COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

From: James S. Jarvis, Regulatory Lead, Hazardous Materials and Waste Management Division

Through: Jennifer T. Opila, Division Director JTO

Date: July 17, 2019

Subject: **Request for Rulemaking Hearing**
Proposed Amendments to 6 CCR 1007-1 Part 6, X-ray imaging in the healing arts and 6 CCR 1007-1, Part 2, Registration of radiation machines, facilities and services, and Part 12, fees for radiation control services, with a request for a rulemaking hearing to be set for September 18, 2019

The radiation program is proposing significant changes to Part 6 and Part 2 of the radiation regulations and an associated minor change to Part 12 of the radiation regulations. Part 6 pertains to x-ray machine use in the healing arts (medical use) for diagnostic purposes. The rule contains requirements for periodic testing, quality control, safety and operation of x-ray machines at medical facilities to ensure they are safe for patients, operators and members of the public. Part 2 contains requirements for registration of all x-ray machine facilities (non-medical and medical), those providing services to facilities using x-ray machines (including inspection or repair), and qualifications and registration and training requirements for certain operators of x-ray machines. Part 12 addresses radiation program fees. The proposed changes align and make the rules more consistent with the Conference of Radiation Control Program Directors, Inc. (CRCPD) model regulation Part F, which was amended in 2015. The statutory requirement of the Radiation Control Act (25-11-104, CRS) specifies that the radiation regulations be consistent with the CRCPD model regulations, except where the Board of Health determines a deviation, substitute rule, or no rule is warranted while effectively permitting utilization of sources of radiation consistent with the health and safety of all persons potentially exposed to the radiation. While the proposed rule changes strive to maintain the content and spirit of the model rule, some provisions were not incorporated or were modified in consideration of technical limitations and issues, stakeholder feedback and concerns, programmatic considerations, and potential costs and benefits. The more significant items that were excluded from the rule are identified in the draft regulation in the form of temporary side margin notes, and are highlighted in section 6 of the Regulatory Analysis.

The changes incorporated in the 2015 CRCPD Part F model regulation (CRCPD 2015) were based on information and recommendations from a number of guidance documents, including the U.S. Environmental Protection Agency (EPA) Federal Guidance Report (FGR) #14 (EPA 2014), National Council on Radiation Protection (NCRP) Report No. 168 and No. 172 as well as other reports of the American Association of Physicists in Medicine (AAPM) and the American College of Radiology (ACR). Many portions of the Part 6 rule are technical in nature and are primarily intended for those involved in maintaining and testing of x-ray machines, such as registered qualified inspectors, qualified experts, and medical physicists. Other provisions are

intended for a more varied audience, including a wide range of healthcare providers, machine operators and facilities.

The Part 6 rule is very diverse in that it is applicable to all radiation producing (x-ray) machines used in the healing arts for diagnostic (non-therapeutic) imaging purposes. While such use is sometimes referred to as diagnostic use, certain uses may fall outside this definition, including those imaging procedures used for placement of medical equipment or devices (such as needles), commonly known as interventional radiology or imaging. Imaging is also used in treatment planning for subsequent or ongoing radiation therapy procedures, typically for cancer or tumor related illnesses. Such systems include all x-ray systems used in hospitals, medical clinics, physician offices, urgent care facilities, emergency rooms, chiropractic offices and clinics, podiatry clinics and offices, pain management facilities, transplant facilities, orthopedic facilities, and those used in veterinary medicine. Examples of the types of machines governed by the rule include dental imaging systems (e.g., intra-oral, panoramic, volumetric, and cone-beam tomography), computed tomography (CT) systems, fluoroscopic imaging systems (e.g., fluoroscopy systems, c-arm, mini-c arm), as well as mobile and hand-held x-ray systems of various types.

The Part 2 rule is similarly diverse in that it provides requirements for the registration process and associated requirements for all radiation producing machines, facilities, certain operators, and those entities providing services to others pertaining to radiation machines. The rule also outlines the requirements for operators of radiation machines. Unlike Part 6, the requirements of Part 2 are not limited to medical use and are applicable to all types of radiation machines for any and all purposes. The proposed changes to Part 2 are being made in conjunction with Part 6 proposed changes. The Part 2 proposed changes include clarifying the language in some definitions, adding new definitions, and removing definitions which are no longer applicable or that have been replaced. The proposed rule streamlines and simplifies certain aspects of the registration process for service companies. The proposed rule adds phased-in training topics beyond those currently required for operators of fluoroscopy systems and also proposes a registration process for certain fluoroscopy operators potentially expanding the operator pool to a larger number of qualified individuals. Consolidation of all veterinary imaging systems under the same inspection frequency (3 years) is also proposed.

A minor change is proposed for Part 12 to modify and align the category description to incorporate certain fluoroscopy operators into the existing application review fee as specified in Section 2.4.5.5 of the Part 2 proposed draft.

As the proposed changes are many and occur throughout the rule, new text appears as red bold text while deleted current text of this regulation is shown in strikethrough.

At the July 17, 2019 request for rulemaking, the Radiation Program requests that the Board of Health set a rulemaking hearing for September 18, 2019.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1007-1, Part 06, X-ray imaging in the healing arts;
6 CCR 1007-1, Part 02, Registration of radiation machines, facilities and services
6 CCR 1007-1, Part 12, Fees for radiation control services

Basis and Purpose.

The proposed amendments make significant technical and formatting changes to the Part 6 and Part 2 rules based on changes in the model regulation, technical guidance documents, programmatic needs and stakeholder feedback. The more significant proposed changes are outlined below for each section.

Section 6.2 (Definitions)
In the proposed rule, many of the definitions are either modified or newly added for consistency with the basis documents, the model rule, or in some instances federal regulation. Definitions no longer in use in the body of the rule or that have otherwise been deleted from the model regulation have been struck. When applicable and when it did not create a significant conflict with federal rule, stakeholder feedback was used to help guide and shape the wording of some definitions. Similarly, as identified in the draft rule, some deviations from the Part F model rule definitions were necessary, primarily based on stakeholder feedback and in some instances, technical need for maintaining nomenclature used in practice. While the definitions themselves do not explicitly add new requirements, their use in conjunction with other language may constitute new or modified requirements in the body of the rule.

The new definitions "Alert value", "Notification value" and "Substantial radiation dose level (SRDL)" apply to the concept and methods of providing notification to operators of computed tomography (CT) or fluoroscopy x-ray imaging systems that certain pre-determined dose indices or reference value related metrics established by each facility may be exceeded if the imaging procedure continues. This is not intended to be a dose limit – just a pause for the operator to determine whether continuation of the procedure is appropriate based on the medical needs of the patient and best practices. The evaluation helps ensure that mechanisms and processes are in place so users and facilities are made aware when there are deviations from established baseline radiation exposure related metrics for a given procedure relative to similar procedures. The aforementioned definitions along with the newly proposed "Fluoroscopically Guided Interventional (FGI) procedure committee" and "Radiation protocol committee" definitions, tie into the overall review and evaluation process to be established by facilities using CT or interventional fluoroscopic modalities.

Section 6.3 (General and administrative)
This section of the rule provides broad and specific requirements that are applicable to all facilities using x-ray machines for diagnostic, interventional, and non-therapy purposes. The section includes requirements for individuals operating and supervising operation of x-ray machines and for radiation safety and quality control requirements.

The proposed language pertaining to operators and those supervising operators of x-ray machines has a significant change. In recent years, an increasing number of

imaging activities are being performed by mid-level healthcare providers and personnel rather than being performed directly by physicians. These individuals may, in some instances also be providing direction to or supervising operators (such as registered radiologic technologists) in the use of x-ray imaging systems. The language of the current (in-effect) Part 6 generally limits the use or supervision of use of x-ray machines to those in the "doctor" category - specifically identifying physicians, dentists, podiatrists, chiropractors, and veterinarians. There are no proposed changes to the requirements associated with individuals in the doctor category and authorizations will continue as they are under the current rule. Similarly, the current authorizations for nationally registered radiologic technologists who typically operate x-ray systems under the general or direct supervision of others would also not change. The proposed changes however, would permit certain non-physician mid-level health-care providers who are already licensed (by the Department of Regulatory Agencies) under medical practitioner related regulations to operate or supervise operation of x-ray imaging systems under specific circumstances. As identified in the proposed rule, such use must be within the limitations of applicable regulations, statutes and the individual's license as well as their training, experience and scope of practice. X-ray imaging supervised or performed by mid-level providers has evolved with time and changes in the healthcare profession. These individuals have also not been clearly addressed by the x-ray regulations. The proposed rule changes are intended to improve this situation by providing an improved framework and clarifying the requirements. Note that in the model Part F rule, similar supervision and operation requirements are general and are typically left to each state regulatory agency as requirements vary from state to state. The proposed language in this section would therefore be Colorado specific. Individuals who participated in the stakeholder meetings and submitted comments were generally supportive of this approach, as long as limitations are in place and that individuals are properly qualified through training and experience. Stakeholders also recommended that the sections pertaining to operation and supervision of operation be combined into one area of the rule for ease of use.

The current and proposed Part 6 rule (and current Part 4 rule) requires x-ray facilities to have a radiation safety program and perform quality assurance activities and testing related to their machines and imaging. The proposed requirements of section 6.3 prescribe these requirements in further detail, generally consistent with updates to the Part F model rule. One area of the proposed rule where additional clarity is added is with regard to use of mobile and portable x-ray systems. With certain exceptions, fixed x-ray installations require an evaluation by a qualified expert to determine if room radiation shielding is required based on the machine in use, workload/frequency of use, levels of radiation produced and the type of imaging performed. Mobile or portable x-ray systems do not have a similar requirement unless they are used frequently in the same area or location. The proposed rule attempts to clarify and strengthen radiation safety requirements by specifying that facilities evaluate their use of these machines and establish a written procedure or policy on use of mobile and portable equipment to ensure that public and occupational dose limits are within the specified limits of the regulations.

The proposed rule also limits use of portable and mobile equipment to cases where it is impractical to transfer the patient, or where the patient's medical condition would prohibit such a transfer. Such situations may include surgery suites and recovery

rooms, intensive care unit rooms, neonatal care areas, etc. This was a requirement in past amendments to Part 6 but was removed some time ago. Consistent with the model Part F rule, the requirement is reinstated which was supported by some stakeholders. Other stakeholders expressed some concern with this requirement due to specific applications of these mobile and portable machines in hospital and similar settings. Rule language was modified as a result of these concerns to allow flexibility based on the medical condition of the patient. Use of any x-ray device in temporary locations can present a potential for exposure to nearby patients, members of public, facility staff, and operators but can generally be alleviated through proper safety evaluation.

Consistent with the model regulation, the proposed requirements pertaining to protection of staff and other personnel present during imaging procedures is expanded and made more explicit. The proposed requirement specifies persons in the area be protected from the direct x-ray beam or scatter radiation through use of shielding, but also permits flexibility based on radiation safety evaluations, or when it would benefit the patient.

Additional radiation safety requirements include a proposed requirement for annual inspection of lead-equivalent safety equipment/garments, such as leaded gloves, aprons and thyroid shields which may be used to protect patients or staff. Such equipment is required under the current regulation, but there is no provision to ensure that it is maintained in safe operating condition. The requirement for inspecting the protective equipment is consistent with the approach found in the model rule.

The current rule contains quality assurance (QA) requirements, but additional detail and specificity is added to these in the proposed rule. Quality assurance requirements originally derived from the model rule are incorporated but are modified based on stakeholder feedback. The proposed requirements include establishing a formal quality assurance program with written procedures based on nationally accepted standards. The draft rule specifies that a person be assigned to maintain the QA program to ensure that facilities routinely evaluate images for artifacts, perform repeat/reject analysis at certain facilities, perform routine maintenance on x-ray systems, and that records for and about the QA program are maintained.

The remaining provisions in this section are mostly retained as-is from the current rule, with slight language modifications for consistency with the model rule, for clarification, or those changes based on stakeholder feedback and suggestions.

Section 6.4 (Diagnostic and interventional)

This section of the rule provides technical requirements that are generally applicable to all types of x-ray systems unless specifically exempted. Most of these requirements follow federal rule requirements and include design criteria, warning label, beam filtration, and radiation leakage requirements that are verified through routine inspections. Proposed changes to this section of the rule involve updates for consistency with the model regulation and FDA requirements. Although requirements remain in the model rule, we are proposing to phase out capacitor energy storage equipment by prohibiting their use after 2022. These types of x-ray units are older, portable systems which are reported to have poorer image quality. Stakeholders involved in inspecting x-ray machines suggested this phase-out recommendation and

have indicated that they are not aware of such systems being used in Colorado. No comments to the contrary were received from stakeholders.

Section 6.5 (Fluoroscopy)
This section of the proposed rule addresses the use of fluoroscopic imaging systems, including those used for interventional procedures. Interventional procedures involving fluoroscopy (referred to in the rules as Fluoroscopically Guided Interventional or FGI procedures) involve the use of live imaging with fluoroscopy to carry out a clinical task, typically beyond just a diagnosis. Examples of FGI procedures include placement of drug stents, angioplasty of vessels, joint replacement surgeries, or for guiding drugs to a specific location in the body.

Unlike other sections of the rule, and with some exceptions, this section has been replaced in its entirety with the Part F model rule language and format. This was determined to be the preferred approach by x-ray staff early in the rule development process. This section contains numerous technical requirements that are specific to fluoroscopy systems derived from federal rule and guidance via the model regulation. Included are requirements for testing of radiation output at certain source to skin distances (SSD), system display and signal requirements, protecting persons from scatter radiation during procedures, as well as operator and system operation. Based on stakeholder feedback, some language or wording has been modified as FDA regulatory language has not always been kept consistent with modern technology or practices. (This is something that the working group developing the model rule also identified). A more significant proposed change derived from the model regulation based on EPA guidance, mandates that each facility performing FGI procedures establish a committee to oversee the FGI program. The facility and committee would be required to develop (or review existing) procedures, processes, and methods to manage patient dose, and to periodically review the FGI program as a whole. The rule is written with general language to allow flexibility in implementing such a committee, including flexibility in makeup, meeting and communication methods of the committee, and ability to combine with other existing committees, or team with other facilities. The proposed rule allows for a two year phase-in period to achieve compliance with the FGI committee related requirements.

The additional requirements proposed for FGI imaging systems are driven by the significant increase in use of radiation imaging systems in many different medical applications over the past two decades, with the goal of reducing patient and occupational dose. The decades of overall increases in the US per capita radiation dose from medical procedures is due less to FGI procedures than some other modalities, but FGI procedures typically result in some of the highest organ doses (especially to the skin) of all diagnostic imaging procedures (EPA 2014). While many lifesaving or life enhancing procedures are performed with these systems to the benefit of many patients, increased use of radiation in imaging may result in increased radiation exposure related risks. Radiation-induced skin injuries can sometimes occur after a clinically complex procedure, but may also, on other occasions, result from the use of inappropriate equipment or poor operational techniques.

Section 6.6 (General purpose x-ray)
This section of the rule is used in conjunction with other broad rule sections and prescribes technical requirements that apply to x-ray imaging systems used for general

purposes, such as chest, abdominal, joint, spine or extremity imaging. General purpose x-ray systems are commonly found at hospitals, emergency and urgent care clinics, family clinics, orthopedic offices, or podiatry and chiropractic facilities. This section explicitly excludes other specialty use x-ray imaging systems such as fluoroscopy, dental, veterinary, computed tomography and mammography systems since those are addressed in other sections of the rule. Specified in this section are requirements related to periodic certification evaluations (inspections), x-ray field/beam limitation and alignment, exposure and safety controls, notification systems and other requirements for fixed, mobile, and portable systems.

As discussed earlier, mobile and portable x-ray systems are intended for use on a temporary basis in one or more areas of a facility not necessarily designed or intended for routine x-ray imaging of ambulatory patients. Use locations may include surgical suites, post-operation recovery areas, intensive care units, or for immobile patients, such as those in nursing homes or under hospice care. Mobile and portable systems should generally not be used in lieu of fixed systems when image quality is at a premium. From a radiation safety perspective the challenge with use of portable and mobile x-ray systems is ensuring protection of nearby workers, members of the public, and operators. The proposed changes regarding use of mobile and portable systems include the addition of more specific and clarifying language to help determine if the requirements for a fixed system should apply, and to provide the additional option for use of lead-equivalent protective garments when they do not apply. Similar to other requirements related to mobile and portable use, some flexibility in implementing the requirements, based on radiation safety evaluations, is written into the rule.

Section 6.7 (Dental)
This section of the rule is used in conjunction with other broad rule sections and prescribes requirements that are specific to the use of x-ray imaging systems in dentistry.

The draft rule proposes to phase out (after January 1, 2022) those dental intraoral x-ray imaging systems that operate at less than 51 kVp. Stakeholders recommended this proposed change as various guidance documents indicate that systems operating below 51 kVp use older technology, result in higher doses to the patient, and the lower energy x-rays do not contribute to image formation. These systems are generally no longer manufactured.

The proposed rule also specifies a requirement to phase in (by January 1, 2022) the use of rectangular collimators to reduce radiation dose to patients. Modern dental intraoral imaging systems most commonly use a rectangular image receptor (digital or film), but the most common x-ray collimators are often round, resulting in a mismatch of x-ray beam to receptor. This mismatch in shapes allows unnecessary radiation to expose the patient with no benefit. Studies have shown that use of matching the shape of collimators and image receptors through use of rectangular collimation can result in a significant reduction in patient dose. A 2006 report by the American Dental Association Council on Scientific Affairs (ADA 2006) suggested that use of rectangular collimator decreases the radiation dose to the patient by up to fivefold for the most common radiographs. A 2019 retrospective study published in the International Dental Journal (Shetty 2019) indicated that radiation dose reduction ranged from 40% to 92% when using a rectangular collimator in lieu of a circular collimator, which suggested

that this provides sufficient justification for implementation in clinical settings. The study went on to say that the perceived barriers to use of rectangular collimation often cited by practitioners are the lack of adequate training and increased incidence of errors, which the authors believe could be addressed with proper training.

The proposed rule language also specifies that thyroid shielding be used for pediatric patients when performing intra-oral imaging. This is supported by a strong recommendation of the American Dental Association Council on Scientific Affairs (ADA 2006). The rule language permits flexibility in the requirements where such use will interfere with the imaging procedure as determined by the dental practitioner. The current rule specifies that thyroid shielding is required to reduce patient exposure without consideration of patient age, so the proposed rule reduces the regulatory burden slightly by limiting the requirement to pediatric patients.

Section 6.8 (Veterinary medicine)
Section 6.8 provides requirements unique to veterinary medicine and is used in conjunction with other sections of the rule. Although the Part F model rule does not contain an equivalent section for veterinary use of x-ray systems, this section is retained based on stakeholder feedback and interest in consolidating some specific requirements that are directly applicable to veterinary use.

There are only a few mostly minor changes proposed for Section 6.8 for consistency with other sections of the rule.

Section 6.9 (Computed Tomography (CT))
This section contains numerous technical requirements which are applicable to uses of Computed Tomography imaging systems and is used in conjunction with other broad sections of the rule. Computed Tomography imaging systems are typically computer controlled systems that use x-ray technology to create cross sectional images (slices) of the patient to evaluate internal organs and cavities. Like some other x-ray imaging modalities, the frequency and use of CT imaging systems as a diagnostic tool in healthcare has grown significantly over the years. Such systems have saved countless patients through avoidance of open surgery procedures. As recognized in EPA guidance report 14 (EPA 2014), a 2009 report of the National Council on Radiation Protection (NCRP 2009) estimates that the number of CT imaging studies performed annually increased from 3 million in 1980 to 62 million in 2006. It is estimated that the resulting per capita effective dose due to all diagnostic x-ray imaging studies increased from 39 mrem (0.39 mSv) to 223 millirem (2.23 mSv) per person per year – an almost six fold increase. The report estimates that 49% of this per capita increase in radiation dose to the U.S. population was due to CT imaging studies. While there has been some leveling off of CT use in recent years and improved technology allows for imaging at lower patient doses than 20 years ago, patient dose remains higher with the CT imaging modality than with other techniques and is a primary driver for the proposed changes.

Similar to the requirements for fluoroscopy discussed earlier, the proposed rule specifies that a committee be established to have oversight of CT use and the CT imaging program. Termed the Radiation Protocol Committee or RPC, the proposed rule prescribes the make-up of the committee, its focus, and meeting frequency. The requirement is written with some flexibility to allow for differences in implementing the requirements at different types of facilities.

Section 6.10 (Mammography)
This section prescribes the requirements applicable to facilities that perform mammography and similar imaging. The minor changes proposed for this section are intended to clarify the rule language. Requirements for mammography facilities are more strictly regulated via federal requirements found in the Mammography Quality Standards Act. Requirements in this section generally defer to the MQSA for more specific criteria.

Section 6.11 (Bone densitometry or DXA systems)
This is a new section added to address bone densitometry imaging systems for consistency with the format and content of the model (Part F) rule. Without the proposed change, bone densitometry systems fall primarily under the general system requirements of Section 6.6 and other sections that are applicable to all machines. Although this section is new to Part 6, the proposed changes in this section are generally not new requirements and can be found in other rule sections with broader language.

Part 6 Appendices
The appendices of Part 6 address a variety of topics including shielding and operator booth design, criteria for determining when x-ray machines are unsuitable for use, requirements for hand-held x-ray systems, and requirements for facilities intending to perform healing arts screening. Additionally, the proposed rule contains appendices that have been relocated from the body of the existing rule. There are mostly minor changes proposed for the majority of the existing appendices, with the exception of Appendix 6E. This appendix provides requirements applicable to x-ray systems that are designed to be hand-held during operation and are typically used in the fields of dentistry and veterinary medicine. In recent years, the use of these systems has continued to increase. Data for these hand-held systems tends to indicate that the occupational radiation dose is comparable to that of fixed dental systems. Therefore, the current requirement to use a lead apron and extremity monitoring is relaxed for those hand-held systems which include a backscatter shield or that otherwise provide a comparable level of protection.

Part 2
The proposed Part 2 changes include the addition of several definitions, primarily with regard to non-physician x-ray machine operators and specific certifications and registrations.

Additional proposed changes include streamlining of the registration process for service companies who provide x-ray related services to others. These proposed changes are expected to slightly reduce the regulatory burden for stakeholders.

A provision is added in section 2.4 of the proposed rule to clarify that individuals who are nationally registered as a technologists do not require separate registration or licensing with the Department or another state agency.

Section 2.4.5.2 pertaining to registration as Colorado computed tomography (CT) operators is amended as this program ended in 2017. Since August 2017, the program

has deferred to a national certification process for CT operators as outlined in Appendix 2E of the rule rather than a state specific program. Therefore the detailed qualification requirements in the current rule are no longer needed.

The proposed rule adds new section 2.4.5.5 and Appendix 2O to address training and application requirements specific to non-physician fluoroscopy operators. Under the current in-effect Part 2 rule, non-physician operators (or those supervising operation) of fluoroscopy imaging machines/procedures must also be American Registry of Radiologic Technologists (ARRT) certified technologists, or must be registered by a specialty board that has been accepted by the department as having substantially equivalent requirements for certification. Currently, there are no specialty boards that have categorical approval from the department under this criteria. A handful of individuals who are not ARRT certified have been granted individual approvals based on specific fluoroscopy training and experience they have demonstrated. Such approvals have been issued on a case-by-case basis. The proposed rule is intended to provide a clearer and more consistent pathway for individuals to be authorized to operate or supervise operation of fluoroscopy imaging systems and would require completion of certain fluoroscopy focused training and testing requirements through an existing ARRT process. The proposed pathway for fluoroscopy operators was brought forth through discussions with stakeholders, and in consideration of the increasing tasks of some non-physician/non-technologist mid-level providers in the healthcare field.

Table 2-1, which contains the listing of inspection frequencies for all types of x-ray machines and facilities was revised and reformatted for clarity. With the exception of veterinary facilities, all inspection frequencies remain the same. Based on stakeholder feedback the inspection frequency for all veterinary systems has been set at three years. Under the current rule, the inspection frequency varies from 1-3 years depending upon the machine type. The proposed rule simplifies the requirement and provides some regulatory relief, establishing a single inspection frequency for all veterinary x-ray systems.

Section 2.6.1.5 contains additional training requirements for fluoroscopy operators and identifies when they are deemed adequately trained. The provisions of this section continue to apply to all fluoroscopy operators and supervisors of fluoroscopy operators and include rephrasing of the fundamental training topics for consistency with the model Part F rule. Additionally, this section adds a tie-in to the proposed Appendix 2O and also proposes a phased-in (by January 2022) requirement to incorporate additional training topics derived from the model Part F rule. The additional training increases the focus on radiation and patient safety aspects of fluoroscopy operation.

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.

Statutes that inform or direct the rule content: N/A

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

_X_ No. This rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed. Though the rule does not contain a state mandate, the rule may apply to a local government if the local government has opted to perform an activity, or local government may be engaged as a stakeholder because the rule is important to other local government activities.

___ No. This rulemaking 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
___ Other: _____

Has an elected official or other representatives of local governments disagreed with this categorization of the mandate? ___Yes ___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.

REGULATORY ANALYSIS
for Amendments to
6 CCR 1007-1, Part 06, X-ray imaging in the healing arts;
6 CCR 1007-1, Part 02, Registration of radiation machines, facilities and services
6 CCR 1007-1, Part 12, Fees for radiation control services

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

The broad category of individuals and entities who are impacted by the proposed rules are those registered entities using x-ray machines for imaging and other non-radiation therapy purposes in the healing arts who are required to adhere to the requirements of Part 6 and 2 of the regulations. These facilities will generally bear the costs of the majority of the proposed rule changes.

The individuals who will potentially benefit from the proposed rule include service companies, equipment manufacturers and similar entities who sell and service x-ray systems and sell components for x-ray systems, and specifically rectangular collimator devices. Qualified Inspectors, Registered Medical Physicists and other individuals who work under contract at medical facilities may also potentially benefit from certain proposed requirements that involve additional time or effort to support or implement certain proposed rule changes. Non-physician qualified mid-level providers licensed in the healing arts who are interested in becoming registered fluoroscopy operators under the proposed rule changes, may benefit by having additional career or other opportunities after becoming registered. Such individuals could potentially include Nurse Practitioners, Physician Assistants and Advance Practice Nurses.

A. Identify each group of individuals/entities that rely on the rule to maintain their own businesses, agencies or operation, and the size of the group:

There are approximately 4,779 x-ray facilities in Colorado registered in the healing arts (medical) category. To varying degrees, and depending on the type of equipment and procedures performed, all of these facilities are potentially impacted by the proposed rule changes. This includes facilities that perform imaging involving x-ray systems including hospitals, clinics, physician offices, chiropractic offices and dental offices, research facilities, radiation therapy facilities, podiatry and veterinary facilities. These registered entities are required to follow the regulations as a condition of registration with the department.

Additionally, approximately 136 registered qualified experts, 158 qualified inspectors (including registered medical physicists) and 190 service companies that perform activities for end user x-ray machine (user) facilities are potentially impacted by certain portions of the proposed rule changes. Those providing services to others must also adhere to or otherwise implement the applicable portions of the regulations in providing services to others as a registered entity.

B. Identify each group of individuals/entities interested in the outcomes the rule and those identified in #1.A achieve, and if applicable, the size of the group:

Entities interested in the outcomes of the proposed rule changes include numerous regional and local professional organizations, societies, and associations that represent individual healthcare providers, businesses, entities or registered facilities that

operate, supervise operation or are otherwise involved with x-ray machine use in the field of medicine. These organizations represent advanced practice nurses, certification organizations, chiropractors, dentists, dental hygienists, hospitals medical physicists, nurses, physicians, physician assistants, radiologic technologists, and veterinarians. Also interested are those entities who provide services to facilities that use x-ray machines as well as private and public institutions of higher education who provide initial and ongoing education and training in x-ray machine use. Combined, these organizations potentially represent 20,000 individuals and entities.

C. Identify each group of individuals/entities that benefit from, may be harmed by or at-risk because of the rule, and if applicable, the size of the group:

Overall, the proposed rule will benefit Coloradoans by establishing common and consistent requirements and standards for radiation safety programs, quality assurance, and testing and operating x-ray imaging systems used in the healing arts, that are generally consistent with the intent and spirit of the model regulation, federal regulations, manufacturer information and nationally accepted standards and guidance. Such requirements are intended to provide a consistent regulatory framework and level of regulatory oversight to ensure adequate radiation protection for patients, occupational radiation workers and members of the public, commensurate with the radiation risk(s) presented by the use of the particular radiation producing machine.

Some aspects of the proposed rule may benefit certain healthcare facilities by clarifying requirements and permitting non-physician licensed individuals who have the necessary training and experience, and who are operating within their scope of practice and applicable regulations, to operate or supervise the operation of certain x-ray imaging systems. This may benefit some rural facilities and communities where mid-level providers may be the only providers available to cost effectively provide some limited procedures using x-ray imaging techniques. Additionally, this same requirement will likely benefit the licensed individuals who operate or supervise the operation of x-ray imaging systems by providing additional opportunities in their chosen field.

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.

A. For those that rely on the rule to maintain their own businesses, agencies or operations:

Describe the anticipated favorable and non-favorable non-economic outcomes (short-term and long-term), and if known, the likelihood of the outcomes:

Favorable non-economic outcomes:

- Ensuring that the proposed rules are more consistent with the spirit and intent of the 2015 CRCPD model F rule as dictated by statute, and to some extent making the rule consistent with certain national practices and recommendations related to radiation safety;
- Improved radiation safety through enhanced and clarified requirements in the rule language based on stakeholder feedback, and model rule requirements;

- Within the constraint and spirit of federal rule requirements specific to x-ray machines, address and revise outdated terminology;
- Incorporate a process for non-physician licensed individuals to supervise others in the operation or operate x-ray machines as authorized by their respective license, licensing board, regulations, statutory requirements and authorizations, and consistent with their scope of practice and training.

Unfavorable non-economic outcomes:

- Although consistent with the model rule and some national recommendations, the proposed requirements will require some facilities to expend personnel resources in the form of time and effort needed to implement some of the additional controls and requirements intended to improve radiation safety.

Anticipated financial impact:

Anticipated Costs:	Anticipated Benefits:
Description of costs that must be incurred. FGI COMMITTEE Under the proposed requirements of Section 6.5, facilities using fluoroscopic imaging systems to perform FGI procedures are required to establish and maintain a FGI Committee to monitor the use of these systems at their facility. There are anticipated costs associated with establishing this committee, developing and reviewing procedures required by the proposed rule, and annual meetings to review the FGI program. Some cost savings may be realized by combining the committee with other existing committees, such as a radiation safety committee, or partnering with other regional or sister facilities.	Description of financial benefit. FGI COMMITTEE The establishment of an FGI Committee is not necessarily expected or intended to provide a financial benefit to the regulated facility. However it is expected that some safety benefit to patients would be realized as a result of implementing this proposed requirement.
Cost or cost range. Estimated cost of FGI committee per facility $_2,957_____ Initial $_2,008_____ Annual	Savings or range of savings. $____NONE____ or ___ No data available.
CT COMMITTEE Under the proposed requirements of Section 6.9, facilities using computed tomography (CT) imaging systems are	CT COMMITTEE The establishment of a CT Committee is not expected or intended to result in a financial

required to establish and maintain a CT specific Radiation Protocol Committee (RPC) to monitor the use of these systems at their facility. There are anticipated costs associated with establishing this committee, developing and review the procedures required by the proposed rule, and conducting periodic meetings. Some cost savings may be realized by combining the committee with other existing committees, such as a radiation safety committee, provided the required committee makeup can be retained. Facilities may also partner with other associated facilities for cost sharing purposes.	benefit to the regulated facility. However it is expected that some patient safety benefit would be realized as a result of implementing this proposed requirement.
Cost or cost range. Estimated cost of CT RPC committee per facility $_2,876 -$3,882*___ Initial $_1,715_____ Annual *Facilities with CT fluoro will require additional procedures to address this combined modality.	Savings or range of savings. $____NONE____ or ___ No data available.
RECTANGULAR COLLIMATOR REQ. Under the proposed requirements of Section 6.7, facilities performing intraoral dental imaging would be required to use rectangular collimators beginning in 2022 which would require purchase of additional equipment for facilities that do not already have them. The cost to purchase a single rectangular collimator is estimated to be in the range of $75-$500, with an average estimated cost of $200 per collimator (machine). For facilities having more than one intra oral machine, a single collimator could be purchased and used on multiple machines provided they fit. Facilities may purchase higher priced units that have additional or advanced features such as laser guided positioning. Such systems are not required however.	RECTANGULAR COLLIMATOR REQ. The purchase of rectangular collimators would be expected to monetarily benefit Colorado registered service companies.

Description of variable or unknown costs that may be incurred. The factors that will impact the per-facility cost for rectangular collimators in dental facilities is dependent on the number of machines that require these collimators, whether collimators can be shared between machines and whether a facility already possess rectangular collimators. In Colorado, the average dental facility has a 3 intraoral x-ray machines. The type of collimator each machine has is not maintained in the x-ray registrant database.	
Cost or cost range. Average estimated cost of rectangular collimators for dental facilities per facility** $_600_____ **Estimate assumes an average of 3 machines per facility and that the facility does not currently possess rectangular collimators.	Savings or range of savings. $_____ or _X__ No data available.
Dollar amounts that have not been captured and why: • Some costs that are a result of technical changes related to x-ray machine certification (testing) are not easily quantifiable and are not included in the estimates.	Dollar amounts that have not been captured and why:

B. <u>For those that are affected by or interested in the outcomes the rule and those identified in #1.A:</u>

Describe the favorable or unfavorable outcomes (short-term and long-term), and if known, the likelihood of the outcomes:

The various entities and associations are interested in the proposed rule and its outcome because they, as collective organizations, represent the individuals or facilities that will be impacted by any proposed rule changes.

Favorable non-economic outcomes: N/A

Unfavorable non-economic outcomes: N/A

Any anticipated financial costs monitored by these individuals/entities? The financial costs associated with purchase of rectangular collimators would be of interest to organizations representing dentists. However, such organization did not provide comments against this during the stakeholder process.

Any anticipated financial benefits monitored by these individuals/entities? N/A

C. For those that benefit from, are harmed by or are at risk because of the rule, the services provided by individuals identified in #1.A, and if applicable, the stakeholders or partners identified in #1.B.

Describe the favorable or unfavorable outcomes (short-term and long-term), and if known, the likelihood of the outcomes:

If implemented appropriately, it would be expected that some favorable outcomes of the rule for the patient community would be an improvement in the level of radiation safety by:

- Ensuring x-ray machines are evaluated and inspected routinely and consistently with national standards, and the recommendations of the registered medical physicists/qualified inspectors serving their facility;
- Ensuring that patient dose reduction methods for higher risk imaging procedures are continuing to be evaluated and implemented through facility based efforts and added focus;
- Permitting, through a structured process, other qualified health care providers to provide or continue to provide imaging related services to patients, consistent with their license, scope of practice and within the constraint of the proposed regulations. This would be expected to benefit some rural healthcare facilities who may not otherwise have licensed physicians on staff to perform some specific procedures.

Financial costs to these individuals/entities:
Although it is not expected that facilities implementing these requirements will incur a significant financial burden, it is conceivable that some increased costs to patients could be incurred if costs are passed along to healthcare consumers.

Financial benefits to or cost avoidance for these individuals/entities:
No financial benefits are anticipated.

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:

Type of Expenditure	Year 1	Year 2
Staff will spend minimal additional time reviewing and processing applications for fluoroscopy operators. However, this time would be paid for by the applicant through the	$ NET NEUTRAL	$ NET NEUTRAL

application review fee in Part 12, currently set at $60 per application. It is estimated that 6-12 applications per year will be reviewed and processed.		
Total	$0 NET NEUTRAL	$0 NET NEUTRAL

Anticipated CDPHE Revenues:
The proposed rule does not explicitly increase or decrease fees. The proposed change expands the description for an existing training and application review fee to include certain licensed non-physician, non-radiologic technologist individuals who wish to apply for the ARRT fluoroscopy examination and become registered.

This rulemaking modifies fees:

Entity Type	# of Entities	Current Fee	Proposed Fee	% increase or decrease
Specific Fluoroscopy Operators	6-12 per year	$60	$60	No Change (0%)

The Department anticipates that it will need to modify fees to support the department's costs. The fees are established by the Board of Health. The Department anticipates that the fee will be revised as follows: No fee changes expected.

Entity Type	# of Entities	Current Fee	Proposed Fee	% increase or decrease
N/A	N/A	N/A	N/A	N/A

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.

Check mark all that apply:
_XX_ Inaction is not an option because the statute requires rules be promulgated.

_XX_ The proposed revisions are necessary to comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.

_XX_ The proposed revisions appropriately maintain alignment with other states or national standards.

_XX_ The proposed revisions implement a Regulatory Efficiency Review (rule review) result, or improve public and environmental health practice.

_XX_ The proposed revisions implement stakeholder feedback.

___ The proposed revisions advance the following CDPHE Strategic Plan priorities:

Goal 1, Implement public health and environmental priorities
Goal 2, Increase Efficiency, Effectiveness and Elegance

Goal 3, Improve Employee Engagement
Goal 4, Promote health equity and environmental justice
Goal 5, Prepare and respond to emerging issues, and
Comply with statutory mandates and funding obligations

Strategies to support these goals:
___ Substance Abuse (Goal 1)
___ Mental Health (Goal 1, 2, 3 and 4)
___ Obesity (Goal 1)
___ Immunization (Goal 1)
___ Air Quality (Goal 1)
___ Water Quality (Goal 1)
___ Data collection and dissemination (Goal 1, 2, 3, 4 and 5)
___ Implements quality improvement or a quality improvement project (Goal 1, 2, 3 and 5)
___ Employee Engagement (career growth, recognition, worksite wellness) (Goal 1, 2 and 3)
___ Incorporate health equity and environmental justice into decision-making (Goal 1, 3 and 4)
___ Establish infrastructure to detect, prepare and respond to emerging issues (Goal 1, 2, 3, 4, and 5)

___ Other favorable and unfavorable consequences of inaction:

An unfavorable consequence of inaction will be that the Part 6 rule will be less consistent with the model rule, applicable federal rule and guidance, and some other states implementing the model rule requirements.

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 in conjunction with stakeholders with the intent of adhering to the updated model rule requirements. The benefits 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 a level of consistency with the model rule as specified in statute.

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

A number of requirements having a potentially significant impact on the regulated community contained in the model Part F rule, were considered but eventually omitted or modified from the current proposed Part 6 rule following further consideration of discussions, comments, and feedback from stakeholders. The department and some stakeholders felt that it was not feasible to implement these items due to reasons outlined below.

A. Excluded from section 6.5 (fluoroscopy) was a Part F requirement specifying additional and extensive training for fluoroscopy operators, including board certified and registered operators. Part F prescribes 4 hours of initial general fluoroscopy training, 8 hours of FGI specific training (including 1 hour of demonstrated hands-on training), and 2 hours of biennial refresher training for all operators (or those supervising operators) of fluoroscopy machines. Such training requirements would be applicable to a wide category of physicians, registered radiologic technologists, and certain other individuals involved in fluoroscopy imaging operations. The concept of additional training was generally opposed by the majority of stakeholders early in the stakeholder process who questioned the need for the training and cited the cost and implementation of such training requirements. Questions arose about the acceptable delivery and training methods, and stakeholders cited concerns over the ability to track individuals over a wide spectrum of potentially impacted healthcare providers to ensure training was completed. It should be noted that fluoroscopy training requirements vary greatly from state to state, with some states requiring a separate fluoroscopy training and formal licensing or certification process. Other state's regulatory agencies have attempted to bring forth additional fluoroscopy training requirements through regulation but were opposed during final rule promulgation. The department feels that any proposals to modify or increase the training requirements associated with fluoroscopy would require a specific rulemaking and stakeholder process focused on this topic. We believe that the higher standards for fluoroscopy training are not warranted at this time.

B. Excluded from Section 6.6 (requirements for general purpose machines) of the proposed rule was a model rule requirement pertaining to measurements of the light field. This was excluded from Part 6 based on further evaluation and stakeholder discussion. The additional requirement to periodically and quantitatively measure the light field with specific instrumentation would not appear to improve radiation safety significantly and are more applicable at the point of manufacture of the x-ray system or perhaps during periodic maintenance activities. Stakeholders also cited the need and costs for instrumentation to take such measurements. Current requirements to evaluate and ensure the light field is visible under ambient conditions is deemed adequate for radiation safety purposes.

C. Excluded from Section 6.7 (dental imaging) of the proposed rule was a model rule requirement for facilities performing dental imaging to provide training and perform an evaluation annually for staff performing dental imaging. Stakeholders cited the fact that dentistry was being singled out since other healing arts modalities did not have a similar periodic evaluation process proposed, and that there have been no significant incidents or events involving patient exposures.

D. Excluded from Section 6.9 (computed tomography) of the proposed rule was a requirement for facilities performing Computed Tomography (CT) to become accredited (Section 6.9) by one of three federally accepted accrediting organizations. This was based on the same requirement found in the Part F model rule (as derived from the EPA guidance report). Accreditation costs can range from $6k-$10k per facility and can take several years to complete, depending upon the accrediting body chosen and facility. While there was limited stakeholder support for the concept of the accreditation requirement, most stakeholders participating in the stakeholder process were opposed to this proposed requirement. Those in favor of an accreditation requirement indicated that accreditation has had a positive outcome for other

modalities such as mammography. Supporters also indicated that if implemented, some facilities would need to be exempted from the accreditation requirement due to technical and procedural limitations. Those stakeholders opposed to the accrediting concept cited specific concerns by facilities in rural locations who may not be able to fund the accreditation process or have sufficient numbers or types of studies to meet accreditation criteria. Other stakeholders opposing the accreditation requirement similarly indicated that accreditation processes are expensive, lengthy, and rely upon outside private entities for requirements and may not lead to a proven benefit to radiation safety. Although it remains a voluntary process, at least 60% of the 234 registered CT facilities in Colorado are currently accredited, and facilities requesting reimbursement for the imaging procedure technical component under Part B of Medicare are required to be accredited.

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.

In addition to comments from stakeholder facilities and professionals from the regulated community, the following documents were used as a basis for requirements or were otherwise considered in the development of the rule requirements. These documents are cited throughout the rule package.

AAPM 2019. American Association of Physicists in Medicine (AAPM), Position Statement on the Use of Patient Gonadal and Fetal Shielding, Policy PP 32-A, April 2-3, 2019.

ADA 2006. American Dental Association Council on Scientific Affairs. The use of dental radiographs: update and recommendations. JADA 2006; 137(9):1304-1312.

CRCPD 2015. Conference of Radiation Control Program Directors, Inc. (CRCPD). 2015. Suggested State Regulations for Control of Radiation. Part F: Medical Diagnostic and Interventional X-Ray and Imaging Systems.

EPA 2014. Federal Guidance Report No. 14: Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures. EPA-402-R-10003.

NCRP 2009. NCRP Report No. 160: Ionizing radiation exposure of the population of the United States. Bethesda, MD: National Council on Radiation Protection and Measurements.

Shetty, et al. 2019. Shetty A, Almeida F, Ganatra S, et al., Evidence on radiation dose reduction using rectangular collimation: a systematic review. *Intl Dental J* 2019 69: 84-97.

STAKEHOLDER ENGAGEMENT
for Amendments to
6 CCR 1007-1, Part 06, X-ray imaging in the healing arts;
6 CCR 1007-1, Part 02, Registration of radiation machines, facilities and services
6 CCR 1007-1, Part 12, Fees for radiation control services

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:
The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

Organization	**Representative(s)**
Colorado Hospital Association (CHA) representing approximately 110 hospitals in Colorado	Amber Burkhart, Policy Analyst Lila Cummings, Manager, Public Policy
Colorado Dental Association (CDA), representing over 3,000 dentists in Colorado	Jennifer Goodrum, Director of Government Relations
Rocky Mountain Chapter of the American Association of Physicists in Medicine (RMC-AAPM) representing 135 medical physicists in the region	-
Colorado Associates in Medical Physics (CAMP) (Private medical physics provider/company)	Nathan Busse
Colorado Association of Nurse Anesthetists (CoANA) representing 625 advanced practice nurses in Colorado	Lisa Pearson, State Reimbursement Specialist and Federal Political Director Mary H. Stuart, Attorney Husch Blackwell LLP
American Society of Radiologic Technologists (ASRT) representing 3,000 imaging technologists in Colorado	Greg Morrison, Associate Executive Director Christine Lung, Vice President of Government Relations
Cardiovascular Credentialing International (CCI) representing 332 cardiovascular technology professionals	Jerel Noel, Executive Director
KaVoKerr, Manufacturer of hand held x-ray units (Private manufacturing company)	Erika Martin, Senior Manager, Regulatory Affairs
Colorado Podiatric Medical Association representing approximately 100 foot and ankle specialists in Colorado	-
Colorado Veterinary Medicine Association representing 2,200 veterinary professionals in the Rocky Mtn Region	-
Colorado Academy of Physician Assistants which represents 2,850 physician assistants in Colorado	-
Colorado Medical Society which represents approximately 7,500 physicians in Colorado	-
Colorado Chiropractic Association which represents chiropractors in Colorado	-
Colorado Radiological Society which represents	-

radiology physicians in Colorado	
Public and private institutions of higher education	-
Colorado Dental Hygiene Association	-
All entities registered as x-ray facilities for medical use	-
All individuals registered as a qualified inspector	-
All individuals registered as a qualified expert	-
All individuals registered as a medical physicist	-
All entities registered as a service company	-
All individuals registered as a limited scope operator	-
All individuals registered as a bone densitometry operator	-

The stakeholder process for Part 6 and Part began in early 2017. Prior to drafting changes to the Part 6 and 2 rules, the department notified nearly 5,000 stakeholders via email and postcard and posted on its website, a highlighted version on the CRCPD model Part F rule, on which the current and proposed Part 6 is based. The highlighted text indicated the more significant changes reflected in the 2015 model rule as compared to the current (in-effect) Part 6 rule and which would potentially be considered for incorporation in the Part 6 and 2 rules. The program posted this highlighted document for over 45 days to solicit feedback and comments from stakeholders. Additionally, three stakeholder meetings were held in Denver, Grand Junction, and Colorado Springs during this outreach effort to present, discuss and obtain feedback and input on the more significant changes to the model rule. A total of 42 individuals participated in these early stakeholder meetings. Comments were received from 25 individuals and organizations. The radiation program used this feedback to help guide the development of the draft of the proposed rule.

Throughout the subsequent year, regulatory staff worked with the x-ray program to develop draft rules. A draft Part 6 and Part 2 rule was made available for an extended stakeholder comment period beginning in late May 2018. This 90 day comment period was held in conjunction with a series of four general stakeholder meetings held at several locations in the state, including Denver, Loveland, Grand Junction, and Colorado Springs. In general, stakeholders were contacted via email prior to each of the meetings which also offered phone-in capability with meeting materials posted on the website. Despite notification to nearly 5,000 entities, participation at these evening general stakeholder meetings was generally fewer than 5 individuals per meeting, with the exception of the Denver meeting where there were 16 participants. In addition to the general stakeholder meetings, a series of five focus group meetings were held to review, discuss, and solicit feedback, comment and suggest changes on specific sections of the proposed draft rules. These meetings were productive and had somewhat better attendance than the general stakeholder meeting, averaging 6-12 individuals and typically lasting 3-4 hours each. The largest group represented at these focus group meetings was the medical physics community, all of whom typically also serve as qualified inspectors of x-ray machines and practice in the field of medical physics at regulated facilities. Also present and participating to a lesser degree were individuals representing or from the hospital association, dental association, non-medical physicist qualified inspectors, dental school, veterinary medicine community, nurse anesthetist association, an equipment manufacturer and one or more radiation safety officers from regulated x-ray facilities.

After consideration of comments received and rule editing following the summer 2018 stakeholder process, another shorter (30 day) comment period was held In April-May 2019.

Again, over 5,000 entities and individuals were notified of the opportunity to comment. For this most recent comment period, 61 individual comments were received from 9 individuals or organizations. The radiation program worked to resolve all comments provided to the extent practical while trying to maintain the spirit and intent of the model Part F requirements in place.

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).

_X__ Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.

____ Yes.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

The following section outlines some of the major factual and policy issues encountered, broken down by topical area.

