

**COLORADO**Department of Public  
Health & Environment

To: Members of the State Board of Health

From: James H. Grice, Radiation Program Manager, Hazardous Materials and Waste Management Division  
James S. Jarvis, Regulatory Lead, Hazardous Materials and Waste Management Division

Through: Tracie M. White, Division Director *TMCW*

Date: **October 18, 2023**

Subject: **Rulemaking Hearing for 6 CCR 1007-1 Part 3, Licensing of radioactive materials**

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The Division is proposing changes to Part 3 of the radiation control regulations to incorporate general license requirements for antiquity items containing radium-226. These requirements were omitted during past rule changes. The proposed change will make the rule consistent with final regulations of the U.S. Nuclear Regulatory Commission (NRC) in 10 CFR Part 30, and Part 31. **A recently identified cross-reference correction in federal rule is also incorporated into the proposed Part 3 changes.** Consistent with its agreement with the NRC, Colorado must maintain its radiation regulations compatible with those of NRC and therefore is proposing updates Colorado rules.

Radium-226 is a naturally occurring radioactive material that was discovered in the late 1800's. Believed, at that time, to provide healthful benefits, refined radium was added to food products, consumer items, luminescent paints, and was used in military applications beginning in the early 1900's. Some of these radium containing items remain of interest to collectors and museums, but can present a radiological hazard if mishandled or when there are large numbers of items stored in one location. The proposed rule incorporates a "general license" that allows continued use, possession and transfer of these radium-226 items, but places limitations on storage and disposal, and compels the possessor to provide additional information if requested by the department. Minor technical corrections, rewording and formatting changes are also proposed for consistency with Colorado and federal rules. Amendment of this regulation will help ensure Colorado is consistent with the national framework for regulation of radioactive materials.

We did not receive any written comments from stakeholders regarding the proposed changes to Part 3.

Since the rule changes impact select areas of the rule, only those impacted sections are included in the proposed draft. Throughout the rule, new text appears as red bold text while deleted current text of this regulation is shown in strikethrough. **Changes since the request for rulemaking in July are highlighted in yellow, consistent with Board practice.**

**The Radiation Program respectfully requests that the Board of Health adopt the proposed changes for this rule.**

DRAFT STATEMENT OF BASIS AND PURPOSE  
AND SPECIFIC STATUTORY AUTHORITY  
for Amendments to  
6 CCR 1007-1 Part 3, Licensing of radioactive materials

Basis and Purpose.

Understanding the regulatory approach used in the regulation of radioactive materials may help with understanding the proposed Part 3 changes. As described below, the regulation and control of radioactive materials in Colorado and nationwide follows a three-tiered approach, based on the radiological risk from the use or handling of the materials, devices or items:

- **Exempt items/materials.** Small quantities of certain radioactive materials or certain items containing radioactive materials that present a low risk may be exempt from further regulations or requirements once they are manufactured and distributed to the end user. These items are known as “exempt” items or materials. The current Part 3 regulation provides an exemption for certain low risk items and quantities of radioactive material which parallels that in federal rule. The NRC retains the sole authority for issuing licenses to distribute exempt items.
- **Generally licensed items/materials.** Items or materials with slightly higher quantities of radioactive material that present some risk to end users may be regulated under a general license. These items or materials are considered to be “generally licensed”. Generally licensed items/materials typically require minimal or no training to use them as designed and may or may not require registration with the department. Generally licensed items/materials may be obtained without authorization from the department with the licensing being implicit in the regulations. There are limits and some requirements that apply to generally licensed items.
- **Specifically licensed items/materials.** Items or quantities of radioactive material that have the highest potential for exposure to radiation requires specific training, qualifications and facilities to use them are termed “specifically licensed” items or materials. Specifically licensed items/materials require significant effort and cost to obtain a license from the department. The applicant must meet all regulatory requirements and receive a specific license from the department before the radioactive material can be possessed.

**Background on radium-226**

Radium-226 was introduced into some consumer products in the early 1900’s, shortly after the discovery of radioactivity. The use of radium-226 in consumer products continued until the 1970’s or so, but a number of items that may contain radium-226 are still of interest to collectors today. These items may include antique revigator jars, small radium sources, watches, clocks and military gauges with radium containing luminescent paint. While most of these radium-226 antiquity items present a low risk when handled and stored properly as collector items, some activities may result in spread of radioactive contamination and possible exposure to individuals handling them. The risks increase when many radium-226 items are stored in a single location, are manipulated to intentionally remove or disturb the radium materials, or are sufficiently damaged such that the radium becomes loose or separated from the item.

