

**STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
FOR
AMENDMENTS TO THE COLORADO STATE BOARD OF HEALTH
RULES AND REGULATIONS PERTAINING TO RADIATION CONTROL
6 CCR 1007-1**

Part 3, Licensing of Radioactive Material

NOVEMBER 29, 2010

Basis and Purpose.

The Colorado Radiation Control Act, Title 25, Article 11, Colorado Revised Statutes (the Act), requires the State Board of Health to formulate, adopt and promulgate rules and regulations pertaining to radiation control. Section 25-11-104 of the Act requires Colorado's radiation regulations to be consistent with the Suggested State Regulations for Control of Radiation (SSRCR) of the Conference of Radiation Control Program Directors, Inc., except when the Board of Health concludes, on the basis of detailed findings, that a substantial deviation from the SSRCR is warranted. The Department's regulations, in certain parts, must also be compatible with the regulations adopted by the U.S. Nuclear Regulatory Commission (NRC). The Act establishes the SSRCR as the model for Colorado to use in adopting NRC regulatory provisions. Part 3, Licensing of Radioactive Material, is based upon Part C of the SSRCR. Part 3 was last revised May 18, 2005, with an effective date of July 30, 2005.

This amendment revises Part 3 to make multiple changes. The changes are:

1. Throughout the Part, a global change for references to 10 CFR were made to read "(January 1, 2010)".
2. Throughout the Part, a global change was made to delete all references to "Licensing State" and to shorten "the U.S. Nuclear Regulatory Commission" to "NRC", consistent with other Parts that have been changed in recent years.
3. Throughout the Part where not changed in prior revisions, a global change was made to add "Agreement" to the word "State" such that it reads "Agreement State" to be consistent with other parts of the radiation regulations.
4. In 3.1.1.1, 3.1.2.1, 3.1.3.1, and 3.1.3.2, subparagraph numbering was added to maintain consistency with the Secretary of State format and other Parts of Regulations. No requirements were changed.
5. In 3.1.3.2, reference to Part 5 and 16 is added to be consistent with same parts referenced in 3.1.3.1.

6. In 3.1.4.1, 3.1.4.2 subparagraph numbering was added, including subsections (1) through (6) to maintain consistency with the Secretary of State format and other Parts of Regulations. No requirements were changed.
7. In 3.1.5.1, subparagraph numbering was added to maintain consistency with the Secretary of State format and other Parts of Regulations. No requirements were changed.
8. In 3.2.3, changed alphabetical number in Schedule 3C to an alphabetical-numerical format for clarity. Schedule 3C, Sections 3C-A, through 3C-H become 3C.1, through 3C.8, to be more consistent with numbering in other appendices throughout the radiation regulations.
9. In 3.3.1.1, subsections 3.3.1.1(1) and 3.3.1.1(2) add clarifying language consistent with SSRCR Part C. These subsections require formatting consistent with the Secretary of State format for regulations.
10. In 3.3.1.2, the wording is edited slightly replacing “pursuant to” with the words “consistent with”. Additional global changes are also made as described below.
11. In 3.3.2, the subsection 3.3.2.2 is edited to refer to federal regulations rather than reference to “reserved” section. Reference to the Ra-226 exemption is deleted. Subsections 3.3.2.3 and 3.3.2.4 are edited slightly for clarification. Subsection 3.3.2.5 is added for clarity to prohibit combining multiple exempt sources into a device or non-exempt quantity. Additional global changes are also made as described below.
12. In 3.3.3, added subparagraph numbering, and modified references to Schedule 3C subsections for new formatting. Schedule 3C renumbered to be more consistent with numbering in other appendices throughout the radiation regulations. Deleted reference to Schedule 3C-M which was removed from NRC regulations.[NOTE – The reference to Schedule 3C should also include 3C.9 and will be corrected in final revision]
13. In 3.4, the sentences are individually numbered/re-formatted for the Secretary of State XML system and ease of citation in inspection reports.
14. In 3.5.3.1, formatted into subparagraph with new number.
15. In 3.5.4, updated name for the Department of Natural Resources Division having jurisdiction. Changed Division of “Minerals and Geology” to Division of “Reclamation, Mining, and Safety”.
16. In 3.6.4.2(1), added clarifying words “for distribution to persons generally licensed”. Re-format into subsections, and delete redundant wording.

