



To: Members of the State Board of Health

From: James H. Grice, Radiation Program Manager, Hazardous Materials and Waste Management Division  
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Through: Jennifer T. Opila, Division Director *JTO*

Date: **August 19**, 2020

Subject: **Rulemaking Hearing** concerning proposed amendments to 6 CCR 1007-1 Part 2, Registration of radiation machines, facilities and services, and Part 6, X-ray imaging in the healing arts.

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The radiation program is proposing non-substantial technical corrections and informational changes to Part 6, and Part 2 of the radiation regulations. The primary purpose of these revisions is to correct technical deficiencies for compliance with the Colorado Administrative Procedure Act.

Proposed changes made to these rules include the addition of a revised incorporation by reference section and updates to applicable references within the rule. The revised language will benefit regulated entities and stakeholders by providing additional, specific information where incorporated documents can be found online and in-person. Additionally, several typographical, cross-reference, omission, and formatting errors are corrected in the rules.

Only those impacted sections of the rules are included in the draft rules. Proposed changes occur in limited areas of the rules, with new text appearing as red bold text and deleted text shown as strikethrough. **Consistent with Board practice, items highlighted in yellow have been added since the request for rulemaking in June.**

The Radiation Program requests that the Board **adopt the rules as proposed.**

STATEMENT OF BASIS AND PURPOSE  
AND SPECIFIC STATUTORY AUTHORITY  
for Amendments to

6 CCR 1007-1, Part 06, X-ray imaging in the healing arts;  
6 CCR 1007-1, Part 02, Registration of radiation machines, facilities and services

Basis and Purpose.

The proposed amendments make minor technical and formatting changes to the Part 6 and Part 2 rules for consistency with the Colorado Administrative Procedure Act with regard to provisions pertaining to documents incorporated by reference. Although in place for a number of years, the current language of the rule was determined to not meet the full intent of documents incorporated by reference. The proposed changes are outlined below, including those that have been added since the request for rulemaking and which are highlighted in yellow in the rule package and draft rules.

Section 2.1.5, and 6.1.5.

The proposed rules incorporate expanded language to inform rule users and stakeholders where documents incorporated by reference in the rule such as state and federal regulations and guidance documents may be found online or at other specified locations or sources. The language also clarifies that unless otherwise specifically identified in the rule, the versions of cited documents are those that were in effect based on the effective date of the rule.

Throughout both Part 2 and Part 6

Minor typographical and formatting corrections are made, including corrections or removal of specific dates for incorporated documents. Following the request for rulemaking, additional formatting changes were needed, primarily to remove unnecessary blank lines between provisions found in the current rule. This resulted in the reincorporation of sections and areas of the rule not previously identified for change. There are however no changes to the text or requirements of these sections and only unneeded blanks are removed.

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.

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Is this rulemaking due to a change in state statute?

Yes, the bill number is \_\_\_\_\_. Rules are \_\_\_ authorized \_\_\_ required.

No

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

Yes  URL

No

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

Yes

No

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

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

6 CCR 1007-1, Part 06, X-ray imaging in the healing arts;  
 6 CCR 1007-1, Part 02, Registration of radiation machines, facilities and services

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/CLG/S/B
Registered entities using x-ray machines for imaging and other non-radiation therapy purposes in the healing arts who are required to adhere to the requirements of Part 6 and 2 of the regulations.	Approx. 5,000	C
Registered entities who provide services related to x-ray imaging systems/machines, including those who perform inspections, servicing activities. These entities are required to adhere to the requirements of Part 6 and 2 of the regulations.	Approx. 500	C
Entities interested in the outcomes of the proposed x-ray related rule changes include numerous regional and local professional organizations, societies, and associations that represent individual healthcare providers, businesses, entities or registered facilities that operate, supervise operation or are otherwise involved with x-ray machine use in the field of medicine.	Unknown, but estimated at 20K.	S
All Coloradans who may receive services provided by a registered x-ray facility.	Unknown	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, a description of 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, 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.