Changes to the Part 3 rule are being proposed to provide better controls and safety for these older radium items. The proposed amendment makes technical and formatting changes to several sections in the Part 3 rule based on 2007 changes in federal regulation and introduces a general license for the possession, use, disposal, and handling of certain antiquity items containing radium-226 that were manufactured prior to 2007.

Under the current Part 3 rule there is no exempt quantity for radium-226, and therefore nearly all of the antiquity items listed in the proposed 3.6.8 would fall to the highest level of regulation and require a specific license. Specific licenses are both time intensive and costly to obtain and maintain. However, the proposed general license for these radium-226 items will provide regulatory relief by allowing for an easier, less restrictive pathway for the continued possession and use of these radium-226 antiquity items, while maintaining health and safety.

The Part 3 proposed changes related to radium-226 items were inadvertently left out during past rulemaking activities. This rulemaking will ensure that Colorado regulations are consistent with federal regulations of the U.S. Nuclear Regulatory Commission and other agreement state regulations. The proposed changes are outlined and discussed below for each rule section and are also discussed in the side margin comments of the draft regulation.

#### **Changes throughout Part 3**

- The word “Part” is added to the rule when there are references to federal (CFR) rules. Typographical errors, omissions, and alignment of text is also being corrected.

#### **Changes to Section 3.1.4**

- Rulemaking dates and links to regulatory web pages are revised and corrected.

#### **Changes to Section 3.5.2.1**

- While unlikely to be authorized, language is added to clarify that the department or (other) agreement states could authorize the application of source material to human beings. The current language incorrectly limits such authorizations to only the Nuclear Regulatory Commission (NRC).

#### **Changes to Section 3.6.7**

- Language is revised and added to make the phrasing gender neutral, consistent with federal rules in [10 CFR Part 31.8\(a\)](#).

#### **Changes to Section 3.6.7.6**

- Language is added to clarify that in addition to manufacturing, the general license requirements also apply to the import and export of americium-241, plutonium, or radium-226, consistent with federal rules in [10 CFR Part 31.8\(d\)](#) and [31.8\(e\)](#).

#### **Changes to Section 3.6.8**

- This is a new section to add a general license pathway for specific items that contain radium-226 that were manufactured before November 30, 2007, consistent with federal regulations in [10 CFR Part 31.12](#). The general license would apply to certain antiquities (radium water jars, radon generators, refrigerator cards, etc.), intact timepieces (watches and clocks), uninstalled timepiece hands, luminous items (gauges, dials, etc.), and small radium sources as specified in the rule. The general license for radium-226 items requires the possessor/user to follow certain requirements. This new provision -

- Requires notification of the department if there is damage to the item that could result in a loss of the radioactive material;
- Prohibits abandonment of the material;
- Requires export of radium-226 products to be conducted in accordance with a federal authorization under 10 CFR Part 110;
- Requires disposal at a facility licensed to receive radium-226;
- Requires response to written requests for information from the department.
- This general license does not authorize manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that disassembly and repair of timepieces is allowed. Disassembly and repair of items other than timepieces would require a specific license.

The general license in 3.6.8 does not require registration with the department or payment of any fee.

#### **Changes to Section 3.6.9.5, and 3.22.2**

- Revisions are made to make the rule gender neutral.

#### **Changes to Section 3.12.10.1**

- A cross-reference to federal rule is corrected. The proposed change is based on a change to the equivalent section in federal rule that occurred in August 2023 while the Part 3 rulemaking was in process and following the request for rulemaking. This correction does not change the intent or requirements.

#### **Changes to Schedule 3C, section 3C.10**

- Clarifying language is added for consistency with federal rule. The added language clarifies that the exempt license is authorized only by NRC under federal rules in 10 CFR Part 40.52.

#### **Changes to Schedule 3C, section 3C.11.1.8**

- The language is revised to clarify that the current exemption for timepieces containing up to 37 kBq (1 uCi) of radium-226 applies to intact timepieces (rather than all timepieces) that were manufactured prior to November 30, 2007, consistent with federal regulations in [10 CFR Part 30.15\(a\)\(1\)\(viii\)](#).

