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
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Through: Tracie M. White, Division Director TMW

Date: August 17, 2022

Subject: Request for rulemaking concerning proposed amendments to 6 CCR 1007-1 Part 7, Use of radionuclides in the healing arts, Part 17, Transportation of radioactive materials, and Part 22, Physical protection of category 1 and category 2 quantities of radioactive material.

The radiation program is proposing changes to the Part 7, 17 and 22 regulations primarily to conform to the 2020 and 2021 federal rule changes of the U.S. Nuclear Regulatory Commission (NRC) in 10 CFR Part 35, 10 CFR Part 37, and 10 CFR Part 71. Parts 7, 17, and 22 provide requirements applicable to medical use of radioactive materials, transportation of radioactive materials, and increased security for certain radioactive materials, respectively. As an Agreement State, and in accordance with state statute, Colorado is required to adopt rules which are compatible and consistent with the applicable federal regulations and is therefore the primary driver for these proposed rule changes. In addition to the federally driven changes, minor technical and formatting corrections are also proposed for consistency with other recently amended Colorado regulations.

The proposed rule changes consist of minor technical changes that will clarify and help in the application and understanding of the rules. The proposed changes to the Part 7 rule will update the name of the organization that establishes education and training criteria for nuclear pharmacists, and aligns phrasing related to NRC master material licenses with federal rule language. The proposed changes to the Part 17 rule will remove an outdated reference. The proposed changes to the Part 22 rule will update a formula for calculating the sum of fractions, consistent with federal rule. Select areas of all three rules will be updated to format and align text for appearance purposes.

No feedback or comments were received during the stakeholder comment period as a result of the proposed changes.

Since the rule changes impact select areas of the rule, only those impacted sections are included in the proposed drafts. New text appears as red bold text and deleted text shown as strikethrough text.

The Radiation Program respectfully requests that the Board of Health set a rulemaking hearing for October 19, 2022 to adopt the proposed changes for these rules.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to 6 CCR 1007-1,
Part 7, Use of radionuclides in the healing arts
Part 17, Transportation of radioactive materials
Part 22, Physical protection of category 1 and category 2
quantities of radioactive material

Basis and Purpose.

The proposed Part 7, 17 and 22 amendments revise the rule language in select areas, in order to be consistent with recent 2020 and 2021 federal rule changes in 10 CFR Part 35, 10 CFR Part 37, and 10 CFR Part 71. A summary and description of the federal changes can be found in the U.S. Nuclear Regulatory Commission (NRC) Regulation Amendment Tracking System (RATS). Website links for the applicable RATS items are linked below and can be found in the informational side margin comments in each proposed rule.

Similar to other recent radiation regulation amendments, changes are also proposed to make minor technical and formatting updates to the rule for consistency with the Colorado Administrative Procedure Act with regard to documents incorporated by reference.

The specific proposed changes to these rules are outlined for each section below as well as shown in the redline draft of the proposed rules.

Part 7, Section 7.2, and throughout rule
Minor phrasing corrections are made, including replacing the term “licensee” with “license” (or vice-versa) in select areas, based on the context of the rule language and its use in federal rule as described in NRC RATS 2021-1. These changes ensure consistency with the intent of the federal rule language. The proposed changes will not modify the intended use or application of the definition.

Part 7, Appendix 7C
The organization that accredits pharmacy education programs for nuclear pharmacists is updated to reflect the current renamed organization, which is the Accreditation Council for Pharmacy Education (ACPE). This change is consistent with current federal rule as described in NRC RATS 2021-1.

Throughout Part 17
Minor typographical and formatting corrections are made, including adding the part and section when referencing other Colorado or federal rules.

Part 17, Section 17.11.4.3
Provision (1) of this section is removed due to outdated (1995) information and is placed in “reserved” status for future use and retention of current rule numbering. The change is made for consistency with a recent federal rule change to 10 CFR Part 71 as described in NRC RATS 2020-3. The information found in the outdated reference can be found on the NRC website as identified in provision (2) or by contacting NRC as identified in provision (3) of this section.

Part 17, Appendix 17A, Table 17A1
The specific activity (a constant which describes the amount of radioactivity per unit mass) for the isotope Samarium-147 (Sm-147) is corrected for consistency with a correction to federal rule in 10 CFR Part 71 as described in NRC RATS 2020-3. This reduces the original value in the table, but is not expected to have an impact on Colorado licensees, as none are licensed specifically for this radionuclide nor is the radiation program aware of its use by licensees.

Part 22, Section 22.2 through 22.2.4
Minor updates are made to the rule, consistent with other radiation regulations. Standard "basis and purpose" language is added, consistent with other rule formatting.

Part 22, Appendix A, Table 1 equation
Consistent with 2021 federal rule changes in 10 CFR Part 37 as described in NRC RATS 2021-2, the "sum of fractions" equation found in the footnotes following the table is updated to mathematically reflect that an indefinite number of nuclides may be included in the calculation. The sum of fractions calculation is used to determine applicability of the Part 22 rule when a licensee possesses multiple radionuclides. There is no change to the outcome of the calculation as a result of the proposed change.

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.
__X___ No

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

__X___ Yes ___ URL
_____ No

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

_____ Yes
__X___ No

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

_X_ 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.

REGULATORY ANALYSIS
for Amendments to 6 CCR 1007-1,
Part 7, Use of radionuclides in the healing arts
Part 17, Transportation of radioactive materials
Part 22, Physical protection of category 1 and category 2
quantities of radioactive material

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/S/B**
Specific radioactive materials licensees of all types (medical, industrial, research, etc)	310	C / B
Other stakeholders having an interest in radiation regulations	630	S / B

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, please refer to the following relationship categorization key:

C = individuals/entities that implement or apply the rule.
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, and any financial benefits.

Please describe any anticipated financial costs or benefits to these individuals/entities.
C: None. There is no quantitative economic impact of the rule change. Licensees will not incur additional costs nor will costs be reduced as a result of the rule changes.

S: None. There is no quantitative economic impact of the rule change. Individuals in this category will not incur additional costs nor will costs be reduced as a result of the rule changes.

B: None. There is no quantitative economic impact of the rule change. Individuals in this category will not incur additional costs nor will costs be reduced as a result of the rule 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.

The anticipated favorable non-economic outcome is that the proposed rule changes are expected to add clarity and understanding to the rule for all stakeholders and the department. Additionally, the proposed changes will make the rule more consistent with the national framework of regulating radioactive materials and will help ensure Colorado maintains its status as an NRC Agreement State.

There are no expected non-favorable non-economic outcomes as a result of the proposed rule changes.

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: The rule changes are net neutral and there are no anticipated costs associated with implementing the proposed rule changes. The proposed changes are clarifying in nature and will only assist CDPHE in carrying out its requirements.

B. Anticipated CDPHE Revenues: There are no change in revenues as a result of the proposed changes. The proposed changes do not impact or change fees.