FLUOROSCOPY TRAINING

As discussed in the basis and purpose, the model Part F rule contains more extensive fluoroscopy training requirements than that found in the current or proposed Part 6 rule, and which would apply to all physician and non-physician operators in different fields of medicine. During the early stakeholder engagement process in early 2017 when these training requirements from the model rule were presented, stakeholders were generally opposed to any additional training requirements and cited numerous technical and practical concerns over implementing this additional training. These early stakeholder meetings were attended by stakeholders representing a diversity of facilities and occupations. Later, during review and discussion of fluoroscopy specific training requirements in a focus group meeting (summer 2018), some stakeholders suggested and concurred that at least the refresher fluoroscopy training requirements should be retained/incorporated in the proposed Part 6 rule. This focus group was represented primarily by those in the medical physics community. Support for such training was again restated by at least one individual during the most recent 2019 stakeholder comment period. While the program holds the medical physics community in high regard and sees them as great partners in radiation protection and regulatory compliance, we believe implementing additional fluoroscopy related training requires concurrence from a wider and more diverse audience. The program supports additional efforts that will help reduce radiation exposure from fluoroscopy but due to the potential expense and implementation complexities we feel that fluoroscopy training should be a specific focus for a possible future rulemaking effort. The implementation of the proposed FGI procedure committee is expected to benefit radiation safety aspects of fluoroscopy use, and perhaps help to identify additional training needs.

RECTANGULAR COLLIMATORS IN DENTISTRY

As discussed in the basis and purpose, the draft rule proposes a phased requirement for use of rectangular collimators in intra oral dentistry. This requirement is not found in the model Part F rule, but was brought forth by stakeholders from the medical physics community during a dental specific focus group meeting in summer 2018. The medical physics community is involved in the periodic inspection of dental machines. A representative from the dental association was in attendance at the focus group meeting along with a dentist who trains new dentists. This was brought forth during the April 2019 comment period. The department received one comment letter expressing concerns about possible repeat exposures due to use of rectangular collimators, and another comment was received questioning whether the dental community had been notified of the proposed change. The dental community through the dental association was involved in the discussions surrounding this topic initially and suggested we consider a proposed change to allow for exceptions to the requirement when performing imaging for endodontic procedures or in those instances when a broader exposure field is needed. An additional modification to the rule resulted in excluding hand-held units from this requirement due to challenges with maintaining a tighter alignment between the x-ray beam and image receptor as based on discussions with a manufacturer of hand-held units.

ESTABLISHMENT OF COMPUTED TOMOGRAPHY (CT) AND FLUOROSCOPICALLY GUIDED INTERVENTIONAL (FGI) COMMITTEES

The proposed rule contains requirements for a committee to review and evaluate the CT program, and a committee to review and evaluate FGI activities at the facility. Hospitals in rural facilities have some concern with implementing such committees due to a lack of regular staffing to support the activities of these committees. The department heard from only one facility directly but received a comment letter from the organization representing hospitals that expressed similar concerns. The department took this into consideration, but decided to retain the provisions in the spirit and intent of the model rule in the proposed regulations. We believe the rule itself provides flexibility in implementing such a committee, such as expanding or clarifying the makeup of the committee, or through sharing resources or combining or partnering with other sister facilities on tasks or activities. The radiation program has put forth an extended implementation date beyond the rule effective date for this specific provision to allow time for facilities to prepare and budget if necessary. The department is also always willing to work directly with regulated facilities on a case-by-case basis to help overcome any challenges with implementing the proposed requirements.

REQUIREMENTS PERTAINING TO THYROID AND GONADAL SHIELDING

A topic which surfaced during various stakeholder discussions and comments relates to the use of shielding for patients during imaging procedures, such as thyroid, gonadal, and other lead-equivalent shielding. Such shielding potentially reduces patient exposure to radiation arising from outside the patient, primarily from scatter. Use of thyroid shielding during intraoral dental imaging has been a recommended practice in dentistry for many years. As compared to traditional film based systems, digital imaging methods typically result in reduced patient exposure while maintaining a high degree of image quality. The current (in-effect) Part 6 rule requires use of thyroid shields for dental facilities for all patients (regardless of age) except in the case where it will interfere with the diagnostic procedure. It is not clear where this requirement originated in prior rulemaking efforts for Part 6. The model Part F rule does not address or specifically require thyroid shielding, despite being recommended by EPA (EPA 2014). The radiation program considered the viewpoints of stakeholders and reduced the regulatory burden somewhat by limiting the thyroid shield

requirement to pediatric patients only, while still providing for exceptions when such use will interfere with the diagnostic procedure. The thyroid gland in children is considered one of the most radiosensitive organs. Unlike most x-ray imaging procedures which are often driven by suspected disease other specific medical conditions, routine and periodic intraoral imaging of the teeth is considered as a necessary part of ongoing oral healthcare. However, some stakeholders have suggested that thyroid shielding is no longer necessary for any patient regardless of age. National organizations generally continue to recommend thyroid shielding for intraoral imaging. Until additional organizations come forth with clear recommendations on eliminating thyroid shielding completely, it is felt that the proposed rule limiting thyroid shielding to pediatric patients provides a reasonable compromise and approach.

Discussions relating to gonadal shielding also arose during stakeholder discussions and comments. The current in-effect Part 6 rule requires gonadal shielding for all modalities, except in those cases where it interferes with the diagnostic procedure. The rule goes on to specify additional clarifying requirements for patients who are not beyond the reproductive age. Both of these requirements are specific to direct (non-scatter) exposure of the patient, where gonadal areas may be present in the beam. Modern x-ray systems provide controls that adjust radiation levels automatically based on patient conditions. The use of gonad shielding with such systems can result in increased patient radiation levels due to the system compensating for the reduction in radiation levels presented by shielding when placed in the direct x-ray beam. The model Part F rule does not specifically mention or explicitly require gonadal shielding. A recently issued policy statement of the AAPM (AAPM 2019) on use of gonadal and fetal shielding states that such shielding for patients is no longer warranted due to the potential for obscuring anatomical information or causing increases in patient dose, and that diagnostic imaging doses are not associated with measurable harm. The organization also states that such routine use be discontinued for diagnostic imaging for the aforementioned reasons. While we greatly value the opinions and expertise of this organization with regard to the clinical aspects of medical imaging and radiation safety, the policy document is the opinion of one organization. Other organizations involved in the radiation safety of patients continue to specify that gonadal and similar shielding continue to be used. While less specific than the current rule, the proposed Part 6 rule specifies that beam collimation, positioning and shielding of radiosensitive organs is to be used when it will not interfere with imaging or the medical procedure to reduce radiation exposure whenever possible. The radiation program feels the proposed language provides flexibility in the implementation of shielding while encouraging use of different methods of dose reduction for patient imaging procedures.

LIMITATIONS ON USE OF MOBILE AND PORTABLE X-RAY SYSTEMS

It is recognized that when used properly, mobile and portable x-ray systems provide a great benefit to patients in diagnosing conditions. Such systems however present challenges from a radiation safety and perhaps, a quality perspective. Stakeholders in the medical physics community (who inspect, establish and verify quality control and safety measures for such systems) have indicated that mobile systems may have somewhat reduced image quality relative to images produced in a fixed facility. With some exceptions, they have contended that mobile systems should not be used for routine imaging on patients who can otherwise be imaged in a fixed facility. It is recognized that not all patient imaging can be performed in a fixed x-ray installation due to the specific imaging or localization or medical procedure, or because of the patient's medical status. However, use of mobile systems also present potential for increased occupational radiation exposure, and exposure to nearby members of the public and facility staff. Use of mobile and portable x-ray systems should be evaluated routinely, as part of the registrant's comprehensive radiation safety program. The Part F

model rule prescribes that portable or mobile x-ray equipment is to be used only where it is impractical to transfer the patient to a stationary x-ray installation. Similar language has been proposed in the draft Part 6. The model rule (and the current in-effect Part 6), uses vague language regarding when additional requirements are required for mobile systems that are “used continuously for greater than one week”. The proposed draft attempts to remove some uncertainty with regard to these requirements while still requiring a reasonable level of focus on radiation safety. Stakeholders expressed concerns with the requirement that patients be imaged with mobile or portable systems only where it is impractical to image them in a fixed facility. Other stakeholders however, support this concept. The proposed rule goes beyond the model rule in specifically requiring that the facility evaluate their use of mobile and portable x-ray systems, and, as suggested by stakeholders, to establish written policies and procedures to govern their use. Incorporated into the proposed rules are also provisions to allow flexibility and exceptions where the medical condition of the patient make it unfeasible to relocate the patient to a fixed imaging room. The radiation program again feels that the flexibility allowed by the proposed rule will allow continued use of mobile and portable x-ray machines in safe manner.

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

Overall, after considering the benefits, risks and costs, the proposed rule (select all that apply):

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

DRAFT 1 07/01/19

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

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 September 18, 2019, effective date November 14, 2019.

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 ~~by or under the supervision of an individual authorized by and licensed in accordance with State of Colorado statutes to engage~~ 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 9 and~~ Part 24 **also**~~specifically apply~~**applies** to ~~some particular~~**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 **In accordance with Section 24-4-103(12.5)(c), CRS, https://www.colorado.gov/cdphe/radregs identifies where incorporated material is available to the public on the internet at no cost. If the incorporated material is not available on the internet at no cost to the public, copies of the incorporated material has been provided to the State Publications Depository and Distribution Center, also known as the State Publications Library. The State Librarian at the State Publication Library retains a copy of the material and will make the copy**

Commented [jsj1]: For simplicity, the current title of the rule will be retained rather than changing the title to match Part F. (Part F has the title of "Medical diagnostic and interventional x-ray and imaging systems"). As discussed below, Part F refers to the model regulation used as the basis for the Part 6 proposed changes.

Commented [jsj2]: **EDITORIAL NOTE 1:** ALL COMMENTS (SUCH AS THIS ONE) SHOWN IN THE RIGHT SIDE MARGIN OF THIS DOCUMENT ARE FOR INFORMATION PURPOSES ONLY TO ASSIST THE READER IN UNDERSTANDING THE PROPOSED RULE DURING THE DRAFT 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.

EDITORIAL NOTE 2: ALIGNMENT AND FORMATTING CORRECTIONS AND MINOR TYPPOGRAPHICAL ADJUSTMENTS ARE MADE THROUGHOUT THE RULE AND MAY NOT BE SPECIFICALLY IDENTIFIED WITH A SIDE MARGIN COMMENT.

EDITORIAL NOTE 3: THE ACRONYM "CRCPD" REFERS TO THE CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS (CRCPD), INC., WHICH DEVELOPS SUGGESTED STATE REGULATIONS FOR CONTROL OF RADIATION (KNOWN AS SSRCR'S). PER THE COLORADO RADIATION CONTROL ACT (LAW) AND UNLESS OTHERWISE DETERMINED BY THE BOARD OF HEALTH, COLORADO'S RADIATION RULES ARE TO BE CONSISTENT WITH THE SSRCR MODEL REGULATIONS.

THE SSRCRS MAY BE FOUND ONLINE AT:
http://www.crcpd.org/page/SSRCRs
THE PROPOSED AMENDMENTS IN THIS DRAFT PART 6 RULE ARE PRIMARILY BASED ON THE 2015 VERSION OF THE PART F MODEL RULE HEREIN REFERRED TO AS "PART F".

Some cross references to 21 CFR 1020 may be provided in the side margins for reference/information purposes.

Commented [JJ3]: These dates reflect the date of anticipated adoption and effective date based on the rulemaking schedule. Dates are subject to change pending additional review, approvals, and department rulemaking schedule.

Commented [jsj4]: Language added, consistent with Part F, Section F.1.

PART F was amended in 2015 to incorporate interventional x-ray systems which, while used for imaging, are not necessarily used for diagnostic purposes. Language is deleted to instead defer to the rule contents regarding authorization for use.

Commented [jsj5]: Language is updated to improve the clarity and understanding.

Commented [JJ6]: For consistency with other recent rule revisions, the following standard language is added.

available to the public.~~Published material incorporated in Part 6 by reference is available in accord with 1.4.~~

6.2 Definitions.

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

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

~~"AAPM Report 4" means "Basic Quality Control In Diagnostic Radiology", AAPM Report No. 4 by the Diagnostic Radiology Committee, Task Force on Quality Assurance Protocol of the American Association of Physicists in Medicine (November 1977).~~

~~"AAPM Report 74" means "Quality Control in Diagnostic Radiology", AAPM Report No. 74 by Task Group 12 of the Diagnostic X-ray Imaging Committee of the American Association of Physicists in Medicine (July 2002).~~

~~"AAPM Report 93" means "Acceptance Testing and Quality Control of Photostimulable Storage Phosphor Imaging Systems", AAPM Report No. 93 by Task Group 10 of the Radiography and Fluoroscopy Subcommittee of the Diagnostic Imaging Council CT Committee of the American Association of Physicists in Medicine (October 2006).~~

"AAPM Report 96" means "The Measurement, Reporting, and Management of Radiation Dose in CT", AAPM Report No. 96 by Task Group 23 (CT Dosimetry) of the Radiography and Fluoroscopy Subcommittee of the Diagnostic Imaging Council CT Committee of the American Association of Physicists in Medicine (January 2008).

~~"Added filtration" means addition of a filter to the inherent filtration.~~

"Alert value" means a dose index that is set by the registrant to trigger an alert to the CT operator prior to scanning within an ongoing examination. The alert value represents a universal dose index value well above the registrant's established range for the examination that warrants more stringent review and consideration before proceeding.

"Aluminum equivalent" means the thickness of aluminum (type 1100 alloy with a nominal chemical composition of aluminum 99.00 percent minimum and copper 0.12 percent maximum) affording the same attenuation, under specified conditions, as the material in question.

"Articulated joint" means a joint between two separate sections of a tabletop which joint provides the capacity of one of the sections to pivot on the line segment along which the sections join.

"Attenuation block" means a block or stack **of type 1100 aluminum alloy, or aluminum** ~~that has a thickness of 3.8 cm, is made of aluminum (type 1100 aluminum alloy with a nominal chemical composition of aluminum 99.00 percent minimum and copper 0.12 percent maximum) or other material(s)~~ having equivalent attenuation, **with dimensions 20 centimeters (cm) or larger by 20 cm or larger by 3.8 cm, that**~~and~~ is large enough to intercept the entire x-ray beam.

"Automatic exposure control" (AEC) means a device ~~that~~**which** automatically controls ~~settings~~**one or more technique factors** in order to obtain at the pre-selected location**(s)** a required quantity of radiation. See also "phototimer".

Commented [JJ7]: In Section 6.2, definitions are added, updated, or removed from Section 6.2, in general consistency with the Part F model regulation.

Some definitions from the current Part 6 may be retained due to being Colorado specific requirements based on business, technical, or statutory requirements or needs.

Commented [JJ8]: A newer report by AAPM Task Group 270, referenced later in this section addresses newer technology displays. As some older display types may still be in use, this referenced is retained.

Commented [JJ9]: Due to changes in the body of the rule, these specific definitions/reports are no longer referenced in the rule.

Commented [JJ10]: Definition "added filtration" is removed as it is not used in Part 6 or Part F.

Commented [jsj11]: The definition of "Alert value" is added – with slight modification - consistent with Part F, Section F.2.

The examples of dose index (CTDI and DLP) given within the Part F "alert value" definition have been excluded from the Part 6 version of the definition since the Department will not be proposing reporting criteria or dose tracking associated with this (alert value) term.

The Alert value term is used in Section 6.9 relating to Computed Tomography (CT).

Commented [jsj12]: Definition added, consistent with definition in Part F, Section F.2 and 21 CFR 1020.

Commented [jsj13]: Definition modified, consistent with definition in Part F, Section F.2 and 21 CFR 1020.

Commented [jsj14]: Definition modified, consistent with definition in Part F, Section F.2 and 21 CFR 1020.

"Automatic exposure rate control" (AERC) means a device that automatically controls one or more **technique factors**~~exposure settings~~ in order to obtain at the pre-selected location(s) a required quantity of radiation per unit time.

"Automatic film processor" means a device that produces an image from a film-screen system in mechanical steps with limited human intervention.

"Barrier". See "protective barrier".

"Beam axis" means, for purposes of Part 6, a line from the source through the center of the x-ray field.

"Beam-limiting device" means a device that provides a means to restrict the dimensions of the x-ray field.

"Bone densitometry" means a noninvasive measurement of certain physical characteristics of bone that reflect bone strength. Test results are typically reported as bone mineral content or density and are used for diagnosing osteoporosis, estimating fracture risk, and monitoring changes in bone mineral content.

~~"Bone densitometry system" means a device that uses electronically-produced ionizing radiation for the sole or primary purpose of determining the density of bone structures in human patients.~~

"Bone densitometer" means a device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories. A bone densitometer is synonymous with dual-energy x-ray absorptiometry (DXA) systems.

~~"C-arm x-ray system" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system or coordinated in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.~~**"C-arm fluoroscope" means a fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.**

"Cantilevered tabletop" means a tabletop designed such that the unsupported portion can be extended at least 100 cm beyond the support.

"Cassette holder" means a device, other than a spot-film device, that supports and/or fixes the position of the image receptor during a radiographic exposure.

"Cephalometric~~ device~~" means ~~a device~~ **imaging equipment or methods that are used**~~intended~~ for the radiographic visualization and measurement of the dimensions of the human head.

~~"Certified component" means an x-ray imaging system component that is subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.~~

~~"Certified system" means any x-ray system that has any certified component.~~

~~"Changeable filters" means any filter, exclusive of inherent filtration, that can be removed from the useful beam through any electronic, mechanical, or physical process under operator control.~~

"Coefficient of variation" (C) means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

Commented [jsj15]: Definition added, consistent with definition in Part F, Section F.2

Commented [jsj16]: Definition added, consistent with definition in Part F, Section F.2.

Commented [jsj17]: Definition updated, consistent with definition in Part F, Section F.2 and 21 CFR 1020.
The prior term "C-arm x-ray system" is no longer used in Part 6 and is therefore deleted.

Commented [jsj18]: Definition added, consistent with definition in F.2 and 21 CFR 1020.

Commented [jsj19]: Definition added, consistent with the updated definition in F.2

Commented [JJ20]: The language is modified for clarity based on x-ray unit staff recommendation.

Commented [jsj21]: The definition "certified component" does not appear in Part F and as a result it has been removed from Part 6. Similar requirements in Part F defer to the regulations of 21 CFR rather than this 1968 statute.

Commented [jsj22]: The definition "certified system" does not appear in Part F and is therefore removed from Part 6.

Commented [jsj23]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\sum_{i=1}^{n}\frac{\left(x_i - \bar{x}\right)^2}{n-1}\right]^{1/2}$$

21 cfr

where

s = Estimated standard deviation of the population

$\bar{x}$ = Mean value of observations in sample

x_i = i^{th} observation in sample

n = Number of observations sampled

"Computed radiography" (CR). See "photostimulable storage phosphor system."

"Computed tomography" (CT) means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

"Cone Beam Computed Tomography (CBCT)" means a volumetric imaging modality that uses a two-dimensional digital flat-panel detector to yield a three dimensional volumetric image in one rotation. Reconstruction algorithms can be used to generate images of any desired plane.

~~"Contrast-to-noise ratio" (CNR) relates the contrast of an object in an acquired image to the inherent noise in the image.~~

"Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, **keypads, touchscreens,** and other hardware **or software** necessary for the operator to manually select exposure settings.

"Cradle" means:

(1) A removable device which supports and may restrain a patient above an x-ray table; or

(2) A device;

(i) Whose patient support structure is interposed between the patient and the image receptor during normal use;

(ii) Which is equipped with means for patient restraint; and

(iii) Which is capable of rotation about its long (longitudinal) axis.

"CT" (see "computed tomography").

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the ~~exposure settings~~**technique factors as defined in 6.2**.

~~"~~CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures**,** ~~and~~ frames**, and covers** ~~that~~ **which** hold **and/or enclose** these components **within a computed tomography system**.

"CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image

Commented [jsj24]: Based on stakeholder feedback and potential unintended consequences with the originally proposed Part F definition, a modified definition is proposed. Due to wording of the originally proposed Part F definition, the CBCT definition could have included other types of Computed Tomography (CT) systems that were not intended to fall under the CBCT designation.

The proposed definition differs from Part F, but is derived from International Commission on Radiological Protection (ICRP) Publication 129 (2015) language.

Commented [JJ25]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

Commented [jsj26]: Definition is updated, consistent with definition in F.2 with the exception that "or software" is added to recognize that control panels may involve software and hardware systems.

Commented [jsj27]: Definition is added, consistent with the equivalent definition in Part F, Section F.2.

While the definition is new to Part 6, the definition has existed in Part F prior to the 2015 revision.

Commented [jsj28]: Definition is updated, for consistency with definition in F.2
The proposed updated definition retains the phrase "…but not limited to…" which does not appear in Part F.

Commented [jsj29]: Definition is updated, consistent with definition in F.2

The proposed updates add more specificity/detail to the definition and is specific to CT systems.

Commented [jsj30]: Definition and equation is added, consistent with definition in F.2.

Commented [jsj31]: Although it does not appear as red/bold text in the draft rule, this equation is new to the proposed Part 6 rule.

$$\overline{CTN} = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant, a normal value of 1,000 when the Houndsfield scale of CT number is used;

μ_x = Linear attenuation coefficient of the material of interest;

μ_w = Linear attenuation coefficient of water.

"Dead-man switch" means a switch so constructed that a circuit-closing contact can be maintained only by continuous pressure on the switch by the operator.

"Detector" (See "Radiation detector")

~~"Diagnostic imaging system" (also "diagnostic x-ray imaging system" or "diagnostic x-ray system") means an assemblage of components for the generation, emission, and reception of x-rays and the transformation, storage and visual display of the resultant x-ray image, with the assembled system designed and used for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.~~

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

"Digital radiography" **(DR)** means ~~use of~~ an x-ray imaging **method (or radiography) which produces a digital rather than analog image. DR includes both computed radiography and direct digital radiography.**~~processing system to produce a radiographic image displayed on a video monitor after mathematical transformation.~~

"Direct digital radiography" (DDR; also see CR and DR) means an x-ray imaging method in which a digital sensor is used to capture an x-ray image.

~~"Direct scattered radiation" means that scattered radiation that has been deviated in direction only by materials irradiated by the useful beam. See "scattered radiation".~~

"Dose area product (DAP) (aka kerma-area product (KAP))" means the product of the air kerma and the area of the irradiated field and is typically expressed in Gy-cm², so it does not change with distance from the x-ray tube.

"Dose profile" means the dose as a function of position along a line.

~~"Elemental area" means the smallest area within a digitally acquired image for which the x-ray attenuation properties of a body are depicted. See also "picture element".~~

"Equipment". See "x-ray equipment".

~~"Established operating level" means the value of a particular quality assurance parameter that has been established as an acceptable normal level by the facility's quality assurance program.~~

Commented [JJ32]: The definition "diagnostic imaging system" is deleted as it is not used in Part 6 nor is it found in Part F.

Some alternate terms "diagnostic x-ray imaging system" and "diagnostic x-ray system" are however used in Part 6. There is also a separate (simpler) definition for "Diagnostic x-ray system" below (which is also used in Part F).

Commented [jsj33]: Definition is added, consistent with definition in F.2.

While this definition is new to Part 6, the definition as proposed was not modified in the 2015 revision to Part F.

Commented [jsj34]: Definition is updated, consistent with the equivalent new definition in F.2.

Commented [jsj35]: Definition is modified and simplified from that in Part F based on stakeholder feedback. The specific and detailed definition as originally written in Part F would likely exclude some newer digital technologies.

Commented [JJ36]: Although this definition appears in Part F it does not appear to provide additional radiation safety benefit over the definition "scattered radiation" and may be confusing. Stakeholders have commented that this definition does not provide clarity and/or added value.

Commented [jsj37]: Definition is added, consistent with the equivalent new definition in F.2.

Commented [JJ38]: This definition is deleted as it is not defined in Part F.

Commented [JJ39]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

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

"Facility", for mammography (to supplement the Part 1 meaning of "facility"), means a hospital, outpatient Department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: operation of equipment to produce a mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation.

"Field emission equipment" means equipment that uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Filter" means material placed in the useful beam to preferentially absorb selected radiations.

"Floor plan" means, for purposes of Part 6, a plan view of the overall layout to scale of a room or group of rooms, including the location and configuration of any radiation producing machines in each room.

~~"Fluoroscopic air kerma display device" means a device, subsystem, or component that provides the display of air kerma rate and cumulative air kerma. It includes radiation detectors (if any), electronic and computer components, associated software, and data displays.~~

"Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a set of ~~visible~~**fluoroscopic** images **or radiographic images recorded from the fluoroscopic image receptor**. It includes the image receptor(s), electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

"Fluoroscopic irradiation time" means the cumulative duration during an examination or procedure of operator-~~enabled~~**applied continuous pressure to the device, enabling** x-ray tube activation in any fluoroscopic mode of operation.

"Fluoroscopically-Guided Interventional (FGI) Procedures" means an interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy.

"FGI Procedures Committee" means the representative group of individuals in a FGI facility responsible for the ongoing review and management of FGI procedures to ensure that exams being performed achieve the desired diagnostic image quality at the lowest radiation dose possible while properly exploiting the capabilities of the equipment being used.

"Fluoroscopy" means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images.

"Focal spot (actual)" means the area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

"General purpose radiographic x-ray system" means any radiographic x-ray system ~~that~~**which**, by design, is not limited to radiographic examination of specific anatomical regions.

~~"Gonad shield" means a protective barrier for the testes or ovaries.~~

"Half-value layer" (HVL) means the thickness of specified material **which attenuates the beam of radiation to an extent such that the air kerma rate (AKR) is reduced by one-half of its original value.**~~needed to reduce a radiation beam to one-half of its original intensity.~~ **In** ~~T~~this definition**, the contribution of all scattered radiation, other than any which might be present initially in the beam**

Commented [JJ40]: Definition for examination is added for clarity, consistent with the definition found in Part 1 of the regulations.

Commented [jsj41]: Consistent with deletion from Part F, this definition is deleted from Part 6.

The definition language does not appear in the current Part 6.

Commented [jsj42]: Definition is updated, consistent with the equivalent definition in F.2.

Commented [jsj43]: Definition is updated, consistent with the equivalent definition in F.2.

Commented [jsj44]: Definition is added, consistent with the new equivalent definition in F.2.

Commented [JJ45]: Following discussions with and comments from stakeholders, the originally proposed term/definition "Case Review Committee (or CRC)" is modified to FGI Procedures Committee to better reflect the focus of this committee as it applies to fluoroscopy.

Commented [jsj46]: Definition is updated, consistent with the equivalent definition in F.2.

Commented [JJ47]: This definition "gonad shield" is deleted as it is not found in Part F.

Commented [jsj48]: Definition is updated, consistent with the equivalent definition in F.2.

[The definition for air kerma rate is found in the current Part 1 of the regulations.]

concerned, is deemed to be excluded. ~~excludes all scattered radiation other than any present initially in the beam.~~

"Hand-held x-ray equipment" **means a type of portable x-ray equipment that is designed to be held in the operators hand during operation**. See "x-ray equipment"~~, under "portable x-ray equipment"~~.

~~"Hard copy processor" means a device that produces a printed image from digital image data.~~

"Healing arts screening" means, for purposes of these regulations, the **testing or evaluation resulting in the** exposure of any human being ~~using~~ **to** an x-ray ~~imaging~~ machine for the detection or evaluation of health indications when such a test is not specifically and individually ordered by a licensed physician, chiropractor, dentist**,** ~~or~~ podiatrist **or other person** legally authorized to prescribe such a test for the purpose of diagnosis or treatment.

"Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds (kVp - mA - second).

"HVL". See "half-value layer".

"Image intensifier" means a device, installed in its housing, that instantaneously converts an x-ray pattern into a corresponding visible light image and electronically amplifies the brightness of that visible image.

"Image receptor" means any device, such as a fluorescent screen**,** ~~or~~ radiographic film, x-ray image intensifier tube, photostimulable phosphor, or solid-state or gaseous detector~~,~~ that transforms incident x-ray photons either into a visible image or into another form that can be made into a visible image by further transformations. **In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device.**

~~"Image receptor support device" means, for mammographic systems, that part of the system designed to support the image receptor perpendicular to the beam axis during a mammographic examination and also designed to provide a primary protective barrier.~~

~~"Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.~~

~~"Irradiation" means the exposure of matter to ionizing radiation.~~

"Isocenter" means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

"Kerma-area product (KAP)". See "Dose area product"

"Kilovolts peak". See "**P**~~p~~eak tube potential".

"kV" means kilovolt.

"kVp". See "**P**~~p~~eak tube potential".

"kWs" means kilowatt-second.

"Last image hold radiograph" (LIH) means an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure~~. or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.~~

~~"Laterality", in mammography, means the designation of either the left or right breast.~~

Commented [jsj49]: Definition is updated, consistent with the equivalent definition in F.2.

The phrase "…type of portable…" is added for clarity, consistent with the definition under "x-ray equipment". Similarly, the wording "…in the operators hand…" is added for clarity. Neither wording appears in Part F.

Commented [JJ50]: This definition "hard copy processor" is deleted as it is not used in Part 6 nor is it found in Part F.

Commented [JJ51]: This definition is generally consistent with a similar Part F definition, but is updated to add clarity/specificity and to recognize that other licensed individuals may be authorized to prescribe an x-ray exam (by their designated licensing board or regulation) resulting in an exposure and consistent with the updated language found in Section 6.3.1.6 and 6.3.1.7.

Commented [jsj52]: Definition is updated, consistent with the equivalent definition in F.2.

Commented [jsj53]: The definition "image receptor support device" is deleted as it is not used in Part 6 nor is it found in Part F.

Commented [JJ54]: The definition "inherent filtration" is deleted as it is not found in Part F.

Commented [JJ55]: "Irradiation" is currently defined in Part 1 and is therefore not needed here.

Commented [jsj56]: Definition is added, consistent with the equivalent definition in F.2.

The definition is used several times in Part 6.

Commented [jsj57]: Definition is added, consistent with the equivalent definition in F.2.

Commented [JJ58]: Due to changes in technology and based on stakeholder discussions, this definition is modified.

Commented [JJ59]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

"Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

~~"Leakage control settings" means the exposure settings associated with the diagnostic source assembly that are used in measuring leakage radiation, defined as follows:~~

~~(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulomb, that is, 10 mAs, or the minimum obtainable from the unit, whichever is larger;~~

~~(2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.~~

~~(3) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for that maximum-rated peak tube potential.~~

"Leakage radiation" means ~~the portion of ionizing~~ radiation ~~originating~~**emanating** from the ~~x-ray imaging system~~**diagnostic source assembly** ~~that is not part of the useful beam. See "useful beam".~~ **except for:**

(1) The useful beam; and

~~(1)~~**(2) Radiation produced when the exposure switch or timer is not activated.**

"Leakage technique factors" means the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (or 10 milliampere-seconds) or the minimum obtainable from the unit, whichever is larger;

(2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; and

(3) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

"Light field" means that area of the intersection of the light beam from the beam-limiting device, and one of the set of planes parallel to, and including, the plane of the image receptor, whose perimeter is the locus of points, at which the illumination is one-fourth of the maximum in the intersection.

~~"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential.~~

~~Percent line-voltage regulation = 100 $(V_n - V_l)/V_l$,~~

~~where V_n = no-load line potential and~~

~~V_l = load line potential.~~

Commented [jsj60]: Definition is deleted and replaced with the similar "Leakage technique factors" definition below, consistent with the definition in F.2.

Commented [jsj61]: Definition is updated, consistent with the equivalent definition in F.2.

The definition is expanded to include radiations produced once the machine has been shut off.

Commented [jsj62]: Definition is added, consistent with the equivalent definition in F.2.

While this is a new definition for Part 6, the definition was not new or updated with the 2015 revision to Part F.

Commented [JJ63]: Although this term appears in Part F, the definition for "Line-voltage regulation" is deleted based on early radiation advisory committee discussions regarding the capacity of medical physicists to perform this testing. Typically, such voltage testing may be performed by x-ray machine service engineers.

~~"Luminance" means the amount of light that passes through or is emitted from a particular area and falls within a given solid angle.~~

"Mammogram" means a radiographic image produced through mammography.

~~"Mammography" means radiography of the breast. See also 6.10.1.1.~~ **"Mammography" means radiography of the breast, but for purposes of this part, does not include:**

(1) Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or

(2) Radiography of the breast performed with an investigational mammography device as a scientific study conducted in accordance with FDA regulations.

"Mammography phantom" means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

~~"Mammography medical outcomes audit" means a systematic comparison of positive mammogram assessment data to corresponding pathology results.~~

~~"Mammography modality" means a technology for radiography of the breast.~~

"Manual film **developing**~~process~~" means a way to produce an image that requires human intervention to move the film from developer to fixer to wash.

"mAs" means milliampere-seconds (mAs), a measure of electrical current produced over a set amount of time via an x-ray tube.

~~"Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.~~

~~"Mini-c-arm x-ray system" means a system that meets the following criteria:~~

~~(1) Source-image receptor distance less than or equal to 45 cm (18 inches);~~

~~(2) Field of view less than or equal to 15 cm (6 inches);~~

~~(3) Maximum kVp less than or equal to 80 kVp; and~~

~~(4) Maximum mA less than or equal to 0.25 mA.~~

"Mobile x-ray equipment". See "x-ray equipment".

"Mode of operation" means**, for fluoroscopic systems,** a distinct method of fluoroscopy, ~~mammography,~~ or radiography provided by the manufacturer and selected with a set of several ~~exposure~~ **technique factors or other** control settings uniquely associated with the mode.

(1) The set of distinct **technique factors and control** settings for the mode may be selected by the operation of a single control.

(2) Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog or digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, ~~mammography~~ and photospot recording.

Commented [jsj64]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

(The term "illuminance" is used in Part F but is not defined. Part 6 language has been changed to use the term "illuminance".)

Commented [JJ65]: The current mammography definition is replaced with an updated clarifying definition.

Commented [JJ66]: A revised clarifying definition for mammography is added to address those breast imaging procedures which may not be considered mammography and are performed for specific medical purposes.
The definition is derived from federal rule, but is not found in Part F.

Commented [JJ67]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

Commented [JJ68]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

Commented [JJ69]: Definition updated for clarity and to ensure consistent use in merging language of Part F and Part 6.

Commented [JJ70]: Definition added as it is used throughout the rule.

Commented [JJ71]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

Commented [jsj72]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

However, for clarity the criteria specific to a mini-c-arm system from this (deleted) definition is incorporated into 6.3.2.4(1) where it is used in Part 6.

Commented [jsj73]: Definition is updated, consistent with Part F, Section F.2.

(3) In a specific mode of operation, certain system variables affecting air kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

"Multiple tomogram system" means a computed tomography x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

"NCRP Report 147" means National Council on Radiation Protection and Measurements Report No. 147, "Structural Shielding Design For Medical Imaging Facilities" (November 2004).

"Noise" ~~means the fluctuation of a signal within a measured region of interest, for example, as a result of statistical fluctuation of the signal and electronic noise in the detector.~~**in CT means the standard deviation of the fluctuations in CT number expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:**

$$S_n = \frac{100 \cdot \overline{CS} \cdot s}{\mu_w}$$

where:

$\overline{CS}$ **= Contrast scale (the change in linear attenuation coefficient per CT number relative to water).**

μ_w **= Linear attenuation coefficient of water.**

s **= Estimated [S]standard deviation of the CT numbers of picture elements in a specified area of the CT image.**

"Nominal tomographic section thickness" means the measured full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

"Notification value" means a protocol-specific dose index that is set by the registrant to trigger a notification to the CT operator prior to scanning when the dose index exceeds the established range for the examination.

"Optical Density" (OD) equals log (1/transmittance), where the transmittance of the film is the fraction of incident light transmitted by the film.

"Patient" means a human being or an animal to whom ~~radioactive materials or~~ machine-produced radiation is delivered for healing arts examination**, screening**, diagnosis, or treatment. ~~In addition, for mammography, patient means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.~~

"PBL". See "positive beam limitation".

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Photostimulable storage phosphor ~~imaging~~" (PSP) means **a material used to capture and store radiographic images in computed radiography systems** ~~an x-ray image processing system that employs reusable imaging plates and associated hardware and software to acquire and display digital projection radiographs~~.

~~"Phototimer" means a method for controlling radiation exposure to image receptors by the amount of radiation that reaches radiation monitoring device(s) as part of an electronic circuit that controls the duration of time the tube is activated. See "automatic exposure control".~~

Commented [jsj74]: Definition is added, consistent with F.2.

Commented [jsj75]: This definition is updated consistent with Part F.

Commented [JJ76]: This term is revised, consistent with the definition in 21 CFR 1020.33.
The definition found in Part F appears to be incorrect and inconsistent with federal rule.

Commented [jsj77]: Definition is added, consistent with F.2., with the exception that "measured" is added based on stakeholder feedback.

Commented [jsj78]: The definition of "Notification value" is added – with slight modification - consistent with Part F, Section F.2. The examples of dose index (CTDI and DLP) given within the notification value definition were excluded. The CTDI and DLP examples are excluded as the definitions associated with these terms are also excluded from Part 6.

The notification value term is used in Section 6.9 relating to Computed Tomography (CT).

Commented [jsj79]: The Part 6 rule is specific to radiation machines and is not applicable to radioactive materials. Reference to radioactive materials is therefore deleted.

The definition here is more detailed than that found in Part F, but provides additional clarity to the rule.

Commented [JJ80]: Definition updated for consistency with Part F definitions.

Commented [JJ81]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

"Picture element" (pixel) means an elemental area of a digitally acquired image.

"PID". See "position indicating device".

"Pitch" means the table incrementation, in CT, per x-ray tube rotation, divided by the nominal x-ray beam width at isocenter.

~~"Pixel". See "picture element".~~

"Portable x-ray equipment". See "x-ray equipment".

"Position indicating device" (PID) means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance, without regard to whether the device incorporates or serves as a beam-limiting device.

"Positive beam limitation" (PBL) means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

"Primary protective barrier" means the material, excluding filters, placed to attenuate the useful beam for radiation protection purposes.

"Protective ~~apron~~**apparel**" means a garment made of radiation-absorbing materials used to reduce radiation exposure to the ~~torso of the~~ wearer.

"Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. ~~See "primary protective barrier" and "secondary protective barrier".~~

~~"Protective glove" means a glove made of radiation-absorbing materials used to reduce radiation exposure to the wearer.~~

"Protocol" means a collection of settings and parameters that fully describe an examination.

"Pulsed mode" means operation of a fluoroscopic x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

"Qualified inspector (QI)" is as defined in Section 2.2 of Part 2 of these regulations.

"Qualified trainer" is as defined in Section 2.2 of Part 2 of these regulations.

"Quality assurance (QA)" means a written monitoring and verification program which uses testing, auditing and inspection to ensure that deficiencies, deviations, defective equipment, or unsafe practices, or a combination thereof, relating to the use, disposal, management, or manufacture of radiation devices are identified, promptly corrected, and reported to the department where required.

"Radiation Protocol Committee (RPC)" means the representative group of individuals in a CT facility responsible for the ongoing review and management of CT protocols to ensure that exams being performed achieve the desired diagnostic image quality at the lowest radiation dose possible while properly exploiting the capabilities of the equipment being used.

"Radiation therapy simulation system" means a radiographic~~/~~ **or** fluoroscopic x-ray system or a computed tomography system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Radiograph" means an image ~~receptor on which the image is~~ created directly or indirectly by ~~an x-ray~~**x-rays** ~~pattern and results~~**resulting** in a permanent ~~record~~**visible image on film or digital record**.

Commented [JJ82]: Originally proposed for deletion in the initial draft, this definition retained for consistency with Part F and is used in definition for "Noise".

Commented [jsj83]: Definition is added, consistent with Part F, Section F.2.

Commented [JJ84]: The definition "pixel" is deleted as it is not used in Part 6 nor is it found in Part F.

Commented [JJ85]: Based on x-ray staff recommendation, the definition is modified to have wider application in the rule, with protective apron's being a natural subset of protective apparel.

Although the term protective apparel does not appear in Part F the radiation program believes it to be a more appropriate term.

Commented [jsj86]: This definition not found in Part F but is used in several areas of Part 6 and is therefore retained in the rule.

Commented [jsj87]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

Commented [jsj88]: Definition is added, consistent with F.2.

Commented [JJ89]: Referential definition added for clarity.

Commented [JJ90]: Based on a Radiation Advisory Committee recommendation to clarify certain terms that are used in Part 6, but are otherwise specifically defined in other regulatory parts, a referential definition for "qualified trainer" is added.

Commented [JJ91]: Definition added, consistent with Part F, Section F.2, with wording modified for clarity.

Commented [jsj92]: Definition added, consistent with Part F, Section F.2, with the exception of excluding FGI procedures, based on radiation advisory committee discussions. This definition and associated requirements for such a committee would be required at facilities that perform Computed Tomography (CT) procedures. Based on stakeholder discussions, "qualified" is removed from the rule. Make up of RPC is defined in Section 6.9.

Commented [JJ93]: Based on advisory committee review and discussions, definition is updated to reflect current terminology and differs from what is found in Part F.

~~"Radiographic imaging system" means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.~~

"Radiography" means a technique for generating and recording an x-ray pattern for the purpose of providing the user with the image(s) after termination of the exposure.

~~"Rating" means the operating limits specified by the manufacturer.~~

~~"Recording" means producing a retrievable form of an image resulting from x-ray photons.~~

"Reference plane" means a plane ~~that~~**which** is **parallel to and which can be offset (as specified in manufacturer information provided to users) from the location** ~~displaced from and parallel to~~**of** the tomographic plane**(s)**.

"Registered medical physicist (RMP)" is as defined in Section 2.2 of Part 2 of these regulations.

~~"Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.~~

"Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a pre-selected set of two or more scans performed consecutively under pre-selected CT conditions of operation.

"Scan time" means the time elapsed during the accumulation of x-ray transmission data for a single scan.

"Scatter~~ed~~ radiation" means ionizing radiation **that,** ~~emitted by interaction of ionizing radiation with~~ **during passage through** matter, ~~the interaction being accompanied by a change in direction of the radiation~~**has been deviated in direction**. ~~See "direct scattered radiation".~~

~~"Secondary protective barrier" means a barrier sufficient to attenuate scattered and leakage radiation for radiation protection purposes.~~

"Sensitivity profile" means the relative response of the CT x-ray system as a function of position along a line perpendicular to the tomographic plane.

"Shutter" means a device attached to the tube housing assembly that can intercept the entire cross sectional area of the useful beam and that has a lead equivalency not less than that of the tube housing assembly.

"SID". See "source-image receptor distance".

~~"Signal-to-noise ratio" (SNR) means the magnitude of the signal of interest compared to the magnitude of the noise of the background of that signal.~~

"Single tomogram system" means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

Commented [JJ94]: This definition is deleted - as it is not used in Part 6 or Part F.

Commented [JJ95]: This definition deleted from Part F.

Commented [JJ96]: While this definition appears in Part F it is not used consistently throughout the rule and is therefore deleted.

Commented [jsj97]: Definition updated, consistent with Part F, Section F.2.

Commented [JJ98]: Based on a Radiation Advisory Committee review and discussions a referential definition for "registered medical physicist" is added.

Commented [JJ99]: This definition is not used in the Part 6 or in Part F.

Commented [jsj100]: Definition added, consistent with Part F, Section F.2.
The definition is not new to Part F, and was previously omitted from Part 6. The term is used in the current Part 6.

Commented [jsj101]: Definition added, consistent with Part F, Section F.2.

The definition is not new to Part F, and was previously omitted from Part 6. The term is used in the current Part 6.

Commented [jsj102]: Definition added, consistent with Part F, Section F.2.
The definition is not new to Part F, and was previously omitted from Part 6. The term does appear in the current Part 6.

Commented [jsj103]: Definition is updated and simplified, consistent with the language of Part F, Section F.2. Direct scattered radiation is deleted consistent with deletion of this term in 6.2.

Commented [JJ104]: This definition is used only in the definition for primary barrier in the current Part 6 and is not in Part F and is therefore deleted.

Commented [jsj105]: Definition added, consistent with Part F, Section F.2.

While not used in the body of Part 6, this definition is used in the (proposed) definition of "Nominal tomographic section thickness".

Commented [JJ106]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

Commented [jsj107]: Definition added, consistent with Part F, Section F.2.

"**Size-specific dose estimate (SSDE)" means a patient dose estimate which takes into consideration corrections based on the size of the patient, using linear dimensions measured on the patient or patient images.**

~~"Solid state x-ray imaging device" means an assembly that intercepts x-ray photons and converts the photon energy into a modulated electronic signal representative of the x-ray intensity over the area of the imaging device.~~

"Source"~~, for an x-ray machine,~~ means the focal spot of the x-ray tube.

"Source-image receptor distance" (SID) means the distance from the source to the center of the input surface of the image receptor.

"Source-skin distance" (SSD) means the distance **from the source to the center of the entrant x-ray field in the plane tangent to the patient skin surface**~~between the source and the skin of the patient~~.

~~"Spot check" means a procedure that is performed to assure that a previous calibration continues to be valid.~~

"Spot image" means a radiograph that is made during a fluoroscopic examination to permanently record conditions that exist during that fluoroscopic procedure.

"Spot-image device" means a device intended to transport and/or position a radiographic image receptor ~~(for example, a film-screen cassette or a CR cassette)~~ between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of the fluoroscopic image receptor for the purpose of producing a radiograph. **A spot-film device is an older type of spot-image device.**

"SSD". See "source-skin distance".

~~"Standard breast" means a 4.2-cm-thick compressed breast consisting of fifty (50) percent glandular and fifty (50) percent adipose tissue.~~

"Stationary x-ray equipment". See "x-ray equipment".

"Stray radiation" means the sum of leakage and scattered radiation.

"**Substantial radiation dose level" (SRDL) means an appropriately-selected reference value used to trigger additional dose-management actions during a procedure and medical follow-up for a radiation level that might produce a clinically-relevant injury in an average patient. There is no implication that radiation levels above an SRDL will always cause an injury or that radiation levels below an SRDL will never cause an injury.**

"Technique factor" means an exposure control setting that specifies the peak tube potential in kV and

~~(1) Either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs; or~~

(~~2~~1) For capacitor energy storage equipment, quantity of charge in mAs; or

(~~3~~2) For field emission equipment rated for pulsed operation, number of x-ray pulses; or

(3) For CT systems designed for pulsed operation, scan time in seconds and either:

(a) Tube current in mA, x-ray pulse width in seconds and the number of x-ray pulses per scan; or

Commented [jsj108]: Definition added, consistent with Part F, Section F.2.

Commented [jsj109]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

Commented [jsj110]: Definition added, consistent with Part F, Section F.2.

Commented [JJ111]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

Commented [JJ112]: This definition is nearly identical to the Part F definition for "spot-film device". The current term "spot-image device" better reflects current technology and is retained from the current part 6. Statement regarding spot-film devices is added for clarity.

Commented [JJ113]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

Commented [JJ114]: Definition added, consistent with Part F, Section F.2., with the following exceptions:
(1) The original word "dose" is replaced with "reference value"; and
(2) Language clarifying that radiation levels above/below SRDLs do not necessarily implicate injury or lack of injury potential.
Both items are added for consistency with NRCP report 168 language and are based on stakeholder feedback/recommendations during stakeholder meetings/comments.

Commented [jsj115]: Definition updated, consistent with Part F, Section F.2.

Commented [jsj116]: This provision is retained, but is moved to item "(5)" of this list for consistency with the formatting of Part F.

(b) The product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(4) For CT systems **not designed for pulsed operation**, either:

(a) Tube current in mA and scan time in seconds; or

(b) The product of tube current and **exposure time in mAs and the scan time when the scan time and exposure time are equivalent** ~~rotation time in mAs, as modified to account for helical pitch.~~**; and**

(5) For all other equipment, either:

(a) Tube current in mA and exposure time in seconds; or

(b) The product of tube current and exposure time in mAs.

~~"Termination of irradiation" means the stopping of irradiation in a fashion that will not permit continuance of irradiation without the resetting of operating conditions at the control panel.~~

"The Report of AAPM Task Group 270" means the report on Display Quality Assurance issued by the American Association of Physicists in Medicine (AAPM), January 2019.

"Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

"Tomographic plane" means that geometric plane that is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

~~"Tomosynthesis" means to mathematically reconstruct a planar image using views acquired from multiple x-ray beam projection angles.~~

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed, including high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

~~"Tube rating chart" means the set of curves that specify the rated limits of operation of the tube in terms of the exposure settings. These curves are typically displayed on a graph.~~

"Useful beam" means the radiation ~~emanating from~~**which passes through** the tube housing port ~~or the radiation head and passing through~~**and** the aperture of the beam limiting device when the exposure **switch or timer is activated** ~~controls are in a mode to cause the system to produce radiation~~.

~~"Variable-aperture beam-limiting device" means a beam-limiting device that has capacity for stepless adjustment of the x-ray field size at a given SID.~~

"Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

"Volumetric dental imaging system" means an x-ray machine that produces, for oral and maxillofacial structures, a three-dimensional tomographic data set or a time sequence of three-dimensional tomographic data sets. A dental x-ray machine only capable of producing a two-dimensional image is not considered to be a volumetric dental imaging system.

