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**To:** WND1.WNP9(ndb2)  
**Date:** 3/21/97 1:49pm  
**Subject:** Revisions to Colorado's Regulations

Hi Nancy!

I am not sure how the attachments were separated from the transmittal letter addressed to Paul, but I do apologize. Attached are the proposed draft revisions to Part 4, the Statement of Basis and Purpose and the Regulatory Analysis.

If you have any problems receiving these documents, don't hesitate to contact me via e-mail at michelle.sims@state.co.us, or by phone at (303) 692-3034.

Thanks and have a great weekend!

**CC:** ud1.internet3("nmmdaughe@smtpgate.dphe.state.co.us"...

PART 4 - STANDARDS FOR PROTECTION AGAINST RADIATION

1     RH 4.22     Use of Process or Other Engineering Controls.   The licensee shall  
2                   use, to the extent ~~practicable~~ **PRACTICAL**, process or other  
3                   engineering controls, such as, containment or ventilation, to  
4                   control the concentrations of radioactive material in air.

5  
6     RH 4.23     Use of Other Controls.   When it is not ~~practicable~~ **PRACTICAL** to  
7                   apply process or other engineering controls to control the  
8                   concentrations of radioactive material in air to values below  
9                   those that define an airborne radioactivity area, the licensee  
10                  shall, consistent with maintaining the total effective dose  
11                  equivalent ALARA, increase monitoring and limit intakes by one or  
12                  more of the following means:

RH 4.24.1.3.5

Determination by a physician prior to initial fitting  
of respirators, and ~~at least~~ **EITHER** every 12 months  
thereafter **OR PERIODICALLY AT A FREQUENCY DETERMINED**  
**BY A PHYSICIAN**, that the individual user is ~~physically~~  
~~able~~ **MEDICALLY FIT** to use the respiratory protection  
equipment.

4.24.2.1

The licensee selects respiratory protection equipment that provides a protection factor, specified in Appendix A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the ~~peak concentration~~ **MULTIPLE DEFINED IN THE PRECEDING SENTENCE** is inconsistent with the goal specified in RH 4.23 of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.

4.32.3

The licensee or registrant shall perform the monitoring required by RH 4.32.2 as soon as ~~practicable~~ **PRACTICAL** after receipt of the package, but not later than 3 hours after the package is received at the licensee's or registrant's facility if it is received during the licensee's or registrant's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

4.42.2.1

Records of the results of surveys to determine the  
dose from external sources of radiation **AND** used, in  
the absence of or in combination with individual  
monitoring data, in the assessment of individual dose  
equivalents; and

## Part 4

APPENDIX CQUANTITIES<sup>1</sup> OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity
	( $\mu$ Ci) *

Aluminum-26	10
Argon-39	1,000
Argon-41	1,000
Beryllium-10	1
Beryllium-7	1,000
Calcium-41	100
Calcium-45	100
Calcium-47	100
Carbon-11	1,000
Carbon-14	<del>1,000</del> 100
Chlorine-36	10
Chlorine-38	1,000
Chlorine-39	1,000

\* To convert  $\mu$ Ci to kBq, multiply the  $\mu$ Ci value by 37.

**REGULATORY ANALYSIS  
FOR  
COLORADO RULES AND REGULATIONS  
PERTAINING TO RADIATION CONTROL  
6 CCR 1007-1**

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

March 19, 1997

The Radiation Control Act, Title 25, Article 11, Colorado Revised Statutes 1989 (the Act) requires the Colorado Department of Public Health and Environment (Department) to issue licenses pertaining to radioactive materials, to require registration of other sources of ionizing radiation, and to develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing radiation.

In 1968 the State of Colorado entered into an agreement with the federal government whereby the State assumed the responsibility for the regulation of certain types of radioactive materials. These are source material, byproduct material and special nuclear material. Because of this agreement between the Federal government and the State for the State to assume authority over certain types of radioactive materials, the State regulations must be compatible with regulations of the U.S. Nuclear Regulatory Commission (NRC). Were the State not to have compatible regulations, the majority of our licensees would have to meet the same regulatory requirements under licenses issued by the NRC.

The Department is proposing to revise Part 4 of the *Colorado Rules and Regulations Pertaining to Radiation Control* (Regulations). The proposed revisions to the Regulations are based on provisions adopted by the NRC and are in committee drafts of the *Suggested State Regulations for the Control of Radiation* (SSRCR).

The proposed revisions include:

1. An amendment to the regulations regarding the frequency at which medical examinations are required to ensure the safe use of respiratory protection equipment.
2. An amendment to the regulations to provide editorial correction and clarification, adopting the phrasing currently used by the NRC, but preserving the original intent of the regulation.
3. An amendment to the regulations to correct a typographical error in Part 4 Appendix C, "Quantities of Licensed or Registered Material Requiring Labeling."