C. Anticipated personal services, operating costs or other expenditures by another state agency: CDPHE is the only regulatory agency having statutory authority to regulate radioactive materials in Colorado, and therefore, there will be no financial or other impacts to other state agencies as a result of the proposed changes.

D. Anticipated Revenues for another state agency: None. The proposed rule does not impact revenues for CDPHE or another state agency.

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:

_X_ Comply with a statutory mandate to promulgate rules.
_X_ Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
_X_ Maintain alignment with other states or national standards.
_X_ Implement a Regulatory Efficiency Review (rule review) result
_X_ 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 CO2e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO2e per year by June 30, 2020 and to 113.144 million metric tons of CO2e 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

2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023.

___ Reduces volatile organic compounds (VOC) and oxides of nitrogen (NOx) from the oil and gas industry.
___ Supports local agencies and COGCC in oil and gas regulations.
___ Reduces VOC and NOx emissions from non-oil and gas contributors

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.

___ Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes.
___ Increases physical activity by promoting local and state policies to improve active transportation and access to recreation.
___ 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.

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.

___ Ensures access to breastfeeding-friendly environments.

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.

___ 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.
___ Performs targeted programming to increase immunization rates.
___ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).

6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023.

___ Creates a roadmap to address suicide in Colorado.
___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate.
___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries.
___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.

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.

___ Conducts a gap assessment.
___ Updates existing plans to address identified gaps.
___ Develops and conducts various exercises to close gaps.

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.

___ Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident.
___ Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment.
___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.

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.

___ Implements the CDPHE Digital Transformation Plan.
___ Optimizes processes prior to digitizing them.
___ Improves data dissemination and interoperability methods and timeliness.

10. Reduce CDPHE's Scope 1 & 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.

___ Reduces emissions from employee commuting
___ Reduces emissions from CDPHE operations

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.
___ Used a budget equity assessment
___ Advance CDPHE Division-level strategic priorities.

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 by failing to implement the proposed changes will make portions of the rule inconsistent with federal regulations and the national framework for regulation of sources of radiation. Such inconsistencies can result in increased federal oversight and/or ultimately revocation of Colorado's status as an Agreement State. Similarly, failing to update provisions pertaining to the incorporation by reference language will potentially make the rule incompatible with the Colorado Administrative Procedure Act.

There are no benefits of inaction.

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. 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, and are the most feasible manner to achieve compliance with statute.

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

Alternatives to this rulemaking were considered, but were determined to be not feasible. Failure to implement regulatory changes and requirements that are consistent with federal rule will potentially put Colorado's Agreement State program in jeopardy with our NRC agreement and the national materials program for regulation of radioactive materials. Failure to implement requirements that are consistent with the requirements of the Administrative Procedure Act for documents incorporated by reference may result in the rule being negated or invalidated by the legislature.

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 change did not require a data based evaluation or analysis. The proposed changes are technical corrections and wording changes based on federal rule language that will improve the implementation and understanding of the rule requirements. The proposed updates pertaining to documents incorporated by reference are consistent with information found in other recently amended Department rules and regulations.

STAKEHOLDER ENGAGEMENT
for Amendments to
6 CCR 1007-1,
Part 7, Use of radionuclides in the healing arts
Part 17, Transportation of radioactive materials
Part 22, Physical protection of category 1 and category 2
quantities of radioactive material

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:

Approximately 310 specific radioactive materials licensees were notified via email of the opportunity to comment and provide feedback on the proposed draft rule changes, which were available for review on the Department website.

Along with specific licensees, approximately 630 individuals having an interest in radiation regulations were also notified of the opportunity to comment. These additional individuals may represent or be employed by existing licensees, interest groups, and professional associations, societies or organizations.

Due to the limited scope, nature, and overall anticipated beneficial impact of the proposed rule changes, no stakeholder meetings were held. A 30+ day comment period was held May 23, 2022 through June 30, 2022. Mid-way through the comment period, a second email was sent to stakeholders reminding them of the opportunity to comment. No comments were received during the comment period.

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 10th of the month following the Request for Rulemaking).

_X__ 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.

No major factual or policy issues were encountered during the stakeholder process. The proposed changes involve minor technical updates and corrections and are made to improve the effectiveness, understanding and clarity of the rule. The proposed changes will help maintain consistency with existing federal rule. No stakeholders provided comments or

feedback on the proposed rule changes during the comment period.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking.

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

	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.
X	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.
X	Other: Benefits stakeholders with additional information where to locate documents incorporated into the rule to help aide compliance with the requirements.	X	Other: Ensures consistency with federal rule and the national framework for regulation of radioactive materials.

DRAFT 1 07/21/2022

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

RADIATION CONTROL - USE OF RADIONUCLIDES IN THE HEALING ARTS

6 CCR 1007-1 Part 07

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

Adopted by the Board of Health ~~June 17, 2020~~October 19, 2022, effective date ~~August 14, 2020~~December 15, 2022.

PART 7: USE OF RADIONUCLIDES IN THE HEALING ARTS

USE OF RADIONUCLIDES IN THE HEALING ARTS

Section A – General Information

7.1 Purpose and scope.

7.1.1 Authority

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

7.1.2 Basis and Purpose.

A statement of basis and purpose accompanies this part and changes to this part. A copy may be obtained from the Department.

7.1.3 Scope.

This part establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in these regulations.

7.1.4 Applicability.

The requirements and provisions of these regulations apply to applicants and licensees subject to this part unless specifically exempted.

7.1.5 Published material incorporated by reference.

7.1.5.1 Throughout this Part 7, federal regulations, state regulations, and standards or guidelines of outside organizations have been adopted and incorporated by reference. Unless a prior version of the incorporated material is otherwise specifically indicated, the materials incorporated by reference cited herein include only those versions that were in effect as of the most recent effective date of this Part 7 (~~August 2020~~**December 15, 2022**), and not later amendments or editions of the incorporated material.

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: The acronym "RATS 2021-1" referenced in the side margin comments of this draft refers to the U.S. Nuclear Regulatory Commission (NRC) regulation amendment tracking system (RATS). This system and documents are used to identify and summarize changes to federal regulations that may be required for adoption by an NRC agreement state. To maintain agreement state status, and be consistent with statute, Colorado's radiation regulations must be compatible with federal regulations of the NRC.

Colorado statute also prescribes that the radiation control regulations must be consistent with the model regulations of the Conference of Radiation Control Program Directors, Inc. (CRCPD). The CRCPD model regulation equivalent to part 7 was last updated in 2003, and does not yet reflect federal rule changes since that time.

Editorial note 4: This is not a complete rule. Some unaffected sections or provisions have been removed from the rule and are not shown in this draft. Unaffected sections/provisions are denoted with a " * * * ".

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.

