

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 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.

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 Published material incorporated in Part 2 by reference is available in accord with 1.4.

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.

“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.

“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(N), respectively.

“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 “Volumetric Dental Imaging Systems”.

“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.

“NMTCB” means the Nuclear Medicine Technology Certification Board, Inc.

“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 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.

“Radiologic technologist” means an individual who is currently registered in radiography with the American Registry of Radiologic Technologists, designated ARRT(R).

“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.

“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:
- 2.3.4.1 the 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 the 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 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 for registration under 2.4.2 shall identify and provide:
- (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; and
 - (b) Certification that each service technician has been instructed in, and demonstrates an understanding of the requirements of:
 - (i) these regulations; and
 - (ii) the Federal Performance Standard (21 CFR Chapter I, Subchapter J; and

- (3) Documentation of the type of personnel dosimetric monitoring 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.
- (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).
 - (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 \pm six (6) percent (95 percent confidence level) in the mammography energy range.

2.4.5 Registration of specific radiation machine Operators.

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.
 - (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 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;
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.

2.4.5.3 Bone Densitometry Equipment Operator (BDEO).

- (1) Each operator of 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.
 - (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.

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

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

Category	Frequency
Each radiation machine, including under reciprocity, unless otherwise provided below:	Every year
Each non-healing-arts x-ray imaging machine or system regulated by Parts 5, 8 or 9	Every two years
Each bone densitometry, dental, podiatry or veterinary radiation machine, except as required below:	Every three years
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.	Every year
Pursuant to 2.5.1.3(2), each x-ray machine used in podiatry at more than 30 mA	Every 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

- 2.5.1.4 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 Any radiation machine and/or facility not inspected in accordance with 2.5.1.1 through 2.5.1.5, or otherwise determined to be out of compliance with these regulations, shall be subject to a Department enforcement inspection and subject to the fees specified in Part 12.
- 2.5.2 Procedures for Certification Evaluations by Qualified Inspectors.
- 2.5.2.1 Each qualified inspector who performs a certification evaluation of a radiation machine and facility evaluation shall use procedures that are sufficient to determine compliance with these regulations.
- 2.5.2.2 If a radiation machine fails to meet any requirement specified by these regulations, including manufacturer's required specifications, the qualified inspector shall immediately so inform the registrant and RSO.
- 2.5.2.3 If the radiation machine is determined to be unsafe (as provided in Part 6 and described in Appendix 6D), the qualified inspector shall affix to such radiation machine system, in a location clearly visible to the operator and patient, if applicable, an "Unsafe for Use" label authorized and issued by the Department, indicating, as applicable, that such machine is not authorized for human, animal or other use.
- 2.5.2.4 Reporting and Labeling Procedures.
- (1) Each qualified inspector shall provide an accurate and complete Certification Evaluation Report to the registrant and to the Department on Form R-59-1, "X ray 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, provided that it is in the same format and provides all of the information required by Form R591.
- (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, "X-ray Facility Compliance Evaluation Report," in accordance with the instructions contained in that form.
- (c) Report(s) required by 2.5.2.4(1) shall indicate full or partial compliance and any specific violation of these regulations.
- (d) Report(s) required by 2.5.2.4(1) shall include recommendations for corrective actions by the registrant (if applicable) to assist in achieving full compliance or improving radiation safety and the quality of the imaging process.

- (e) The Department shall be notified within three (3) business days of radiation machine violations. Report(s) required by 2.5.2.4(1) that does not indicate violations shall be received by the Department no later than fifteen (15) calendar days after the inspection date, unless otherwise authorized by the Department.
- (2) A certification label issued by the Department shall be affixed in a location clearly visible to the machine operator and patient, if applicable, when it is determined that the machine requirements of these regulations are fully met.
 - (a) For a machine that was found to be in full compliance, the certification label shall be affixed no later than fifteen (15) calendar days (unless otherwise authorized by the Department) after the inspection date.
 - (b) For a noncompliant machine, the certification label shall be affixed no later than fifteen (15) calendar days (unless otherwise authorized by the Department) after the date that full compliance was achieved.
- (3) Each qualified inspector shall ensure that the following documentation is provided to the Department to confirm that each violation was corrected as required by 2.6.3.1 and/or 2.6.4.1 within thirty (30) calendar days of the date of inspection.
 - (a) For a noncompliant machine for which full compliance has been achieved, the completed documentation (on Form R-59-1 or equivalent) shall be received by the Department no later than fifteen (15) calendar days after the date that compliance was achieved.
 - (b) For a noncompliant facility, the completed documentation (on Form R 59-2 or equivalent) shall be received by the Department no later than fifteen (15) calendar days after the date that full compliance was achieved.
- (4) Concealing, defacing or altering of Department-issued certification labels is prohibited.
- (5) Repeated failure by a qualified inspector, to affix certification labels or to accomplish timely completion of certification evaluation reports as provided in this subsection shall be subject to review and audit as provided in 2.9 and also subject to the non routine inspection fee as provided in Part 12.

