



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
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Hazardous Materials and Waste Management Division

Through: Gary Baughman, Division Director *GWB*

Date: May 17, 2017

Subject: **Rulemaking Hearing**
Proposed Amendments to 6 CCR 1007-1, Part 22, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material for the rulemaking hearing to occur in May of 2017

The Division is proposing to make minor technical corrections to the Part 22 radiation regulations, titled *Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material*. Part 22 is a newer rule which contains security requirements for certain licensees who possess and use radioactive materials which have been determined by the federal government to present a security risk. The Part 22 rule is not applicable to facilities using radiation machines or those licensees using lower risk radioactive materials not identified as Category 1 or Category 2 materials. (The Part 22 rule itself specifies the criteria for those materials and conditions which invoke the requirements of the rule).

The rule requires an amendment to make several corrections as a result of changes in certain Nuclear Regulatory Commission (NRC) organizational structure, contact information, addresses and web site references that are used in the rule. A cross-reference error not identified during the initial development and finalization of Part 22 in 2015 is also corrected for consistency with federal rule. 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 22 rule by reference. Minor typographical and formatting errors are also corrected during this rulemaking effort.

Further details of the proposed rule changes 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 22 rulemaking is being amended concurrent with other rulemaking activities for Part 3 and Part 4. The changes being proposed for these rules are not related.

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STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1007-1, Physical Protection of
Category 1 and Category 2 Quantities of Radioactive Material

Basis and Purpose.

The proposed rule change makes several minor technical and editorial changes as a result of changes to the Nuclear Regulatory Commission organization, contact information and regulations in 10 CFR Part 37. Additionally, the rule corrects a cross-reference error that was not identified until after the final Part 22 rule was published in 2015. The current rulemaking effort corrects this error, consistent with 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.
 No

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

Yes
 No

Does this rule incorporate materials by reference?

Yes If "Yes," the rule needs to provide the URL of where the
 No 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, Physical Protection of
Category 1 and Category 2 Quantities 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 22 rule is applicable to a limited number (less than 10%) of radioactive materials licensees regulated by the Department. Since the proposed changes are non-substantive informational changes, no entities are expected to bear any cost due to the proposed rule changes.

The licensees regulated under Part 22 will benefit from the amended rule being consistent with the information contained in current federal regulation.

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 nature of the proposed corrections to the rule, there will be no quantitative impact. The qualitative (positive) impact will be that the regulation is made consistent with federal rule and that all references to NRC websites, organizations, and contact information will be true and correct.

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 outstanding comments and inconsistency with currently published federal regulations. 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 continued conflict with federal requirements, incorrect information, 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 purpose of the proposed rule change is to make several technical corrections. There are no anticipated no costs other than the costs associated with the rulemaking process itself. There are no less costly or less intrusive methods for achieving the primary purpose of the proposed rule change which is to provide true and correct information that is consistent with federal regulation.

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

The proposed changes are technical corrections necessary for compatibility and consistency with federal rule. There are no alternate rules or alternatives available rulemaking to address the needed corrections.

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, 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:

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 changes under consideration. The Part 22 rule applies specific security related requirements for those radioactive materials which have been determined to present a national security risk. Although the rule applies only to a small percentage of all radioactive materials licensees, 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 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 identified one additional item in Part 22 requiring correction which has been addressed in the most recent draft of the Part 22 rule.

As the rulemaking process for Part 22 is being processed concurrent with other technical rulemaking activities for Part 3 and Part 4, 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.