[* * * DENOTES UNAFFECTED SECTIONS/PROVISIONS IN THE DRAFT RULE]

* * *

7.2 Definitions.

As used in this part, these terms have the definitions set forth as follows:

* * *

"Authorized medical physicist" (AMP) means an individual who meets the requirements of Appendix 7B; or

(1) Is identified as an authorized medical physicist or teletherapy physicist on:

a. A specific medical **use** license issued by the Department, NRC, or Agreement State;

b. A medical use permit issued by an NRC master material ~~license~~**licensee**;

c. A permit issued by an NRC or Agreement State broad scope medical use licensee; or

d. A permit issued by an NRC master material license broad scope medical use ~~license~~**permittee.**

"Authorized nuclear pharmacist" (ANP) means a pharmacist who meets the requirements of Appendix 7C; or

(1) Is identified as an authorized nuclear pharmacist on:

a. A specific license issued by the Department, NRC, or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

b. A permit issued by an NRC master material ~~license~~**licensee** that authorizes medical use or the practice of nuclear pharmacy;

c. A permit issued by an NRC or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

d. A permit issued by an NRC master material license broad scope medical use ~~permitee~~**permittee** that authorizes medical use or the practice of nuclear pharmacy; or

(2) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(3) Is designated as an authorized nuclear pharmacist in accordance with Part 3.

"Authorized user" (AU) means a physician, dentist, or podiatrist who meets the applicable requirements of Appendix 7D through Appendix 7M; or

(1) Is identified as an authorized user on:

Commented [JSJ3]: Select definitions in 7.2 are updated for consistency with federal rule language and for consistency with formatting of Colorado rule.

Commented [JSJ4]: Minor wording corrections are made, consistent with the current language in 10 CFR Part 35.2.

Commented [JSJ5]: Minor wording corrections are made, consistent with the current language in 10 CFR Part 35.2.

Commented [JSJ6]: Minor wording corrections are made, consistent with the current language in 10 CFR Part 35.2.

a. A Department, NRC, or Agreement State license that authorizes the medical use of radioactive material;

b. A permit issued by an NRC master material ~~license~~**licensee** that is authorized to permit the medical use of radioactive material;

c. A permit issued by an NRC or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

d. A permit issued by an NRC master material license broad scope ~~permitee~~**permittee** that is authorized to permit the medical use of radioactive material.

* * *

"Ophthalmic physicist" means an individual who:

(1) Meets the requirements in 7.41.6.1(2) and 7.65; and

(2) Is identified as an ophthalmic physicist on a:

a. Specific medical use license issued by the Department, NRC or an Agreement State;

b. Permit issued by the Department, NRC or Agreement State broad scope medical use licensee;

c. Medical use permit issued by a NRC master material licensee; or

d. Permit issued by a NRC master material ~~license~~**license** broad scope medical use permittee.

* * *

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

* * *

7.3.1.1 A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the Department, an Agreement State or NRC, or as allowed in ~~7.3.1.1 or~~ 7.3.1.2.

* * *

7.3.2.3 A licensee not authorized pursuant to **Part 3, Section** 3.11 shall apply for and receive approval of a specific amendment to its Department license before conducting research involving human subjects;

* * *

7.3.4.5 An applicant that satisfies the requirements specified in **Part 3, Section** 3.11 may apply for a Type A specific license of broad scope.

Commented [JSJ7]:
Updated for consistency with similar phrasing in other proposed changes in this rule due to recent changes in federal rule.

Note - we believe that current wording in federal rule (10 CFR 35.2) for this provision is incorrect and inconsistent with other recent federal rule changes. This proposed change has been verified with NRC.

NRC Compatibility B

Commented [JSJ8]:
Definition is updated for clarity and consistency with language in 10 CFR Part 35.2.

Commented [JSJ9]:
Circular reference to 7.3.1.1 is not needed and is therefore deleted.

Commented [JSJ10]:
Language updated for consistency with formatting of other radiation regulations.

* * *

7.3.5.7 The mobile medical service shall designate and manage each area of use in the client's facility as a restricted area while radioactive material is present. For each location where radioactive materials will be routinely used, the licensee shall provide to the Department:

(1) A diagram of the location of use, including information about the placement of required postings; and

(2) Calculation(s) or survey(s) results that demonstrate compliance with applicable dose limits in **Part 4, Sections** 4.14 and 4.15 at the location of use.

7.3.5.8 The mobile medical service shall ensure that:

(1) Supervision by an authorized user is in accordance with 7.10.1;

(2) Radiation exposures to the client's personnel working in the client facility are:

(a) Below the dose limits to members of the public listed in **Part 4, Section** 4.14; or

(b) The client's personnel are instructed as described in **Part 10, Section** 10.3 and monitored for exposure in accordance with **Part 4, Section** 4.18 unless the licensee can demonstrate that **Section** 4.18 does not apply.

* * *

7.3.6 A licensee possessing a Type A specific license of broad scope for medical use, issued under Part 3 of these regulations, is exempt from:

Commented [JSJ11]:
Comma added.

* * *

7.4 License amendments.

A licensee shall apply for and must receive a license amendment:

7.4.1 Before it receives, prepares, or uses radioactive material for a type of use that is permitted under this part but is not authorized on the licensee's current license issued under this part;

7.4.2 Before it permits anyone to work as an authorized user, authorized medical physicist, ophthalmic physicist, or an authorized nuclear pharmacist under the license, except:

7.4.2.1 For an authorized user, an individual who meets the requirements in Appendix 7P and one or more of the following: Section 7D1 of Appendix D, Section 7E1 of Appendix E, Section 7F1 of Appendix F, Section 7G1 of Appendix 7G, Section 7H1 of Appendix 7H, Section 7K1 of Appendix K, Section 7J1 of Appendix J, or Section 7M1 of Appendix M;

7.4.2.2 For an authorized nuclear pharmacist, an individual who meets the requirements in Section 7C1 of Appendix 7C and 7.65;

7.4.2.3 For an authorized medical physicist, an individual who meets the requirements in Section 7B1 of Appendix 7B and 7.65;

7.4.2.4 An individual who is identified as an authorized user, an authorized nuclear pharmacist, authorized medical physicist, or an ophthalmic physicist ~~on~~:

Commented [JSJ12]:
Minor wording corrections are made, consistent with the language in 10 CFR Part 35.13**.

[**NOTE: Colorado made NRC aware of a likely error in 10 CFR Part 35 during the drafting of the rule. The provisions of 35.13(b)(4)(i) through (iv) in the official CFR (which parallel 7.4.2.4(1)-(4)) appear to have been inadvertently deleted from the final federal rule in 2018. The NRC is aware of this issue and has indicated a rulemaking will be initiated to correct this error in late 2022 or 2023.]

(1) **On a**~~A~~ NRC or Agreement State license or other equivalent permit or license recognized by the Department that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(2) **On a**~~A~~ permit issued by a NRC or Agreement State specific license of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(3) On a permit issued by a NRC master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

(4) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

* * *

7.5 Notifications and maintenance of records.

* * *

7.5.2 A licensee shall notify the Department in writing no later than 30 days after:

* * *

7.5.2.4 The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in **Part 3, Section** 3.15.2 of these regulations; or

* * *

7.7 Authority and responsibilities for the radiation protection program

7.7.1 In addition to the radiation protection program requirements of **Part 4, Section** 4.5 of these regulations, a licensee's management shall approve in writing:

* * *

7.10 Supervision.

Commented [JSJ13]:
Text is formatted in Section 7.10 for alignment purposes. There are no changes to rule text or requirements.