C and CLG: None. There is no quantitative economic or quantitative non-economic impact of the proposed rule change. The rule expands and clarifies existing language to provide stakeholders and regulated entities and individuals with additional information on where to locate documents that are referenced or incorporated into the rules.

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

S: No financial costs or benefits.

B: No financial costs or benefits.

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.

Clarity in rule language would be expected to decrease workload for regulated entities (category S) and other stakeholders (category B) because information on where to find documents incorporated by reference is improved and clarified.

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: There are limited to no anticipated costs associated with the proposed changes.
  - B. Anticipated CDPHE Revenues: No change in revenues as a result of the proposed changes.
  - C. Anticipated personal services, operating costs or other expenditures by another state agency:

Anticipated Revenues for another state agency: None.

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:

Comply with a statutory mandate to promulgate rules.

Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.

- Maintain alignment with other states or national standards.
- Implement a Regulatory Efficiency Review (rule review) result
- Improve public and environmental health practice.
- Implement stakeholder feedback.

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

<p>1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO<sub>2</sub>e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO<sub>2</sub>e per year by June 30, 2020 and to 113.144 million metric tons of CO<sub>2</sub>e by June 30, 2023.</p> <p><input type="checkbox"/> Contributes to the blueprint for pollution reduction</p> <p><input type="checkbox"/> Reduces carbon dioxide from transportation</p> <p><input type="checkbox"/> Reduces methane emissions from oil and gas industry</p> <p><input type="checkbox"/> Reduces carbon dioxide emissions from electricity sector</p>
<p>2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023.</p> <p><input type="checkbox"/> Reduces volatile organic compounds (VOC) and oxides of nitrogen (NO<sub>x</sub>) from the oil and gas industry.</p> <p><input type="checkbox"/> Supports local agencies and COGCC in oil and gas regulations.</p> <p><input type="checkbox"/> Reduces VOC and NO<sub>x</sub> emissions from non-oil and gas contributors</p>
<p>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.</p> <p><input type="checkbox"/> Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes.</p> <p><input type="checkbox"/> Increases physical activity by promoting local and state policies to improve active transportation and access to recreation.</p> <p><input type="checkbox"/> 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.</p>
<p>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.</p> <p><input type="checkbox"/> Ensures access to breastfeeding-friendly environments.</p>
<p>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.</p> <p><input type="checkbox"/> 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.</p> <p><input type="checkbox"/> Performs targeted programming to increase immunization rates.</p>

<p>___ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).</p>
<p>6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023.</p> <p>___ Creates a roadmap to address suicide in Colorado.</p> <p>___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate.</p> <p>___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries.</p> <p>___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.</p>
<p>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.</p> <p>___ Conducts a gap assessment.</p> <p>___ Updates existing plans to address identified gaps.</p> <p>___ Develops and conducts various exercises to close gaps.</p>
<p>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.</p> <p>___ Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident.</p> <p>___ Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment.</p> <p>___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.</p>
<p>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.</p> <p>___ Implements the CDPHE Digital Transformation Plan.</p> <p>___ Optimizes processes prior to digitizing them.</p> <p>___ Improves data dissemination and interoperability methods and timeliness.</p>
<p>10. Reduce CDPHE's Scope 1 &amp; 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.</p> <p>___ Reduces emissions from employee commuting</p> <p>___ Reduces emissions from CDPHE operations</p>
<p>11. Fully implement the roadmap to create and pilot using a budget equity</p>

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:

Failing to implement the proposed changes pertaining to documents incorporated by reference may make the rule incompatible with the Colorado Administrative Procedure Act.

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 or are the most feasible manner to achieve compliance with statute.

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

No alternatives to this rulemaking were considered. Failure to implement requirements that are consistent with the requirements of the Administrative Procedure Act 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 language is generally consistent with other commonly accepted language and information found in other Department rules and regulations.



