



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

To: Members of the State Board of Health

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Through: Gary Baughman, Division Director *GWB*

Date: May 17, 2017

Subject: **Rulemaking Hearing**
Proposed Amendments to 6 CCR 1007-1, Part 3, Licensing of Radioactive Material
for the rulemaking hearing to occur in May of 2017

The Division is proposing to make minor technical amendments to the Part 3 radiation regulations, titled *Licensing of Radioactive Material*. Part 3 is a rule which contains the foundational requirements for licensing of radioactive materials facilities. The rule requires an amendment to correct an error not identified during a prior rulemaking that is necessary to maintain compatibility with federal rules and to maintain Colorado's status as an agreement state. Specifically, in a provision containing an exemption for common carriers of radioactive materials, the current regulation makes reference to federal statute (the Atomic Energy Act) but should instead make reference to state statute (e.g., the Colorado Radiation Control Act). The proposed amendment corrects this error. Additionally, a new provision is added to serve as a resource to the regulated community to provide additional information on where to locate documents that are incorporated in the Part 3 rule by reference.

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 rule changes under consideration. No comments were received during the comment period.

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

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

Basis and Purpose.

The proposed rule change makes a minor technical correction to the rule. During a prior Part 3 rulemaking in late 2015, a new provision was added in section 3.9 for consistency with federal rules in 10 CFR 30.13. The incorporated provision was added exactly as stated in federal rule. Unfortunately, for state use, the incorporated provision in 3.9 should have made reference to Colorado statute instead of federal statute. The current rulemaking request corrects this error. Although the draft rule was provided to the U.S. Nuclear Regulatory Commission (NRC) for review, the error was not identified until after the rule became final.

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.
 No

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

Yes
 No

Does this rule incorporate materials by reference?

Yes
 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
 No

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REGULATORY ANALYSIS
for Amendments to

6 CCR 1007-1, Part 3, Licensing of Radioactive Material

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 3 rule is both a broad and specific rule containing the “fundamental” licensing requirements for radioactive materials facilities. The proposed technical reference change is not expected to impact radioactive materials licensees in any way.

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 from referencing the federal statute in current rule to referencing state statute (as proposed) will have little impact, since both statutes have similar requirements in this area.

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 is a technical cross-reference correction and has no monetary cost associated with implementation.

The rule requirements are enforced only by the Department. No other agency will encounter costs as a result of the proposed 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 and federal rule changes from the NRC so the rule will be made consistent with the national framework of regulating licensed facilities. The rule amendment will help ensure that Colorado’s status as an agreement state is maintained.

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 changes are minor technical corrections with no associated costs other than the rulemaking process itself. There are no less costly or less intrusive methods for achieving the purpose of the proposed rule.

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.

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

The proposed change is primarily 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.

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STAKEHOLDER COMMENTS
for Amendments to
6 CCR 1007-1, Part 3, Licensing 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:

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 3 rule applies the fundamental regulatory processes for licensing of entities using radioactive materials, 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 3.

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

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 of the notice of the rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

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

Yes.

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

There were no 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 - LICENSING OF RADIOACTIVE MATERIAL**

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

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

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

8 _____

9 **Adopted by the Board of Health on December 16, 2015.**

10 **LICENSING OF RADIOACTIVE MATERIAL**

11 * * * = Indicates omission of unaffected rules/rule sections

14 * * *

15 **3.1.4.3** In accordance with Section 24-4-103(12.5)(c), CRS,
16 <https://www.colorado.gov/cdphe/radregs> identifies where incorporated material is
17 available to the public on the internet at no cost. If the incorporated material is not
18 available on the internet at no cost to the public, copies of the incorporated material has
19 been provided to the State Publications Depository and Distribution Center, also known as
20 the State Publications Library. The State Librarian at the State Publication Library retains a
21 copy of the material and will make the copy available to the public.

22 * * *

23 **ADDITIONAL EXEMPTIONS**

24 **3.7 Carriers**

25 Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service
26 are exempt from the regulations in this Part and Parts 5, 7, 16, 19, and 22 and the requirements
27 for a license set forth in ~~section 81 of the Atomic Energy Act~~ **Section 25-11-103, CRS** to the
28 extent that they transport or store radioactive material in the regular course of carriage for another
29 or storage incident thereto.

30 * * *

31 * * *

Commented [jsj1]: NOTE 1: Stakeholders should be aware that the proposed change affects only one section of the Part 3 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.

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

Adopted and effective dates relocated for consistency with other rules of the Department.

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

Commented [jsj4]: As written in the current rule, this provision is equivalent to that found in 10 CFR 30.13. However, NRC has identified that Colorado should substitute an equivalent reference in Colorado’s Radiation Control Act (RCA) in lieu of referencing the (federal) Atomic Energy Act. The proposed change addresses this required substitution.

NRC Compatibility “B”
NRC RATS 2013-1
NRC Ltr 08/03/16