7.10.1 A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 7.3.1.2(1) shall:

7.10.1.1 In addition to the requirements of **Part 10, Section** 10.3 of these regulations, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of Part 7, and license conditions with respect to the use of radioactive material; and

7.10.1.2 Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of Part 7, and license conditions with respect to the medical use of radioactive material.

7.10.2 A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 7.3.1.2(2), shall:

7.10.2.1 In addition to the requirements of **Part 10, Section** 10.3, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's use of radioactive material; and

7.10.2.2 Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, the regulations of Part 7, and license conditions.

* * *

7.23 Report and notification of a dose to an embryo/fetus or a nursing child

7.23.1 A licensee shall report any dose to an embryo/fetus that is greater than 5 mSv (500 mrem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

7.23.2 A licensee shall report any dose to a nursing child, that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast feeding individual that:

7.23.2.1 Is greater than 5 millisievert (500 mrem) total effective dose equivalent; or

7.23.2.2 Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

7.23.3 The licensee shall notify by telephone the Department no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in 7.23.1 or 7.23.2.

7.23.4 The licensee shall submit a written report to the Department within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 7.23.1 or 7.23.2.

7.23.4.1 The written report must include:

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect on the embryo/fetus or the nursing child;

(6) What actions, if any, have been taken, or are planned, to prevent recurrence; and

(7) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

7.23.4.2 The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

Commented [JSJ14]: In Section 7.23, text is formatted for alignment purposes along with removal of unneeded/excess space.
There are no changes to rule text or requirements.

Commented [JSJ15]: Remove unneeded space between 7.23.4.2 and 7.23.4.3; and align/format text.
There are no changes to rule text or requirements.

7.23.5 The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under 7.23.1 or 7.23.2, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of 7.23.5, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

7.23.6 A licensee shall:

7.23.6.1 Annotate a copy of the report provided to the Department with the:

(1) Name of the pregnant individual or the nursing child who is the subject of the event; and

(2) Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event.

7.23.7 A copy of the record required under 7.23.6 shall be provided to the referring physician, if other than the licensee, within 15 days after discovery of the event.

* * *

Section F – Sealed Sources for Diagnosis

7.40 Use of sealed sources and medical devices for diagnosis.

7.40.1 A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

7.40.2 A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

7.40.3 Sealed sources and devices for diagnostic medical uses may be used in research in accordance with ~~and~~**an** active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of 7.14.1 are met.

Commented [JSJ16]: Correction of typographical error.

7.40.4 Training for use of sealed sources and medical devices for diagnosis.

The licensee shall require an authorized user under 7.40 to meet the requirements of Appendix 7J.

Section G – Manual Brachytherapy

7.41 Calibration measurements of brachytherapy sources.

7.41.1 Before the first medical use of a brachytherapy source, a licensee shall have:

7.41.1.1 Determined the source output or activity using a dosimetry system that meets the requirements of 7.53;

7.41.1.2 Determined source positioning accuracy within applicators; and

7.41.1.3 Used published protocols currently accepted by nationally recognized bodies to meet the requirements of 7.41.1.1 and 7.41.1.2.

7.41.2 Instead of a licensee making its own measurements as required in 7.41.1, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with 7.41.1.

7.41.3 A licensee shall mathematically correct the outputs or activities determined in 7.41.1 for physical decay at intervals consistent with 1 percent physical decay.

7.41.4 An authorized medical physicist shall perform or review the measurements and calculations made pursuant to 7.41.1, 7.41.2, or 7.41.3.

7.41.5 A licensee shall retain a record of each calibration as follows:

7.41.5.1 A licensee shall maintain a record of the calibrations of brachytherapy sources required by 7.41.1 for 3 years after the last use of the source.

7.41.5.2 The record must include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

7.41.6 Strontium-90 sources for ophthalmic treatments.

7.41.6.1 Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in 7.41.6.2 are performed by either:

(1) An authorized medical physicist; or

(2) An individual who:

(a) Is identified as an ophthalmic physicist on a specific medical use license issued by NRC or an Agreement State; permit issued by a NRC or

Commented [JSJ17]: Section 7.41 is formatted for alignment of text.
There are no changes to rule text or requirements.

Commented [JSJ18]: Formatted for alignment of text.
There are no changes to rule text or requirements.

Commented [JSJ19]:
Updated for consistency with similar phrasing in other proposed changes in this rule due to recent amendments to federal rule.

[Note - the current wording in federal rule (10 CFR Part 35.433(a)(2)(i)) equivalent to this provision is inconsistent with other recent federal rule changes. NRC has been made aware of this error in the federal rule and will be initiated a rulemaking to address this in the future.]

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Agreement State broad scope medical use licensee; medical use permit issued by a NRC master material licensee; or permit issued by a NRC master material ~~licensee~~**license** broad scope medical use permittee; and

(b) Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

(c) Has successfully completed 1 year full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(d) Has documented training in:

(i) The creation, modification, and completion of written directives;

(ii) Procedures for administrations requiring a written directive; and

(iii) Performing the calibration measurements of brachytherapy sources as detailed in 7.41.1 through 7.41.5.

7.41.6.2 The individuals who are identified in 7.41.6.1 must:

(1) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 7.41.1 through 7.41.5; and

(2) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in 7.41.6.1 will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

7.41.6.3 Licensees must retain a record of the activity of each strontium-90 source as follows:

(1) A licensee shall maintain a record of the activity of a strontium-90 source required by 7.41.6 for the life of the source.

(2) The record must include:

(a) The date and initial activity of the source as determined under 7.41.1 through 7.41.5; and

(b) For each decay calculation, the date and the source activity as determined under 7.41.6.

* * *

7.43 Safety instruction.

In addition to the requirements of Part 10 of these regulations:

Commented [JSJ20]:
Section 7.41.6.3 is formatted for alignment of text.
There are no changes to rule text or requirements.

7.43.1 The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with 7.26.

7.43.2 The instruction required by 7.43.1 shall be commensurate with the duties of the personnel and include:

7.43.2.1 Size and appearance of the brachytherapy sources;

7.43.2.2 Safe handling and shielding instructions in case of a dislodged source;

7.43.2.3 Patient or human research subject control;

7.43.2.4 Visitor control, including both;

(1) Routine visitation to hospitalized individuals in accordance with **Part 4, Section** 4.14.1.1; and

(2) Visitation authorized in accordance with **Part 4, Section** 4.14.3; and

7.43.2.5 Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject dies or has a medical emergency.

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Section 7.43.2.5 is formatted for alignment of text.
There are no changes to rule text or requirements.