#### **Changes to Section 3F.2.1, 3F.2.3.2, and 3G.1.1**

- Cross-reference errors are corrected.

## Specific Statutory Authority.

Statutes that require or authorize rulemaking:

25-1.5-101(1)(k), 25-1.5-101(1)(l), 25-11-103, 25-11-104, and 25-1-108, C.R.S.

Is this rulemaking due to a change in state statute?

 Yes, the bill number is \_\_\_\_\_. Rules are \_\_\_ authorized \_\_\_ required. No

Does this rulemaking include proposed rule language that incorporate materials by reference?

 Yes  URL No

Does this rulemaking include proposed rule language to create or modify fines or fees?

 Yes No

Does the proposed rule language create (or increase) a state mandate on local government?

 No.

- The proposed rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed;
- The proposed rule requires a local government to perform or increase a specific activity because the local government has opted to perform an activity, or;
- The proposed rule reduces or eliminates a state mandate on local government.

 Yes.

This rule includes a new state mandate or increases the level of service required to comply with an existing state mandate, and local government will not be reimbursed for the costs associated with the new mandate or increase in service.

The state mandate is categorized as:

 Necessitated by federal law, state law, or a court order Caused by the State's participation in an optional federal program Imposed by the sole discretion of a Department

Has an elected official or other representatives of local governments disagreed with this categorization of the mandate?  Yes  No. If "yes," please explain why there is disagreement in the categorization.

Please elaborate as to why a rule that contains a state mandate on local government is necessary.

For consistency with the national framework for regulation of radioactive materials and consistent with Colorado's agreement with the U.S. Nuclear Regulatory Commission, all facilities regardless of ownership, must adhere to the same public health and safety requirements and regulations for use and possession of radioactive materials in Colorado. The proposed rule changes result in requirements that will equally impact all types of persons who may possess antiquity items under the general license whether private, or governmentally owned or operated.

DRAFT REGULATORY ANALYSIS  
6 CCR 1007-1 Part 3, Licensing of radioactive materials

1. A description of the classes of persons affected by the proposed rule, including the classes that will bear the costs and the classes that will benefit from the proposed rule.

Group of persons/entities Affected by the Proposed Rule	Size of the Group	Relationship to the Proposed Rule Select category: C/CLG/S/B
Members of the public that collect, store, repair, or display antiquity items that may contain radium-226. <sup>a</sup>	Unknown	C
Museums that collect, store, repair, or display antiquity items that may contain radium-226. <sup>a</sup>	Unknown	C
Private companies and their employees providing repair services of clocks and watches for members of the public. <sup>a</sup>	Unknown	C
Hobby groups that collect and repair watches and clocks, or military vehicle gauges that may contain radium-226. <sup>a</sup>	Unknown	C
Other stakeholders who requested notification of proposed non-medical related radiation rule changes. This includes private organizations and companies.	431	S
Specific radioactive materials licensees. <sup>b</sup>	300	C

<sup>a</sup> While various companies, organizations, or private individuals may collect, preserve, handle or store antiquity or luminescent items addressed by the rule, it cannot be known whether those items actually contain radium-226. Entities were selected based on the type of organization and/or their focus and greater likelihood of being in possession of radium-226 items described in the proposed rule language.

<sup>b</sup> It is expected that radioactive materials specific licensees would be minimally impacted by the proposed changes related to radium-226 antiquities (3.6.8, 3C.11.1.8) as these facilities are generally not involved with antiquity items. Specific licensees will generally benefit by the broader proposed administrative changes to Part 3 that are non-radium related.

While all are stakeholders, groups of persons/entities connect to the rule and the problem being solved by the rule in different ways. To better understand those different relationships, the following relationship categorization key is used:

- C = individuals/entities that implement or apply the rule.
- CLG = local governments that must implement the rule in order to remain in compliance with the law.
- S = individuals/entities that do not implement or apply the rule but are interested in others applying the rule.
- B = the individuals that are ultimately served, including the customers of our customers. These individuals may benefit, be harmed by or be at-risk because of the standard communicated in the rule or the manner in which the rule is implemented.

More than one category may be appropriate for some stakeholders.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

#### Economic outcomes

Summarize the financial costs and benefits, include a description of costs that must be incurred, costs that may be incurred, any Department measures taken to reduce or eliminate these costs, any financial benefits.