Commented [JJ117]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

Commented [JJ118]: Report added at the recommendation of stakeholders. The report addresses evaluation of digital and similar imaging system displays not addressed in prior reports.

Commented [JJ119]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

Commented [jsj120]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

Commented [jsj121]: Definition is updated and simplified, consistent with Part F, Section F.2.

Commented [jsj122]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

~~"Wedge filter" means a filter that effects continuous change in transmission over all or a part of the useful beam.~~

"X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

"X-ray exposure control" means a device, switch, button or other similar means by which an operator initiates and/or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timers and back-up timers.

"X-ray equipment" means an x-ray system, subsystem, or component thereof. **Types of x-ray equipment are as follows:**

(1) "Mobile ~~or portable~~ x-ray equipment" means x-ray equipment **mounted on a permanent base with wheels or casters for moving while completely assembled;**~~that is designed to be transported from place to place.~~

~~(1)~~ **(2) "Portable x-ray equipment" means x-ray equipment designed to be hand-carried;**

~~(a) Mobile x-ray equipment is often mounted in a vehicle or on a permanent base with wheels and/or casters for moving while completely assembled.~~

~~(b) Portable x-ray equipment includes x-ray equipment that is designed to be hand-carried and hand-held during use.~~

(~~2~~**3**) "Stationary x-ray equipment" means x-ray equipment that is installed in a fixed location.

(4) "Hand-held x-ray equipment" means x-ray equipment that is designed to be hand-held during operation.

"X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the air kerma rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device that transforms electrical energy from the potential supplied by the x-ray exposure control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other elements.

~~"X-ray image processing system" means an assemblage of components for creating a visible or viewable image.~~

~~"X-ray imaging subsystem" means any combination of two or more components of an x-ray imaging system.~~

"X-ray imaging system" or "x-ray system" means an assemblage of components for the controlled production of x-rays.

(1) At a minimum, an x-ray imaging system includes an x-ray high-voltage generator, an x-ray exposure control, a tube housing assembly, a beam-limiting device, and necessary supporting structures.

(2) Additional components such as the image receptor(s) that function with the system are considered integral parts of the system.

Commented [JJ123]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

Commented [jsj124]: Definition is added, consistent with PART F, Section F.2.

The definition is not new to Part F, and was previously omitted from Part 6. The term does appear in the current Part 6.

Commented [jsj125]: Definition is updated, consistent with PART F, Section F.2.

Commented [jsj126]: This definition is deleted as it is not used in Part 6 nor is it found in Part F.

"X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor **or x-ray tube** during radiography and/or ~~above table~~ fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or **B**~~b~~ucky), cassette tunnel, fluoroscopic image receptor, or ~~spot-film~~**spot-image** device beneath the tabletop.

"X-ray tube" means any electron tube that is designed to be used primarily for the production of x-rays.

"X-ray system". See "x-ray imaging system".

GENERAL REGULATORY PROVISIONS

6.3 General **and administrative** ~~R~~**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 (~~July 1, 2009~~**April 1, 2014**).

(1) **Diagnostic** X-ray ~~imaging~~ 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**,** ~~(July 1, 2009~~**April 1, 2014**) shall be maintained in compliance with applicable requirements of **that standard**~~21 CFR 1020.30 through 1020.33 (July 1, 2009)~~.

(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.~~The owner shall keep a record of the date, service provider and details of each component or system modification.~~

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

Commented [JJ127]: Spot-film is changed to spot-image, which is believed to be more current terminology.

As discussed by stakeholders, and expressed in later sections of the rule, certain x-ray systems allow for positioning the image receptor and tube at 180 degrees opposite one another, typically with the table positioned between the patient and receptor or tube (except in a lateral position). Clarifying language is added to address other possible configurations.

Commented [jsj128]: Reference to federal rule date is updated. The 2014 edition of the CFR was the rule in effect at the time the Part F draft was finalized in 2015.

Commented [JJ129]: Language updated for consistency with Part F, Section F.4l.

Commented [JJ130]: F.4g

Commented [JJ131]: Language is updated, consistent with Part F, Section F.4h.ii.

Commented [JJ132]: This provision is not found in Part F, but is added to clarify that service companies will need to submit records of system modifications to the Department.

(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 shall direct operation of the x-ray imaging system(s) under the registrant's administrative control.~~

Commented [JJ133]: The requirements of this provision are deleted here and have been incorporated into 6.3.3.

~~6.3.1.4 The registrant or the registrant's agent shall assure that all applicable requirements of Parts 1, 2, 4, 6 and 10 are met in the operation of the x-ray imaging system(s).~~

Commented [JJ134]: The requirements of this provision are deleted here and have been incorporated into 6.3.3.

6.3.1.~~5~~**3** The registrant or the registrant's agent shall use approved providers of services, consistent with **Part 2, Section** 2.6.~~1~~, 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.~~6~~**4** ~~An x-ray imaging system that continues to be in noncompliance with a requirement of these regulationsshall not be used for any purpose unless such use or operationis explicitly authorized by the Department, for example, by correction in accordance with 2.6.3 and/or Form 59-1.~~**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:**

Commented [JJ135]: Based on stakeholder feedback indicating the language of the original provision was unclear, the language is revised. The intent of the provision is to clarify and allow the machine to be operated beyond the normal 30 day repair period despite having a non-critical compliance issue.

(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.~~7~~**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.

Commented [JJ136]: Wording is added, consistent with the Appendix 6D title.

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:

Commented [JJ137]: Based on stakeholder meeting discussions and comments, this section in revised from that originally proposed in Draft F. The purpose is to delineate requirements for those operating x-ray machines with and without supervision. The proposed language is also intended to allow other licensed, non-physician individuals to operate or supervise the operation of x-ray machines within the specified limitations and provided they meet the required training and qualifications.

Periodically, state regulatory bodies/agencies/boards may permit - through statutory, regulatory, or other mechanisms - certain licensed persons the ability to request or authorize x-ray based imaging, or may permit the actual use of x-ray machines by these licensed individuals.
Licensed entities are those individuals licensed through the Colorado Department of Regulatory Agencies.

(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.

6.3.1.7 Exposure under Part 6 of any human being to the useful beam of an x-ray system shall be solely for healing arts purposes 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.

6.3.1.8 The requirements of 6.3.1.7 specifically prohibits deliberate exposure for the following purposes:

(1) Exposure of an individual for training, demonstration or other non-healing-arts purposes; and

(2) Exposure of an individual for the purpose of healing arts screening except as authorized by the Department in accordance with Section 6.3.3.4

~~6.3.1.8 Use of a radiation machine in the healing arts shall be by or under the general supervision of a physician, chiropractor, dentist, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts.~~

6.3.1.9 Adequate Radiation Safety Training and Experience for a Radiation Machine Operator.

(1) Each individual who will be operating an x-ray imaging system shall:

(a) Be adequately instructed in the safe operating procedures;

(b) Be competent in the safe use of the equipment; and

(c) Meet each applicable ~~registration~~ requirement of **Part 2, Section** 2.6.1.

6.3.1.10 If radioactive materials are also present at the facility, the facility registrant shall coordinate, as appropriate, requirements under Part 6 with any related requirement of the **radioactive materials** license.

6.3.1.11 The registrant shall maintain for inspection, for each x-ray imaging system, the model and serial number of each tube housing assembly and control panel:

Commented [JJ138]: Relocated from 6.3.3.5 as suggested by stakeholders.

Provision is updated to address - in a more general manner - those additional types of practices/licensure whose licensing boards or bodies have authorized licensed individuals to request (but not necessarily use) radiation imaging.

For example, through the dental practice act (law), licensed dental hygienists are permitted to authorize (request) certain dental x-ray imaging activities, perform x-ray imaging, and are also authorized to interpret such images for diagnosis of dental hygiene-related conditions without supervision by a dentist.

Proposed language is Colorado specific and is a hybrid of the current Part 6 requirements and variation on the originally proposed language in the prior draft. The revised proposed language specifies the authorization for exposing a human to the licensed physician category but also allows authorization by other healing arts practitioners who are duly authorized by their respective statute/regulations/license/board/scope of practice to authorize such imaging. This section limits the topic to authorization for imaging, but not performing the actual imaging activity (e.g., operation of the x-ray machine).

Commented [JJ139]: The contents of this provision have been relocated from 6.3.3.5, based on stakeholder suggestions to consolidate requirements related to operation or supervision of others operating x-ray machines, and authorization for x-ray imaging studies.

Commented [jsj140]: The requirements of this provision have been incorporated into 6.3.1.6.

Commented [jsj141]: The phrase "radioactive materials" is added for clarity.

Commented [JJ142]: The requirements in this section have been relocated here from (prior) 6.3.2.5 with no changes.

(1) One unique identification number that designates the entire radiation machine shall be permanently assigned by the facility registrant to each radiation machine and provided in all correspondence with the Department.

(a) If feasible, the identification number shall be the "control serial number" in Item 4 on U.S. Food and Drug Administration (FDA) Form 2579, or equivalent.

(2) If available, the serial number(s) from the manufacturer shall be clearly visible as a label or stencil on the control panel and on the tube housing assembly.

(a) Each serial number shall be the same as the corresponding number found on FDA Form 2579, unless prior written approval is obtained from the Department.

(3) If either the control panel or the tube housing assembly serial number from the manufacturer is used as the one unique identification number that designates the entire radiation machine, and then subsequently the designated control panel or the tube housing assembly is replaced, the registrant shall assign a new unique identification number for the entire radiation machine and immediately provide that new number to the Department.

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

6.3.2.1 Evaluation of Shielding Design Prior to Commencement of Operation.

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

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

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

(a) Construction of a new facility;

(b) Any renovation or modification of an existing facility that has a potential to reduce the effectiveness of existing shielding from x-ray radiation; or

(c) Installation of a new radiation machine in an existing facility.

(4) A qualified expert who completes the shielding design required by 6.3.2.1(2) shall provide the shielding design to the facility registrant, including the annotated dimensional drawing specified by 6.3.2.3.

(a) The shielding design shall meet the requirements of Appendix 6C.

(5) The facility registrant shall construct the shielding and configure the equipment in accordance with the recommendation(s) provided by the qualified expert pursuant to 6.3.2.1(4).

Commented [JJ143]: Since this is the first occurrence of the use of FDA in Part 6, it is spelled out here.

6.3.2.2 Evaluation of Shielding Design After Commencement of Operations.

(1) A qualified expert shall review and modify **a** shielding design, consistent with 6.3.2.1 and Appendices 6A, 6B and 6C, whenever:

(a) A certification evaluation or a survey during operation shows that a dose in excess of a limit in Part 4 is possible;

(b) An existing facility is to be modified such that the existing shielding might be inadequate;

(c) The primary beam orientation is changed;

(d) The primary shielding is altered due to the modification or renovation of a facility;

(e) ~~Mobile or non-handheld portable x-ray equipment is used regularly in the same location;~~**Mobile or non-hand-held portable x-ray equipment is used frequently and regularly in the same area or room.**

Commented [JJ144]: Language is modified here for consistency with the proposed wording of 6.3.2.4.

(f) Radiation machine workload (for example, mA-minute-per-week workload) has increased or is projected to increase above that which was the basis for the original shielding design; or

(g) The registrant is unable to produce for inspection a written shielding design completed in accordance with 6.3.2.1 and/or 6.3.2.2.

(2) If qualified expert analysis of operating conditions required by 6.3.2.2(1) indicates that an individual might receive a dose in excess of the limits in **Part 4, Sections** 4.6, 4.12, 4.13, 4.14 or 4.15, then the facility registrant shall modify the shielding and/or equipment configuration in accordance with the recommendation(s) of the qualified expert.

6.3.2.3 ~~The registrant shall retain, for each room in which a stationary x-ray imaging system is located, a current dimensional drawing that includes indication of the:~~**Except for facilities exempted in 6.3.2.4, the registrant shall retain a copy of a current dimensional drawing for each room in which a stationary x-ray imaging system is located. The dimensional drawing shall include the following information:**

Commented [JJ145]: This provision is reworded for clarity.

(1) **Identification and use**~~Use~~ of each area adjacent to the **x-ray** room and an estimation of the extent of occupancy in each such area; and

Commented [JJ146]: This provision is reworded for clarity.

(2) Results **of calculations (as provided** by a qualified expert**)** ~~from calculation(s) for~~**indicating** the type and thickness of material(s) in each protective barrier (for example, lead equivalency):

Commented [JJ147]: This provision is reworded for clarity.

(a) After installation and, if possible, prior to commencement of operation, consistent with 6.3.2.1; and

(b) Whenever shielding is modified, consistent with 6.3.2.2.~~; and/or~~

(c) **Calculations should be performed prior to construction. When pre-construction calculations are not available, other methods must be used to verify the presence of any necessary shielding.**

Commented [JJ148]: A provision is added to clarify the requirements based on radiation advisory committee comments/discussions pertaining to whether the calculations are performed pre or post construction.
This provision is not found in Part F.

(3) If the registrant is unable to produce for inspection the calculation(s) required by 6.3.2.3(2), ~~results from~~ survey(s) **shall be** conducted by a qualified expert to determine radiation levels present under specified test conditions at the operator's position and at ~~cognizable~~**clearly identifiable** points outside the room.

(4) The registrant shall maintain for inspection, for each x-ray imaging system for which a shielding design is required:

(a) The installation as-built drawing(s); and

(b) The signed statement required by Part 2, Section 2.7.1.1 and retained in accord with Part 2, Section 2.4.1.1, that all floor plan and equipment configuration specifications in any applicable written shielding designs required by 6.3.2 were explicitly followed.

6.3.2.4 ~~A facility area is exempt from the requirements of 6.3.2.1 (and consequently exempt from 6.3.2.2 and 6.3.2.3) if:~~**A facility, or room within a facility, where x-ray imaging is conducted, is exempt from the requirements of 6.3.2.1, 6.3.2.2, and 6.3.2.3 under the following conditions:**

(1) Only dental intraoral**, hand-held intraoral**, dental panoramic, mini-c-arm or bone densitometry **x-ray** equipment is used in the area **or room**; **or**

(2) ~~Mobile or portable x-ray equipment is used infrequently not routinely in the same location; or~~**Mobile or portable x-ray equipment is used infrequently in the same area or room and the facility has established a written procedure or policy prescribing any limitations necessary to demonstrate that such use will preclude any individual from receiving a dose in excess of the public or occupational dose limits in Part 4 and that such use is consistent with the As Low As Reasonably Achievable (ALARA) concept of Part 4, Section 4.5.2; or**

(3) Exemption for a particular **area or room** ~~area or location~~ has been applied for in writing and granted by the Department.

6.3.2.5 ~~The registrant shall maintain for inspection, for each x-ray imaging system, the model and serial number of each tube housing assembly and control panel:~~

~~(1) One unique identification number that designates the entire radiation machine shall be permanently assigned by the facility registrant to each radiation machine and provided in all correspondence with the Department.~~

~~(a) If feasible, the identification number shall be the "control serial number" in Item 4 on FDA Form 2579, or equivalent.~~

~~(2) If available, the serial number(s) from the manufacturer shall be clearly visible as a label or stencil on the control panel and on the tube housing assembly.~~

~~(a) Each serial number shall be the same as the corresponding number found on FDA Form 2579, unless prior written approval is obtained from the Department.~~

~~(3) If either the control panel or the tube housing assembly serial number from the manufacturer is used as the one unique identification number that designates the entire radiation machine, and then subsequently the designated control panel or the tube housing assembly is replaced, the registrant shall assign a new unique~~

Commented [JJ149]: This provision is reworded for clarity.

Commented [JJ150]: The requirements of this section have been relocated from (prior) 6.3.2.6.

Commented [JJ151]: Wording in this provision is revised for clarity and consistency in terminology.

Commented [JJ152]: The proposed language clarifies that due to their low exposure potential, hand-held intraoral x-ray systems are categorically exempt from the shielding analysis consistent with the requirement for stationary intraoral systems.

Commented [JJ153]: Based on feedback from stakeholders, the proposed language requires the facility to establish a written procedure or policy that establishes limits or restrictions on use of portable/mobile systems to ensure dose limits and the ALARA concept is met.

Commented [JJ154]: This section is relocated to 6.3.1.9.

~~identification number for the entire radiation machine and immediately provide that new number to the Department.~~

~~6.3.2.6 The registrant shall maintain for inspection, for each x-ray imaging system for which a shielding design is required:~~

~~(1) The installation as-built drawing(s); and~~

~~(2) The signed statement required by 2.7.1.1 (without exception after June 30, 2010) and retained in accord with 2.4.1.1(4), that all floor plan and equipment 0configuration specifications in any applicable written shielding designs required by 6.3.2 were explicitly followed.~~

6.3.3 General Radiation Safety and Control of Radiation Exposure.

The registrant shall be responsible for directing the operation of the x-ray system(s) under their administrative control and shall assure that the requirements of Parts 1, 2, 4, 6 and 10 are met in the operation of the x-ray system(s).

6.3.3.1 Consistent with Part 4, Section 4.5.1 of the regulations, each facility registrant shall have a radiation protection program. In addition to the provisions necessary for compliance with Part 4, the radiation protection program shall include requirements that:

(1) The use of ionizing radiation be within the registrant's scope of practice for healing arts purposes and shall be performed in accordance with existing laws and regulations;

(2) Portable and mobile x-ray equipment requirements.

(a) Except for dental and veterinary use, portable or mobile x-ray equipment be used only:

(i) For examinations where it is impractical to transfer the patient to a stationary x-ray installation; or

(ii) When the medical status of the patient prohibits transfer of the patient to a stationary x-ray installation.

(b) Each facility develop a written procedure specific to the use of portable and mobile x-ray systems that prescribes the requirements necessary to limit an individual from receiving a dose in excess of the applicable public or occupational dose limits in Part 4 and that such use is consistent with the As Low As Reasonably Achievable (ALARA) concept in Part 4, Section 4.5.2.

(c) The Radiation Safety Officer shall review the implementation of portable or mobile x-ray equipment annually.

(3) Except for veterinary use, neither the x-ray tube housing nor the collimating device be held during an exposure with the exception of Department approved devices specifically designed to be hand-held during operation and in accordance with Appendix 6E.

(4) The useful x-ray beam be limited to the area of clinical interest.

(5) All x-ray equipment be installed by a registered service company except those systems that do not require a physical installation to become operational.

Commented [JJ155]: This section has been relocated to (new) 6.3.2.3(4).

Commented [JJ156]: This provision is relocated from (original) 6.3.1.3 and 6.3.1.4 and the language updated for consistency with Part F, Section F.3a.
Exemptions from some requirements as identified in F.3c are incorporated here for ease of use.

Commented [JJ157]: New provisions added, consistent with the contents of F, Section F.3a.i, with the following exceptions which are omitted from the proposed draft part 6:
1. Based on stakeholder feedback and comments during the early stakeholder process along with numerous technical challenges associated with implementation, the concept surrounding determination and reporting of "medical events" (as described in the model Part F rule), is excluded from the current proposed rule.

2. A provision in Part F (F.3a) requires the x-ray facility to have a mechanism in place for referring physicians to access information on selecting the most appropriate diagnostic procedure for the clinical question. The radiation program feels such a requirement may be difficult for facilities to implement as well as being difficult to enforce from a regulatory perspective. However, we understand that this may be a requirement of CMS (Centers for Medicare and Medicaid Services) in 2019 for facilities accepting CMS reimbursement.

Commented [JJ158]: Exception to the specified requirement from the language in Part F is given for dental and veterinary uses due to the increased use of x-ray units designed to be held during operation, and in particular in the field of dentistry. The requirement in this provision is intended to apply to uses of radiation machines on living humans primarily for radiation safety and image quality purposes. The exception for veterinary uses is provided since imaging may involve large animals that are not easily relocated or imaged in a fixed facility. Additional exceptions are allowed based on stakeholder feedback and medical need.

Commented [JJ159]: Added, consistent with Part F, Section F.3a.iv., with the following exception: clarifying language is added to address those types of x-ray units which do not require hardwiring or similar electrical or installation work before the x-ray system can be operated. Examples can include battery operated hand held systems or mobile/portable systems that require only a standard electrical outlet to be made operational.

(a) For those x-ray systems that do not require a physical installation to initially operate the machine, the facility registrant be responsible for submitting the information required by Part 2, Section 2.7.2.1 through 2.7.2.4 to the department. Such systems may include hand-held x-ray units and certain mobile or portable systems.

(6) All x-ray equipment be used in accordance with the equipment manufacturer's specifications, unless otherwise directed by the licensed practitioner authorized in 6.3.1.6(1) or (2).

(7) The registrant use auxiliary equipment designed to minimize human patient and personnel exposure commensurate with the needed diagnostic information.

The requirements of 6.3.3.1(8) and 6.3.3.1(9) are not applicable to veterinary facilities.

(8) Consideration be given to selecting the appropriate technique and employing available dose reduction methods and technologies across all patient sizes and clinical indications.

(9) A documented procedure be in place for verification of patient identity and exam to be performed, including identification of the appropriate body part.

6.3.3.~~1~~2 Written safety procedures shall be developed and provided for safe operation of each x-ray imaging system.

(1) The written safety procedures shall be readily available to each individual radiation machine operator prior to operating x-ray imaging equipment.

(2) The operator shall be able to demonstrate familiarity with the procedures applicable to safe use of the system being operated.

(3) The procedures shall include:

(a) Any restriction on **the operating** technique particular to the system, consistent with 6.3.3.~~2~~3;

(b) Limitation on beam size, to the smallest area that is clinically necessary, including appropriate collimation:

(i) For each tube with variable collimation, the collimation procedure shall specify whether positive beam limitation (PBL) or manual collimation shall be used; and

(ii) For tubes collimated manually, all images shall provide a positive indication of collimation, except ~~as provided by 6.10.2.3 or~~ when diagnosis might be compromised;

(c) Patient holding instructions consistent with 6.3.3.8.

(d) Requirements and limitations on the use of portable or mobile x-ray systems consistent with 6.3.3.1(2).

6.3.3.~~2~~3 To reduce radiation exposure to the minimum that is necessary~~, the registrant shall maintain a documented protocol for technique selection for each type of~~

Commented [JJ160]: There may be instances where the licensed and qualified healthcare provider authorized for use of the x-ray system may determine that use of the x-ray system beyond that specified by the manufacturer is appropriate for a specific clinical task.
This provision is not specified in Part F, but was suggested by stakeholders.

Commented [JJ161]: Added, consistent with Part F, Section F.3a.x.

Commented [JJ162]: For ease of use, this section header is added to group those provisions which are not applicable to veterinary use and in lieu of a stand- alone "exemption" section as found in F.3.c

Commented [JJ163]: Added, consistent with Part F, Section F.3a.xiv.

Commented [JJ164]: Added, consistent with Part F, Section F.3a.xv.
For clarity, ease of use, and based on stakeholder comment, the exception provided in Part F, Section F.3 is added here.

Commented [JJ165]: The requirements of this current provision parallel those of Part F, Section F.3a.xvii.

Commented [jsj166]: "operating" is added for consistency with Part F, Section F.3a.xvii.

Commented [JJ167]: Although not found in Part F, this provision is added to reinforce the procedural requirements specific to portable or mobile systems.

Commented [jsj168]: Language modified, consistent with Part F.3a.xvi.

For clarity, the first portion of the sentence pertaining to reducing radiation exposure is retained, although this language is not included in Part F. Retention of the original language helps explain the purpose of the requirement.

~~examination performed by each x-ray imaging system.~~ **for general radiographic systems not equipped or not used with an anatomic programming option, protocols shall be documented and readily available to the operator.**

(1) ~~A chart based on the~~**Written exam** protocol(s) shall be located near each system's control panel **or available to the operator in digital form**.

(a) The ~~chart~~**exam protocols** shall state the exposure settings to be used corresponding to the patient's **(adult and pediatric, if appropriate)** body part and anatomical size, or body part thickness, or age (for pediatrics), including but not limited to:

(**i**) **Technique factors (kVp, mAs if manual mode is used);**

(~~i~~**ii**) Type of image receptor to be used;

(~~iiii~~**iii**) Type **of grid, if any**~~and focal distance of the grid to be used, if any and if variable~~;

(~~iii~~**iv**) Source to image receptor distance to be used, except for intraoral radiography in accordance with ~~6.7.2.2(1)~~**6.7.2.3**;

~~(iv~~**v**~~) kVp;~~

(v) Mode of operation; and

~~(vi~~**vii**~~) mAs, if manual mode is used; and~~

~~(b)~~**(vi)** Type and location of placement of patient shielding ~~(for example, gonad or thyroid shielding) to be~~ **if** used.

~~(2) The requirement of 6.3.3.2(1)(a) is considered met if anatomically programmable controls are used.~~

(**2**~~3~~) For computed and digital radiography, the ~~chart~~**exam protocols** required by ~~6.3.3.2(1)~~**6.3.3.3(1)** shall:

(a) Portray how to determine applicable exposure settings in accord with documented protocol;

(b) Specify a control range for the exposure indicator in accordance with the manufacturer's **or RMP** recommendation; and

(c) Specify pediatric protocol for each unit that images pediatric patients.

(**4**~~3~~) The settings to be used during an exposure shall be indicated before the exposure begins.

(a) If automatic exposure controls are used, the exposure settings that are set prior to the exposure shall be indicated.

(b) The requirement of ~~6.3.3.2(4)~~**6.3.3.3(3)** may be met by permanent markings on equipment having fixed exposure settings.

(~~5~~**4**) The ~~chart~~**exam protocol** shall be revised as necessary whenever a ~~certified~~ component is replaced or added.

Commented [JJ169]: Based on x-ray staff recommendations, references to "charts" is replaced by "exam protocols" since the information may not necessarily be in the form of a chart.

Since most systems are now digital and/or digitally controlled, written procedures and protocols are often maintained in digital formats on network systems accessible to the operator. This language is added for clarity but is not found in Part F.

Commented [jsj170]: Language updated, consistent with Part F.3a.xvi(2).

Commented [JJ171]: Updated/simplified language, consistent with Part F, Section F.3a.xvi.

Commented [JJ172]: Based on x-ray staff recommendations, references to the "charts" is replaced by "exam protocols" since the information may not necessarily be in the form of a chart.

Based on stakeholder feedback, language is modified to allow for consideration of registered medical physicist recommendations as an alternative to those of the manufacturer, with regard to the control range for the exposure indicator.

~~6.3.3.3 Exposure under Part 6 of any human being to the useful beam shall be solely for healing arts purposes and only after such exposure has been authorized by a physician, chiropractor, dentist, or podiatrist who has a current active State of Colorado license and has met all applicable requirements of Part 2.~~

Commented [JJ173]: The requirements of this provision have been relocated to 6.3.1.7.

~~(1) Deliberate exposure of an human being for training, demonstration or other non-healing-arts purposes is strictly prohibited; and~~

Commented [JJ174]: The requirements of this provision have been relocated to 6.3.1.8, based on stakeholder discussions.

~~(2)~~

6.3.3.4 Healing Arts Screening.

Commented [JJ175]: Language updated, consistent with Part F, Section F.3a.xxii.

Certain language specific to Colorado's registration process for healing arts screening is retained.

(1) Any person proposing to conduct a healing arts screening program on living humans shall not initiate such a program without prior approval of the Department. Authorization for healing arts screening may be granted by the Department provided the registrant demonstrates that such healing arts screening will not result in undue risk.

(a) Each healing arts screening program shall obtain prior written approval by the Department.

(b) Each applicant for Department approval of a healing arts screening program shall submit to the Department a completed Form R-300, "Application for Registration – Healing Arts Screening," including as provided in **Part 2, Section** 2.4.1.2 all of the information required by Appendix 6F and/or by Form R-300 and any accompanying instructions, together with the required fee(s).

(c) ~~The Department shall be notified immediately if any information submitted to the Department becomes invalid or outdated.~~**The registrant shall immediately notify the Department if any information related to the healing arts screening program previously submitted to the Department becomes invalid or outdated.**

Commented [JJ176]: Language is not specific to Part F but is updated for clarity.

(~~3~~2) FDA/MQSA-certified facilities that are registered with the ~~D~~department for the use of dedicated mammographic equipment for mammography screening are approved for mammography screening only and are considered to have met **the healing arts screening requirements of ~~6.3.3.3(2)~~6.3.3.4(1)**.

Commented [JJ177]: Language is not found in Part F but is updated for clarity.

6.3.3.~~4~~**5** ~~Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic or fluoroscopic exposure.~~**When imaging human patients, the registrant shall restrict the presence of individuals in the immediate area of the patient being examined to those required or in training for the medical procedure, or the parent or guardian of a patient – while the x-ray tube is energized. The following applies to all individuals, other than the patient being examined:**

Commented [jsj178]: Language updated consistent with Part F, Section F.3a.xviii, and the exception in F.3c.iii.

Although veterinary use is excluded from this requirement, section 6.8 (veterinary uses) provides veterinary specific protection requirements.

(1) All persons shall be positioned such that no part of the body will be struck by the useful beam unless protected by at least 0.5 millimeter lead equivalent material except where the radiation safety officer has determined that use of protective equipment is not in the best interest of radiation safety for the patient or individuals in the immediate area.

Commented [jsj179]: Language added/updated consistent with Part F, Section F.3a.xviii(1), with the exception that based on stakeholder feedback, language is proposed to allow for exceptions to use of protective equipment where such shielding may be contraindicated from a radiation safety perspective.

Some medical procedures may require the physician/operators hands to be exposed to the useful beam. Technical studies and stakeholders have indicated that use of lead-equivalent gloves in such instances can result in increased radiation (skin) dose to the patient due to automatic exposure controls on the x-ray system.

(2) All persons shall be protected from scatter radiation by protective garments, safety equipment or whole body protective barriers of at least 0.25 millimeter lead equivalent material except where the radiation safety officer has determined that use of protective equipment is not in the best

Commented [jsj180]: Language added/updated consistent with Part F, Section F.3a.xviii(2), with the exception that "scatter" is used instead of "secondary" for consistency with definition(s) in 6.2. Similar exception language found in 6.3.3.7(1) is also added here.

interest of radiation safety for the patient or individuals in the immediate area.

(3) Instances may warrant having human patients other than the one being examined in the room during the exam.

(a) If the procedure results in scatter radiation in excess of 0.02 mSv (2 mR) in any one hour at the position of these non-imaged patients, they shall be protected from the scatter radiation by whole body protective barriers or apparel of at least 0.25 millimeter lead equivalent material or shall be positioned so that the 0.02 mSv (2 mR) in any one hour limit is met.

6.3.3.~~5~~6 Each facility shall have **a sufficient number of lead equivalent protective apparel, equipment** ~~protective aprons and gloves~~ **and shields** available ~~in sufficient numbers~~ to provide **the necessary radiation** protection to all individuals who are involved with x-ray operations and who are otherwise not shielded.

(1) All protective apparel and auxiliary shields shall be evaluated annually for integrity.
Registrants shall establish a written procedure and criteria for the integrity evaluation and shall:

(a) Visually inspect the protective apparel and shields for breaks, tears or holes that would significantly compromise the protective capability of the equipment;

(b) Perform a tactile test by placing the protective apparel on a smooth surface and feeling for broken or missing shield material.

(2) Protective garments and shields shall be:

(a) Clearly labeled with their lead equivalence;

(b) Hung and not folded to prevent damage, as applicable.

(3) If results of the integrity test indicate breaks, tears, holes, missing material or gaps in that would significantly compromise the protective capability of the material, the protective apparel shall be:

(a) Removed from service and marked as such; or

(b) Repaired or replaced as required.

(4) Records of the integrity check required by 6.3.3.6 shall be maintained by the registrant for 3 years after the integrity checks are completed.

6.3.3.~~6~~7 ~~To reduce direct radiation exposure, individual shielding shall be provided for all modalities (except for a case in which shielding would interfere with the gonad, thyroid, dental or other diagnostic procedure).~~**Beam collimation, positioning, and shielding of radiosensitive organs that will not interfere with the imaging or medical procedure shall be used to reduce radiation exposure to the patient whenever possible.**

Commented [jsj181]: Language added/updated consistent with Part F, Section F.3a.xviii(3), with the exception that clarifying wording added.

Commented [jsj182]: Language added, consistent with Part F, Section F.3a.vi., with the exception of retaining the language from the current Part 6 that pertains to the protection of "all individuals". (Part F uses the terms "patients and personnel", which could exclude other persons who, to the benefit of the patient, may be needed to assist in the imaging process such as parents, pet guardians, etc.).

Commented [JJ183]: The general requirement for annual protective apparel inspection is added, consistent with Part F, Section F.3a.vii.

Since Part F does not specify the requirements or process of inspection or the response when damage is discovered, proposed requirements are incorporated into this section.

The proposed criteria and process is based on information in EPA Federal Guidance Report No. 14 and review of other technical documents/papers.

Commented [JJ184]: Provision (b) is added, consistent with recommendation on storing lead equivalent garments/equipment.

Commented [JJ185]: In order to allow more flexibility by the facility/registrant, the proposed requirement allows some judgement and flexibility with regard to replacing damaged equipment out of service or having it repaired.
The adjusted language is based on stakeholder feedback.

This is not a Part F provision, but was added as described in a side margin note above.

Commented [JJ186]: A provision is proposed to maintain a record of the garment check. Such record need not be overly complex and is necessary to demonstrate compliance.

Commented [JJ187]: This provision/language as found in the current Part 6 rule does not appear in Part F and is therefore deleted and replaced with language based on stakeholder feedback and discussions.

Technical guidance documents have mixed recommendations with regard to recommending or not recommending use of shielding for patients during patient exams.

Provisions (3) and (4) in section 6.3.3.7 have been replaced by similar requirements in 6.3.3.8, and 6.3.3.5(1), consistent with Part F.

~~(1) For a human patient who has not passed beyond the reproductive age, during radiographic procedures in which the gonads are in the useful beam, gonad shielding of not less than 0.5 millimeter lead equivalent shall be used.~~

~~(2) For a human patient during all radiographic procedures in which the thyroid is in the useful beam, thyroid shielding of not less than 0.25 millimeter lead equivalent shall be used.~~

~~(3) In a case where the patient must hold the image receptor (except during an intraoral dental examination), any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.~~

~~(4) Each individual other than the patient being examined shall be positioned such that no part of the body will be struck by the useful beam unless protected by a minimum of 0.5 millimeter lead equivalent.~~

~~6.3.3.7 To reduce scatter radiation exposure, individual shielding shall be provided as follows:~~

Commented [JJ188]: Deleted due to overlap with (new) 6.3.3.5.

~~(1) The operator, other staff and ancillary personnel, and each other individual required for the medical procedure or who cannot be removed from the room, shall be protected from direct scatter radiation:~~

~~(a) By a protective apron or whole body protective barrier of not less than 0.25 millimeter lead equivalent; and/or~~

~~(b) Shall be so positioned that the nearest portion of the body is at least a distance of 2 meters (more than 6 feet) from the:~~

~~(i) Tube head; and~~

~~(ii) Nearest edge of the image receptor; and~~

~~(iii) Patient;~~

~~(c) Except that protective positioning shall be as determined by the operator of a mini-c-arm x-ray system or a portable hand-held x-ray device (as provided in Appendix 6E).~~

Commented [JJ189]: Deleted per recommendation of x-ray staff.

6.3.3.8 **In cases where a patient or image receptor requires additional support, mechanical support devices shall be used whenever possible.** ~~When~~**If** a patient or image receptor must be provided with ~~auxiliary~~**additional** support during a radiation exposure:

~~(1) Mechanical holding devices shall be used when the technique permits; and~~

Commented [jsj190]: This provision is deleted as the requirement has been incorporated into (new) 6.3.3.8 (above).

~~(2)~~ ~~The w~~**W**ritten safety procedures**, as** required by ~~6.3.3.1~~**6.3.3.2,** shall **indicate the requirements for selecting a human holder and the procedure the human holder shall follow.**~~:~~

Commented [JJ191]: Language added/updated consistent with Part F, Section F.3a.xx(1).

Part F does not contain the word “human” and is added for clarity.

~~(a) Indicate the requirements for selecting a holder and the procedure the holder shall follow; and~~

~~(b) Expressly limit routine use of personnel who are subject to the occupational dose limits in 4.6 for holding a patient solely to immobilize the patient during radiographic examinations; and~~

~~(3)~~2) The human holder shall be instructed in personal radiation safety and protected as required by ~~6.3.3~~**6.3.3.2**;

~~(4)~~3) No individual shall be used routinely to hold **the** image receptor~~s~~ or patients **during a radiation exposure**.

(4) In those cases where the patient must hold the image receptor, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by at least 0.5 millimeter lead equivalent material except where use of protective equipment would interfere with the examination or is contraindicated for radiation safety reasons.

~~6.3.3.9 Image processing procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.~~

6.3.3.9~~(1)~~ The speed of film, or film-screen combination, imaging plate or receptor and image processing, shall be the fastest speed or speed equivalent consistent with the diagnostic objective of the examinations.

~~(2) X-ray systems subject to 6.6 shall not be utilized in procedures where the source to patient distance is less than 30 cm, except for veterinary systems.~~

6.3.3.10~~(3)~~ If anti-scatter grids are used between the patient and the image receptor to decrease scattered radiation to the ~~film~~**image receptor** and improve contrast, the grid shall be:

~~(a)~~**(1)** Positioned properly, with the tube side facing the correct direction, and centered to the central ray; and

~~(b)~~**(2)** Of the proper focal distance for the SID being used.

6.3.3.~~10~~**11** **When individual exposure monitoring is required by Part 4, Section 4.18,** ~~Each~~**each occupationally exposed** individual who is associated with the operation of an x-ray imaging system shall meet the requirements of **Part 4, Sections** 4.6, 4.10, 4.12, 4.13, 4.14, and 4.18.

(1) When personnel dosimetric monitoring devices are required, they shall be worn in accordance with **Part 4, Section** 4.6.3.

(2) Each operator of ~~portable~~ hand-held x-ray equipment shall **follow the requirements of Appendix 6E regarding personnel monitoring devices**~~wear whole body and extremity personnel dosimetric monitoring devices.~~

(3) Deliberate exposure of a personnel dosimetric monitoring device to deceptively indicate a dose delivered to an individual is ~~strictly~~ prohibited.

6.3.4 ~~Measurements,~~ Maintenance **of**~~, and~~ Records.

6.3.4.1 The registrant shall maintain **the following information on each x-ray system** for inspection by the Department **as specified below:**~~records for the previous three (3) years of~~

(1) The records in (a) through (d) are required to be retained for 3 years:

Commented [JJ192]: F.3a.xx(2).

Commented [JJ193]: Language added/updated consistent with Part F, Section F.3a.xx(3).

Commented [JJ194]: Language added/updated consistent with Part F, Section F.3a.xx(4), with the exception that flexibility is allowed when contraindicated for medical or radiation safety reasons.

Commented [jsj195]: The requirements of this provision have been incorporated into 6.3.3.1(7).

Commented [JJ196]: Provision retained as a good radiation safety practice based on stakeholder feedback.
There is not an equivalent provision in Part F.

Commented [jsj197]: The equivalent provision in Part F was removed (from F.3a.ix(4)) during the 2015 revision to Part F and is therefore removed here. However, a similar requirement is found in the general ragiographic machine section at 6.3.3.9(2).

Commented [jsj198]: Based on stakeholder feedback, a modified provision is retained as a good radiation safety practice despite a similar provision being removed from Part F.

Commented [jsj199]: Although provisions of (1), (2), and (3) of 6.3.3.11 do not appear in Part F, the Radiation Program believes they add clarity to the rule.

The word “strictly” is removed as it adds no regulatory benefit.

Commented [JJ200]: Language modified to consolidate the requirements for hand-held units to Appendix 6E.

Commented [jsj201]: Language updated, partially consistent with Part F in F.3.xxiii. The record retention time period was retained at 3 years rather than the 5 years as specified in Part F, as the department has not seen issues with the current shorter retention time.

(a) Records of surveys ~~measurements~~, calibrations, maintenance, **and** modifications **(e.g., major software and hardware upgrades) performed on the x-ray system(s);**

(b) Records of ~~,~~ certification evaluations pursuant to 2.5, Department Forms 59-1 and 59-2, and corrective actions for each x-ray imaging system with the names of persons who performed such services ~~.~~**;**

(c) A copy of all correspondence with the Department regarding the x-ray system.

(d) Each facility shall maintain a printed or electronic record containing each patient's identifier, the type of examination(s), machine operator identifier, and the date(s) the examination(s) were performed.

The records in (2) are required to be retained for the life of the system:

(2) Model and serial numbers of all major components, and user's manuals for those components, including software.

The records in (3) and (4) are required to be retained for the life of the facility:

(3) ~~**(a)**~~ ~~6.3.4.2 The registrant shall retain a~~ **The most recent** dimensional drawing and accompanying calculation(s) and/or survey(s) as provided in 6.3.2.3 for each room in which a stationary x-ray system is located, except as exempted under 6.3.2.4.

(4) ~~**(b)**~~ ~~6.3.4.3~~ Consistent with **Part 2, Section** 2.4.1**,** and 6.3.2, the registrant shall retain on file at the facility ~~for the life of the facility each~~**the most recent** shielding design along with installer as-built drawings.

~~6.3.4.4 Each facility shall have available a printed or electronic record containing each patient's name, the type of examination(s), and the date(s) the examination(s) were performed.~~

6.3.5 Quality Assurance (QA) Program.

6.3.5.1 The registrant shall establish and maintain a quality assurance (QA) program. In addition to the standards in the modality specific sections of Part 6, the registrant shall:

(1) Maintain documentation of credentials for practitioners, radiation safety officers, and x-ray operators, as required by Part 2 of the regulations.

(2) Designate an appropriately trained individual to manage the QA program.

(3) Establish and maintain written QA and quality control (QC) procedures, including evaluation frequencies and tolerances or use standards of an appropriate nationally recognized organization, for example, the American College of Radiology or American Association of Physicists in Medicine.

(4) Evaluate image quality by checking each imaging study for artifacts. If an artifact impacting image interpretation or indicating an imaging system problem is present, the source shall be identified and appropriate action taken.

Commented [jsj202]: This provision is specific to CO and is needed for business purposes and is not found in Part F.

Commented [JJ203]: This provision is relocated from (original) 6.3.4.4 below. The provision incorporates updated language consistent with Part F, Section F.3a.xiv. Additionally, this adds a recordkeeping timeframe that was not previously specified.

Commented [JJ204]: Consistent with Part F, the record retention period is made for the life of the system rather than the facility life.

Commented [JJ205]: Language added due to changes in wording in the earlier provision relating to retention of user manuals, etc.

Dimensional drawings and shielding analysis are needed to be retained for the life of the facility in the event they would need to be evaluated following an over exposure.

Commented [jsj206]: This provision is specific to Colorado and is not found in Part F. Based on stakeholder comment, language clarified to include only the most recent dimensional drawing and not all drawings.

Commented [jsj207]: This provision is specific to Colorado and is not found in Part F. Based on stakeholder comment, language clarified to include only the most recent shield design.

Commented [JJ208]: The requirements of this provision have been incorporated into 6.3.4.1(1)(d) above.

Commented [jsj209]: New section added, consistent with Part F, Section F.3b.

The added section provides for broad, generic QA requirements.

Commented [JJ210]: The requirements/language associated with using standards of ACR or AAPM is relocated here from original section 6.3.5.1.

Commented [jsj211]: The word "imaging" is added for clarity. Stakeholders have indicated that it is common for images to have some type of artifact, most of which are of no significance. The added language requires only those artifacts of clinical significance be acted upon.

(5) With the exception of Dental facilities performing only intra-oral, panoramic, cephalometric or volumetric dental imaging, Podiatry facilities, and Veterinary facilities, perform repeat / reject analysis of radiographic images at least quarterly following specifications of a nationally recognized organization.

(6) Perform periodic preventative maintenance on the x-ray systems in accordance with manufacturer requirements or those of nationally accepted standards.

(7) Maintain documentation showing the calibration date and serial number for testing instruments used in determining compliance with the provisions of section 6.3.5. Test instrument calibration frequency shall be consistent with the regulations or nationally accepted standards.

(8) Complete and document an annual review of the QA program.

(9) Retain QA/QC records of evaluations and reviews for no less than three years.

(10) Follow manufacturer's recommendations for image processing systems, except where otherwise specified in the regulations or where it is inconsistent with nationally accepted standards.

~~6.3.5.1 To avoid unnecessary or duplicative radiation exposures, each human use facility shall have an active image processing quality control and quality assurance (QA) program that follows manufacturers' specifications and/or the standards of an appropriate nationally recognized organization, for example, the American College of Radiology or American Association of Physicists in Medicine.~~

~~6.3.5.2 Each registrant that uses a hard copy imaging system with transmission viewing, whether with or without liquid chemistry, shall document that quality control and quality assurance have been performed according to specifications of the manufacturer or a registered medical physicist and/or a nationally recognized organization, including:~~

~~(1) Periodic printing of a sensitometric strip or pattern;~~

~~(2) Documentation of low, medium and high density calibration and that any calibration which failed to meet a manufacturer's specification was corrected before the image printer was used to print another image; and~~

~~(3) Annual review of all quality control tests.~~

~~6.3.5.3 Each registrant that uses an automatic film processor shall adopt an acceptable sensitometric quality control program.~~

~~(1) Film processors used to develop radiographs shall be adjusted and maintained to meet the technical development specifications for the radiography film in use.~~

~~(2) For all x-ray imaging systems, a continuous and documented sensitometric quality control program, including quality control tests for speed, contrast and fog, shall be performed according to specifications of the manufacturer and/or a registered medical physicist and/or a nationally recognized organization.~~

Commented [JJ212]: F.3b.i(5).

Commented [JJ213]: Based on stakeholder feedback, this provision is modified from Part F, Section F.3b.i(5) to defer to the manufacturer or nationally accepted standards for the frequency of the maintenance, consistent with other wording in the proposed rule. Part F requires a minimum 12 month frequency.

Commented [JJ214]: Based on stakeholder feedback, this provision is modified from Part F. Facilities may not own their own testing equipment and instead rely upon contractors, manufacturers, or service providers to perform certain x-ray system tests. It may be unreasonable for facilities to maintain calibration and similar records owned by other entities. The revised provision instead specifies that the facility ensure that system testing documentation shows the calibration date and serial number of test equipment. Should additional documentation be needed, this approach will allow tracing back to the providers instrument.

Commented [JJ215]: For clarity, the specific section reference is added.

Commented [JJ216]: Provision is added at the recommendation of x-ray staff.

Language rephrased to fit format of section and, based on stakeholder comment, an allowance is made to alternately defer to nationally accepted standards.

Commented [JJ217]: Requirements of original provision of 6.3.5.1 are rolled into (new section) 6.3.5.1.

Commented [JJ218]: The requirements in this provision are addressed in other areas of 6.3.

Commented [JJ219]: The requirements applicable to automatic film processing have been relocated to 6.3.5.2 for consistency with the formatting of Part F.

Commented [JJ220]: Deleted due to redundancy with (new) 6.3.5.2.

Commented [JJ221]: Deleted due to redundancy with 6.3.5.5

6.3.5.~~4~~2 Each registrant that uses **analog image receptors (e.g., radiographic film)** ~~a manual film process~~ shall **have available suitable equipment for handling and processing radiographic film in accordance with the following provisions**:

Manually developed film:

(1) **Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and**

(2) Developing solutions shall be prepared, replenished, and replaced following manufacturer recommendations.

(3) The temperature of solutions in the tanks shall be maintained within the range of 60° F to 80° F (16° C to 27° C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or ~~Follow applicable manufacturer's development time and temperature specifications, which shall be available for review.~~ **in the absence of such recommendations, use the time-temperature chart found in Appendix 6H**;

(4) Devices shall be utilized which will indicate the actual temperature of the developer solution and signal the passage of a preset time.

(~~5~~) Measure and log developer~~ment~~ temperature each day of use; ~~and~~

(~~6~~) Document in a written log the change of developer chemicals at least every month.

Automatic processors and other closed processing systems:

(7) Shall be operated and maintained following manufacturer specifications.

(8) Films shall be developed in accordance with the time temperature relationships recommended by the film manufacturer. In the absence of such recommendations, the film shall be developed using the chart in Appendix 6G.

6.3.5.3 Deviations from the processing requirements of 6.3.5.2 shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).

~~6.3.5.5 The registrant shall control darkroom lighting such that:~~

~~(1) Exposure of a film to the darkroom safelight for one minute does not increase the optical density of that film by more than 0.1 optical density units when the test film has a latent image sufficient to produce a density between 1.0 and 2.0 optical density units prior to safe light exposure.~~

~~(2) If used, daylight film handling boxes preclude fogging of the film.~~

~~(3) The base plus fog of an unexposed film does not exceed 0.25 optical density units when developed by the routine procedure used by the facility.~~

6.3.5.~~6~~4 **Additional requirements for facilities using x-ray film**

(1) All film storage **and**~~, including~~ pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

Commented [JJ222]: Language amended, consistent with Part F, F3.b.ii content and formatting.

