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DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

RADIATION CONTROL - STANDARDS FOR PROTECTION AGAINST RADIATION

6 CCR 1007-1 Part 04

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

Adopted by the Board of Health on ~~May 17, 2017~~ October 18, 2023; effective ~~June 30, 2017~~December 15, 2023.

PART 4: STANDARDS FOR PROTECTION AGAINST RADIATION

[* * * DENOTES UNAFFECTED SECTIONS/PROVISIONS IN THE DRAFT RULE]

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STANDARDS FOR PROTECTION AGAINST RADIATION

4.1 Purpose and Scope

4.1.1 Authority.

4.1.1.1 Rules and regulations set forth herein are adopted pursuant to the provisions of Sections 25-1-108, 25-1.5-101(1)(k) and (1)(l), and 25-11-104, CRS.

4.1.2 Basis and Purpose.

4.1.2.1 A statement of basis and purpose of these regulations is incorporated as part of these regulations; a copy may be obtained from the Department.

4.1.3 Scope.

4.1.3.1 This Part 4 establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Department.

4.1.3.2 The requirements of Part 4 are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in Part 4. However, nothing in Part 4 shall be construed as limiting actions that may be necessary to protect health and safety.

4.1.4 Applicability.

4.1.4.1 Except as specifically provided in other parts of these regulations, Part 4 applies to persons licensed or registered by the Department to receive, possess, use, transfer, or dispose of sources of radiation. The limits in Part 4 do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical

Commented [JSJ1]:
Editorial note 1: All comments (such as this one) shown in the right side margin of this draft document are for information purposes only to assist the reader in understanding the proposed rule change during the review and comment process.
These side margin notes are **not** part of the rule and all comments will be deleted prior to publication of the final rule by the Colorado Secretary of State.

Editorial note 2: Alignment and formatting corrections and minor typographical adjustments may be made in the rule and may not be specifically identified with a side margin comment.

Editorial note 3: To maintain agreement state status, and be consistent with statute, Colorado's radiation regulations must be compatible with federal regulations of the U.S. Nuclear Regulatory Commission (NRC) and, be consistent with the current model rules of the Conference of Radiation Control Program Directotors (CRCPD), Inc.

Editorial note 4: This draft is not a complete rule. Unaffected sections or provisions have been removed from the rule and are not shown in this draft. Unaffected sections/provisions are denoted with a " * * * " and remain as-is in the current rule with no changes. Some provisions may be shown with no changes and are provided for reference purposes.

Commented [JSJ2]:
The stated adoption and effective dates are tentative and subject to change, pending the Board of Health meeting schedule, preliminary acceptance by the Board, final adoption by the Board, and the Colorado Register publication dates.

The anticipated dates are based on the annual rulemaking hearing schedule (regulatory agenda) for the Department which may be found online.

diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with 7.26, or to exposure from voluntary participation in medical research programs.

~~4.1.4.2 In accordance with Section 24-4-103(12.5)(c), CRS, https://www.colorado.gov/cdphe/radregs identifies where incorporated material is available to the public on the internet at no cost. If the incorporated material is not available on the internet at no cost to the public, copies of the incorporated material has been provided to the State Publications Depository and Distribution Center, also known as the State Publications Library. The State Librarian at the State Publication Library retains a copy of the material and will make the copy available to the public.~~

Commented [JSJ3]: This provision is replaced by new Section 4.1.5 (below).

4.1.5 Published Material Incorporated by Reference.

Commented [JSJ4]: This provision incorporates updated language regarding materials incorporated by reference. The new provision is added for consistency with Colorado Administrative Procedure act requirements and other recently amended radiation control regulations.

4.1.5.1 Throughout this Part 4, federal regulations, state regulations, and standards or guidelines of outside organizations have been adopted and incorporated by reference. Unless a prior version of the incorporated material is otherwise specifically indicated, the materials incorporated by reference cited herein include only those versions that were in effect as of the most recent effective date of this Part 4 (December 2023), and not later amendments or editions of the incorporated material.

4.1.5.2 Materials incorporated by reference are available for public inspection, and copies (including certified copies) can be obtained at reasonable cost, during normal business hours from the Colorado Department of Public Health and Environment, Hazardous Materials and Waste Management Division, 4300 Cherry Creek Drive South, Denver, Colorado 80246. Additionally, https://www.colorado.gov/hm/radregs identifies where the incorporated material is available to the public on the internet at no cost. Due to copyright restrictions, certain materials incorporated in this Part are available for public inspection at the state publications depository and distribution center.

4.1.5.3 Availability from Source Agencies or Organizations.

(1) All federal agency regulations incorporated by reference herein are available at no cost in the online edition of the Code of Federal Regulations (CFR) hosted by the U.S. Government Publishing Office, online at https://www.govinfo.gov/app/collection/cfr/.

(2) All state regulations incorporated by reference herein are available at no cost in the online edition of the Code of Colorado Regulations (CCR) hosted by the Colorado Secretary of State's Office, online at https://www.sos.state.co.us/CCR/Welcome.do.