**1. A description of the classes of persons who will bear the costs and/or benefits from the proposed rule.**

The proposed amendments to the rules will currently apply to 352 radioactive material licensees and to approximately 20 Department employees who are responsible for licensing and inspection activities for these licensees or for emergency response for accidents involving radioactive materials. All of the Department employees could be impacted by all of the rules changes discussed in this Regulatory Analysis. All of the 352 licensees could be impacted by the minor editorial corrections and clarifications.

Of the 352 licensees, it is expected that two subclasses - uranium mills and universities - could be impacted by the proposed amendments regarding the frequency at which medical examinations are required for respiratory protection. These subclasses also could be impacted by the minor editorial correction that regards use of individual respiratory equipment.

A maximum of 48 licensees could be impacted by the correction of the typographical error regarding the quantity of carbon-14 requiring labeling. These 48 licensees include research and development laboratories, universities, and hospitals using carbon-14 in research.

**2. A description of the probable quantitative and qualitative impacts of the proposed rule, economic and otherwise, upon the affected classes.**

Quantitative:

The editorial corrections and clarifications proposed for Part 4 will have negligible effect, since they are minor corrections to the rules that preserve the original intent of the regulations.

The amendment regarding the frequency at which medical examinations are required for respiratory protection will constitute a reduction of regulatory burden and an increase in flexibility for those potentially impacted, without any significant reduction in worker health or safety. Under the proposed change, the licensees and the Department may continue with the current annual medical examination schedule if desired and, if so, would experience no impact from the amendment.

If the licensees were to reduce the frequency of medical examinations for respiratory protection as allowed by the proposed rule change under recommendation of the examining physician, it is expected that this reduction would be done in accordance with the guidance of the American National Standards Institute provided in ANSI Z88.6-1984. ANSI recommends a frequency of examination based on age: every 5 years up to age 35; every 2 years up to age 45; and annually thereafter. The estimated potential cost reduction based on the number of current licensee participants in respiratory protection programs and their age distribution is \$5,100 per year. This estimated potential cost reduction assumes that each medical examination costs \$150 and that the licensees would reduce the number of medical examinations performed per year from 106 to 72.

Potential cost reduction to the Department resulting from the proposed rule change is \$600 per year, based on an estimated reduction of medical examinations performed per year from 20 to 16.

The amendment correcting the typographical error for the amount of carbon-14 requiring a label would have negligible impact. There are no current State licenses for manufacture or distribution of carbon-14. Those parties currently licensed for using or storing carbon-14, would receive this material already labeled. If additional labeling were required, the cost of this labeling would be negligible.

Qualitative:

The net impact of these changes is 1) to provide greater flexibility and potential cost reduction regarding medical examinations for the use of respiratory protection equipment and 2) to correct and clarify phrasing and typographical errors in the rule while preserving the original intent of the regulation. Any impact resulting from 1 would be a cost reduction and at the discretion of the impacted organization, since the organization can continue to provide medical examinations on an annual basis as is currently required. Any impact from 2 is negligible, since the corrections and clarifications maintain the original intent of the rule and result in no significant change to current practice.

**3. Probable costs to the Department and to local health departments and anticipated effects on state revenues.**

There are no additional costs to the Department or to local health departments, nor are there anticipated effects on state revenues that would result from these changes.

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

There are no significant probable increased costs of the proposed rules. Probable benefits include potential cost reduction to licensees and to the Department as a result of a reduced frequency of medical examinations for safe use of respiratory protection equipment. Cost of inaction would be in costs to the affected licensees or to the Department for unnecessary medical examinations and to all licensees in the confusion resulting from lack of correction and clarification to the rules and lack of consistency between NRC and State regulations.

**5. A determination of whether there are less costly or less intrusive means to achieve the purpose of the proposed rule.**

There are no less costly or less intrusive means to achieve the purpose of the proposed rules.

**6. A description of alternative methods for achieving the purpose of the proposed rule.**

The Division considered the alternative of not adopting these rules. The advantages to Colorado licensees of adhering to the uniform and consistent national framework strongly outweigh inaction.

**STATEMENT OF BASIS AND PURPOSE  
FOR  
COLORADO RULES AND REGULATIONS  
PERTAINING TO RADIATION CONTROL  
6 CCR 1007-1**

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

March 19, 1997

**OVERVIEW**

In 1968 the State of Colorado entered into an agreement with the federal government whereby the State assumed the responsibility for the regulation of certain types of radiation and radioactive material.

The Radiation Control Act, Title 25, Article 11, Colorado Revised Statutes 1989 (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.

Section 25-11-104 requires the state Board of Health to formulate, adopt, and promulgate rules and regulations pertaining to radiation control, and that "all such regulations shall be modeled after and shall be neither more or less stringent than those proposed by the Conference of Radiation Control Program Directors, Inc. (CRCPD) under the title of *Suggested State Regulations for Control of Radiation*; (SSRCR) except that, in the event said board concludes on the basis of detailed findings that a substantial deviation from any said suggested state regulations is warranted..."

In order to maintain its agreement with the federal government, these regulations, in certain areas, must also be compatible with the regulations of the U.S. Nuclear Regulatory Commission (NRC). The revisions to the regulations under consideration reflect the NRC provisions being used by CRCPD as a basis for incorporation into the SSRCR. The changes are matters of compatibility with the NRC.

