COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

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Through: Tracie M. White, Division Director TMW

Date: February 21, 2024

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

The Division is proposing changes to x-ray machine regulations Part 6 and Part 2 primarily to clarify existing provisions, requirements and language in the rules relating to provisional mammographers, limited scope operators, routine certification evaluations, and to incorporate cardiac catheterization lab personnel into the current fluoroscopy operator registration. Following additional consideration, the Division is also proposing to remove language for a future requirement mandating the use of rectangular collimators for most dental intra-oral imaging due, primarily, to an inability for the regulated community to achieve compliance as a result of the lack of equipment availability. This requirement was added during the prior 2019-20 rulemaking and becomes effective in 2025 if no change is made.

During the stakeholder comment period we received two written comments from stakeholders regarding the Part 6 proposed change in 6.7.2.3(3)(b) that would remove the requirement for rectangular collimators during routine dental intra-oral imaging procedures which is currently scheduled to go into effect January 1, 2025. One commenter supports the proposal to remove this provision citing greater potential for repeat examinations due to operator error in aligning the imaging port with the image receptor along with unreasonable burdens to train individuals to ensure this does not happen. The other commenter stated their opposition to removing provision 6.7.2.3(3)(b), noting the patient dose reduction benefits are well established and recognized by multiple professional associations, that voluntary adoption by the dental community is not likely, and that regulatory action by the department is necessary.

While we continuously support efforts to identify methods that will help reduce human exposure as outlined further in the rule package, we are proposing to remove this provision primarily due to the lack of market availability of universal add-on type collimator systems originally contemplated during the 2019-20 rulemaking. Secondarily, consultation with representatives of the U.S. Food and Drug Administration (FDA) indicate that add-on devices, such as collimators, become part of the tube assembly that must be recertified under federal rules through the FDA similar to other components of an x-ray system.

Prior to and following the stakeholder process, our Radiation Advisory Committee reviewed and discussed the proposed rule changes and supported moving the rule forward as proposed and with no specific concerns opposing the proposed changes.

Since these rule changes affect select areas of the rule, only those impacted sections are included in the proposed draft. Throughout the rule, new text appears as red bold text while deleted language shows as strikethrough text. Changes since the request for rulemaking in December 2023 are highlighted in yellow, consistent with Board practice.

The Radiation Program respectfully requests that the Board of Health adopt the proposed changes for these rules.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1007-1, Part 02, Registration of radiation machines, facilities and services
6 CCR 1007-1, Part 06, X-ray imaging in the healing arts;

Basis and Purpose.

Although there is some overlap in the proposed changes between Part 2 and Part 6 for this rulemaking, the updates for each regulatory part are described in further detail in separate sections below.

Part 2
Part 2 contains broad and specific requirements applicable to all x-ray machine facilities for any purpose, including non-medical and medical uses, it is applicable to those providing services to facilities that use x-ray machines (including inspection or repair), and also incorporates qualifications, training, and state registration requirements for certain operators of x-ray machines. For this rulemaking, most proposed changes apply to medical uses of machines.

As outlined for each section below, changes to the Part 2 rule are proposed to improve the clarity and understanding of certain rule requirements. This includes updates to select definitions, reaffirming that facility registration is an annual process, clarifying language and slightly reorganizing tables pertaining to machine certification evaluations, and adding clarifying language to ensure that the department is notified promptly when a machine fails inspection criteria as specified in statute.

Without changing current requirements, we are also revising language to clarify that the body of the rule contains requirements for fully qualified mammographers, and the appendix (2M) is intended for use by those in training to become qualified mammographers.

The rule is clarified to indicate that training on imaging of the abdomen, and performing abdominal imaging in the field, may be performed by qualified Limited Scope Operators (LSOs), consistent with most training programs and practice at facilities in Colorado. Abdominal imaging is one of the more common exams performed at facilities that employ LSOs. The level of supervision while LSOs are undergoing training is also clarified, consistent with current training programs and practice.

The registration process and criteria for fluoroscopy operators is amended to incorporate certain qualified and nationally registered individuals working in cardiac catheterization labs in Colorado. These individuals are and have been performing certain aspects of fluoroscopy operation under supervision by a physician at many Colorado facilities for many years. Under the present rule, these individuals fall outside of current criteria for registered fluoroscopy operators and registration of these individuals is evaluated on a case-by-case basis.

Summary of Part 2 changes by section

Changes throughout Part 2

- The word “Part” is added to the rule when there are references to federal (CFR) rules. Typographical errors, omissions, and alignment of text are also being corrected.

Changes to Section 2.1

- Updates are made to rulemaking adoption and effective dates and links to regulatory web pages.

Changes to Section 2.2 (Definitions)

- We are modifying the definition "Direct supervision" to remove language pertaining to mammography that is redundant with the revised Appendix 2M changes. Language is added to Appendix 2M to clarify the level of supervision during certain portions of an individual's mammography training. This is not a change from the current requirements;
- The term "Personal supervision" is used in several sections of Part 2 and other rules, and therefore a reference to the Part 1 definition is added to Part 2 for clarity and understanding;
- We are revising the definitions "Provisional mammographer" and "Qualified mammographer" to reference the applicable sections in Appendix 2M or 2.4.5.4, consistent with other changes to these sections; and
- Minor additions and clarifications are made to the "Radiologic technologist" and similar abbreviations consistent with language used by a primary certifying organization – the American Registry of Radiologic Technologists (ARRT).

Changes to Section 2.3.2

- Section 2.3.2 is amended using plain language for clarity and understanding, and for consistency with the 2009 CRCPD Part B model rule.

Changes to Section 2.4.1(2)

- Section 2.4.1(2) is amended to include reaffirming and clarifying language that facility registrations are an annual process, consistent with current practice and the current annual fee payment cycle in Part 12 of the regulations.

Changes to Section 2.4.5.4

- Section 2.4.5.4 pertains to mammographers (operators of x-ray imaging systems for mammography imaging) and is amended to improve the clarity and intent of the rule consistent with current practices and requirements and in conjunction with parallel changes to Appendix 2M. The rule is clarified to indicate that Appendix 2M will be used solely for the registration of individuals who are in training to become qualified mammographers (known as "provisional mammographers") and Section 2.4.5.4 will provide requirements for individuals who are considered qualified mammographers.

  Section 2.4.5.4 currently provides requirements for individuals who are in training to become fully qualified and nationally registered mammographers consistent with state and federal requirements. Under current rule, individuals in training are required to register with the department as "provisional mammographers" until they become nationally certified and registered. We are revising 2.4.5.4 and the associated Appendix 2M to improve the clarity and understanding of the requirements and to follow current processes for registration used by the department. We are not making any changes to the overall requirements with this proposed change.

Changes to Section 2.4.5.5

- Section 2.4.5.5 is being revised to clarify requirements pertaining to fluoroscopy operators and incorporate qualified individuals as fluoroscopy operators under the

revised Appendix 2O, as these individuals are not adequately captured by the current rule. The added language of 2.4.5.5 and subsections will allow the department additional flexibility in implementing the rule for individuals who do not fall within the current criteria for fluoroscopy operators.

Changes to Section 2.5 and Table 2-1

- Section 2.5 and Table 2-1 are being updated to align and ensure consistency between the text of the rule and table. This section of the rule provides the certification evaluation (routine inspection) frequencies for all radiation machine types. There has been some confusion with regard to the timing of certification evaluations (inspections) for new machine installations versus already installed machines and whether a machine can be used for imaging exams prior to inspection. New installations of certain machines including Computed Tomography and Mammography systems require inspection prior to use on humans, while other systems may be used on humans following initial installation and testing by the manufacturer or service company. All systems are required to have a certification evaluation completed within 90 days of installation. We are proposing updates to section 2.5 to clarify the existing requirements and improve understanding. There is no change to the current frequency of certification evaluations (inspections) with these updates.

Changes to Section 2.5.2.2

- We are clarifying Section 2.5.2.2 to restate a statutory requirement that notification to the department is required within 3 days for machines that fail requirements. State statute has required this notification for many years.

Changes to Section 2.6.1.4

- We are adding examinations of the abdomen to section 2.6.1.4 as an imaging procedure that may be performed by department registered limited scope operators (LSOs). This is consistent with current practice in Colorado facilities that train and employ LSOs. Limited scope operators must continue to adhere to the requirements of 2.6.1.4(2).

Changes to Section 2.6.1.6

- We are revising Section 2.6.1.6, consistent with parallel changes to Appendix 2M. Language is added to clarify that registered provisional mammographers in training can operate machines while under the specified level of supervision. While an individual is undergoing training, the rule specifies that personal (in the room) supervision is required for the initial 20 exams and direct supervision is required after the initial exams, consistent with federal Mammography Quality Standards Act (MQSA) requirements.

Changes to Appendix 2D, Section 2D.2.2

- In parallel with the change in 2.6.1.4 discussed above, we are clarifying the supervision requirements for Limited Scope Operators (LSOs) who are in training, to be consistent with how students are taught and how they operate in x-ray facilities that employ LSO's. We are updating 2D.2.2 of Appendix 2D to reflect that direct (in the facility) supervision is required rather than personal (in the exam room) supervision. The direct supervision and personal supervision terms are defined in Section 2.2 and Part 1.

Changes to Appendix 2F, Section 2F.2.4

- We are deleting the reference to the passing score for the American Registry of Radiologic Technologists (ARRT) Bone Densitometry Equipment Operators (BDEO) exam in Section 2F.2.4 of the rule. The ARRT, not the department, determines the passing score for the BDEO exam. Also, the ARRT recently provided notification that they are transitioning to a "scaled score" for most testing results rather than a percentage based scoring. Removing the current "percent" based passing score value from Part 2 will eliminate any future conflict between the rule and ARRT passing scores.

Changes to Appendix 2O

- The 2019-20 amendment to Part 2 added a fluoroscopy operator registration process for properly trained and qualified Physician Assistants (PAs) and Advanced Practice Registered Nurses (APRNs) to become operators of fluoroscopy systems, consistent with their scope of practice and licensing. The 2019-20 changes did not, at the time, recognize some other allied healthcare personnel who have and continue to provide various levels of support involving fluoroscopy systems as part of a medical procedure in cardiac catheterization labs throughout Colorado.

  Appendix 2O is revised to incorporate into the existing fluoroscopy registration process, fully qualified and nationally certified cardiac catheterization lab ("cath lab") professionals who meet similar training and experience requirements as PAs and APRNs as outlined in current rule. Presently, these cath lab personnel are evaluated on an individual basis and may be granted registration as fluoroscopy operators when appropriate. The proposed rule changes would streamline this process by recognizing the cardiac cath lab personnel in regulation, and reflect the current state of practice at facilities in Colorado.

  Appendix 2O continues to require that operation of fluoroscopy machines be in accordance with the operator's level of training, their respective scope of practice and under the appropriate level of supervision.

Part 6

Part 6 is specific to x-ray machine use in the healing arts (medical use) for diagnostic purposes and contains requirements for periodic testing, quality control, and requirements for operation of x-ray machines at medical facilities to help ensure they are safe for patients, operators and members of the public.

Changes to the Part 6 rule are being proposed to incorporate and align with related changes associated with the Part 2 rule surrounding fluoroscopy operators, and to clarify that purposeful exposure to living human research subjects for research purposes is to be authorized by specified individuals and meet certain additional requirements of Part 2. Language is revised to incorporate more consistent language and to streamline and reduce redundancy in language regarding the frequency and conditions for routine certification evaluations (machine inspections) by deferring to Part 2 for those requirements. The provision in current rule requiring the use of rectangular collimators for most dental intraoral imaging procedures by 2025 is removed due, primarily, to the discontinued manufacturing/lack of availability on the market of universal add-on collimator devices.

Summary of Part 6 changes by section

Changes throughout Part 6

- Minor formatting updates and corrections are made to Part 6.

Changes to Section 6.1

- Rulemaking adoption and effective dates and links to regulatory web pages are updated for the current rulemaking.

Changes to Section 6.3.1.6

- We are adding provision (4) to section 6.3.1.6 to allow machine operation by specific department registered fluoroscopy operators meeting the applicable Appendix 2O requirements. More specifically, and as outlined in changes proposed for Part 2, the change permits trained and qualified, nationally certified cardiac catheterization lab personnel to register as fluoroscopy operators.

Changes to Section 6.3.1.7

- We are adding language to section 6.3.1.7 to clarify that Part 6 applies to research uses of x-ray machines when it involves purposeful exposure to living human research subjects.

Changes to Section 6.5.12.1

- We are rephrasing section 6.5.12.1 to clarify that operation of fluoroscopy systems shall be done under direct (i.e., in the building) supervision, except where it is otherwise specified in regulation. The scope of practice for fluoroscopy operators varies and may require a higher or lower level of supervision or autonomy during operation. By deferring to other parts of the regulations, including those that require following the applicable scope of practice, allows flexibility in the rule.

Changes to Section 6.5.14.1

- We are revising section 6.5.14.1 to remove redundant language for certification evaluations (inspections) of fluoroscopy machines, and instead will defer to Part 2 for these requirements.

Changes to Section 6.6.1.2

- For consistency in terminology used in the rule, in 6.6.1.2 and throughout other sections of the rule, we are modifying the language to use "inspection" instead of "testing".

Changes to Section 6.7.2.3(3)(b)

- We are proposing to rescind provision 6.7.2.3(3)(b) that requires rectangular collimators when performing most intraoral dental imaging procedures. This provision was added during the 2019-20 rulemaking with an effective date of January 1, 2025. To our knowledge, Colorado is currently the only state to require the use of rectangular collimators for routine dental intraoral imaging. Due to a lack of market availability for universal add-on type collimator devices along with implementation concerns that may be needed to meet FDA requirements when using such devices, implementation and compliance by January 1, 2025 is believed to be unfeasible at this time. Refer to additional information below for further details.