Commented [jsj223]: Added, consistent with Part F, F3.b.ii.(1)(a)

Commented [JJ224]: Added, consistent with Part F, F3.b.ii.(1)(b)

Commented [jsj225]: Language updated, consistent with Part F, F3.b.ii.(1)(c), with the exception that some phrasing is modified for clarity.

Commented [JJ226]: Added, consistent with Part F, F3.b.ii.(1)(d)

Commented [JJ227]: This provision does not appear in Part F, but is retained as a best practice for facilities using manual film developing.

Commented [JJ228]: This provision does not appear in Part F, but is retained as a best practice for facilities using manual film developing.

Commented [JJ229]: Language adopted from Part F (F3b.ii)

Commented [JJ230]: Added, consistent with Part F, F3.b.ii.(2)(b).

Commented [jsj231]: Added, consistent with Part F, F3b.ii.(3).

Commented [JJ232]: Provision deleted due to redundancy with requirements of 6.3.5.5.

Commented [jsj233]: Section title added consistent with Part F3.b.iii.

The department recognizes that most facilities have transitioned to using all digital (non-film) systems for which the requirements of this section would not apply. However, a number of facilities continue to use standard x-ray film and chemical development processes. The intent of the added provisions is to help ensure that the standard films continue to be handled and processed in a manner that will ensure high quality images and avoid unnecessary radiation exposures within the limitations of the system in use.

(2) Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

(3) Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

(4) Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary.

(5) Outdated x-ray film shall not be used.

(6) The film and intensifying screen shall be spectrally compatible.

(7) Facilities shall maintain a light-tight darkroom or closed processing system, use proper safelighting and safeguards, and evaluate darkroom integrity and daylight loading systems for film fog every six months and after a change that may impact film fog or an event that may impact the integrity of the closed processing system.

(8) Facilities other than dental, podiatry, and veterinary shall:

(a) Have a continuous and documented sensitometric quality control program, including quality control tests for speed, contrast and fog. These tests shall be performed according to specifications of the manufacturer, an RMP, or a nationally recognized organization.

(b) Maintain a light-tight darkroom or processing system and use proper safelighting and safeguards such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in optical density greater than 0.1 when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

(c) Limit the base plus fog of unexposed film to an optical density less than 0.25 when developed by the routine procedure used by the facility.

6.3.5.5 Facilities Using Computed Radiography (CR), Digital Radiography (DR), or Direct Digital Radiography (DDR).

(1) Facilities shall establish and follow an image quality control program in accord with the recommendations of an RMP, the system manufacturer, or a nationally recognized organization.

(2) In addition to 6.3.5.5(1), CR facilities shall perform erasure of all CR cassettes, at least on a weekly basis.

6.3.5.~~7~~6 The registrant shall ensure that each monitor **under the control of the registered facility** used for primary image interpretation is evaluated according to specifications of the manufacturer and/or a registered medical physicist and/or a nationally recognized organization, for example, in **The Report of AAPM Task**

Commented [jsj234]: Provisions 6.3.5.4(2) through (5) are added, consistent with updates to F3.b.iii(2) through (5).

Commented [jsj235]: Provisions 6.3.5.4(6) and (7) are new to Part F and are added consistent with F3.b.iii(6), and (7)).

Commented [jsj236]: Provision 8 (and subsections) are new to Part F and are added consistent with (F.3b.iii(8)).

Commented [JJ237]: The phrasing “or processing system” is not found in Part F but is added based on stakeholder comments which indicated that closed processing systems used in lieu of a darkroom should also be maintained light tight.

Commented [jsj238]: This provision is new to Part F and is added consistent with (F3.b.iv), with the exception that a an originally proposed requirement from the Part F model rule for tracking of exposure indicators at all facilities is excluded due to concerns with facilities not being able to meet the requirement without a data management system other software. This was not an explicit requirement in EPA FGR#14, but a recommendation. The term “Digital Radiography” is added.

Commented [JJ239]: Although requirements are based on national standards, the language of this provision is specific to Colorado and therefore does not appear in Part F.

These requirements have been in place for a number of years and are intended to ensure high quality images on imaging and interpretation monitoring systems.
Clarifying language added to address those monitors that are within the control of the registered facility.

Commented [JJ240]: This recent report of this task group is added at the recommendation of stakeholders. As it is possible some older CRT systems may still be in use, the older standard is retained as an example reference.

Group 270 (January 2019), or AAPM Online Report OR-03 (April 2005), including but not limited to:

(1) Frequent careful cleaning of each primary image interpretation workstation and data acquisition workstation monitor;

(2) ~~Periodic visual assessment of Society of Motion Picture and Television Engineers (SMPTE) Pattern or equivalent test pattern~~**Periodic visual assessment using nationally accepted test patterns appropriate for the evaluation**;

(3) ~~Initial and annual v~~**V**erification that monitor calibration conforms with the DICOM Part 14 Grayscale Standard Display Function ~~(see AAPM Online Report OR-03)~~, or equivalent:

(a) Visualization of low contrast patches;

(b) Visualization of spatial resolution targets;

(c) ~~Measurement~~**Evaluation** of ambient light levels;

(d) Measurement of the luminance from a sufficient number of driving levels;

(e) Measurements to assure that the luminance for multiple monitors are within **10%**~~5%~~ of each other when more than one monitor is being utilized at a primary image interpretation workstation.

(4) The requirements of 6.3.5.6(1) through (3) must be completed initially, annually, and when a monitor is replaced or undergoes a significant repair.

(5) For monitors used in mammography image interpretation, the applicable monitor QA requirements of MQSA shall be followed.

~~6.3.5.8 The registrant shall ensure that computed and digital radiography cassettes and cassette readers used for primary image interpretation are evaluated periodically according to specifications of the manufacturer and/or a registered medical physicist and/or a nationally recognized organization, for example, in AAPM Report 93, in a program reviewed annually by a registered medical physicist.~~

~~6.3.5.9 Special requirement for viewboxes and lighting in mammography.~~

~~(1) A viewbox used for clinical quality review and interpreting mammograms shall be capable of producing a luminance of at least 3,000 candela per square meter (cd·m^{-2}).~~

~~(2) The registrant shall make special lights for film illumination (that is, hot lights), capable of producing light levels greater than that provided by the view box, available to the interpreting physician.~~

6.4 ~~Requirements for Safe Use of a Diagnostic X-ray Imaging System of Any Kind.~~Requirements for use of all diagnostic and interventional x-ray imaging systems.

6.4.1 Administrative Controls.

Commented [JJ241]: Based on stakeholder comments, language is modified to include other test patterns that are nationally accepted as the SMPTE test pattern may not be appropriate for all testing applications.

Commented [JJ242]: Reference to this report is deleted here since it is referenced earlier in this section.

Commented [JJ243]: As recommended by stakeholders and consistent with the AAPM report identified in 6.3.5.6(3) above, value is changed to 10 %.

Commented [JJ244]: The frequency of monitor quality control requirements are relocated to a stand-alone provision for clarity. At the recommendation of the Colorado Radiation Advisory Committee, monitor cleaning and testing is also specified when the monitor is replaced or undergoes a significant repair.

Commented [JJ245]: This provision is added based on internal review, as mammography monitors have specific requirements.

6.4.1.1 In addition to the general requirements of 6.3, the requirements of 6.4 apply to all diagnostic **and interventional** x-ray imaging **systems**~~equipment~~ and associated facilities, except as provided by 6.7.5.1 for dental uses and 6.8.5.1 for veterinary uses.

Additional requirements specific to dental intra-oral, panoramic, cephalometric, and volumetric dental imaging equipment are included in Section 6.7.

6.4.1.2 Each individual who operates an x-ray imaging system used on living humans shall meet the applicable radiation safety training and experience requirements of **Part 2, Section** 2.6.1.

6.4.2 Each diagnostic x-ray imaging system shall meet the following equipment design and configuration requirements.

6.4.2.1 Warning Label.

(1) **On systems manufactured on or before June 10, 2006, T**~~t~~he control panel containing the main power switch shall bear this or an equivalent warning statement, **or the warning statement in 6.4.2.1(2),** legible and accessible to view:

"WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(2) On systems manufactured after June 10, 2006, the control panel containing the main power switch shall bear the warning statement, legible and accessible to view:

"WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed."

6.4.2.2 Battery Charge Indicator.

(1) On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

6.4.2.3 Leakage Radiation from the Diagnostic Source Assembly.

(1) The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 0.88 **milligray (**mGy**) air kerma** (100 **milliroentgen (**mR**) exposure**) in any 1 hour when the x-ray tube is operated at its leakage ~~exposure settings~~**technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly.**

(2) Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

6.4.2.4 Radiation from Components Other Than the Diagnostic Source Assembly.

(1) The radiation emitted by a component other than the diagnostic source assembly shall not exceed **an air kerma of** 18 **microgray (**µGy**)** (2 **milliroentgens (**mR**)**

Commented [JJ246]: "Systems" replaces "equipment" for consistency within paragraph and definitions section.

Commented [jsj247]: The word "interventional", and the last sentence is added, consistent with F.4.

Commented [JJ248]: Also required by (new) 6.3.1.7.

Commented [jsj249]: Language added, consistent with F.4a.

Commented [jsj250]: Language added, consistent with F.4a.ii. This is a new provision in Part F.

Commented [JJ251]: F.4g.

Commented [jsj252]: Added/expanded wording and sentence is added, consistent with Part F, Section F.4b.

The added language and sentence is not new to Part F, but is not currently contained within Part 6.

21 CFR 1020.30(k).

Commented [jsj253]: Added/expanded wording and sentence is added, consistent with Part F, Section F.4c.

The added language and sentence is not new to Part F, but is not currently contained within Part 6.

21 CFR 1020.30(l).

exposure) in any one hour at 5 cm from any accessible surface ~~(that can be easily or accidentally touched by an individual without the use of a tool)~~ of the component when it is operated in an assembled x-ray system under any conditions for which it was designed.

(2) Compliance shall be determined by measurements averaged over an area of 100 square **centimeters (**cm**)** with no linear dimension greater than 20 cm.

6.4.2.5 Beam Quality: Half-value Layer

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

Table 6-1

X-Ray Tube Voltage (kilovolt peak)		Minimum HVL (mm of aluminum)			
		Dental X-ray Systems With Intraoral Image Receptors		All X-ray Systems Other Than Dental X-ray Systems	
Designed Operating Range	Measured Operating Potential	Made On, Before, or After December 1, 1980		Made Before June 10, 2006	Made On or After June 10, 2006
Below 51	30	1.5		0.3	0.3
	40	1.5		0.4	0.4
	50	1.5		0.5	0.5
51 to 70	51	1.5		1.2	1.3
	60	1.5		1.3	1.5
	70	1.5	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.1	2.5
	80	2.3	2.3	2.3	2.9
	90	2.5	2.5	2.5	3.2
	100	2.7	2.7	2.7	3.6
	110	3.0	3.0	3.0	3.9
	120	3.2	3.2	3.2	4.3
	130	3.5	3.5	3.5	4.7
	140	3.8	3.8	3.8	5.0
	150	4.1	4.1	4.1	5.4

Commented [JJ254]: To reduce the size of the body of the rule, this table has been relocated to Appendix 6I.

(2) If it is necessary to determine such half-value layer at an x-ray tube potential that is not listed in **Appendix 6I,** ~~Table 6-1~~, linear interpolation or extrapolation is acceptable. **Positive means shall be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. In the case of a system, which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector which will prevent x-ray emissions if the minimum required filtration is not in place.**

(3) Optional filtration on fluoroscopic systems. Fluoroscopic systems manufactured on or after June 10, 2006, incorporating an x-ray tube(s) with a continuous output of 1 kilowatt or more and an anode heat storage capacity of 1 million heat units or more shall provide the option of adding x-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the half-value layer provisions of 6.4.2.5. The selection of this additional x-ray filtration shall be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the x-ray beam shall be provided.

(4) For capacitor energy storage x-ray equipment still in use, compliance with the applicable requirements of 6.4.2.5 shall be determined with the system fully charged and for the highest clinically used mAs.

(a) Due to reduced image quality and potential for higher patient exposures, capacitor energy storage x-ray equipment shall no longer be used for human patient imaging beyond January 1, 2022.

~~6.4.2.6 Beam Quality: Additional Special Requirements.~~

~~(1) Beryllium window tubes, except those used for mammography, shall have a minimum of 0.5 mm aluminum equivalent filtration permanently installed in the useful beam.~~

~~(2) For capacitor energy storage equipment, compliance with the requirements of 6.4.2.5 shall be determined with the system fully charged and for the highest clinically used mAs.~~

~~(3) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials that are always present between the source and the patient.~~

~~(4) For x-ray systems that have variable kVp and variable filtration for the useful beam, a filtration control device shall:~~

~~(a) Link the kVp selector with the filter(s); and~~

~~(b) Prevent an exposure unless the minimum amount of filtration required by 6.4.2.5 is in the useful beam for the given kVp that has been selected.~~

6.4.2.~~7~~**6** Tube Heads.

Commented [jsj255]: Added/expanded wording and sentence is added, consistent with Part F, Section F.4e.i

The added sentence is not new to Part F, but is not currently found in Part 6.

Requirement is consistent with 21 CFR 1020.30(m), and 1020.30.

Commented [JJ256]: Added wording and sentence is added, consistent with Part F, Section F.4e.ii

21 CFR 1020.30(m)(2)

Commented [JJ257]: The requirements of this provision have been relocated from the existing provision in (prior) 6.4.2.6(2) below. Based on stakeholder comments, the current language is preferred over the Part F proposed language which specified setting the charge to the maximum. Stakeholders have indicated that this may damage equipment.

Capacitor storage x-ray equipment is an older technology which generally has poorer image quality and higher patient exposures than modern mobile x-ray equipment. The Department is not aware of such capacitor storage x-ray equipment still in use in Colorado, and is therefore recommending such systems be phased out for human use.

Commented [JJ258]: Section deleted based on stakeholder feedback and discussion. Similar requirements found/relocated to 6.4.2.5.

Commented [jsj259]: This provision not found in Part F and is therefore removed from Part 6.

Commented [jsj260]: Provision relocated to 6.4.2.5.

Commented [jsj261]: This provision not found in Part F but the concept is addressed in 6.4.2.5(3).

Commented [jsj262]: This provision not found in Part F and is therefore excluded from the proposed Part 6 rule.

(1) The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

(2) Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes that have been selected shall be clearly indicated prior to initiation of the exposure. **Only the selected tube(s) can be energized.**

(a) This indication shall be both on the x-ray control **panel** and at or near the tube housing assembly that has been selected.

(3) ~~Any i~~Information displayed at the tube ~~head shall~~**housing assembly** meet manufacturer's specifications.

6.4.2.~~8~~**7** Locks.

(1) All position locking, holding, and centering devices on the x-ray system and/or components shall function as ~~designed~~**intended**.

6.4.2.~~9~~**8** The x-ray control shall provide:

(1) Visual indication observable at or from the operator's protected position whenever x-rays are produced; and

(2) A signal audible to the operator to indicate that the exposure has terminated.

6.5 ~~Special Rrequirements for Ssafe Uuse of Ffluoroscopy Ssystems.~~Requirements for use of a fluoroscopy system.

~~6.5.1 Administrative Controls.~~

~~6.5.1.1 In addition to the provisions of 6.3 and 6.4, the requirements of 6.5 apply to all fluoroscopic x-ray imaging equipment and facilities.~~

~~6.5.1.2 Supervision and use of a fluoroscopic x-ray system for the purpose of localization to obtain images for diagnostic purposes shall be by an individual who has adequate radiation safety training and experience.~~

~~(1) A physician, chiropractor, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts shall directly supervise use of a fluoroscopic x-ray system.~~

~~(2) Training and experience shall be as provided in 2.6.1, in particular 2.6.1.5 and any applicable appendix to Part 2, and 6.3.1.9.~~

~~(3) Interpretation of both real-time and stored fluoroscopic images shall be by a physician, chiropractor, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts.~~

~~6.5.2 Each fluoroscopic x-ray system shall meet the following equipment design and configuration requirements.~~

~~6.5.2.1 Only image-intensified or direct-digital-receptor fluoroscopic equipment shall be used.~~

~~6.5.2.2 Limitation of the Useful Beam.~~

Commented [JJ263]: F.4j., F.7i.

Commented [jsj264]: Language added, consistent with F.4.i.

Commented [JJ265]: Language is modified for consistency with the wording of other provisions in this section.

Commented [jsj266]: Language added, consistent with F.4k.

Commented [JJ267]: For consistency with Part F, Section 6.5 has been replaced in its entirety with the provisions contained in Part F, Section F.5, with some modifications necessary to fit the format of Part 6.

Variations are generally identified in each of the provisions.

Commented [JJ268]: The requirements of 6.5.1.1 have been relocated to new 6.5.1.

Commented [JJ269]: The requirements of this provision have been relocated to new 6.5.1.1.

~~(1) Primary Protective Barrier to Limit the Useful Beam.~~

~~(a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier that intercepts the entire cross section of the useful beam at any SID.~~

~~(b) The x-ray tube used for fluoroscopy shall not produce x-rays unless the primary protective barrier is in position to intercept the entire useful beam.~~

~~(2) Limitation of the X-ray Field.~~

~~(a) For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following apply:~~

~~(i) Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID.~~

~~(ii) The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.~~

~~(iii) The error in alignment shall be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor.~~

~~(3) To permit further limitation of the x-ray field, the following specifications shall also be met.~~

~~(a) Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square cm shall be provided with means for stepless adjustment of the x-ray field.~~

~~(b) All equipment with a fixed SID and a visible area of 300 square cm or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square cm or less.~~

~~(c) If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5cm by 5cm or less.~~

~~(d) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable:~~

~~(i) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and~~

~~(ii) The entire cross section of the useful beam shall be intercepted by the primary protective barrier at any SID.~~

~~(e) Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.~~

Commented [JJ270]: The requirements of this provision have been relocated to new 6.5.2.1(1), and (2).

Commented [JJ271]: The requirements of this provision have been relocated to new 6.5.3.5(1).

Commented [JJ272]: The requirements of this provision have been relocated to new 6.5.3.2

Commented [JJ273]: The requirements of this provision have been relocated to new 6.5.3.2(5)

(i) Measurement shall be made in perpendicular directions corresponding to the vertical and horizontal directions on the video monitor image.

(ii) For collimating systems that are not circular, measurement shall be made along the directions closest to the vertical and horizontal direction on the video monitor image yielding the smallest dimension in each direction.

(4) Additional X-ray Field Specifications for Spot-film Devices:

Commented [JJ274]: The requirements of this provision have been relocated to new 6.5.3.3.

(a) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor that has been selected on the spot film selector.

(i) Such adjustment shall be automatically accomplished except when the x ray field size in the plane of the image receptor is smaller than that of the selected portion of the image receptor.

(ii) If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

(b) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three (3) percent of the SID when adjusted for full coverage of the selected portion of the image receptor.

(i) The sum, without regard to sign, of the length and width differences shall not exceed four (4) percent of the SID.

(c) It shall be possible to adjust the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor.

(i) The minimum field size at the greatest SID shall be equal to, or less than, 5cm by 5cm, or 125cm² for a fixed SID.

(d) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within two (2) percent of the SID.

(e) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(5) Override.

Commented [JJ275]: The requirements of this provision have been relocated to new 6.5.3.4, and 6.5.3.7.

(a) If a means exists to override any of the automatic x-ray field size adjustments required in 6.5.2.2, that means shall:

(i) Be designed for use only in the event of system failure and not as a substitute for prompt repair;

(ii) Incorporate a signal visible at the operator's position that will indicate whenever the automatic field size adjustment is overridden; and

(iii) Be clearly and durably labeled as follows:

"FOR X-RAY FIELD LIMITATION SYSTEM FAILURE"

6.5.2.3 Activation of the Fluoroscopic Tube.

(1) X-ray production in the fluoroscopic mode shall be controlled by a device that requires continuous pressure by the operator for the entire time of any exposure.

(2) When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

6.5.2.4 Fluoroscopic Timer for Units Made Before June 10, 2006.

(1) Means shall be provided to preset the cumulative irradiation time of the fluoroscopic x ray tube.

(2) The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting.

(3) A signal audible to the operator shall indicate the completion of any preset cumulative irradiation time and shall continue to sound while x-rays are produced until the timing device is reset.

(4) Fluoroscopic equipment may be modified in accordance with 1020.30(q) to comply with the requirements of 1020.32(h)(2), and, if modified, shall bear a label indicating the statement: "Modified to comply with 21 CFR 1020.32(h)(2)."

6.5.2.5 For x-ray controls manufactured on or after June 10, 2006, each fluoroscopic tube shall be provided with both a display and audible signal.

(1) The display, which shall show the fluoroscopic irradiation time in minutes and tenths of minutes at the fluoroscopist's working position independently of the audible signal required by 6.5.2.5(2), shall:

(a) Display continuously when the x-ray tube is activated and be updated at least once every 6 seconds (0.1 minute);

(b) Display within 6 seconds (0.1 minute) of termination of an exposure and remain displayed until reset; and

(c) Be provided with means to reset the display to zero prior to the beginning of a new examination or procedure.

(2) A signal audible to the fluoroscopist shall sound:

(a) For each passage of 5 minutes of fluoroscopic irradiation time during an examination or procedure; and

Commented [JJ276]: The requirements of this provision have been relocated to new 6.5.4.

Commented [JJ277]: The requirements of this provision have been relocated to new 6.5.8(1).

Commented [JJ278]: The requirements of this provision have been relocated to new 6.5.8.2.

(b) Until manually reset or, if automatically reset, for at least 2 seconds.

6.5.2.6 Indication of potential and current is required.

(1) During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.

6.5.2.7 Last-Image-Hold (LIH) display.

(1) For an LIH image obtained by retaining pre-termination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.

(2) For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the exposure settings for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.

(3) Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

(4) The predetermined or selectable options for producing the LIH radiograph shall include a description of any exposure settings applicable for the selected option and the impact of the selectable options on image characteristics and the magnitude of radiation emissions.

6.5.2.8 The following requirements apply to displays of the values of AKR and cumulative air kerma for each x-ray tube used during an examination or procedure:

(1) Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma.

(2) When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min shall be continuously displayed and updated at least once every second.

(3) The cumulative air kerma in units of mGy shall be displayed either within 5 seconds of termination of an exposure or displayed continuously and updated at least once every 5 seconds.

(4) The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.

(5) The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope. The reference location shall be identified and described specifically in the information provided to users as required by 2.7.1.3.

(a) For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference locations shall be the

Commented [JJ279]: The requirements of this provision have been relocated to new 6.5.6.

Commented [JJ280]: The requirements of this provision (excluding 6.5.2.7(4)) have been relocated to new 6.5.9.

Commented [JJ281]: 6.5.2.7(4) will not be carried over to the revised 6.5 sections.

All x-ray systems may not be capable of providing a selectable option for last image hold.

Commented [JJ282]: The requirements of this provision have been relocated to new 6.5.10.

respective locations specified in 6.5.4.1 (1), 6.5.4.1 (2), or 6.5.4.1 (4) for measuring compliance with air-kerma rate limits.

(b) For c-arm fluoroscopes, the reference location shall be 15 cm from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.

(6) Consistent with 6.5.2.8(1), a method shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

(7) The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than +/-35 percent over the range of 6 mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than 3 seconds.

(8) AKR and air kerma display calibration shall be verified annually by a registered medical physicist.

6.5.2.9 Spot Imager Exposure Reproducibility.

(1) Fluoroscopic systems equipped with spot image mode shall meet the following exposure reproducibility requirements when operating in the spot image mode:

(a) When all exposure settings are held constant, including control panelcselections associated with an automatic exposure control system, the coefficient of variation of air kerma for both manual and automatic exposure control systems shall not exceed 0.05.

6.5.2.10 Barrier Transmitted Radiation Rate Limits.

(1) The AKR due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 0.334×10^{-6} of the entrance AKR (one-third of one millionth of the entrance AKR) at 10cm from any accessible surface (that can be easily or accidentally touched by an individual without the use of a tool) of the fluoroscopic imaging assembly beyond the plane of the image.

6.5.3 Radiation Exposure Control Devices And Operation.

6.5.3.1 Air Kerma Rate (AKR) Limits for Fluoroscopic Equipment Manufactured Before May 19, 1995.

(1) Equipment without AERC is not permitted.

(2) Fluoroscopic equipment that is provided with AERC shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min) measured per 6.5.4:

(a) Except during recording of fluoroscopic images when the recorded images are intended for subsequent interpretation by a physician, chiropractor, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts; or

Commented [JJ283]: At the suggestion of stakeholder(s), this provision is retained for fluoroscopy in (new) 6.5.14.1(8).

Commented [JJ284]: The requirements of this provision have been relocated to new 6.5.2.1(3).

Commented [JJ285]: With the exception of 6.5.3.1(1), the requirements of this provision have been are contained in/relocated to new 6.5.5.1.

Commented [JJ286]: Per X-Ray staff, this specific provision (6.5.3.1(1)) will not be carried over to the revised/new section 6.5. However, a requirement which specifies the limits under which equipment without AERC can be used is addressed in (new) 6.5.5.1(2).

(b) Except when an optional high-level control is provided.

(i) Unless the high-level control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 44 mGy per minute (5 R/min) at the point where the center of the useful beam enters the patient.

(ii) Special means of activation of high-level controls shall be operable only when continuous manual activation is provided by the operator.

(iii) A continuous signal audible to the operator shall indicate that the high-level control is being employed.

(3) Fluoroscopic equipment that is provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min) measured per 6.5.4:

(a) Except during recording of fluoroscopic images when the recorded images are intended for subsequent interpretation by a physician, chiropractor, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts; or

(b) Except when the mode or modes have an optional high-level control.

(i) Unless the high-level control is activated, that mode or modes shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 6.5.3.1(1)(a). 6.5.3.1(2)(a), or 6.5.3.1(3)(a) as measured per 6.5.4.

(ii) Special means of activation of high-level controls shall be required.

(iii) The high-level control shall be operable only when continuous manual activation is provided by the operator.

(iv) A continuous signal audible to the operator shall indicate that the high-level is being employed.

(4) Fluoroscopic units that have the high-level control activated and an entrance AKR exceeding 0.1 Gy per minute (11 R/min) shall be posted with the measured maximum AKR, on a sign that:

(a) Is visible at the operator's position;

(b) States that “The system may exceed an entrance AKR exceeding 0.1 Gy per minute (more than 10 R/min)”.

6.5.3.2 Entrance AKR Limits For Fluoroscopic Equipment Manufactured on and after May 19, 1995.

(1) Fluoroscopic equipment operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (5 R/min) at the

Commented [JJ287]: The requirements of this provision have been relocated to new 6.5.5.2.

~~point where the center of the useful beam enters the patient shall be equipped with AERC.~~

~~(a) Manual selection of exposure settings may also be provided.~~

~~(2) Fluoroscopic equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min) measured per 6.5.4.~~

~~(3) For equipment manufactured prior to June 10, 2006, exception to 6.5.3.2(2) is allowed during the recording of images from an x-ray image-intensifier tube using photographic film or a video camera when the x-ray source is operated in a pulsed mode when the recorded images are intended for subsequent interpretation by a physician, chiropractor, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts.~~

~~(4) For equipment manufactured on or after June 10, 2006, exception to 6.5.3.2(2) is allowed during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image(s) after termination of the exposure.~~

~~(a) Such recording does not include images resulting from a last-image-hold feature that are not recorded.~~

~~(5) Exception to 6.5.3.2(2) is allowed when the high-level control is activated.~~

Commented [JJ288]: The requirements of this provision have been relocated to new 6.5.5.3.

~~(a) The equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 176 mGy per minute (20 R/min) at the point where the center of the useful beam enters the patient.~~

~~(b) Special means of activation of high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator.~~

~~(c) A continuous signal audible to the operator shall indicate that the high-level control is being employed.~~

~~6.5.3.3 A mini-c-arm x-ray system shall have an exposure rate less than or equal to 88 mGy (10 R) per minute at the exit port.~~

Commented [JJ289]: This specific provision (6.5.3.3) will not be carried over to the revised 6.5 sections as Part F does not utilize the term “mini-c-arm”. Requirements for exposure rates for all fluoroscopic machine types are adequately addressed in section 6.5.5.

~~6.5.3.4 Control of Scattered Radiation.~~

~~(1) Conventional fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation that originates from under the table.~~

~~(a) The attenuation required shall be not less than 0.25 millimeter lead equivalent.~~

~~(2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities or head, shall be exposed to unattenuated scattered radiation unless that individual:~~

(a) Is at least 2m (more than 6 feet) from the center of the useful beam, or

(b) The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 6.3.3.5.

(3) Exception to 6.5.3.4(2) is allowed if the facility has a written policy that applies to when the use of drapes or self-supporting curtains is contra-indicated and the diagnosis might be compromised, such as where a sterile field will not permit the use of the normal protective barriers.

(a) If the use of pre-fitted sterilized covers for the barriers is practical, exemption is not appropriate.

6.5.4 Each fluoroscopic x-ray system shall fulfill the following measurement and maintenance requirements.

Commented [JJ290]: The requirements of this provision have been relocated to new 6.5.5.4.

6.5.4.1 Compliance with the requirements of 6.5.3 shall be determined as follows:

(1) If the source is below the table, AKR shall be measured one centimeter above the tabletop or cradle.

(2) If the source is above the table, the AKR shall be measured at 30cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(3) For a c-arm type of fluoroscope, the AKR shall be measured 30 cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the spacer assembly or beam-limiting device is not closer than 30 cm from the input surface of the fluoroscopic imaging assembly.

(a) For a c-arm type of fluoroscope having an SID less than 45cm, the AKR shall be measured at the minimum SSD, or corrected to the minimum SSD using the inverse square law.

(4) Each lateral-type fluoroscope, either stationary or mobile, AKR shall be measured at a point 15cm from the centerline of the table (isocenter) and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(a) If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15cm to the centerline of the table.

(5) Periodic measurement of AKR shall be performed as follows:

Commented [JJ291]: -AKR measurements are under the conditions addressed in new 6.5.5.4;
-AKR measurement of maximum AKR is addressed in new 6.5.14;
-Annual measurement of AKR is addressed in new 6.5.14.1;
-AKR for systems w/AERC & max output is addressed in new 6.5.14.1(1);
-AKR for systems w/o AERC & max mAs output is addressed in new 6.5.14.1(1)(a);

(a) Such measurements shall be made annually or after any maintenance of the system that might affect the exposure rate.

(b) Conditions of periodic measurement of AKR are as follows:

(i) The measurement shall be made under the conditions that satisfy the requirements of 6.5.4.1;

(ii) The kVp shall be the maximum kVp that can be produced by the x-ray system;

(iii) The x-ray system(s) that incorporates automatic exposure rate control shall have the beam collimated to the size of the detector and have sufficient material placed in the useful beam to intercept the entire beam so that output of the machine is a maximum for the x-ray system; and

(iv) X-ray system(s) that do not incorporate an automatic exposure rate control shall utilize the maximum milliamperage typical of the clinical use of the x-ray system.

(6) For other fluoroscopic systems not described above, the AKR shall be measured at the point specified by the manufacturer for maximum dose rate measurements.

6.5.4.2 Source-skin distance (SSD) shall not be less than:

Commented [JJ292]: The requirements of this provision have been relocated to new 6.5.7

(1) 38 cm on stationary fluoroscopes;

(2) 30 cm on all mobile and portable fluoroscopes, including c-arm fluoroscopes having a maximum source image receptor distance greater than or equal to 45 cm and o-arm fluoroscopes;

(3) 20 cm for mobile fluoroscopes used for specific surgical application;

(a) The written safety procedures must provide precautionary measures to be adhered to during the use of these systems;

(4) 19 cm for stationary, mobile, or portable mini-c-arm fluoroscopic systems having a maximum source image receptor distance less than 45 cm manufactured on or after June 10, 2006;

(a) Such systems shall be labeled for extremity use only;

(b) In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm;

(c) The written safety procedures must provide precautionary measures to be adhered to during the use of these systems; and

(5) The distance in cm recommended by the manufacturer for equipment not specified in 6.5.4.2(1) through 6.5.4.2(4).

6.5.4.3 Measuring Barrier Transmission.

Commented [JJ293]: The requirements of this provision have been relocated to new 6.5.2.2.

(1) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(2) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop.

(3) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm.

(4) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(5) The attenuation block shall be positioned in the useful beam 10 cm from the point of measurement of AKR and between this point and the input surface of the fluoroscopic imaging assembly.

6.5.4.4 Each registered facility shall maintain records of:

Commented [JJ294]: The requirements of this provision have been relocated to new 6.5.15.7.

(1) Cumulative fluoroscopic exposure time and/or other patient dose estimation data (for example, kerma-area-product); and

(2) The type and date of each examination, patient identification, system used, and operator's name.

6.5.5 Each fluoroscopic x-ray system shall have written quality control and quality assurance procedures.

Commented [JJ295]: Requirements related to quality assurance are addressed in the more general requirements of 6.3.5.

6.5.5.1 The quality control and quality assurance procedures shall be consistent with 6.3.5 and shall follow:

(1) Specifications of the manufacturer; and

(2) Specifications of a registered medical physicist; and/or

(3) Standards of an appropriate nationally recognized organization.

6.5.5.2 Systems shall be evaluated periodically by a registered medical physicist in accordance with standards and protocols published by nationally recognized organizations (for example, AAPM Report 4 and AAPM Report 74), 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 [JJ296]: Although less specific, the requirements related to quality assurance references are addressed in 6.3.5.

6.5.6 Radiation Therapy Simulation Systems.

6.5.6.1 Radiation therapy simulation systems shall be exempt from all the requirements of 6.5.2.2, 6.5.2.4, 6.5.2.5, 6.5.2.10, 6.5.3.1 and 6.5.3.2, provided that:

Commented [JJ297]: Requirements and exemptions from certain requirements for radiation therapy simulation systems are spread through the individual requirements in the revised 6.5.

(1) Each system is designed and used in such a manner that no individual other than the patient, required staff and ancillary personnel is in the x-ray room during any period of time when the system is producing x-rays; and

(2) Each system that does not meet the requirements of 6.5.2.4 and 6.5.2.5 is provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

~~(3) Staff and ancillary personnel shall be protected in accordance with 6.3.3.5, 6.3.3.6, 6.3.3.7 and 6.3.3.8.~~

6.5.1 In addition to the provisions of 6.3 and 6.4, the requirements of 6.5 apply to all fluoroscopic facilities and equipment used for fluoroscopic imaging or for recording images from the fluoroscopic image receptor.

6.5.1.1 Only image-intensified or direct-digital receptor fluoroscopic equipment shall be used for fluoroscopy.

6.5.2 Primary Protective Barrier.

6.5.2.1 Limitation of useful beam.

(1) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

(2) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

(3) The AKR due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic imaging receptor shall not exceed 3.34×10^{-3} percent of the entrance AKR, at a distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor.

(4) Radiation therapy simulation systems shall be exempt from 6.5.2.1 provided the systems are intended only for remote control operation.

6.5.2.2 Measuring compliance.

(1) The AKR shall be measured in accordance with 6.5.5.

(2) The AKR due to transmission through the primary barrier combined with radiation from the fluoroscopic image receptor shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(3) If the source is below the tabletop, the AKR measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop.

(4) If the source is above the tabletop and the SID is variable, the AKR measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm.

(5) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(6) For all AKR measurements, the attenuation block shall be positioned in the useful beam 10 cm from the point of measurement of entrance AKR and between this point and the input surface of the fluoroscopic imaging assembly.

Commented [JJ298]: The language of 6.5.1, combines the wording of prior 6.5.1 and F.5., with the exception that some originally proposed language (in prior draft C) regarding supervision and use of fluoroscopic machines is deleted as this is already addressed in 6.3.1 which also ties into specific training requirements of Part 2 for certain modalities.

Commented [JJ299]: F.5.b

Commented [JJ300]: F.5b.i. 21CFR 1020.32(a)(1)

Commented [JJ301]: This is not a new requirement - a similar provision is found in current 6.5.2.10.

Commented [JJ302]: F.5b.i. 21CFR 1020.32(a)(2)

6.5.3 Field Limitation.

6.5.3.1 Angulation.

(1) For fluoroscopic equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(2) Compliance with 6.5.3.5 and 6.5.3.6 shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

6.5.3.2 Further means of limitation.

(1) Means shall be provided to permit further limitation of the x-ray field to sizes smaller than the limits of 6.5.3.5 and 6.5.3.6.

(2) Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or capability of a visible area of greater than 300 cm^2, shall be provided with means for stepless adjustment of the x-ray field.

(3) Equipment with a fixed SID and the capability of a visible area of no greater than 300 cm^2 shall be provided with either:

(a) Stepless adjustment of the x-ray field; or

(b) A means to further limit the x-ray field size at the plane of the image receptor to 125 cm^2 or less.

(4) Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of 5 cm by 5 cm.

(5) Compliance with 6.5.3.2 shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(1) Measurement shall be made in perpendicular directions corresponding to the vertical and horizontal directions on the video monitor image.

(2) For collimating systems that are not circular, measurement shall be made along the directions closest to the vertical and horizontal direction on the video monitor image yielding the smallest dimension in each direction.

6.5.3.3 Spot-image devices.

The following requirements shall apply to spot-image devices, except when the spot-image device is provided for use with a radiation therapy simulation system:

(1) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-image selector.

Commented [JJ303]: F.5c

Commented [JJ304]: F.5c.i
21 CFR 1020.32(b)(1)

Commented [JJ305]: F.5c.ii
21CFR 1020.32(b)(2)

Commented [JJ306]: Relocated from prior 6.5.2.2(3)(e).

Commented [JJ307]: Section added, consistent with F.5c.iii with the exception that Part F uses the term “spot-film”. As discussed in section 6.2, spot-film is changed to the more current term “spot-image” device.

21CFR1020.31(h)

Commented [JJ308]: F.5c.iii(1)
21CFR1020.31(h)(1)

(a) Such adjustment shall be accomplished automatically when the x-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor.

(b) If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

(2) Neither the length nor width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor.

Commented [JJ309]: F.5c.iii(2) 21CFR1020.31(h)(2)

(a) The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID.

(b) On spot-image devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(3) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within 2 percent of the SID.

Commented [JJ310]: F.5c.iii(3) 21CFR1020.31(h)(3)

(4) Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

Commented [JJ311]: F.5c.iii(4) 21CFR1020.31(h)(4)

(a) For spot-image devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square cm; or

Commented [JJ312]: F.5c.iii(4)(a) 21CFR1020.31(h)(4)(i)

(b) For spot-image devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of 5 cm by 5 cm.

Commented [JJ313]: F.5c.iii(4)(b) 21CFR1020.31(h)(4)(ii)

6.5.3.4 A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure.

Commented [JJ314]: F.5c.iv 21CFR1020.31(h)(5)

If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

For X-ray Field Limitation System Failure

6.5.3.5 Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently circular image receptors.

Commented [JJ315]: F.5c.v 21CFR 1020.32(b)(4)(i)

(1) For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following applies:

(a) Neither the length nor width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

Commented [JJ316]: F.5c.vi(1)(a) 21CFR 1020.32(b)(4)(i)(A)

(b) For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

Commented [JJ317]: F.5c.vi(1)(b) 21CFR 1020.32(b)(4)(i)(B)

(2) For fluoroscopic equipment manufactured on or after June 10, 2006, other than radiation simulation systems, the maximum area of the x-ray field in the plane of the image receptor shall conform with one of the following requirements:

Commented [JJ318]: F.5c.v(2) 21CFR 1020.32(b)(4)(ii)

(a) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34 cm in any direction, at least 80 percent of the area of the x-ray field overlaps the visible area of the image receptor, or

Commented [JJ319]: F.5c.v(2)(a) 21CFR 1020.32(b)(4)(ii)(A)

(b) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 34 cm in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than 2 cm.

Commented [JJ320]: F.5c.v(2)(b) 21CFR 1020.32(b)(4)(ii)(B)

6.5.3.6 Fluoroscopy and radiography using fluoroscopic imaging assembly with inherently rectangular image receptors.

Commented [JJ321]: F.5c.vi 21CFR1020.32(b)(5)

For x-ray systems manufactured on or after June 10, 2006, the following applies:

(1) Neither the length nor width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

Commented [JJ322]: F.5c.vi(1) 21CFR1020.32(b)(5)(i)

(2) The error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

Commented [JJ323]: F.5c.vi(2) 21cfr1020.32(b)(5)(ii)

6.5.3.7 Override capability.

Commented [JJ324]: F.5c.vii 21CFR 1020.32(b)(6)

If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

6.5.4 Activation of Tube.

6.5.4.1 X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure.

Commented [JJ325]: F.5d
21CFR 1020.32(c)

6.5.4.2 When recording serial radiographic images from the fluoroscopic image receptor, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

6.5.5 Air Kerma Rates.

Commented [JJ326]: Language updated consistent with F.5e.

Language of F.5e.v pertaining to the exceptions for fluoroscopy systems used in radiation therapy simulation systems has been incorporated into 6.5.5.1 through 6.5.5.4.
[21CFR 1020.32(d)(4)]

6.5.5.1 Except for fluoroscopic equipment used for radiation therapy simulation purposes, the following requirements apply to fluoroscopic equipment manufactured before May 19, 1995:

(1) Equipment provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in 6.5.5.4, except as specified in 6.5.5.1(5).

Commented [JJ327]: Language updated consistent with F.5e.i(1)
21CFR 1020.32(d)(1)(i)

(2) Equipment provided without AERC shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 44 mGy per minute (5 R/min exposure rate) at the measurement point specified in 6.5.5.4, except as specified in 6.5.5.1(5).

Commented [JJ328]: Language updated consistent with F.5e.i(2)
21CFR 1020.32(d)(1)(ii)

(3) Equipment provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) in either mode at the measurement point specified in 6.5.5.4, except as specified in 6.5.5.1(5).

Commented [JJ329]: Language updated consistent with F.5e.i(3)
21CFR 1020.32(d)(1)(iii)

(4) Equipment may be modified in accordance with this Part to comply with 6.5.5.2. When the equipment is modified, it shall bear a label indicating the date of the modification and the statement:

MODIFIED TO COMPLY WITH 21 CFR 1020.32(H)(2)

Commented [JJ330]: Language updated consistent with F.5e.i(4)
21CFR 1020.32(d)(1)(iv)

(5) The AKR requirements of 6.5.5.1(1) through (3) are not applicable during:

(a) Recording of (spot) fluoroscopic images; or

(b) Operation in high-level control mode(s) as equipped.

Commented [JJ331]: Updated consistent with F.5e.i(5) with clarifying language added.
Clarifying wording and provision (b) added based on stakeholder comments and for consistency with 21 CFR 1020.32(d).

6.5.5.2 Except for fluoroscopic equipment used for radiation therapy simulation purposes, the following requirements apply to fluoroscopic equipment manufactured on or after May 19, 1995:

(1) Shall be equipped with AERC if operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (5 R/min exposure rate) at the measurement point

Commented [JJ332]: Relocated from 6.5.3.2 and updated consistent with F.5e.ii(1).
21CFR 1020.32(d)(2)(i)

specified in 6.5.5.4. Provision for manual selection of technique factors may be provided.

(2) Shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in 6.5.5.4, except as specified in 6.5.5.2.(3).

Commented [JJ333]: Language updated consistent with F.5e.ii(2).
21CFR 1020.32(d)(2)(ii)

(3) The AKR limits of 6.5.5.2(1) and (2) are not applicable to equipment manufactured prior to June 10, 2006, during the recording of images from a fluoroscopic image receptor using photographic film or a video camera when the x-ray source is operated in a pulsed mode.

Commented [JJ334]: Language updated consistent with F.5e.ii(3), with the exception that wording is simplified/clarified based on stakeholder comment.

21CFR 1020.32(d)(2)(iii)(A)
21CFR 1020.32(d)(2)(iii)(B)

(4) The AKR limits of 6.5.5.2(1) and (2) are not applicable to~~:~~ equipment manufactured on or after June 10, 2006:

(a) During recording of spot images from the fluoroscopic image receptor;

(b) To images resulting from a last-image-hold feature that are not recorded;

(c) During operation in high-level control mode(s) as equipped.

6.5.5.3 Except for fluoroscopic equipment used for radiation therapy simulation purposes, the following requirements apply to fluoroscopy equipment with optional high-level control

Commented [JJ335]: Language updated consistent with F.5e.iii.

This provision is new in the SSRCR Part F 2015 revision.

(1) When high-level control is selected and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 176 mGy per minute (20 R/min exposure rate) at the measurement point specified in 6.5.5.4.

(2) Special means of activation of high-level controls shall be required.

(a) The high-level control shall be operable only when continuous manual activation is provided by the operator.

(b) A continuous signal audible to the fluoroscopist shall indicate that the high-level control is employed.

6.5.5.4 Measuring compliance.

Except for fluoroscopic equipment used for radiation therapy simulation purposes, the following requirements apply to compliance with 6.5.5.1 through 6.5.5.3 and shall be determined as follows:

(1) If the source is below the x-ray table, the AKR shall be measured at 1 cm above the tabletop or cradle.

Commented [JJ336]: Language updated consistent with F.5e.iv(1)
21CFR 1020.32(d)(3)(i)

(2) If the source is above the x-ray table, the AKR shall be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

Commented [JJ337]: Language updated consistent with F.5e.iv(2)
21CFR 1020.32(d)(3)(ii)

(3) For a C-arm type of fluoroscope, the AKR shall be measured at 30 cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly.

Commented [JJ338]: Language updated consistent with F.5e.iv(3)
21CFR 1020.32(d)(3)(iii)

(4) For a C-arm type of fluoroscope having an SID less than 45 cm, the AKR shall be measured at the minimum SSD.

Commented [JJ339]: Language updated consistent with F.5e.iv(4)
21CFR 1020.32(d)(3)(iv)

(5) For a fixed lateral type of fluoroscope, the air kerma rate shall be measured at a point 15 cm from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(a) If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 cm to the centerline of the x-ray table.

Commented [JJ340]: Language updated consistent with F.5e.iv(5), with the exception that word "fixed" is added to help clarify that the provision applies to (older) machines that may be fixed in a lateral position. For machines that are not fixed in such a way, the other applicable requirements of (1), (2), (3), or (4) would apply.
21CFR 1020.32(d)(3)(v)

(6) For fluoroscopic systems not specifically addressed in 6.5.5.4(1) through (5) above, the RMP shall determine the measurement point(s) representing the highest expected dose rate and which is based on nationally accepted standards and practices.

Commented [JJ341]: Provision added, based on stakeholder discussions and comments to address machines that do not specifically fit in other system categories described in this section.

6.5.6 Indication of potential and current.

Commented [JJ342]: Language updated, consistent with F.5f. A similar provision is found in (current) 6.5.2.6.
21CFR 1020.32(f)

6.5.6.1 During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated.

6.5.6.2 Deviation of x-ray tube potential and current from the indicated value shall not exceed the maximum deviation as stated by the manufacturer.

6.5.7 Source-skin distance.

Commented [JJ343]: Language updated consistent with F.5g

6.5.7.1 Means shall be provided:

(1) To limit the source-skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluoroscopes.

(2) In addition, for fluoroscopes intended for specific surgical or interventional applications that would be prohibited at the source-skin distances specified in 6.5.7.1(1), provisions may be made for operating at shorter source-skin distances but in no case less than 20 cm, provided a process for such use is justified and documented in the facility procedures and is periodically reviewed by the FGI procedures committee or RMP.

Commented [JJ344]: Based on stakeholder feedback and discussions and due to possible abuse of the exception in this provision, language is added to require documentation and periodic review by the RMP (or the FGI committee if applicable).

6.5.7.2. For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm, means shall be provided to limit the source-skin distance to not less than 19 cm.

(1) Such systems shall be labeled for extremity use only; and

(2) For those systems intended for specific surgical or interventional applications that would be prohibited at the source-skin distance

Commented [JJ345]: Based on stakeholder feedback and discussions and due to possible abuse of the exception in this provision, language is added to require documentation and periodic review by FGI committee or RMP.

specified in 6.5.7.2, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm, provided a process for such use is justified and documented in the facility procedures and is periodically reviewed by the FGI procedures committee or RMP.

6.5.8 Fluoroscopic irradiation time, display, and signal.

Commented [JJ346]: Language updated consistent with F.5h

6.5.8.1 Fluoroscopic equipment manufactured before June 10, 2006:

(1) Shall be provided with means to preset the cumulative irradiation time of the fluoroscopic tube.

