendix 3F, but the indicated change in 3F.2.3.2 was not included at that time. Section 3F.2.1 is equivalent to Paragraph A, in the prior rule.

This does not change the requirements or intent of the rule.

Section 3F.2.3 has been formatted to align text.

Commented [JSJ33]: Prior to final publication, ensure Appendix 3G begins at the top of a new page.

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 The proposed change corrects a cross reference error that occurred during a past revision to Appendix 3G. A prior amendment to Part 3 revised the format and numbering of Appendix 3G (formerly Appendix 3B), but the indicated change in 3G.1.1 was not included at that time. 3G.2 and 3G.3 are equivalent to Section II and Section III, respectively, in the prior rule.

This change does not change the requirements or intent of the rule.

Section 3G.1.1 has been formatted to align text.

814 decommissioning costs, and on a demonstration that the company passes the financial test
815 ~~Section III~~ **3G.2** of this Appendix.

816 3G.1.1.1 The terms of this self-guarantee are in ~~Section III~~ **3G.3** of this Appendix.

817 3G.1.1.2 This Appendix establishes criteria for passing the financial test for the self-
818 guarantee and establishes the terms for a self-guarantee.
819

820 **3G.2 Financial Test**

821 3G.2.1 To pass the financial test, a company must meet the all of the following criteria:

822 * * *
823

824 **3G.3 Company Self-Guarantee**

825 3G.3.1 The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

826 * * *
827

828 **[NO FURTHER CHANGES TO THE RULE BEYOND THIS POINT]**

Commented [JSJ35]:
3G.2 is provided for reference only. There are no changes to 3G.2.

Commented [JSJ36]:
3G.3 is provided for reference only. There are no changes to 3G.3.