



Dedicated to protecting and improving the health and environment of the people of Colorado

To: Members of the State Board of Health

From: Jennifer Opila, Program Manager
James Jarvis, Regulatory Lead
Hazardous Materials and Waste Management Division

Through: Gary Baughman, Division Director *GB*

Date: March 15, 2017

Subject: **Request for Rulemaking Hearing**
Proposed Amendments to 6 CCR 1007-1, Part 4, Standards for Protection Against Radiation with a request for a rulemaking hearing to be set for May of 2017

The Division is proposing to make minor technical amendments to the Part 4 radiation regulations, titled *Standards for Protection Against Radiation*. Part 4 is a rule which contains the basic radiation protection requirements for all facilities using radiation machines or radioactive materials. However, the proposed technical changes impact only radioactive materials licensees.

The rule requires an amendment to correct an error not identified during a 2015 rulemaking and is necessary to maintain compatibility with federal rule and status as an agreement state. Specifically, a value in appendix 4C lists the incorrect threshold value for an uncommon isotope which would require labeling. Additionally, a new provision is added to the rule to serve as a resource to the regulated community to provide additional information on where to locate documents that are incorporated into the Part 4 rule by reference. Minor typographical and formatting errors are also corrected during this rulemaking effort.

Further details of the proposed rule are listed in a Statement of Basis and Purpose and Specific Statutory Authority for the proposed rule, which, along with a Regulatory Analysis and supporting information, is available at: <https://www.colorado.gov/cdphe/radregs>

During early stakeholder engagement outreach efforts in December 2016, approximately 600 stakeholders were notified of the opportunity to provide comments on the proposed rule changes under consideration. No comments were received during the comment period.

For efficiency purposes, this Part 4 rulemaking is being amended concurrent with other rulemaking activities for Part 3 and Part 22. The changes being proposed for these rules are not related.

At the March 2017 request for rulemaking, the Radiation Program requests that the Board of Health set a rulemaking hearing for May of 2017.

DRAFT

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1007-1, Part 4, Standards for Protection Against Radiation

Basis and Purpose.

The proposed rule change makes a few minor technical and editorial corrections to the rule. During a prior Part 4 rulemaking in 2015, a new appendix 4C was added to the rule for consistency with federal rules of appendix C to 10 CFR 20. The incorporated table was obtained from the Nuclear Regulatory Commission (NRC) and was based on the online (web based) federal rule. Unfortunately, the online table obtained from NRC contained an unknown error. The value differed from the value as published in the federal register and was not recognized until after the final Part 4 rule was published. The current rulemaking effort corrects this error, consistent with the printed (official) version of the code of federal regulations.

The proposed rule change also incorporates additional resource information for the regulated community on where to locate secondary documents that may be incorporated by reference in the rule.

Specific Statutory Authority.

These rules are promulgated pursuant to the following statutes:
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

Is this rulemaking due to a federal statutory or regulatory change?

_____ Yes
__X__ No

Does this rule incorporate materials by reference?

_____ Yes
__X__ No

If "Yes," the rule needs to provide the URL of where the material is available on the internet (CDPHE website recommended) or the Division needs to provide one print or electronic copy of the incorporated material to the State Publications Library. § 24-4-103(12.5)(c), C.R.S.

Does this rule create or modify fines or fees?

_____ Yes
__X__ No

DRAFT

REGULATORY ANALYSIS
for Amendments to

6 CCR 1007-1, Part 4, Standards for Protection Against Radiation

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

The Part 4 rule is both a broad and specific rule containing the “fundamental” radiation protection (safety) requirements for radioactive materials facilities and radiation machine users. However, the technical change under consideration does not impact radiation (x-ray) machine users. The proposed technical change in the value labeling value would benefit any licensee using protactinium-230 by not requiring them to label unless the quantity met or exceeded 0.1 uCi, a factor of 10 higher than the current labeling value. The proposed change thereby provides some regulatory relief. Pa-230 is an uncommon radionuclide and the Department is unaware of any licensees using this isotope.

Since there are no known users of Pa-230 in Colorado, no entities will bear the cost of the proposed rule nor will any entities benefit from this change in the proposed rule. The change is however necessary for consistency with federal regulations.

It is expected that all users of the rule will generally benefit from the proposed new provision regarding documents that are incorporated by reference. The added language will allow the regulated community to readily locate documents that are incorporated by reference.

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.

It is expected that due to the minor change of the proposed technical correction to the rule there will be no quantitative or qualitative impact. The proposed change in the labeling value will have no impact, since there are no regulated entities known to be using Pa-230.

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.

The proposed change contains minor technical and editorial corrections and has no monetary cost associated with implementation or enforcement.

The rule requirements are enforced only by the Department. No other agency will encounter costs as a result of the proposed changes.

The costs to the Department or state revenues will not change as a result of the proposed rule changes.

The agency cost to implement the new reference materials on the website is expected to be negligible and in line with the routine course of business operations. The costs to the Department or state revenues will not change as a result of the proposed rule changes.

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

The benefits of amending the rule will be to address an outstanding comment/inconsistency with a numerical value in the currently published federal rules. Amending the rule will help Colorado operate within the national framework of regulating radioactive material and to maintain its status as an NRC agreement state by maintaining consistency with federal regulations.

Inaction on the proposed rule will result in potential conflict with federal requirements and may jeopardize Colorado's agreement state status. Inaction would also limit Colorado's consistency within the national regulatory framework for radioactive materials regulation.

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

The proposed change is a technical correction with no costs other than the costs associated with the rulemaking process itself. There are no less costly or less intrusive methods for achieving the purpose of the proposed rule which is to correct an error in a numerical value.