  Background and basis for rectangular collimators and past rulemaking
  The 2019-20 rulemaking for Part 6 incorporated a requirement for use of rectangular collimators in routine dental intra-oral imaging at the suggestion of stakeholders to help reduce patient dose. The U.S. Food and Drug Administration (FDA), has estimated that intraoral imaging is the most common x-ray image taken in dentistry with over 100 million imaging exams taken each year in the United States[a]. While dental intraoral imaging is common with most patients being imaged on an annual basis (as determined by the dental practitioner), patient effective dose from such imaging is low when using modern digital based systems (typically between 0.1 and 0.8 millirem[c]) and studies show it is reduced further when using rectangular collimators. Modern dental intraoral imaging systems commonly use a rectangular image receptor (digital or film), but the most common x-ray collimators – devices which shape the x-ray beam as it exits the tube head - continue to be round. A round x-ray beam combined with the rectangular image receptor results in a mismatch of the shapes resulting in dose to the patient that does not contribute to the image. As noted in the 2019-20 Part 6 rulemaking package[b] (that added the rectangular collimator requirement to current rule), the American Dental Association (ADA) report in 2006 suggested that patient dose can be reduced by up to fivefold for the most common radiographs. Other studies have generally confirmed dose reductions by 50% or more when using rectangular collimators. The effective doses from a typical intraoral exam represent approximately 0.1% of the annual average background dose of 620 mrem[d] to individuals in the U.S. and contribute 0.2% of the annual average dose from medical procedures[d].

  In June of 2022 and as a follow up to the 2019-20 Part 6 rulemaking and previous Board of Health request, the x-ray certification unit developed and sent a survey to dental facilities to evaluate the current implementation status and to help identify barriers to compliance and implementation for rectangular collimators at registered facilities. The survey was sent to approximately 2,707 dental registrants in Colorado and approximately 7.3% (198) registrants responded to the survey. Survey results are summarized in Table 1 below.

Table 1. Summary of rectangular collimator key survey results sent to dental facilities in June 2022. Note that some percentage numbers have been rounded.

Rectangular collimator survey question	Response of those participating in survey
1. Regarding which method the facility intends to use to implement the rectangular collimator requirement:	• 83% of respondents intend to use an add-on rectangular collimator device • 12% of respondents intend to use a combination of new machine replacement and add-on collimators • 5% of respondents intend to replace the entire machine
2. Regarding the key barriers or concerns to implementing the rectangular collimator requirement:	• 47% of respondents indicated that cost was the primary barrier • 12% of respondents noted no foreseen barriers • 11% of respondents were unaware of the requirement • 8% of respondents noted that training was a concern • 22% of respondents indicated that other items/issues were a barrier, including supply availability, other concerns, or did not believing in the science behind the use of rectangular collimators.
3. Regarding whether respondents were familiar with the new (2019-20 rulemaking) requirement for rectangular collimators:	• 46% were somewhat familiar with the requirement • 36% of facilities were not familiar with the requirement • 17% were very familiar with the requirement
4. Regarding the number (~fraction) of rectangular collimators a respondent has already installed on the facilities machines:	• 92% of respondents indicated that no collimators are installed on their machines • 6% of respondents indicated that all machines have collimators installed • 2% of respondents indicated that ½ of machines have collimators installed • 1% of respondents indicated that ¼ of machines have collimators installed
5. Regarding whether the facility considers itself to be in an underserved / under resourced community:	• 72% of respondents indicated that they did not consider their facility to be in an under resourced community • 20% of respondents indicated that they considered their facility to be in an under resourced rural community • 8% of respondents indicated that they considered their facility to be in an under resourced urban community

Discussion of collimator survey results
Overall, the survey results indicate that most (63%) of respondents were at least familiar with the requirement for rectangular collimators in the current rule with the provision having a 2025 effective date. Despite this, less than 10% of respondents indicated that they had installed rectangular collimators on one or more machines, and a high number - 92% - of respondents indicated they had not installed rectangular collimators on any machine. This later issue is of concern due to current 2025 effective date for this requirement along with device availability in sufficient quantities.

While most questions in the survey were multiple choice, question 2 above was "open ended" allowing for specific text input and feedback from stakeholders regarding the barriers to implementation. Respondents most frequently cited that there would be an increase in "cone cuts" (cutting off portions of the image due to a smaller radiation field and need for greater accuracy), resulting in having to repeat some images. Repeating images is something that should be avoided with any radiographic imaging in general as each image contributes to radiation dose. However, if rectangular collimator devices are used and are able to reduce exposure by half (or more) to begin with, repeating even 25% of the images will still result in a potential lower total dose to the patient by about a third (36%). Data shows that rectangular collimators appear to have a greater than 50% dose reduction, in which case the overall total patient dose reduction will be even larger, even accounting for some repeat images. At least one retrospective study has shown that some images with cone cuts may still contain adequate diagnostic information.

When the collimator provision was initially proposed in the prior rulemaking, the department felt that the most cost-effective approach to implementing rectangular collimators was for facilities to purchase one or more universal add-on type collimator devices that could be easily installed by the operator on existing x-ray machines. This approach was thought to allow flexibility, where collimators could be removed by the operator to perform any specialized wide view imaging, such as for endodontic procedures. At the time of the original rulemaking, such devices appeared to be readily available on the market with multiple websites advertising them at a cost of around $150 per unit. For an average dental registrant having three intraoral machines, the total cost would be on the order of $450 per facility. The option to purchase fewer universal add-on collimator devices that could be shared amongst machines was also a consideration and is not prohibited by the 2020 rule. To use rectangular collimator devices properly it was recognized in the prior rulemaking that facilities would need to spend some time training on the new collimators due to tighter alignment tolerances and need for greater accuracy.

Basis for current rulemaking change with regard to rectangular collimators
While the radiation program continues to support the science and principles behind the use of rectangular collimators for most common dental intraoral imaging procedures, and believes it would contribute to overall patient dose reduction in the long run, some additional challenges have arisen with regard to facilities being able to achieve compliance with the pending 2025 requirement.

CDPHE staff members performed a comprehensive search for all distributors and manufacturers of the universal add-on collimator devices and subsequently contacted each one to assess the availability of the devices. The distributors and manufacturers

have universally indicated that the add-on collimator devices envisioned by the current rule have been discontinued, are no longer being manufactured, and are not available for purchase on the open market. While some web sites continue to advertise the devices, the reality is that they are not available.

In an effort to expand the alternatives to help achieve compliance with the current collimator provision, dental x-ray positioning indicator device (PIDs) that incorporate a rectangular collimation component were considered and included in the department outreach to manufacturers and distributors. Unfortunately, all of these devices identified have also been discontinued and are no longer being manufactured. While there were limited quantities found to be available for purchase, there were less than 10 total confirmed to be available. Considering the roughly 8,000 machines in approximately 2,700 dental facilities that would require these devices for compliance, the availability is woefully inadequate to enable compliance by 2025.

A secondary consideration regarding the ability of facilities to comply with the rule relates to compliance with federal rules which apply to x-ray machine manufacturing and certification. Within the past year since initiating the current rulemaking effort, the radiation program reached out to our partners in the U.S. Food and Drug Administration (FDA). The FDA regulates the design aspects of radiation-emitting products including x-ray machines prior to distribution in the United States. Our discussions with FDA indicate that universal add-on rectangular collimator devices envisioned in the 2019-20 rulemaking would constitute a modification of the x-ray machine. This could additionally present additional cost burden on the regulated facilities in the form of service provider or qualified inspector fees associated with testing of the machines to confirm compliance with the federal standards.

The department continues to maintain the position that measures taken to reduce dose when reasonably achievable are desirable and consistent with the As Low As Reasonably Achievable (ALARA) concept in radiation protection. However, the current challenges to acquiring the equipment to achieve compliance cannot be ignored. The idea of rule of law should also be considered during the creation and maintenance of regulations and an important aspect of this concept is that a regulated community should be required to comply with regulations with which they can and will comply. Maintaining regulations that cannot and will not be complied with serves to erode the validity of the regulations and the communities respect for the regulatory program as a whole. As a public health agency, CDPHE intends to continue to strive for reductions in radiological dose to all Colorado residents and will encourage all strategies associated with dose reduction through continued education and guidance. As a regulatory body it would be detrimental to the overall program to retain requirements that would result in widespread noncompliance and as such we believe that it is necessary to remove the current rectangular collimator requirement at this time.

REFERENCES:

[a] Dental Radiography: Doses and Film Speed, U.S. Food and Drug Administration (https://www.fda.gov/radiation-emitting-products/nationwide-evaluation-x-ray-trends-next/dental-radiography-doses-and-film-speed, accessed 10/25/2023)

[b] 6 CCR 1007-1, Part 6, X-ray in the healing arts, 2019-20 Part 6 rulemaking package, Colorado Secretary of State, eDocket tracking # 2019-00555. Adopted 11/20/2019, effective 1/14/2020.

[c] Radiation doses in dental radiology, The International Atomic Energy Agency, (https://www.iaea.org/resources/rpop/health-professionals/dentistry/radiation-doses, accessed 11/02/2023)

[d] Doses in Our Daily Lives, U.S. Nuclear Regulatory Commission (https://www.nrc.gov/about-nrc/radiation/around-us/doses-daily-lives.html, accessed 11/02/2023)

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.
__XX__ No

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

__XX__ Yes _XX_ URL
_____ No

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

_____ Yes
__XX__ No

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

_XX_ 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.

___ Yes.

This rule includes a new state mandate or increases the level of service required to comply with an existing state mandate, and local government will not be reimbursed for the costs associated with the new mandate or increase in service. The state mandate is categorized as:

___ Necessitated by federal law, state law, or a court order
___ Caused by the State's participation in an optional federal program
___ Imposed by the sole discretion of a Department

Has an elected official or other representatives of local governments disagreed with this categorization of the mandate? ___Yes _X_No. If "yes," please explain why there is disagreement in the categorization.

Please elaborate as to why a rule that contains a state mandate on local government is necessary.

For consistency with the national framework for regulation of sources of radiation, all facilities regardless or ownership, must adhere to the same or equally protective public health and safety requirements and regulations for possession and use of radiation sources in Colorado. The proposed rule changes result in requirements that will equally

impact all types of persons who may possess, operate, or service radiation machines whether private, or governmentally owned or operated.

DRAFT REGULATORY ANALYSIS

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

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.

The persons affected by any given proposed change will depend, largely, on the type of x-ray machine in use or the type of facility, with the majority of changes impacting medical use facilities and/or certain operators.

Group of persons/entities affected by the Proposed Rule changes	**Size of the Group**	**Relationship to the Proposed Rule Select category: C/CLG/S/B**
Medical use facility registrants (excluding dental facilities)	Approximately 2,100	C
Registered Dental facilities	Approximately 2,700	C
Limited Scope Operators (LSOs) - registered	338	C
Limited Scope Operator (LSOs) - applicants	Approximately 25 applications received per month, some of which are cath lab personnel;	C
Provisional mammographers – currently registered[e]	55	C
Future Fluoroscopy operator - applicants	Approximately 2 applications per month or 24 per year	C
Other stakeholders who requested notification of proposed x-ray related radiation rule changes. This includes private organizations, professional societies and companies.	Approximately 700	S
Private companies that manufacture or sell/distribute rectangular collimator devices on the open market. This would include companies both inside and outside of Colorado.	Unknown	S

[e] The provisional mammographer registration with the department is a short term registration that is limited to 1 year, with the option to extend by a one additional year. Typically, after 1-2 years, the individual will become nationally certified and registered with ARRT to become a fully qualified mammographer (ARRT(R)(M)) and the provisional mammography status is no longer needed.

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, the following relationship categorization key is used:

C = individuals/entities that implement or apply the rule.
CLG = local governments that must implement the rule in order to remain in compliance with the law.

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, any financial benefits.

Financial/economic costs:

C and CLG:

1. The registration of certain qualified fluoroscopy operators took effect in 2021, following the 2019-20 rule amendments to Part 2 and Part 6. Certain fluoroscopy operator applicants (physician assistants and advanced practice registered nurses) are addressed specifically under the current rule, while others are evaluated on a case-by-case basis. The proposed rule changes in 2.4.5.5, and Appendix 2O will incorporate nationally certified and registered cardiac catheterization lab personnel as fluoroscopy operators under current requirements rather than evaluate them on a case by case basis, reflecting the current practice in the field. This will require these individuals to submit a registration application with the specified $60 application fee. As noted earlier, the department currently receives only 1-2 applications per month for fluoroscopy operator registration. With the proposed change, this number may increase.

2. Removing the current requirement for rectangular collimators could result in a financial/economic cost in terms of revenues lost by companies that manufacture and distribute the devices. Assuming that 4,000 rectangular collimators were purchased for roughly half of the 8,000 dental intraoral imaging machines in Colorado at a cost of $150 per unit, it would result in net sales of around $360k assuming a 40% markup. Net sales would be shared among numerous companies inside and outside of Colorado to varying extents. However, this may be moot since devices are not available on the open market.

There are no expected financial/economic costs for the remainder of the proposed changes to either Part 2 or Part 6, as changes consist of language clarifications and updates of current requirements and processes.

Financial/economic benefits:

Certain X-ray registrants are expected to have an economic/financial benefit where the elimination or easing of applicable requirements will require less resources. Eliminating the rectangular collimator provision in Part 6 is expected to result in a financial benefit (cost savings) for most dental facilities since they would no longer need to implement that requirement by January 1, 2025. Not purchasing collimators saves about $150 per machine and about $450 for the average facility with 3 machines. There are approximately 8,000 intraoral dental imaging machines in Colorado. If collimators were shared among machines and a total of only 4,000 collimators are purchased by facilities state-wide, the gross cost savings would be on the order of $600k ($150 per collimator x 4,000 machines).

There are no expected financial/economic benefits for the remainder of the proposed changes to either Part 2 or Part 6, as changes consist of language clarifications and updates of current requirements and are not a change to current processes.

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

S: As a result of eliminating the rectangular collimator requirement, some organizations representing the dental community may want to develop and issue revised communications for their membership. This would likely involve minimal resources to be expended by any given organization.

B: While the majority of proposed changes do not directly impact the end recipient of services of registered x-ray facilities (such as patients at medical facilities), the elimination of the requirement for rectangular collimators could monetarily benefit the end user patient in a very small way. Without the requirement for dental intraoral collimators, patients who receive dental intraoral imaging services would not realize a cost increase for the purchase of the collimators by the facility which are passed on to the patient. However, due to the low cost of the collimators (as outlined earlier) the cost on a per patient basis would expect to be miniscule.

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.

C/CLG: The overall anticipated favorable outcome for the proposed changes to the Part 2 and Part 6 rules, will be improved clarity and understanding of the regulations and requirements by the regulated community and radiation program staff. The incorporation of nationally registered and certified cardiac cath lab personnel as registered fluoroscopy operators is expected to be a benefit to facilities and applicants for registration since current rules do not recognize these individuals as fluoroscopy operators. Since many of these individuals are already working in cardiac cath labs, this will allow a clearer pathway to compliance.