7.43.3 A licensee shall retain a record of individuals receiving safety instructions required by 7.43.1 and maintain such records for 3 years. The record must include a list of the topics covered, the date of the instruction, the names(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

7.44 Safety precautions.

Commented [JSJ22]:
Section 7.44 is formatted for alignment of text.
There are no changes to rule text or requirements.

7.44.1 For each patient or the human research subject that is receiving brachytherapy and cannot be released in accordance with 7.26, a licensee shall:

7.44.1.1 Not place the patient or the human research subject in the same room with a patient who is not receiving radiation therapy;

7.44.1.2 Visibly post the patient's or human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

7.44.2 A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

7.44.2.1 Dislodged from the patient; or

7.44.2.2 Lodged within the patient following removal of the source applicators.

7.44.3 A licensee shall notify the RSO, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

* * *

7.47 Therapy-related computer systems.

7.47.1 The licensee shall perform acceptance testing on the treatment planning system **of therapy-related computer systems** in accordance with published protocols accepted by nationally recognized bodies.

7.47.2 At a minimum, the acceptance testing required by 7.47.1 shall include, as applicable, verification of:

7.47.2.1 The source-specific input parameters required by the dose calculation algorithm;

7.47.2.2 The accuracy of dose, dwell time, and treatment time calculations at representative points;

7.47.2.3 The accuracy of isodose plots and graphic displays; and

7.47.2.4 The accuracy of the software used to determine radioactive source positions from radiographic images.

Section H - Photon Emitting Remote Afterloader Units, Teletheraphy Units, and Gamma Stereotactic Radiosurgery Units

7.48 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

7.48.1 A licensee must only use sealed sources:

7.48.1.1 Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses; or

7.48.1.2 In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of 7.14.1 are met.

7.48.2 A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

7.48.2.1 Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

7.48.2.2 In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 7.14.1 are met.

7.48.3 Training For Use of a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.

The licensee shall require an authorized user under 7.48 to meet the requirements of Appendix 7M.

* * *

7.58 Periodic spot checks for teletherapy units.

Commented [JSJ23]:
Language added for clarity and consistency with the current 10 CFR Part 35.457.

Section 7.47.2 has also been formatted for alignment of text.

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Section 7.48 is formatted for alignment of text. There are no changes to rule text or requirements.

7.58.1 A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit once in each calendar month~~,~~ that include determination of:

7.58.1.1 Timer accuracy, and timer linearity over the range of use;

7.58.1.2 “On off” error;

7.58.1.3 The coincidence of the radiation field and the field indicated by the light beam localizing device;

7.58.1.4 The accuracy of all distance measuring and localization devices used for medical use;

7.58.1.5 The output for one typical set of operating conditions measured with the dosimetry system described in 7.53; and

7.58.1.6 The difference between the measurement made in 7.58.1.5 and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

7.58.2 A licensee shall perform spot checks required by 7.58.1 in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the output spot-check measurements.

7.58.3 A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall ~~promptly~~ notify the licensee **as soon as possible** in writing of the results of each spot check.

7.58.4 A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

7.58.4.1 Electrical interlocks at each teletherapy room entrance;

7.58.4.2 Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam “on off” mechanism;

7.58.4.3 Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

7.58.4.4 Viewing and intercom systems;

7.58.4.5 Treatment room doors from inside and outside the treatment room; and

7.58.4.6 Electrically assisted treatment room doors with the teletherapy unit electrical power turned “off”.

7.58.5 If the results of the checks required in 7.58.4 indicate the malfunction of any system, a licensee shall lock the control console in the “off” position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

7.58.6 A licensee shall maintain a record of each spot check required by 7.58.1 and 7.58.4, and a copy of the procedures required by 7.58.2 for 3 years. The record shall include:

7.58.6.1 The date of the spot check;

Commented [JSJ25]:
Remove unneeded comma in 7.58.1.

Where needed, 7.58.1 through 7.58.6.9 has been formatted for alignment of text.

Commented [JSJ26]:
Language clarified for consistency with 10 CFR Part 35.642(c).

7.58.6.2 The manufacturer's name, model number, and serial number for the teletherapy unit, source, and instrument used to measure the output of the teletherapy unit;

7.58.6.3 An assessment of timer linearity and constancy;

7.58.6.4 The calculated “on off” error;

7.58.6.5 A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device

7.58.6.6 The determined accuracy of each distance measuring or localization device;

7.58.6.7 The difference between the anticipated output and the measured output;

7.58.6.8 Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

7.58.6.9 The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

* * *

PART 7, APPENDIX 7A: TRAINING FOR RADIATION SAFETY OFFICER (RSO) AND ASSOCIATE RADIATION SAFETY OFFICER (ARSO)

Commented [JSJ27]: Prior to final publication, ensure that this Appendix **and all subsequent appendices** begin at the top of the page.

Except as provided in Appendix 7P, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) or an individual assigned duties and tasks as an Associate Radiation Safety Officer (ARSO) as provided in 7.7 to be an individual who:

7A1 Is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in 7A4 of this Appendix. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC’s Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

7A1.1

(1) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(2) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics;

and

(3) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry;

or

7A1.2

(1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

and

(2) Have 2 years of full-time practical training and/or supervised experience in medical physics:

(a) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by an Agreement State or NRC;

or

(b) In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for Authorized Users in Appendix 7P, Appendix 7E or Appendix 7F;

and

(3) Pass an examination administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety.

or

7A2

7A2.1 Has completed a structured educational program consisting of both:

(1) 200 hours of classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Radiation biology; and

(e) Radiation dosimetry;

and

(2) One year of full-time radiation safety experience, under the supervision of the individual identified as the RSO, on a NRC or an Agreement State license or permit issued by a NRC master material licensee that authorizes similar type(s) of use(s) of radioactive material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a NRC or an Agreement State license or permit issued by a NRC master material licensee. The full-time radiation safety experience must involve the following:

(a) Shipping, receiving, and performing related radiation surveys;

(b) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(c) Securing and controlling radioactive material;

(d) Using administrative controls to avoid mistakes in the administration of radioactive material;

(e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(f) Using emergency procedures to control radioactive material; and

(g) Disposing of radioactive material;

and

7A2.2 This individual must obtain a written attestation, signed by a preceptor RSO or ARSO who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a RSO or an ARSO. The written attestation must state that the individual has satisfactorily completed the requirements in 7A2.1 and 7A4 of Appendix 7A and is able to independently fulfill the radiation safety related duties as a RSO or as an ARSO for a medical use license;

or

7A3

7A3.1 Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State under Appendix 7B, Section 7B1, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as RSO or an ARSO, and meets the requirements in 7A4.

or

7A3.2 Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Department, NRC or an Agreement State license, a permit issued by a NRC master material ~~license~~**licensee**, a permit issued by a NRC or an Agreement State licensee of broad scope, or a permit issued by a NRC master material **license** broad scope ~~permitee~~**permittee**, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as the RSO or ARSO, and meets the requirements in 7A4;

or

7A3.3 Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use permit issued by a NRC master material ~~license~~**licensee**. The individual must also meet the requirements in 7A4.

and

Commented [JSJ28]:
Minor technical correction/update for consistency with federal regulations in 10 CFR 35.50(c)(3).