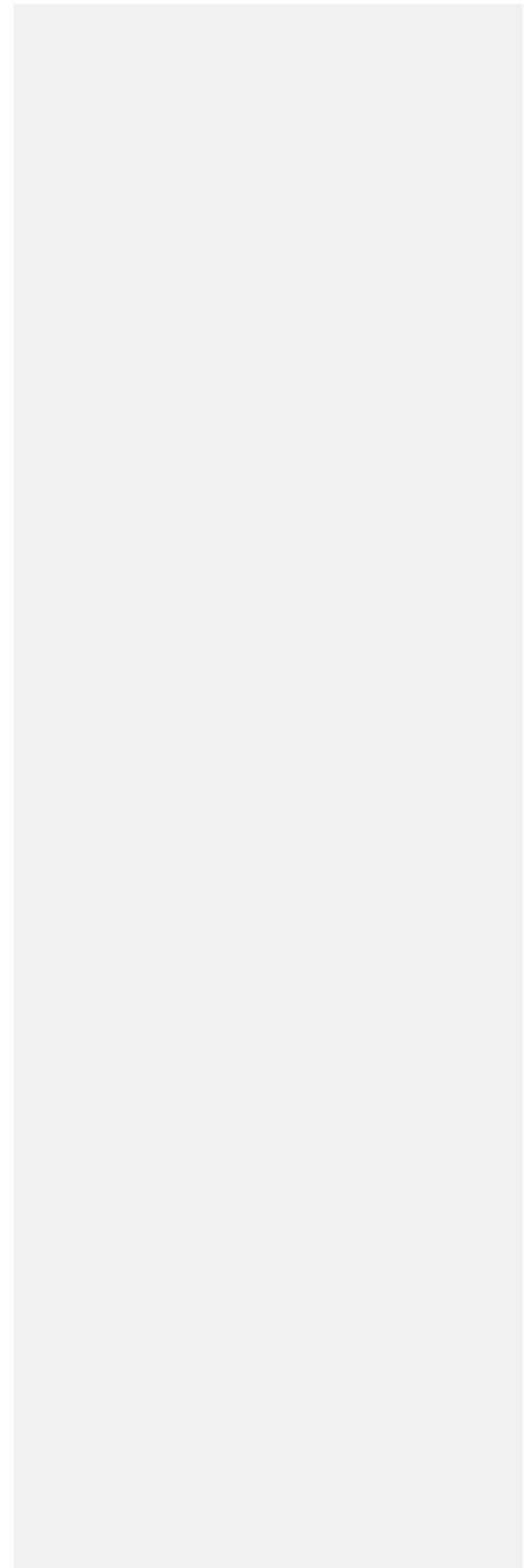
Yes.

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 early stakeholder engagement 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 – PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2
5 QUANTITIES OF RADIOACTIVE MATERIAL

6 6 CCR 1007-1 Part 22

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

8 Adopted by the Board of Health May 17, 2017; effective date July 15, 2017

10 Adopted by the Board of Health May 15, 2015

11 Affected licensees shall be compliant with this Part on or before March 19, 2016

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

15 22.2.2.3 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
19 material has been provided to the State Publications Depository and Distribution
20 Center, also known as the State Publications Library. The State Librarian at the
21 State Publication Library retains a copy of the material and will make the copy
22 available to the public.

24 22.9.7.8 Records.

25 A. The licensee shall retain documentation regarding the trustworthiness and reliability of
26 individual employees for 3 years from the date the individual no longer requires
27 unescorted access to category 1 or category 2 quantities of radioactive material.

29 22.11.3 Procedures for processing of fingerprint checks.

30 A. For the purpose of complying with this Part, licensees shall submit to the U.S. Nuclear
31 Regulatory Commission, Director, Division of Facilities and Security, 11545 Rockville
32 Pike, Rockville, MD 20852-2738, ATTN: Criminal History Program, Mail Stop ~~T-~~
33 ~~03B46M~~TWB-05 B32M, one completed, legible standard fingerprint card (Form FD-258,
34 ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint
35 record for each individual requiring unescorted access to category 1 or category 2
36 quantities of radioactive material. Copies of these forms may be obtained by writing the
37 Office of the Chief Information Officer Information Services, U.S. Nuclear Regulatory
38 Commission, Washington, DC 20555-0001, by calling ~~1-301-415-7543~~1-630-829-9565,
39 or by email to FORMS.Resource@nrc.gov. Guidance on submitting electronic fingerprints

Commented [jsj1]:
NOTE 1: Only those radioactive materials licensees possessing an aggregated Category 1 or Category 2 quantity of radioactive material are governed by this rule and the associated proposed changes. Category 1 and Category 2 quantities of radioactive material are specified in the current Part 22 rule which may be found at: <https://www.colorado.gov/cdphe/radregs>
There are no proposed changes to the Category 1 or Category 2 quantities of radioactive material.