B:

1. A possible favorable outcome with the elimination of the rectangular collimator requirement for entities that represent the dental community, will be that they would not necessarily need to spend additional time helping their clients find ways to achieve compliance.

S:
1. Elimination of the rectangular collimator requirement is a non-favorable outcome that will result in no additional dose savings for patients who receive imaging from intraoral dental systems.
2. The incorporation of RCIS individuals to the current fluoroscopy registration process is is a favorable outcome expected to benefit the end user patient who undergoes cardiac cath lab procedures. The proposed rule language helps ensure that individuals operating fluoroscopy machines have sufficient training and certifications necessary for safe operation during patient exams.
3. The remaining proposed changes are primarily technical and clarification changes and not expected to have any direct or indirect impact or outcomes for the end user.

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 may be some minor additional personal services expended as a result of an increase in fluoroscopy operator applications, beyond those currently received. As noted earlier, the radiation program typically receives about 2 fluoroscopy operator applications per month on average. Even with an increase in numbers of fluoroscopy registration applications received, it is expected they can be absorbed into current resources and funding levels.

Anticipated CDPHE Revenues:
With regard to the proposed provision to incorporate cath lab personnel into the current fluoroscopy operator registration process, there may be some negligible amount of additional revenue due to an increase in fluoroscopy operator registration applications. The number of applicants is not easily predictable, but assuming the number of applications received doubles from the current 2 per month to 4 per month would result in an additional $120 per month ($1,440 per year) of revenue.

All other proposed changes to Part 2 and Part 6 are not expected to impact CDPHE revenues.

B. **Anticipated personal services, operating costs or other expenditures by another state agency:** Not Applicable

Anticipated Revenues for another state agency: Not Applicable

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 for most of the proposed changes will result in Colorado regulations being less clear and understandable. Most of the proposed changes involve revising, rewording or rearranging existing requirements.

With regard to the proposed elimination of the rectangular collimator provision in 6.7.2.3(3)(b), the cost of inaction (e.g., retaining the requirement with the current effective date of January 1, 2025) will likely be that a vast majority of regulated entities will be in a state of non-compliance due to unavailability of devices to purchase on the open market.

With regard to the incorporation of cath lab specialists into the fluoroscopy registration process (2.4.5.5, Appendix 2O, and 6.3.1.6), inaction on these changes will result in cath lab specialists continuing to be out of compliance with the current regulations. RCIS individuals are not currently recognized or addressed by the current rule as operators of fluoroscopy systems.

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 specific revisions proposed in this rulemaking were developed by radiation program staff and with consideration of feedback from stakeholders and in consideration of the feasibility and likelihood of achieving full compliance. 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.

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

No alternative rules or alternative rulemaking was considered for the majority of the proposed rule changes which are primarily based on the need for additional clarity and understanding in the rule as expressed by stakeholders (and staff), and the need to incorporate certain qualified fluoroscopy operators who are not currently addressed by the regulations.

Following our stakeholder process, and with regard to the proposal to rescind the rectangular collimator requirement for dental intraoral imaging systems in Part 6, several alternative approaches were considered and evaluated.

- One alternative considered was to retain the current rectangular collimator requirement and due date of January 1, 2025 without revision.
    - As discussed earlier and following stakeholder feedback from the 2022 dental facility survey, collimator device availability on the open market is a significant concern. Recently, Division staff performed a search for all distributors and manufacturers of the universal add-on collimator devices or similar shielding devices and subsequently contacted each one to assess the availability of the devices. The distributors and manufacturers have universally indicated that the add-on collimator devices envisioned by the current rule have been discontinued, are no longer being manufactured, and are not available for purchase on the open market. While some web sites continue to advertise the devices, the reality is that they are not available.

- Another alternative considered was to revise the current requirement to extend the due date beyond the current January 1, 2025 date to allow for additional implementation time and market availability of universal add-on collimator devices or other devices that meet the intent and purpose of these collimators.
    - This alternative was rejected primarily due to a lack of market availability of add-on collimator devices. While some regulations may drive market availability, in this instance, that does not appear to be happening. Open market availability of certain equipment or devices required by regulation is

something not under the direction or control of the Division.

- At the suggestion of a stakeholder, the Division also considered modifying the existing rule language to require that all new intraoral dental imaging systems installed after at a future date (to be determined), would be required to have rectangular collimators inherent as part of the tube assembly design.
    - This alternative was rejected since it was felt that there would be insufficient time to research this alternative and gain additional stakeholder feedback under the current rulemaking schedule. The Division would need more time to assess the market availability of this type of system and the associated economic impacts of such a requirement. An additional confounding issue involves implementation concerns expressed by stakeholders where certain imaging studies need a wider field of view. Systems with fixed rectangular collimators would not allow the flexibility of the originally envisioned universal add-on type collimators. This could potentially limit the care provided by a given dental facility with only one machine.

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.**

   As outlined earlier, the data gathered during the 2022 dental facility survey indicated that a high percentage (over 90%) of dental facilities have not yet implemented the use of rectangular collimators at their facilities, since being added to rule in 2020. This is in spite of department and stakeholder organization efforts to communicate the pending requirement.

STAKEHOLDER ENGAGEMENT
for Amendments to
6 CCR 1007-1, Part 02, Registration of radiation machines, facilities and services
6 CCR 1007-1, Part 06, X-ray imaging in the healing arts

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 in the development of these proposed rules:

Organization	Representative Name and Title (if known)
Approximately 5,259 x-ray registrants in Colorado representing: • Facilities that use x-ray devices for medical purposes; • Facilities that use x-ray devices for non-medical purposes; • Registered service companies; • Registered Qualified Inspectors and Qualified Experts.	NA
Approximately 1,404 stakeholders with an interest in changes to rules and regulations pertaining to radiation control, including private individuals and companies, professional medical societies, associations and related organizations.	NA

In early September, stakeholders in the above identified categories or groups were notified by email of the opportunity to comment on the proposed draft rules that were posted on the department website. In addition to the initial notification, a follow-up email notice was sent reminding stakeholders of the opportunity to participate in two virtual stakeholder meetings that were held in early October 2023 and prior to the conclusion of the comment period. A total of 6 individuals attended the two stakeholder meetings. During the stakeholder process, the department received written comments from two stakeholders. The summary of those comments are discussed in further detail below.

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.

During the comment period, there were two opposing comments provided by stakeholders. Both comments are related to the proposed elimination of the dental collimator provision in 6.7.2.3(3)(b), which is set to become effective in approximately 14 months (January 1, 2025) as identified in current rule.

Comment supporting elimination of the rectangular collimator provision
One stakeholder was in support of removing the requirement for rectangular collimators for the reasons given (in the draft rule and associated documents), but also because they believe it could lead to greater exposure to radiation due to difficulty of assistants to align the tube-head to avoid cone-cuts even with existing positioners. The commenter noted that there are other devices to help mitigate this (cone-cuts), but stated that they are costly and cumbersome. With high turnover rates in dental offices the commenter noted it would lead to a significant burden to train and motivate employees to avoid retakes.

Comment opposed to elimination of the rectangular collimator provision
One stakeholder stated their opposition to removing the proposed requirement for rectangular collimators for routine intra-oral imaging. In their comments, the stakeholder noted that the benefits of rectangular collimation for routine intraoral imaging are well established, stating that in no other application of x-rays for imaging do the regulations allow the gross misalignment of x-ray field to image receptor size. The commenter felt that the public will not be protected by the voluntary adoption of these requirements and that regulatory action is necessary. The commenter noted that in addition to the organizations identified by the department (in the 2019-20 rule package) that support rectangular collimator use, the American Academy of Oral and Maxillofacial Radiology also concurs with their use. The commenter felt that the department is acting against the recommendations of these professional associations.

The commenter opposed to eliminating the rectangular collimators provided a rebuttal to several of the statements in the informational notes in the draft rule and associated documents on the following topical areas:

- Facilities identified concerns over possible imaging errors when using rectangular collimators.

  As the commenter pointed out, this topic was discussed and evaluated during the original 2019-20 rulemaking initially implementing the collimator requirement. The more recent 2022 survey of dental facilities indicates there is continued concern with this subject. Based upon the available literature, we agree that this concern may be somewhat exaggerated and that stakeholders have perhaps not fully evaluated it or reviewed technical documents, it remains a concern of stakeholders.

- The need for additional staff training and that 5 years (between the rule effective date and rectangular collimator requirement effective date) is sufficient.

  We do not disagree with this observation.

- Equipment availability based on internet searches

As discussed earlier, the Division contacted multiple manufacturers and distributors of rectangular collimators. Our evaluation indicated that while some websites continue to advertise availability of the items, direct contact with these vendors indicated no current availability.

The commenter also made the following specific recommendations:

- Require that all newly installed machines after a specified date be (inherently) capable of rectangular collimation.

  This option presents several challenges for the Division without further market and impact evaluations and additional stakeholder outreach and feedback considerations. Although the demand for x-ray systems with inherent rectangular collimation would likely be less, since purchases are spread out over time (as a dental facility would determine the need for new machine purchases), market availability must still be considered. The potential cost differences between rectangular vs round collimator machines systems must be evaluated further. Establishing such a machine based rectangular collimator requirement would potentially prohibit wider imaging fields and needs additional consideration.

- Maintain the 2025 deadline for rectangular collimation, but grant an automatic enforcement waiver until the next required QI evaluation, thus spreading out the purchasing wave.

  Market availability for universal add-on collimation devices has not been driven by the current regulatory requirement, so (implicitly) extending this date by issuance of waivers would also not be expected to drive manufacturing and distribution. Additionally, establishing plans for an "automatic waiver" is not deemed to be a good practice from a regulatory perspective and is unlikely to drive compliance. Additionally, it's unclear whether an evaluation performed by Qualified Inspectors (regardless of when it occurs) would meet the FDA requirements. It is our understanding that devices which alter the x-ray beam are required be certified components which typically must go through a manufacturer certification process with FDA. Despite requests from the division, both FDA and a manufacturer of a shielded x-ray Position Indicating Device (PID), have not provided information to clarify if this type of device must be a certified component. Without additional information, it is our interpretation that devices that alter the x-ray beam must be certified components.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking: None.

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.	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.**
	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.
	Other: Ensures consistency with federal rule and the national framework for regulation of radioactive materials.		Other:_____ _____

DRAFT 1 11/30/2023

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

State Board of Health

RADIATION CONTROL - REGISTRATION OF RADIATION MACHINES, FACILITIES AND SERVICES

6 CCR 1007-1 Part 02

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

Adopted by the Board of Health ~~June 16, 2021~~February 21, 2024, effective date ~~August 14, 2021~~April 14, 2024

PART 2: REGISTRATION OF RADIATION MACHINES, FACILITIES AND SERVICES

2.1 Purpose and Scope.

* * *

[* * * indicates unaffected sections of the rule]

2.1.5 Published Material Incorporated by Reference.

2.1.5.1 Throughout this Part 2, 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 2 (~~October, 2020~~**April, 2024**), and not later amendments or editions of the incorporated material.

2.1.5.2 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/cdphe/radregs~~ **https://cdphe.colorado.gov/hm/radregs** identifies where the incorporated federal 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~~ **https://www.govinfo.gov/app/collection/cfr/**.

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: Colorado's radiation regulations are to be consistent with the current model rules of the Conference of Radiation Control Program Director's (CRCPD), Inc. except where the Board of Health determines a deviation is necessary.

Editorial note 4: This draft is not a complete rule. Unaffected/unchanged 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.

(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~~ **https://www.sos.state.co.us/CCR/NumericalDeptList.do#1000**.

(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~~**https://www.arrt.org/**

2.2 Definitions.

2.2.1 Definitions of general applicability to these regulations are in Part 1, section 1.2.

2.2.2 As used in Part 2, each term below has the definition set forth.

"ARRT" means the American Registry of Radiologic Technologists, 1255 Northland Drive, St. Paul, MN 55120, Phone (651) 687-0048, web site: https://www.arrt.org/.

"ASRT" means the American Society of Radiologic Technologists.

* * *

"Direct supervision" means the supervisor is present in the facility and immediately available to furnish assistance and direction to the supervisee throughout the performance of a procedure.

(1) The direct supervisor is not required to be present in the room when the procedure is performed.

~~(2) Direct supervision during the performance of a mammography examination means that the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination.~~

* * *

"Personal supervision" is as defined in Part 1 of the regulations.

"Provisional ~~M~~mammographer" means an individual who **is in-training to become a Qualified mammographer and** meets the requirements of **Appendix 2M.**~~2M.2 and has current department approval to perform mammograms under direct supervision in order to meet the requirements to become a Qualified Mammographer.~~

* * *

"Qualified mammographer" means a mammographer who meets the applicable requirements of ~~Appendix 2M~~**2.4.5.4(1) and 2.4.5.4(2)**.

"Qualified trainer" (QT) means an individual whose training and experience adequately prepares the individual to carry out specified training assignments as illustrated in Appendix 2J.

Commented [JSJ3]: This mammography specific language is deleted due to being addressed and clarified in the proposed changes to Appendix 2M (2M.3).

Commented [JSJ4]: Definition is added for clarity since the definition is used in Part 2 in several instances.

Commented [JSJ5]: This definition is updated, consistent with proposed changes to Section 2.4.5.4 and Appendix 2M. The type/level of supervision - direct versus personal - will vary during the training process for provisional mammographers and is outlined in Appendix 2M, 2M.3..

"Radiology Practitioner Assistant" means an individual who is currently registered as RPA by the Certification Board for Radiology Practitioner Assistants and are designated RPA (CBRPA).

"Radiographic Examination" means performing a procedure, including selection of exposure settings, positioning the x-ray system and the patient, and initiating and terminating the exposure.

"Radiologic technologist" means an individual who is currently registered in radiologic technology with the ~~American Registry of Radiologic Technologists~~**ARRT**. See "R.T.(CT)**(ARRT)**", "R.T.**(R)**(M)**(ARRT)**", "R.T.(N)**(ARRT)**", "R.T.(R)**(ARRT)**", and "R.T.(T)**(ARRT)**".

"Registered Radiologist Assistant" means an individual who is certified by the ARRT as a Registered Radiologist Assistant designated as R.R.A. (ARRT).