#### Financial/economic costs:

C and CLG: There are no costs expected for entities or individuals that wish to continue to acquire, receive, possess, use, or transfer certain items and self-luminous products containing radium-226 addressed under the proposed general license in 3.6.8. No registration or fee is proposed for this general license. New section 3.6.8 should provide a less costly pathway than current regulations that would potentially require a specific license for acquiring, receiving, possessing, using or transferring of radium-226 items other than the timepiece exemption provided by section 3C.11.1.8.

Costs may be incurred by any entity if it becomes necessary to dispose of radium-226 items at a licensed radioactive waste facility, or if a facility becomes contaminated as a result of mishandling of radium containing items. These disposal or clean-up costs would be for the most part consistent with current costs associated with these items and activities under the current regulations and will not be increased as a result of the propose rule. Additionally, there will be specific licensing associated costs required if activities beyond those allowed under the general license are conducted, such as disassembly and repair of non-timepiece radium-226 items.

#### Financial/economic benefits:

Licensees are expected to benefit through cost savings due to the elimination or easing of certain requirements that should require less resources. Cost savings are expected as a result of allowing entities or individuals to continue to acquire, receive, possess, use, or transfer certain items and self-luminous products containing radium-226 under the general license rather than a specific license as required under current regulations.

Please describe any anticipated financial costs or benefits to these individuals/entities.

S: There are no anticipated financial costs or benefits to these entities resulting from the proposed changes.

B: There are no anticipated financial costs or benefits to these entities resulting from the proposed changes.

#### Non-economic outcomes

Summarize the anticipated favorable and non-favorable non-economic outcomes (short-term and long-term), and, if known, the likelihood of the outcomes for each affected class of persons by the relationship category.

C/CLG: The favorable outcomes for entities that possess or use radium-226 antiquity and luminous items is that they may continue to use these items under a general license at no

cost rather than a more restrictive specific license. Additionally, the requirements proposed for these items will align with the national framework for this type of radioactive materials.

B: Overall, the proposed requirements are expected to benefit public safety by providing a simpler pathway for continued possession and use of radium-226 items.

S: The favorable non-economic outcome for this group is having the additional awareness of how these items have and will be regulated on a national and state level.

3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

A. Anticipated CDPHE personal services, operating costs or other expenditures:

There are no additional expected costs to the division on a routine, recurring basis, since the general license for antiquity items does not require registration. An incident involving a loss of containment of material, or the discovery of an abandoned antiquity item may result in some action and resource expenditure by radiation program staff. Such an expenditure amount is variable depending upon the incident and resources needed and is unknown.

Anticipated CDPHE Revenues: NA

B. Anticipated personal services, operating costs or other expenditures by another state agency: NA

Anticipated Revenues for another state agency: NA

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

Along with the costs and benefits discussed above, the proposed revisions:

- Comply with a statutory mandate to promulgate rules.
- Comply with federal or state statutory mandates, federal or state regulations, and Department funding obligations.
- Maintain alignment with other states or national standards.
- Implement a Regulatory Efficiency Review (rule review) result
- Improve public and environmental health practice.
- Implement stakeholder feedback.

Advance the following CDPHE Strategic Plan priorities (select all that apply):

1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO<sub>2</sub>e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO<sub>2</sub>e per year by June 30, 2020 and to 113.144 million metric tons of CO<sub>2</sub>e by June 30, 2023.
- Contributes to the blueprint for pollution reduction
  - Reduces carbon dioxide from transportation
  - Reduces methane emissions from oil and gas industry
  - Reduces carbon dioxide emissions from electricity sector