4.2 Definitions.

4.2.1 Reserved.

4.3 Implementation.

4.3.1 Any existing license or registration condition that is more restrictive than Part 4 remains in force until there is an amendment or renewal of the license or registration.

4.4 Reserved.

RADIATION PROTECTION PROGRAMS

4.5 Radiation Protection Programs.

Commented [JSJ5]: There are no changes proposed for section 4.5 or subsections. This section is shown in the draft rule for reference purposes only.

4.5.1 Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of Part 4. See 4.41 for recordkeeping requirements relating to these programs.

4.5.2 The licensee or registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

4.5.3 The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

4.5.4 To implement the ALARA requirements of 4.5.2 and notwithstanding the requirements in 4.14 of this part, a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its decay products, shall be established by licensees, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 0.1 millisievert (10 mrem) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report such event as provided in 4.53.2 and promptly take appropriate corrective action to ensure against recurrence.

OCCUPATIONAL DOSE LIMITS

4.6 Occupational Dose Limits for Adults.

Commented [JSJ6]: There are no changes proposed for section 4.6 or subsections. This section is shown in the draft rule for reference purposes only.

4.6.1 The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to 4.11, to the following dose limits:

4.6.1.1 An annual limit, which is the more limiting of:

(1) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

(2) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem).

4.6.1.2 The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

(1) A lens dose equivalent of 0.15 Sv (15 rem), and

(2) A shallow dose equivalent of 0.5 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.

4.6.2 Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned

special exposures that the individual may receive during the current year and during the individual's lifetime. See 4.11.5.1 and 4.11.5.2.

4.6.3 Assigned dose equivalent.

4.6.3.1 When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC.

4.6.3.2 The assigned deep dose equivalent must be for the part of the body receiving the highest exposure.

4.6.3.3 The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure.

4.6.3.4 The deep-dose equivalent, lens dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

4.6.3.5 In the case of occupational exposures to x-rays with accelerating voltages of less than 145 kVp and where the worker utilizes lead garment protection, the registrant may calculate the assigned dose equivalent using methods discussed in NRC Regulatory Information Summary (RIS) 2002-06[1], other methods as specifically approved by the Department, or by use of the following equation:

1 NRC RIS 2002-06, Evaluating Occupational Dose For Individuals Exposed To NRC-licensed Material And Medical X-Rays, April 16, 2002 (http://www.nrc.gov/; ML021000613).

(1) Lead apron and no thyroid collar:

assigned deep dose equivalent = 0.06 x (collar dose – waist dose) + waist dose

(2) Lead apron and thyroid collar:

assigned deep dose equivalent = 0.02 x (collar dose – waist dose) + waist dose

4.6.4 Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table 4B1 of Appendix 4B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See 4.46.

4.6.5 Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix 4B.

4.6.6 The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See 4.10.3.1 and 4.10.5.

* * *

4.10 Determination of Prior Occupational Dose.

Commented [JSJ7]:
Formatting and alignment changes are proposed for Sections 4.10 through 4.13, and are provided for reference purposes in the draft rule.

No wording changes to these sections are being proposed.

4.10.1 For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to 4.18, the licensee or registrant shall determine the occupational radiation dose received during the current year.

4.10.2 Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

4.10.2.1 The internal and external doses from all previous planned special exposures; and

4.10.2.2 All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual.

4.10.3 In complying with the requirements of 4.10.1 or 4.10.2, a licensee or registrant may:

4.10.3.1 Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and

4.10.3.2 Accept, as the record of cumulative radiation dose, an up-to-date Department Form R-16, Cumulative Occupational Exposure History, or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

4.10.3.3 Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

4.10.4 Record of Exposure History.

4.10.4.1 The licensee or registrant shall record the exposure history, as required by 4.10.1 or 4.10.2, on Department Form R-16, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing Department Form R-16 or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on Department Form R-16 or equivalent indicating the periods of time for which data are not available.

4.10.4.2 Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the Regulations in Part 4 in effect before

January 1, 1994. Further, occupational exposure histories obtained and recorded before January 1, 1994 on Department Form R-16 or equivalent, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

4.10.5 If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

4.10.5.1 In establishing administrative controls pursuant to 4.6.6 for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

4.10.5.2 That the individual is not available for planned special exposures.

4.10.6 The licensee or registrant shall retain the records on Department Form R-16 or equivalent until the Department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Department Form R-16 or equivalent for 3 years after the record is made.

4.11 Planned Special Exposures.

A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in 4.6 provided that each of the following conditions in 4.11.1 through 4.11.7 is satisfied:

4.11.1 The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

4.11.2 The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

4.11.3 Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

4.11.3.1 Informed of the purpose of the planned operation; and

4.11.3.2 Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

4.11.3.3 Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

4.11.4 Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by 4.10.2 during the lifetime of the individual for each individual involved.

4.11.5 Subject to 4.6.2, the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

4.11.5.1 The numerical values of any of the dose limits in 4.6.1 in any year; and

4.11.5.2 Five times the annual dose limits in 4.6.1 during the individual's lifetime.

4.11.6 The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with 4.45 and submits a written report in accordance with 4.54.