"Registered medical physicist" (RMP) means an individual who meets the applicable requirements of Appendix 2I and has current Department approval to perform medical physics activities, including shielding design, performing radiation surveys, and providing consultation for radiation protection and quality assurance and clinical medical physics for radiation therapy, computed tomography, mammography and/or other healing arts facilities.

"R.T.(CT)**(ARRT)**" means an individual who is certified and registered by the ARRT ~~in~~ **with a specialty post-secondary certification in** computed tomography. **(Note: Since CT certification is a post-secondary registration and has several primary paths, the "(R)" is not included as it may vary between individuals depending on their primary certification.)**

"R.T.**(R)**(M)**(ARRT)**" means an individual who is certified and registered by the ARRT in **radiography with a specialty certification in** mammography.

"R.T.(N)**(ARRT)**" means an individual who is certified and registered by the ARRT in nuclear medicine technology.

"R.T.(R)**(ARRT)**" means an individual who is certified and registered by the ARRT in radiography.

"R.T.(T)**(ARRT)**" means an individual who is certified and registered by the ARRT in radiation therapy.

* * *

2.3.2 Radiation machines ~~while~~ in transit or **in** storage incident ~~thereto~~**to transit** are exempt from the requirements of Part 2.

* * *

REQUIREMENTS FOR DEPARTMENT APPROVAL AND/OR REGISTRATION

2.4 State of Colorado Authorization or Approval Recognized by the Department is Required for Each Category Designated in This Section.

2.4.1 Registration of a Facility.

2.4.1.1 Each person possessing or in the process of coming into the possession of a radiation machine facility shall:

(1) Be registered with the Department prior to using a radiation producing machine at the facility;

Commented [JSJ6]: This and associated definitions (found below) are updated for consistency with the designations used and recommended by the American Registry of Radiologic Technologists for registered individuals.

Commented [JSJ7]: This and associated and subsequent related definitions are updated for consistency with the designations used and recommended by the ARRT for registered individuals.

Certain registrations issued by ARRT are considered "primary" registrations and others are post-secondary registrations. Primary registrations are a path to obtain a post-secondary registration. Primary registrations include those in radiography, nuclear medicine technology, and radiation therapy. Mammography is post-secondary registration that first requires certification in radiography and is why the "(R)" designation is included. Computed Tomography (CT) registration is a post-secondary registration, and there are several primary paths to receive certification.

Commented [JSJ8]: Language is revised for clarity and consistency with the CRCPD model rule Part B.

(2) Before the facility registration expiration date, **at least every twelve (12) months,** submit a complete application for registration on the applicable Department R-4 series Form, and include all of the information required by the form and any accompanying instructions. The facility shall:

(a) Designate a radiation safety officer who meets the applicable requirements of Appendix 2A to be responsible for overall radiation protection for the facility; and

(b) Document that a written shielding design has been:

(i) Completed in accordance with Parts 6, 8, or 9 of these regulations, as applicable, prior to any radiation machine installation; and

(ii) Retained on file at the facility for the life of the facility.

(c) Pay the radiation machine facility registration fee for radiation control services indicated by Part 12, Category 26. The radiation machine facility registration fee is not required for registration updates required by 2.4.6.5 unless the update is submitted less than thirty (30) days prior to the registrant's expiration date.

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.

2.4.1.3 In addition to the other requirements of 2.4, any research using radiation machines on **living** humans shall be approved by an Institutional Review Board (IRB).

* * *

2.4.5 Registration of specific radiation machine operators.

Except as otherwise specified in these regulations, registration with the Department is not required for an individual who holds a current, valid national registry in radiography, nuclear medicine technology, radiation therapy, computed tomography or mammography as issued by the ARRT or NMTCB (with specialty certification in Computed Tomography) or other nationally recognized registry specifically accepted by the Department. Additional requirements may be applicable in accordance with Appendix 2E, Appendix 2G, Appendix 2M, or Appendix 2O. All other non-physician individuals operating x-ray imaging systems on living humans who are not nationally registered or certified by ARRT or NMTCB must meet the requirements specified in the regulations and shall register with the Department, when applicable.

* * *

~~2.4.5.4 Provisional Mammographer.~~

~~(1) Any individual performing mammography exams under supervision in order to meet the initial requirements of 2M.1.3 shall be registered as a Provisional Mammographer prior to performing such exams.~~

~~(2) The application to be registered in the State of Colorado as a Provisional Mammographer shall be submitted on the Form R-64 series application and shall~~

Commented [JSJ9]:
Clarifying language is added to help ensure registrants understand that facility registrations are required to be renewed annually. The annual facility registration process helps keep information up to date in the department registration database.

There is no change to the frequency of the registration which coincides with the annual fee payment as specified in Part 12.

Commented [JSJ10]:
The word "living" is added to clarify that the use of non-living humans (i.e., cadavers) would not require IRB approval.

Commented [JSJ11]:
This section is revised in its entirety as shown/discussed below.

~~contain all information required by the Department as indicated on the form(s) and all accompanying instructions.~~

~~(3) Provisional mammographer registration is issued for a period of one year.~~

~~(4) A Provisional Mammographer registration may be renewed once.~~

2.4.5.4 Mammographer

Any individual performing mammography shall:

(1) Be certified by the ARRT in Mammography (R.T.(R)(M)(ARRT)); and

(2) Meet the qualifications of and maintain the education and experience requirements for MQSA under 21 CFR Part 900.12(a)(2);

Or

(3) Register as a provisional mammographer, meet the requirements of Appendix 2M, and be considered to be in-training until the requirements of 2.4.5.4(1) and 2.4.5.4(2) are met.

2.4.5.5 Fluoroscopy operator

(1) On or after January 1, 2021, each individual operating a fluoroscopy imaging system on living humans shall be registered **with the department** as a fluoroscopy operator consistent with 2.4.5.5(2) **or 2.4.5.5(3)**, except for:

(a) A physician who has an active license from the applicable State of Colorado licensure board consistent with the requirements of Section 2.6.1.2; or

(b) A Registered Radiologist Assistant or Radiology Practitioner Assistant (RPA) who meets the requirements of Appendix 2G; or

(c) An individual with a current R.T.(R), **R.T.(CV), R.T.(CI), R.T.(VI),** or R.T.(T) registration.

(2) Individuals whose training and experience has been evaluated **by the department** in writing prior to ~~the effective date of the rule~~**January 1, 2021**, as having met the training and experience requirements of Appendix 2O:

(a) Need not complete the training or testing requirements of Appendix 2O.1; and

(b) Shall be required to obtain and maintain registration in accordance with 2.4.5.5(3)(b) through 2.4.5.5(3)(f) on or after January 1, 2021.

(3) Registration

(a) In order to apply for registration as a fluoroscopy operator, the applicant for fluoroscopy operator registration must complete the requirements of Appendix 2O in a structured and documented training program that meets the requirements of ARRT **or another program as authorized by the regulations or as approved in writing by the department**.

Commented [JSJ12]: Section 2.4.5.4 is revised in conjunction with Appendix 2M for clarity and understanding and to reflect the current requirements and processes for qualified mammographers and those in-training as provisional mammographers.

Under the revised language, individuals are considered to be qualified mammographers and can perform exams unsupervised if they meet the requirements of 2.4.5.4(1) and 2.4.5.4(2). This is consistent with current requirements.

If individuals performing mammography do not currently have mammography certification (they do not meet 2.4.5.4(1)), and desire to become qualified mammographers, they will need to meet 2.4.5.4(3) and register as a provisional mammographer while in training in accordance with the requirements of Appendix 2M.

Commented [JSJ13]: Language is added to clarify that in this provision the registration is with the department rather than an outside certifying body.

Commented [JSJ14]: Secondary certifications are added for clarity, and include Cardiovascular-Interventional Radiography (CV), Cardiac Interventional Radiography (CI) and Vascular Interventional Radiography (VI).

Commented [JSJ15]: The proposed change removes the more generic language “the effective date of the rule” and replaces it with the specific date that the provision was initially introduced into the rule (as listed in (2)(b)). The provision was added to allow grandfathering of individuals to continue their use of fluoroscopy. Prior to the January 1, 2021 rule, individuals were evaluated on a case by case basis.

Commented [JSJ16]: Language is added to conform to proposed changes in Appendix 2O, which will incorporate the registration process for certain qualified and nationally registered cardiac catheterization lab professionals who are currently being evaluated on a case by case basis.

(b) Each fluoroscopy operator shall complete an R-50 series application form with all of the information required, together with the fee required by Part 12, Category 24.

(i) The Form R-50 series application form shall be used to confirm the completion of the requirements of Appendix 2O.

(c) Except for those individuals meeting the requirements of 2.4.5.5(2), application for registration as a fluoroscopy operator shall be made within one year ~~upon~~**following** completion of the training requirements of Appendix 2O.

(d) If an applicant cannot achieve a passing score **on the applicable national registration exam** per Appendix 2O**, section 2O.1.3.1 or 2O.1.3.2** within three attempts, the applicant must restart the training required by Appendix 2O.

(e) ~~Issuance of a~~**A** fluoroscopy operator registration is valid for a two year period.

(f) Registrants must meet the requirements of 2O.2 in order to renew the fluoroscopy operator registration.

(i) The Form R-50 series application form shall be used to renew the fluoroscopy operator registration every two years.

(g) Reciprocal recognition of a registration or license specifically authorizing fluoroscopy use and granted by another state **or organization** shall be submitted to the Department for review and evaluation on an individual case-by-case basis.

(h) Department registered fluoroscopy operators shall operate machines within their respective scope of practice, training, and experience.

2.4.6 General Requirements Applicable to Issuance and Maintenance of Department Registrations.

2.4.6.1 The application to be registered in the State of Colorado shall be submitted on the appropriate Department form(s) and shall contain all information required by the Department as indicated on the form(s) and all accompanying instructions.

2.4.6.2 Upon a determination that an applicant meets the requirements of the regulations, the Department shall issue a Notice of Registration.

2.4.6.3 The Department may incorporate in the Notice of Registration at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant's activities as the Department deems appropriate or necessary.

2.4.6.4 Approval to conduct or perform activities in accordance with the registration requirements of these regulations shall be:

(1) For a period of two (2) years, except as otherwise specified by these regulations or the Department; and

Commented [JSJ17]: The language of this provision is revised to reflect the revised scope of Appendix 2O.

Commented [JSJ18]: Revised for clarity.

Commented [JSJ19]: The addition of "or organization" will allow review of unforeseen registrations or licensing on a case by case basis. One example may be a fluoroscopy operator license or registration from another country.

Commented [JSJ20]: Department registered fluoroscopy operators may have varying levels of independence and/or supervision when operating fluoroscopy machines. This provision is added to clarify that such operation is to be within the individuals scope of practice, level of training and experience.

(2) Limited to the category or categories of activities specifically designated in the Notice of Registration.

2.4.6.5 The registrant shall notify the Department in writing within thirty (30) calendar days of making any change of information contained in the application for registration and/or the Notice of Registration.

2.4.6.6 Except as provided by 2.4.6.7, each Notice of Registration shall expire at the end of the month in the year stated therein.

2.4.6.7 In any case in which a registrant, not less than thirty (30) calendar days prior to the expiration of the registrant's authorization, has filed an application in proper form for renewal or for a new registration authorizing the same activities, such existing authorization shall not expire until final action by the Department.

2.4.6.8 The Department will not review or otherwise process a new application or application for renewal for which no fee is received.

(1) All application fees are non-refundable.

2.4.6.9 The Department may deny, withdraw, limit or qualify its approval of any person to perform activities upon determining that such action is necessary in order to prevent undue hazard to health and safety, or for other reasonable cause.

* * *

CERTIFICATION EVALUATION

2.5 Certification Evaluations.

2.5.1 Frequency of Certification Evaluations.

2.5.1.1 Each radiation machine registrant shall have its radiation machine(s) and facility evaluated by a Department-approved qualified inspector annually, except as provided in 2.5.1.2 through 2.5.1.5.

(1) Each certification evaluation shall determine if the machine is safe for each intended use and is in compliance with the specifications of the equipment manufacturer and these regulations.

(2) Each certification evaluation subsequent to the initial certification evaluation shall be completed in or prior to the same calendar month as the previous certification evaluation.

(3) The calendar month of a certification evaluation of a machine in any month prior to the month in which it is due shall become the calendar month in which the subsequent certification is due.

(4) A certification evaluation conducted after the month in which it was due shall not change the month in which subsequent certification evaluations are due.

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

Commented [JSJ21]:
Additional machine types are added as examples for clarity and understanding of the rule. This does not change the current inspection frequency of these devices which already fall within a 2 year inspection cycle.

human security screening, **foodstuff, packaging or equipment inspections or measurements**.

2.5.1.3 Each bone densitometry, dental, podiatry or veterinary radiation machine shall be inspected at least every three (3) years, except that:

(1) Each radiographic x-ray machine used in non-intraoral dentistry or podiatry that is capable of continuously variable kilovoltage peak (kVp) or continuously variable milliamperage (mA) or continuously variable collimation shall be inspected annually.

(2) Each machine used in podiatry that is capable of operating at more than 30 mA shall be inspected annually.

(3) Each volumetric dental imaging system or computed tomographic system for human use shall be inspected annually.

(4) Each portable hand-held instrument used for any purpose on living humans shall be inspected annually.

TABLE 2-1: SUMMARY OF FREQUENCY OF RADIATION MACHINE ~~INSPECTION~~**CERTIFICATION EVALUATIONS**

Category	Frequency **of certification evaluation**
Excluding systems used in veterinary medicine, and unless otherwise specified in this Table 2-1, each: • General use x-ray system; • CT (Computed Tomography) system; • Fluoroscopy system; • Dental Cone Beam Computed Tomography (CBCT) system; • Volumetric dental imaging system; • Hand-held x-ray imaging systems for human use; • **Podiatry system used at more than 30 mA;** • **Non-intraoral dentistry or podiatry x-ray system capable of continuously variable kilovoltage peak (kVp) or continuously variable milliamperage (mA) or continuously variable collimation;** • **Therapy systems for human or veterinary use;** • Security scanner x-ray systems used on living humans; • All systems identified above entering the state under reciprocity **for more than 180 days**.	Every one (1) year

Commented [JSJ22]: This provision is not new – it is relocated from the bottom of the table.

Commented [JSJ23]: This provision is relocated from the lower part of Table 2-1 to group all systems with an annual (1 year) frequency together in the table.