Commented [JJ347]: Language is updated consistent with F.5h.i(1).

These are not new requirements – the updated language is similar to that found in (original section) 6.5.2.4 above.

21CFR 1020.32(h)(1)(i)

(a) The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.

(b) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative irradiation time.

(c) Such signal shall continue to sound while x-rays are produced until the timing device is reset.

(d) Fluoroscopic equipment may be modified in accordance with 21 CFR 1020.30(q) to comply with the requirements of 6.5.8.1.

(e) When the equipment is modified, it shall bear a label indicating the statement:

Modified to comply with 21 CFR 1020.32(h)(2)

(2) As an alternative to the requirements of 6.5.8.1, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations.

Commented [JJ348]: Language added, consistent with Part F, Section F.5h.i(2).
A similar requirement is found in the current 6.5.6.1
21CFR 1020.32(h)(1)(ii)

6.5.8.2. For x-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:

Commented [JJ349]: Language updated consistent with F.5h.ii

(1) A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display shall function independently of the audible signal described in 6.5.8.2(2). The following requirements apply:

Commented [JJ350]: Language updated consistent with F.5h.ii(1)
(variation of 21CFR 1020.32(h)(2)(i))

(a) When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every 6 seconds.

Commented [JJ351]: Language updated consistent with F.5h.ii(1)(a)
21CFR 1020.32(h)(2)(i)(A)

(b) The fluoroscopic irradiation time shall also be displayed within 6 seconds of termination of an exposure and remain displayed until reset.

Commented [JJ352]: Language updated consistent with F.5h.ii(1)(b)
21CFR 1020.32(h)(2)(i)(B)

(c) Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure.

Commented [JJ353]: Language updated consistent with F.5h.ii(1)(c)
21CFR 1020.32(h)(2)(i)(C)

(2) A signal audible to the fluoroscopist shall sound for each passage of 5 minutes of fluoroscopic irradiation time during an examination or procedure.

Commented [JJ354]: Language updated consistent with F.5h.ii(2)
21CFR 1020.32(h)(2)(ii)

(a) The signal shall sound until manually reset or, if automatically reset, for at least 2 seconds.

6.5.9 Display of last-image-hold (LIH).

Fluoroscopic equipment manufactured on or after June 10, 2006, shall be equipped with means to display LIH image following termination of the fluoroscopic exposure.

6.5.9.1 For an LIH image obtained by retaining pretermination fluoroscopic images, if the number of images and method of combining a predetermined number of images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.

6.5.9.2 For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.

6.5.9.3 Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

6.5.10 Displays of values of AKR and cumulative air kerma.

Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure:

6.5.10.1 When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min shall be continuously displayed and updated at least once every second.

6.5.10.2 The cumulative air kerma in units of mGy shall be displayed either within 5 seconds of termination of an exposure or displayed continuously and updated at least once every 5 seconds.

6.5.10.3 The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.

6.5.10.4 The AKR and cumulative air kerma shall represent the value for conditions of free-in- air irradiation at one of the following reference locations specified according to the type of fluoroscope.

(1) For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of fixed lateral type, the reference location shall be the respective locations specified in 6.5.5.4(1). 6.5.5.4(2), or 6.5.5.4(5).

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(2) For C-arm fluoroscopes, the reference location shall be 15 cm from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.

Commented [JJ355]: Language updated, consistent with F.5i. These are not new requirements – original section 6.5.2.6 contains similar requirements.
21CFR 1020.32(j)

Commented [JJ356]: Language updated, consistent with F.5i.i with the exception of adding "…a predetermined number of…" as suggested by stakeholders.
21CFR 1020.32(j)(1)

Commented [JJ357]: Language updated, consistent with F.5i.ii
21CFR 1020.32(j)(2)

Commented [JJ358]: Language updated, consistent with F.5i.iii
21CFR 1020.32(j)(3)

Commented [JJ359]: Language updated consistent with F.5j Similar language appears in original 6.5.2.8.
21CFR 1020.32(k)

Commented [JJ360]: Language updated consistent with F.5j.i
21CFR 1020.32(k)(1)

Commented [JJ361]: Language updated consistent with F.5j.ii
21CFR 1020.32(k)(2)

Commented [JJ362]: Language updated consistent with F.5j.iii
21CFR 1020.32(k)(3)

Commented [JJ363]: Language updated consistent with F.5j.iv
21CFR 1020.32(k)(4)

Commented [JJ364]: Language updated consistent with F.5j.iv(1)
21CFR 1020.32(k)(4)(i)

Commented [JJ365]: Language updated consistent with F.5j.iv(2)
21CFR 1020.32(k)(4)(ii)

6.5.10.5 Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

6.5.10.6 The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than ±35 percent over the range of 6 mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively.

(1) Compliance shall be determined with an irradiation time greater than 3 seconds.

6.5.11 Protection from scatter radiation.

6.5.11.1 For stationary fluoroscopic systems, ancillary shielding, such as drapes, self-supporting curtains, or viewing shields, shall be available and used as supplemental protection for all individuals other than the patient in the room during a fluoroscopy procedure.

6.5.11.2 Where sterile fields or special procedures prohibit the use of normal protective barriers or drapes, all of the following conditions shall be met:

(1) Shielding required under 6.5.11.1 shall be maintained to the degree possible under clinical conditions;

(2) All persons, except the patient, in the room where fluoroscopy is performed shall wear protective apparel (aprons) or shall be positioned behind a stationary or portable shield that provides a lead equivalent shielding of at least 0.25mm;

(3) The fluoroscopic field size shall be reduced to the minimum required for the procedure being performed (area of clinical interest); and

(4) Operating and safety procedures shall reflect the above conditions, and fluoroscopy personnel shall exhibit awareness of situations requiring the use and/or non-use of the protective drapes.

6.5.12 Fluoroscopy specific operator qualifications

6.5.12.1 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.

6.5.13 Equipment operation

6.5.13.1 All fluoroscopic images shall be interpreted by an individual authorized by and licensed in accordance with State of Colorado statutes to engage in the healing arts and whose license, licensing body, or licensing regulations and requirements authorize such activity and is otherwise within the standard and acceptable scope of practice for the licensed individual.

6.5.13.2 Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

6.5.13.3 Operators shall be instructed in accordance with Part 2 requirements.

6.5.13.4 Procedure planning for fluoroscopic procedures on pregnant patients shall include feasible modifications to minimize the dose to the conceptus.

Commented [JJ366]: Language updated consistent with F.5j.v 21CFR 1020.32(k)(5)

Commented [JJ367]: Language updated consistent with F.5j.vi 21CFR 1020.32(k)(6)

Commented [jsj368]: Requirements here partially parallel those of prior section 6.5.3.4 but are updated to reflect revision to Part F, in F.5k.

NOTE: The Joint Commission (TJC) is updating standard EC.02.02.01 (effective July 1, 2018) for hospital facilities to include general language specifying that proper shielding be used during fluoroscopic procedures.

Commented [JJ369]: Language updated consistent with F.5k.i

Commented [JJ370]: Language updated consistent with F.5k.ii

Commented [JJ371]: Based on stakeholder comment, an allowance for use of stationary or portable/mobile shields is added as an alternative to use of protective aprons.

Commented [JJ372]: Language updated consistent with F.5l "Flouroscopy specific" phrasing does not appear in Part F but is added for clarity.

Commented [JJ373]: The phrase "living humans" is added for clarification as the specific training requirements are applicable only to human use.

Language updated consistent with F.5l with the following exceptions: The Part F requirement for a minimum of 4 hours of fluoroscopy training, and 8 hours of initial FGI training is excluded. Feedback received during the early stakeholder engagement process indicated that completing such training is challenging to implement.

Part 2 is the primary rule which contains specific training and qualification requirements for x-ray machine operators (and those supervising operation of machines) and therefore the requirements pertaining to fluoroscopy operator training from Part F, Section F.5I have been incorporated into Appendix 2O of Part 2.

Commented [JJ374]: Language of this section is updated consistent with F.5m, except as noted.

Commented [JJ375]: Part F.5m language is modified to be Colorado specific, with the exception that the original proposed language referring to fluoroscopic images that are viewed "directly or indirectly" was unclear and is excluded from the current draft. The radiation program recognizes that different medical related boards have authorized non-physicians to perform some level of image interpretation. The intent of the modified language is to recognize the authority of other boards to specify certain/applicable training requirements.

6.5.13.5 Procedure planning for fluoroscopic procedures on pediatric patients shall include feasible modifications to minimize dose.

6.5.13.6 The facility shall establish a written policy regarding patient dose management in fluoroscopically guided procedures in conformance with the ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (ACR Resolution 44-2013), NCRP Report 168, or equivalent.

(1) Consistent with facility policy and procedures, the operator shall use methods available on the fluoroscopy system to monitor dose during a fluoroscopic procedure.

(2) The written policy shall include a requirement to designate a person in the room to notify the operator that a SRDL or other dose metric value specified in the facility policy is approaching or has been exceeded.

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.

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.

Commented [JJ376]: As originally proposed in the prior draft (and Part F), the requirement may have implied that every method available on the fluoroscopy system must be used to monitor patient dose during a fluoroscopy procedure. This may be impractical during conduct of a procedure or for other reasons. Therefore, based on stakeholder comment, the language is modified to specify that those methods provided in the written procedures and policies of the facility be used to monitor patient dose. Also, the wording is modified to specify the machine operator be responsible for monitoring dose.

Commented [JJ377]: Based on stakeholder suggestion, this provision is added to ensure that the operator is notified of any approaching (or exceeded) dose metrics established by the facility. The provision is not found in Part F.

Commented [JJ378]: Language updated consistent with F.5n

Section header adds "…of fluoroscopic equipment…" for clarity.

Commented [JJ379]: Language updated consistent with F.5n.i

Part F specifies a 30 day window. However, based on some stakeholder feedback and programmatic needs, the initial post-installation inspection period will remain at 90 days.

Commented [JJ380]: The phrase "representative sample" replaces "full range" found in Part F, which is more reasonable. Based on stakeholder feedback, the requirement to also test entrance exposure rates for digital subtraction and cinefluorography modes is removed as these will not significantly impact entrance exposure rates.

Commented [JJ381]: Part F specifies evaluation of both high and low contrast resolution. Based on early stakeholder feedback, there are technical challenges in performing high and low contrast resolution/image quality evaluations in a meaningful way. Review of technical literature indicates certain testing criteria related to high/low resolution testing is subjective. There may not be appropriate technical standards when operating in specific modes. Therefore, the provisions in Part F pertaining to testing in specific modes are modified to defer to testing in modes that are clinically relevant.

Commented [JJ382]: Stakeholder feedback indicates beam quality remains same during fluoro and spot image modes, therefore testing in fluoro mode (only) is acceptable. Part F specifies both fluoro and spot image modes. Collimation caveat added based on stakeholder feedback.

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

(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.

6.5.14.2 Measurements required in 6.5.14.1 shall be:

(1) Performed in accordance with manufacturer recommendations or nationally accepted standards using a calibrated dosimetry system;

(2) Dosimetry systems used for measurements shall be calibrated in accordance with manufacturer recommendations or nationally accepted standards not to exceed 2 years.

(3) Records indicating the model, serial number and calibration date of equipment used for dosimetry calibrations on FGI systems shall be maintained for 3 years for inspection by the Department.

6.5.15 Additional requirements for facilities performing fluoroscopically-guided interventional (FGI) procedures.
The requirements of 6.5.15 and other requirements associated with an FGI Procedure Committee in 6.5.15 shall become effective on or after January 1, 2022.

6.5.15.1 A registrant performing FGI procedures shall establish a FGI Procedure Committee in accordance with the following:

(1) The registrant may establish a system-wide committee if the registrant has more than one site;

(2) Two or more registrants may form a cooperative FGI Procedure Committee as long as each facility has a representative on the committee; and

(3) If the registrant has already established a radiation safety committee, the requirements of 6.5.15 may be delegated to that committee if the members meet the requirements of 6.5.15.5.

6.5.15.2 A quorum of the FGI Procedure Committee shall meet as often as necessary, but at intervals not to exceed 12 months.

6.5.15.3 A record of each FGI Procedure Committee meeting shall include the date, names of individuals in attendance, minutes of the meeting, and any actions taken. The registrant shall maintain the record for 3 years for inspection by the Department.

6.5.15.4 Provide an annual report to the radiation safety committee or radiation safety officer, in the absence of a radiation safety committee.

6.5.15.5 FGI Procedure Committee members shall include but not be limited to the following individuals involved in FGI procedures:

(1) A supervising physician of the healing arts who meet the requirements in 6.3.1.6(1);

(2) A licensed individual who meets the requirements of 6.3.1.6(2), where applicable;

(3) A Registered Medical Physicist;

(4) A technologist, where applicable; and

(5) Other individuals as deemed necessary by the registrant.

Commented [JJ383]: Stakeholders indicated that original proposed (Part F) wording was unclear and the task was not typically the responsibility of RMP. Modified to clarify that the evaluation pertains to changes in the fluoro system.

Commented [JJ384]: Provision added at the suggestion of stakeholder(s). The requirement is found in other sections of the rule that exclude or are not applicable to fluoroscopy.
The provision is found in the current (in-effect) Part 6 in effect 6.5.2.9.

Commented [jsj385]: Language updated consistent with F.5n.i
This provision is new to Part F.
Due to the poor wording of the original provision in part F, the structure and formatting has been modified for clarity.

Commented [JJ386]: Based on stakeholder comment, and consistent with other proposed changes, language added to allow use of nationally accepted standards.

Commented [JJ387]: Based on stakeholder comment, and consistent with other proposed changes, language added to allow use of nationally accepted standards.

Commented [JJ388]: Based on stakeholder feedback, this provision is modified from Part F. In lieu of actual test equipment calibration records which are maintained by the qualified inspector, only information necessary to trace the calibration record are required.

Commented [jsj389]: Language updated consistent with F.5o.
This provision is new to Part F.
The proposed language provides a 2+ year phase in period for the FGI Procedure Committee related requirements to allow registrants to prepare and implement these activities.

Commented [JJ390]: Language updated consistent with F.5o.i. with the following exception: Due to the variation and complexity of FGI procedures indicated by stakeholders and the fact that some FGI systems do not use the same type of computer controls systems as found in CT imaging, it was felt that the term “protocol” committee may not be applicable for FGI procedures, despite that term being used in some technical literature. Therefore the “FGI Procedure Committee” is proposed. The committee requirements remain the same.

“Utilizing” is changed to “performing” for clarity.

Commented [JJ391]: Language updated consistent with F.5o.ii.

Commented [JJ392]: Language updated consistent with F.5o.iii

Commented [JJ393]: Language updated consistent with F.5o.iv.

Commented [JJ394]: Added for consistency with Part F, SectionF.5o.v, with the exception that language added to clarify the committee should include those individuals involved in FGI procedures.

Commented [JJ395]: Provision added, based on stakeholder comments.
As identified in other areas of the proposed rule, the department is aware that licensed mid-level, non-physician providers operate or supervise the operation of x-ray imaging systems. The intent of the added language in this section is to include these mid-level providers as part of the FGI committee when applicable.

6.5.15.6 Establish and implement FGI procedures

(1) The FGI Procedure Committee shall establish and implement written procedures, or procedures documented in an electronic recordkeeping system, that include but are not limited to the following:

- **(a) Identification of individuals who are authorized to use fluoroscopic systems for interventional purposes.**
- **(b) Methods for patient radiation dose management during FGI procedures.**
- **(c) Establishing dose metric notification levels for fluoroscopy procedures at which point the physician, or other authorized operator is notified.**
- **(d) SRDL values following nationally recognized standards**
- **(e) Actions to be taken for cases when a SRDL is exceeded which may include patient follow-up.**
- **(f) A review of the established processes and procedures at an interval not to exceed 12 months.**

(2) A record of each procedure developed by the committee shall be maintained for inspection by the Department. If the FGI Procedure Committee revises a procedure, documentation shall be maintained that includes the justification for the revision and the previous procedure for inspection by the Department.

6.5.15.7 Procedures for maintaining records for fluoroscopic systems

(1) A record of radiation output information shall be maintained in the event a dose reconstruction calculation or estimate is necessary in accordance with established procedures. The record shall include the following:

- **(a) Operator identification;**
- **(b) Patient identification;**
- **(c) Type and date of examination;**
- **(d) Identification of the fluoroscopic system used; and**
- **(e) Peak skin dose, cumulative air kerma or dose area product used, beam entry angle(s), and patient position if the information is available on the fluoroscopic system.**
- **(f) If the peak skin dose, cumulative air kerma or dose area product are not displayed on the fluoroscopic system, records shall include other available information in the event a dose reconstruction calculation or estimate is necessary in accordance with established procedure or the following as necessary:**
  - **(i) Fluoroscopic mode, such as, high-level or pulsed mode of operation;**
  - **(ii) Cumulative fluoroscopic exposure time; and**
  - **(iii) Number of films or recorded exposures.**

(2) The registrant shall maintain records required by 6.5.15.7(1) for inspection by the Department for 3 years.

Commented [JJ396]: Language updated consistent with F.5o.vi., except as otherwise noted.

Commented [JJ397]: Language updated consistent with F.5o.vi.(1) with the exception that “electronic report system” is changed to “electronic recordkeeping system”. This was recommended during radiation advisory committee discussions.

Commented [JJ398]: Based on stakeholder feedback, the wording of this provision is modified from the Part F language. FGI systems may provide different mechanisms for the operator to monitor the radiation dose (or a corollary to radiation dose) to the patient during the procedure. The language clarifies that the operator may use the method of choice to accomplish this based on the capabilities of the system, procedure, etc.

Commented [JJ399]: Provision revised from Part F based on stakeholder comment/suggestion. The Part F language as originally proposed may imply dose limits rather than notification levels. The original Part F also may have implied that physician actions were mandatory, which may not be applicable in all cases.

Commented [JJ400]: Based on stakeholder feedback, and consistent with the approach of this section to limit the use of the term “protocol” in conjunction with FGI procedures, the phrase “process and procedures” is used.

Commented [JJ401]: Language updated consistent with F.5o.vi.(2) with the exception that FGI Procedure Committee is used instead of RPC.
“…developed by the committee…” added for clarity.

Commented [JJ402]: Language updated consistent with F.5o.vii.

Commented [JJ403]: With the exception of (1)(a), this provision is updated consistent with F.5o.vii(1). Provision (1)(a) and other requirements are carried over from 6.5.4.4, with the exception that wording is modified based on stakeholder comment.

Stakeholders expressed concern with the Part F wording implying that the values displayed by modern fluoroscopy systems cannot be used to determine radiation dose. The Department does not fully agree with this assessment. Technical papers and studies indicate that the indirect parameters/data displayed by fluoroscopy machines (as listed in this section) can be used to approximate, with degrees of variability and uncertainty, radiation dose (or dose corollary) to the patient. Alternative language is therefore proposed.

Commented [JJ404]: Newer systems will display a number of these parameters.

Beam entry angle and patient position are added at the suggestion of stakeholder(s).

Commented [JJ405]: Similar, to the changes and reasoning in 6.5.15.7(1) above, the language here is modified from Part F.

~~SPECIAL REQUIREMENTS FOR GENERAL PURPOSE DIAGNOSTIC X-RAY IMAGING SYSTEMS~~

6.6 ~~Design and Cconfiguration for Ssafe Uuse of a Ggeneral Ppurpose Xx-ray limaging Ssystem (Oother Tthan Ddental, Ffluoroscopic, Vveterinary, Ccomputed Ttomography, or Mmammography).~~Requirements for use of general purpose x-ray imaging systems

6.6.1 Administrative ~~C~~controls.

6.6.1.1 ~~In addition to the provisions of 6.3 and 6.4, the special requirements of 6.6 apply to all x-ray imaging equipment and associated facilities other than:~~**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**~~(in 6.5)~~;

(2) Dental **use which is described in 6.7**~~(in 6.7, with cross-reference in 6.7.2.1 to 6.6.2 and in 6.7.3.1 to 6.6.3)~~;

(3) Veterinary **use which is described in 6.8**~~(in 6.8)~~;

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

(5) Mammography **use which is described in 6.10**~~(in 6.10)~~.

~~6.6.1.2 Each individual who operates an x-ray imaging system subject to 6.6 shall meet the applicable adequate radiation safety training and experience requirements of 2.6.1.~~

6.6.1.2 Certification evaluation (testing) requirements.

(1) Within 90 days of use:

(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.

6.6.2 **Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems.** ~~For each general purpose stationary, mobile and/or portable x-ray imaging system subject to 6.6, the useful beam shall be limited to the area of clinical interest.~~**Mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements:**

Commented [jsj406]: Section updated for general consistency with F.6.

Some phrasing may be different to add clarity to the rule or to address the differences in the formatting/numbering between Part F and Part 6.

Commented [jsj407]: This is deleted from this section as it is redundant with other sections (e.g., 6.3.1.9(c), 6.4.1.2, 6.5.1.2(2), 6.5.8.1)

Commented [jsj408]: Section header added, and section reformatted for clarity and flow.
With the exceptions identified below, this provision is updated for consistency with Part F, Section F6.a.

Exceptions to Part F:
1. Consistent with the x-ray unit business process and database limitations, a 90 day testing criteria is retained. (Part F specifies a 30 day timeframe).
2. The Part F provision specifies a 12 month inspection cycle. Rather than specifically list the frequency in Part 6, a reference to Part 2 is made which contains the inspection frequency for all x-ray systems.
3. The term “certification evaluation” replaces the more generic “evaluated” term found in Part F.
4. Part F appears to include an exemption from the certification evaluation requirements for podiatry x-ray systems. For safety reasons, In Colorado, all x-ray systems including podiatry systems require initial testing. This Part F exemption is not incorporated into Part 6.
5. Phrasing and clarification is added to (3) to require testing of those monitors under the control of the registrant. The registrant should establish policies and procedures for testing of monitors not under the control of the registrant. Allowance for performance under supervision of RMP is added, based on stakeholder feedback.

Commented [JJ409]: Updated for consistency with SSRCR Part F, Section F.6e.

21 CFR 1020.31(d)

6.6.2.1 **Variable x-ray field limitation.** A means for stepless adjustment of the size of the x-ray field shall be provided.

(1) ~~For certified systems, stepless adjustment of the size of the x-ray field shall be provided such that the minimum field size at an SID of 100 cm shall be equal to or less than 5 cm by 5 cm.~~**Each dimension of the minimum field size at an SID of 100 cm shall be equal to or less than 5 cm.**

6.6.2.2 **Visual definition.** ~~A method shall be provided~~ **Means** for visually defining the perimeter of the x-ray field **shall be provided**.

(1) The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two (2) percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(2) A light localizer used to define the x-ray field of a certified system shall provide illumination sufficient to permit visual determination of the x-ray field under ambient light conditions of up to 500 lux (46 foot candles).

~~6.6.2.3 The Department may grant an exemption on non-certified x-ray systems to 6.6.2.1 and 6.6.2.2 provided the registrant makes a written application for such exemption and in that application demonstrates that:~~

~~(1) It is impractical to comply with 6.6.2.1 and 6.6.2.2; and~~

~~(2) The purpose of 6.6.2.1 and 6.6.2.2 will be met by other methods.~~

6.6.2.~~4~~3 **Field indication and alignment on stationary general purpose x-ray equipment**~~Additional Beam Limitation Requirements for Each Stationary General Purpose X-Ray System~~. **Except when spot-image devices are in use, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in 6.6.2.**

(1) ~~A method~~**Means** shall be provided to:

(a) Indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

(b) Align the center of the x-ray field with respect to the center of the image receptor to within two (2) percent of the SID; and

(c) Indicate the SID to within two (2) percent.

(2) The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

(3) Indication of field size dimensions and SID's shall be specified in inches and/or cm, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor that correspond to those indicated by the beam-limiting device to within two (2) percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

Commented [JJ410]: Updated for consistency with SSRCR Part F, Section F.6e.i.

21 CFR 1020.31(d)(1)

Commented [JJ411]: Modified for consistency with SSRCR Part F, Section F.6e.ii

Commented [JJ412]: Modified for consistency with SSRCR Part F, Section F.6e.ii(1)
21 CFR 1020.31(d)(2)(i)

Commented [JJ413]: Based on stakeholder discussions and further evaluation, the requirements of Part F, Section F.6e.ii(2) and (3) which specify additional detailed evaluation of the light field measurements as part of periodic testing were not incorporated here. The current provisions of the in-effect Part 6 rule are retained as the current rule provides adequate steps to maintain radiation safety and radiation safety would not be significantly improved by incorporating the additional testing and measurements.

Commented [JJ414]: This provision is not needed as Part 1, Section 1.5.1 already provides exceptions and exemptions from the regulations.

This provision was Colorado specific and does not appear in Part F.

Commented [JJ415]: Updated for consistency with F.6f

21 CFR 1020.31(e)

Commented [JJ416]: Updated for consistency with F.6f.i

21 CFR 1020.31(e)(1)

Commented [JJ417]: F.6f.ii

21 CFR 1020.31(e)(2)

Commented [JJ418]: F.6f.iii

21 CFR 1020.31(e)(3)

(4) Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate~~.~~

6.6.2.~~5~~4 **Field limitation on x-ray equipment other than general purpose radiographic systems.**

(1) ~~Beam Limitation Requirements for Each~~ X-Ray System**s** Designed for One Image Receptor Size.

(~~1~~**a**) Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two (2) percent of the SID; or

(~~2~~**b**) Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

6.6.2.~~6~~5 Beam Limitation Requirements for Each X-Ray System **Not**~~Other Than~~ Governed by 6.6.2.1 through 6.6.2.~~5~~4**:**

(1) **Which are also designed for use with extraoral image receptors and when used with an extraoral image receptor** ~~Means~~ shall**:**

(a) ~~be~~**Be** provided **with means** to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two (2) percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor~~.~~**; and**

(b~~2~~) ~~Means shall be~~**Be** provided **with means** to align the center of the x-ray field with the center of the image receptor to within two (2) percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(~~3~~**2)** **The requirements of** ~~6.6.2.6(1)~~**6.6.2.5(1)** ~~and 6.6.2.6(2)~~ may be met with a system that meets the requirements for a general purpose x-ray system as specified in ~~6.6.2.1 and 6.6.2.2~~**6.6.2 and 6.6.2.3**, or, when alignment means are also provided, may be met with either:

(a) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(b) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

Commented [JJ419]: Added for consistency with F.6f.iv

Although new to Part 6, this provision appeared in an earlier version of Part F.

Based upon stakeholder feedback specific SID (numerical) values given as examples in Part F have not been included in the proposed Part 6 revision. Stakeholders indicated that including them may cause confusion. It appears that Part F intended these values to be examples only.

21 CFR 1020.31(e)(4)

Commented [JJ420]: F.6g

Commented [JJ421]: Updated for consistency with wording in F.6g.i

Commented [JJ422]: Current language of Part 6 is modified slightly but retained for this section header as it provides more clarity and detail than that of SSRCR Part F, Section F.6g.ii.

21 CFR 1020.31(f)(4)

Commented [JJ423]: Language is slightly modified for rule flow and clarity from that in SSRCR Part F due to formatting differences between Part 6 and Part F.

21 CFR 1020.31(f)(4)

Commented [JJ424]: F.6g.ii(2)

21 CFR 1020.31(f)(4)(ii)

Commented [JJ425]: F.6g.ii(3)

21 CFR 1020.31(f)(4)(iii)

6.6.2.~~7~~6 Positive Beam Limitation (PBL). ~~for a diagnostic x-ray system with any certified component.~~ **The requirements of 6.6.2.6 shall apply to radiographic systems which contain PBL.**

(1) **Field size.** When a PBL system is provided, it shall prevent x-ray production when:

(a) Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than three (3) percent of the SID; or

(b) The sum of the length and width differences as stated in ~~6.6.2.7~~**6.6.2.6**(1)(a) without regard to sign exceeds four (4) percent of the SID.

(c) The beam-limiting device is at a SID for which PBL is not designed for sizing.

(2) **Conditions for PBL.** When provided, the PBL system shall function as described in ~~6.6.2.7(1)~~**6.6.2.6(1)** whenever all the following conditions are met:

(a) The image receptor is inserted into a permanently mounted cassette holder;

(b) The image receptor length and width are less than 50 cm;

(c) The x-ray beam axis is within ± three (3) degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within ± three (3) degrees of horizontal and the SID is 90 cm to 205 cm inclusive;

(d) The x-ray beam axis is perpendicular to the plane of the image receptor to within ± three (3) degrees;

(e) Neither tomographic nor stereoscopic radiography is being performed;

~~(f) Manual collimation is not used;~~

~~(g) The machine is used for procedures other than therapy simulation; and~~

~~(h) The PBL system has not been intentionally overridden.~~

(3) Measuring compliance.

(a) Compliance with the requirements of 6.6.2.6(1) shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of 6.6.2.6(2) are met; and

(b) Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

(~~3~~4) **Override of PBL.** ~~If a means of overriding the PBL system exists, that means shall:~~

(a) A capability may be provided for overriding PBL in case of system failure and for servicing the system.

Commented [JJ426]: F.6h

21 CFR 1020.31(g)

Commented [JJ427]: F.6h.i

21 CFR 1020.31(g)(1)

Commented [JJ428]: F.6h.ii

21 CFR 1020.31(g)(2)

Commented [JJ429]: Provisions (f), (g), and (h) are not found in Part F and are therefore removed. They are also not present in the source rule 21 CFR 1020.31.

Commented [JJ430]: Updated for consistency with F.6h.iii

This provision restates and replaces (prior) 6.6.2.7(3) such that it now immediately follows the section it references.

21 CFR 1020.31(g)(3)

~~(a) Be designed for use only in the event of PBL system failure, or if the system is being serviced; and~~

(b) This override may be for all SIDs and image receptor sizes.

(c) A key shall be required for any override capability that is accessible to the operator.

(i) It shall not be possible to remove the key while PBL is overridden.

(ii) Each such key switch or key shall be clearly and durably labeled as follows:

For X-Ray Field Limitation System Failure

~~(b)~~**(d) The override capability is considered accessible to the operator:**

(i) ~~Require, if in a position that the operator would consider it part of the operational controls, or if~~**If** it is referenced in the operator's manual, or in other materials intended for the operator~~, that:~~**;or**

(ii) If its location is such that the operator would consider it part of the operational controls.

~~(i) A key be utilized to defeat the PBL;~~

~~(ii) The key remain in place during the entire time the PBL system is overridden; and~~

~~(iii) The key or key switch be clearly and durably labeled as follows:~~

~~"FOR X-RAY FIELD LIMITATION SYSTEM FAILURE" ; and~~

~~(c)~~**(e)** Not be used as a substitute for prompt repair.

~~(4) Compliance with 6.6.2.7 shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of 6.6.2.7(2) are met.~~

~~(5) Compliance shall be determined no sooner than five (5) seconds after insertion of the image receptor.~~

~~(6)~~**(5) Operator initiated undersizing.** The PBL system shall be capable of ~~operation~~**operating such that**, at the discretion of the operator, ~~such that~~ the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size.

~~(7)~~**(a) Each dimension of the**~~The~~ minimum field size at an SID of 100 cm shall be equal to or less than 5 cm~~ by 5 cm~~.

(b) Return to PBL function as described in 6.6.2.6(1) shall occur automatically upon any change of image receptor size or SID.

Commented [JJ431]: Section reformatted for better consistency with F.6h.v.

21 CFR 1020.31(g)(5)

Commented [JJ432]: The requirements of this section are retained but are replaced by 6.6.2.6(3) so that it immediately follows the section it references.

Commented [JJ433]: The requirements of this section are retained but are replaced by 6.6.2.6(3) so that it immediately follows the section it references.

Commented [JJ434]: Updated for consistency with SSRCR Part F, Section F.6h.iv

21 CFR 1020.31(g)(4)

~~(8) The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in 6.6.2.7, then any change of image receptor size or SID must cause the automatic return.~~

(6) Disabling of PBL. A facility has the option to permanently functionally disable a PBL system. When this option is chosen, the standards for manual collimation apply.

6.6.3 Radiation Exposure Control ~~Devices~~.

6.6.3.1 Exposure initiation

(1) 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.

(2) In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

6.6.3.2 Exposure Indication

(1) Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced.

(2) In addition, a signal audible to the operator shall indicate that the exposure has terminated.

6.6.3.~~1~~**3** Timers.

(1) 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.

(~~2~~**a**) **Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second.**

~~(3) 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.~~

(~~3~~**b**) **Except during panoramic dental radiography,** ~~T~~termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero".

(c) During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

6.6.3.~~2~~**4** X-ray Control.

~~(1) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:~~

~~(a) Exposure of one-half (0.5) second or less, or~~

~~(b) During serial radiography when a means shall be provided to permit completion of any single exposure of the series in process.~~

Commented [JJ435]: The requirements of this section are retained but are replaced by 6.6.2.6(5) for consistency with flow of SSRCR Part F, Section F.6h(v).

21 CFR 1020.31((g)(4)

Commented [JJ436]: This is a new provision for Part 6. Language is added for consistency with SSRCR Part F, Section F.6h.vi.

This requirement is new to the 2015 SSRCR Part F revision.

Commented [JJ437]: Section title updated, consistent with SSRCR Part F, Section F.6k.

Commented [JJ438]: Provision added, consistent with SSRCR Part F, Section F.6k.i

This does not appear to be a new provision in Part F.

Commented [JJ439]: Provision added, consistent with SSRCR Part F, Section F.6k.ii

Similar requirements also appear in other sections of Part 6, including 6.4, 6.5, 6.7 and 6.9

Commented [jsj440]: F.6b.i

21 CFR 1020.31(a)(2)

Commented [JJ441]: This provision is replaced by 6.6.3.1(1) which provides expanded requirements.

Commented [JJ442]: Provision updated consistent with SSRCR Part F, Section F.6b.i(1)

Commented [JJ443]: Provision added, consistent with SSRCR Part F, Section F.6b.i(2)

21 CFR 1020.31(a)(2)(ii)

Commented [JJ444]: The requirements of this provision are addressed above in 6.6.3.3(1)(a), and (c).

~~(2)~~**(1)** Except for ~~a~~ bone densitometry **and veterinary** system**s**, each x-ray control shall be located in such a way as to meet the following requirements:

(a) **Stationary radiographic systems.**

~~For stationary x-ray systems, and mobile or portable systems used routinely in one location, the x-ray control permanently mounted in a separated area behind a whole body protective barrier (of not less than 0.25 millimeter lead equivalent) where the operator is required to remain during the entire exposure.~~**Stationary radiographic systems shall be required to have the x-ray control, including the exposure switch, permanently mounted in a protected (shielded) area so that the operator is required to remain in that protected area during the entire exposure. Design of the operator protected area shall be consistent with Appendix 6B**.

(b) **Mobile and portable systems.**

Mobile and portable x-ray systems **which are:**

(i) ~~in one location shall be required to have an exposure switch so arranged that the operator can stand at least 2 meters (more than 6 feet) from the patient, the x-ray tube and the useful beam.~~**Used daily for seven (7) or more consecutive working days in the same location (a room or area), shall meet the requirements of a stationary system in 6.6.3.4(1)(a), unless otherwise evaluated and exempted by the requirements of 6.3.3.1(2);**

(ii) Used daily for less than seven (7) consecutive working days in the same location (a room or area), shall be provided with at least one of the following:

1. A lead-equivalent protective barrier at least 2 meters (more than 6 feet) high for operator protection during exposures; or

2. Means to allow the operator to be at least 2 meters (more than 6 feet) from the patient, x-ray tube and the useful beam during the exposure; or

3. A lead-equivalent protective garment with thyroid shielding.

~~(i) Mobile and portable x-ray systems used in surgery are considered to be not routinely used in one location.~~

~~(ii) A separate exposure switch is not required for portable hand-held x-ray equipment that has the control on the device.~~

(c) Podiatry facilities shall meet the protection requirements in 6.6.3.4(1)(b)(ii).

~~(3)~~**(2) For x-ray equipment capable of displaying technique factors,** ~~The settings~~**the technique factors** to be used during an exposure shall be indicated before the exposure begins.

Commented [jsj445]: Provision (1)(a) is updated for consistency with Part F, Section F.6k.iii(1) with the exception that "shielded" is added in parenthesis for clarity.

Commented [JJ446]: Although not found in Part F, a reference to the operators booth requirements of Appendix 6B is added for clarity based on staff recommendation.

Commented [JJ447]: Section (b), and (c) updated for consistency with SSRCR Part F, Section F.6k.iii.(2)(a), (b), and (3), with the following exception:The original language of Part F is interpreted to mean that the use is daily and consecutive, so the proposed language of Part 6 uses this language, and "one week" is replaced with "7 days".

Commented [JJ448]: The language of Part F specifies that machines "used less than one week…" must follow the specified requirements.

Based upon radiation advisory committee discussions, allowance for use of a lead-equivalent protective garment is added. Thyroid and eye protection is included to provide more complete protection.

Commented [JJ449]: The language of the current rule is retained over that in Part F, due to possible concerns with some current machines/facilities not meeting the requirement. Additionally, the wording of the current rule should provide for additional protection by having the operator be positioned away from those areas that provide the most significant scatter and direct radiation.

Commented [jsj450]: F.6k.iii(3).

Commented [jsj451]: F.4d

(a) When automatic exposure controls are used, the exposure settings that are set prior to the exposure shall be indicated.

(b) ~~On equipment having fixed exposure settings, permanent markings visible from the operator's position are acceptable .~~**On equipment having fixed technique factors, the requirement of 6.6.3.4(2)(a) may be met by having permanent markings on the equipment. Technique factors shall be visible from the operator's position except when performing spot imaging during fluoroscopy.**

(c) The accuracy of the indicated kilovoltage peak (kVp) shall meet manufacturer specifications. In the absence of a manufacturer specification, kVp accuracy shall be within ±10 percent.

6.6.3.~~3~~5 Automatic Exposure Controls. **When an automatic exposure control is provided:**

(1) ~~When an automatic exposure control is provided, i~~Indication shall be made on the control panel when this mode of operation is selected;

(2) ~~If~~ **When** the x-ray tube potential is equal to or greater than ~~50~~**51 kilovolts peak (**kVp**)**, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two (2) pulses;

(3) The minimum exposure time for all **other** equipment other than that specified in 6.6.3.~~3~~5(2) shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 **miliampere seconds (**mAs**)**, whichever is greater;

(4) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 **kilowatt-seconds (**kWs**)** per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than ~~50~~**51** kVp, **in which case** the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(5) A visible signal shall indicate when an exposure has been terminated at the limits required by ~~6.6.3.3(4)~~**6.6.3.5(4)**, and manual resetting shall be required before further automatically timed exposures can be made.

6.6.3.6 Accuracy.

(1) Deviation of technique factors under Section 6.6.3.3 and 6.6.3.5 from indicated values shall not exceed the limits given by the manufacturer.

(2) If manufacturer specifications are not available, the following criteria shall be used:

(a) The kVp shall not deviate from indicated values by more than ten (10) percent.

(b) The timer accuracy shall not deviate from indicated values by more than:

Commented [JJ452]: Updated consistent with Part F, Section F.4d.ii., with the exception that language was modified from Part F for clarity.

Commented [JJ453]: Updated consistent with Part F, Section F.4d.iii.

Commented [jsj454]: 6.6.3.3(1) – (5) ~ F6b.ii.

21 CFR 1020.31(a)(3)

Commented [jsj455]: Language updated, consistent with Part F, Section F6b.ii(1)

The value of 50 kVp is changed to 51 kVp, consistent with Part F and 21 CFR 1020.31(a)(3)(ii).

Commented [JJ456]: Language updated, consistent with Part F, Section F.6b.ii(2)

21 CFR 1020.31(a)(3)(ii)

Commented [JJ457]: Language updated, consistent with Part F, Section F.6b.ii(3)

21 CFR 1020.31(a)(3)(iii)

Commented [JJ458]: = Part F, Section F.6b.ii(4)

21 CFR 1020.31(a)(3)(iii)

Commented [JJ459]: Added, consistent with SSRCR Part F, Section F.6b.iii

Variation of 21 CFR 1020.31(a)(4)

(i) Ten (10) percent for an indicated time of greater than 20 ms; or

(ii) Fifty (50) percent for an indicated time of 20 ms or less, or 1 pulse, whichever is greater.

6.6.3.~~4~~7 ~~Timer~~ Reproducibility.

(1) **Coefficient of variation.** For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than 0.05.

~~(2) Measuring compliance for linearity shall be in accord with 21 CFR 1020.31.~~

(2) Measuring compliance.

(a) Determination of compliance shall be based on 10 (or as otherwise specified in nationally accepted standards) consecutive measurements of air kerma taken within a time period of 1 hour.

(b) Equipment manufactured after September 5, 1978, shall be subject to the additional requirement that all variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement.

(c) For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field emission equipment rated for pulsed operations or no less than one-tenth second.

6.6.3.8 Linearity.

The following requirements apply for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated value:

(1) For equipment having independent selection of x-ray tube current (mA), the average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum.

This is: $|X_1 - X_2| \leq 0.10(X_1 + X_2)$;

Where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(2) Equipment having selection of x-ray tube current-exposure time product (mAs).

For equipment manufactured after May 3, 1994, the average ratios of

Commented [JJ460]: =F.6c

Commented [JJ461]: Language updated for consistency with SSRCR Part F, Section F.6c.i

21 CFR 1020.31(b)(1)

Commented [JJ462]: This provision has been replaced by the requirements of 6.6.3.8.

Commented [JJ463]: Provision added, consistent with SSRCR Part F, Section F.6c.ii, with the following exception: A provision from Part F pertaining to measurement of line voltage is not included in Part 6 based on advisory committee statements that it is not a task that medical physicists can routinely or safely perform.

21 CFR 1020.31(b)(2)

Commented [JJ464]: This provision has been relocated from 6.6.3.7(2) (formerly 6.6.3.4(2)). The specific requirements have been spelled out rather than reference the CFR.

Commented [JJ465]: 21 CFR 1020.31(c)(1)

Commented [JJ466]: 21 CFR 1020.31(c)(2)

air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum.

This is: $|X_1 - X_2| \leq 0.10(X_1 + X_2)$

Where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) Measuring compliance.

Commented [JJ467]: 21 CFR 1020.31(c)(3)

(a) Determination of compliance will be based on 10 exposures (or as specified in nationally accepted standards), made within 1 hour, ~~at each of the two settings.~~ at two or more settings over a range of clinically relevant mAs values.

(i) These ~~two~~ settings may include any two focal spot sizes except where one is equal to or less than 0.45 mm and the other is greater than 0.45 mm.

(ii) For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer.

6.6.3.~~5~~**9** Source-Skin Distance.

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

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

Commented [JJ468]: Added, consistent with Part F, Section F.6(i) and relocated from original provision 6.3.3.9(2) (which was subsequently deleted from that section).

6.6.3.~~6~~**10** Exposure Reproducibility.

(1) When all exposure settings are held constant, including control panel selections associated with automatic exposure control systems the coefficient of variation of air kerma for both manual and automatic exposure control systems shall not exceed 0.05.

Commented [jsj469]: ~F.6.c.

~~(2) The facility registrant may request an exemption for any machines manufactured prior to 1974 that cannot meet this requirement. The exemption request must verify that this exposure reproducibility variation will not result in unnecessary patient radiation exposure due to the need for repeat examinations.~~

Commented [jsj470]: This provision does not appear in Part F and is therefore deleted.

6.6.3.~~7~~**11** Radiation from Capacitor Energy Storage Equipment. ~~in Standby Status.~~

Commented [JJ471]: Updated, consistent with Part F, Section F.6j.

21 CFR 1020.31(l)

Radiation emitted from the x-ray tube shall not exceed:

(1) **An air kerma of 0.26 microGy (0.03 mR exposure) in 1 minute at 5 cm from any accessible surface of the diagnostic source assembly,** ~~Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 0.5 µC/kg (2 mR) per hour at 5 cm from any accessible surface (that can be easily or accidentally touched by an individual without the use of a~~

Commented [jsj472]: Updated, consistent with F.6j.i.

21 CFR 1020.31(l)(2)

~~tool) of the diagnostic source assembly,~~ with the beam-limiting device fully open**, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated**.

(a) Compliance shall be determined by measurements averaged over an area of 100 cm, with no linear dimensions greater than 20 cm; and

(2) An air kerma of 0.88 milliGy (100 mR exposure) in one hour at 100 cm from the x-ray source, with beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power.

(a) Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total number of discharges in 1 hour (duty cycle).

(b) The measurements shall be averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

~~6.6.3.8 Linearity for a diagnostic x-ray system with any certified component shall be in accord with 21 CFR 1020.31(c)(3).~~

~~6.6.3.9 Accuracy for a diagnostic x-ray system with any certified component.~~

~~(1) Deviation of exposure settings from indicated values shall not exceed the limits specified for that system by its manufacturer.~~

~~(2) If manufacturer specifications are not available, the following criteria shall be used:~~

~~(a) The kVp shall not deviate from indicated values by more than ten (10) percent.~~

~~(b) The timer accuracy shall not deviate from indicated values by more than:~~

~~(i) Ten (10) percent for an indicated time of greater than 20 ms; or~~

~~(ii) Fifty (50) percent for an indicated time of 20 ms or less, or 1 pulse, whichever is greater.~~

~~6.6.4 For each general purpose x-ray imaging system, the registrant shall ensure that manufacturer maintenance specifications are followed.~~

~~6.6.5 For each general-use diagnostic radiographic x-ray system, the registrant shall ensure that written quality control and quality assurance procedures are available and in use, including for facility operations and emergencies.~~

~~6.6.5.1 The quality control and quality assurance procedures shall be consistent with 6.3.5 and shall follow:~~

~~(1) Specifications of the manufacturer; and~~

~~(2) Specifications of a registered medical physicist; and/or~~

~~(3) Standards of an appropriate nationally recognized organization.~~

Commented [jsj473]: Language is added consistent with F.6.j.ii.

The added language and sentence is not new to Part F, but is not currently in Part 6.

21 CFR 1020.31(l)(2)

Commented [jsj474]: This specific provision (as written) is not found in Part F, but is replaced by the revised and expanded 6.6.3.8. Rather than reference the requirements of the CFR, the revised/new section 6.6.3.8 lists the specific linearity requirements.

Commented [JJ475]: Deleted language has been relocated to 6.6.3.6 so it is physically closer to the sections it makes reference to, and to follow the structure of Part F.

Commented [JJ476]: This section is deleted as similar requirements generally appear in other sections of the rule.

Commented [JJ477]: This section is deleted as similar requirements appear in:
-6.3.5.1(3) [similar to the requirements in F.3b.i(3)]
-6.3.5.1(8)
-6.3.5.6(4) [similar to the requirements in F.3b.iii(4)]
-6.3.5.9

~~6.6.5.2 Routine periodic quality control shall be comparable to the following:~~

~~(1) Cassette maintenance (for example, erasure and/or screen cleaning);~~

~~(2) Images inspected for evidence of clinically relevant artifacts (for example, dust and non-uniformities) with appropriate corrective action (for example, cleaning of screens) taken as needed and documented;~~

~~(3) Analysis of repeated and/or rejected images;~~

~~(4) Investigation of errors outside a control range;~~

~~(5) Measurements using phantoms, if required (for example, in bone densitometry); and~~

~~(6) Measurements of scattered radiation at the operator's position, if required (for example, in bone densitometry).~~

~~6.6.5.3 Annual quality assurance shall be comparable to the following:~~

~~(1) All quality control tests shall be reviewed annually;~~

~~(2) Imaging systems shall be tested in accordance with standards and protocols published by a nationally recognized organization; and~~

~~(3) The frequency of quality control testing and corrective actions taken as a result are followed and documented.~~

6.6.4 Tube stands for portable x-ray systems.

Except during veterinary field operations where it is impractical to do so, a tube stand or other mechanical support shall be used for portable x-ray systems that are not intended to be hand-held during operation.

6.7 ~~Safe Uuse of a Ddental Xx-Rray imaging Ssystem.~~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.~~1~~2 ~~In addition to the provisions of 6.3 and 6.4, the requirements of 6.7 apply to equipment and associated facilities for dental x-ray imaging.~~**All dental facilities using any type of x-ray equipment for dental x-ray imaging, shall:**

(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:

Commented [JJ478]: The provision from Part F, Section F.6l is added, but is modified slightly for clarification.

Specifically, the phrase "…that are not intended to be hand-held during operation…" replaces the Part F language that states "…so that the x-ray tube housing assembly need not be hand-held during an exposure".

The modified language was added to better distinguish between portable x-ray systems which may be readily movable but are generally not intended to be hand-held during operation, and those systems which are both portable and designed to be hand-held during operation, such as some battery operated units.

Commented [JJ479]: Added, consistent with Part F, Section F.7r.

