

**STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY FOR

AMENDMENTS TO THE STATE OF COLORADO
RULES AND REGULATIONS PERTAINING TO RADIATION CONTROL
6 CCR 1007-1**

Part 4, Standards for Protection Against Radiation

Adopted by the Board of Health on February 20, 2013

Basis and Purpose

The *Colorado Radiation Control Act*, Title 25, Article 11, *Colorado Revised Statutes* (the Act), Section 25-11-104, requires the State Board of Health (Board) to formulate, adopt and promulgate rules and regulations pertaining to radiation control.

Section 25-11-103 of the Act requires the Colorado Department of Public Health and Environment (Department) to develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing radiation, including to require registration of sources of ionizing radiation such as radiation machines and to issue licenses pertaining to radioactive materials.

Section 25-11-104 of the Act requires Colorado's radiation regulations to be compatible with the *Suggested State Regulations for Control of Radiation* (SSRCR) of the Conference of Radiation Control Program Directors, Inc., except when the Board concludes, on the basis of detailed findings, that a substantial deviation from the SSRCR is warranted.

This amendment makes multiple revisions to Part 4, *Standards for Protection Against Radiation*, previously adopted May 18, 2005, which became effective July 31, 2005. The proposed changes to Part 4 are being initiated in order to maintain compatibility with federal regulations, to ensure consistency between and within the regulatory parts, and to make minor corrections or improvements in the regulatory program. Certain proposed changes to Part 4 may be initiated in conjunction with or prior to changes to Part 3.

The editorial comments, notes, and information that may be shown in the right side margin of draft regulations are for information only and are not part of the regulation. These will be removed from the final regulation prior to publishing in the Colorado register.

The following outlines the proposed changes to Part 4:

1. Throughout Part 4, numbering is added/modified for consistency between and within the regulation parts, and typographical errors are corrected. For brevity, not all items are specifically identified in the numbered items below.

2. In 4.6.3.1, a new provision is added for consistency and compatibility with 10 CFR 20.1201(c). The requirement clarifies that the “deep-dose equivalent” (DDE) must be used in place of the “effective dose equivalent” (EDE) when external monitoring devices are used, unless the EDE method is approved by the Department. (Both DDE and EDE are defined in Part 1 of the regulations).
3. In 4.6.3.5, language is added to reference an NRC Regulatory Information Summary (RIS) in a new footnote which outlines additional methods that may be used to determine dose when multiple dosimeters are used, such as may be encountered during certain x-ray machine and radioactive materials use. The language of the RIS allows flexibility in using other calculation methods. The specific method currently identified in the regulations is less common and is retained based on stakeholder feedback. (Subsequent footnotes are renumbered throughout Part 4 as).
4. In 4.10, deleted references related to “lifetime cumulative” dose as that term and concept is no longer used nor required per 10 CFR 20, except when there are planned special exposures. Other cross-references are made consistent with Part 20.
5. In 4.10.3, and 4.10.4.1, a reference is added for consistency with 10 CFR 20.2104.
6. In 4.15.5, pertaining to radiation (x-ray related) machines/systems in dental and non-dental facilities, the language is reworded and expanded at the request of the X-ray program to be consistent with language in Part 6, Section 6.3.2.4. The language added exempts additional specific systems from certain regulatory requirements.
7. In 4.16.1.2, and 4.16.1.3, cross-references to Part 3 are corrected.
8. In 4.16.1.5, a typographical error is corrected.
9. In 4.16.4, and at the request of stakeholders, language is added for clarity and to tie-in where recordkeeping requirements for the provision may be found.
10. In 4.17.1, and 4.17.2, language is added to require and clarify that routine surveys and associated records that are already required by regulation or license condition for maintaining compliance, must now include surveys of the subsurface where subsurface contamination is known to exist. As with other required surveys, the licensee must also keep records of such subsurface surveys for purposes related to future decommissioning (see 4.17.2). This requirement and the proposed language added is consistent with 10 CFR 20.1501 which became effective in December 2012.

Section 4.17 is renumbered as a result of the proposed changes.

11. In 4.17.1.2(2), language is added at the request of NRC to clarify that the requirement

pertains to “residual radioactivity”. The change is necessary for compatibility with NRC requirements.

12. In 4.18.3.1, a cross-reference to Part 1 is corrected.
13. In 4.19.7, and 4.20.2, added the phrase “not used in the healing arts”, in reference to Part 9. Part 9 is specific to particle accelerators not used in the healing arts, whereas Part 24 addresses requirements for accelerators used in medicine. The addition clarifies the existing requirements.
14. In 4.27.3, the word “shall” is replaced with “may”. As originally written, the requirement for additional information on signage is somewhat ambiguous since no other specifications for the additional information is specified. The proposed change allows greater flexibility for the licensee or registrant. As proposed, the language is consistent with 10 CFR 20.1901 language.
15. In 4.32.2.1, the reference to Part 1 is corrected.
16. In 4.33.1.4, additional regulatory section references are added that relate to options for disposal of licensed radioactive material. One of the two additional sections referenced is an existing provision. The other reference is for a new section (4.39). The sections newly referenced pertain to provisions that certain materials may be disposed of as non-radioactive materials (Section 4.37, an existing provision) where certain criteria are met, and that certain specified materials not defined as low-level radioactive waste may be disposed of or treated as if it were low-level radioactive waste (4.39.2). The proposed changes are consistent with the references contained in 10 CFR Part 20.2001(a)(4).
17. In 4.38.5, a documentation provision is added that requires completion of a specific NRC waste manifest when disposing of radioactive material at a facility licensed (by NRC) under 10 CFR Part 61.
18. In 4.38.5, and 4.39.2, changed format of “Byproduct material” to italics where specific definition is referenced, consistent with 10 CFR 20. The B in Byproduct material is capitalized consistent with 10 CFR 20.
19. In 4.39, a new section and title is added to support the addition of two new subsections in 4.39.2. The subsections are necessary for compatibility with 10 CFR 20.
20. In 4.39.2, added more specific Part 1 reference.
21. Two new provisions – 4.39.1 and 4.39.2 are added for consistency with 10 CFR 20.2008. The additional provisions clarify that type 3 and 4 byproduct material (which consist of discrete sources of Radium-226, and discrete sources of NORM) may be disposed of as if they were low-level radioactive waste even though they do not fit the formal definition of

low-level radioactive waste. Types 3, and 4 byproduct material were added to the federal regulations as a result of the EPAct of 2005.