17. In 3.6.4.3(3), added clarifying words “the tests required by 3.6.4.3(2) of this section and”, consistent with 10 CFR 31.5(c)(3).
18. Within 3.6.4.3, added subparagraph numbering, consistent with Secretary of State format.
19. Within 3.6.4.3(4), increases requirement to retain test records from 1 or 2 years to 3 years, consistent with the federal requirements of 10 CFR 31.5(c)(4).
20. In 3.6.4.3(5)(a) through 3.6.4.3(5) (d), the wording was changed to be more firm and specific with respect to handling of leaking radioactive sources.
21. In 3.6.4.3(8), add subparagraph (c) – “comply with 10 CFR 31.5(c)(8)(iii), as applicable.”
22. In 3.6.6, added subparagraph numbering consistent with Secretary of State format.
23. In 3.8.1, Delete requirement to file a radioactive material license application in duplicate. The Division has determined that in practice only one copy is necessary.
24. In 3.8.7.1, add words “or in accordance with the requirements of Part 18 if applicable”. Wording added to be consistent with requirements of the Act.
25. In 3.8.8.2, change in wording from “authorized” to “required”. This change is being made to be consistent with changes to the Act.
26. In 3.9.5.3(2)(c), the words “greater than” are deleted and the words “shall be used as the schedule 3B value”. Schedule 3B provides quantities of radioactive material which require a decommissioning warranty. This change is intended to provide clarity to the requirements and is not a substantive change.
27. Within 3.9.5.4, subparagraph lettering/numbering is added for consistency in format.
28. In 3.9.5.4(3)(c)(i), clarification is added to ensure the appropriate appendix – 3F - is referenced.
29. In 3.9.5.6, and 3.9.5.7, language is added to maintain consistency with the Act with respect to annual reporting and content requirements for specific financial warranties.
30. In 3.9.5.8(2), and 3.9.5.8(3), two additional provisions are added pertaining to financial warranties. This adds additional requirements for licensees who have financial warranties. The added language is consistent with that of the Act.
31. In 3.9.5.10(4)(a), (b), and 3.9.5.10(5), added subparagraph numbering.

32. In 3.9.6.1, and 3.9.6.2, sentence added to establish a lower limit for alpha emitting radionuclides not listed in Schedule 3B, consistent with change in 3.9.5.3(2)(c).
33. In 3.9.6.2 and 3.9.6.3, a date that has passed is deleted from this Part and consistent with changes to the Act.
34. Within 3.9.11.3 and 3.9.11.4, added subparagraph numbering consistent with Secretary of State format. Changed capital "A" with lower case "a".
35. In 3.9.10.1, adds subparagraph (2), "for each proposed..." pertaining to license hearings. This change incorporates requirements from the Act, and is being changed consistent with Part 18 which is being amended concurrent with this Part.
36. In 3.11.1, deleted wording that is redundant with earlier/renumbered section.
37. Numbering was added throughout 3.12.1 to ensure consistency in format.
38. In 3.12.1, the wording is modified to state: "A licensee authorized to introduce radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under 3.3.1.1 shall meet the requirements of 10 CFR 32.11 and any other applicable NRC requirement." Change made to be consistent with federal requirements.
39. In 3.12.1.1, this deletes certain wording pertaining to distribution of exempt sources by specific licensees. The NRC is the only authorized agency to issue licenses for distribution of exempt sources. This change results in deferring to the NRC requirements rather than be redundant or conflict with them.
40. Section 3.12.2 is modified to state: "No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempted pursuant to 3.3.2, under 10 CFR 30.14 or equivalent regulations of an Agreement State, except in accordance with a license issued under 10 CFR 32.11." Similar to 3.12.1.1 changes, this defers to NRC requirements.
41. In 3.12.3 deletes existing wording and is now reserved.
42. In 3.12.4.1(3)(c)(ii), add word "radiation" for clarity.
43. The sections and paragraphs of Schedules 3A through 3E, and in Appendices 3F and 3G, were renumbered/re-lettered for consistency and to avoid confusion of sections.

Specific Statutory Authority.

These rules are promulgated pursuant to the provisions of Sections 25-1.5-101(1)(l), 25-1-108(1)(c), and 25-11-104, C.R.S.

Major Factual and Policy Issues Encountered.

There are no significant factual or policy issues anticipated with these changes. Changes in the federal regulations have resulted in some deletions in this part. Changes to the Act have resulted in additions and clarifications to this Part.

Alternative Rules Considered and Why Rejected.

The primary purpose of this revision to Part 3 is to incorporate requirements from and to ensure consistency with the statute (Colorado Radiation Control Act) which was revised in 2010. Changes are also proposed to incorporate changes to the federal regulations. Changes are also made to correct minor typographical errors and ensure consistency in formatting with other regulatory parts and the secretary of state required format for regulations. Making the changes is preferable to the alternative of no action.

The Colorado Radiation Advisory Committee is currently reviewing these changes.