COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

From: James H. Grice, Radiation Program Manager, Hazardous Materials and Waste Management Division
James S. Jarvis, Regulatory Lead, Hazardous Materials and Waste Management Division

Through: Tracie M. White, Division Director TMW

Date: October 18, 2023

Subject: Rulemaking hearing for 6 CCR 1007-1 Part 4, Standards for protection against radiation.

Part 4 provides basic radiation safety related requirements applicable to all facilities using sources of radiation for any purpose, including x-ray machines and radioactive materials.

We are proposing changes to the Part 4 regulation related to occupational monitoring requirements primarily to remove the current language of 4.18.3 and replace it with a recordkeeping requirement specific to x-ray registrants. The current rule provides two options for a facility to discontinue the use of external dosimetry by occupational radiation workers by submitting data and a dosimetry waiver request for review. The facility must demonstrate that thresholds for occupational monitoring in 4.18.1 are not likely to be met. The current 4.18.3 wording is technically problematic in a number of ways, which has resulted in some confusion among staff and the regulated community. Under the proposed change, x-ray registrants will continue to be able to make a determination about whether occupational monitoring is or is not needed, and require retention of the determination record for future inspection. No submission to the department by x-ray registrants will be required under the proposed change. Radioactive materials licensees will be minimally impacted by the proposed change as the licensing process already requires review of the facility occupational monitoring program by the Division. The Division will supplement this rule change with guidance that will describe acceptable methods for evaluating occupational monitoring and will be similar to the approach described in the current rule.

Stakeholders did not provide any written comments during the rule comment period. Those attending stakeholder meetings expressed general support of the proposed changes.
The U.S. Nuclear Regulatory Commission (NRC) also reviewed the proposed changes and had no comments.

Since the rule changes impact select areas of the rule, only those sections are included in the proposed draft. New text appears as red bold text and deleted text shown as strikethrough text in the draft rule. Side margin comments are for information only and are not part of the rule. Changes in the rule and rule package since the request for rulemaking in July are highlighted in yellow, consistent with Board practice.

The Radiation Program respectfully requests that the Board of Health adopt the proposed changes for this rule.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to 6 CCR 1007-1,
Part 4, Standards for protection against radiation

Basis and Purpose.

Part 4 is a broad regulation applicable to entities using radioactive materials and x-ray devices, including those that provide radiation services to licensees or registrants. Part 4 parallels requirements in 10 CFR Part 20, for posting, notifications, public dose, and occupational dose among other radiation safety related requirements. The focus of the proposed amendment to Part 4 is on revising the rule language in sections 4.18.1, and 4.18.3 relating to occupational monitoring due to ambiguous language and technical inaccuracies in the current 4.18.3.

Similar to other recent radiation regulation amendments, changes are proposed to make minor technical and formatting updates to the rule for consistency with the Colorado Administrative Procedure Act with regard to published materials and documents incorporated by reference.

Additional details on the proposed changes to the rule are outlined below for each section. The redline draft and side margin comments of the proposed rule also provide information regarding the proposed changes.

Changes to section 4.15
A new section 4.1.5 is added to the rule to incorporate information about published material incorporated by reference, consistent with other recently amended radiation regulations and for consistency with the intent of the Colorado Administrative Procedure Act (APA).

Changes to Part 4, Section 4.18.1
The phrase “or the registrant” is added to this section to clarify that the requirement for occupational monitoring applies to both radioactive material licensees and x-ray registrants.

Changes to Part 4, Section 4.18.3
We significantly revised this section to replace current language that describes “alternatives to the use of continuous individual monitoring devices” with a recordkeeping requirement specific to x-ray registrants. The proposed language helps ensure that x-ray facilities will maintain records of their evaluation for occupational monitoring, similar to other records related to their radiation safety program. For radioactive materials licensees, the explicit recordkeeping requirement is not needed as any changes to the radiation program are captured through the licensing process which will continue to require review by the department.

In 2004 section 4.18.3 was added to Part 4 to allow x-ray facilities to request a waiver from external monitoring if the facility could demonstrate that the threshold for occupational monitoring (in 4.18.1) is not likely to be met. A facility could either perform occupational monitoring for 6 months or have a formal occupational dose evaluation completed by a Qualified Expert (QE) and submit the documentation for review by the department. The department evaluates the information and provides a

written waiver if results indicate that monitoring thresholds are not likely to be met. Although originally intended for use only by x-ray registrants, the current 4.18.3 provision can be interpreted to also apply to radioactive materials licensees. However, some terminology used in the current provision is specific to x-ray facilities, making it unclear. This and other nuanced technical related phrasing in 4.18.3 has resulted in confusion for radiation program staff and regulated entities.