NRC RATS 2021-1
NRC Compatibility B

7A4 Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by an RSO, an Associate RSO, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

* * *

PART 7, APPENDIX 7C: TRAINING FOR AND AUTHORIZED NUCLEAR PHARMACIST (ANP)

Except as provided in Appendix 7P, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

7C1 Is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

7C1.1 Have graduated from a pharmacy program accredited by the **Accreditation Council for Pharmacy Education (ACPE) (previously named the** American Council on Pharmaceutical Education**)** ~~(ACPE)~~ or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

* * *

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Minor technical correction/update for consistency with 2021 federal regulation changes to 10 CFR 35.55(a)(1).

NRC RATS 2021-1
NRC Compatibility B

PART 7, APPENDIX 7P: TRAINING FOR EXPERIENCED RADIATION SAFETY OFFICER, TELETHERAPY OR MEDICAL PHYSICIST, AUTHORIZED MEDICAL PHYSICIST, AUTHORIZED USER, NUCLEAR PHARMACIST, AND AUTHORIZED NUCLEAR PHARMACIST.

7P1

7P1.1 An individual identified on a Department, NRC or an Agreement State license or a permit issued by a Department, NRC or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before August 14, 2020 need not comply with the training requirements of Appendix 7A, 7B, or 7C, respectively, except the Radiation Safety Officers and authorized medical physicists identified in 7P1.1 must meet the training requirements in 7A4 of Appendix 7A or 7B3 of Appendix 7B, as appropriate, for any material or uses for which they were not authorized prior to this date.

7P1.2 Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of Appendix 7A to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on an NRC or an Agreement State license or NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

7P1.3 Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, xray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in Appendix 7B, for those materials and uses that these individuals performed on or before October 24, 2005.

7P1.4 A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of Appendix 7A, 7B, or 7C respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and during the time period identified in 7P1.4, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of the regulations.

7P2

7P2.1 Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or an Agreement State, a permit issued by a NRC master material licensee, a permit issued by a NRC or an Agreement State broad scope licensee, or a permit issued by a NRC master material license broad scope permittee on or before August 14, 2020, who perform only those medical uses for

which they were authorized on or before that date need not comply with the training requirements of Sections D through H.

7P2.2 Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the NRC or an Agreement State, a permit issued by a NRC master material licensee, a permit issued by a NRC or an Agreement State broad scope licensee, or a permit issued ~~by~~**in accordance with** a NRC master material ~~license of~~ broad scope **license** on or before October 24, 2005, need not comply with the training requirements of Sections D through H for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

* * *

Commented [JSJ30]:
Minor technical correction for wording consistency with 2021 federal regulation changes to 10 CFR 35.57(b)(2).

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DRAFT 1 07/21/2022

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

RADIATION CONTROL - TRANSPORTATION OF RADIOACTIVE MATERIALS

6 CCR 1007-1 Part 17

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

Adopted by the Board of Health ~~August 19, 2020~~October 19, 2022, effective date ~~October 15, 2020~~December 15, 2022.

PART 17: TRANSPORTATION OF RADIOACTIVE MATERIALS

GENERAL PROVISIONS

17.1 Purpose and Scope.

17.1.1 Authority.

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

17.1.2 Basis and Purpose.

A statement of basis and purpose accompanies this part and changes to this part. A copy may be obtained from the Department.

17.1.3 Scope.

This part establishes requirements for packaging, preparation for shipment, and transportation of radioactive material.

17.1.4 Applicability.

17.1.4.1 This part applies to any person who transports radioactive material or delivers radioactive material to a carrier for transport.

(1) This part applies in particular to any licensee authorized by specific or general license to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the license, or transports that material on a public highway.

(2) The transport of licensed material or delivery of licensed material to a carrier for transport is subject to the:

(a) General provisions of 17.1 through 17.5, including referenced DOT regulations;

(b) Quality assurance requirements of 10 CFR Part 71; and

Commented [JSJ31]:
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: The acronym "RATS 2020-3" shown in the side margin notes in this draft refers to the U.S. Nuclear Regulatory Commission (NRC) regulation amendment tracking system (RATS). This system is used to identify and summarize changes to federal regulations that may be required for adoption by an NRC agreement state. To maintain agreement state status, and consistent with statute, Colorado's radiation regulations must be compatible with federal regulations of the NRC.

Colorado statute also prescribes that the radiation control regulations must be consistent with the model regulations of the Conference of Radiation Control Program Directors, Inc. (CRCPD). The CRCPD model regulation equivalent to part 17 was last updated in 2014, and does not yet reflect federal rule changes since that time.

Editorial note 4: This is not a complete rule. Some unaffected sections or provisions have been removed from the rule and are not shown in this draft. Unaffected sections/provisions are denoted with a " * * * ".

Commented [JSJ32]:
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.

(c) Operating controls and procedures requirements of 17.11 through 17.17.

(3) No provision of this part authorizes possession of licensed material.

(4) Exemptions from the requirement in 17.3 for a license are specified in 17.4.

(5) The general license under 17.7 requires that a NRC Certificate of Compliance or other package approval be issued for the package to be used under the general license.

(6) General licenses for which no package approval is required are issued in 17.8 and 17.9.

(7) These rules apply to any person required to obtain a Certificate of Compliance or an approved compliance plan from the NRC pursuant to 10 CFR **Part** 71 if the person delivers radioactive material to a common or contract carrier for transport or transports the material outside the confines of the person's plant or other authorized place of use.

Commented [JSJ33]: Added "Part" for consistency with format of references to federal rule.

17.1.4.2 The packaging and transport of radioactive material are also subject to other parts of these regulations and to the regulations of other agencies (such as the DOT, the United States Postal Service and the NRC) having jurisdiction over means of transport.

Commented [JSJ34]: Formatted for alignment of rule text.

17.1.4.3 The requirements of this part are in addition to, and not in substitution for, other requirements.

17.1.5 Published Material Incorporated by Reference.

17.1.5.1 Throughout this Part 17, federal regulations, state regulations, and standards or guidelines of outside organizations have been adopted and incorporated by reference. Unless a prior version of the incorporated material is otherwise specifically indicated, the materials incorporated by reference cited herein include only those versions that were in effect as of the most recent effective date of this Part 17 (~~October 2020~~**December 2022**), and not later amendments or editions of the incorporated material.

Commented [JSJ35]: Updated for consistency with revised effective date.

17.1.5.2 Materials incorporated by reference are available for public inspection, and copies (including certified copies) can be obtained at reasonable cost, during normal business hours from the Colorado Department of Public Health and Environment, Hazardous Materials and Waste Management Division, 4300 Cherry Creek Drive South, Denver, Colorado 80246. Additionally, https://www.colorado.gov/cdphe/radregs identifies where the incorporated material is available to the public on the internet at no cost. Due to copyright restrictions, certain materials incorporated in this Part are available for public inspection at the state publications depository and distribution center.