Although the Department believes there are a limited number of these machines in use in Colorado, a 2 year phase out period is proposed for dental x-ray machines having an output less than 51 kVp. Such machines have a higher patient dose. After the proposed date, operation of machines below 51 kVp would be prohibited.

Commented [jsj480]: Language updated, consistent with Part F, Section F.7.

Based on comments during review and discussions by the Radiation Advisory Committee, this section is reworded and restructured for clarity.

(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.~~2~~**5** Each individual who operates a dental x-ray imaging system shall meet the applicable adequate radiation safety training and experience requirements of 2.6.1, in particular ~~2.6.1.11~~**2.6.1.10**.

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

6.7.2 Each dental x-ray imaging system shall meet the following equipment design and configuration requirements.

6.7.2.1 Warning Label.

(1) Warning labels shall be maintained in accordance with 6.4.2.1.

6.7.2.~~1~~**2** Cephalometric and volumetric dental ~~x-ray~~**imaging** systems shall meet the equipment design and configuration requirements of 6.3.2 and 6.6.2, except that:

(1) The shielding design described in 6.3.2 is required for the **imaging** room(s) of any facility having a cephalometric ~~and/~~or volumetric dental ~~x-ray~~**imaging** system**, or a system that can be operated in a cephalometric mode** regardless of **the** occupancy **of adjoining rooms**.

(2) A dental facility may apply **to the Department** in writing and **may** be granted **an** exemption **from the**~~by the Department~~ **requirements of 6.7.2.2** for a particular room and x-ray equipment configuration.

6.7.2.~~2~~**3** Intraoral and panoramic dental x-ray systems shall meet the following requirements:

(1) The useful x-ray beam shall be limited to the area of clinical interest.

~~(1)~~**(2)** Source-Skin Distance (SSD) for Intraoral Dental X-ray Systems.

(a) ~~Each x~~**X**-ray imaging system designed for use with an intraoral image receptor shall be provided with means to limit **the** SSD, to not less than 18 cm if operable above 50 kVp.

~~(2)~~**(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:

Commented [jsj481]: Provision added, consistent with Part F, Section F.7a.ii.

Commented [JJ482]: Based on stakeholder feedback, the phrase “or processor system” is added for clarity to address those facilities which use enclosed automatic processors in lieu of a walk-in type darkroom used in traditional film imaging. The “or processor” language does not appear in SSRCR Part F.

Commented [jsj483]: This provision is modified from Part F by specifying that training records be maintained in accordance with Part 2.

Commented [jsj484]: Language added, consistent with F.7b.

Rather than repeat the warning label requirements of F.7b, the language is written to defer to Section 6.4.2.1 which contains the same language.

Commented [JJ485]: “X-ray systems” is modified to “imaging systems” for consistency with the “volumetric dental imaging systems” definition.

Commented [JJ486]: Language is modified for clarity.

Commented [JJ487]: The current Part 6 provision is retained as is, consistent with 21 CFR 1020.31(i). (Prior drafts of the rule proposed a limit which was applicable to general use machines and not applicable to intraoral dental imaging systems).

Commented [JJ488]: Provision is retained as found in the current rule for consistency with 21 CFR 1020.31(f)(i)(1). The Part F model rule appears to be inconsistent with this requirement and is therefore not incorporated.

(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, 2022, only rectangular collimators shall be used for routine intraoral dental imaging.

~~(3)~~**(4)** As provided in 6.3.2.4, neither the shielding design described in 6.3.2 nor the dimensional drawing, calculation or survey described in 6.3.2.3 are required for intraoral or panoramic dental equipment.

6.7.2.4 Extraoral, panoramic and cephalometric units.

(1) X-ray systems designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x- ray field in the plane of the image receptor so that such field does not exceed each dimension 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. In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and alignment the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
The requirements of 6.7.2.4(1) may be met with:

(a) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(b) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

6.7.2.5 Modification of diagnostic x-ray components and systems shall be done only in accordance with 6.3.1.2(3).

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

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 ~~instead of the requirements in 6.6.3~~:

(1) Timers.

Commented [JJ489]: This new, phased-in requirement is added based on recommendations/discussions with stakeholders during the Part 6 stakeholder process.
Most dental image receptors are typically rectangular in shape while most collimators in use are round, causing a mismatch between the actual radiation field and imaging receptor. The additional radiation extends beyond the receptor device and area of interest resulting in unnecessary radiation exposure to the patient. Advisory bodies and technical papers have indicated that use of rectangular collimation along with rectangular image processors will provide radiation dose reduction to patients.

Commented [JJ490]: Language added, consistent with F.7p.iii.(1)

21 CFR 1020.31(f)(4)

Commented [JJ491]: Language added, consistent with F.7p.iii.(1)(a)

21 CFR 1020.31(f)(4)(ii)

Commented [JJ492]: Language added, consistent with F.7p.iii.(1)(b)

21 CFR 1020.31(f)(4)(iii)

Commented [JJ493]: Provision added to defer to Section 6.3.1.2(3) consistent with the requirement of Part F, Section F.7s.

Rather than repeat the provision in 6.7, the rule defers to Section 6.3.

Commented [JJ494]: Reference to 6.6.3 is removed since the applicable requirements are incorporated into 6.7.3.2.

(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.

(~~a~~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.

(~~b~~c) Each control **location and operator protection.** ~~shall be located as follows:~~

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** ~~For stationary x-ray systems, and mobile or non-handheld portable systems used routinely in one location, the x-ray control permanently mounted in a separated area behind a whole body protective barrier (of not less than 0.25 millimeter lead equivalent) where the operator is required to remain during the entire exposure, or the exposure control shall be such that the operator can stand at least 2 meters (more than 6 feet) from the patient, the x-ray tube and the useful beam;~~

(ii) **At least 2 meters (more than 6 feet) from the patient, x-ray tube, and the useful beam, while making exposures.** ~~Mobile and non-hand-held portable x-ray systems not routinely used in one location shall be required to have an exposure switch so arranged that the operator can stand at least 2 meters (more than 6 feet) from the patient, the x-ray tube and the useful beam; or~~

~~(iii)~~ **The requirements of Appendix 6E shall be followed for x-ray equipment intended to be hand held during**

Commented [JJ495]: F.7n.

Commented [JJ496]: This provision does not appear in F.7, but does appear in other areas of Part F (F.6) which are not applicable to dental use.

Commented [JJ497]: This provision does not appear in F.7, but does appear in other areas of Part F (F.6) which are not applicable to dental use.

Commented [JJ498]: Although this provision does not appear in Part F, it is retained in Part 6 as it remains a requirement of FDA in 10 CFR 21.

Commented [jsj499]: Language updated, consistent with Part F, Section F7.c

Commented [JJ500]: This provision does not appear in F.7, but does appear in other areas of Part F (F.6, F.11) which are not applicable to dental use.
However, this remains a requirement of 21 CFR 1020.31(a)(2)(i).

Commented [jsj501]: Language of (2)(c) updated, consistent with Part F, Section F7.d.i, ii.

The phrase "during operation" is added for clarity.

Commented [JJ502]: The language of the current rule is retained over that in Part F, due to possible concerns with some current machines/facilities not meeting the requirement. Additionally, the wording of the current rule should provide for additional protection by having the operator be positioned away from those areas that provide the most significant scatter and direct radiation.

Commented [JJ503]: The phrasing of this provision is revised to enable it fit within the format and revisions to the prior sections.

operation~~Portable hand-held x-ray equipment shall meet Appendix 6E~~.

~~(3) Exposure Reproducibility.~~

~~(a) The estimated coefficient of variation of radiation exposure shall be no greater than 0.05, for any specific combination of selected exposure settings.~~

~~(4) Linearity shall be in accord with 21 CFR 1020.31(c)(3).~~

~~(5)~~**(3)** Accuracy.

(a) Deviation of exposure settings from indicated values shall not exceed the limits specified for that system by its manufacturer.

(b) If manufacturer specifications are not available, accuracy of all exposure factors shall be within ten (10) percent of the selected factor(s).

~~(6)~~**(4)** Beam Quality.

(a) All dental x-ray systems shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent.

(b) Systems operating above 70 kVp are subject to the filtration requirements of 6.4.2.5(1).

(c) The Half Value Layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in Appendix 6I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Appendix 6I, linear interpolation or extrapolation may be made.

(i) Positive means shall be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure.

(ii) In the case of a system, which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector which will prevent x-ray emissions if the minimum required filtration is not in place.

~~(7)~~**(5)** Patient and image receptor holding devices shall be used when the techniques permit.

~~(8)~~**(6)** ~~The tube housing and the PID shall not be hand-held during an exposure, except as provided in Appendix 6E for portable hand-held x-ray equipment.~~**Except for units designed to be hand held during operation, the tube housing and position indicating device (PID) shall not be hand-held during an exposure.**

~~(9)~~**(7)** The x-ray system shall be operated in such a manner that the area of the useful beam at the patient's skin is minimized **while ensuring adequate coverage of relevant anatomy**.

Commented [JJ504]: This provision is replaced by the requirements of 6.7.3.11.

Commented [JJ505]: This provision does not appear in Part F, Seciton F.7 and is therefore deleted.

Additionally, the linearity tests required by 21 CFR 1020 cannot be performed on basic dental machines due to their limited design and capabilities.

Commented [JJ506]: Added, consistent with F.7q.

Commented [jsj507]: Part F, Section F.7e.i

Commented [JJ508]: Language updated consistent with F.7e.ii.

The phrase “during operation” is added for clarity.

Commented [JJ509]: There is no equivalent provision in Part F, but this general provision is retained in consideration of patient radiation safety.

~~(10)~~**(8)** Dental fluoroscopy without image intensification or direct digital receptors shall not be used.

6.7.3.3 The x-ray control shall provide:

(1) Visual indication observable at the operator's protected position whenever x-rays are produced; and

(2) A signal audible to the operator shall indicate that the exposure has terminated.

6.7.3.4 ~~A thyroid shield shall be used to reduce patient exposure to scattered radiation (except for a case in which shielding would interfere with the diagnostic procedure).~~ **Excluding cases in which shielding would interfere with the diagnostic procedure, thyroid shielding shall be required for pediatric patients when performing intra-oral imaging.**

6.7.3.5 Absent structural protection against scatter radiation, during radiation machine operation at least a 2-meter distance (more than 6 feet) shall be maintained from any bystander location and between patient operating chairs.

6.7.3.6 Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube which has been selected shall be clearly indicated prior to initiation of the exposure. Only the selected tube can be energized.

(1) This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

6.7.3.7 Mechanical support of tube head. Excluding hand-held systems, tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

6.7.3.8 On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

6.7.3.9 All position locking, holding, and centering devices on the x-ray system and/or components shall function as intended.

6.7.3.10 For x-ray equipment capable of displaying technique factors, the technique factors to be used during an exposure shall be indicated before the exposure begins.

(1) If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

(2) The requirement of 6.7.3.10(1) may be met by permanent markings on equipment having fixed technique factors.

6.7.3.11 For any specific combination of selected technique factors, the coefficient of variation of the air kerma shall be no greater than 0.05.

6.7.3.12 Deviation of technique factors from indicated values shall not exceed the limits provided by the manufacturer.

Commented [JJ510]: F.7g.

Commented [JJ511]: F.7g
The current wording of Part 6 is slightly more prescriptive than that of F, but is believed to be in the best interest of radiation safety.

Commented [JJ512]: Although a specific requirement for thyroid shielding is not found in the Part F model regulation, in the interest of radiation safety and following discussions with the Radiation Advisory Committee, stakeholders, and review of recommendations of external organizations, a modified requirement from the current Part 6 is retained.

EPA's Federal Guidance Report #14 (on which Part F is partially based) and the National Council on Radiation Protection (NRCP) Report No. 145 (which precedes the EPA report) specifies requiring thyroid shielding for children and recommending it for adult patients.

The American Dental Association also recommends that thyroid shields be used whenever possible, and in particular for children, pregnant women, and women of child-bearing age.

Commented [JJ513]: Provision added, consistent with F.7h. A similar provision also appears in 6.4.2.6(2).

Commented [JJ514]: Provision added, consistent with F.7i. A similar provision also appears in 6.4.2.6(1).

Commented [JJ515]: Provision added, consistent with F.7j. A similar provision also appears in 6.4.2.2(1).

Commented [JJ516]: Provision added, consistent with F.7k. A similar provision also appears in 6.4.2.7.

Commented [JJ517]: Provision added, consistent with F.7l.i

21 CFR1020.31(a)(1)

Commented [JJ518]: Provision added, consistent with F.7l.ii

21 CFR1020.31(a)(1)

Commented [JJ519]: Provision added, consistent with F.7m

21 CFR1020.31(b)(1)

Commented [JJ520]: Provision added, consistent with F.7o

Variation of 21 CFR1020.31(a)(4)

(1) At a minimum, the kVp on variable kVp units shall be accurate to within 10 percent and within 20 percent on fixed kVp units.

6.7.4 For each dental x-ray imaging system, manufacturer maintenance specifications shall be followed.

6.7.5 For each dental x-ray imaging system, written quality control and quality assurance procedures shall include:

6.7.5.1 For **manual** processing of intraoral films, performance of the following:

(1) Follow applicable manufacturer's time and temperature specifications, which shall be available for review;

(2) Measure and log temperature each day of use; and

(3) Document in a written log the change of developer chemicals at least every month.

6.7.5.2 For volumetric dental **imaging** systems, conduct periodic calibrations and annual quality control tests according to the manufacturer's specifications, including any additional or more frequent testing necessary at the recommendation of the registered medical physicist **or consistent with the standards of an appropriate nationally recognized organization, for example, the American Association of Physicists in Medicine**.

6.7.5.3 Annual review of all quality control tests.

6.8 ~~Safe Uuse of a Vveterinary Mmedicine limaging Ssystem.~~Requirements for use of a veterinary medicine imaging system.

6.8.1 Administrative Controls.

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 ~~2.6.1.13~~**2.6.1.12**.

6.8.2 Each veterinary medicine installation shall meet the following equipment design and configuration requirements.

6.8.2.1 Equipment.

(1) The protective tube housing shall be equivalent to the requirements of 6.4.2.3.

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

(3) The total filtration permanently in the useful beam shall meet the requirement of 6.4.2.5(1).

(4) All stationary, mobile or portable x-ray systems shall be provided with either:

Commented [JJ521]: This provision does not appear in F.7A but is retained since similar requirements in 6.3.5.1(5) are not applicable to dental machines.

Commented [JJ522]: The original provision is not found in Part F but is retained in the interest of safety.

Although this does not appear in Part F.7, reference to other national standards is added for consistency with the general quality assurance program requirements of 6.3.5.1(3).

Commented [JJ523]: There is no equivalent section to 6.8 on veterinary use in Part F. In Part F, veterinary requirements are combined with other sections.

Based on stakeholder feedback it was recommended that Section 6.8 be retained as a veterinary specific section.

Commented [jsj524]: Although Part F does not contain a specific section on requirements applicable to veterinary medicine, for consistency in protection of workers/ancillary personnel throughout the rule, the language of F6.k.iv is integrated into this veterinary section.

Allowance for use of a lead-equivalent apron and eye protection is added based on Radiation Advisory Committee discussion, comments, and additional evaluation.

(a) A lead-equivalent protective garment with thyroid shielding and lead-equivalent eye protection.

(b) A 2 meter (more than 6 feet) high protective barrier for operator protection during exposures; or

(c) Shall be provided with means to allow the operator to be at least 2 meters (more than 6 feet) from the patient, x-ray tube, and the useful beam during exposures.

Commented [JJ525]: The language of the current rule is retained over that in Part F, due to possible concerns with some current machines/facilities not meeting the requirement. Additionally, the wording of the current rule should provide for additional protection by having the operator be positioned away from those areas that provide the most significant scatter and direct radiation.

6.8.2.2 A method shall be provided for visually defining the perimeter of the x-ray field.

(1) The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 (two) percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

6.8.2.3 Structural Shielding.

(1) All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with 4.6, 4.12, 4.13, and 4.14.

(2) A veterinary installation shall meet the requirements of 6.3.2 in order to minimize radiation exposure to personnel and individual members of the public.

(3) Veterinary facilities are exempt from the requirements of Appendix 6B so long as the requirements of 6.8.3 are met.

6.8.2.4 Linearity shall be in accord with 21 CFR 1020.31(c)(3).

6.8.2.5 Accuracy.

(1) Deviation of exposure settings from indicated values shall not exceed the limits specified for that system by its manufacturer.

(2) If manufacturer specifications are not available, the following criteria shall be used:

(a) The kVp shall not deviate from indicated values by more than ten (10) percent.

(b) The timer accuracy shall not deviate from indicated values by more than:

(i) Ten (10) percent for an indicated time of greater than 20 ms; or

(ii) Fifty (50) percent for an indicated time of 20 ms or less, or 1 pulse, whichever is greater.

6.8.2.6 Timers.

(1) 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.

(2) 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.

(3) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to “zero”.

6.8.2.7 Exposure Reproducibility.

(1) The coefficient of variation of exposure shall not exceed 0.05 when all exposure settings are held constant.

6.8.2.8 A dead-man type of exposure switch or equivalent remote device shall enable the operator to stand out of the useful beam.

6.8.3 Each veterinary medicine installation shall have the following operating and radiation exposure control procedures.

6.8.3.1 Whenever possible, the operator shall be positioned during radiographic exposures so that the nearest portion of the body is at least 2 meters (more than 6 feet) from **the patient, x-ray tube and the useful beam**~~both the tube head and the nearest edge of the image receptor~~.

6.8.3.2 No individual, other than the operator, shall be in the x-ray room while exposures are being made, unless such individual's assistance is required and the person is adequately protected by shielding and/or distance.

(1) All other staff and ancillary personnel required for the procedure shall ~~be protected from~~**:**

(a) ~~direct scatter~~**Be protected from scatter** radiation by protective **apparel (**aprons**)** or whole body protective barriers of not less than 0.25 millimeter lead equivalent**; and**

(b) Be protected from the useful beam by 0.5 millimeter lead equivalent.

6.8.3.3 When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used.

(1) Each individual other than the animal being examined shall be positioned such that no part of the body will be struck by the useful beam unless protected by a minimum of 0.5 millimeter lead equivalent **protective apparel or shield**.

(2) If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective **apparel (**gloves and apron**)**, and the individual shall be so positioned that no part of the individual’s body will be struck by the useful beam.

(3) The exposure of any individual used for this purpose shall be maintained below the limits specified in 4.6, 4.12, and 4.13.

6.8.3.4 No human shall hold the image receptor during radiography unless that individual is protected with appropriate shielding devices **or protective apparel**~~, such as protective~~ **(**gloves and apron**)**, and that any part of his/her body struck by the useful beam shall be monitored.

Commented [JJ526]: The language of the current rule is retained over that in Part F, due to possible concerns with some current machines/facilities not meeting the requirement. Additionally, the wording of the current rule should provide for additional protection by having the operator be positioned away from those areas that provide the most significant scatter and direct radiation.

Commented [JJ527]: Although Part F does not contain a specific section on requirements applicable to veterinary medicine, for consistency in protection of workers/ancillary personnel throughout the rule, the language of F6.k.iv is integrated into this part of the rule.

(1) The exposure of any individual used for this purpose shall be maintained below the limits specified in 4.6, 4.12, and 4.13.

6.8.3.5 Use of ~~portable~~ hand-held x-ray equipment shall be consistent with Appendix 6E.

6.8.4 Each veterinary x-ray imaging system shall follow manufacturer maintenance specifications.

6.8.5 Each veterinary x-ray imaging system shall have written quality control and quality assurance procedures that include:

6.8.5.1 For processing of veterinary films, performance of the following:

(1) Follow applicable manufacturer's time and temperature specifications, which shall be available for review;

(2) Measure and log temperature each day of use; and

(3) Document in a written log the change of developer chemicals at least every month.

6.8.5.2 Annual review of all quality control tests.

~~**SPECIAL REQUIREMENTS FOR COMPUTED TOMOGRAPHY**~~

6.9 ~~Safe Use of a Computed Tomography System.~~Requirements for use of computed tomography (CT) imaging systems.

6.9.1 Administrative Controls.

6.9.1.1 In addition to the provisions of 6.3 and 6.4, the requirements of 6.9 apply to equipment and associated facilities used for computed tomography.

6.9.1.2 Supervision and operation of a computed tomography system used on living humans shall be by an individual who has adequate radiation safety training and experience.

(1) Supervision shall be consistent with ~~6.3.1.8~~**6.3.1.6**.

(2) Training and experience shall be as provided in **6.3.1.6**~~2.6.1, in particular 2.6.1.9 and Appendix 2E, and 6.3.1.7~~**.**

6.9.1.3 The technical and safety information relating to the conditions of operation, dose information and imaging performance provided by the CT manufacturer shall be maintained by the facility for the life of the machine.

6.9.2 Each computed tomography facility shall meet the following equipment design and configuration requirements.

6.9.2.1 Termination of Exposure.

(1) Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection.

Commented [jsj528]: Section title modified to be consistent with titles of other major sections.

Commented [jsj529]: Provision added for consistency with SSRCR Part F, Section F.11a.ii.
It is expected that most CT facilities would already maintain this information and would therefore not present a significant burden. Requirement to maintain the information for the life of the machine is added, based on stakeholder(s) recommendation.

Commented [jsj530]: No change to this provision - current provision is consistent with Part F, Section F.11a.iii.

(a) Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices that monitor equipment function.

(2) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by 6.9.2.1(1).

(3) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

6.9.2.2 Tomographic Plane Indication and Alignment.

(1) **For any single tomogram system,** ~~M~~**m**eans shall be provided to permit visual determination of the **tomographic plane or** ~~location of~~ a reference **plane offset from the** tomographic plane.

(2) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

(~~2~~3) If a ~~device~~**mechanism** using a light source is used to satisfy 6.9.2.2(1) **or 6.9.2.2(2)**, the light source shall ~~provide illumination levels sufficient to permit~~**allow** ~~visual determination of~~ **visualizing** the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux (46 foot candles).

6.9.2.3 Beam-On and Shutter Status Indicators and Control Switches.

(1) The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

(2) Each emergency button or switch shall be clearly labeled as to its function.

6.9.2.4 Patient Communication.

(1) Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

(2) Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

(3) **When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.**

(4) Patient scanning shall be allowed only when a viewing system is available and in use.

6.9.3 Each computed tomography facility shall have the following operating procedures and radiation exposure controls.

6.9.3.1 Console Performance.

Commented [JJ531]: F.11a.iv

Commented [jsj532]: Provision updated for consistency with F.11a.iv(1).

21 CFR 1020.33(g)(1)

Commented [jsj533]: Provision added for consistency with F.11a.iv(2).

21 CFR 1020.33(g)(1)

Commented [jsj534]: Provision updated for consistency with F.11a.iv(3). Wording added/rephrased for clarity.

21 CFR 1020.33(g)(5)

Commented [JJ535]: Current provision equivalent to F.11a.v.

21 CFR 1020.33(h)(1)

Commented [JJ536]: Current provision equivalent to F.11b.i.

Commented [JJ537]: Current provision equivalent to F.11b.ii(1).

Commented [jsj538]: Provision added for consistency with F.11b.ii(2).

This provision adds a new requirement to have a back-up system in the event of failure of the primary electronic based viewing system. An example of such a facility would be one in which the CT system is located in a room adjacent to the control room but has no window for visual observation and relies solely on a video or similar monitoring system.

Commented [jsj539]: Although this provision is not specified in Part F, it is retained from the current Part 6 rule for radiation safety purposes.

(1) ~~The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.~~**The operator of the CT x-ray system shall meet the minimum operator requirements of these regulations and be specifically trained on the operational features of the unit by a manufacturer's application specialist, RMP, or someone deemed as a qualified trainer.**

~~(2) Information shall be readily available regarding the operation of the system.~~

(~~3~~2) ~~Information regarding calibration of the system shall be readily available, including~~**The following information shall be readily available to the CT operator**:

~~(a) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;~~

(b~~a~~) ~~Instructions on the use of the CT performance phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;~~**Instructions on performing routine QC, including the use of the CT phantom(s), a schedule of routine QC appropriate for the system, allowable variations set by the RMP for the indicated parameters, and the results of at least the most recent routine QC completed on the system;**

(b) Scanning protocols established by the RPC, including instructions on reporting deviations.

~~(c) When operators must select exposure settings, a current protocol shall be available at the control panel that specifies for each routine examination the CT conditions of operation and the typical number of scans per examination, including guidance for age-appropriate scanning.~~

(3) If the RMP evaluation or routine QC of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the RMP, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the RMP.

6.9.3.2 Indication of CT Conditions of Operation.

(1) The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence.

(2) On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings.

(3) Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

~~6.9.3.3 Extraneous Radiation.~~

~~(1) When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by 6.4.2.3.~~

6.9.3.3 CT Radiation Protocol Committee (RPC)

Commented [jsj540]: Provision revised for consistency with Part F, Section F.11b.ii(2).

Commented [jsj541]: Provision revised and expanded for consistency with Part F, Section F.11c.iv(2).

Commented [jsj542]: This provision will require use / availability of scanning protocols that are established by the CT Radiation Protocol Committee (RPC).
[The requirements of the RPC are discussed in section 6.9.3.3].

Commented [jsj543]: Provision added for consistency with Part F, Section F.11c.iv(3).

Commented [jsj544]: Current provision is equivalent to Part F, Section F.11a.vi.

Commented [jsj545]: Original provision deleted, consistent with deletion from Part F, Section F.11v.

Commented [jsj546]: New provision added for consistency with Part F, Section F.11d.
This proposed provision establishes a committee to provide oversight and review of the use of CT systems in use at a facility with a focus on radiation protection. The registrant has flexibility with implementing such a committee including integrating it into an existing committee. Although meeting in person is generally preferred, there is also no prohibition on holding meetings using technology when members cannot be present in one location for a meeting.

The proposed language provides a 2+ year phase in period for the CT Radiation Protocol Committee related requirements to allow registrants to prepare and implement these activities.

The requirements of 6.9.3.3 and other requirements associated with a Radiation Protocol Committee shall become effective on or after January 1, 2022.

The registrant shall develop and maintain an RPC in accordance with the following:

(1) Members of the RPC.

(a) Members of the RPC shall include but not be limited to the:

(i) Lead CT radiologist;

(ii) Lead CT technologist;

(iii) RMP; and

(iv) Other individuals as deemed necessary by the registrant (e.g., Radiation Safety Officer, Chief Medical or Administrative Officer, Radiology Department Administrator or Manager).

(b) If the registrant has more than one site with CT, they may establish a system-wide RPC.

(c) Two or more registrants may form a cooperative RPC as long as each facility has a representative on the committee.

(d) If the registrant has already established a radiation safety committee, the requirements of 6.9.3.3 may be delegated to that committee if the members meet the requirements of 6.9.3.3(1).

(2) Responsibilities of the RPC.

(a) The RPC shall:

(i) Review existing CT protocols, taking into consideration the capabilities and diagnostic tasks of the system, along with the evaluation and implementation of new and innovative technologies that can improve image quality and/or lower patient dose in comparison with the older protocol.

(ii) Determine and review the protocols used frequently or that could result in significant doses. The review shall include acquisition and reconstruction parameters, image quality, and radiation dose. At a minimum, the facility shall review the following clinical protocols, if performed, at intervals not to exceed 12 months:

(1) Pediatric Head;

(2) Pediatric Abdomen;

(3) Adult Head;

(4) Adult Abdomen;

(5) Adult Chest;

(6) Brain Perfusion.

(iii) Establish and implement written protocols, or protocols documented in an electronic recordkeeping system, that include but are not limited to the following:

(1) A method to be used to monitor the CT radiation output (dose indices).

(2) To the extent possible, a standardized protocol naming process.

~~(1)~~(3) A notification value and alert value for CT procedures reviewed in 6.9.3.3(2)(a)(ii). Notification and alert values may be applied by using trigger values in conformance with nationally accepted standards or facility established values and procedures as defined by the RMP.

(4) Actions to be taken when the notification or alert value is exceeded.

(5) A process determining who has access and authority to make changes to the protocol management systems, including a method to prevent inadvertent or unauthorized modifications to a CT protocol.

(iv) If CT fluoroscopy is performed, the RPC shall establish and implement operating procedures and training designed to minimize patient and occupational radiation exposure.

(v) Provide an annual report to the radiation safety committee or radiation safety officer, in the absence of a radiation safety committee.

(vi) At a minimum the RPC members in 6.9.3.3(1)(a)(i) through (iii) shall meet as often as necessary to conduct business but at intervals not to exceed 12 months.

(3) Records

(a) A record of each RPC meeting shall be maintained. The record shall include the date, names of individuals in attendance, minutes of the meeting, and any action taken.

(b) The registrant shall maintain a record of RPC policies and procedures.

(c) The registrant shall maintain a record of radiation output (dose indices) information so the radiation dose may be estimated in accordance with established protocols (e.g., SSDE). The record shall include:

Commented [JJ547]: For clarity and based on discussions during a Radiation Advisory Committee meeting, the term "recordkeeping" is used in lieu of the Part F term "reporting".

The term "dose indices" is added in parenthesis for clarity. Modern CT systems report some form of dose estimate indices/indicators.

Commented [JJ548]: At the suggestion of stakeholder(s), language is revised (from Part F) to add flexibility, recognizing possible challenges with similarly named but differing medical imaging procedures for specified or unique purposes.

Commented [JJ549]: In the proposed prior draft C provided to stakeholders and in Part F, a reference is made to NEMA XR-29 standard. This was changed to nationally accepted standards as it was determined that the NEMA standard originally referenced does not contain trigger values.

Commented [JJ550]: This provision is modified from that in Part F. Based on stakeholder feedback and further consideration, specific Part F language regarding patient follow-up is removed since notification and alert values are applied as decision points at the time of scanning.

Commented [JJ551]: For clarity and based on discussions during a Radiation Advisory Committee meeting, the term "dose indices" is added in parenthesis for clarity.

(i) Patient identification;

(ii) Type and date of examination;

(iii) Identification of the CT system used;

~~(i)~~(iv) The dose values the CT system provides (e.g., Dose-Length Product, SSDE); and

(v) Any change to the established protocol for the specific patient.

(d) Records required by this section shall be retained for inspection by the department for a period of 3 years following the date of the record.

6.9.3.4 CT systems used in treatment planning.

CT systems solely used for treatment planning in radiation oncology shall meet the requirements in Part 24.9 of these regulations.

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 evaluation on the CT system following nationally recognized guidelines or those of the manufacturer at intervals not to exceed 12 months.

(2) In lieu of 6.9.4.3, routine QC checks shall be completed at intervals not to exceed 1 week. These checks shall be established and documented by a RMP following nationally recognized guidelines or those of the manufacturer.

(3) 6.9.3.1(2)(b) (RPC)

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.

Commented [JJ552]: This provision does not appear in Part F, but is believed to be a good practice to document when a protocol was modified at the time of the imaging for a particular patient.

Commented [jsj553]: New provision added for consistency with Part F, Section F.11.e.

Commented [jsj554]: New provision added for consistency with Part F, Section F.11.f.

Clarification is added to the lead in sentence based on stakeholder feedback.

Commented [JJ555]: Based on stakeholder(s) recommendation, use of manufacturer performance evaluation is added in lieu of the Department approved evaluation.

Commented [JJ556]: Based on stakeholder(s) recommendation, use of manufacturer performance evaluation is added in lieu of the Department approved evaluation.

Commented [jsj557]: New provision added for consistency with Part F, Section F.11.g.

Commented [jsj558]: New provision added for consistency with Part F, Section F.11.h.

Commented [JJ559]: Provision is modified from language in Part F to defer to CFR requirements rather than a specific value.

Commented [JJ560]: For information/reference purposes:
6.4 contains broad requirements applicable to all diagnostic and interventional x-ray imaging systems
6.6.3.1 contains requirements for exposure initiation
6.6.3.2 contains requirements for exposure indication
6.6.3.4(1) contains requirements for x-ray controls for stationary, mobile, and portable systems
6.8.2.1(4) contains requirements for protective barriers/equipment applicable to veterinary systems
6.9.1.3 contains requirements for maintenance of technical and safety information for the CT system
6.9.2.1 contains requirements for termination of exposure
6.9.2.3 contains requirements for beam-on indicators
6.9.3.2 contains requirements for indications of CT conditions of operation
6.9.3.8 contains additional requirements for CT systems manufactured after a specific date

(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.

(3) A performance 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 results.

(4) The registrant shall follow the QC recommendations provided by the CBCT manufacturer.

(a) In the absence of manufacturer provided QC recommendations, the registrant shall implement and document QC guidelines established by a RMP in accordance to nationally recognized guidelines or those recognized by the Agency.

(5) The registrant or RPC, if established, shall implement and document

a policy addressing deviations from established protocols.

(6) The CBCT x-ray system shall only be operated by an individual who has been specifically trained in its operation.

(7) The following information shall be readily available to the CBCT operator:

(a) Instructions on performing routine QC, including the use of the CBCT phantom(s), a schedule of routine QC appropriate for the system, allowable variations set by the RMP, if required, for the indicated parameters, and the results of at least the most recent routine QC completed on the system.

(8) Exemption.

(a) The registrant using fluoroscopy systems capable of CBCT shall meet the applicable requirements of 6.9.3.7 excluding 6.9.3.7(1)(d).

6.9.3.~~4~~**8** Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After ~~September 2, 1992~~**September 3, 1985**.

(1) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

(2) If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(3) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus ~~1~~**2** millimeter with any mass from 0 to 100 kg resting on the support device.

(a) The patient support device shall be incremented from a typical starting position to the maximum incremented distance, the manufacturer's specified distance, or 30 cm, whichever is less, and then returned to the starting position.

(b) Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

(c) When table increment is not the primary means of slice position location, the registered medical physicist may provide for prior written Department review and approval alternative measurement procedures to determine the accuracy of slice position.

(4) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

CT surveys, performance evaluations, routine QC, and operating procedures

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

6.9.4.1 **Radiation Protection** ~~Surveys and~~ Evaluations.

(1) ~~A radiation~~ **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 ~~for~~**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;

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

Commented [JJ561]: Exemption provisions added consistent with Part F, Section F.11h.ix.

Commented [jsj562]: This provision is updated for consistency with Part F, Section F.11a.vii, which also appears to be consistent with 21 CFR 1020.30(a)(3).

The requirements of 6.9.3.8(1) parallel 21 CFR 1020.33(g)(3)
The requirements of 6.9.3.8(2) parallel 21 CFR 1020.33(h)(1)
The requirements of 6.9.3.8(3) parallel 21 CFR 1020.33(i)
The requirements of 6.9.3.8(4) parallel 21 CFR 1020.33(f)(2)(i)

Commented [JJ563]: Value based on AAPM 2017 CT quality control manual guidance, which represents best industry standards. Value differs from the current (1mm) value derived from 21 CFR 1020.33(i).

Commented [jsj564]: Added, consistent with F.11.c

Commented [jsj565]: Updated consistent with the language of Part F, F.11.c.i, with the exception that the phrase "area radiation survey" is used in lieu of "radiation protection survey" for clarity. Additionally, the phrase "or measurement" is added throughout the section to allow for alternative methods of determining compliance with the Part 4 requirement, such as use of fixed radiation monitoring devices.

Commented [jsj566]: The current requirement of Part 6 does not specify a timeframe by which the survey must be completed – other than upon installation. The proposed language clarifies the timeline.

F.11.c.i (1)

(b**c**) ~~Any initial or new location for~~**Upon first use of** a **portable or mobile** CT imaging system**, consistent with the applicable requirements of 6.3.2.4.** ~~that is designed to be transported from place to place~~.

Commented [jsj567]: As a good practice, a modification of the current Part 6 is retained. There is no equivalent provision in Part F.

(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.

Commented [jsj568]: Provision added, consistent with Part F, Section F.11.c.i(2).

~~(2) Notwithstanding the provisions of 2.5.1.2, CT x-ray systems that have undergone an x-ray tube change within 12 months of the last annual evaluation do not require a complete calibration at the time of the x-ray tube change, provided that:~~

~~(a) The CT x-ray system operation after the tube change meets the criteria established by the registered medical physicist.~~

~~(b) Each CT system shall receive a certification evaluation (CE) at least within one year of the previous CE.~~

Commented [JJ569]: This provision is deleted as it does not appear in Part F.

As proposed, this will now require that CT systems have a full calibration following replacement of an x-ray tube.

6.9.4.2 ~~Radiation Dosimetry~~**CT System performance evaluations**.

Commented [jsj570]: Section retitled, consistent with F.11.c.ii

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

Commented [jsj571]: This provision is updated, consistent with Part F, Section F.11.c.ii(1).

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

Commented [jsj572]: This provision is added, consistent with Part F, Section F.11.c.ii(2).

~~(a) At intervals (not exceeding one year) specified by a registered medical physicist;~~

Commented [jsj573]: This provision exists in Part 2, Section 2.5.1 and is therefore deleted here.

(b~~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;~~(c) With a calibrated dosimetry system:~~

Commented [jsj574]: This provision is replaced by the similar language (from Part F) in 6.9.4.2(5) below.

~~(i) Traceable to a national standard; and~~

~~(ii) Calibrated within the preceding two (2) years.~~

~~(2) CT dosimetry shall be evaluated by a registered medical physicist in accordance with protocols published by a nationally recognized organization.~~

~~(3) Records of measurements performed shall be maintained for a period of three (3) years for inspection by the Department.~~

(3) The evaluation of 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

Commented [jsj575]: This provision is added, consistent with Part F, Section F.11.c.ii(3), with the exception that 90 days (instead of 30 days) is used, consistent with current x-ray unit business processes.
Based on discussions during a Radiation Advisory Committee meeting, the term “dose indices” is added in parenthesis for clarity.

This provision has been reformatted for clarity.

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

(4) The evaluation shall include but not be limited to:

(a) Geometric factors and alignment including:

(i) Alignment light accuracy;

(ii) Table increment accuracy.

(b) Image localization from scanned projection radiograph (localization image);

(c) Radiation beam width;

(d) Image quality including:

(i) High-contrast (spatial) resolution;

(ii) Low-contrast resolution;

(iii) Image uniformity;

(iv) Noise;

(v) Artifact evaluation.

(e) CT number accuracy;

(f) Image quality for acquisition workstation display devices;

(g) A review of the results of the routine QC;

(h) A safety evaluation of audible and visual signals, and posting requirements;

(i) Dosimetry.

(5) The measurement of the radiation output (dose indices) of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system hall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceeding 2 years.

6.9.4.3 ~~Spot Checks~~**Routine quality control**.

A routine QC program on the CT system shall:

(1) ~~The spot-check procedures shall be in writing and shall have been developed by a registered medical physicist.~~**Be developed by a registered medical physicist and include acceptable tolerances for points evaluated;**

(2) ~~The spot-check procedures shall i~~Incorporate the use of a ~~commensurate CT performance~~ **water equivalent** phantom. **At a minimum, noise, CT number, and artifacts shall be evaluated.**

Commented [jsj576]: This provision is added, consistent with Part F, Section F.11.c.ii(4).

Commented [jsj577]: This provision is added, consistent with Part F, Section F.11.c.ii(5).

This provision contains similar requirements currently in Part 6 and replaces the deleted language in (prior) 6.9.4.2(2)(c).

For clarity and based on discussions during a Radiation Advisory Committee meeting, the term “dose indices” is added in parenthesis for clarity.

Commented [jsj578]: Section 6.9.4.3 updated, consistent with Part F, Section F.11.c.iii.

(3) ~~All spot checks shall be performed~~**Be completed** at time intervals and under system conditions specified by a registered medical physicist. **The interval shall not exceed 1 week.**

~~(4) Images shall be retained, at least until a new calibration is performed, as follows:~~

~~(a) Photographic copies of the images obtained from the image recording device; or~~

~~(b) Images stored in digital form on a storage medium compatible with the CT x-ray system.~~

~~(5)~~**(4)** ~~Written or electronic records of the spot checks performed shall b~~**B**e **documented and** maintained for inspection by the Department **for a period of 3 years following the date of the record**.

~~6.9.5 Each computed tomography system shall have written quality control and quality assurance procedures, including:~~

~~6.9.5.1 If a calibration required by 6.9.4.2 or a spot check required by 6.9.4.3 identifies that a system operating parameter is outside a specified or recommended tolerance or range:~~

~~(1) The CT x-ray system shall not be used on a patient except as permitted by documented instructions of the registered medical physicist; and~~

~~(2) Correction or modification shall be made within 30 days of the date of the test identifying the problem.~~

~~6.9.5.2 The computed tomography system shall meet the specifications of the manufacturer or registered medical physicist and/or appropriate nationally recognized organization, or equivalent approved by the Department, for:~~

~~(1) Alignment light accuracy;~~

~~(2) Slice thickness;~~

~~(3) Image quality; and~~

~~(4) CT number accuracy.~~

~~6.9.5.3 All quality control tests shall be reviewed by a registered medical physicist at least annually.~~

~~**SPECIAL REQUIREMENTS FOR MAMMOGRAPHY**~~

6.10 ~~**Safe Use at a Mammography Facility.**~~**Requirements for use of mammography and other x-ray based breast imaging systems.**

6.10.1 Administrative Controls.

6.10.1.1 ~~In addition to the provisions of 6.3 and 6.4, the requirements of 6.10 apply to equipment and associated facilities used for mammography.~~**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:

Commented [jsj579]: This provision is not found in Part F and is therefore deleted here. Stakeholders have expressed some concern regarding usage of storage space to retain such documentation long term.

Commented [jsj580]: These provisions are removed and replaced by 6.9.4.

Commented [jsj581]: Title changed to be consistent with titles of other major sections, and to address other types of breast imaging that are not necessarily considered mammography.

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

~~(1)~~**(2)** Meet the requirements of **Subpart B of** 21 CFR 900;

~~(2) Have a valid certificate issued by the U.S. Department of Health and Human Services pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 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 ~~qualified inspector~~**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, ~~2.6.1.8~~**2.6.1.5** and Appendix 2M.

~~6.10.1.5 In the State of Colorado, the regulatory requirements of Part 6 shall also apply as appropriate to radiography of the breast performed:~~

~~(1) During invasive interventions for localization or biopsy (for example, stereotactic biopsy procedures); or~~

~~(2) With an investigational device as part of a scientific study conducted in accordance with FDA investigational device exemption regulations; or~~

~~(3) During any other procedure for radiography of the breast that the Department determines and designates.~~

~~6.10.1.6 The registrant shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility, which program shall:~~

~~(1) Follow manufacturers' specifications and/or the standards of an appropriate nationally recognized organization, for example, the American College of Radiology or American Association of Physicists in Medicine; and~~

~~(2) Apply to and be adhered to for each procedure subject to 6.10.1.~~

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

Commented [JJ582]: Added consistent with Part F, Section F.6m.

Commented [jsj583]: A similar provision was removed from Part F.

Commented [JJ584]: This provision is removed as the requirements are addressed elsewhere in Part 6 and in the revised definition for mammography found in Section 6.2.

Commented [JJ585]: This provision is removed as the requirements are addressed elsewhere in Part 6 (6.10.1.2(3), 6.3.3.5).

Commented [JJ586]: This is a new section, consistent with Part F, Section F.15

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 DXA system.

6.11.4 During operation of any DXA system:

6.11.4.1 In the absence of a radiation survey performed by or under the supervision of a RMP the operator, ancillary personnel, and members of the general public shall be positioned at least 2 meters (at least 6 feet) from the patient, x-ray tube, and useful beam during the examination.

6.11.5 Quality assurance.

6.11.5.1 In addition to the applicable requirements in 6.3.5.1, a facility performing DXA shall:

(1) Conform to the DXA system manufacturer recommendations and recommendations of recognized professional societies such as the International Society for Clinical Dosimetry or the American College of Radiology.

6.11.6 Records.

6.11.6.1 The registrant shall keep the following records for a minimum of 3 years:

(1) The maintenance and QC tests as prescribed by 6.11.2.3 and 6.11.5.1.

Commented [JJ587]: For clarity, the wording of this provision is modified from Part F.
The language of the current rule is retained over that in Part F, due to possible concerns with some current machines/facilities not meeting the requirement. Additionally, the wording of the current rule should provide for additional protection by having the operator be positioned away from those areas that provide the most significant scatter and direct radiation.

PART 6, APPENDIX 6A: INFORMATION REQUIRED FOR EVALUATION OF RADIATION SHIELDING

6A.1 In order to provide an evaluation and technical advice on shielding requirements for a radiation installation, the following information shall be submitted to the qualified expert or registered medical physicist.

6A.1.1 The submittals shall **include a dimensional, scaled drawing of the facility which shows the following:**~~show at least the following:~~

(1) The normal location of the x-ray imaging system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.

(2) The structural composition and thickness of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

(3) The dimensions of the room(s) concerned and inter-floor distances if space above or below is occupied.

(4) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned.

(5) If there is an exterior wall, the distance to the closest area(s) where it is likely that individuals may be present.

(6) A description of the x-ray imaging system and components, including the make and model of the equipment.

(7) The type of examination(s) or treatment(s) that will be performed with the equipment.

6A.1.2 Information on the anticipated workload of the x-ray imaging system(s).

Commented [jsj588]: Insert a page break at the beginning of Appendix 6A such that it appears at the top of the page in the final published rule.

Commented [JJ589]: Clarifying language added based on stakeholder feedback.

PART 6 APPENDIX 6B: DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH

Commented [jsj590]: Insert a page break at the beginning of Appendix 6B such that it appears at the top of the page in the final published rule.

6B.1 Space Requirements:

6B.1.1 The operator shall be allotted not less than 0.7 m^2 (8 ft^2) of unobstructed floor space in the booth.

6B.1.2 The operator's booth may be of any geometric configuration with no dimension less than 0.6 m (2 ft).

6B.1.3 The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.

6B.1.4 The booth shall be located or constructed such that unattenuated ~~direct~~ scatter radiation originating on the examination table or at the wall cassette cannot reach the operator's location within the booth.

6B.2 Structural Requirements:

6B.2.1 The booth walls shall be permanently fixed barriers at least 2 m (~~7~~**6.5** ft) high.

6B.2.2 When a door or movable panel is used as an integral part of the booth structure, it must have an interlock that will prevent an exposure when the door or panel is not closed in its shielding position.

6B.2.3 Shielding shall be provided to meet the requirements of Part 4.

6B.3 Viewing System Requirements:

6B.3.1 Each booth shall have at least one viewing device that will:

(1) Be so placed that the operator can view the patient during any exposure, and

(2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door that allows access to the room cannot be seen from the booth, then that door must have either an interlock controlling the exposure that will prevent the exposure if the door is not closed; or a warning light must be activated at the control panel when the door is opened.

6B.3.2 When the viewing system is a window, the following requirements also apply:

(1) The viewing area shall be at least 0.1 m^2 (1 ft^2).

(2) The design of the booth shall be such that the operator's expected position when viewing the patient and operating the x-ray system is at least 0.5 m (1.5 ft) from the edge of the booth.

(3) The material constituting the window shall have **at least** the same lead equivalence as that required in the booth's wall in which it is mounted.

6B.3.3 When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of 6B.3.1.

6B.3.4 When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements of 6B.3.1.

(2) There shall be an alternate viewing system as a backup for the primary system, unless the x-ray room is not used in the case of viewing system failure.

PART 6, APPENDIX 6C: CONTENT OF A SHIELDING DESIGN

6C.1 Each written shielding design prepared by a qualified expert shall include identifying information, if available, such as the facility name, address, owner, contact telephone numbers and contact e-mail addresses.

6C.2 Each written shielding design prepared by a qualified expert shall include:

6C.1.2 Evaluation from a radiation protection point-of-view of the overall layout of the room(s) floor plan, including the location and configuration any radiation producing machines in each room, based on the information required in Appendix 6A and 6B.

6C.1.3 Evaluation of suitable workload, based on the volume of work and equipment usage anticipated in the information provided pursuant to 6A.1.2, in relation to the overall layout.

6C.1.4 Detailed consideration, using guidelines based on National Council on Radiation Protection and Measurements Report No. 147, “Structural Shielding Design for Medical Imaging Facilities”, or equivalent guidance, of:

~~6C.1.4.1~~**(1)** Location and types of permanent and temporary barriers and shielding;

~~6C.1.4.2~~**(2)** Location of controls and any control booth;

~~6C.1.4.3~~**(3)** Location of exposure switch; and

~~6C.1.4.4~~**(4)** Interior and exterior walls, doors and windows, and floors and ceilings.

6C.1.5 Calculations of potential exposures based on occupancy and workload distribution.

6C.1.6 For each room in which a stationary x-ray imaging system is located, a current dimensional drawing as required by 6.3.2.3 with accompanying specifications for construction and layout to meet all requirements of these regulations, in particular to preclude an individual from receiving a dose in excess of the limits in **Part 4, Sections** 4.6, 4.12, 4.13, 4.14 and 4.15.