### STAKEHOLDER ENGAGEMENT

for Amendments to

6 CCR 1007-1, Part 06, X-ray imaging in the healing arts;  
6 CCR 1007-1, Part 02, Registration of radiation machines, facilities and services

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:

The proposed revisions correct technical deficiencies for compliance with the Colorado Administrative Procedure Act. Due to the minor and informational nature of the changes, no stakeholder processes or stakeholder meetings were conducted prior to the request for rulemaking. Stakeholders will be notified of the proposed changes prior to the rulemaking hearing, if scheduled.

#### 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 10<sup>th</sup> 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.

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. The proposed changes are informational in nature and are added for consistency with the Colorado Administrative Procedure Act.

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:

Select all that apply.

	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.	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.	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 located documents incorporated into the rule to help aide compliance with the requirements. _____	Other: _____ _____

1 **DRAFT 2 (07/22/2020)**

2 **DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

3 **Hazardous Materials and Waste Management Division**

4 **State Board of Health**

5 **RADIATION CONTROL - REGISTRATION OF RADIATION MACHINES, FACILITIES AND SERVICES**

6 **6 CCR 1007-1 Part 02**

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

9 **Adopted by the Board of Health ~~November 20, 2019~~ August 19, 2020, effective date January 14 October 15, 2020**

12 **PART 2: REGISTRATION OF RADIATION MACHINES, FACILITIES AND SERVICES**

14 **2.1 Purpose and Scope.**

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

16 \* \* \*

17 **2.1.5 Published Material Incorporated by Reference.**

18 ~~2.1.5.1 In accordance with Section 24-4-103(12.5)(c), CRS,~~  
19 ~~<https://www.colorado.gov/cdphe/radregs> identifies where incorporated material is~~  
20 ~~available to the public on the internet at no cost. If the incorporated material is not~~  
21 ~~available on the internet at no cost to the public, copies of the incorporated material has~~  
22 ~~been provided to the State Publications Depository and Distribution Center, also known~~  
23 ~~as the State Publications Library. The State Librarian at the State Publication Library~~  
24 ~~retains a copy of the material and will make the copy available to the public.~~

25 ~~2.1.5.2 The materials incorporated by reference in this Part include only those versions that were~~  
26 ~~in effect at the time of the most recent adoption of this Part, and not later amendments to~~  
27 ~~the incorporated material, unless a prior version of the incorporated material is otherwise~~  
28 ~~specifically noted, and in such case that prior version shall apply.~~

29 ~~2.1.5.1 Throughout this Part 2, federal regulations, state regulations, and standards or~~  
30 ~~guidelines of outside organizations have been adopted and incorporated by~~  
31 ~~reference. Unless a prior version of the incorporated material is otherwise~~  
32 ~~specifically indicated, the materials incorporated by reference cited herein include~~  
33 ~~only those versions that were in effect as of the most recent effective date of this~~  
34 ~~Part 2 (October, 2020), and not later amendments or editions of the incorporated~~  
35 ~~material.~~

36 ~~2.1.5.2 Materials incorporated by reference are available for public inspection, and copies~~  
37 ~~(including certified copies) can be obtained at reasonable cost, during normal~~  
38 ~~business hours from the Colorado Department of Public Health and Environment,~~  
39 ~~Hazardous Materials and Waste Management Division, 4300 Cherry Creek Drive~~  
40 ~~South, Denver, Colorado 80246. Additionally,~~  
41 ~~<https://www.colorado.gov/cdphe/radregs> identifies where the incorporated federal~~

**Commented [JSJ1]:**  
**EDITORIAL NOTE 1:**  
These side margin comments as shown here are not part of the rule and are for information only with the intent to aid the reader in understanding the proposed changes in the draft regulations. All side margin comments will be removed prior to publication as a final rule.

**Commented [JSJ2]:**  
Adoption and effective dates are tentative and subject to change, pending Board of Health meeting schedule, final adoption of the rule, and the Colorado Register publication dates.