<p>2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023.</p> <ul style="list-style-type: none"> <li>___ Reduces volatile organic compounds (VOC) and oxides of nitrogen (NOx) from the oil and gas industry.</li> <li>___ Supports local agencies and COGCC in oil and gas regulations.</li> <li>___ Reduces VOC and NOx emissions from non-oil and gas contributors</li> </ul>
<p>3. Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023.</p> <ul style="list-style-type: none"> <li>___ Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes.</li> <li>___ Increases physical activity by promoting local and state policies to improve active transportation and access to recreation.</li> <li>___ Increases the reach of the National Diabetes Prevention Program and Diabetes Self-Management Education and Support by collaborating with the Department of Health Care Policy and Financing.</li> </ul>
<p>4. Decrease the number of Colorado children (age 2-4 years) who participate in the WIC Program and have obesity from 2120 to 2115 by June 30, 2020 and to 2100 by June 30, 2023.</p> <ul style="list-style-type: none"> <li>___ Ensures access to breastfeeding-friendly environments.</li> </ul>
<p>5. Reverse the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023.</p> <ul style="list-style-type: none"> <li>___ Reverses the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023.</li> <li>___ Performs targeted programming to increase immunization rates.</li> <li>___ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).</li> </ul>
<p>6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023.</p> <ul style="list-style-type: none"> <li>___ Creates a roadmap to address suicide in Colorado.</li> <li>___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate.</li> <li>___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries.</li> <li>___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.</li> </ul>
<p>7. The Office of Emergency Preparedness and Response (OEPR) will identify 100% of jurisdictional gaps to inform the required work of the Operational Readiness Review by June 30, 2020.</p>

<ul style="list-style-type: none"> <li><input type="checkbox"/> Conducts a gap assessment.</li> <li><input type="checkbox"/> Updates existing plans to address identified gaps.</li> <li><input type="checkbox"/> Develops and conducts various exercises to close gaps.</li> </ul>
<p>8. For each identified threat, increase the competency rating from 0% to 54% for outbreak/incident investigation steps by June 30, 2020 and increase to 92% competency rating by June 30, 2023.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident.</li> <li><input type="checkbox"/> Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment.</li> <li><input type="checkbox"/> Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.</li> </ul>
<p>9. 100% of new technology applications will be virtually available to customers, anytime and anywhere, by June 20, 2020 and 90 of the existing applications by June 30, 2023.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Implements the CDPHE Digital Transformation Plan.</li> <li><input type="checkbox"/> Optimizes processes prior to digitizing them.</li> <li><input type="checkbox"/> Improves data dissemination and interoperability methods and timeliness.</li> </ul>
<p>10. Reduce CDPHE's Scope 1 &amp; 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Reduces emissions from employee commuting</li> <li><input type="checkbox"/> Reduces emissions from CDPHE operations</li> </ul>
<p>11. Fully implement the roadmap to create and pilot using a budget equity assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Used a budget equity assessment</li> <li><input type="checkbox"/> Advance CDPHE Division-level strategic priorities.</li> </ul>

The costs and benefits of the proposed rule will not be incurred if inaction was chosen. Costs and benefits of inaction not previously discussed include:

The cost of inaction will result in Colorado regulations being inconsistent with the national framework and federal regulations pertaining to the general licensing of certain items and self-luminous products containing radium-226. Failing to have final regulations that are compatible with those of the NRC could result in enhanced regulatory oversight of the radiation program and potential revocation of authorization as an agreement state. The proposed requirements are required for compatibility.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute or state agreement. The specific revisions proposed in this rulemaking were developed by the federal government and incorporated feedback from stakeholders on a national level at the time the rule was implemented. The benefits, risks and costs of these proposed revisions were compared to the costs and benefits of other options. The proposed revisions provide the most benefit for the least amount of cost, are the minimum necessary or are the most feasible manner to achieve compliance with statute and federal regulations.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

No alternative rules or alternative rulemaking was considered. To varying degrees, Colorado's rules pertaining to radiation control must be maintained consistent with the regulations of the U.S. NRC in order to maintain its status as an Agreement State.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

The proposed changes to the requirements in Part 3 are based upon past changes to the overarching federal regulations which establish a national and consistent framework for regulation of radioactive materials. The discussion, considerations, and evaluation of the federal rule changes being incorporated into Part 3 may be found in the following federal register document:

[72 FR 55864 \[Federal Register Volume 72, Issue 189, Oct 1, 2007\]](#)

Note: With the exception of the radium-226 related provisions proposed for Part 3 as outlined in the draft rule, the basis and purpose, and stakeholder engagement documents, other regulatory changes discussed in the above federal register document were previously incorporated into Colorado regulations.