Category	Frequency **of certification evaluation**
Each industrial (non-healing-arts) x-ray imaging machine or system regulated under Parts 5, 8 or 9 including: • Security scanners for non-living human use; • X-ray fluorescence (XRF) systems; • Industrial radiography/Non-destructive testing; • Forensics; • Tissue specimen imaging systems~~.~~**;** • **Scanning systems for food production or packaging inspection.** • **Therapy systems for non-healing arts use.**	Every two (2) years
Except as otherwise specified in this Table 2-1, each: • Bone densitometry (DXA) system; • Dental system; • Podiatry system used at less than or equal to 30 mA; • Veterinary system, including hand-held units.	Every three (3) years
~~Each radiographic x-ray machine used in:~~ ~~• Non-intraoral dentistry or podiatry x-ray systems capable of continuously variable kilovoltage peak (kVp) or continuously variable milliamperage (mA) or continuously variable collimation.~~ •	~~Every one (1) year~~
~~Pursuant to 2.5.1.3(2), each x-ray machine used in podiatry at more than 30 mA~~	~~Every one (1) year~~

2.5.1.4 ~~Except as otherwise specified in regulation, each radiation machine system shall be evaluated within ninety (90) calendar days of installation or service that could potentially affect radiation output or technique settings. Such service includes, but is not limited to, the repair or replacement of high voltage generators, tube heads, consoles or image receptor systems.~~**Except as otherwise specified in regulation, each radiation machine shall have a certification evaluation performed within ninety (90) calendar days of:**

(1) The initial installation of a new radiation machine, a radiation machine that is new to the facility, or a radiation machine that is relocated to a new area or room of an existing facility; or

(2) Any service after initial installation that could potentially affect radiation output (dose indices) or technique settings, including but not limited to the repair or replacement of high voltage generators, tube heads, consoles or image receptor systems.

Commented [JSJ24]: This provision is retained and relocated above with other machines on a 1 year certification evaluation (inspection) frequency.

Commented [JSJ25]: This requirement has been relocated to the top section of Table 2-1 for consistency with other machines/uses that require annual inspection.
There is no change to the inspection frequency.

Commented [JSJ26]:
This provision is amended with the intent to use consistent language and to clarify the requirements involving initial and recurring machine certification evaluations (inspections).

The proposed changes are intended to clarify existing requirements relating to initial and routine certification evaluations for all types of radiation producing machines.

Commented [JSJ27]:
The language of this provision is intended to address the initial installation of a brand new machine, a used machine that was acquired but is new to the facility, or an existing machine that has been relocated within an existing facility.

(3) Receipt of a new radiation machine that does not require a physical installation, including hand-held x-ray systems, or portable or fixed x-ray systems that are battery operated or that plug into an electrical outlet.

2.5.1.5 ~~Each new installation of a mammography system shall be evaluated by a registered medical physicist authorized in mammography prior to being used to perform any human examination.~~**The following radiation machines shall have a certification evaluation performed within ninety (90) calendar days of installation and prior to being used to perform any examination on living humans:**

(1) Each initial (new) installation of a mammography imaging system. The evaluation must be performed by a registered medical physicist authorized in mammography;

(2) Each initial (new) installation of a Computed Tomography (CT) system, excluding volumetric dental imaging systems, dental CBCT systems, and digital breast tomosynthesis systems. The evaluation must be performed by or under the personal supervision of a registered medical physicist authorized in CT.

2.5.1.6 ~~Excluding volumetric dental imaging systems, dental CBCT, and digital breast tomosynthesis systems, each new installation of a CT system shall be evaluated by a registered medical physicist authorized in CT prior to being used to perform any human examination.~~

2.5.1.~~7~~**6** Any radiation machine and/or facility not inspected in accordance with 2.5.1.1 through 2.5.1.~~6~~**5**, or otherwise determined to be out of compliance with these regulations, shall be subject to a Department enforcement inspection and subject to the fees specified in Part 12.

2.5.2 Procedures for Certification Evaluations by Qualified Inspectors.

2.5.2.1 Each qualified inspector who performs a certification evaluation of a radiation machine and facility evaluation shall use procedures that are sufficient to determine compliance with these regulations.

2.5.2.2 If a radiation machine fails to meet any requirement specified by these regulations, including manufacturer's required specifications, the qualified inspector shall ~~immediately so inform the registrant and RSO.~~**notify the owner (registrant) or operator immediately and shall notify the department within three days after the determination.**

2.5.2.3 If the radiation machine is determined to be unsafe (as provided in Part 6 and described in Appendix 6D), the qualified inspector shall affix to such radiation machine system, in a location clearly visible to the operator and patient, if applicable, an “Unsafe for Use” label authorized and issued by the Department, indicating, as applicable, that such machine is not authorized for human, animal or other use.

2.5.2.4 Reporting and Labeling Procedures.

(1) Each qualified inspector shall provide an accurate and complete Certification Evaluation Report to the registrant and to the Department on Form R 59-1, “X ray

Commented [JSJ28]: This is a new provision that is intended to clarify the certification evaluation requirements for x-ray machines that do not require a “traditional” installation, such as machines that are self-contained and operate via battery power or may become operable by simply plugging them into an electrical outlet.

Commented [JSJ29]: Similar to the changes proposed for 2.5.1.4, this provision is revised to clarify that for installations of a new system, that a certification evaluation must be completed prior to use on humans and within 90 days of installation. This is a revision of the language in the current 2.5.1.6.

Commented [JSJ30]: The requirements of this provision are incorporated in the revised provision 2.5.1.5 (above).

Commented [JSJ31]: Due to the elimination/incorporation of prior 2.5.1.6, this provision is renumbered.

Commented [JSJ32]: Clarifying language is revised and added to ensure that notification to the department is made in a timely manner, consistent with state statute (law) in 25-11-104(8)(a), CRS.

Machine Certification Evaluation Report," in accordance with the instructions contained in that form.

(a) A clear and legible report may be substituted for Form R 59-1, provided that it is in the same format and provides all of the information required by Form R 59-1.

(b) Violations of the regulations not related to the performance of the specific radiation machine(s) shall be reported to the registrant and Department using Form R 59-2, "X-ray Facility Compliance Evaluation Report," in accordance with the instructions contained in that form.

(c) Report(s) required by 2.5.2.4(1) shall indicate full or partial compliance and any specific violation of these regulations.

(d) Report(s) required by 2.5.2.4(1) shall include recommendations for corrective actions by the registrant (if applicable) to assist in achieving full compliance or improving radiation safety and the quality of the imaging process.

(e) The Department shall be notified within three (3) business days of radiation machine violations. Report(s) required by 2.5.2.4(1) that does not indicate violations shall be received by the Department no later than fifteen (15) calendar days after the inspection date, unless otherwise authorized by the Department.

(2) A certification label issued by the Department shall be affixed in a location clearly visible to the machine operator and patient, if applicable, when it is determined that the machine requirements of these regulations are fully met.

(a) For a machine that was found to be in full compliance, the certification label shall be affixed no later than fifteen (15) calendar days (unless otherwise authorized by the Department) after the inspection date.

(b) For a noncompliant machine, the certification label shall be affixed no later than fifteen (15) calendar days (unless otherwise authorized by the Department) after the date that full compliance was achieved.

(3) Each qualified inspector shall ensure that the following documentation is provided to the Department to confirm that each violation was corrected as required by 2.6.3.1 and/or 2.6.4.1 within thirty (30) calendar days of the date of inspection.

(a) For a noncompliant machine for which full compliance has been achieved, the completed documentation (on Form R 59-1 or equivalent) shall be received by the Department no later than fifteen (15) calendar days after the date that compliance was achieved.

(b) For a noncompliant facility, the completed documentation (on Form R 59-2 or equivalent) shall be received by the Department no later than fifteen (15) calendar days after the date that full compliance was achieved.

(4) Concealing, defacing or altering of Department-issued certification labels is prohibited.

(5) Repeated failure by a qualified inspector, to affix certification labels or to complete certification evaluation reports in a timely manner as provided in 2.5.2.4 shall be subject to review and audit as provided in 2.9 and also subject to the non routine inspection fee as provided in Part 12.

2.6 Facility Registrant Responsibilities.

2.6.1 The registrant shall allow only individuals who are adequately trained in radiation safety to operate the machine and perform a radiographic examination. Training shall include instruction on the specific x-ray system to be used and review of the applicable and critical requirements of the operator manual.

2.6.1.1 The facility registrant shall evaluate and document the qualifications of each individual permitted to operate any radiation machine at the facility.

(1) Each operator shall meet all radiation safety training and experience requirements of the respective State of Colorado professional licensure board, as applicable, and any applicable requirements of this Part 2.

(2) The registrant shall maintain a list of all operators of any radiation machine used by the facility registrant.

(a) For fluoroscopy equipment used in examination of a living human, a list of operators and individuals providing supervision of operators shall be maintained.

(b) The list of all operators and supervisors shall be updated at least annually as part of the radiation safety program required by Part 4, Section 4.5.

(3) Records of evaluations shall:

(a) Include current certifications and qualifications;

(b) Be updated annually by the facility; and

(c) Be produced for examination upon request during any inspection conducted under the requirements of these regulations.

2.6.1.2 A physician, chiropractor, dentist, podiatrist, or veterinarian who meets the applicable requirements of Part 6, Section 6.3.1.6(1) and these regulations, is considered to have demonstrated adequate training in radiation safety and the safe and effective use of the radiation machine (consistent with 2.6.1.5) and may operate radiation machines as part of a medical, chiropractic, dental, podiatric or veterinary practice, respectively.

2.6.1.3 For a radiologist assistant “adequately trained” shall mean that the individual is qualified as provided in Appendix 2G.

2.6.1.4 For any radiographic x-ray system used on a living human (consistent with 2.6.1.2, 2.6.1.3 and 2.6.1.5 through 2.6.1.14), “adequately trained” shall mean that the individual meets the requirements of Appendix 2D.

(1) Limited-scope x-ray machine operator approval is limited to imaging procedures for x-ray examination of the skull, chest, hip/pelvis and spine/sacrum, upper extremities and lower extremities**, and abdomen**.

Commented [JSJ33]:
Images of the abdomen are added as permitted examinations that an LSO can perform. This is an imaging procedure commonly performed at facilities by LSOs. The approach is similar to imaging of the lower spine and coccyx, but with a wider field of view.

(2) A limited-scope x-ray machine operator shall not perform radiologic procedures involving the administration or utilization of contrast media, bone densitometry, fluoroscopic, mammography, computed tomography, or radiation therapy procedures.

2.6.1.5 For fluoroscopy equipment used in examination of a living human, "adequately trained" shall mean that, in addition to meeting all applicable requirements in 2.4.5.5, 2.6.1.1 through 2.6.1.4, and Appendix 2O:

(1) Each individual who either supervises a fluoroscopy procedure or operates a fluoroscopy imaging system shall have adequate training in its safe operation. This training shall be documented and include the following:

(a) Basic properties of radiation;

(b) Biological effects of x-ray;

(c) Principles and safe operation of the specific fluoroscopic x-ray system(s) to be used;

(d) Dose management including dose reduction techniques, monitoring, and recording;

(e) Applicable requirements of these regulations.

After January 1, 2022, the training required by 2.6.1.5 shall also include:

(f) Radiation protection methods for patients and staff;

(g) Units of measurement and dose, including DAP (dose-area product) values and air kerma;

(h) Factors affecting fluoroscopic outputs;

(i) High level control options; and

(j) Fluoroscopic and fluorographic (radiation) outputs of each mode of operation on the system(s) to be used clinically.

2.6.1.6 For mammography equipment used in radiography of the human breast, "adequately trained" shall mean that the individual operator meets the requirements of ~~Appendix 2M~~**2.4.5.4(1) and 2.4.5.4(2)**.

(1) Registered provisional mammographers may operate machines and perform radiographic examinations under supervision while in-training as specified in Appendix 2M.

2.6.1.7 For any computed tomography (CT) system used on a living human (excluding Volumetric Dental Imaging Systems, CBCT systems, and systems used for digital breast tomosynthesis) "adequately trained" shall mean that the individual operator meets the requirements of Appendix 2E.

2.6.1.8 For any bone densitometry equipment used in examination of a living human, "adequately trained" shall mean that the individual operator meets the requirements of Appendix 2F.

Commented [JSJ34]:
This provision is revised to reference section 2.4.5.4 rather than Appendix 2M, consistent with changes to these other sections. Appendix 2M will be used specifically and exclusively for provisional mammographers.

Individuals meeting 2.4.5.4(1) and (2) are considered to be qualified mammographers as defined in section 2.2. Provision (1) is added to clarify that registered provisional mammographers may perform examinations while in-training and under the applicable level of supervision, but they are not considered "qualified mammographers" until the requirements of 2.4.5.4(1) and 2.4.5.4(2) have been met.

2.6.1.9 For radiographic equipment used in the practice of medicine, "adequately trained" shall mean that the individual operator meets all applicable requirements of the Colorado medical board.

2.6.1.10 For radiographic equipment used in chiropractic, "adequately trained" shall mean that the individual operator meets all applicable requirements of the Colorado Board of Chiropractic Examiners and Rule 19 of 3 CCR 707-1.~~.~~

Commented [JSJ35]: Error correction – removal of unneeded period.

2.6.1.11 For radiographic equipment used in dentistry, including Volumetric Dental Imaging Systems, "adequately trained" shall mean that the individual operator meets all applicable requirements of the Colorado Dental Board and Rule X of 3 CCR 709-1.

2.6.1.12 For radiographic equipment used in podiatry, "adequately trained" shall mean that the individual operator meets all applicable requirements of the Colorado Podiatry Board and ~~Rule 700 of 3 CCR 712-9~~**3 CCR 712-1**.

Commented [JSJ36]: Update the cross-reference due to recodification of Podiatry rules.

2.6.1.13 For radiographic equipment used in veterinary medicine, "adequately trained" shall mean that the individual operator meets all applicable requirements of the Colorado Board of Veterinary Medicine and 4 CCR 727-1.

2.6.1.14 An individual, enrolled in an ARRT-recognized program or graduated from such a program, may operate radiation machines so long as the individual works under the direct supervision of a radiologic technologist or other qualified trainer and has documentation of having completed education and experience equal to that specified in the program.

(1) A graduate from an ARRT-recognized program is granted ninety (90) calendar days from the date of graduation to schedule, take and pass the ARRT radiologic technology registry examination.