Section 4.18 requires all facilities to monitor occupational exposure to radiation and require the use of individual monitoring devices when certain thresholds are met. This requirement will not change due to the change to 4.18.3. Certain facilities using sources presenting a higher risk for occupational exposure will continue to be required to provide occupational monitoring when required by other parts of the regulations, by license condition, or other requirement. Revising 4.18.3 will remove ambiguous and incorrect language and ensure that x-ray registrants retain documentation demonstrating that they evaluated the need for occupational monitoring. This will benefit x-ray registrants by not requiring involvement by the department.

Specific Statutory Authority.
Statutes that require or authorize rulemaking:

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.

__X___ No

Does this rulemaking include proposed rule language that incorporate materials by reference?

__X___ Yes ___ URL

_____ No

Does this rulemaking include proposed rule language to create or modify fines or fees?

_____ Yes

__X___ No

Does the proposed rule language create (or increase) a state mandate on local government?

_X_ No.

- The proposed rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed;
- The proposed rule requires a local government to perform or increase a specific activity because the local government has opted to perform an activity, or;
- The proposed rule reduces or eliminates a state mandate on local government.

REGULATORY ANALYSIS
for Amendments to 6 CCR 1007-1,
Part 4, Standards for protection against radiation

1. A description of the classes of persons affected by the proposed rule, including the classes that will bear the costs and the classes that will benefit from the proposed rule.

Group of persons/entities Affected by the Proposed Rule	**Size of the Group**	**Relationship to the Proposed Rule Select category: C/S/B**
Specific radioactive materials licensees of all types (medical, industrial, research, etc)	310	C
X-ray facility registrants	5,435	C
Qualified experts (QI's), Qualified inspectors (QI's)	199	C
Registered Service Companies	179	C
Other stakeholders having an interest in radiation regulations	525	C/S/B

While all are stakeholders, groups of persons/entities connect to the rule and the problem being solved by the rule in different ways. To better understand those different relationships, please refer to the following relationship categorization key:

C = individuals/entities that implement or apply the rule.
S = individuals/entities that do not implement or apply the rule but are interested in others applying the rule.
B = the individuals that are ultimately served, including the customers of our customers. These individuals may benefit, be harmed by or be at-risk because of the standard communicated in the rule or the manner in which the rule is implemented.

More than one category may be appropriate for some stakeholders.

2. To the extent practicable, describe the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

Economic outcomes
Summarize the financial costs and benefits, to include a description of costs that must be incurred, costs that may be incurred, any Department measures taken to reduce or eliminate these costs, and any financial benefits.

Please describe any anticipated financial costs or benefits to these individuals/entities.

C: There are no additional costs expected as a result of the proposed changes. A small benefit is expected for X-ray registrants as they will not need to expend resources to submit documentation and completion of the waiver request form to the department for review. The proposed change will allow the registrant to develop, review, and retain the necessary documentation without department involvement.

S: None. There is no quantitative economic impact of the rule change. Individuals in this category will not incur additional costs nor will costs be reduced as a result of the rule changes.

B: None. There is no quantitative economic impact of the rule change. Individuals in this category will not incur additional costs nor will costs be reduced as a result of the rule changes.

Non-economic outcomes

Summarize the anticipated favorable and non-favorable non-economic outcomes (short-term and long-term), and, if known, the likelihood of the outcomes for each affected class of persons by the relationship category.

The anticipated favorable non-economic outcome is that the proposed rule changes are expected to add clarity and understanding to the rule for all stakeholders and the department. The proposed change to 4.18.3 should help to streamline most occupational monitoring determinations by allowing x-ray registrants to make their own determination regarding occupational monitoring and retain the record for future inspection.

A potential non-favorable non-economic outcome due to the proposed rule change will be some reduced oversight by the department during the approval process for facilities that decide to discontinue external occupational dose monitoring. The department currently relies upon registrants to retain many other radiation safety records including those related to the training of x-ray machine operators, machine maintenance and quality control, and annual program reviews. Reliance on registrants to maintain the occupational monitoring evaluation records in the revised 4.18.3 is similar. It is expected that these records be retained for future inspection by the department and the qualified inspector during routine machine certification evaluations. Oversight is therefore accomplished during the inspection process rather than during a preapproval process.