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

The proposed change is a technical correction necessary for compatibility with federal rule. There are no alternate rules or alternatives available rulemaking to address this correction.

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 is a technical correction necessary for compatibility with federal rule. There is no quantifiable data associated with the proposed rule change.

DRAFT
STAKEHOLDER COMMENTS
for Amendments to
6 CCR 1007-1, Part 4, Standards for Protection Against Radiation

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:

The Governor appointed members of the Colorado Radiation Advisory Committee who represent the healing arts, industry and higher education reviewed the proposed rule changes and had no comments on the proposed changes. The Part 4 rule applies the fundamental regulatory and radiation safety requirements for radioactive materials licensees and therefore all 320 active radioactive material licensees were notified of the rule changes being considered for amendment and were given the opportunity to provide input. Additionally, another 280 stakeholders representing a diverse group of entities, including non-licensees, public interest groups and individuals, federal agencies and others were also notified of the rule change being considered and were invited to provide input and comments. No comments were received during this early stakeholder engagement period.

As part of the agreement state process, the Nuclear Regulatory Commission (NRC) reviewed the draft rule changes for consistency and compatibility with federal rule. The NRC provided no comments on the proposed rule changes specific to Part 4.

As the rulemaking process for Part 4 is being processed concurrent with other technical rulemaking activities for Part 3 and Part 22, the same early stakeholder engagement process and contact lists were used for all parts concurrently.

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

There were no major factual or policy issues encountered during the stakeholder process. No stakeholders provided comments on the proposed rule change.

Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradoans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?

The proposed rule change impacts Coloradoans equally. The proposed rule changes are minor technical corrections that do not provide an opportunity to advance HEEJ. The content of the proposed rule change is driven by the need for consistency with federal rule and the national framework for regulating radioactive materials and radiation sources.

1 **DRAFT 1 02/27/17**

2 **DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

3 **Hazardous Materials and Waste Management Division**

4 **RADIATION CONTROL - STANDARDS FOR PROTECTION AGAINST RADIATION**

5 **6 CCR 1007-1 Part 04**

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

7 **Adopted by the Board of Health May 17, 2017; effective date July 15, 2017.**

8 _____

9 ~~Adopted by the Board of Health June 17, 2015.~~

10 **PART 4: STANDARDS FOR PROTECTION AGAINST RADIATION**

11 **STANDARDS FOR PROTECTION AGAINST RADIATION**

12 * * * = Indicates omission of unaffected rules/rule sections
13
14

15 * * *

16 **4.1.4.2 In accordance with Section 24-4-103(12.5)(c), CRS,**
17 **<https://www.colorado.gov/cdphe/radregs> identifies where incorporated material is**
18 **available to the public on the internet at no cost. If the incorporated material is not**
19 **available on the internet at no cost to the public, copies of the incorporated material has**
20 **been provided to the State Publications Depository and Distribution Center, also known as**
21 **the State Publications Library. The State Librarian at the State Publication Library retains a**
22 **copy of the material and will make the copy available to the public.**

23 * * *

24 **Table 4B3 "Releases to Sewerage"**

25 The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in
26 4.35. The concentration values were derived by taking the most restrictive occupational stochastic oral
27 ingestion ALI and dividing by 7.3×10^6 (ml). The factor of 7.3×10^6 (ml) is composed of a factor of $7.3 \times$
28 10^5 (ml), the annual water intake by reference man, and a factor of 10, such that the concentrations, if the
29 sewage released by the licensee were the only source of water ingested by a reference man during a
30 year, would result in a committed effective dose equivalent of 0.5 rem (5 mSv).

31 * * *

32 * * *

33

Comment [jsj1]: NOTE 1: Stakeholders should be aware that the proposed changes affect only a few limited sections of the Part 4 rule and that there are gaps in numbering in the draft due to the unaffected sections being excluded. Gaps/excluded sections are denoted by " * * * ".

NOTE 2: Side margin comments such as this are for information only to aid the reader in evaluating the proposed changes and are not part of the rule. These side margin notes will be removed prior to final submission to the Colorado Secretary of State for publication in the Colorado Register.

Comment [jsj2]: These dates reflect the anticipated adoption and effective dates and are subject to change.

Comment [jsj3]: A new provision is added to provide an online location resource for documents referenced in the rule.

Comment [jsj4]: Correction of typographical/formatting errors:
-Correction of spelling "off" to "of";
-Incorporation of international (SI) units of mSv ("millisievert"), consistent with other provisions in Part 4 which typically list both rem and Sv.

PART 4, APPENDIX 4C: QUANTITIES OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

QUANTITIES^j OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

* To convert μCi to kBq, multiply the μCi value by 37.

Radionuclide	Abbreviation	Quantity (μCi)
* * *	* * *	* * *
Protactinium-230	Pa-230	0.010.1
* * *	* * *	* * *

* * *

Comment [jsj5]:

NOTE: The proposed change to Appendix 4C impacts only the value for Protactinium-230. No other values in Table 4C (before or after Pa-230) are impacted. For brevity of the draft rule, only the impacted table entry is shown rather than the full table.

Comment [jsj6]: During the prior amendment to Part 4 in 2015, NRC provided a table to replace the Appendix 4C in effect at that time using a table equivalent to that found on NRC's website. The value for Pa-230 originally provided by NRC was later found to be incorrect and differed from the "official" value found in the printed version of the Code of Federal Regulations (CFR). The proposed change corrects this error and makes the rule consistent with Appendix C of 10 CFR Part 20.

The proposed change will provide some regulatory relief as the threshold for requiring labeling will be higher by a factor of 10. Protactinium-230 is an uncommon isotope and it is expected that few if any licensees would be impacted by the proposed change.

NRC Compatibility "C"
NRC Ltr 11/18/15