**STAKEHOLDER ENGAGEMENT**  
for Amendments to  
6 CCR 1007-1 Part 3, Licensing of radioactive materials

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:

The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

Organization	Representative Name and Title (if known)
Colorado museums/organizations with a focus on military aircraft and/or vehicles (Wings over the rockies; Homelake veterans history museum; Peterson air and space museum; Colorado-Wyoming association of museums; 4 <sup>th</sup> infantry division museum; Vintage aero flying museum)	Varied/staff
Timepiece (clock/watch) collector organizations/horological groups, and private watch/clock repair companies (Colorado chapters of the National association of watch and clock collectors; multiple private companies that repair and restore clocks and watch repair companies)	Varied/staff
Organization representing antiques and collectibles (Antiques and collectibles national association)	Varied/staff
Military vehicle collectors of Colorado (MVCC)	Varied/staff
All radioactive materials licensees in Colorado	Radiation Safety Officer(s) named on the license
Other stakeholders with interest in changes to rules and regulations pertaining to radiation control.	NA

Approximately 625 stakeholders in the above identified categories or groups were notified by email, of the opportunity to comment on the proposed draft rules that were posted on the department website in April 2023. Stakeholders were also provided with frequently asked questions (FAQ) document regarding the general license for radium-226 containing items. In addition to the initial notification, emails were sent reminding stakeholders of the opportunity to participate in two stakeholder meetings that were held in April and May 2023. A total of two individuals attended the stakeholder meetings. The department received no comments from stakeholders. Additionally, the U.S. NRC reviewed the proposed rule changes and had no comments.

Stakeholder Group Notification

The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10<sup>th</sup> of the month following the Request for Rulemaking).

Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.

Yes.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department’s efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

There were no comments received from stakeholders during the comment period. There were no factual or policy issues identified by stakeholders.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking: None.

Overall, after considering the benefits, risks and costs, the proposed rule:

Select all that apply.

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.		Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.	X	Reduces occupational hazards; improves an individual’s ability to secure or maintain employment; or, increases stability in an employer’s workforce.
	Improves access to food and healthy food options.	X	Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals.
	Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of roles and responsibilities, or what occurs under a rule.		Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the effectiveness of its efforts and outcomes.
	Increases a child’s ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity.		Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.
	Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.		Ensures a competent public and environmental health workforce or health care workforce.
	Other: Ensures consistency with federal rule and the national framework for regulation of radioactive materials.		Other: _____ _____

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.]*

7 \_\_\_\_\_

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**

11 \* \* \*  
12 [ \* \* \* indicates unaffected sections of the rule]

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](http://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.

\* \* \*

**Commented [JSJ7]:**  
Wording change to make the rule gender neutral.

102 **3.6 General Licenses<sup>2</sup> - Radioactive Material Other Than Source Material.**

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

104 3.6.1 Reserved.

105 <sup>3</sup> 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 State<sup>4</sup>

**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.

124 <sup>4</sup> 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.



- 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  $\mu$ 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  $\mu$ Ci) of americium-241, 185 kBq (5  $\mu$ Ci) of plutonium, or 185 kBq (5  
 381  $\mu$ 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).<sup>5</sup> DO NOT TOUCH  
 392 RADIOACTIVE PORTION OF THIS SOURCE.

393 <sup>5</sup> Showing only the name of the appropriate material.

394

\_\_\_\_\_  
 Name of manufacturer or importer

- 395
- 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
- 403 (5) Not use such source for any purpose other than the calibration of radiation  
 404 detectors or the standardization of other sources.  
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407 3.6.7.6 These general licenses do not authorize the manufacture, import, or export of  
 408 calibration or reference sources containing americium-241, plutonium or radium-226.  
 409

410 3.6.8 ~~Reserved.~~ General license for certain items and self-luminous products containing radium-  
 411 226.  
 412

413 3.6.8.1 A general license is hereby issued to any person to acquire, receive, possess, use,  
 414 or transfer, in accordance with the provisions of 3.6.8.2 through 3.6.8.4.,  
 415 radium-226 contained in the following products manufactured prior to November  
 416 30, 2007.  
 417

- 418 (1) Antiquities originally intended for use by the general public.  
 419

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

**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  $\mu$ 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  $\mu$ 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.<sup>6</sup>

487 <sup>6</sup> 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  $\mu$ 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.<sup>8</sup>

610 <sup>8</sup> 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 products<sup>16</sup>:

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

692 <sup>16</sup> 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**<sup>18</sup> 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 <sup>18</sup> 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 \* \* \*

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.

**Commented [JSJ34]:**  
 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.