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.

A. Anticipated CDPHE personal services, operating costs or other expenditures: The rule changes are expected to result in a slight cost savings for the department as review of dosimetry waiver requests will be eliminated. Based on 2018-2022 data, the department receives an average of 58 dosimetry waiver request applications per year for an annual estimated staff cost of $4,350. (1.5 hours per waiver @ an assumed hourly rated of $50/hour x 58 reviews). Additionally, the proposed changes will help in clarifying requirements and will assist CDPHE in carrying out its regulatory program.

B. Anticipated CDPHE Revenues: There are no change in revenues as a result of the proposed changes. No fees are charged for the current dosimetry waiver process. The proposed changes do not impact or change fees.

C. Anticipated personal services, operating costs or other expenditures by another state agency: CDPHE is the only regulatory agency having statutory authority to

regulate sources of radiation in Colorado, and therefore, there will be no financial or other impacts to other state agencies as a result of the proposed changes.

D. Anticipated Revenues for another state agency: None. The proposed rule does not impact revenues for CDPHE or another state agency.

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

Along with the costs and benefits discussed above, the proposed revisions:

_X_ Comply with a statutory mandate to promulgate rules.
_X_ Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
_X_ Maintain alignment with other states or national standards.
_X_ Implement a Regulatory Efficiency Review (rule review) result
_X_ Improve public and environmental health practice.
_X_ Implement stakeholder feedback.

Advance the following CDPHE Strategic Plan priorities (select all that apply):

1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO2e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO2e per year by June 30, 2020 and to 113.144 million metric tons of CO2e by June 30, 2023. ___ Contributes to the blueprint for pollution reduction ___ Reduces carbon dioxide from transportation ___ Reduces methane emissions from oil and gas industry ___ Reduces carbon dioxide emissions from electricity sector
2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023. ___ Reduces volatile organic compounds (VOC) and oxides of nitrogen (NOx) from the oil and gas industry. ___ Supports local agencies and COGCC in oil and gas regulations. ___ Reduces VOC and NOx emissions from non-oil and gas contributors
3. Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023. ___ Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes. ___ Increases physical activity by promoting local and state policies to improve active transportation and access to recreation. ___ Increases the reach of the National Diabetes Prevention Program and Diabetes Self-Management Education and Support by collaborating with the Department of Health Care Policy and Financing.
4. Decrease the number of Colorado children (age 2-4 years) who participate in the WIC Program and have obesity from 2120 to 2115 by June 30, 2020 and to 2100 by

June 30, 2023.

___ Ensures access to breastfeeding-friendly environments.

5. Reverse the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023.

___ Reverses the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023.
___ Performs targeted programming to increase immunization rates.
___ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).

6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023.

___ Creates a roadmap to address suicide in Colorado.
___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate.
___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries.
___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.

7. The Office of Emergency Preparedness and Response (OEPR) will identify 100% of jurisdictional gaps to inform the required work of the Operational Readiness Review by June 30, 2020.

___ Conducts a gap assessment.
___ Updates existing plans to address identified gaps.
___ Develops and conducts various exercises to close gaps.

8. For each identified threat, increase the competency rating from 0% to 54% for outbreak/incident investigation steps by June 30, 2020 and increase to 92% competency rating by June 30, 2023.

___ Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident.
___ Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment.
___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.

9. 100% of new technology applications will be virtually available to customers, anytime and anywhere, by June 20, 2020 and 90 of the existing applications by June 30, 2023.

___ Implements the CDPHE Digital Transformation Plan.

___ Optimizes processes prior to digitizing them. ___ Improves data dissemination and interoperability methods and timeliness.
10. Reduce CDPHE's Scope 1 & 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023. ___ Reduces emissions from employee commuting ___ Reduces emissions from CDPHE operations
11. Fully implement the roadmap to create and pilot using a budget equity assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023. ___ Used a budget equity assessment ___ Advance CDPHE Division-level strategic priorities.

The costs and benefits of the proposed rule will not be incurred if inaction was chosen. Costs and benefits of inaction not previously discussed include:

The cost of inaction by failing to implement the proposed changes will result in retaining ambiguous and technically incorrect information in the rule. Similarly, failing to update provisions pertaining to the incorporation by reference language will potentially make the rule incompatible with the Colorado Administrative Procedure Act.