**Commented [JSJ3]:**  
Provisions in section 2.1.5, are revised and amended for consistency with the Colorado Administrative Procedure Act (24-4-103(12.5)(a)(2), CRS) regarding documents incorporated by reference.

**Commented [JSJ4]:** Website address modified to correct typographical error.

and state regulations are available to the public on the internet at no cost. A copy of the materials incorporated in this Part is available for public inspection at the state publications depository and distribution center.

2.1.5.3 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 Printing Office, online at [www.govinfo.gov](http://www.govinfo.gov).

(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/RegisterHome.do>.

(3) Copies of the standards or guidelines of outside organizations are available at no cost or for purchase from the source organizations listed below.

(a) American Registry of Radiologic Technologists  
1255 Northland Drive  
St. Paul, MN 55120-1155  
Phone (651) 687-0048  
aart.org

Commented [JSJ5]: Appendix 2D refers to the continuing education requirements document published by the ARRT. Information on where to locate the document is therefore added here.

\* \* \*

2.4.1.2 As prescribed by 6.3.3.4 for a healing arts screening program, registrants shall complete and submit a Healing Arts Screening application including all of the information required by Part 6, Appendix 6F).

Commented [JSJ6]: Deletion of unneeded parenthesis.

\* \* \*

2.4.4.6 Certification evaluation measurements shall be made with instruments that are sufficiently sensitive to determine compliance with these regulations.

Commented [JSJ7]: There are no changes to the text or requirements of this provision or its subsections.

The section is amended for formatting purposes only to remove four (4) unneeded (spacing) lines between 2.4.4.6(5) and 2.4.5. currently shown in the final (in-effect) rule. All text remains as-is found in the current rule.

(1) \* \* \*

(2) \* \* \*

(3) \* \* \*

(4) \* \* \*

(a) \* \* \*

(b) \* \* \*

(c) \* \* \*

(5) \* \* \*

2.4.5 Registration of specific radiation machine operators.

\* \* \*

81 2.4.8 No person, in any advertisement, shall refer to the fact that the person is registered with the  
 82 Department pursuant to the provisions of 2.4.1, 2.4.2, 2.4.3, 2.4.4, and 2.4.5 and no person shall  
 83 state or imply that the quality of conduct or performance of any activity under such registration  
 84 has been approved or endorsed by the Department.

**Commented [JSJ8]:** There are no changes to the text or requirements of this provision.

The section is amended for formatting purposes only to remove three (3) unneeded (spacing) lines between 2.4.8 and the subsequent unnumbered "CERTIFICATION EVALUATION" text currently shown in the final (in-effect) rule. All text remains as-is found in the current rule.

85 **CERTIFICATION EVALUATION**

86 **2.5 Certification Evaluations.**

87 \* \* \*

88 2.5.1.2 Each non-healing-arts x-ray imaging machine or system regulated by Parts 5, 8 or 9  
 89 shall be inspected at least every two (2) years. These include, but are not limited to, x-ray  
 90 machines used for industrial radiography, nondestructive analysis, forensics or security  
 91 screening.

**Commented [JSJ9]:** A missing hyphen is added to "x-ray".

92 2.5.1.3 \* \* \*

**Commented [JSJ10]:** There are no changes to the text or requirements of this provision and its subsections.

The section is amended for formatting purposes only to remove three (3) unneeded (spacing) lines between 2.5.1.3 (and subsections) and the subsequent "TABLE 2-1" header text currently shown in the final (in-effect) rule. All text and Table 2-1 remains as-is found in the current rule.

93 (1) \* \* \*

94 (2) \* \* \*

95 (3) \* \* \*

96 (4) \* \* \*

97 **TABLE 2-1: SUMMARY OF FREQUENCY OF RADIATION MACHINE INSPECTION**

98 \* \* \*

99 2.5.2.4 Reporting and Labeling Procedures.