Commented [JSJ36]: Formatted for alignment of rule text.

17.1.5.3 Availability from Source Agencies or Organizations.

(1) All federal agency regulations incorporated by reference herein are available at no cost in the online edition of the Code of Federal Regulations (CFR) hosted by the U.S. Government Printing Office, online at www.govinfo.gov.

(2) All state regulations incorporated by reference herein are available at no cost in the online edition of the Code of Colorado Regulations (CCR) hosted by the Colorado Secretary of State's Office, online at https://www.sos.state.co.us/CCR/RegisterHome.do.

17.2 Definitions.

17.2.1 Definitions of general applicability to these regulations are in Part 1, Section 1.2.2.

17.2.2 Terms used in Part 17 have the definitions set forth as follows.

[* * * DENOTES UNAFFECTED SECTIONS/PROVISIONS IN THE DRAFT RULE]

* * *

"Type B package" means a Type B packaging together with its radioactive contents.[1]

1 A Type B package design is designated as B(U) or B(M). On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700kPa (100 lb/in2) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 CFR Part 71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. No distinction is made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, refer to 49 CFR Part 173. A Type B package approved prior to September 6, 1983 was designated only as Type B; limitations on its use are specified in 17.8.

Commented [JSJ37]: In footnote "1", "Part" is added for consistency with format of references to federal rule.

* * *

QUALITY ASSURANCE

17.10 Quality Assurance Requirements.

17.10.1 Subpart H of 10 CFR Part 71 describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in Subpart H of 10 CFR Part 71, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.

17.10.2 Each licensee is responsible for satisfying the applicable quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to the applicable requirements set forth in Subpart H of 10 CFR Part 71 (excluding 10 CFR Part 71.101(c)(2), (d), and (e) and 10 CFR Part 71.107 through 71.125).

Commented [JSJ38]: Added "Part" for consistency with format of references to federal rule.

17.10.3 Before the use of any package for the shipment of licensed material subject to Subpart H of 10 CFR Part 71, each licensee shall obtain Department approval of its quality assurance program. Each licensee shall file with the Department, a description of its quality assurance program, including a discussion of which requirements of Subpart H of 10 CFR Part 71 are applicable and how they will be satisfied.

17.10.4 Radiography containers.

A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of Part 5, sections 5.12.4 through 5.12.6 or equivalent Agreement State or NRC requirement, is deemed to satisfy the requirements of 17.7.2 and 10 CFR Part 71.101(b).

17.11 Advance Notification of Shipment of Nuclear Waste.

Commented [JSJ39]: Certain provisions of Section 17.11 have been formatted for alignment of text.

17.11.1 As specified in 17.11.3, 17.11.4, and 17.11.5, each licensee shall provide advance notification to the governor of a state, or the governor's designee, of the shipment of licensed material (nuclear waste), within or across the boundary of the state, before the transport, or delivery to a carrier, for

transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

17.11.2 As specified in 17.11.3, 17.11.4, and 17.11.5 of this section, after June 11, 2013, each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in 17.11.4.3(3), or the official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

17.11.3 Advance notification is also required under this section for the shipment of licensed material, other than irradiated fuel, meeting the following three conditions:

17.11.3.1 The licensed material is required by this part to be in Type B packaging for transportation;

17.11.3.2 The licensed material is being transported to or across a state boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

17.11.3.3 The quantity of licensed material in a single package exceeds the least of the following:

(1) 3000 times the A1 value of the radionuclides as specified in Appendix 17A, Table A1 for special form radioactive material; or

(2) 3000 times the A2 value of the radionuclides as specified in Appendix 17A, Table A1 for normal form radioactive material; or

(3) 1000 TBq (27,000 Ci).

17.11.4 Procedures for submitting advance notification

17.11.4.1 The notification must be made in writing to:

(1) The office of each appropriate governor or governor's designee;

(2) The office of each appropriate Tribal official or Tribal official's designee;

(3) The Department; and

(4) The NRC's Director, Office of Nuclear Security and Incident Response.

17.11.4.2 A notification delivered by mail must be postmarked at least 7 days before the beginning of the 7 day period during which departure of the shipment is estimated to occur.

17.11.4.3 A notification delivered by any other means than mail must reach the office of the governor or of the governor's designee or the Tribal official, or Tribal official's designee at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(1) ~~A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306)~~**RESERVED.**

(2) Contact information for each State, including telephone and mailing addresses of governors and governors' designees, and participating Tribes, including

Commented [JSJ40]:
This provision is removed and reserved for consistency with the 2020 amendments to 10 CFR Part 71.97(c)(3)(i). The information in the current rule (and original federal rule) references information in the 1995 Federal Register. This information is out of date. Current information can be found on the website specified in 17.11.4.3(2), or by contacting the NRC as indicated in provision (3).

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telephone and mailing addresses of Tribal officials and Tribal official's designees, is available on the NRC Web site at: https://scp.nrc.gov/special/designee.pdf.

(3) A list of the names and mailing addresses of the governor's designees and Tribal official's designees of participating Tribes is available on request from the Director, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

17.11.4.4 The licensee shall retain a copy of the notification as a record for 3 years.

* * *

17.17 Shipment Records.

* * *

17.17.3 The licensee shall maintain sufficient written records to furnish evidence of the quality of packaging.

17.17.3.1 The records to be maintained shall include:

(1) Results of the determinations required by 10 CFR **Part** 71.85(a) through (c);

Commented [JSJ41]: Added "Part" for consistency with format of references to federal rule.

(2) Design, fabrication, and assembly records;

(3) Results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and

(4) Results of maintenance, modification, and repair activities.

* * *

Appendix 17A - Determination of A1 and A2

17A1 Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations are given in Table 17A1. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) value. The Terabecquerel values are the regulatory standard. The curie values are for information only and are not intended to be the regulatory standard. Where values of A_1 or A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

17A2 For individual radionuclides whose identities are known, but which are:

17A2.1 Not listed in Table 17A1:

(1) The A_1 and A_2 values Table 17A3 may be used.

(2) Otherwise, the licensee shall obtain prior NRC approval of the A_1 and A_2 values for radionuclides not listed in Table 17A1, before shipping the material. The licensee shall submit such request for prior approval to NRC in accordance with 10 CFR Part 71.1.

17A2.2 Not listed in Table 17A2:

(1) The exempt material activity concentration and exempt consignment activity values contained in Table 17A3 may be used.

(2) Otherwise, the licensee shall obtain prior NRC approval of the exempt material activity concentration and exempt consignment activity values for radionuclides not listed in Table 17A2, before shipping the material. The licensee shall submit such request for prior approval to NRC in accordance with 10 CFR **Part** 71.1.

* * *

Commented [JSJ42]: Added “Part” for consistency with format of references to federal rule.