NOTE 2: Stakeholders should be aware that the proposed changes affect only a few limited sections of the Part 22 rule and that there are gaps in numbering in this draft due to the unaffected sections being excluded. Gaps/excluded sections are denoted by " * * * ".

NOTE 3: 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 Office 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.

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

Commented [jsj4]: The Part 22 rule currently contains two sections which are numbered 22.9.7. Due to the inadvertent duplication in section numbering, this section is renumbered as 22.9.8.

Commented [jsj5]: As a result of an organizational change at the Nuclear Regulatory Commission (NRC) following the publication of Part 22, the reference in Part 22 to the appropriate NRC office and mailing information is updated. Other contact related information is also updated in subsections A, and B (of 22.11.3) for consistency with federal rule.

[Note: While the Radiation Program strives to avoid making references to website URL's (uniform resource locator) phone numbers and other information that may change, Part 22 relies upon a partnership with federal agencies to carry out certain portions of the requirements of the Part 22 rule and therefore reference to federal partner information is required.]

NRC Compatibility "B"
NRC RATS 2015-5
10 CFR 37.27(c)(1)
NRC Ltr 12/27/16

40 can be found at <http://www.nrc.gov/site-help/e-submittals.html>~~site-~~
41 ~~help/esubmittals.html.~~

- 42 B. Fees for the processing of fingerprint checks are due upon application. Licensees shall
43 submit payment with the application for the processing of fingerprints through corporate
44 check, certified check, cashier's check, money order, or electronic payment, made
45 payable to "U.S. NRC." (For guidance on making electronic payments, contact the
46 Security Branch, Division of Facilities and Security at ~~301-415-7513~~**301-492-3531**.)
47 Combined payment for multiple applications is acceptable. The U.S. Nuclear Regulatory
48 Commission publishes the amount of the fingerprint check application fee on the NRC's
49 public Web site. (To find the current fee amount, go to the Electronic Submittals page at
50 <http://www.nrc.gov/site-help/e-submittals.html> and see the link for the Criminal History
51 Program under Electronic Submission Systems.)

- 52 C. The U.S. Nuclear Regulatory Commission will forward to the submitting licensee all data
53 received from the FBI as a result of the licensee's application(s) for criminal history
54 records checks.
55
56 * * *
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58 22.16.3 Training.

- 59 A. Each licensee shall conduct training to ensure that those individuals implementing the
60 security program possess and maintain the knowledge, skills, and abilities to carry out
61 their assigned duties and responsibilities effectively. The training must include instruction
62 in:
- 63 1. The licensee's security program and procedures to secure category 1 or category
64 2 quantities of radioactive material, and in the purposes and functions of the
65 security measures employed;
 - 66 2. The responsibility to report promptly to the licensee any condition that causes or
67 may cause a violation of Department requirements;
 - 68 3. The responsibility of the licensee to report promptly to the local law enforcement
69 agency and licensee any actual or attempted theft, sabotage, or diversion of
70 category 1 or category 2 quantities of radioactive material; and
 - 71 4. The appropriate response to security alarms.
- 72 B. In determining those individuals who shall be trained on the security program, the
73 licensee shall consider each individual's assigned activities during authorized use and
74 response to potential situations involving actual or attempted theft, diversion, or sabotage
75 of category 1 or category 2 quantities of radioactive material. The extent of the training
76 must be commensurate with the individual's potential involvement in the security of
77 category 1 or category 2 quantities of radioactive material.
- 78 C. Refresher training must be provided at a frequency not to exceed 12 months and when
79 significant changes have been made to the security program. This training must include:
- 80 **1.** Review of the training requirements of ~~22.16.3-A~~ and any changes made to the
81 security program since the last training;
 - 82 2. Reports on any relevant security issues, problems, and lessons learned;
 - 83 3. Relevant results of Department inspections; and

Commented [jsj6]:

The Part 22 rule was a new regulation initially adopted May 15, 2015. Following issuance of the rule it was determined that a cross-reference error existed in Section 22.16.3.C.1. The current provision in 22.16.3.C.1 references only subsection "A" of 22.16.3 and therefore incorrectly limits the scope of the requirements specific to security refresher training.