**Commented [JSJ11]:** There are no changes to the text or requirements of this provision and its subsections.

The section is amended for formatting purposes only to remove two (2) unneeded (spacing) lines between 2.5.2.4 (and subsections) and the subsequent 2.6 section header text currently shown in the final (in-effect) rule. All text and Table 2-1 remains as-is found in the current rule

100 (1) \* \* \*

101 (a) \* \* \*

102 (b) \* \* \*

103 (c) \* \* \*

104 (d) \* \* \*

105 (e) \* \* \*

106 (2) \* \* \*

107 (a) \* \* \*

108 (b) \* \* \*

109 (3) \* \* \*

110 (a) \* \* \*

111 (b) \* \* \*

112 (4) \* \* \*

114 (5) \* \* \*

115 2.6 Facility Registrant Responsibilities.

116 \* \* \*

118 2.8.1.2 \* \* \*

119 (1) \* \* \*

120 (2) \* \* \*

121 (3) In the case of a request to perform mammography screening within the State, a  
122 copy of the facility's mammography certificate issued by the FDA (21 CFR  
123 900.11(a), April 1, 2010) and applicable American College of Radiology  
124 credentials shall be included with the reciprocity request.

Commented [JSJ12]: The reference to a specific CFR date is removed and instead defers to the revised standard incorporation by reference language in section 2.1.5.

125 \* \* \*

126 2F.2.5 Has maintained a minimum of eighteen (18) hours continuing education every three  
127 years, documented by certificate(s) or other attestation(s) of satisfactory completion.

128 PART 2, APPENDIX 2G: RADIOLOGIST ASSISTANT (RA) ADEQUATE RADIATION SAFETY  
129 TRAINING AND EXPERIENCE

Commented [JSJ13]: There are no changes to the text or requirements of Appendix 2F or 2G. The section is formatted to remove the blank page that precedes Appendix 2G, such that it begins at the top of the next available page after provision 2F.2.5 of Appendix 2F in the final published rule with no preceding blank page as found in the current in-effect rule.

130 \* \* \*

131 2I.5.1.4 A equivalent specialty board or certification approved by the department.

132 PART 2, APPENDIX 2J: QUALIFIED TRAINER (QT) ADEQUATE RADIATION SAFETY TRAINING  
133 AND EXPERIENCE

Commented [JSJ14]: There are no changes to the text or requirements of Appendix 2I or 2J. The section is formatted to remove the blank page that precedes Appendix 2J, such that it begins at the top of the next available page after provision 2I.5.1.4 of Appendix 2I in the final published rule with no preceding blank page as found in the current in-effect rule.

134 \* \* \*

135 2K.2.2.1 An approved formal training program, approved by the Residency  
136 Review Committee of the Accreditation Council for Graduate Medical  
137 Education or Committee on Post-Graduate the Council on Postdoctoral  
138 Training of the American Osteopathic Association; and

Commented [JSJ15]: This proposed change, identified after the request for rulemaking, is necessary to identify the correct name of the committee, consistent with recently adopted changes to the Part 7 regulation.

139 \* \* \*

140 2L.1.1.1 The Joint Review Committee on Education in Radiologic Technology  
141 (consult the 1988 Essentials and Guidelines of an Accredited  
142 Educational Program for the Radiation Therapy Technologist or the 2001  
143 Standard for an Accredited Educational Program in Radiological  
144 Sciences); or

Commented [JSJ16]: This proposed change, identified after the request for rulemaking, removes date specific and document specific information since the Joint Review Committee periodically updates their standards documents.

145 \* \* \*

146 \* \* \*

147 2M.3.2.1 A mammographer shall have performed a minimum of 200 mammography  
148 examinations within the immediate prior 24 months.

Commented [JSJ17]: There are no changes to the text of Appendix 2M or 2N.

The section is formatted to ensure a page break is placed between 2M.3.2.1(1) and the beginning of Appendix 2N. In the current rule, these appendices are not separated by a page break.