Three sets of changes in Colorado's *Rules and Regulations Pertaining to Radiation Control* are made:

1. A proposed revision would amend the regulations regarding the frequency at which medical examinations are required to ensure the safe use of respiratory protection equipment.
2. A proposed revision would amend the regulations to provide editorial correction and clarification, adopting the phrasing currently used by the NRC, but preserving the original intent of the regulation.

3. A proposed revision would amend the regulations to correct a typographical error in Part 4 Appendix C, "Quantities of Licensed or Registered Material Requiring Labeling."

## **BASIS AND PURPOSE FOR PROPOSED AMENDMENT**

1. Frequency of Medical Examinations for Use of Respiratory Protection Equipment (Modification to Part 4)

RH 4.24.1.3.5 currently requires the determination by a physician prior to initial fitting of respirators, and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protection equipment. The proposed revision would require determination by a physician prior to initial fitting of respirators and either every 12 months thereafter or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment.

On September 29, 1995, the NRC published a Final Rule, effective March 13, 1995, modifying the existing rule regarding frequency of medical examinations for use of respiratory protection equipment. The proposed revision to Part 4 of Colorado's *Rules and Regulations Pertaining to Radiation Control* is consistent with the NRC's modification.

The proposed revision reflects the current assessment by the NRC Regulatory Review Group that the frequency of medical examinations for respiratory protection usage could be reduced as determined by the examining physician without adverse impact on worker safety. This assessment is supported by a 1984 American National Standards Institute (ANSI) committee and public review of its proposed standard Z88.6, which found no reasons for not reducing the frequency of medical examination. Reduction in medical examination frequency could result in a corresponding reduced financial burden for the licensee. However, the licensee would maintain the option of adhering to the annual medical examination schedule, if desired. The proposed revision uses the terminology "medically fit," rather than "physically able," to use a respirator in order to more accurately reflect the purpose of the medical examination.



2. Editorial Corrections and Clarifications (Modification to Part 4)

- a. Editorial changes include replacement of the word "practicable" with the word "practical" in one sentence each of sections RH 4.22, RH 4.23, and RH 4.32.3. This replacement provides consistency with the definition of ALARA that is found in section RH 1.4.

As defined in RH 1.4, "As low as is reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical,..."

- b. Another editorial change to section RH 4.24.2.1 corrects phrasing related to use of individual respiratory equipment, while preserving the original intent of the rule. Current and proposed wordings of sentences pertinent to this change are given below.

The current rule states that "The licensee selects respiratory protection equipment that provides a protection factor, specified in Appendix A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the **PEAK CONCENTRATION** is inconsistent with the goal specified in RH 4.23 of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor provided that such a selection would result in total effective dose equivalent that is ALARA." [Upper case with bolding added to this paragraph to indicate words that are to be changed.]

The proposed revision states that "The licensee selects respiratory protection equipment that provides a protection factor, specified in Appendix A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the **MULTIPLE DEFINED IN THE PRECEDING SENTENCE** is inconsistent with the goal specified in RH 4.23 of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor provided that such a selection would result in total effective dose equivalent that is ALARA." [Upper case with bolding added to this paragraph to indicate revised wording.]

- c. The final editorial change is to section RH 4.42.2.1, regarding records of survey. This change adds the word "and" to the section, consistent with the NRC wording and with the intention of the rule.

The proposed revision states "Records of the results of surveys to determine the dose from external sources of radiation **AND** used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents;...". [Upper case with bolding added to indicate the change.]

3. Correction to a typographical error in Appendix C, "Quantities of Licensed or Registered Material Requiring Labeling" (Modification to Part 4

This proposed change corrects a typographical error, originated and now corrected in the NRC rules, whereby the quantity for carbon-14 is corrected to read "**100**" ( $\mu\text{Ci}$ ), rather than "**1000**" ( $\mu\text{Ci}$ ) in Part 4, Appendix C, "Quantities of Licensed or Registered Material Requiring Labeling."

# AGREEMENT STATE REGULATIONS REVIEW RECORD

## Colorado Part 4 Proposed Revisions

March 1997

<u>Division and CFR citation</u>	<u>Rule subject</u>	<u>State citation</u>	<u>Comments</u>
1 20.1701	Use of process or other engineering controls	[RH 4.22]	:
1 20.1702	Use of other controls	[RH 4.23]	:
1 20.1703 [except(a)(3)(v)]	Use of individual respiratory protection equipment	[RH 4.24]	:amends 4.24.2.1 [equiv to 20.1703(B)(2)]
2 20.1703(a)(3)(v)	Frequency of Medical Examinations for respirator use	[RH 4.24.1.3.5]	:
2 20.1906	Procedures for receiving and opening packages	[RH 4.32]	:amends 4.32.3 [equiv to 20.1906(c)]
2* 20.2103	Records of surveys	[RH 4.42]	:
1 20 Appendix C	Quantities of licensed material requiring labeling	[Part 4 App C]	:amends entry for Carbon-14