Consistent with the equivalent provision (and cross-reference) in 10 CFR 37.43, provision 22.16.3.C.1 should cross reference all of section 22.16.3 for the requirements for security related refresher training. The proposed change corrects this error.

NRC Compatibility "B"
10 CFR 37.43
RATS 2013-1

- 84 4. Relevant results of the licensee's program review and testing and maintenance.
- 85 D. The licensee shall maintain records of the initial and refresher training for 3 years from
- 86 the date of the training. The training records must include dates of the training, topics
- 87 covered, a list of licensee personnel in attendance, and related information.

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90 **22.23 Reporting of Events.**

91 22.23.1 The licensee shall immediately notify the LLEA after determining that an unauthorized
 92 entry resulted in an actual or attempted theft, sabotage, or diversion of a category 1 or category 2
 93 quantity of radioactive material. As soon as possible after initiating a response, but not at the
 94 expense of causing delay or interfering with the LLEA response to the event, the licensee shall
 95 notify the Department. In no case shall the notification to the Department be later than 4 hours
 96 after the discovery of any attempted or actual theft, sabotage, or diversion.

97 22.23.2 The licensee shall assess any suspicious activity related to possible theft, sabotage, or
 98 diversion of category 1 or category 2 quantities of radioactive material and notify the LLEA as
 99 appropriate. As soon as possible but not later than 4 hours after notifying the LLEA, the licensee
 100 shall notify the Department

101 ~~22.24~~23.3 The initial telephonic notification required by 22.23.1 must be followed within a period of
 102 30 days by a written report submitted to the Department address specified in 22.4. The report
 103 must include sufficient information for Department analysis and evaluation, including identification
 104 of any necessary corrective actions to prevent future instances.

Commented [jsj7]: The proposed change is a technical correction. This section is currently incorrectly numbered as 22.24.3 since it resides in subsection 22.23. The proposed change corrects the numbering error.

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108 **22.27 Advance Notification of Shipment of Category 1 Quantities of Radioactive Material.**

109 22.27.1 As specified in 22.27.1.A. and 22.27.1.B., each licensee shall provide advance
 110 notification to the Department and the governor of a State, or the governor's designee, of the
 111 shipment of licensed material in a category 1 quantity, through or across the boundary of the
 112 State, before the transport, or delivery to a carrier for transport of the licensed material outside
 113 the confines of the licensee's facility or other place of use or storage.

114 A. Procedures for submitting advance notification.

115 1. The notification to the office of each appropriate governor or governor's designee
 116 is available on the NRC's Web site at ~~http://nrc-~~
 117 ~~stp.ornl.gov/special/designee.pdf~~<https://scp.nrc.gov/special/designee.pdf>. A
 118 list of the contact information is also available upon request from the Director,
 119 Division of Material Safety, State, Tribal, and Rulemaking Programs, Office of
 120 Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission,
 121 Washington, DC 20555-0001. The notification to the Department must be made
 122 to the address specified in 22.4.
 123 * * *

Commented [jsj8]: As a result of a change to the Nuclear Regulatory Commission (NRC) website URL following issuance of Part 22, the reference to the NRC website in Part 22 is updated.

 NRC Compatibility "B"
 NRC RATS 2013-1
 10 CFR 37.77(a)(1)
 NRC LTR 11/03/15

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125 **Editor's Notes**

126 6 CCR 1007-1 has been divided into separate parts for ease of use. Versions prior to 04/01/2007 are
127 located in the first section, 6 CCR 1007-1. Prior versions can be accessed from the All Versions list on the
128 rule's current version page. To view versions effective on or after 04/01/2007, select the desired part of
129 the rule, for example 6 CCR 1007-1 Part 01 or 6 CCR 1007-1 Part 10.

130 **History**

131 Part 22 entire rule eff. 07/15/2015.