- 22. In 4.51.1.1, a typographical error is corrected – a comma added after the word “stolen”.
- 23. In 4.54, 4.58, and 4.59, added subsection numbering for formatting consistency within regulatory part.
- 24. In 4.55, a previously “reserved” section is modified to incorporate existing requirements currently contained in license condition. Presently, certain licensees who have radioactive materials meeting the Part 1 definition of a “nationally tracked source”, must adhere to additional security related requirements. These licensees have license conditions that require them to report any transactions associated with those sources. The proposed language of 4.55 would eliminate the need for the current license conditions by moving/incorporating the requirements to regulation for approximately 30 existing licensees and any future licensees. The movement of requirements from license condition to regulations does not add, change, or reduce the requirements for these specific licensees. There are no changes to the actual requirements currently being enforced by the Department. The added regulatory language is consistent with 10 CFR 20.2207.

Movement of the requirements from license condition to regulation will streamline the licensing process and aid the Department and licensees by removing the additional 4 pages of license conditions now contained in these licenses.

- 25. In 4.57.2, requirements are added consistent with 10 CFR 20.2205. Licensees are currently required to send a report to the Department when specific criteria regarding occupational or public exposures are exceeded. The proposed language requires that this same report also be sent to the individual occupational worker (employee) or identified member of the public.

Additionally, the reference to 4.53 was changed to 4.53.2 which is more consistent with the reference in Part 20.2205.

- 26. In 4.61.3.1, language is added for consistency with 10 CFR 20.1403(a). The additional language requires that the detriment/risk from traffic accidents as a result of (additional) decontamination or transportation of radioactive materials for disposal must be considered when evaluating whether residual contamination levels are ALARA.
- 27. In 4.61.3.3, language is added consistent with 10 CFR 20.1403. The added language reaffirms requirements of Part 3 pertaining to sites released under restricted conditions such that adequate financial funding is available to ensure that entities taking over a site for long term monitoring and surveillance activities have the funding in place to do so.
- 28. Added subsection formatting to 4.61.3.4, for clarification.

29. In 4.61.4.1(4), language consistent with 10 CFR 20.1404(a)(5) is added. The paragraph added is for similar reasons to that identified for 4.61.3.3 above – to ensure that adequate funding is available for responsible entities responsible for long term control and maintenance for a closed site whose license was terminated under alternate termination criteria.
30. In the main body of Appendix 4B, added “4B” where the table numbers are referenced. Previously, only table numbers (e.g., Table 1, Table 2, Table 3) were referenced. The change ties Appendix 4B with the table numbers for consistency within the document.
31. In Appendix 4B, the following changes are made to Table 4B1, 4B2, and 4B3:
- a. References to the tables within this appendix are corrected by adding a “4B” before each referenced table number;
 - b. The isotopes of Nitrogen-13, and Oxygen-15 and corresponding values are added to Tables 4B1, 4B2, and 4B3, consistent with 10 CFR 20 Appendix B. These isotopes were not previously regulated by NRC. Following the EPAct of 2005, NRC modified its requirements to regulate accelerator produced radioactive materials. Although Colorado has always regulated such accelerator produced material, values for these isotopes were not included in the tables of Appendix 4B.
 - c. The header information of these tables is also realigned for formatting purposes.
[NOTE: DUE TO SPECIFIC FORMATTING NEEDS, THE REVISED TABLES OF APPENDIX 4B ARE CONTAINED IN A DOCUMENT SEPARATE FROM MAIN BODY OF PART 4];
32. In Appendix E, a “4” is added to clarify that reference is being made to Appendix 4E. Throughout Appendix 4E, references to “4B” tables are corrected to reference “4E” tables.
33. A new Appendix 4G is added. This appendix lists criteria for nationally tracked sources and is utilized in conjunction with (new) section 4.55, and is also currently referenced in Part 1 in the definition for “Nationally tracked source”. This added table of Appendix 4G does not add or change the requirements which are already implemented through legally binding license conditions. Equivalent requirements/table are contained in Appendix E of 10 CFR 20.

Specific Statutory Authority

These rules are promulgated pursuant to the provisions of sections 25-1-108 and 25-1.5-101(1)(k) and (1)(l).

Major Factual and Policy Issues Encountered

As summarized above, these revisions do not involve major factual issues. Colorado's rules closely mirror and are intended to be compatible with those of NRC and the 37 other Agreement States under the U.S. Atomic Energy Act. The NRC compatibility category determinations process governing Agreement State implementation of these changes are listed in *Procedures Manual SA-200*, available at <http://nrc-stp.ornl.gov/procedures/sa200.pdf>. The individual compatibility categories for any given regulation are available at http://nrc-stp.ornl.gov/regsumsheets_newregs.html.

Alternative Rules Considered and Why Rejected

No alternative rules were considered because the primary purpose of this revision to Part 4 of Colorado's radiation regulations is to maintain internal consistency and national compatibility as an Agreement State.