149  
150  
151  
152  
153

(1) A mammographer who fails to meet this continuing experience requirement shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified mammographer before resuming the performance of unsupervised mammography examinations.

1 **DRAFT 2 07/22/2020**

2 **DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

3 **Hazardous Materials and Waste Management Division**

4 **State Board of Health**

5 **RADIATION CONTROL - X-RAY IMAGING IN THE HEALING ARTS**

6 **6 CCR 1007-1 Part 06**

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

8 \_\_\_\_\_

9 **Adopted by the Board of Health ~~November 20, 2019~~ August 19, 2020, effective date January**  
10 **14 October 15, 2020.**

11 **PART 6: X-RAY IMAGING IN THE HEALING ARTS**

12

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

14

15 **6.1.5** Published Material Incorporated by Reference.

16 ~~6.1.5.1 In accordance with Section 24-4-103(12.5)(c), CRS,~~  
17 ~~<https://www.colorado.gov/cdphe/radregs> identifies where incorporated material is~~  
18 ~~available to the public on the internet at no cost. If the incorporated material is not~~  
19 ~~available on the internet at no cost to the public, copies of the incorporated material has~~  
20 ~~been provided to the State Publications Depository and Distribution Center, also known~~  
21 ~~as the State Publications Library. The State Librarian at the State Publication Library~~  
22 ~~retains a copy of the material and will make the copy available to the public.~~

23 ~~6.1.5.2 The materials incorporated by reference in this Part include only those versions that were~~  
24 ~~in effect at the time of the most recent adoption of this Part, and not later amendments to~~  
25 ~~the incorporated material, unless a prior version of the incorporated material is otherwise~~  
26 ~~specifically noted, and in such case that prior version shall apply.~~

27 ~~6.1.5.1 Throughout this Part 6, federal regulations, state regulations, and standards or~~  
28 ~~guidelines of outside organizations have been adopted and incorporated by~~  
29 ~~reference. Unless a prior version of the incorporated material is otherwise~~  
30 ~~specifically indicated, the materials incorporated by reference cited herein include~~  
31 ~~only those versions that were in effect as of the most recent effective date of this~~  
32 ~~Part 6 (October, 2020), and not later amendments or editions of the incorporated~~  
33 ~~material.~~

34 ~~6.1.5.2 Materials incorporated by reference are available for public inspection, and copies~~  
35 ~~(including certified copies) can be obtained at reasonable cost, during normal~~  
36 ~~business hours from the Colorado Department of Public Health and Environment,~~  
37 ~~Hazardous Materials and Waste Management Division, 4300 Cherry Creek Drive~~  
38 ~~South, Denver, Colorado 80246. Additionally,~~  
39 ~~<https://www.colorado.gov/cdphe/radregs> identifies where the incorporated federal~~  
40 ~~and state regulations are available to the public on the internet at no cost. A copy~~

**Commented [JSJ18]:**  
**EDITORIAL NOTE 1:**  
These side margin comments as shown here are not part of the rule and are for information only with the intent to aid the reader in understanding the proposed changes in the draft regulations. All side margin comments will be removed prior to publication as a final rule.

**Commented [JSJ19]:**  
Adoption and effective dates are tentative and subject to change, pending Board of Health meeting schedule, final adoption of the rule, and the Colorado Register publication dates.

**Commented [JSJ20]:**  
Provisions in section 6.1.5, are revised and amended for consistency with the Colorado Administrative Procedure Act (24-4-103(12.5)(a)(2), CRS) regarding documents incorporated by reference.

**Commented [JSJ21]:** Website address modified to correct typographical error.



of the materials incorporated in this Part is available for public inspection at the state publications depository and distribution center.