(2) During the 90-day period allowed by 2.6.1.14(1), the graduate is considered to satisfy Appendix 2D requirements.

(3) A student or graduate who fails to pass the registry examination has not met the requirements of Appendix 2D and shall not operate any radiation machine system on a living human unless otherwise authorized by the Department.

* * *

RECIPROCITY

2.8 Out-of-State Radiation Machines.

2.8.1 Subject to these regulations, any person who desires to bring radiation machines into this state for temporary use is hereby granted authorization to conduct activities using these machines for a period not to exceed a total of 180 days in any calendar year, provided that:

2.8.1.1 The out-of-state registration, and/or other documents authorizing the use of radiation machines issued by the agency having jurisdiction where the out-of-state registrant maintains an office for directing the registered activity and at which radiation safety records are normally maintained, does not limit the activity authorized by such document to specified installations or locations; and

2.8.1.2 The person proposing to bring such machines into Colorado shall give written notice to the Department at least fifteen (15) calendar days before such machine is to be used in

the state, unless otherwise authorized by the Department as provided in 2.8.2. The notice shall be made using the Department's "X-ray Reciprocity Request" Form R-200 and shall include all information required by that form.

(1) As part of this notice, the person requesting reciprocity shall certify that:

(a) A copy of all applicable parts of these regulations shall be available at each use location in State of Colorado;

(b) Each machine has been evaluated and determined to be in compliance with these, or equivalent, regulations; and

(c) The operation of each radiation machine shall be in accordance with the applicable requirements of these regulations.

(2) In the case of a request to perform a healing arts screening program within the State, submit a completed Form R-300, "Application for Registration – Healing Arts Screening," with the reciprocity request, including all of the information required, pursuant to Part 6, Appendix 6F, by the form and any accompanying instructions.

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

(4) The person requesting reciprocity shall also supply such other information as the Department may request.

2.8.1.3 The out-of-state registrant complies with all applicable regulations of the Department; and

2.8.1.4 The out-of-state registrant shall at all times during work at any work location within the State have available the pertinent documentation as required by these regulations, including:

(1) Pertinent registration documentation;

(2) Written authorization from the Department for in-state activities;

(3) Applicable sections of these regulations as certified pursuant to 2.8.1.2(1)(a);

(4) Documentation that each radiation machine has been evaluated in accordance with these regulations, or other state regulations which are equivalent; and that

(a) The machines comply with the manufacturer's required specifications;

(b) The evaluations are current, having been performed within one year prior to entry into the State as required in 2.5; and

(5) In the case of mammography-related functions, a copy of the mammography certificate issued by the FDA, applicable American College of Radiology credentials, quality control records, personnel records, and the most recent medical physicist survey.

2.8.2 Based upon an application that includes documentation of why it is not possible or is an undue hardship to provide fifteen (15) calendar days notice, the Department may:

2.8.2.1 Grant permission to proceed sooner; or

2.8.2.2 Waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities pursuant to 2.8.1.

2.8.3 While in the State of Colorado, all radiation machines are subject to inspection and may ~~be required to be inspected and/or certified~~**require a certification evaluation** by a qualified inspector who is registered with the Department.

2.8.4 The out-of-state registrant shall notify the Department within one hour after arrival at the actual work location within the State and shall notify the Department within one hour after any change of work location within the State.

2.8.5 If multiple individuals work concurrently at more than one work location under an approval granted pursuant to 2.8.1, each day worked per location shall be counted separately toward the limit of 180 cumulative total days per calendar year.

2.8.6 The Department may revoke, limit, or qualify its approval for the use of radiation machines in the State upon determining that the approval was based on false or misleading information submitted to the Department or that such action is necessary in order to prevent undue hazard to public health and safety or property.

2.8.7 Each person operating a radiation machine within the State under reciprocity in areas of exclusive federal jurisdiction shall comply with the applicable federal requirements.

* * *

PART 2, APPENDIX 2D: X-RAY SYSTEM OPERATOR ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE, INCLUDING LIMITED SCOPE X RAY MACHINE OPERATOR (LSO)

Each operator of a radiation machine used for healing arts purposes on living humans other than in dentistry, chiropractic or podiatry, shall meet the following education and experience requirements:

2D.1 Is certified or registered by:

2D.1.1 The American Registry of Radiologic Technologists as a Radiologic Technologist; or

2D.1.2 A specialty board determined by the department to have substantially equivalent requirements for certification as the American Registry of Radiologic Technologists,

Or

2D.2 Is certified by the Department as a State of Colorado-registered limited scope operator, to conduct only those radiographic examinations specified in Section 2.6.1.4 and having satisfactorily completed:

2D.2.1 At least 80 hours of didactic training providing the minimum hours of instruction in the specific subjects listed in 2D.2.1.1 through 2D.2.1.6:

2D.2.1.1 Basic X-Ray Physics—20 hours

(1) Structure of matter and the atom

(2) General description of production of x-rays

(3) X-ray emission, quantity and quality

(4) Function of filtration and effects it has on x-ray beam collimation

(5) Types of function of beam limiting devices

(6) Design, features and functions of x-ray tubes

(7) Circuitry of the x-ray machine

2D.2.1.2 Radiobiology—3 hours

(1) Effects of ionizing radiation on the human body

(2) Molecular and cellular radiobiology

(3) Factors that cause somatic and genetic damage

2D.2.1.3 Radiation Protection—6 hours

(1) ALARA

(2) Shielding materials

(3) Radiation quantity and units of measurement

604		(4)	Basic interactions of x-rays with matter
605		(5)	Primary and secondary scatter
606		(6)	Importance of time, distance, shielding
607		(7)	Maximum permissible doses: occupational and public
608		(8)	Patient protection
609	2D.2.1.4.		Principles of Exposure—15 hours
610		(1)	Factors that control and influence radiographic quality
611		(2)	Properties of x-rays
612		(3)	Size distortion
613		(4)	Shape distortion
614		(5)	kVp, mAs, time
615		(6)	AEC and manual
616		(7)	Grids
617		(8)	Collimation
618		(9)	Intensifying screens
619		(10)	X-ray films and holders
620		(11)	Artifacts
621		(12)	Inverse square law
622	2D.2.1.5		Procedures and Processing—4 hours
623		(1)	Film storage and handling
624		(2)	Manual, automatic processing film processing and troubleshooting
625		(3)	Computed Radiography (CR)
626		(4)	Digital Radiography (DR)
627		(5)	PACs
628		(6)	Quality assurance / quality control
629	2D.2.1.6		Anatomy and Positioning—32 hours
630		(1)	Chest—4 hours
631		(2)	Extremity—12 hours

(3) Spine—8 hours

(4) Skull—8 hours;

and

2D.2.2 At least 480 hours of clinical training during which time the individual may perform x-ray examinations ~~only~~ under ~~personal~~**direct** supervision of a qualified trainer, including:

2D.2.2.1 At least 320 hours experiential training at a clinic; and

2D.2.2.2 No more than 160 hours of laboratory training (exclusive of the didactic hours required by 2D.2.1.1 through 2D.2.1.6);

and

2D.2.3 Performance of the following imaging procedures (at least ~~80~~**84** examinations in total, with record of each examination kept on file):

2D.2.3.1 Ribs—4 examinations;

2D.2.3.2 Hand—4 examinations;

2D.2.3.3 Wrist—4 examinations;

2D.2.3.4 Forearm—4 examinations;

2D.2.3.5 Elbow—4 examinations;

2D.2.3.6 Humerus—4 examinations;

2D.2.3.7 Shoulder—4 examinations;

2D.2.3.8 Clavicle—4 examinations;

2D.2.3.9 Femur—4 examinations;

2D.2.3.10 Tibia – Fibula—4 examinations;

2D.2.3.11 Ankle—4 examinations;

2D.2.3.12 Foot—4 examinations;

2D.2.3.13 Sinuses—4 examinations;

2D.2.3.14 Skull—4 examinations;

2D.2.3.15 Facial Bones—4 examinations;

2D.2.3.16 C-Spine—4 examinations;

2D.2.3.17 Thoracic Spine—4 examinations;

2D.2.3.18 Lumbar Spine—4 examinations;

Commented [JSJ37]:
The proposed change clarifies that supervision must be direct rather than personal during the clinical training period, consistent with the language of 2.6.1.14.

"Direct supervision" means that the supervisor must be available in the facility to assist the individual being supervised, while "personal supervision" means the supervisor is in the same room as the supervised individual. Both "direct" and "personal" supervision are defined in Part 1 of the radiation regulations.

Commented [JSJ38]:
The total number of exams is updated to reflect the added abdominal exams. Training on abdomen exams is typically included in the curriculum of LSO training programs.

2D.2.3.19 Chest—4 examinations;

2D.2.3.20 Hip / Pelvis—4 examinations;

2D.2.3.21 Abdomen—4 examinations.

and

2D.2.4 A passing score on the American Registry of Radiologic Technologists (ARRT) examination for the Limited Scope of Practice in Radiography. A passing score is:

2D.2.4.1 A score of at least 75% correct on the Core Module, and

2D.2.4.2 An average score of at least 75% correct on the Radiographic Procedures Modules for Chest, Extremities, Skull/Sinuses, and Spine.

2D.2.5 And, has maintained a minimum of twenty-four (24) hours of continuing education every two years in the areas of radiology, radiation safety, radiography and similar fields. This education shall:

2D.2.5.1 Conform to guidelines equivalent to the most current revision of the ARRT *Continuing Education Requirements for Renewal of Registration*;

* * *

Commented [JSJ39]:
Consistent with the changes in 2.6.1.4(1), abdomen exams are incorporated here.

PART 2, APPENDIX 2F: BONE DENSITOMETRY (BD) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

Each operator of a dual-energy x-ray absorptiometry system used on a living human shall meet the following education and experience requirements:

2F.1 Is certified or registered:

2F.1.1 As R.T.(R), R.T.(M), R.T.(N), R.T.(T), or CNMT; or

2F.1.2 By The International Society for Clinical Densitometry (ISCD), combined with or including the didactic radiation safety training in 2F.2.1.1, 2F.2.1.2 and 2F.2.1.3; or

2F.1.3 By A specialty board determined by the department to have substantially equivalent requirements for certification;

Or

2F.2 Is accepted by the Department as having satisfactorily completed:

2F.2.1 At least 30 hours of didactic training recognized by the Department that provided the minimum hours of instruction (as part of, or in addition to, specialty certificate and equipment operation training) in the specific subjects listed in 2F.2.1.1 through 2F.2.1.9:

* * *

and

2F.2.2 At least 480 hours of clinical training during which time DXA examinations are performed only under direct supervision of a Colorado qualified bone densitometry equipment operator or other qualified trainer:

2F.2.3 Performance of the following imaging procedures (at least 30 examinations in total, with record of each examination kept on file):

2F.2.3.1 DXA scanning of the forearm—10 examinations;

2F.2.3.2 DXA scanning of the lumbar spine—10 examinations;

2F.2.3.3 DXA scanning of the proximal femur—10 examinations;

and

2F.2.4 A passing score on the American Registry of Radiologic Technologists (ARRT) Bone Densitometry Equipment Operator Examination. ~~A passing score is a score of at least 75% correct.~~

and

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

Commented [JSJ40]:
For Bone Densitometry Operators, the acceptable score is not determined by the department, but rather, is determined by the testing organization (ARRT). The ARRT provides the applicant with the score and notes whether it is passing or not passing. Due to changes in the ARRT test scoring process from a “percentage” value to a “scaled” value score, the reference to 75% is removed from the rule.

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

Any person who acts as a Radiologist Assistant or Radiologist Practitioner Assistant shall be an individual who is 18 years of age and has provided written documentation as evidence of:

2G.1 Current certification as both R.T.(R) and a

2G.1.1 Registered Radiologist Assistant (R.R.A.**(ARRT)**); or

2G.1.2 Radiology Practitioner Assistant (RPA) prior to January 1, 2008;

And

2G.2 Having:

2G.2.1 Met the specific qualifications in education recognized by the ARRT, ASRT, ACR, or equivalent nationally recognized entity; and

2G.2.2 Been trained and worked under the direction of a radiologist.

* * *

~~**PART 2, APPENDIX 2M: QUALIFIED MAMMOGRAPHER ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE**~~

~~Any individual who performs mammography shall meet the following educational and experience requirements:~~

~~2M.1 Is certified by the American Registry of Radiologic Technologists in Mammography and meets the following initial requirements;~~

~~2M.1.1 Forty (40) hours or more documented training including breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants; and~~

~~2M.1.2 Eight (8) hours or more documented training in each mammography modality to be used by the technologist in performing mammography examinations; and~~

~~2M.1.3 Performance of at least 25 mammograms under the direct supervision of a qualified mammographer.~~

~~2M.2 Or, is a provisional mammographer working under the direct supervision of a qualified mammographer, who:~~

~~2M.2.1 Is enrolled in or has completed a structured and documented training program that meets the requirements of 2M.1.1 and 2M.1.2; and~~

~~2M.2.2 Has been approved as a Provisional Mammographer prior to performing mammograms to meet the requirements of 2M.1.3.~~

~~2M.3 Continuing education and continuing experience:~~

~~2M.3.1 Continuing education:~~

~~2M.3.1.1 A mammographer shall complete fifteen (15) hours of continuing education within the immediate prior 36 months.~~

~~(1) A mammographer who fails to meet the continuing education requirement of 2M.3.1.1 shall obtain a sufficient number of continuing education units in mammography to bring their total up to at least fifteen (15) in the previous 36 months.~~

~~(2) A mammographer who fails to meet the continuing education requirement of 2M.3.1.1shall work only under direct supervision of a qualified mammographer until the requirement is met.~~

~~2M.3.2 Continuing Experience~~

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

Commented [JSJ41]:
The title and body of Appendix 2M is revised in its entirety for consistency with other proposed changes in Part 2 relating to mammography.

Refer to the proposed changes and side margin comments below for additional information.

~~(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.~~

PART 2, APPENDIX 2M: REQUIREMENTS FOR REGISTRATION AS A PROVISIONAL MAMMOGRAPHER

Any individual who performs mammography and does not meet the requirements of 2.4.5.4(1):

2M.1 Shall have completed or be currently enrolled in a structured and documented training program that requires:

2M.1.1 Forty (40) hours or more of documented training that includes breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants; and

2M.1.2 Eight (8) hours or more documented training in each mammography modality to be used by the technologist in performing mammography examinations;

And

2M.2 Shall, prior to performing mammograms on living humans, register with the department as a Provisional Mammographer.