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TABLE 17A1: A1 AND A2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)b	A_2 (TBq)	A_2 (Ci).	Specific activity	
						(TBq/g)	(Ci/g)
* * *	* * *	* * *	* * *	* * *	* * *	* * *	* * *
Sm-145	Samarium (62)	1.0X10 [1]	2.7X10 [2]	1.0X10 [1]	2.7X10 [2]	9.8X10 [1]	2.6X10 [3]
Sm-147	.	Unlimited	Unlimited	Unlimited	Unlimited	~~8.5X10 -4~~ **8.5X10 -10**	2.3X10 -8
Sm-151	.	4.0X10 [1]	1.1X10 [3]	1.0X10 [1]	2.7X10 [2]	9.7X10 -1	2.6X10 [1]
* * *	* * *	* * *	* * *	* * *	* * *	* * *	* * *

207 * * *

208 [NO FURTHER CHANGES TO THE RULE BEYOND THIS POINT]

209

Commented [JSJ43]:
For brevity, most unaffected radionuclides are not shown in Table 17A1, but remain as-is with no changes.

Commented [JSJ44]:
The specific activity value is revised for Sm-147 to maintain consistency with 2020 technical corrections to 10 CFR Part 71, Appendix A, Table A-1.

The specific activity is a standardized value/constant rather than a limit and can be found in other references or can be calculated or converted from the adjacent Ci/g value. No impacts are expected by this change as this is an isotope not commonly used or transported/shipped by licensees.

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DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

RADIATION CONTROL – PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

6 CCR 1007-1 Part 22

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

Adopted by the Board of Health on ~~August 19, 2020~~ October 19, 2022; effective ~~date October 15, 2020~~ December 15, 2022.

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

22.1 Authority.

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

Section A – General provisions

22.2 Scope, Purpose and Applicability.

22.2.1 Scope and Purpose.

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

22.2.2 Applicability.

22.2.2.1 Sections B and C of this part apply to any person who, under these regulations~~,~~ possesses or uses at any site, an aggregated category 1 or category 2 quantity of radioactive material.

22.2.2.2 Section D of this part applies to any person who, under these regulations:

(1) Transports or delivers to a carrier for transport in a single shipment, a category 1 or category 2 quantity of radioactive material; or

(2) Imports or exports a category 1 or category 2 quantity of radioactive material; the provisions only apply to the domestic portion of the transport.

22.2.3 Published material incorporated by reference.

Commented [JSJ45]: **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: The acronym "RATS 2021-2" shown in side margins of this draft refers to the U.S. Nuclear Regulatory Commission (NRC) regulation amendment tracking system (RATS). This system is used to identify and summarize changes to federal regulations that may be required for adoption by an NRC agreement state. To maintain agreement state status, and consistent with statute, Colorado's radiation regulations must be compatible with federal regulations of the NRC.

Colorado statute also prescribes that the radiation control regulations must be consistent with the model regulations of the Conference of Radiation Control Program Directors, Inc. (CRCPD). The CRCPD model regulation equivalent to part 22 was last updated in 2014, and does not yet reflect federal rule changes since that time.
Editorial note 4: This is not a complete rule. Some unaffected sections or provisions have been removed from the rule and are not shown in this draft. Unaffected sections/provisions are denoted with a " * * * ".

Commented [JSJ46]: 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 [JSJ47]: 22.2.1 has been formatted for alignment of text.

Commented [JSJ48]: Delete unneeded space.
22.2.2 has been formatted for alignment of text.

22.2.3.1 Throughout this Part 22, federal regulations, state regulations, and standards or guidelines of outside organizations have been adopted and incorporated by reference. Unless a prior version of the incorporated material is otherwise specifically indicated, the materials incorporated by reference cited herein include only those versions that were in effect as of the most recent effective date of this Part 22 (~~October 15, 2020~~**December 15, 2022**), and not later amendments or editions of the incorporated material.

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

22.2.3.3 Availability from Source Agencies or Organizations.

(1) All federal agency regulations incorporated by reference herein are available at no cost in the online edition of the Code of Federal Regulations (CFR) hosted by the U.S. Government Printing Office, online at www.govinfo.gov.

(2) All state regulations incorporated by reference herein are available at no cost in the online edition of the Code of Colorado Regulations (CCR) hosted by the Colorado Secretary of State's Office, online at https://www.sos.state.co.us/CCR/RegisterHome.do.

22.2.4 Basis and Purpose.

22.2.4.1 A statement of basis and purpose accompanies this part and changes to this part. A copy may be obtained from the Department.

[* * * DENOTES UNAFFECTED SECTIONS/PROVISIONS IN THE DRAFT RULE]

* * *

Part 22, Appendix A - Category 1 and Category 2 Radioactive Materials

Table 1—Category 1 and Category 2 Threshold

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

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Americium-241	60	1,620	0.6	16.2
Americium-241/Be	60	1,620	0.6	16.2
Californium-252	20	540	0.2	5.40
Cobalt-60	30	810	0.3	8.10
Curium-244	50	1,350	0.5	13.5
Cesium-137	100	2,700	1	27.0
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,160	0.8	21.6
Plutonium-238	60	1,620	0.6	16.2
Plutonium-239/Be	60	1,620	0.6	16.2

Commented [JSJ49]: In addition to the identified change in effective date, provisions in 22.2.3 have been formatted for alignment of text and appearance.

Commented [JSJ50]: Standard language added for consistency with formatting and content of other regulatory parts.

Promethium-147	40,000	1,080,000	400	10,800
Radium-226	40	1,080	0.4	10.8
Selenium-75	200	5,400	2	54.0
Strontium-90	1,000	27,000	10	270
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81.0

Note: *Calculations Concerning Multiple Sources or Multiple Radionuclides* The ''sum of fractions'' methodology for evaluating combinations of multiple sources or multiple radionuclides is to be used in determining whether a location meets or exceeds the threshold and is thus subject to the requirements of this Part.

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

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

R_1 = total activity for radionuclide 1
R_2 = total activity for radionuclide 2
R_N = total activity for radionuclide n
AR_1 = activity threshold for radionuclide 1
AR_2 = activity threshold for radionuclide 2
AR_N = activity threshold for radionuclide n

$$\sum_{1}^{n}\left[\frac{R_1}{AR_1}+\frac{R_2}{AR_2}+\frac{R_n}{AR_n}\right]\geq 1.0$$

$$\frac{R_1}{AR_1}+\frac{R_2}{AR_2}+\cdots+\frac{R_n}{AR_n}\geq 1.0$$

Commented [JSJ51]:
The current sum of fractions equation is deleted and replaced with an updated sum of fractions equation. The correction is necessary to make the expression mathematically reflect that an indefinite number of nuclides may be included in the calculation. The change is consistent with the December 2021 updates to federal rule in 10 CFR Part 37.

[Editorial note: due to the equations being an image/graphic in WORD, the normal strike out text and bold/colored text using "track changes" functions do not work, and a manual strikeout method is used/shown.]

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