4.11.7 The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to 4.6.1 but shall be included in evaluations required by 4.11.4 and 4.11.5.

4.12 Occupational Dose Limits for Minors.

The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in 4.6.

4.13 Dose Equivalent to an Embryo/Fetus.

4.13.1 The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). See 4.46 for recordkeeping requirements.

4.13.2 The licensee or registrant shall make efforts to avoid substantial variation[2] above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 4.13.1.

2 The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.5 mSv (0.05 rem) to the embryo/fetus be received in any one month.

4.13.3 The dose equivalent to an embryo/fetus is the sum of:

4.13.3.1 The deep dose equivalent to the declared pregnant woman; and

4.13.3.2 The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

4.13.4 If the dose equivalent to the embryo/fetus is found to have exceeded 5 mSv (0.5 rem), or is within 0.5 mSv (0.05 rem) of this dose, by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with 4.13.1 if the additional dose equivalent to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

* * *

4.18 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Part 4. As a minimum:

4.18.1 Each licensee or registrant shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee **or the registrant** and shall supply and require the use of individual monitoring devices by:

4.18.1.1 Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 4.6.1;

Commented [JSJ8]:
Language is updated for clarity and consistency with other wording throughout the Part 4 rule.

4.18.1.2 Minors likely to receive, in 1 year from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem), a lens dose equivalent in excess of 1.5 mSv (0.15 rem), or a shallow dose equivalent to the skin or to the extremities in excess 5 mSv (0.5 rem);

4.18.1.3 Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem)[3]; and

3 All of the occupational doses in 4.6 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.

4.18.1.4 Individuals entering a high radiation area or a very high radiation area.

4.18.2 Each licensee or registrant shall monitor, to determine compliance with 4.9, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

4.18.2.1 Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) in Table 4B1, Columns 1 and 2, of Appendix 4B;

4.18.2.2 Minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 1 mSv (0.1 rem); and

4.18.2.3 Declared pregnant women likely to receive during the entire pregnancy, a committed effective dose equivalent in excess of 1 mSv (0.1 rem).

4.18.3 ~~Upon approval of the Department, an acceptable alternative to the use of continuous individual monitoring devices in order to demonstrate compliance with 4.18.1 and 4.18.2 may be used.~~**Registrants shall maintain records of the evaluation of likely external dose and the determination to monitor or not monitor individuals to demonstrate compliance with the occupational dose limits of Part 4. The registrant shall retain the record required by 4.18.3 for inspection until the Department terminates the registration requiring the record.**

~~4.18.3.1 Acceptable alternative demonstrations that doses will not exceed 10 percent of the annual limits in 4.6.1, 4.12 and 4.13 include submittal to the Department of:~~

~~(1) An acceptable application documenting six months of the use of continuous individual monitoring devices; or~~

~~(2) An acceptable assessment from a qualified expert, as defined in 1.2, that takes into account design configuration, workload, radiation-producing machine output, and survey data.~~

~~4.18.3.2 To maintain approval of an acceptable alternative to the use of continuous individual monitoring devices:~~

~~(1) Reapplication under 4.18.3.1(1) or reassessment under 4.18.3.1(2) is required for any change in configuration, equipment or workload; and~~

~~(2) The licensee or registrant shall include assessment of individual monitoring in the review of the radiation protection program required annually by 4.5.~~

* * *

[NO FURTHER CHANGES TO THE RULE BEYOND THIS POINT]

Commented [JSJ9]: Changes are proposed for Part 4.18.3 due to unclear and ambiguous wording. The current language of 4.18.3 states that is provides an "alternative" to monitoring but instead it provides mechanisms to demonstrate that monitoring is not required for occupationally exposed individuals. Further, as currently written, the mechanisms appear applicable to both radioactive materials licensees and x-ray, but reference to the "qualified expert" complicates the intent. For these reasons, changes to 4.18.3 are being proposed.

The current language of 4.18.3 is replaced with a recordkeeping requirement for x-ray registrants whose employees may receive occupational exposure.

With the elimination of existing language in 4.18.3 there is no longer a method to capture records related to a section 4.18.1 evaluation. The proposed new recordkeeping language intends to address this by explicitly requiring the registrant to maintain records of 4.18.1 evaluations when monitoring is not provided for occupationally exposed individuals.

The Department plans to develop guidance outlining acceptable methods for evaluating likely external dose and determining to monitor or not monitor individuals. This guidance would provide mechanisms similar to those outlined in the current 4.18.3.

The proposed language of 4.18.3 does not specify radioactive materials licensees or applicants because the licensing processes already requires documentation regarding occupational exposure monitoring. Additionally, licensing documentation is reviewed by the Department prior to issuance of a license or amendment. All documents submitted by a radioactive materials applicant or licensee becomes part of the licensee record.

Neither the current provision nor the proposed changes to 4.18.3 are found in federal rule, or model regulations of the CRCPD.