There are no benefits of inaction.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute. The benefits, risks and costs of these proposed revisions were compared to the costs and benefits of other options. The proposed revisions provide the most benefit for the least amount of cost, are the minimum necessary, and are the most feasible manner to achieve compliance with statute.

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

Alternatives for this rulemaking were considered, but were determined to be a less desirable option. We considered revising 4.18.3 to retain the current approach and waiver process, while removing the ambiguous language and technical errors. Such an approach would be slightly redundant with the intent of current language in 4.18.1, since registrants are already able to evaluate whether external occupational monitoring is needed without 4.18.3. In the end, replacing the language of 4.18.3 with a recordkeeping requirement was thought to be the best approach, and will benefit both the regulated community and the department.

Alternatives to the revised language regarding incorporating documents by reference were not considered as this change is necessary to meet requirements of the Administrative Procedure Act. Failure to incorporate this language may result in the

rule being negated or invalidated by the legislature.

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 did not require a data based evaluation or analysis. The proposed changes are technical changes that are expected to improve the implementation and understanding of the requirements. The proposed updates pertaining to documents incorporated by reference are consistent with information found in other recently amended Department rules and regulations.

STAKEHOLDER ENGAGEMENT
for Amendments to 6 CCR 1007-1,
Part 4, Standards for protection against radiation

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:

Approximately 5,723 email notifications were sent to stakeholders in our regulated community, including specific radioactive materials licensees, x-ray facility registrants, x-ray service companies, and qualified inspectors and qualified experts. We notified stakeholders via email of the opportunity to comment and provide feedback on the proposed draft rule changes. The draft rule along with additional supporting documents were also posted for review on the Department website.

Additionally, approximately 525 individuals having an interest in radiation regulations were notified of the opportunity to comment on the proposed changes. These stakeholders have a wide diversity in interests and may represent or be employed by existing licensees, x-ray registrants, interest groups, and professional associations, societies or organizations.

A 30+ day comment period was held April 24, 2023 through May 29, 2023. During the comment period, two stakeholder meetings were held – one virtual and one in-person. A total of 25 individuals participated in the two stakeholder meetings. We sent several reminder emails about the opportunity to comment and stakeholder meetings during the comment period. We received no written comments during the comment period. Concurrent with the stakeholder process, and consistent with the requirements for maintaining status as an Agreement State, the draft rule was sent to the U.S. Nuclear Regulatory Commission (NRC) for review and comment. NRC did not provide any comments regarding the proposed changes.

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 the notice of 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.

_X_ 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.

No major factual or policy issues were encountered during the stakeholder process. However, several stakeholders asked questions regarding implementation of the revised language during stakeholder meetings. These questions included:

- What the minimum monitoring period would be to determine if dosimetry is necessary.

  Although the presentation to stakeholders provided several examples with different timeframes, staff noted that the minimum monitoring period would remain at 6 months as it is for the current process. The 6 month minimum would be stated in guidance.

- Whether a Qualified Expert (QE) or a Qualified Inspector (QI) would be able to perform a calculation or measurement to establish whether dosimetry is necessary.

  Staff noted that similar to the approach in current rule, a QE would be required if a facility would be using calculations and/or measurements to determine if the threshold for occupational monitoring would be met in lieu of monitoring for a 6 month period. This information would be stated in guidance. Although a QE would be required for the calculation approach, a QI could assist a facility in evaluating their monitoring data if that method is used.

- How would a QI would determine if there is a change in workload from the prior review period to determine if such a change is significant and warrants a change in occupational monitoring.

  Staff noted that the any evaluation of dosimetry would need to note the general operating conditions at the facility. Guidance will be used to help identify and outline additional information to capture for future reference and comparison.

  The proposed changes for Part 4 are expected to improve the effectiveness, understanding and clarity of the rule.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking.

Overall, after considering the benefits, risks and costs, the proposed rule

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.		Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.	X	Reduces occupational hazards; improves an individual's ability to secure or maintain employment; or, increases stability in an employer's workforce.
	Improves access to food and healthy food options.	X	Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals.
X	Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of roles and responsibilities, or what occurs under a rule.		Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the effectiveness of its efforts and outcomes.
	Increases a child's ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity.		Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.
	Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.		Ensures a competent public and environmental health workforce or health care workforce.
X	Other: Benefits stakeholders with additional information where to locate documents incorporated into the rule to help aide compliance with the requirements.	X	Other: Ensures consistency with federal rule and the national framework for regulation of radioactive materials.

DRAFT 2 09/05/2023

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]

* * *

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.