6.1.5.3 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 Printing Office, online at www.govinfo.gov.
(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/RegisterHome.do.
(3) Copies of the standards or guidelines of outside organizations are available either at no cost or for purchase from the source organizations listed below.
a. American Association of Physicists in Medicine (AAPM) 1631 Prince Street Alexandria, VA 22314 Phone 571-298-1300 aapm.org
b. National Council on Radiation Protection and Measurements (NCRP) 7910 Woodmont Avenue, Suite 400 Bethesda, MD 20814-3095 Phone: 301-657-2652 ncrponline.org

\* \* \*

6.2 Definitions.

As used in Part 6, these terms have the definitions set forth as follows:

"AAPM Online Report 03" means "Assessment of Display Performance for Medical Imaging Systems", AAPM Online Report No. 03 by Task Group 18 of the American Association of Physicists in Medicine (April 2003).

\* \* \*

"Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

\* \* \*

GENERAL REGULATORY PROVISIONS

6.3 General and administrative requirements.

6.3.1 Administrative Controls.

Commented [JSJ22]: Date corrected to match current version of report and current 6.3.5.6.

Commented [JSJ23]: The current definition for "Detector" - a term used a few times in Part 6 - in turn refers to "Radiation detector", which does not exist in the current rule. This addition does not change or introduce any new requirements and is for clarification only.

This definition is added to address this cross reference problem as it was inadvertently omitted during the 2019 amendment to Part 6.

The definition originates from the suggested state regulations Part F (2015) of the Conference of Radiation Control Program Directors (CRCPD), Inc.

82 6.3.1.1 Each radiation machine used in the healing arts in the State of Colorado shall be  
83 registered with the Department as required by Part 2, Section 2.4 and inspected as  
84 prescribed in Part 2, Section 2.5.

85 6.3.1.2 Each radiation machine used on humans shall meet the Federal Performance Standards,  
86 Subchapter J - Radiological Health, 21 CFR 1020.30 through 1020.33 (~~April 1, 2014~~).

**Commented [JSJ24]:**  
References to rule dates are deleted for consistency with the amended incorporation by reference language of 6.1.5 regarding federal regulations.

87 (1) Diagnostic X-ray systems and their associated components used on humans and  
88 certified pursuant to the Federal X-Ray Equipment Performance Standard (21  
89 CFR 1020.30 through 1020.33, ~~April 1, 2014~~) shall be maintained in compliance  
90 with applicable requirements of that standard.

91 \* \* \*

92 6.3.2 General Specifications for Facility and Equipment Design, Configuration and Preparation.

93 6.3.2.1 Evaluation of Shielding Design Prior to Commencement of Operation.

94 (1) The floor plan and equipment configuration of a radiation machine facility shall be  
95 designed to meet all applicable requirements of these regulations and in  
96 particular to preclude an individual from receiving a dose in excess of the limits in  
97 Part 4, Sections 4.6, 4.12, 4.13, 4.14 and 4.15.

98 (2) The floor plan and equipment configuration of each radiation machine facility  
99 shall be submitted to a qualified expert for determination of shielding  
100 requirements in accordance with Appendices 6A, 6B and 6C.

101 (3) The qualified expert shielding design required by 6.3.2.1(2) shall be completed  
102 prior to:

**Commented [JSJ25]:** This cross-reference is corrected to more appropriately reference the broader requirements of 6.3.2.1 of the section.

103 \* \* \*

104 6.4.2.5 Beam Quality: Half-value Layer

105 (1) The half-value layer of the useful beam for a given x-ray tube potential shall not  
106 be less than the values shown in Appendix 6I.

107 (2) If it is necessary to determine such half-value layer at an x-ray tube potential that  
108 is not listed in Appendix 6I, linear interpolation or extrapolation is acceptable.  
109 Positive means shall be provided to ensure that at least the minimum filtration  
110 needed to achieve beam quality requirements is in the useful beam during each  
111 exposure. In the case of a system, which is to be operated with more than one  
112 thickness of filtration, this requirement can be met by a filter interlocked with the  
113 kilovoltage selector which will prevent x-ray emissions if the minimum required  
114 filtration is not in place.