6C.1.7 The signature of the qualified expert who prepared the shielding design and the date signed.

Commented [jsj591]: Insert a page break at the beginning of Appendix 6C such that it appears at the top of the page in the final published rule.

Commented [JJ592]: Reformat numbering, consistent with other appendices.

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

6D.1 The operating condition of an radiation machine and related equipment shall not be such that the continued operation of that machine endangers the public health and safety.

6D.2 An radiation machine shall be considered unsafe for human, animal or other use if:

6D.2.1 The radiation machine system has a malfunctioning component or components that could result in an inadvertent exposure to members of the public, the operator, or the patient. Examples include but are not limited to: a timer that fails to terminate the exposure, an exposure switch when activated once produces multiple exposures, a system that produces x-rays without activation of the exposure switch.

6D.2.2 The radiation machine is not equipped with a means of determining when x-rays are in production.

6D.2.3 The radiation machine is equipped with variable exposure settings and the selectors and/or indicators of these exposure settings do not permit the operator to determine the factors in use or if the indicated versus the exposure settings are in error by fifty (50) percent or more, except for exposure times selected less than 50 millisecond.

6D.2.4 The collimation of the x-ray beam of a fluoroscopic/spot film system is such that either the length or width of the x-ray field in the plane of the image receptor differs (in excess) from the corresponding image receptor dimensions by more than 25 percent of the source to image distance (SID).

6D.2.5 The half-value layer of aluminum (or equivalent) filtration in the useful beam is more than fifty (50) percent below the values specified in 6.4.2.5.

6D.2.6 The quality of the imaging is significantly degraded such that significant additional exposures or imaging is needed to obtain an adequate image.

~~6D.2.6~~**6D.2.7** In addition to the above items a fluoroscopic x-ray system will be considered unsafe if:

(1) In normal fluoroscopic mode:

(a) No operational image intensifier or direct digital image receptor is provided.

(b) Except for radiation oncology simulators, the primary protective barrier does not intercept 100 percent of the x-ray beam of a fluoroscopic x-ray system.

(c) Except for radiation oncology simulators, the fluoroscopic x-ray system is capable of producing x-rays when the primary protective barrier is not in position to intercept the beam.

(d) The fluoroscopic x-ray system has a tabletop AKR equal to or greater than 220 mGy per minute (25 R/min) at the point where the useful beam enters the patient, except:

(i) During the recording of fluoroscopic images, or

Commented [jsj593]: Insert a page break at the beginning of Appendix 6D such that it appears at the top of the page in the final published rule.

Commented [JJ594]: This provision is added as a result of elimination of the originally proposed provision in 6.3.3.2 that was derived from Part F, Section F.3a.ii. Section F.3a.ii is a very broad provision, but does contain a reference to image quality degradation which should be considered in determining whether a machine should be placed out of service.

Stakeholders and staff believe that the requirements of Appendix 6D more adequately address the conditions which would require a machine to be placed out of service.

The additional provision is intended to address the topic of image quality degradation required by the Part F model rule.

(ii) When an optional high-level control is activated.

(2) ~~Note that this is normal fluoroscopic mode, and the FDA's regulations (21 CFR 1020.32(e)(2)(II), April 1, 2004) allow up to 176 mGy per minute (20 R/min) when recording or using high-level control.~~**When using a high-level control, the equipment is operable at any combination of tube potential and current that will result in an AKR in excess of 176 mGy per minute (20 R/min), consistent with 21 CFR 1020.32(d)(2)(iii)(C), April 1, 2017.**

Commented [JJ595]: Updated to reference applicable section in the 2017 edition of 21 CFR 1020.32.

~~6D.2.7~~**6D.2.8** An electro-mechanical defect exists that endangers human life or safety when a radiograph is made or fluoroscopy is performed.

PART 6, APPENDIX 6E: ~~HUMAN USE OF PORTABLE~~ USE OF HAND-HELD X-RAY EQUIPMENT

6E.1 ~~The following requirements are applicable, as determined by the Department, to any human use x-ray radiographic device , in particular for dental intraoral use, that is designed to be operated as a hand-held unit.~~**The following requirements are applicable, as determined by the Department, to any x-ray radiographic device that is designed to be held in the hand during operation.**

6E.1.1 Requirements for any location:

(1) The facility shall adopt and follow procedures provided by the manufacturer regarding the safe operation of the device.

~~6E.1.1.1~~**(2)** ~~Each operator of a hand-held device shall be specifically trained to operate such equipment.~~**The facility shall maintain documentation that each operator has completed training as specified by the manufacturer.**

~~6E.1.1.2~~**(3)** The operator shall ensure there are no bystanders within a radius of at least 2 meters (~~six~~**more than 6** feet) from the patient being examined with a hand-held ~~intraoral~~ radiographic unit.

~~6E.1.1.3~~**(4)** If a hand-held device was designed with an optional, removable ~~secondary~~**scatter** radiation block, it shall be installed and used during patient examination **and shall:**~~.~~

(a) Provide not less than 0.25 mm lead equivalent;

(b) Be at least 15.2 cm (6 inches) in diameter;

(c) Be positioned as close as practicable to the distal end of the position indication device.

(5) When operating a hand-held x-ray system, operators shall:

(a) Wear whole body dosimetry in accordance with Part 4, Section 4.6.3; and

(b) Wear 0.25 mm lead-equivalent protective apparel, unless the device is used with a scatter shield meeting the requirements of 6E.1.1(4) or as otherwise exempted in writing by the Department.

~~6E.1.1.4~~**(6)** ~~The device shall be held without any motion, in~~**In** order to prevent repeat imaging due to motion that reduces image quality**, motion shall be minimized as much as possible when holding and operating the device**. If the operator has difficulty in holding the device stationary, the operator shall use a stand or tripod to immobilize the device.

~~6E.1.1.5 The operator shall be protected from direct scatter radiation by protective material of not less than 0.25 millimeter lead equivalent and a thyroid collar unless the radiation safety officer and Department determine that no added protection is needed for the device model and/or use.~~

~~6E.1.1.6 Personnel monitoring shall be at least as required by 6.3.3.10.~~

Commented [jsj596]: Insert a page break at the beginning of Appendix 6E such that it appears at the top of the page in the final published rule.

The title of the appendices is updated to better reflect the application of x-ray devices that are intended to be operated while being held in the hands. Additionally, references to specific uses of the devices are removed since these devices are becoming more common in a variety of medical applications.

Commented [JJ597]: Provision added, consistent with Part F, Section F.7f.iii., with the exception that "protocols" was changed to the more common language "procedures".

Commented [jsj598]: Language revised, consistent with Part F, Section F.7f.ii.

Commented [jsj599]: Added, consistent with Part F, Section F.7f.i., with the exception that formatting is different.

Commented [JJ600]: This language was originally proposed in (original) 6E1.1.5 (below), but was relocated here for flow. Consistent with Part F, Section F.7f.v.

Commented [JJ601]: Provision is added to consolidate requirements for hand-held x-ray units in this Appendix.

Commented [JJ602]: Rephrased but consistent with the intent of Part F, Section F.7f.v.

Commented [JJ603]: Provision is replaced by 6E.1.1(6)(b).

6E.1.2 Additional requirements for ~~operations~~**use of hand-held x-ray equipment** in permanent facilities:

~~6E.1.2.1 As provided in 6.3.2.4, a hand-held device is exempt from 6.3.2.1 and consequently is exempt from 6.3.2.2 and 6.3.2.3.~~

~~6E.1.2.2~~**(1)** A hand-held device shall not be used for patient examinations in hallways and waiting rooms.

6E.2 **When not under the control of the operator, the registrant shall secure the hand-held device from unauthorized removal or use.**~~Portable hand-held x-ray equipment shall be kept in a secured location when not in use.~~

Commented [JJ604]: Modified for consistency with the change in title of the appendices and for clarity.

Commented [JJ605]: Exemptions for facility shielding requirements are already addressed in 6.3.2.4 and do not need to be repeated here.

Commented [JJ606]: Updated, consistent with Part F, Section F.7f.vi., with the exception that wording at the beginning of the sentence is added for clarity.

PART 6, APPENDIX 6F: INFORMATION TO BE SUBMITTED BY A PERSON PROPOSING TO CONDUCT HEALING ARTS SCREENING

Commented [jsj607]: Insert a page break at the beginning of Appendix 6F such that it appears at the top of the page in the final published rule.

6F.1 A person requesting that the Department approve a healing arts screening program shall submit the following information and evaluation when completing Department Form R-300:

6F.1.1 Name and address of the applicant and, when applicable, the names and addresses of all locations within this State, where the service will be provided.

6F.1.2 Diseases or conditions for which the x-ray examinations are to be used in diagnoses.

6F.1.3 A detailed description of the x-ray examinations proposed in the screening program.

6F.1.4 Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

6F.1.5 An evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations.

6F.1.6 An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program prior to being placed into operation. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these regulations.

6F.1.7 A description of the image processing quality control program, if applicable.

6F.1.8 A copy of the technique protocols for the x-ray examination procedures to be used as required under ~~6.3.3.2~~**6.3.3.3**.

6F.1.9 Documentation that each individual who will be operating the x-ray system(s) fulfills Department requirements for adequate radiation safety training and experience.

6F.1.10 Documentation that each individual who will be supervising the operators of the x-ray system(s) fulfills Department requirements for adequate radiation safety training and experience. The extent of supervision and the method of work performance evaluation shall be specified.

6F.1.11 The name and address of the individual who will interpret the radiograph(s) or other results from the x-ray examinations.

6F.1.12 Name of who will oversee the program with a current license from Board of Medical Examiners of Physician(s) of a physician, chiropractor, dentist or podiatrist **or other legally authorized individual** who has a current active State of Colorado license to practice the healing arts.

6F.1.13 A copy of the order for the screening program to be conducted, prescribed by a physician, chiropractor, dentist or podiatrist **or other legally authorized individual** who has a current active State of Colorado license to practice the healing arts.

6F.1.14 A description of the procedures to be used by a physician, chiropractor, dentist or podiatrist **or other legally authorized individual** who has a current active State of Colorado license to practice the healing arts to advise the individuals screened about the results of the screening procedure and any further medical needs indicated.

6F.1.15 A description of the procedures for the retention or disposition of the radiographs, if applicable, and other records pertaining to the x-ray examinations.

6F.1.16 A shielding analysis, if applicable.

6F.1.17 A copy of the policy and procedures to ensure that all applicable dose limitation requirements of Part 4, “Standards for Protection Against Radiation”, are met.

6F.1.18 A copy of the ALARA policy and procedures.

6F.1.19 Copies of personnel monitoring reports for any employee involved in screening.

6F.1.20 Any additional information that has been requested by the Department.

PART 6, APPENDIX 6G: AUTOMATIC FILM PROCESSOR TECHNIQUE CHART

Developer Temperature		Minimum Immersion Time[a/]
°C	°F	Seconds
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30

[a/] *Immersion time only, no crossover time included.*

Commented [jsj608]: Insert a page break at the beginning of Appendix 6G such that it appears at the top of the page in the final published rule.

Table added, consistent with Part F, F.3.b.ii(1).

PART 6, APPENDIX 6H: MANUAL FILM DEVELOPING TECHNIQUE CHART

Manual Film Developing Technique Chart				
Developer Temperature °C / °F	Developing Time (Minutes)		Developer Temperature °C / °F	Developing Time (Minutes)
26.7 / 80	2.0		20.6 / 69	4.5
26.1 / 79	2.0		20.0 / 68	5.0
25.6 / 78	2.5		19.4 / 67	5.5
25.0 / 77	2.5		18.9 / 66	5.5
24.4 / 76	3.0		18.3 / 65	6.0
23.9 / 75	3.0		17.8 / 64	6.5
23.3 / 74	3.5		17.2 / 63	7.0
22.8 / 73	3.5		16.7 / 62	8.0
22.2 / 72	4.0		16.1 / 61	8.5
21.7 / 71	4.0		15.6 / 60	9.5
21.1 / 70	4.5			

Commented [jsj609]: Insert a page break at the beginning of Appendix 6H such that it appears at the top of the page in the final published rule.

Table added, consistent with Part F, F.3.b.ii(2).

PART 6, APPENDIX 6I: TABLE OF HALF VALUE LAYERS FOR A SPECIFIED kVp AND SYSTEM.

X-Ray Tube Voltage (kilovolt peak)				
Design Operating Range	Measured Operating Potential	Minimum HVL (mm in Aluminum)		
		Specified Dental Systems \1\	Other X-Ray Systems\2\	Other X-Ray Systems\3\
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

\1\ Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.
\2\ Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.
\3\ All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

Commented [jsj610]: Insert a page break at the beginning of Appendix 6I such that it appears at the top of the page in the final published rule.

The table was updated consistent with Part F, F.4e.

To reduce the size of the body of the rule, the table was relocated to the appendices from Section 6.4.

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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 September 18, 2019, effective date November 14, 2019

~~**Adopted by the Board of Health February 18, 2015**~~

PART 2: REGISTRATION OF RADIATION MACHINES, FACILITIES AND SERVICES

2.1 Purpose and Scope.

2.1.1 Authority

2.1.1.1 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.

2.1.2 Basis and Purpose.

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

2.1.3 Scope.

2.1.3.1 This part provides for:

(1) Registration of facilities;

(2) Certification of radiation machines;

(3) Registration of persons providing radiation machine services including assembly, installation, maintenance and repair;

(4) Registration of qualified inspectors and qualified experts; and

(5) Approval of radiation safety officers, mammographers and other operators.

2.1.4 Applicability.

2.1.4.1 The requirements and provisions of this part apply to each person who uses, operates, services or certifies radiation machines and to each registrant or applicant for registration subject to this part unless specifically exempted.

Commented [JJ611]: **EDITORIAL NOTE 1:** ALL COMMENTS (SUCH AS THIS ONE) SHOWN IN THE RIGHT SIDE MARGIN OF THIS DOCUMENT ARE FOR INFORMATION PURPOSES ONLY TO ASSIST THE READER IN UNDERSTANDING THE PROPOSED RULE DURING THE DRAFT REVIEW AND COMMENT PROCESS.

THESE SIDE MARGIN NOTES ARE **NOT** PART OF THE RULE AND ALL COMMENTS WILL BE DELETED PRIOR TO FINAL PUBLICATION.

EDITORIAL NOTE 2: ALIGNMENT AND FORMATTING CORRECTIONS AND ADJUSTMENTS ARE MADE THROUGHOUT THE RULE AND MAY NOT BE SPECIFICALLY IDENTIFIED WITH A SIDE MARGIN COMMENT.

EDITORIAL NOTE 3: THE ACRONYM "CRCPD" REFERS TO THE CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS (CRCPD), INC., WHICH DEVELOPS SUGGESTED STATE REGULATIONS FOR CONTROL OF RADIATION (KNOWN AS SSRCR'S). PER THE COLORADO RADIATION CONTROL ACT (LAW) AND UNLESS OTHERWISE DETERMINED BY THE BOARD OF HEALTH, COLORADO'S RADIATION RULES ARE TO BE CONSISTENT WITH THE SSRCR MODEL REGULATIONS.

THE SSRCRS MAY BE FOUND ONLINE AT:
http://www.crcpd.org/page/SSRCRs
THE PROPOSED AMENDMENTS IN THIS DRAFT PART 2 RULE ARE PRIMARILY BASED ON PROPOSED AMENDMENTS TO PART 6 WHICH IS BEING AMENDED CONCURRENTLY WITH PART 2. ADDITIONAL PROPOSED CHANGES IN PART 2 ARE BASED ON PROGRAMMATIC OR TECHNICAL NEEDS OR FOR CONSISTENCY WITH OTHER MODEL RULES SUCH AS MODEL RULE PART Z.

Commented [JJ612]: These dates reflect the date of anticipated adoption and effective date based on current rulemaking schedules. Dates are subject to change pending additional review and approvals.

2.1.4.2 The provisions of this part are in addition to (and not in substitution for) other applicable provisions in Parts 1, 4, 5, 6, 7, 8, 9, 10, 24 and other parts of these regulations.

2.1.5 Published Material Incorporated by Reference.

2.1.5.1 **In accordance with Section 24-4-103(12.5)(c), CRS, https://www.colorado.gov/cdphe/radregs identifies where incorporated material is available to the public on the internet at no cost. If the incorporated material is not available on the internet at no cost to the public, copies of the incorporated material has been provided to the State Publications Depository and Distribution Center, also known as the State Publications Library. The State Librarian at the State Publication Library retains a copy of the material and will make the copy available to the public.**~~Published material incorporated in Part 2 by reference is available in accord with 1.4.~~

Commented [JJ613]: For consistency with updates to other rules, the following standard language is added.

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/**.

Commented [JJ614]: Definition updated for consistency with Part Z model regulation.

~~"ARRT(N)" means an individual who is registered by the ARRT in Nuclear Medicine Technology.~~

~~"ARRT(R)". See "radiologic technologist".~~

~~"ARRT(T)" means an individual who registered by the ARRT in Radiation Therapy.~~

Commented [JJ615]: These definitions have been moved to later in this section – under the "R.T." heading.

ARRT refers to the registry/certification organization whereas "R.T.(*) is the individual who is certified and the designation they may use.

"ASRT" means the American Society of Radiologic Technologists.

"Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into a radiation machine system or subsystem.

"Calibration" means to adjust and/or determine the:

(1) Response or reading of an instrument relative to a series of conventionally true values; or

(2) Strength of a radiation source relative to a standard or conventionally true value.

"Certification Evaluation" (CE) means the evaluation of a radiation machine at a facility by a qualified inspector or the Department for the purpose of ascertaining the performance of the radiation machine system and/or facility in order to determine conformance with these regulations.

"Certified Nuclear Medicine Technologist" means an individual who is currently registered in nuclear medicine with the NMTCB or ARRT, designated CNMT or ~~ARRT~~**R.T.**(N), respectively.

Commented [JJ616]: Language updated for consistency with the language of the ARRT rules and regulations.

ARRT refers to the certifying organization whereas R.T. is the designation used by the individual who has been registered/certified by that organization.

"Computed tomography" (CT) means the production of a tomogram by the acquisition and computer processing of x-ray transmission data. For the purposes of Part 2, the requirements stated for computed tomography machines do not apply to**:**

(1) "Volumetric Dental Imaging Systems"**; or**

(2) Digital breast tomosynthesis.

"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.

"Dual-energy X-Ray Absorptiometry" (DXA, previously DEXA) means an imaging technique using radiation machines for quantifying bone density, used in the diagnosis and management of osteoporosis.

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

"Facility" means, for purposes of Part 2, the location within one building (or vehicle, or under one roof, or at one address) and under the same administrative control, at which a radiation machine is or was installed, operated and/or located.

"FDA" means the United States Food and Drug Administration.

"Fluoroscopy" means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images.

"Industrial Radiography" means an examination of the structure of materials by the nondestructive method of utilizing ionizing radiation to make radiographic images.

"Inter-comparison" means the direct comparison, in accord with 2.4.4.5, of two instruments designed to measure the same physical quantity.

"Limited-scope operator" (LSO) means an individual who has taken and passed a required test and has approval by the Department pursuant to 2.4.5.1 to operate x-ray systems and to conduct specified radiographic examinations of the chest, extremities, skull, hip/pelvis and spine/sacrum

"MQSA" means Mammography Quality Standards Act.

"NIST" means the National Institute of Standards and Technology.

"NMAA" means a Nuclear Medicine Advanced Associate working as a mid-level provider under the supervision of a licensed physician. The NMAA must be a Certified Nuclear Medicine Technologist registered as an R.T.(N) or CNMT.

"NMTCB" means the Nuclear Medicine Technology Certification Board, Inc**, 3558 Habersham at Northlake, Building I, Tucker, GA 30084-4009, web site: https://www.nmtcb.org/**.

"Operator" means an individual adequately trained in accordance with these regulations in the purpose and experienced in the practice of performing a radiographic examination.

"Performance adjustment" means the adjustment or repair of a function (not including the setting of operator-selectable functions, such as time, mA and/or kVp for an individual exposure) of an x

Commented [JJ617]: Digital breast tomosynthesis is a form of mammography imaging of the breast. Although breast imaging requires specialized training on the part of the operator (typically a radiologic technologist with mammography certification) to meet MQSA requirements, CT specific training is not required for digital breast tomosynthesis and is therefore added to the exclusions.

Commented [JJ618]: This definition has been incorporated into a proposed definition "radiographic examination". Refer to that definition for further information.

Commented [JJ619]: This is a newer, advanced certification for nuclear medicine technologists. The term "mid-level provider" is used in lieu of the originally proposed language "physician extender" which may be more technically accurate.

ray machine or imaging system that is required to bring the machine into compliance with these regulations and the specifications.

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

"Provisional qualified inspector" (PQI) means an individual who meets the applicable requirements of Section 2I.2 of Appendix 2I and has current Department approval in a designated specialty to perform evaluations of radiation machines, facilities, and operators for compliance with these regulations while under the supervision of a qualified inspector.

"QE(R)" means a qualified expert medical physicist approved to design or evaluate shielding for radiation machines used in the healing arts.

"QE(S)" means a qualified expert physicist approved to design or evaluate shielding for radiation machines used for non-healing arts purposes.

"QE(T)" means a qualified expert medical physicist approved to design or evaluate shielding for radiation machines used in radiation therapy.

"Qualified expert" (QE) means an individual who meets the applicable requirements of Appendix 2B or 2C and has current Department approval as QE(S), QE(R), or QE(T) to evaluate radiation shielding design and recommend radiation safety practices, as provided in 2.4.3.

"Qualified inspector" (QI) means an individual who meets the applicable requirements of Appendix 2I and has current Department approval in a designated specialty to perform evaluations of radiation machines, facilities, and operators for compliance with these regulations, as provided in 2.4.4.

"Qualified mammographer" means a mammographer who meets the applicable requirements of Appendix 2M.

"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.

"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 ~~radiography~~**radiologic technology** with the American Registry of Radiologic Technologists.~~,~~ ~~designated ARRT(R).~~ **See "R.T.(CT)", "R.T.(M)", "R.T.(N)", "R.T.(R)", and "R.T.(T)".**

"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.

Commented [JJ620]: This is the original definition for "examination" with the word "radiographic" placed in front of it. It is added for clarity and specificity. The term "examination" is used in the current Part 2 in multiple locations, but is used in different contexts, such as examination of records (by the department) or for describing testing criteria associated with certifications or qualifications (e.g., …having completed an examination…).

Commented [JJ621]: Updated for consistency with other changes.

Commented [JJ622]: Definition added for clarity and due to changes in the body and appendices of the rule.

"R.T.(CT)" means an individual who is certified and registered by the ARRT in computed tomography.

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

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

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

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

"Service company" means a person who is engaged (or offers to engage) in the business of selling, leasing, transferring, lending, assembling, installing, maintaining, repairing, storing, trading out, disabling, or disposing of radiation machines and their related components, or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services.

Service technician" means an individual who is employed by a service company to perform radiation machine servicing or services.

"Shielding design" means physical specifications, such as room layout, floor plan, construction materials, and equipment configuration, to demonstrate compliance with the radiation limits set forth in Part 4 of these regulations.

"Volumetric dental imaging system" means an x-ray machine that produces, for oral and maxillofacial structures, a three-dimensional tomographic data set or a time sequence of three-dimensional tomographic data sets. A dental x-ray machine only capable of producing a two-dimensional image is not considered to be a volumetric dental imaging system. For the purposes of Part 2, the requirements stated for "computed tomography" machines do not apply to "Volumetric Dental Imaging Systems".

EXEMPTIONS FROM THE REGULATORY REQUIREMENTS

2.3 Exemptions.

2.3.1 Electronic equipment that is not designed primarily to produce radiation is exempt from the registration and notification requirements of Part 2, provided that the dose equivalent rate averaged over an area of 10 cm2 does not exceed 5 µSv (0.5 mrem) per hour at 5 cm from any accessible surface of such equipment.

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

2.3.3 Domestic television receivers, computer monitors, and similar devices are exempt from the requirements of Part 2.

2.3.4 A radiation machine that is out of service yet kept at a facility is exempt from the registration and certification evaluation requirements of Part 2 provided:

Commented [JJ623]: Registration designations are updated, consistent with the rules and regulations of the ARRT (2018).

ARRT refers to the registry/certification organization whereas "R.T.(*) refers to the individual who is certified and the designation they may use based on their registry/certification discipline.

2.3.4.1 tThe radiation machine has been made physically inoperable by inactivating or dismantling the electrical circuitry such that the radiation machine is not capable of producing radiation, and

2.3.4.2 tThe Department has received documentation of 2.3.4.1 on Form R 61, "Disposition of a Radiation Machine", or equivalent form, that is signed by a registered service technician.

2.3.5 An electron microscope or electron microprobe is exempt from Part 2 provided that:

2.3.5.1 A survey shows compliance with 2.3.1; or

2.3.5.2 The device is not capable of exceeding an operating voltage of 50,000 electron volts.

2.3.6 The legal owner of electronic equipment which meets the requirements of 2.3.1 but which is not specifically exempted under 2.3.2, 2.3.3, and 2.3.4 shall maintain for the lifetime of the equipment radiation measurement results or certification from the manufacturer or a qualified expert indicating that the equipment complies with the exposure rates specified in 2.3.1.

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;

(2) Before the facility registration expiration date, 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 ~~6.3.3.3~~**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 humans shall be approved by an Institutional Review Board (IRB).

2.4.2 Registration as a Service Company.

2.4.2.1 Each person who is engaged (or offers to engage) in the business of selling, leasing, transferring, lending, assembling, installing, maintaining, repairing, storing, trading out, disabling or disposing of radiation machines and their related components, or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this State, shall be registered with the Department prior to performing such activities.

2.4.2.2 Each Service Company shall complete the Form R-60 series application for registration with all of the information required by the Department indicated on the form and all accompanying instructions, together with the fee required by Part 12, Category 22.

2.4.2.3 Each ~~person applying~~ **applicant** for registration under 2.4.2 shall ~~identify and provide~~**specify**:

(1) The service category for which registration is being requested, including but not limited to:

(a) Selling, leasing, transferring, lending, assembling, installing, maintaining, trading out, disabling or disposing of radiation machines and associated radiation machine components; and

(b) Servicing of radiation machines and associated radiation machine components, to include preventative maintenance, performance adjustment, calibration, or repair.

(2) The name and qualifications of each service technician who will provide service, including:

(a) ~~Documentation of the training and experience that demonstrate compliance with the requirements of Appendix 2H~~**A management attestation that the technician's training and experience was evaluated and meets the requirements of Appendix 2H**; and

(b) ~~Certification~~**A management attestation** that each service technician has been instructed in, and demonstrates an understanding of the requirements of:

(i) **T**~~t~~hese regulations; and

(ii) **T**~~t~~he Federal Performance Standard (21 CFR Chapter I, Subchapter J; and

(3) ~~Documentation of~~ **An attestation that** the type of personnel dosimetric monitoring **in use** ~~used that~~ meets the requirements of 4.17 and 4.18; and

(4) ~~A list of instruments that will be used to ensure that machine performance meets the manufacturer's specifications.~~**An attestation that all calibration and testing**

Commented [JJ624]: In an effort to streamline and simplify certain business processes applicable to the registration of service companies, this section has been modified. The proposed changes are expected to reduce the number of documents submitted by the applicant.

The certification or attestation information will be submitted through completion of an online or similar form.

instruments are adequate to ensure that machine performance and manufacturer's specifications will be met.

(5) ~~Each servicing and services registrant under 2.4.2 shall notify the Department each time the registrant adds or deletes any service technician(s) to the list of service technicians authorized to provide radiation machine service(s).~~**Each service company registrant under 2.4.2 shall notify the Department when any service technician is no longer authorized to provide radiation machine services for the registrant.**

(a) The registrant will be assessed the acceptance review fee required by Part 12, Category 24 when adding a technician, unless ~~the~~ technicians are added during a registration renewal.

2.4.2.4 Service Company registration will be for a one (1) year period.

2.4.3 Registration as a Qualified Expert.

2.4.3.1 Each individual who designs or evaluates protective shielding around a radiation area so the area meets the public exposure requirements of Part 4, shall be registered with the Department as a qualified expert designated QE(R), QE(S) or QE(T).

(1) Each individual who designs or evaluates shielding for a radiation machine regulated by Parts 8 or 9 and not used in the healing arts shall be registered with the department as a QE(S) and meet the requirements of Appendix 2C.

(2) Each individual who designs or evaluates shielding for a radiation machine used in the healing arts as regulated by Part 6, but not used in radiation therapy, shall be registered with the department as a QE(R) and meet the requirements of Appendix 2B

(3) Each individual who designs or evaluates shielding for a radiation machine used in radiation therapy as regulated by Part 24, shall be registered as a QE(T) and meet the requirements of Appendix 2B.

2.4.3.2 Each Qualified Expert shall complete the applicable Form R-68 series application for registration and include all of the information required by the form and any accompanying instructions, together with the fee required by Part 12, Category 22.

2.4.3.3 Qualified Expert registration shall be for a one (1) year period.

2.4.4 Registration as a Qualified Inspector.

2.4.4.1 Each individual who performs a certification evaluation of a radiation machine or an evaluation of a facility shall be registered with the Department as a qualified inspector who meets the criteria established in Appendix 2I.

2.4.4.2 Each individual who performs a certification evaluation on mammography, fluoroscopy or computed tomography machines used in the healing arts or, evaluates the quality assurance programs of digital imaging systems used in the healing arts shall be registered with the department as a qualified inspector with approval in the Registered Medical Physicist category.

(1) Individuals who perform a certification evaluation on Volumetric Dental Imaging Systems shall be registered with the department as a qualified inspector with approval in "Volumetric Dental Imaging Systems".

2.4.4.3 Each individual who performs registered medical physicist duties required by Part 24 shall be registered with the department as a qualified inspector with approval in the radiation therapy Registered Medical Physicist category.

2.4.4.4 Each Qualified Inspector shall complete the applicable Form R-53 series application for registration and include all of the information required by the form and any accompanying instructions, together with the fee required by Part 12.

2.4.4.5 Qualified Inspector registration shall be for a period of one (1) year.

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

(1) The instruments shall be maintained and used in good working order.

(2) The instruments shall be calibrated at least every two (2) years, or in accordance with the manufacturer's recommendation, whichever is more frequent, or after any repair that could affect the calibration of the instrument.

(3) Calibrations shall be NIST-traceable where such traceability is feasible.

(4) Procedures for instrument calibration done by inter-comparison with a suitable and appropriately calibrated instrument must be approved by the department.

(a) The comparison shall be between an instrument that has a current calibration traceable to NIST and an instrument for which a calibration factor is to be determined.

(b) The comparison shall be made using the actual physical quantity to be routinely measured (for example, radiation energy/quality or visible light spectrum) and shall be compared in the same physical geometry.

(c) The procedure(s) for inter-comparison shall be documented and available for review by the department.

(5) In addition to the requirements in 2.4.4.6, instruments used for the certification evaluation report to measure the air kerma or air kerma rate of mammography machines shall be calibrated with an accuracy of ± six (6) percent (95 percent confidence level) in the mammography energy range.

2.4.5 Registration of specific radiation machine ~~O~~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 radiologic technology, nuclear medicine, or radiation therapy 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 2L, 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.

Commented [JJ625]: The added provision is intended to clarify that individuals who hold a national registry/certification for the specific modality they are involved with do not need to register with the Department.

2.4.5.1 Limited Scope Operator.

(1) Each individual operating an x-ray system on living humans in the State of Colorado, shall be registered as a Limited Scope Operator consistent with 2.4.5.1(2), except for:

(a) Those individuals subject to 2.6.1.5, 2.6.1.6, 2.6.1.7, 2.6.1.8, 2.6.1.10, 2.6.1.11, and 2.6.1.12, or

(b) Those individuals having current registration with the American Registry of Radiologic Technologists in radiography.

(2) Registration

(a) The applicant for LSO registration must complete the requirements of 2D.2.1, 2D.2.2 and 2D.2.3 in a structured and documented training program in order to apply for registration as a Limited Scope Operator.

(b) Each Limited Scope Operator shall complete an application with all of the information required by the form and instructions, together with the fee required by Part 12, Category 24 ~~and the fee required by the American Registry of Radiologic Technologists~~.

(i) The Form R-70 series application shall be used to initiate the registration process.

(ii) The Form R-71 series application shall be used to confirm the completion of the requirements of 2D.2.1, 2D.2.2 and 2D.2.3.

(c) Application for registration as a Limited Scope Operator shall be made within one year upon completion of the requirements of 2D.2.1 and within ninety (90) calendar days upon completion of the requirements of 2D.2.2 and 2D.2.3.

(d) If an applicant cannot achieve a passing score per 2D.2.4 within three attempts, the applicant must restart the training required by 2D.2.1, 2D.2.2, and 2D.2.3.

(e) Registrants must meet the requirements of 2D.2.5 in order to renew the Limited Scope Operator ~~approval~~**registration**.

(i) The Form R-90 series application shall be used to renew the registration for a Limited Scope Operator.

2.4.5.2 Computed Tomography Operator

(1) Each individual operating a computed tomography system on living humans shall **meet the requirements of Appendix 2E.** ~~hold a current, valid registry in Radiography, Nuclear Medicine, or Radiation Therapy issued by ARRT, NMTCB, or where the individual has obtained written approval from the Department, another nationally recognized registry organization not listed herein, shall:~~

~~(a) Meet the requirements of 2E.1.1, 2E.1.2, 2E.1.3, or 2E.1.4 for the applicable use specified in 2.6.1.7;~~
~~or~~

~~(b) Meet the requirements of Appendix 2E.2 and be registered with the Department as a Colorado Computed Tomography Operator;~~

Commented [JJ626]: The examination fee required by the American Registry of Radiologic Technologists (ARRT) is no longer collected by the department. Applicants send this fee directly to ARRT and therefore this requirement is no longer applicable.

Commented [JJ627]: The requirements specific to Computed Tomography (CT) registration have been deleted and will fully defer to nationally recognized registry processes for persons not specifically certified/registered in CT.

As specified in the current Part 2 rule, effective after July 31, 2017, the Department no longer has an alternate pathway for registration and certification for CT operators in Colorado. While past registration issued by the Department will continue to be recognized by the Department, issuance of new Department registrations for CT operators ended after July 31, 2017.

Individuals wishing to operate CT machines must complete the applicable education, training and examination requirements specified by a nationally recognized certification organization such as ARRT or NMTCB as outlined in Appendix 2E. Once the individual is registered in the CT specialty by a nationally recognized registry/certification organization, no registration with the Department is required.

~~or~~

~~(c) As a CT operator in training, be under the direct supervision of an individual who meets the requirements of 2.4.5.2(a) or 2.4.5.2(b).~~

~~(2) Registration~~

~~(a) The applicant for Colorado Computed Tomography Operator must complete the requirements of Appendix 2E, 2E.2 in a structured and documented training program.~~

~~(b) The application for registration as a Colorado Computed Tomography Operator shall contain all of the information required by the form and instructions, together with the fee required by Part 12, Category 24.~~

~~(i) The Form R-95 series shall be used to document the requirements of 2E.2.2, 2E.2.3 and 2E.2.4.~~

~~(3) After July 31, 2017, the Department will recognize Computed Tomography Operators previously registered with the Department but will cease registration of new Colorado CT Operators.~~

Commented [JJ628]: Although this provision is deleted here, the Department will continue to recognize CT Operators previously registered with the Department through the requirements of Appendix 2E, Section 2E.2.

2.4.5.3 Bone Densitometry Equipment Operator (BDEO).

(1) Each ~~operator of~~**individual operating** a dual-energy x-ray absorptiometry system used on a living human shall be registered as a Bone Densitometry Equipment Operator, except for:

(a) Those individuals registered with the American Registry of Radiologic Technologists as a radiologic technologist, nuclear medicine technologist or radiation therapist; or

(b) Those individuals registered with the Nuclear Medicine Technology Certification Board (NMTCB) as a certified nuclear medicine technologist.

(2) Registration

(a) The applicant must complete the requirements of 2F.2.1, 2F.2.2, and 2F.2.3 in a structured and documented training program in order to apply for registration as a Bone Densitometry Equipment Operator.

(b) Applicants with International Society of Clinical Densitometry (ISCD) certification must, at a minimum, document the completion of the requirements of 2F.2.1.1 through 2F.2.1.3.

(i) ISCD-certified applicants have met the requirements of 2F.2.1.4 through 2F.2.1.9, 2F.2.2 and 2F.2.3 and are exempt from the requirements of 2F.2.4

(c) Application for the Bone Densitometry Equipment Operator registration shall contain all of the information required by the form and instructions, together with the fee required by Part 12, Category 24 ~~and the fee required by the American Registry of Radiologic Technologists, if applicable~~.

Commented [JJ629]: The examination fee required by the American Registry of Radiologic Technologists (ARRT) is no longer collected by the department. Applicants send this fee directly to ARRT and therefore this requirement is no longer applicable.

(i) The Form R-80 series application shall be used to initiate the registration process.

(ii) The Form R-81 series application shall be used to confirm the completion of the requirements of 2F.2.1, 2F.2.2 and 2F.2.3.

(d) Application for registration as a Bone Densitometry Equipment Operator shall be made within one year upon completion of the requirements of 2F.2.1 and within ninety (90) calendar days upon completion of the requirements of 2F.2.2 and 2F.2.3

(e) If an applicant cannot achieve a passing score per 2F.2.4 within three attempts, the applicant must restart the training required by 2F.2.1, 2F.2.2 and 2F.2.3.

(f) Bone Densitometry Equipment Operator registration is issued for a period of three years.

(g) Registrants must meet the requirements of 2F.2.5 in order to renew the Bone Densitometry Equipment Operator approval.

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 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.

2.4.5.5 Fluoroscopy operator

(1) On or after January 1, 2021, each individual operating a fluoroscopy imaging system on living humans shall be registered as a fluoroscopy operator consistent with 2.4.5.5(2), 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 who meets the requirements of Appendix 2G; or

(c) An individual with a current R.T.(R), or R.T.(T) registration.

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

Commented [JJ630]: The current and proposed requirements help ensure that persons who operate a fluoroscopy systems have the necessary training and experience to safely operate these systems. Procedures involving fluoroscopy typically result in higher patient doses as compared to other x-ray modalities.

This section as originally proposed in Draft C is revised to specify registration of all individual operators of fluoroscopy excluding physicians, radiologic technologists, and other individuals who may be exempted in writing by the department or on a case by case basis.

The proposed requirements would not be effective until ~1+ years beyond the anticipated effective date of the proposed changes to allow for program requirements and processes to be developed and allow for the regulated community to meet the requirements.

Under the current in-effect Part 2 requirements, the only pathway for non-physicians to operate a fluoroscopy system is for them to become a registered technologist (as administered by the ARRT) which may be excessively burdensome. The American Registry of Radiologic Technologists (ARRT) however, has recently started a process for non-physician mid-level providers who have met prescribed training and experience requirements to sit for a fluoroscopy operators exam. This application and testing process would be administered through the Department in conjunction with the ARRT. (The ARRT does not currently offer this testing directly to individuals unless coordinated through each specific state radiation control regulatory agency.)

The proposed requirements will allow for certain qualified medical professionals to be an operator of a fluoroscopy imaging system while under supervision of a licensed physician.

Commented [JJ631]: Provisions 1(a) through1(c) are added for consistency with Part F, Section F5l, with the exception that wording is modified to fit the structure and flow of Part 2, and a phase-in date is added.

(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.

(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 completion of the training requirements of Appendix 2O.

(d) If an applicant cannot achieve a passing score per Appendix 2O within three attempts, the applicant must restart the training required by Appendix 2O.

(e) Issuance of 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 shall be submitted to the Department for review and evaluation on an individual case-by-case basis.

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

(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.

2.4.7 Providing Notice of Registrant's Rights

2.4.7.1 Whenever a business relationship exists between the qualified inspector and a registered service company, a "Notice of Registrant's Rights" Form R-65 shall be provided to the registered facility prior to beginning the service or evaluation, including:

(1) When a qualified inspector is also registered to perform services and servicing;

(2) When a qualified inspector is also a qualified expert; and

(3) When a qualified inspector, a qualified expert and/or a services and servicing provider is a member of the same corporation, partnership or other formal business relationship.

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

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 security screening.

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.

Commented [JJ632]: Updated for consistency with changes in Table 2-1. This helps clarify that CT systems used in veterinary medicine are now to be inspected every 3 years, consistent with other veterinary use x-ray systems.

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

Commented [JJ633]: Table 2-1 is reformatted for clarity and to address newer modalities.

All inspection frequencies remain as they are in the current rule, with the exception that veterinary CT systems are changed from a 1 year frequency to a 3 year frequency, consistent with other veterinary imaging systems.

Category	Frequency
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;**	Every **one (1)** year

• **Volumetric dental imaging system;** • **Hand-held x-ray imaging systems for human use;** • **Security scanner x-ray systems used on living humans;** • **All systems identified above entering the state under reciprocity.** ~~Each radiation machine, including under reciprocity, unless otherwise provided below:~~	
Each **industrial (**non-healing-arts**)** x-ray imaging machine or system regulated ~~by~~**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.**	Every two **(2)** years
~~Each bone densitometry, dental, podiatry or veterinary radiation machine, except as required below:~~**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**~~non~~-intraoral dentistry or podiatry ~~that is~~**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
~~Pursuant to 2.5.1.3(3), each volumetric dental imaging system or computed tomographic system~~	~~Every year~~
~~Pursuant to 2.5.1.3(4), each hand-held x-ray machine used on living humans~~	~~Every year~~

Commented [JJ634]: This and the subsequent table item have been incorporated into other parts of this table.

2.5.1.4 **Except as otherwise specified in regulation,** ~~Each~~**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.~~,~~

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.

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.~~6~~**7** Any radiation machine and/or facility not inspected in accordance with 2.5.1.1 through 2.5.1.~~5~~**6**, 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.

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~~**R 59-1**, “X ray Machine Certification Evaluation Report,” in accordance with the instructions contained in that form.

(a) A clear and legible report may be substituted for Form ~~R591~~**R 59-1**, provided that it is in the same format and provides all of the information required by Form ~~R591~~**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 ~~R592~~**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.

Commented [JJ635]: Here and throughout rule, the format for the form number is updated/corrected.

(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~~**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 ~~accomplish timely completion of~~ **complete** certification evaluation reports **in a timely manner** as provided in ~~this subsection~~**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.

Commented [JJ636]: Reworded for clarity.

2.6 Facility Registrant Responsibilities.

2.6.1 ~~In any fa cility regulated by or requiring registration under these regulations, the registrant shall allow only individuals who are adequately trained in radiation safety and the safe and effective use of the machine to operate any radiation machine.~~**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.**

Commented [JJ637]: Language is updated to improve the phrasing and clarity and to incorporate the definition "radiographic examination". The language originally proposed required review of the operators manual, but it was later recognized that such documents contain extensive information all of which may not be beneficial to the safe operation of the machine in day to day activities. Therefore, the language is modified to indicate those applicable requirements as determined by the facility.

2.6.1.1 The facility registrant shall ~~document evaluation of~~ **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 ~~technical~~ supervision of operators shall be maintained.

Commented [JJ638]: Technical supervision is not defined and therefore the term is deleted here.

(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 ~~such~~ evaluations shall:

(a) Include current certifications ~~of~~**and** qualification**s**;

(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 has a current active license from the appropriate State of Colorado professional licensure board~~ **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~~**4** through 2.6.1.~~14~~**13**), "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.

(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** ~~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:

~~(1)~~**(a)** ~~Fundamental principles of radiation protection;~~**Basic properties of radiation;**

~~(2)~~**(b)** ~~Biological effects of ionizing radiation;~~**Biological effects of x-ray;**

~~(3)~~**(c)** ~~Safe operation of fluoroscopy equipment for each mode of operation to be used;~~**Principles and safe operation of the specific fluoroscopic x-ray system(s) to be used;**

~~(4)~~**(d)** ~~Dose reduction techniques for fluoroscopy; and~~**Dose management including dose reduction techniques, monitoring, and recording;**

~~(5)~~**(e)** ~~Applicable radiation regulations.~~**Applicable requirements of these regulations.**

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

Commented [JJ639]: This provision is updated to simplify the wording and to tie-in with the proposed changes to Part 6.

Commented [JJ640]: Originally proposed for deletion in the prior draft of Part 2 (draft C), this provision is retained.

Commented [JJ641]: The proposed language adds reference to new Appendix 2O to address requirements specific to fluoroscopy operators.

Existing provisions (1) through (5) of this section are updated for consistency with Part F, Section F5.(l)(ii). The modification of items (1) through (5) primarily involve phrasing and therefore current training is deemed adequate to address these topics.

[Proposed modifications to provisions (1) through (5) were originally proposed for inclusion in Appendix 2G of Draft C, but have been moved to this section to maintain consistency in the structure of the current Part 2 rule.]

Commented [JJ642]: The additional training topics specific to fluoroscopy are added based on the requirements specified in Part F, Section F5.(l)(ii).

The proposed language provides for a ~2 year phase in period to allow, if needed, development of training materials for the additional training topics required by Part F.

[Proposed new provisions (f) through (j) were originally proposed for inclusion in Appendix 2G of Draft C, but have been moved to this section to maintain consistency in the structure of the current Part 2 rule.]

(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.

2.6.1.7 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 ~~following requirements~~**requirements of Appendix 2E.**~~:~~

~~(1) Individuals operating a CT system for general imaging purposes shall meet the requirements of 2E.1.1, 2E.1.4, or 2E.2; or~~

~~(2) Individuals operating a CT system in conjunction with nuclear medicine Positron Emission Tomography (PET-CT) or Single Photon Emission Computed Tomography (SPECT-CT) systems (known as hybrid or fusion imaging machines) shall meet the requirements of 2E.1.1, 2E.1.2, 2E.1.4, or 2E.2; or~~

~~(3) Individuals operating a CT system used in conjunction with radiation therapy procedures (treatment simulation or tumor localization imaging) shall meet the requirements of 2E.1.1, 2E.1.3, 2E.1.4, or 2E.2.~~

~~Individuals who are in-training to become a CT operator, shall not be considered adequately trained until they have fully met the requirements of 2.6.1.7(1), or 2.6.1.7(2), or 2.6.1.7(3) and shall not operate such CT machines except under the direct supervision of an individual who meets the requirements of 2.6.1.7(1), or 2.6.1.7(2), or 2.6.1.7(3).~~

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.

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**~~State Board of Medical Examiners.(in particular Rule 700, "State Board of Medical Examiners Rules and Regulations Regarding Education and Training Standards for Unlicensed Personnel Exposing Ionizing Radiation" of 3 CCR 713-16).~~

Commented [JJ643]: The specific rule listed was repealed effective 10/15/2010.

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 ~~State~~ Board of Chiropractic Examiners **and Rule 19 of 3 CCR 707-1.** ~~(in particular Rule 19, "Safety Training for Unlicensed Chiropractic Personnel," of 3 CCR 707-1)~~.

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.**~~State Board of Dental Examiners (in particular Rule X, "Minimum Standards for~~

Commented [JJ644]: Based on stakeholder discussions the language is modified from that originally proposed.

~~Qualifications, Training and Education for Unlicensed Personnel Exposing Patients to Ionizing Radiation," 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 ~~State of~~ Colorado Podiatry Board **and Rule 700 of 3 CCR 712-9.**~~(in particular Rule 700 of 3 CCR 712-9).~~

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 ~~State of~~ Colorado Board of Veterinary Medicine **and 4 CCR 727-1.**~~(in particular 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.

2.6.1.15 For radiation machines used in non-healing-arts applications, "adequately trained" shall mean that the individual operator meets the requirements of Appendix 2N.

(1) For industrial radiography, the requirements in Part 5 apply, as stated in 2N.1.

(2) The requirements of 2N.2 apply to all non-healing-arts applications (including but not limited to analytical, forensic, morgue, and homeland security uses) not subject to Part 5.

2.6.1.16 For assembly, installation and repair of radiation machines, "adequately trained" shall mean that the individual service technician meets the requirements of Appendix 2H.

2.6.1.17 Department recognition of training as adequate pursuant to 2.6.1.3 through 2.6.1.16 shall pertain only to the areas of training and experience specifically identified in these regulations.

2.6.1.18 The Department may, upon application or upon its own initiative, accept as being adequate:

(1) Documented combinations of radiation safety training and experience; or

(2) Equivalent approval by another state or agency.

2.6.2 The facility registrant shall ensure that all required certification and compliance evaluations are performed as required by 2.5.2 in accordance with the instructions that accompany Form ~~R-59-1~~**R 59-1**, "X-ray Machine Certification Evaluation Report" and Form ~~R-59-2~~**R 59-2**, "X-ray Facility Compliance Evaluation Report."