2M.2.1 Each applicant for a provisional mammographer registration shall submit the Form R-64 series application and shall include all information required by the department as indicated on the form(s) and all accompanying instructions.

2M.2.2 The provisional mammographer registration is issued for a period of one year and may be renewed one time.

And

2M.3 While in training, shall perform at least 100 mammography examinations on patients under the supervision of a qualified mammographer as follows:

2M.3.1 The initial 25 mammography examinations shall be performed under the personal supervision of a qualified mammographer.

2M.3.2 All remaining mammography examinations after the initial 25 shall be performed under the direct supervision of a qualified mammographer.

2M.3.2 All mammography examinations required by 2M.3.1 and 2M.3.2 shall be documented.

Documentation shall include the name of the supervised individual (individual in-training), the type of exam/modality, the facility name, the examination date, and the name of the supervising qualified mammographer or individual.

* * *

Commented [JSJ42]: Appendix 2M, including the title, is revised and restructured in its entirety for consistency with other proposed changes in Part 2. There is no intent to change the current process for mammography qualifications or for those in-training to become fully qualified mamographer. The proposed changes are to provide clarity and understanding in the rule.

As proposed, Appendix 2M will apply only to those individuals who are in-training to become fully qualified mammographers in Colorado and who cannot currently meet the requirements of 2.4.5.4(1). The provisional mammographer registration is designed to ensure that those in-training have a clear path to becoming fully qualified as mammographers.

The type/level of supervision required for those in training to become a mammographer will vary through the training process. This is clarified in the proposed changes to reflect the current process and expectations where closer supervision is needed during the initial practice examinations being performed versus those completed later in the training process.

Commented [JSJ43]: The requirements of 2M1 are equivalent to those of 2M1 of the current rule.

Commented [JSJ44]: This revised provision restates and clarifies that an individual must register as a Provisional mammographer prior to performing exams on humans, consistent with current practice. The requirements of this section have been relocated from 2.4.5.4(1) of the current rule.

Commented [JSJ45]: The type/level of supervision required for those in training to become a fully qualified mammographer will vary through the training process. This is clarified in the proposed changes to reflect the current process and expectations where closer supervision is needed during the initial practice examinations being performed versus those completed later in the training process.

Commented [JSJ46]: This is a new provision added to ensure that those in-training maintain the necessary documentation to become fully qualified mammographers.

PART 2, APPENDIX 2O: FLUOROSCOPY IMAGING SYSTEM OPERATOR ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

Except for those individuals exempted in 2.4.5.5(1), any person who operates a fluoroscopic machine or a machine capable of fluoroscopic imaging while in fluoroscopic mode for clinical purposes, shall be limited to a licensed Physician Assistant, ~~or~~ **licensed** Advanced Practice Registered Nurse**, or a nationally certified and registered Cardiovascular Lab Specialist** ~~and~~ who is at least 18 years of age working within their scope of practice, and:

2O.1 Meets the following requirements:

2O.1.1 Has completed a course that includes at least forty (40) hours of education on topics that include, but are not limited to, radiation physics, radiation biology, radiation safety and radiation management applicable to fluoroscopy;

And

2O.1.2 Has completed forty (40) hours of clinical experience in the use of fluoroscopy for guidance in diagnostic and therapeutic procedures under the personal supervision of a Colorado licensed physician;

And

~~2O.1.3 Has received a score of 75% or greater on the ARRT fluoroscopy examination;~~
2O.1.3 Meets the requirements of 2O.1.3.1 or 2O.1.3.2 or 2O.1.3.3, as follows:

2O.1.3.1 Is a Physician Assistant or Advanced Practice Registered Nurse who has received a passing score on the American Registry of Radiologic Technologists (ARRT) fluoroscopy operators examination.

Or

2O.1.3.2 Is registered through Cardiovascular Credentialing International (CCI) as a Registered Cardiovascular Invasive Specialist (RCIS) or a Registered Electrophysiology Specialist (RCES);

Or

2O.1.3.3 Is registered with another organization that has been specifically approved in writing by the department.

And

2O.1.4 Is registered **with the department** in accordance with Section 2.4.5.5.

And

2O.2 ~~Maintains their registration by submission of the following with their registration renewal application:~~**Maintains their department fluoroscopy operator registration by submitting the registration renewal application and required fee along with the following:**

2O.2.1 **Physician Assistants and Advanced Practice Registered Nurses shall submit** ~~A~~**a** current **active** state of Colorado license issued by the Colorado Department of Regulatory Agencies.~~; and~~

Commented [JSJ47]:
This provision relating to a passing score is removed from the rule here as the passing score is determined by the testing organization (ARRT). Additionally, ARRT is moving to a scaled score approach for testing rather than a percentage based score, making the % passing score obsolete in the future.

Commented [JSJ48]:
This adds healthcare professionals who currently work in the field of cardiovascular imaging and treatment alongside and under the supervision of physicians. The addition of these allied health professionals will help align the rule with the actual practices being conducted in Colorado cardiac lab facilities.

Commented [JSJ49]:
This provision is intended to allow flexibility in the rule to allow addressing unique qualifications of a given individual on a case-by-case basis.

Commented [JSJ50]:
With the addition of cardiac catheterization lab professionals to the fluoroscopy registration process, this provision is revised to add clarity for the documents that are required to be submitted during the renewal process. This is not a change from the current requirements.

2O.2.2 **Nationally certified/registered Cardiovascular Lab Specialists shall submit a copy of their active** ~~N~~national certification/ ~~-~~**registration.**~~in their respective profession.~~

[END OF RULE]

DRAFT 1 11/30/2023

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

State Board of Health

RADIATION CONTROL - X-RAY IMAGING IN THE HEALING ARTS

6 CCR 1007-1 Part 06

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

Adopted by the Board of Health ~~August 19, 2020~~February 21, 2024, effective date ~~October 15, 2020~~April 14, 2024.

PART 6: X-RAY IMAGING IN THE HEALING ARTS

6.1 Purpose and Scope.

6.1.1 Authority.

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

6.1.2 Basis and Purpose.

6.1.2.1 A statement of basis and purpose accompanies this part and changes to this part. A copy may be obtained from the Department.

6.1.3 Scope.

6.1.3.1 Part 6 establishes requirements, for which a registrant is responsible, for use of diagnostic and interventional x-ray equipment and imaging systems in the healing arts.

6.1.4 Applicability

6.1.4.1 The provisions of this part are in addition to, and not in substitution for, other applicable provisions in Part 1, 2, 4, 7, 10, 24 and other parts of these regulations.

6.1.4.2 Part 24 also applies to certain healing arts x-ray imaging registrants.

6.1.4.3 The requirements and provisions of this part apply to each registrant or applicant for registration subject to this part unless specifically exempted.

6.1.5 Published Material Incorporated by Reference.

6.1.5.1 Throughout this Part 6, 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

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: Colorado's radiation regulations must be consistent with the current model rules of the Conference of Radiation Control Program Directors (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.

Commented [JSJ3]:
This section updated to reflect expected effective dates of the rule, and revised or more specific web page addresses.

of the most recent effective date of this Part 6 (~~October, 2020~~**April 2024**), and not later amendments or editions of the incorporated material.

6.1.5.2 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/cdphe/radregs~~**https://cdphe.colorado.gov/hm/radregs** identifies where the incorporated federal 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.

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~~ **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/RegisterHome.do~~ **https://www.sos.state.co.us/CCR/NumericalDeptList.do#1000**.

(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

* * *

[* * * indicates unaffected sections of the rule]

GENERAL REGULATORY PROVISIONS

6.3 General and administrative requirements.

6.3.1 Administrative Controls.

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

6.3.1.2 Each radiation machine used on humans shall meet the Federal Performance Standards, Subchapter J - Radiological Health, 21 CFR 1020.30 through 1020.33.

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

(2) Diagnostic x-ray components and systems certified in accordance with 21 CFR Part 1020 shall not be modified such that the component or system fails to comply with any applicable requirement of 21 CFR Part 1020 or Part 6.

(3) The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may have the system modified provided the modification does not result in the failure of the system or component to comply with the applicable requirements of Part 6 and any modification is completed by a registered service company in accordance with 6.3.3.1(5).

(a) The owner who causes such modification need not submit the reports required by Part 6, provided the owner records the date and the details of the modification in the system and maintains this information, and provided the modification of the x-ray system does not result in a failure to comply with Part 6.

(b) Registered service companies shall submit to the Department, records of modifications of the x-ray system, as required by these regulations.

(4) Limited exemption from this requirement may be granted by the Department for a radiation machine manufactured prior to August 4, 1974, provided the registrant demonstrates that such exemption will not result in undue risk.

6.3.1.3 The registrant or the registrant's agent shall use approved providers of services, consistent with Part 2, Section 2.6., including but not limited to operation of equipment, inspection of radiation machines and facilities, and assembly, installation, service and/or calibration of radiation machines.

6.3.1.4 An x-ray imaging system that is found to be non-compliant with the requirements of these regulations 30 days beyond initial discovery, may continue to be used for up to 90 days provided:

(1) The system has not been determined to be unsafe for routine use in accordance with Appendix 6D;

(2) Continued use poses no significant radiation risk to patients, members of the public or employees;

(3) Does not significantly result in degraded image quality; and

(4) The registrant obtains in writing, an authorization for continued use from the Department.

6.3.1.5 An x-ray imaging system that is determined as provided in Appendix 6D to be unsafe for human, animal, or other use shall not be operated for diagnostic or therapeutic purposes.

6.3.1.6 A radiation machine in the healing arts shall be operated:

(1) By a physician, chiropractor, dentist, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts and has met the applicable requirements of Part 2 of the regulations; or

(2) By an individual authorized by and licensed in accordance with State of Colorado statutes to engage in the healing arts and has met the applicable requirements of Part 2 of the regulations; and

(a) Whose license, licensing body, or licensing regulations and requirements authorize such operation; and

(b) Such operation is within the standard and acceptable scope of practice for the licensed individual; or

(3) By an individual who is under the general supervision of a licensed individual authorized in 6.3.1.6(1) or 6.3.1.6(2), where:

(a) The individual operator being supervised has met the applicable training requirements of Part 2; and

(b) Such supervision by a licensed individual is consistent with the individual's license, licensing body, regulations, and the standard and acceptable scope of practice for the supervising individual~~.~~**; or**

(4) By an operator who is under the personal supervision of a licensed individual authorized in 6.3.1.6(1), and where:

(a) The operator being supervised has met the applicable training requirements of Part 2, Appendix 2O; and

(b) Such operation is within the standard and acceptable scope of practice of the operator being supervised.

6.3.1.7 Exposure under Part 6 of any **living** human being to the useful beam of an x-ray system shall be solely for healing arts purposes**, or for the purposeful exposure of a living human research subject in accordance with Part 2, section 2.4.1.3,** and only after such exposure has been authorized by:

(1) A physician, chiropractor, dentist, or podiatrist who has a current active State of Colorado license to practice in the healing arts; or

(2) An individual authorized by and licensed in accordance with State of Colorado statutes to engage in the healing arts, and:

(a) Whose license, licensing body, or licensing regulations and requirements permit authorizing such exposure; and

(b) Such exposure is within the standard and acceptable scope of practice for the licensed individual.

* * *

Commented [JSJ4]:
In parallel with the concurrent (2023) proposed changes to Part 2 of the radiation regulations, this new provision is added to tie-in non-physician cardiac catheterization lab professionals as operators of fluoroscopy systems who operate those systems only under personal (in room) supervision of physicians.

Use of fluoroscopy systems by cardiac catheterization lab professionals is routine and common in Colorado. Such use is under the personal (in room) supervision of a physician.

Qualifications for such individuals has been added in Part 2, Appendix 2O.

Commented [JSJ5]:
Language is added to address the use of x-ray devices on living humans under Part 6 for research purposes.

6.5.12 Fluoroscopy specific operator qualifications

6.5.12.1 Operation of a fluoroscopic x-ray system shall be performed under direct supervision**, except where otherwise specified in these regulations**.

6.5.12.2 In addition to the applicable sections of these regulations, all persons operating or supervising the operation of a fluoroscopic x-ray system (including for FGI procedures) for clinical purposes on living humans shall be limited to persons meeting the applicable requirements of 6.3.1.6, 6.3.1.9, and Part 2, Section 2.4.5.5, and 2.6.1.5.

* * *

6.5.14 Registered Medical Physicist evaluations of fluoroscopic equipment.

6.5.14.1 ~~Fluoroscopic equipment shall be evaluated by a RMP within 90 days of installation and following maintenance of the system that may affect the exposure rate. Thereafter, the measurements shall be made as specified in Part 2, Section 2.5.~~**Fluoroscopic x-ray systems shall have a certification evaluation performed by a RMP under the frequency and conditions specified in Part 2, Section 2.5.**

At a minimum these evaluations shall include:

(1) A measurement of entrance exposure rates that covers a representative sample of patient thicknesses, including those that are expected to drive the system to maximum output in all modes clinically used, including fluoroscopy, high-level control, and acquisition, when available. These measurements shall:

(a) For systems without automatic exposure control, be made utilizing a milliamperage and kVp typical of the clinical use of the fluoroscopic system;

(b) For systems with automatic exposure control, be made utilizing sufficient attenuating material in the useful beam to produce a milliamperage and kVp typical of the clinical use of the fluoroscopic system;

(2) A measurement and verification of compliance of maximum AKR for fluoroscopy and high-level control, if available. Measurements shall be made in accordance with Section 6.5.5.4.

(3) An evaluation of image quality in the modes necessary to achieve the clinical imaging task(s).

(4) An evaluation of the operation of the 5-minute timer, warning lights, interlocks, and collision sensors.

(5) An evaluation of the beam quality and collimation in the fluoroscopy mode. Additional evaluation may be needed where magnification impacts collimation.

(6) An evaluation of the availability and accuracy of technique indicators and integrated radiation dose displays.

(7) An evaluation of changes to the fluoroscopy system impacting radiation safety.

Commented [JSJ6]:
The added language clarifies that there may be conditions where other higher levels of supervision may be required or specified, depending on the qualifications of the individual being supervised and/or their scope of practice.

The terms direct, personal, and general supervision are defined in Part 1 of the regulations.

Commented [JSJ7]:
To avoid duplicate and/or inconsistent language between Part 6 and Part 2, this section is simplified and revised to defer to Part 2 for certification evaluation frequency and conditions.