**Commented [JSJ26]:**  
Correction of typographical error – removal of extra comma.

115 \* \* \*

116 6.6.2.5 Beam Limitation Requirements for Each X-Ray System Not Governed by 6.6.2.1 through  
117 6.6.2.4:

118 (1) \* \* \*

119 (a) \* \* \*

120 (b) \* \* \*

121 (2) The requirements of 6.6.2.5(1) may be met with a system that meets the  
 122 requirements for a general purpose x-ray system as specified in 6.6.2 and  
 123 6.6.2.3, or, when alignment means are also provided, may be met with either:

\* \* \*

**Commented [JSJ27]:** A space is added between "in" and "6.6.2" to correct a typographical error in the current rule.

6.6.3.9 Source-Skin Distance.

126 (1) Each mobile, portable or hand-held radiographic x-ray imaging system shall be  
 127 provided with means to limit the source-skin distance to equal to or greater than  
 128 30 cm.

129 (2) The minimum source-skin distance shall not be less than 30 cm, excluding  
 130 systems addressed in 6.3.3.9(1), dental systems addressed in 6.7, and  
 131 veterinary systems addressed in 6.8.

\* \* \*

**Commented [JSJ28]:**  
 As written, this provision refers to a section/provision (6.3.3.9(1)) that no longer exists in the rule. Therefore, the reference to that non-existent provision is removed here. The cross-reference was inadvertently retained during the 2019 rule amendment.

As proposed, the language contains the necessary exceptions to the SSD requirements.

133 6.7.1.5 Each individual who operates a dental x-ray imaging system shall meet the applicable  
 134 adequate radiation safety training and experience requirements of 2.6.1, in particular  
 135 2.6.1.102.6.1.11.

\* \* \*

**Commented [JSJ29]:** This change fixes a cross-reference error in the current rule.

Provision 6.7.1.5 pertains to dental system use, but incorrectly references a chiropractic related provision in Part 2. The proposed change references the correct provision in Part 2.

6.7.3.2 Intraoral and panoramic dental x-ray systems shall meet the following radiation exposure control requirements:

(1) \* \* \*

(a) \* \* \*

(b) \* \* \*

(c) \* \* \*

(d) \* \* \*

(i) \* \* \*

(2) X-ray Control for Intraoral or Panoramic Dental X-ray Systems.

(a) \* \* \*

(b) \* \* \*

(c) Each Exposure control location and operator protection.

\* \* \*

**Commented [JSJ30]:** Correction of a typographical word usage error for consistency with the CRCPD model Part F rule in F.7.d.

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151 PART 6, APPENDIX 6D: CRITERIA FOR CLASSIFYING A RADIATION MACHINE UNSAFE FOR  
152 ROUTINE HUMAN, ANIMAL OR OTHER USE

153 \* \* \*

154 6D.2.7 In addition to the above items a fluoroscopic x-ray system will be considered unsafe if:

155 (1) \* \* \*

156 (a) \* \* \*

157 (b) \* \* \*

158 (c) \* \* \*

159 (d) \* \* \*

160 (i) \* \* \*

161 (ii) \* \* \*

162 (2) When using a high-level control, the equipment is operable at any combination of  
163 tube potential and current that will result in an AKR in excess of 176 mGy per  
164 minute (20 R/min), consistent with 21 CFR 1020.32(d)(2)(iii)(C), April 1, 2017.

165 \* \* \*

166  
167

Commented [JSJ31]: References to federal rule dates are deleted for consistency with the revised incorporation by reference language of 6.1.5.

168 **PART 2, APPENDIX 2N: INDUSTRIAL RADIATION MACHINE OPERATOR ADEQUATE RADIATION**  
169 **SAFETY TRAINING AND EXPERIENCE**

170 \* \* \*

Commented [JSJ32]: Prior to final publication, insert a page break at the top of Appendix 2N to ensure it begins on a new page.