2.6.2.1 Upon receipt of a Form ~~R-59-1~~**R 59-1** signed by a registered qualified inspector, the facility shall complete the certification evaluation process with that qualified inspector unless department approval is granted or required to have the certification evaluation done by a different qualified inspector.

2.6.3 For each radiation machine finding of noncompliance (Form ~~R-59-1~~**R 59-1**), the facility registrant shall:

2.6.3.1 Correct any failure of a radiation machine or imaging system to meet the requirements of these regulations or manufacturer's required specifications, within thirty (30) calendar days or as otherwise specified by the Department, in particular as identified on Form ~~R 59-1~~**R 59-1**, "X ray Machine Certification Evaluation Report."

2.6.3.2 Not use a radiation machine that has been determined to be unsafe for use, as determined by the criteria in Part 6, Appendix 6D, until subsequent certification by a Department-approved qualified inspector or the Department.

2.6.3.3 Permit only a person who has provided evidence of current registration with the Department in accordance with 2.4.2 to provide radiation machine servicing or services.

2.6.3.4 Notify the qualified inspector who issued the Certification Evaluation Report when the radiation machine violations have been corrected.

(1) A copy of the Certification Evaluation Report, Form ~~R-59-1~~**R 59-1**, with the service repair certification signed and dated by the person providing service, shall be provided to the qualified inspector who initiated the certification evaluation..

(2) A copy of any service report shall be provided to the qualified inspector upon request as evidence of completed corrective action.

2.6.3.5 Retain documentation that each indicated violation has been corrected to bring the machine into compliance in accordance with Section 2.6.6.

~~2.6.3.6 Pay the fee required by Part 12, Category 25 for each certification label issued by the qualified inspector.~~

Commented [JJ645]: Provision has been relocated to 2.6.7 so that it is a standalone item not associated with an inspection finding.

2.6.4 For each finding of facility noncompliance (Form ~~R-59-2~~**R 59-2**), the registrant shall:

2.6.4.1 Correct any violation within thirty (30) calendar days of each finding of facility noncompliance (Form ~~R-59-2~~**R 59-2**) or as otherwise specified by the Department.

2.6.4.2 Provide documentation to the Department to confirm that each indicated violation has been corrected to bring the facility into compliance.

(1) For any item identified for correction on Form ~~R-59-2~~**R 59-2**, "X-ray Facility Compliance Evaluation Report", provide a copy of the Form ~~R-59-2~~**R 59-2** with the "Registrant's Certification of Correction" section signed and dated by the registrant or registrant's agent.

2.6.5 Except as otherwise specified in Part 6 and Part 24 of these regulations, each registrant shall follow all applicable manufacturer's recommended equipment maintenance and quality assurance procedures.

2.6.6 Record Retention and Reports.

2.6.6.1 The registrant shall maintain each diagnostic image in a medical record for each patient as specified by the applicable State of Colorado professional licensure board; absent an applicable board specification, record retention shall be for a period not less than ten (10) years or any period of minority or incompetency.

2.6.6.2 The registrant shall maintain for the duration of the registration, records of each shielding design, and each radiation survey required by 6.9.4.1, performed for the facility.

(1) Upon any transfer of ownership, such shielding design(s) and survey records shall also be transferred to the new owner.

2.6.6.3 The registrant shall maintain for the duration of the registration, until a machine is retired from service, the operator and service manual(s) provided by the manufacturer, if available.

(1) If the operator manual is not obtainable from the manufacturer, such a manual of written operating procedures shall be developed and maintained by the registrant, including:

(a) A description, including purpose and function, of each control panel knob, button, and meter;

(b) Techniques for collimation and centering of the beam to the image receptor;

(c) The function of all locks and detents; and

(d) Emergency shutdown instructions.

2.6.6.4 The registrant shall maintain for inspection for a period of three (3) years for each x-ray imaging or image processing system (six years for a facility or machine inspected only every three years) records of:

(1) Operator certifications;

(2) Operator training;

(3) Service and repair reports;

(4) Radiation machine disposition

(5) Radiation machine inspection certification evaluation reports;

(6) Facility compliance evaluation reports; and

(7) Notices of violation.

2.6.7 For each certification label issued by a qualified inspector, facility registrants shall pay the label fee required by Part 12, Category 25. Facility registrants who fail to pay the label fee may be subject to review, audit, and non-routine inspection fees in accordance with Section 2.9.

Commented [JJ646]: This provision is relocated from 2.6.3.6.

2.7 Service Company Registrant Responsibilities.

2.7.1 No person shall certify or declare that a radiation machine or component is ready for its intended use, until:

2.7.1.1 The shielding design has been completed as required by 6.3.2, as documented by a comment on Form FDA 2579 **(for machines used in the healing arts)** or a signed and dated notification to the Department; and

2.7.1.2 The machine or component meets the manufacturer specifications and the requirements of these regulations; and

2.7.1.3 The registrant has been provided, by the vendor, assembler or services and servicing personnel, the following:

(1) All guidance documents, including instruction manuals, manufacturer specifications and information notices, that are applicable to each newly installed radiation machine system or component; and

(2) ~~A checklist of the registrant's responsibilities under these regulations, including but not limited to requirements of 2.6.3, in particular 2.6.3.4.~~**The Colorado x-ray facility registrant's responsibilities list, as posted on the department website.**

2.7.2 Any person who sells, leases, transfers, lends, assembles, installs, trades out or repairs any radiation machine, or component, which affects radiation output or technique setting in this State shall notify the Department in writing within fifteen (15) calendar days of each transaction subject to this section with the following information:

2.7.2.1 The full name and address of each person who has received the radiation machine or component and the specific location within the facility; and

2.7.2.2 Specific details about the system or sub-system, including the manufacturer, model, and serial number of each radiation machine or component transferred; and

2.7.2.3 The date of transfer, assembly, or installation of each radiation machine or component; and

2.7.2.4 A completed Form FDA 2579 or a signed and dated affirmation that all instruction manuals, written instructions and regulations applicable to the newly installed radiation machine system or components have been delivered to the registrant.

2.7.3 A report of assembly (Form FDA 2579 or equivalent) shall be submitted to the Department within fifteen (15) calendar days following completion of the assembly or installation.

2.7.3.1 The assembly or installation is considered completed when the unit has properly been made operational and is ready for its intended use.

2.7.3.2 Form FDA 2579 or an equivalent report suffices in lieu of any reports required in 2.7.2.

2.7.4 As required by the Department on a Certification Evaluation Report, Form ~~R-59-1~~**R 59-1**, a service company technician who performs a radiation machine repair shall:

2.7.4.1 Sign the service repair certification section of the Certification Evaluation Report, Form ~~R-59-1~~**R 59-1** issued by the qualified inspector who performed the evaluation; and

2.7.4.2 Provide a written detailed description of the service to the registered facility within one (1) business day.

2.7.5 A service technician who performs any activity that could potentially affect the radiation machine output, cause a change to the clinical technique settings of the radiation machine, or affect image

Commented [VB647]: Language added to clarify when a form FDA 2579 is expected. The form FDA 2579 Report of Assembly is required by the FDA only when the machine is designed to be used on living humans. For non-human healing arts and non-healing arts machines, the notification involves a letter or email from the service company to the Department.

Commented [JJ648]: Rather than address or highlight limited requirement(s), the document is posted on the department website. The document is also a list rather than a checklist.

quality shall provide a written detailed description of all service to the registered facility within one business day of the service.

2.7.6 Any person who disables a radiation machine in order to meet the requirements of 2.3.4 shall be registered with the Department as a Service Company.

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 900.11(a), April 1, 2010) 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 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.

ENFORCEMENT

2.9 Department Review of Performance.

2.9.1 The Department as appropriate shall:

2.9.1.1 Notify the registrant or person operating a radiation machine, as appropriate, regarding inadequate action on any item of violation;

2.9.1.2 Determine a schedule for correction of each violation and specifying a date by which compliance must be achieved;

2.9.1.3 Confirm and verify by inspection a corrective action by a registrant or person operating a radiation machine, as appropriate, to assure compliance with these regulations; and

2.9.1.4 Assess a non-routine inspection fee provided in Part 12, at the programmatic hourly rate, for the inspection of a radiation machine system or facility, if:

(1) The registrant or person operating a radiation machine, as appropriate, fails to fulfill the requirements of these Regulations; or

(2) Any item of violation has not been corrected in accordance with the compliance schedule established in 2.9.1.2.

2.9.2 The Department shall periodically review and audit:

2.9.2.1 The compliance of any person registered under 2.4 with these Regulations;

2.9.2.2 The competency of each service technician in meeting standards and requirements for adequate service company performance;

2.9.2.3 The performance of each qualified inspector, in particular:

(1) Adequacy of inspections;

(2) Competency in determining radiation machine system or facility compliance with these regulations; and

(3) Completeness and accuracy of findings on Form ~~R-59-1~~**R 59-1** or ~~R-59-2~~**R 59-2**;

2.9.2.4 The performance of each qualified expert and/or registered medical physicist, in particular:

(1) Adequacy of shielding design reports; and

(2) Competency in performing activities in accordance with these regulations.

2.9.3 The Department shall notify the registrant of any failure to meet a performance standard or requirement of the regulations that is identified as a result of the review or audit.

2.9.4 The Department shall determine a schedule for actions required, specifying the date by which adequacy or competency shall be demonstrated.

2.9.5 For any failure to demonstrate adequacy or competency in accordance with the compliance schedule established in 2.9.4, the Department will assess a non-routine inspection fee at the programmatic hourly rate for Department effort to enforce compliance with a performance standard or requirement of the regulations.

2.9.6 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.

2.9.7 A registrant that fails to comply with these regulations including 2.4.5 and 2.4.6 shall be subject to revocation as provided in 2.10.

MODIFICATION AND REVOCATION OF REGISTRATION

2.10 The terms and conditions of all registrations/certificates shall be subject to amendment, revision, or modification or the registration/certificate may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations, and orders issued by the Department.

PART 2, APPENDIX 2A: RADIATION MACHINE RADIATION SAFETY OFFICER (RSO) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

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Each individual who performs the duties of a Radiation Safety Officer for a facility using radiation machines shall meet the following education and experience requirements:

2A.1 For non-healing arts facilities (such as those governed by Part 8, “Radiation Safety Requirements for Radiation Generating Machines Not Used in the Healing Arts”, and Part 9, “Radiation Safety Requirements for Particle Accelerators Not Used in the Healing Arts”):

2A.1.1 Has current Department approval as a Qualified Expert, or

2A.1.2 Has current Department approval as a registered medical physicist, or

2A.1.2 Has satisfactorily completed a baccalaureate or higher degree in natural or physical science, health physics, radiological sciences, nuclear medicine, nuclear engineering, or

2A.1.3 Has completed a structured educational program that included classroom training in the responsibilities of an RSO, including but not limited to:

2A.1.3.1 Establishing and overseeing operating and safety procedures that maintain radiation exposures as low as reasonably achievable (ALARA), and to review them regularly to ensure that the procedures are current and conform with these regulations;

2A.1.3.2 Ensuring that individual monitoring devices are properly used by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by Part 4;

2A.1.3.3 Investigating and reporting to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these regulations and each theft or loss of source(s) of radiation, determining the cause, and taking steps to prevent its recurrence;

2A.1.3.4 Having a thorough knowledge of management policies and administrative procedures of the registrant and keeping management informed on a periodic basis of the performance of the registrant's radiation protection program, if applicable;

2A.1.3.5 Assuming control and having the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;

2A.1.3.6 Maintaining records as required by these regulations; and

2A.1.3.7 Ensuring that personnel are adequately trained and complying with these regulations, the conditions of the certificate of registration, and the operating and safety procedures of the registrant; or

2A.2 For a healing arts facility not using fluoroscopy, computed tomography, or radiation therapy machines, unless otherwise provided or prohibited by these regulations:

2A.2.1 Has department approval as a registered medical physicist; or

2A.2.2 Is a physician, chiropractor, dentist, podiatrist or veterinarian with a current active license from the appropriate State of Colorado professional licensure board and is performing RSO duties within their scope of practice;

(1) For dental facilities using a Volumetric Dental Imaging System, a dentist with a current active license from the Colorado Board of Dental Examiners may perform the duties of a Radiation Safety Officer;

or

2A.2.3 Meets the applicable operator requirements of 2.6.1.3 through 2.6.1.~~14~~13; and has completed a structured educational program that includes ionizing radiation safety; or

2A.3 For a healing arts facility using fluoroscopic or computed tomography machines, unless otherwise provided or prohibited by these regulations:

2A.3.1 Has department approval as a registered medical physicist; or

2A.3.2 Is a physician or veterinarian who has a current active license from the appropriate State of Colorado professional licensure board; or

2A.4 For a healing arts facility using radiation therapy machines, unless otherwise provided or prohibited by these regulations:

2A.4.1 Has department approval as a radiation therapy registered medical physicist, or

2A.4.2 Is a physician or veterinarian who has a current active license from the appropriate State of Colorado professional licensure board and is performing RSO duties within their scope of practice, or

2A.5 Has prior Department approval pursuant to another part of these regulations as an authorized RSO

PART 2, APPENDIX 2B: ~~REGISTERED MEDICAL PHYSICIST,~~ QE(R) AND QE(T) ADEQUATE TRAINING AND EXPERIENCE

~~2B.1 Each Registered Medical Physicist for a healing arts facility other than those using radiation therapy machines shall be an individual who meets the requirements of 2I.3.~~

~~2B.2 Each Registered Medical Physicist for a healing arts facility using radiation therapy machines regulated by Part 24 shall be an individual who meets the requirements of 2I.5.~~

~~2B.3~~**2B1** Each Qualified Expert who designs or evaluates shielding for a radiation machine used in the healing arts as regulated by Part 6, but not used in radiation therapy, and is designated as a QE(R), or each Qualified Expert who designs or evaluates shielding for a radiation machine used in radiation therapy, and is designated as a QE(T) shall:

~~2B.3.1~~**2B.1.1** Have current certification in health physics or a subfield of medical physics by:

~~2B.3.1.1~~**2B.1.1.1** The American Board of Medical Physics; or

~~2B.3.1.2~~**2B.1.1.2** The American Board of Health Physics; or

~~2B.3.1.3~~**2B.1.1.3** The Canadian College of Medical Physics; or

~~2B.3.1.4~~**2B.1.1.4** The American Board of Radiology in a radiological physics category; or

~~2B.1.3.5~~**2B.1.1.5** American Board of Nuclear Medicine Science; or

~~2B.3.2~~**2B.1.2** Has current certification in an equivalent specialty board recognized by the Department, and;

~~2B.3.2.1~~**2B.1.2.1** Has provided written documentation that the individual:

(1) Holds a master or doctorate degree from an accredited college or university in physics, biophysics, radiological physics, health physics, or medical physics; and

(2) Has satisfactorily completed 2 years of training and work experience acceptable to the Department that includes one year of documented, full-time training in the appropriate field under the supervision of a qualified expert.

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Commented [JJ651]: To avoid duplication of requirements, the specific training and experience requirements for a registered medical physicist (RMP) are contained in Appendix 2I and are therefore deleted here.

Commented [JJ652]: To avoid duplication of requirements in 2B1 and 2B2, the specific training and experience requirements for a registered medical physicist (RMP) are contained in Appendix 2I and are therefore deleted here.

Subsequent provisions are renumbered as a result of this change.

PART 2, APPENDIX 2C: QE(S) – ADEQUATE TRAINING AND EXPERIENCE

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2C.1 Each Qualified Expert who designs or evaluates shielding for a radiation machine not used in the healing arts, designated as QE(S), shall:

2C.1 Have current certification in health physics or a subfield of medical physics by:

2C.1.1 The American Board of Medical Physics; or

2C.1.2 The American Board of Health Physics; or

2C.1.3 The Canadian College of Medical Physics; or

2C.1.4 The American Board of Radiology in a radiological physics category; or

2C.1.5 American Board of Nuclear Medicine Science; or

2C.2 Has current certification in an equivalent specialty board recognized by the Department, and;

2C.2.1 Has provided written documentation that the individual:

2C.2.1.1 Holds a master or doctorate degree from an accredited college or university in physics, biophysics, radiological physics, health physics, or medical physics; and

2C.2.1.2 Has satisfactorily completed 2 years of training and work experience acceptable to the Department that includes one year of documented, full-time training in the appropriate field under the supervision of a qualified expert;

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

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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.~~43~~ 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

(4) Basic interactions of x-rays with matter

(5) Primary and secondary scatter

(6) Importance of time, distance, shielding

(7) Maximum permissible doses: occupational and public

(8) Patient protection

2D.2.1.4. Principles of Exposure—15 hours

(1) Factors that control and influence radiographic quality

(2) Properties of x-rays

(3) Size distortion

(4) Shape distortion

(5) kVp, mAs, time

(6) AEC and manual

(7) Grids

(8) Collimation

(9) Intensifying screens

(10) X-ray films and holders

(11) Artifacts

(12) Inverse square law

2D.2.1.5 Procedures and Processing—4 hours

(1) Film storage and handling

(2) Manual, automatic processing film processing and troubleshooting

(3) Computed Radiography (CR)

(4) Digital Radiography (DR)

(5) PACs

(6) Quality assurance / quality control

2D.2.1.6 Anatomy and Positioning—32 hours

(1) Chest—4 hours

(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 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 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;

2D.2.3.19 Chest—4 examinations;

2D.2.3.20 Hip / Pelvis—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*;

PART 2, APPENDIX 2E: COMPUTED TOMOGRAPHY (CT) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

Each operator of a computed tomography system **on living humans** shall hold a current, valid registry in Radiography, Nuclear Medicine, or Radiation Therapy issued by ARRT, NMTCB, or, where the operator has obtained written approval from the Department, another nationally recognized registry organization not listed herein, shall meet the following **requirements:**~~experience and education requirements:~~

2E.1 Certification:

2E.1.1 For general imaging computed tomography procedures, each operator is certified;

2E.1.1.1 By the ARRT in computed tomography, ~~ARRT~~**R.T.**(CT); or

2E.1.1.2 By the Nuclear Medicine Technology Certification Board (NMCTB) in computed tomography, CNMT(CT);

Or

2E.1.2 For nuclear medicine (hybrid or fusion imaging) computed tomography procedures such as PET-CT or SPECT-CT, is certified;

2E.1.2.1 by the ARRT in nuclear medicine as ~~ARRT~~**R.T.**(N)**;** or

2E.1.2.2 by the NMTCB as CNMT; or

2E.1.2.3 by the NMTCB as NMMA; or

2E.1.2.~~3~~**4** in accordance with 2E.1.1.

Or

2E.1.3 For simulation or localization computed tomography procedures associated with radiation therapy, is certified;

2E.1.3.1 by the ARRT in Radiation Therapy, ~~ARRT~~**R.T.**(T); or

2E.1.3.2 in accordance with 2E.1.1.

Or

2E.1.4 Is certified by a specialty board determined by the department to have substantially equivalent requirements for certification in computed tomography as the American Registry of Radiologic Technologists.

~~or~~**Or**

2E.2 Prior to **August 1, 2017**~~July 31, 2017~~**, and holds a current, valid registry**~~is certified~~ as **an** ~~ARRT~~**R.T.**(R) and **was**~~is~~ also registered with the Department as a Computed Tomography Operator**.** ~~by satisfactorily completing the requirements of 2E.2.1 through 2E.2.3, inclusive:~~

~~2E.2.1 At least 60 hours of didactic training providing the minimum hours of instruction in the specific subjects listed in 2E.2.1.1 through E.2.1.12:~~

~~2E.2.1.1 Intravascular (IV) Procedures—2 hours~~

Commented [JJ655]: For final publication, insert a page break to ensure that each appendices begins on a new page.

Commented [JJ656]: This Appendix is updated consistent with other proposed changes in the rule, including:
1. Updates to the language pertaining to the ARRT formal designations as radiologic technologists in Section 2.2;
2. The addition of the general clarifying paragraph at the beginning of Section 2.4.5;
3. The removal of the Department registration requirements (which expired in 2017) for CT operators in Section 2.4.5.2;

Commented [JJ657]: Beginning August 1, 2017 the Department stopped issuing registrations specific to Computed Tomography and began deferring to the requirements specified by national registry organizations. Therefore, the education and experience requirements of this section are no longer applicable and are therefore removed.

~~(1) Venipuncture~~

~~(a) Site selection~~

~~(b) Aseptic and sterile techniques~~

~~(2) Injection techniques~~

~~(a) Manual~~

~~(b) Automatic~~

~~(i) Single phase~~

~~(ii) Multi-phase~~

~~(iii) Flow rate~~

~~2E.2.1.2 Contrast Agent—6 hours~~

~~(1) Types~~

~~(a) Ionic~~

~~(b) Non-ionic~~

~~(c) Water soluble~~

~~(d) Air~~

~~(e) Water~~

~~(2) Administration route and dose calculations~~

~~(a) IV (angiocatheter or butterfly)~~

~~(b) Oral~~

~~(c) Rectal~~

~~(d) Intrathecal~~

~~(e) Catheters~~

~~(3) Special considerations~~

~~(a) Allergy preparation~~

~~(b) Pathologic processes~~

~~(c) Contraindications~~

~~(d) Indicators~~

~~(4) Adverse reactions~~

~~(a) Recognition and assessment of symptoms~~

~~(b) Treatment (e.g., compresses, medications)~~

~~(c) Documentations~~

~~2E.2.1.3 Radiation Safety and Dosimetry—6 hours~~

~~(1) Technical factors affecting patient dose~~

~~(2) Radiation protection~~

~~(3) Dose Measurement~~

~~(4) Pediatric dose reduction~~

~~2E.2.1.4 Type of Study~~

~~(1) Head~~

~~(2) Neck~~

~~(3) Chest~~

~~(4) Abdomen~~

~~(5) Pelvis~~

~~(6) Musculo-skeletal~~

~~2E.2.1.5. Sectional Anatomy (for each type of study listed in 2E.2.1.4)~~

~~(1) Sagittal plane~~

~~(2) Transverse plane (axial)~~

~~(3) Coronal plane~~

~~(4) Off-axis (oblique)~~

~~(5) Landmarks~~

~~(6) Pathology recognition~~

~~2E.2.1.6 Contrast Media (for each type of study listed in 2E.2.1.4)~~

~~(1) Types of agents~~

~~(2) Indications~~

~~(3) Contraindications~~

~~(4) Dose calculation~~

~~(5) Administration route~~

~~(6) Scan/prep delay~~

~~2E.2.1.7 Scanning Procedures (for each type of study listed in 2E.2.1.4)~~

~~(1) Positioning~~

~~(2) Scout~~

~~(3) Acquisition methods (e.g., spiral, non spiral, dynamic, multi-row detector)~~

~~(4) Parameter selection (e.g., slice thickness, mA, time, algorithm, pitch)~~

~~(5) Protocol modification for pathology or trauma~~

~~(6) Cardiac gating~~

~~2E.2.1.8 Special Procedures (for each type of study listed in 2E.2.1.4)~~

~~(1) 3-D studies~~

~~(2) Biopsies~~

~~(3) Radiation therapy planning~~

~~(4) Drainage and aspiration~~

~~(5) Post-myelography~~

~~(6) CT arthrography and angiography~~

~~(7) Cardiac gating~~

~~2E.2.1.9 Systems Operation and Components—4 hours~~

~~(1) Tube~~

~~(2) Generator and transformers~~

~~(3) Detector configuration~~

~~(4) Data Acquisition Systems (DAS)~~

~~(5) Collimation~~

~~(6) Computer and array processor~~

~~(7) Equipment maintenance~~

~~2E.2.1.10 Image Processing & Display—10 hours~~

~~(1) Image reconstruction~~

~~(a) Filtered back projection reconstruction~~

~~(b) Reconstruction filters (algorithms)~~

(c) Raw data vs. image data

(d) Prospective / retrospective reconstruction (single and multi-row)

(e) Effective slice thickness

(f) Reconstruction interval

(2) Image display

(a) Pixel, voxel

(b) Matrix

(c) Image magnification

(d) Field of view (scan, reconstruction and display)

(e) Attenuation coefficient

(f) Window level, window width

(g) Plane specification (X, Y, Z coordinates)

(h) Cine

(i) ROI (single and multiple image)

(3) Post-processing

(a) Multiplanar reformation

(b) 3-dimensional rendering (MIP, SSD, VR)

(c) Quantitative measurements (volume, distance, diameter)

(4) Data management

(a) Hard/soft copy

(b) Storage / archive

(c) PACS

(d) Security and confidentiality

(e) Networking

2E.2.1.11 Image Quality—4 hours

(1) Spatial resolution

(2) Contrast resolution

(3) Temporal resolution

~~(4) Noise and uniformity~~

~~(5) Quality assurance procedures~~

~~(6) CT number~~

~~(7) Linearity~~

~~2E.2.1.12 Artifact Recognition and Reduction—4 hours~~

~~(1) Beam hardening~~

~~(2) Partial volume averaging~~

~~(3) Motion~~

~~(4) Metallic~~

~~(5) Edge gradient~~

~~(6) Patient positioning~~

~~(7) Equipment-induced~~

~~(a) Rings~~

~~(b) Streaks~~

~~(c) Tube arcing~~

~~(d) Cone beam; and~~

~~2E.2.2 At least 480 hours of clinical training during which time computed tomography examinations are performed only under direct supervision of a qualified computed tomography operator or other qualified trainer who meets the requirements of 2E.1.1, 2E.1.4, or 2E.2; and~~

~~2E.2.3 Has performed, under direct supervision, the following computed tomography imaging procedures:~~

~~2E.2.3.1 Head—10 examinations;~~

~~2E.2.3.2 Neck—10 examinations;~~

~~2E.2.3.3 Chest—10 examinations;~~

~~2E.2.3.4 Abdomen—10 examinations;~~

~~2E.2.3.5 Pelvis—10 examinations; and~~

~~2E.2.3.6 Musculo-skeletal—10 examinations; and~~

~~2E.2.4 Or, having completed didactic training in accord with Section 2E.2.1, is allowed under general supervision during the clinical training required by 2E.2.2 to perform the individual procedure(s) outlined in 2E.2.3.1 through 2E.2.3.6 for which the individual has documented the completion of the number of examinations required in 2E.2.3.~~

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 ~~by~~:

2F.1.1 **As** ~~ARRT~~**R.T.**(R), ~~ARRT~~**R.T.**(M), ~~ARRT~~**R.T.**(N), ~~ARRT~~**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, 2F.2.2 and 2F.2.3~~**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:

RADIATION SAFETY:

2F.2.1.1 Basic X-Ray Physics—2 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

2F.2.1.2 Radiobiology—2 hours

(1) Effects of ionizing radiation to the human body

(2) Molecular and cellular radiobiology

(3) Factors that cause somatic and genetic damage

2F.2.1.3 Radiation Protection—5 hours

(1) ALARA

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Commented [JJ659]: Language updated, consistent with the modifications made in Section 2.2 pertaining to these professional registrations.

Commented [JJ660]: Correction of cross references.

(2) Shielding materials

(3) Radiation quantity and units of measurement

(4) Basic interactions of x-ray with matter

(5) Primary and secondary scatter

(6) Importance of time, distance, shielding

(7) Maximum permissible dose: occupational and public

(8) Patient protection

(a) Patient instruction

(b) Comparison levels of radiation

(i) Natural background radiation

(ii) Central DXA

(iii) Peripheral DXA

2F.2.1.4 Basic Concepts—8 hours

(1) Osteoporosis

(a) World Health Organization definition and diagnostic criteria

(b) Primary vs. secondary

(c) Type I (postmenopausal) vs. Type II (senile)

(d) Risk factors

(i) Controllable (smoking, calcium intake, estrogen, medications)

(ii) Uncontrollable (heredity, race, gender, age, medical conditions)

(2) Bone physiology

(a) Functions of bone

(i) Structural support and protection

(ii) Storage of essential minerals

(b) Types of bone

(i) Cortical

(ii) Trabecular

(c) Bone remodeling cycle

(i) Resorption / formation

(ii) Osteoblasts/osteoclasts

(d) Bone health

(i) Nutrition

(ii) Exercise

(3) BMD testing methods (anatomical sites scanned, key advantages and disadvantages)

(a) Dual-energy X-ray Absorptiometry (DXA)

(b) Single X-ray Absorptiometry (SXA)

(c) Quantitative Ultrasound (QUS)

(d) Radiographic Absorptiometry (RA)

(4) Measuring BMD

(a) Basic statistical concepts

(i) Mean

(ii) Standard deviation

(iii) Coefficient of variation

(b) Reporting patient results

(i) BMD formula

(ii) Z–score

(iii) T–score

2F.2.1.5 Equipment Operation & Quality Control—6 hours

(1) Computer console

(a) Major components

(b) File management

(2) Fundamentals of x-ray energy production

(a) Properties of x-ray beam: quality (kVp), quantity (mA), duration/time (s)

(b) Filters and collimators

(c) X-ray energy production: single; dual

(3) Types of DXA systems

(a) Pencil beam systems

(b) Fan beam systems

(c) Cone beam systems

(4) Quality control

(a) Equipment safety (electrical, pinch points, emergency stop)

(b) Use of phantoms and/or calibration

(c) Troubleshooting

(i) Shift or drift

(ii) Pass / fail

(d) Record maintenance

(5) Determining quality in BMD

(a) Precision (definition)

(b) Accuracy (definition)

(c) Factors affecting accuracy and precision

(i) Scanner

(ii) Operator

(iii) Patient

2F.2.1.6 DXA Scanning of Finger and Heel (OS CALCIS)—1 hour

(1) Anatomy

(a) Regions of interest

(b) Bony landmarks

(c) Radiographic appearance

(2) Scan acquisition

(a) Patient instructions

(b) Patient positioning

(c) Evaluating pre-set scan parameters

(3) Scan analysis: BMD, T score, Z score

(4) Common problems

(a) Nonremovable artifacts

(b) Fractures or pathology

2F.2.1.7 DXA Scanning of Forearm—2 hours

(1) Anatomy

(a) Regions of interest

(b) Bony landmarks

(c) Radiographic appearance

(d) Adjacent structures

(2) Scan acquisition

(a) Patient instructions

(b) Patient positioning

(c) Evaluating pre-set scan parameters

(3) Scan analysis

(a) Accurate ROI placement

(b) BMC, area, and BMD

(c) T-score, Z-score

(4) Common problems

(a) Poor bone edge detection

(b) Nonremovable artifacts

(c) Variant anatomy

(d) Fractures or pathology

(5) Follow-up scans

(a) Unit of comparison: BMD, T-score

(b) Reproduce baseline study

2F.2.1.8 DXA Scanning of Lumbar Spine—2 hours

(1) Anatomy

(a) Regions of interest
(b) Bony landmarks
(c) Radiographic appearance
(d) Adjacent structures
(2) Scan acquisition
(a) Patient instructions
(b) Patient positioning
(c) Evaluating pre-set scan parameters
(3) Scan analysis
(a) Accurate ROI placement
(b) BMC, area, and BMD
(c) T-score, Z-score
(4) Common problems
(a) Poor bone edge detection
(b) Nonremovable artifacts
(c) Variant anatomy
(d) Fractures or pathology
(5) Follow-up scans
(a) Unit of comparison: BMD, T score
(b) Reproduce baseline study

2F.2.1.9 DXA Scanning of Proximal Femur—2 hours

(1) Anatomy
(a) Regions of interest
(b) Bony landmarks
(c) Radiographic appearance
(d) Adjacent structures
(2) Scan acquisition
(a) Patient instructions

(b) Patient positioning

(c) Evaluating pre-set scan parameters

(3) Scan analysis

(a) Accurate ROI placement

(b) BMC, area, and BMD

(c) T-score, Z-score

(4) Common problems

(a) Poor bone edge detection

(b) Nonremovable artifacts

(c) Variant anatomy

(d) Fractures or pathology

(5) Follow-up scans

(a) Unit of comparison: BMD, T-score

(b) Reproduce baseline study;

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.

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 ~~to~~**shall** be an individual who is 18 years of age and has provided written documentation as evidence of:

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

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

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

~~Or~~**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.

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PART 2, APPENDIX 2H: ADEQUATE EDUCATION AND TRAINING TO PERFORM RADIATION MACHINE ASSEMBLY, INSTALLATION AND/OR REPAIR

Any individual who performs radiation machine assembly, installation or service shall meet the following educational and experience requirements:

2H.1 Completion of a structured educational program that includes training in radiation machine safety, assembly, installation and service, including, but not limited to:

2H.1.1 A baccalaureate degree in electrical engineering with specialized training in radiation producing devices; or

2H.1.2 A one-year associate degree in biomedical equipment repair; or

2H.1.3 Equivalent manufacturer, military or other technical school training;

and

2H.2 For each service category requested:

2H.2.1 At least six (6) months of supervised, documented training on assembly, installation and service of the applicable radiation machine.

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PART 2, APPENDIX 2I: QUALIFIED INSPECTOR (QI) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

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As provided by 2.4.4, approval of registration as a qualified inspector shall be given to an individual who:

2I.1 Has provided written documentation that the individual:

2I.1.1 Holds an associates or higher degree in physics, applied physics, biophysics, biophysical engineering, medical physics, radiologic physics, health physics, or equivalent, from an accredited college or university; and

2I.1.2 Has experience with each category of radiation machine for which approval is requested, including, but not limited to:

2I.1.2.1 Measuring ionizing radiation;

2I.1.2.2 Evaluating radiation machines and components;

2I.1.2.3 Evaluating facility radiation safety programs;

2I.1.2.4 Image processing;

2I.1.2.5 The applicable requirements of these regulations; and

2I.1.2.6 ~~d~~**D**igital imaging and image processing system software and hardware, when applicable and available; and

2I.1.3 The experience duration required by 2I.1.2 will be in combination with the education requirements from 2I.1.1 as follows:

2I.1.3.1 One year with a masters or doctorate degree; or

2I.1.3.2 Two years with an arts or sciences baccalaureate degree; or

2I.1.3.3 Three years with an Associate Degree; and

2I.1.4 The experience required by 2I.1.2 shall be acquired:

2I.1.4.1 Within the 7 years preceding the date of application; or

2I.1.4.2 Through documented subsequent continuing education and experience within 7 years preceding the date of the application.

2I.2 Approval for registration as a Provisional Qualified Inspector shall be given to an individual who has met the requirements of 2I.1.1 and has:

2I.2.1 Provided training program documentation describing how the Provisional Qualified Inspector will meet the requirements of 2I.1.2, 2I.1.3 and 2I.1.4. The training program documentation shall:

2I.2.1.1 Require direct supervision of the Provisional Qualified Inspector during the evaluation of at least the initial five (5) radiation machines for each category inspected by the Provisional Qualified Inspector; and

2I.2.1.2 Identification of the Qualified Inspector(s) who will provide the Provisional Qualified Inspector with general supervision until the requirements of 2I.1.2, 2I.1.3 and 2I.1.4 are met.

2I.2.2 At the time when the requirements of 2I.1.2, 2I.1.3 and 2I.1.4 are met, the Provisional Qualified Inspectors must apply for registration as a Qualified Inspector.

2I.2.3 Registered Qualified Inspectors may apply for approval as a Provisional Qualified Inspector for new categories that are being requested.

2I.3 In addition to the requirements of 2I.1, approval for registration in the Registered Medical Physicist category shall be give to an individual who:

2I.3.1 Is certified by:

2I.3.1.1 The American Board of Radiology in Radiological Physics, Diagnostic Medical Physics, Diagnostic Radiological Physics, ~~Nuclear Medical Physics,~~ or Medical Nuclear Physics; or

2I.3.1.2 The American Board of Medical Physics in Diagnostic Radiological Physics ~~or Nuclear Medicine Physics~~; or

2I.3.1.3 The Canadian College of Physicists in Medicine in Radiological Physics; or

~~2I.3.1.4 American Board of Science in Nuclear Medicine in Nuclear Medicine Physics and Instrumentation; or~~

~~2I.3.1.5 A equivalent specialty board or certification approved by the department.~~

2I.3.1.4 The American Board of Radiology in Nuclear Medical Physics, American Board of Medical Physics in Nuclear Medicines Physics, or American Board of Science in Nuclear Medicine in Nuclear Medicine Physics and Instrumentation and who shall be limited to RMP certification evaluation activities associated with CT or hybrid (positron emission tomography/CT and single-photon emission computerized tomography/CT systems only; or

2I.3.1.5 An equivalent specialty board or certification approved in writing by the department.

2I.3.2 Approval for registration as a Provisional Registered Medical Physicist shall be given to an individual who is in the process of certification to meet 2I.3.1 and has:

2I.3.2.1 Passed the initial testing requirements of the respective certifying organization; and

2I.3.2.2 Provided training program documentation describing how the Provisional Registered Medical Physicist will be supervised. The training program documentation will include:

(a) The names of the Registered Medical Physicist(s) who will provide general, direct or personal supervision as the individual works to meet the requirements of their certifying organization; and

(b) A list of specific duties, and the level of supervision for each duty, that the Provisional Registered Medical Physicist will perform.

Commented [JJ664]: The proposed changes consolidate the molecular imaging (nuclear medicine) focused certifications into 2I.3.1.4.

Based on further evaluation and stakeholder feedback, it was determined that certain board certifications and associated training programs may not provide adequate training or focus for some x-ray based modalities. Specifically, the nuclear medicine (molecular imaging) based certifications/training do not adequately address modalities such as fluoroscopy and digital radiography. While these certifications will continue to be accepted, individuals qualifying under these certifications will be limited to RMP duties associated with systems involving nuclear medicine such as PET/CT based x-ray systems.

Current RMPs granted RMP authorization under the existing criteria may continue to be recognized and perform RMP activities for which they have been authorized.

Under 2I.3.1.5, the applicant always has the opportunity to demonstrate additional training and experience that may qualify them for other x-ray based modalities.

Commented [JJ665]: This provision has been relocated to new 2I.3.1.5, below.

2I.4 In addition to the requirements of 2I.1 and 2I.3, approval for registration in the Mammography category shall be approved for a Registered Medical Physicist who:

2I4.1 Has the following combination of initial training and experience:

2I.4.1.1 A master's degree or higher in a physical science from an accredited institution with no less than 20 semester hours in physics; and

2I.4.1.2 Have 20 contact hours of specialized training in conducting mammography facility evaluations; and

2I.4.1.3 Experience of conducting evaluations of at least one mammography facility and a total of at least ten (10) mammography units under the following conditions;

(a) No more than one evaluation of a specific unit within a period of sixty (60) calendar days can be counted towards the total mammography unit survey requirement; and

(b) This experience must be accomplished under the direct supervision of a Registered Medical Physicist with approval in the Mammography category;

2I.4.2 And the following continuing education and experience:

2I.4.2.1 At least fifteen (15) documented hours of continuing education in mammography which are no more than thirty-six months old;

(a) Medical physicists failing to maintain the continuing education requirements of 2I.4.2.1 must meet 2I4.2.1 requirements prior to independently conducting evaluations of mammography facilities.

2I.4.2.2 Surveys of at least six (6) mammography units operated in at least two (2) mammography facilities within the immediately previous twenty-four (24) months;

(a) Medical physicists failing to maintain the continuing experience requirements of 2I.4.2.2 must meet 2I.4.2.2 requirements while under the direct supervision of a Registered Medical Physicist with approval in the Mammography category.

2I.4.2.3 Before a medical physicist may begin independently performing mammographic evaluations of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under 2I.4.1, the physicist must receive at least 8 hours of training in evaluating units of the new mammographic modality.

2I.5 In addition to the requirements of 2I.1, approval for registration as a Registered Medical Physicist for the Therapeutic Radiation Machines category shall be given to an individual who:

2I.5.1 Is certified by:

2I.5.1.1 The American Board of Radiology in Therapeutic Medical Physics, Therapeutic Radiological Physics or Radiological Physics; or

2I.5.1.2 The American Board of Medical Physics in Radiation Oncology Physics; or

2I.5.1.3 The Canadian College of Physicists in Medicine in Radiation Oncology Physics; or

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

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

Any person who acts as a qualified trainer shall be an individual who:

2J.1 Has training and experience commensurate with criteria and standards for the radiation machine application(s) that adequately prepare the individual to carry out the specified training assignment(s).

2J.1.1 An interpreting physician, radiologic technologist or medical physicist who is approved under MQSA program requirements is considered a qualified trainer for the respective competency.

2J.1.2 A physician, radiologic technologist, or operator who is approved pursuant to 2.6.1 is considered a qualified trainer for the respective competency.

2J.1.3 Other examples of an individual who might be considered by the Department to be a qualified trainer for the purpose of providing training to meet the requirements of this part include, but are not limited to:~~,~~

(1) **A~~a~~** trainer in a post-secondary-school training institution**;** or

(2) **A~~a~~** manufacturer's representative**~~.~~; or**

(3) **An individual approved as a RMP in the relevant specialty area; or**

(4) **A program director or faculty member of a CAMPEP (Commission on Accreditation of Medical Physics Education Programs) or AGCME (American College of Graduate Medical Education) medical physics residency program.**

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Commented [JJ667]: Language updated based on stakeholder feedback.

PART 2, APPENDIX 2K: AUTHORIZED USER (24.3.3) FOR RADIATION THERAPY (24.7 OR 24.8)
ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

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Any person who acts as an Authorized User for any therapeutic radiation machine subject to Part 24 shall be a physician who has a current active State of Colorado license and:

2K.1 Has provided evidence of current certification in:

2K.1.1 Radiology or therapeutic radiology by the American Board of Radiology; or

2K.1.2 Radiation oncology by the American Osteopathic Board of Radiology; or

2K.1.3 Therapeutic radiology by the Royal College of Physicians and Surgeons of Canada; or

2K.1.4 Radiology, with specialization in radiotherapy, by the British Royal College of Radiology, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

2K.1.5 Radiation therapy by a recognized specialty board that requires each candidate for certification to:

2K.1.5.1 Satisfactorily complete a certification process that includes training equivalent to that required in 2K.2.1 and supervised practical experience equivalent to that required by 2K.2.2; and

2K.1.5.2 Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, treatment planning, quality assurance, and human use of therapeutic radiation machines; or

2K.2 Has satisfied the following criteria:

2K.2.1 Satisfactory completion of 700 hours in basic techniques applicable to the use of a therapeutic radiation machine unit, including:

2K.2.1.1 At least 200 hours of classroom and laboratory training in the following areas:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

2K.2.1.2 At least 500 hours of work experience, involving:

(1) Reviewing full calibration measurements and periodic quality assurance checks;

(2) Evaluating prepared treatment plans, calculation of treatment times, and patient treatment settings;

(3) Using administrative controls to prevent reportable medical events;

(4) Implementing emergency procedures to be followed in the event of the abnormal operation of a therapeutic radiation machine unit or console; and

(5) Checking and using of radiation survey meters; and

2K.2.2 Completion of 3 years of supervised clinical experience in radiation therapy, including:

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

2K.2.2.2 Supervised clinical experience, under the supervision of an authorized user who meets the requirements of this Appendix 2K, or equivalent requirements, to include:

(1) Examining individuals and reviewing their case histories to determine their suitability for therapeutic radiation machine treatment, and any limitations and/or contraindications;

(2) Selecting proper dose and how it is to be administered;

(3) Calculating the therapeutic radiation machine doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reactions to radiation; and

(4) Post-administration follow-up and review of case histories.

2K.3 Training and experience required by Appendix 2K shall have been obtained:

2K.3.1 Within the 7 years preceding the date of license application; or

2K.3.2 Through documented subsequent continuing education and experience.

PART 2, APPENDIX 2L: RADIATION THERAPIST (24.3.5) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

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Any person who operates a radiation therapy machine on living humans shall be an individual who:

2L.1 Has provided evidence of:

2L.1.1 Successful completion of a training program in radiation therapy which has resulted in a certificate, associate degree, or baccalaureate degree in a radiologic technology program that complies with the requirements of:

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

2L.1.1.2 An accreditation organization recognized by the Council for Higher Education Accreditation as an accrediting agency, other organizations recognized by the United States Department of Education (USDE) or the Council For Higher Education Accreditation (CHEA) to accredit educational programs in radiation therapy; and

2L.1.2 Accreditation as a radiation therapist by, and having continued to maintain registration by meeting the requirements of, The American Registry of Radiologic Technologists (ARRT), or

2L.1.3 Accreditation by a specialty board recognized by the Department as equivalent to ARRT.

2L.2 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 be documented by certificate(s) or other attestation(s) of satisfactory completion.

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

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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.

(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 2N: INDUSTRIAL RADIATION MACHINE OPERATOR ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

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Any person who operates an analytical, industrial or other non-healing-arts radiation generating machine shall be an individual who:

2N.1 For industrial radiography, has complied with all applicable training and experience requirements of Part 5 and these regulations.

2N.2 For all non-healing-arts applications (including but not limited to analytical, forensic, morgue, and homeland security uses) not subject to Part 5, has provided written documentation as evidence of:

2N.2.1 At least eight (8) hours of general training and experience in radiation safety acceptable to the Department, except as follows:

2N.2.1.1 One (1) hour for any hand-held non-healing-arts radiation generating machine; or

2N.2.1.2 One (1) hour for any cabinet or self-contained airport or port-of-entry x ray machine or system; or

2N.2.1.3 Sufficient training and experience acceptable to the Department.

2N.2.2 The training required by 2N.2.1 shall include radiation safety training specific for each radiation machine used, and demonstration of an understanding thereof, including instruction in the:

2N.2.2.1 Proper operating procedures for the equipment, having read the operating manual;

2N.2.2.2 Identification of radiation hazards associated with the use of the equipment;

2N.2.2.3 Significance of the various radiation warning, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment, and the extra precautions required in such cases;

2N.2.2.4 Recognition of symptoms of an acute localized exposure; and

2N.2.2.5 Proper procedures for reporting an actual or suspected exposure; and

2N.2.3 Has subsequent documented annual training.

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 individual 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;

And

2O.1.4 Is registered in accordance with Section 2.4.5.5.

And

2O.2 Maintains their registration by submission of the following with their registration renewal application:

2O.2.1 A current state of Colorado license issued by the Colorado Department of Regulatory Agencies; and

2O.2.2 National certification in their respective profession.

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Commented [JJ673]: This is a new appendices to address requirements specific to certain operators of fluoroscopic imaging systems referenced in Section 2.4.5.5. In the prior draft posted for stakeholder comment, Appendix 2G was modified to incorporate fluoroscopy operator requirements. Upon further consideration, it was determined that creating a new appendix specific to fluoroscopy and returning Appendix 2G to its current use was the preferred option.

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DRAFT 1 07/01/19

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

RADIATION CONTROL - FEES FOR RADIATION CONTROL SERVICES

6 CCR 1007-1 Part 12

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

Adopted by the Board of Health September 18, 2019, effective date November 14, 2019.

~~**Adopted by the Board of Health February 18, 2015.**~~

PART 12: FEES FOR RADIATION CONTROL SERVICES

* * * (indicates no changes to other rule sections)

CATEGORY 24 – REVIEW OF ADEQUATE TRAINING FOR RADIATION MACHINE LIMITED SCOPE OPERATORS, BONE DENSITOMETRY OPERATORS, ~~COMPUTED TOMOGRAPHY OPERATORS~~ SPECIFIC FLUOROSCOPY OPERATORS[18], AND SERVICE COMPANY ENGINEERS~~[18]~~[19]

Maximum fee per each acceptance review: $ 60

18 The fee for fluoroscopy operator application review is applicable only to those individuals applying under Part 2, Section 2.4.5.5.

~~18~~**19** The fee for service company engineers is a "per application" fee for any number of service company engineers to be authorized to work under a service company registration.

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Commented [JSJ674]: **EDITORIAL NOTE 1:** ALL COMMENTS (SUCH AS THIS ONE) SHOWN IN THE RIGHT SIDE MARGIN OF THIS DOCUMENT ARE FOR INFORMATION PURPOSES ONLY TO ASSIST THE READER IN UNDERSTANDING THE PROPOSED RULE DURING THE DRAFT REVIEW AND COMMENT PROCESS.

THESE SIDE MARGIN NOTES ARE **NOT** PART OF THE RULE AND ALL COMMENTS WILL BE DELETED PRIOR TO FINAL PUBLICATION OF THE RULE.

Commented [JSJ675]: These dates reflect the date of anticipated adoption and effective date based on the rulemaking schedule. Dates are subject to change pending additional review, approvals, and department rulemaking schedule.

Commented [JSJ676]: Changes to this fee category are made as follows, consistent with current and proposed changes to Part 2 of the regulations:

1. The computed tomography (CT) operator reference is removed. Prior to July 31, 2017 the department offered a Colorado based CT operator qualification and registration process. As indicated in the current Part 2 rule, this program was eliminated after July 31, 2017. As of this date, the department relies on national certification/registration programs to establish and ensure minimum qualifications for operators of CT x-ray systems.

2. Consistent with the proposed changes to Part 2, Section 2.4.5.5, the fluoroscopy operator application review process is added to this category.