(8) When operating in the spot image mode, an evaluation of the coefficient of variation of air kerma for both manual and automatic exposure control systems to ensure the value does not exceed 0.05.

* * *

6.6 Requirements for use of general purpose x-ray imaging systems

6.6.1 Administrative controls.

6.6.1.1 The requirements of Section 6.6 apply to all registrants using general diagnostic imaging systems, excluding the following:

(1) Fluoroscopy use which is described in 6.5;

(2) Dental use which is described in 6.7;

(3) Veterinary use which is described in 6.8;

(4) Computed tomography use which is described in 6.9;

(5) Mammography use which is described in 6.10.

6.6.1.2 Certification evaluation (~~testing~~**inspection**) requirements.

(1) Within 90 days of ~~use~~**initial installation**:

(a) Digital radiographic systems shall have an initial certification evaluation performed by a RMP;

(b) Non-digital radiographic systems shall have an initial certification evaluation performed by a Qualified Inspector authorized for the specific machine type.

(2) Periodic certification evaluations shall be performed at the frequency specified in Part 2, Section 2.5 by Qualified Inspectors authorized for the specific machine type.

(3) Testing of display monitors which are under the control of the registrant shall be performed by or under the supervision of an RMP in accordance with 6.3.5.6.

(4) Certification evaluations and testing shall follow nationally accepted standards or those recognized by the Department.

* * *

6.7 Requirements for use of dental imaging systems.

6.7.1 Administrative Controls.

6.7.1.1 Intraoral dental x-ray machines shall not be operated at less than a measured 51 kVp, after January 1, 2022.

6.7.1.2 All dental facilities using any type of x-ray equipment for dental x-ray imaging, shall:

Commented [JSJ8]: Language added for clarity and consistency with other rule sections.

Commented [JSJ9]: Language added for clarity and consistency with other rule sections.

(1) Follow the applicable requirements of 6.3 and 6.4;

(2) Follow the applicable requirements of this Section 6.7

6.7.1.3 In addition to the requirements of 6.7.1.2, dental facilities using cone beam computed tomography (CBCT) x-ray equipment for dental x-ray imaging, shall also follow the requirements of Section 6.9 that are applicable to CBCT.

6.7.1.4 Quality assurance. In addition to the general quality assurance provisions in Section 6.3, the following requirements apply to a dental facility:

(1) If using a filmless system, maintain and operate PSP and DDR systems according to manufacturer specifications, or nationally accepted standards.

(2) If using film:

(a) Maintain a light tight darkroom or processor system;

(b) Use proper safelighting and safeguards; and

(c) Evaluate darkroom or processor system integrity and daylight loading systems for film fog every six months and after a change that may impact film fog.

6.7.1.5 Each individual who operates a dental x-ray imaging system shall meet the applicable adequate radiation safety training and experience requirements of **Part 2, sections** 2.6.1, ~~in particular~~**and specifically** 2.6.1.11.

(1) Records of training shall be maintained for inspection by the Department in accordance with Part 2, Section 2.6.6.4.

* * *

(3) Field Limitation for Intraoral Dental X-ray Systems.

(a) Each x-ray imaging system designed for use with an intraoral image receptor shall be provided with means to limit the beam such that:

(i) If the minimum SSD is 18 cm or more, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 7 cm; and

(ii) If the minimum SSD is less than 18 cm, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 6 cm.

~~(b) Excluding hand-held units, endodontic procedures, and those procedures which require a broader exposure field, after January 1, 2025, only rectangular collimators shall be used for routine intraoral dental imaging.~~

* * *

6.7.3 Each dental x-ray imaging system shall meet the following radiation exposure operational control requirements.

Commented [JSJ10]:
Existing language is amended for clarity. The header information in 2.6.1 and 2.6.1.1 provide broad generic requirements applicable to all operators. Provision 2.6.1.11 is specific to dental use.

Commented [JSJ11]:
This provision was originally adopted in November 2019, with a future effective date of January 2025. The future date was intended to allow for additional data gathering by the department and to give facilities time to budget and purchase equipment that would allow them to come into compliance. Following additional review and evaluation by the department, we are proposing to strike this provision from the rule for reasons discussed below.

In 2022, the department sent a survey to dental facilities to evaluate barriers to implementation of the collimator requirement. Facilities identified concerns over possible imaging errors and the need for additional staff training (which was identified during the original rulemaking). Facilities also identified equipment availability associated with supply chain issues as a concern. This did not appear to be a problem during the initial rulemaking.

While the use of rectangular collimators for patient dose reduction is supported by research and is recommended by the American Dental Association (ADA) and the National Council on Radiation Protection (NCRP) and other entities, the department feels that retaining this requirement is no longer feasible. A number of companies that previously manufactured rectangular collimators have discontinued distributing them. Being aware of this equipment shortage, a Colorado based company approached the department with a possible plan to manufacture and sell rectangular collimators. After additional consultation with the U.S. Food and Drug Administration (FDA), it was determined that this would be challenging as collimators are considered part of the x-ray device that must be individually approved (by FDA) for each machine make and model. Further, the FDA indicated that machines would require recertification by a qualified inspector resulting in additional facility costs.

The unavailability of rectangular collimator equipment in the market along with additional unexpected recertification costs was not anticipated during the original rulemaking. Due to these challenges, the department proposes that the provision be removed from the rule.

6.7.3.1 Cephalometric and volumetric beam dental x-ray systems shall meet the radiation exposure control requirements of 6.6.3:

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

(1) Timers.

(a) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(b) It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(c) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero".

(d) Timer Reproducibility.

(i) With a timer setting of 0.5 seconds or less, the average exposure period (T_{avg}) shall be greater than or equal to five (5) times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when four (4) timer tests are performed: $T_{avg} \geq 5(T_{max} - T_{min})$.

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

(a) Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

(b) A control shall be incorporated into each x-ray imaging system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (0.5) second or less.

(c) Exposure control location and operator protection.

Except for units designed to be hand-held during operation, the exposure control shall allow the operator to be:

(i) Behind a protective barrier at least 2 meters (more than 6 feet) tall; or

(ii) At least 2 meters (more than 6 feet) from the patient, x-ray tube, and the useful beam, while making exposures.

(d) The requirements of Appendix 6E shall be followed for x-ray equipment intended to be hand held during operation.

* * *

6.8 Requirements for use of a veterinary medicine imaging system.

6.8.1 Administrative Controls.

Commented [JSJ12]:
This is not a new provision. The provision was an unnumbered paragraph below (2)(c)(ii) but is better determined to be a stand alone provision. There are no changes to requirements as a result of this formatting change.

6.8.1.1 In addition to the provisions of 6.3 and 6.4, the requirements of this 6.8, and as appropriate also 6.5 and 6.9, apply to equipment and associated facilities used for veterinary x-ray imaging.

6.8.1.2 Each individual who operates a veterinary x-ray imaging system shall meet the applicable adequate radiation safety training and experience requirements of ~~Part 2.6.1, in particular 2.6.1.12~~ **Part 2, sections 2.6.1 and specifically 2.6.1.13**.

* * *

6.9 Requirements for use of computed tomography (CT) imaging systems.

* * *

6.9.3.5 PET CT and SPECT CT Systems

CT systems solely used for localization and calculation of attenuation coefficients in nuclear medicine studies shall meet the requirements in Sections 6.9.1, 6.9.2.4, 6.9.3.1, 6.9.3.3, and 6.9.4.1 unless otherwise exempted below:

(1) In lieu of 6.9.4.2, a RMP shall complete a ~~performance~~**certification** evaluation on the CT system following nationally recognized guidelines or those of the manufacturer at intervals not to exceed 12 months.

* * *

6.9.3.6 Veterinary CT Systems.

CT systems, including CBCT systems, solely used in non-human imaging shall meet the requirements of 6.9.4.1(1) (area radiation surveys) and are otherwise exempt from the standards of Section 6.9.

6.9.3.7 Cone Beam Computed Tomography Systems.

(1) CBCT facilities shall meet the following requirements, as applicable:

(a) Excluding veterinary imaging systems the minimum source-skin distance for CBCT imaging systems shall be consistent with the applicable requirements in 21 CFR subchapter J;

(b) 6.4;

(c) 6.6.3.1, 6.6.3.2, 6.6.3.4(1), and 6.8.2.1(4); and

(d) 6.9.1.3, 6.9.2.1, 6.9.2.3, 6.9.3.2, and 6.9.3.8 as applicable.

(2) Beam alignment.

(a) The x-ray field in the plane of the image receptor shall not exceed beyond the edge of the image receptor by more than 2 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(b) In addition, the center of the x-ray field shall be aligned with the center of the image receptor to within 2 percent of the SID.

Commented [JSJ13]: This provision is updated to clarify wording and correct a cross-reference error due to prior renumbering in Part 2.

Commented [JSJ14]: For consistency in the rule, the term “certification evaluation” is used.

(3) A ~~performance~~**certification** evaluation shall be performed by, or under the direct supervision of a RMP.

(a) The evaluation shall follow nationally recognized standards and tolerances or those recognized by the Agency.

(b) The evaluation shall be performed in accordance with Part 2, Section 2.5.1.

(c) The facility shall maintain documentation of the established standards and tolerances and ~~testing~~**certification evaluation** results.

* * *

CT surveys, ~~performance~~**certification** evaluations, routine QC, and operating procedures

6.9.4 Each computed tomography facility shall conduct required surveys, ~~performance~~**certification** evaluations, and routine QC.

6.9.4.1 Radiation Protection Evaluations.

(1) An area radiation survey or measurement shall be made by, or under the direct supervision of, a registered medical physicist or QE, to verify and document compliance with Part 4, Section 4.14 and 4.15 under the following conditions:

(a) All CT x-ray systems installed shall have an area radiation survey or measurement completed by, or under the direct supervision of, the RMP or QE within 90 days of installation;

(b) Any change in the facility or equipment that might cause a significant increase in radiation hazard; or

(c) Upon first use of a portable or mobile CT imaging system, consistent with the applicable requirements of 6.3.2.4.~~.~~

(d) The registrant shall obtain from the registered medical physicist, a written report of the measurements required by 6.9.4.1, and a copy of the report shall be made available to the Department upon request.

6.9.4.2 CT System performance **testing and certification** evaluations.

(1) The testing of the CT x-ray system shall be performed by, or under the personal supervision of, ~~a registered medical physicist~~**an RMP** who assumes responsibility and signs the final performance **testing and certification** evaluation report.

(2) Evaluation standards and tolerances shall be established by the registered medical physicist and maintained by the facility. The standards and tolerances shall be:

(a) In accordance with protocols published by nationally recognized organizations (for example, AAPM Report 96), unless the registered medical physicist determines that a particular recommendation of such report is not warranted for the clinical tasks for which the equipment will be used;

Commented [JSJ15]: Similar to other changes in Part 6, the rule is updated to use more consistent terminology for certification evaluations.

Commented [JSJ16]: Consistent with other changes in the rule, the term certification evaluation is used.

Commented [JSJ17]: Remove unneeded period.

Commented [JSJ18]: Consistent with other changes in the rule, the term certification evaluation is used.

(3) The **certification** evaluation ~~of~~**for** a CT x-ray system shall be performed by or under the personal supervision of an RMP in accordance with Part 2, Section 2.5.1~~. prior to use on human patients and within 90 calendar days of:~~

~~(a) Initial installation or acceptance testing; or~~

~~(b) Any change or service that could cause a change in the radiation output (dose indices) or image quality.~~

* * *

6.10 Requirements for use of mammography and other x-ray based breast imaging systems.

6.10.1 Administrative Controls.

6.10.1.1 The requirements of 6.3 and 6.4 apply to all mammography and x-ray based breast imaging equipment and associated facilities.

6.10.1.2 Each facility performing mammography (as defined in Section 6.2) shall:

(1) Use imaging systems that comply with the Mammography Quality Standards Act of ~~1988~~**1998**.

(2) Meet the requirements of Subpart B of 21 CFR 900;

(3) Ensure that 21 CFR 900 quality control and quality assurance standards for maintaining viewing conditions and interpretation of an image are met.

6.10.1.3 Each RMP who conducts a mammography facility and x-ray machine certification evaluation shall meet the requirements of Part 2, Appendix 2I.

6.10.1.4 Each Individual who performs a mammography examination shall meet the ~~adequate radiation safety~~ training and experience requirements of Part 2, Section 2.4.5.4~~, 2.6.1.5 and Appendix 2M~~.

6.11 Use of dual-energy x-ray absorptiometry (DXA) bone densitometry systems.

6.11.1 In addition to the provisions of 6.3 and 6.4, the requirements of 6.11 apply to all facilities using DXA machines.

6.11.2 DXA Systems shall be:

6.11.2.1 Certified by the manufacturer pursuant to the Medical Device Act and Subchapter C – Electronic Product Radiation Control (EPRC) of Chapter V of the Federal Food, Drug and Cosmetic Act;

6.11.2.2 Registered in accordance with Part 2 of these regulations; and

6.11.2.3 At a minimum, maintained and operated in accordance with the manufacturer's specifications

6.11.3 Operator requirements.

6.11.3.1 ~~In addition to the minimum qualifications outlined in 6.3.1.6 of these regulations, operators shall complete training specific to patient positioning and the operation of the~~

Commented [JSJ19]: Based on stakeholder feedback, language is clarified to refer to Part 2 of the regulations which contain certification evaluation criteria for all machine types, along with specific criteria for certain types of machines.

By deferring to Part 2 for the primary CE criteria, it will avoid potential conflicts between Part 6 and Part 2. Sections 2.5.1.4 and 2.5.1.5 address the certification frequency and requirements following an initial (new CT system) installation versus ongoing, routine, or post repair/maintenance of existing CT systems.

Commented [JSJ20]: Section 6.10.1 has been adjusted for formatting and alignment of text.

Commented [JSJ21]: Correction of date to reflect the current/reaffirmed version of MQSA.

Commented [JSJ22]: This provision is revised in parallel with proposed changes to Part 2 relating to mammography.

Commented [JSJ23]: Language is revised for clarity.

~~DXA system.~~ **Each operator of a bone densitometry machine shall meet the adequate radiation safety training and experience requirements of Part 2, Section 2.4.5.3, and Part 2, Appendix 2F.**

* * *

[END OF RULE – NO FURTHER CHANGES TO PART 6 BEYOND THIS POINT]