2.6 Facility Registrant Responsibilities.

- 2.6.1 In any facility 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.
 - 2.6.1.1 The facility registrant shall document evaluation of 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.
 - (b) The list of all operators and supervisors shall be updated at least annually as part of the radiation safety program required by 4.5.
 - (3) Records of such evaluations shall:
 - (a) Include current certifications of qualification;
 - (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 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 medical, chiropractic, dental, podiatric or veterinary practice, respectively.
- 2.6.1.3 For a radiologist assistant “adequately trained” shall mean that the individual is qualified as provided in Appendix 2G.
- 2.6.1.4 For any radiographic x-ray system used on a living human (consistent with 2.6.1.2, 2.6.1.3, and 2.6.1.5 through 2.6.1.14), “adequately trained” shall mean that the individual meets the requirements of Appendix 2D.
- (1) Limited-scope x-ray machine operator approval is limited to imaging procedures for x-ray examination of the skull, chest, hip/pelvis and spine/sacrum, upper extremities and lower extremities.
 - (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 2.6.1.1 through 2.6.1.4, 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) Fundamental principles of radiation protection;
 - (2) Biological effects of ionizing radiation;
 - (3) Safe operation of fluoroscopy equipment for each mode of operation to be used;
 - (4) Dose reduction techniques for fluoroscopy; and
 - (5) Applicable radiation regulations.

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) “adequately trained” shall mean that the individual operator meets the following requirements:

- (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 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).

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 (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 State Board of Dental Examiners (in particular Rule X, “Minimum Standards for 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 (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 (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, “X-ray Machine Certification Evaluation Report” and Form R-59-2, “X-ray Facility Compliance Evaluation Report.”
- 2.6.2.1 Upon receipt of a Form 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), 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, “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, 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.
- 2.6.4 For each finding of facility noncompliance (Form 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) 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, "X-ray Facility Compliance Evaluation Report", provide a copy of the Form 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.

2.7 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 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.
- 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, 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 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 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 or 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

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; 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 21.3.
- 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 21.5.
- 2B.3 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 Have current certification in health physics or a subfield of medical physics by:
- 2B.3.1.1 The American Board of Medical Physics; or
 - 2B.3.1.2 The American Board of Health Physics; or
 - 2B.3.1.3 The Canadian College of Medical Physics; or
 - 2B.3.1.4 The American Board of Radiology in a radiological physics category; or
 - 2B.1.3.5 American Board of Nuclear Medicine Science; or
- 2B.3.2 Has current certification in an equivalent specialty board recognized by the Department, and;
- 2B.3.2.1 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.

PART 2, APPENDIX 2C: QE(S) – ADEQUATE TRAINING AND EXPERIENCE

- 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)

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

2D.1 Is certified or registered by:

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

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

Or

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

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

2D.2.1.1 Basic X-Ray Physics—20 hours

- (1) Structure of matter and the atom
- (2) General description of production of x-rays
- (3) X-ray emission, quantity and quality
- (4) Function of filtration and effects it has on x-ray beam collimation
- (5) Types of function of beam limiting devices
- (6) Design, features and functions of x-ray tubes
- (7) Circuitry of the x-ray machine

2D.2.1.2 Radiobiology—3 hours

- (1) Effects of ionizing radiation on the human body
- (2) Molecular and cellular radiobiology
- (3) Factors that cause somatic and genetic damage

2D.2.1.3 Radiation Protection—6 hours

- (1) ALARA
- (2) Shielding materials
- (3) Radiation quantity and units of measurement
- (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 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 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(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(N) or

2E.1.2.2 by the NMTCB as CNMT; or

2E.1.2.3 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(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

2E.2 Prior to July 31, 2017, is certified as ARRT(R) and 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

(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 ARRT(R), ARRT(M), ARRT(N), ARRT(T), or CNMT; or

2F.1.2 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; or

2F.1.3 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
- (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 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) and a

2G.1.1 Registered Radiologist Assistant (RRA); or

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

Or

2G.2 Having:

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

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

**PART 2, APPENDIX 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

PART 2, APPENDIX 2I: QUALIFIED INSPECTOR (QI) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

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 digital 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

- 21.2.1.2 Identification of the Qualified Inspector(s) who will provide the Provisional Qualified Inspector with general supervision until the requirements of 21.1.2, 21.1.3 and 21.1.4 are met.
- 21.2.2 At the time when the requirements of 21.1.2, 21.1.3 and 21.1.4 are met, the Provisional Qualified Inspectors must apply for registration as a Qualified Inspector.
- 21.2.3 Registered Qualified Inspectors may apply for approval as a Provisional Qualified Inspector for new categories that are being requested.
- 21.3 In addition to the requirements of 21.1, approval for registration in the Registered Medical Physicist category shall be give to an individual who:
 - 21.3.1 Is certified by:
 - 21.3.1.1 The American Board of Radiology in Radiological Physics, Diagnostic Medical Physics, Diagnostic Radiological Physics, Nuclear Medical Physics, or Medical Nuclear Physics; or
 - 21.3.1.2 The American Board of Medical Physics in Diagnostic Radiological Physics or Nuclear Medicine Physics; or
 - 21.3.1.3 The Canadian College of Physicists in Medicine in Radiological Physics; or
 - 21.3.1.4 American Board of Science in Nuclear Medicine in Nuclear Medicine Physics and Instrumentation; or
 - 21.3.1.5 A equivalent specialty board or certification approved by the department.
 - 21.3.2 Approval for registration as a Provisional Registered Medical Physicist shall be given to an individual who is in the process of certification to meet 21.3.1 and has:
 - 21.3.2.1 Passed the initial testing requirements of the respective certifying organization; and
 - 21.3.2.2 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.
- 21.4 In addition to the requirements of 21.1 and 21.3, approval for registration in the Mammography category shall be approved for a Registered Medical Physicist who:
 - 21.4.1 Has the following combination of initial training and experience:
 - 21.4.1.1 A master's degree or higher in a physical science from an accredited institution with no less than 20 semester hours in physics; and

-
- 21.4.1.2 Have 20 contact hours of specialized training in conducting mammography facility evaluations; and
- 21.4.1.3 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;
- 21.4.2 And the following continuing education and experience:
- 21.4.2.1 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 21.4.2.1 must meet 21.4.2.1 requirements prior to independently conducting evaluations of mammography facilities.
- 21.4.2.2 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 21.4.2.2 must meet 21.4.2.2 requirements while under the direct supervision of a Registered Medical Physicist with approval in the Mammography category.
- 21.4.2.3 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 21.4.1, the physicist must receive at least 8 hours of training in evaluating units of the new mammographic modality.
- 21.5 In addition to the requirements of 21.1, approval for registration as a Registered Medical Physicist for the Therapeutic Radiation Machines category shall be given to an individual who:
- 21.5.1 Is certified by:
- 21.5.1.1 The American Board of Radiology in Therapeutic Medical Physics, Therapeutic Radiological Physics or Radiological Physics; or
 - 21.5.1.2 The American Board of Medical Physics in Radiation Oncology Physics; or
 - 21.5.1.3 The Canadian College of Physicists in Medicine in Radiation Oncology Physics; or
 - 21.5.1.4 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, a trainer in a post-secondary-school training institution or a manufacturer's representative.

PART 2, APPENDIX 2K: AUTHORIZED USER (24.3.3) FOR RADIATION THERAPY (24.7 OR 24.8)
ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

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**

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**

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.3.1.1 shall 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

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.

EDITOR'S NOTES

6 CCR 1007-1 has been divided into separate parts for ease of use. Versions prior to 04/01/2007 are located in the first section, 6 CCR 1007-1. Prior versions can be accessed from the All Versions list on the rule's current version page. To view versions effective on or after 04/01/2007, select the desired part of the rule, for example 6 CCR 1007-1 Part 01 or 6 CCR 1007-1 Part 10.

History

Part 02 entire rule eff. 07/01/2010.

Part 02 Rules 2.4.1.1, 2.4.2.3, 2.4.4.3, 2.5.1.3, 2.5.1.4, 2.6.1.9 – 2.6.1.13, 2.6.4.2, 2.7.1.3, 2.7.3, 2.8.1.2, 2.8.1.4, 2A, 1.4.2, 2B.1.2, 2C – 2C.1.2, 2D.2.4, 2D.3.2, 2F.2.4, 2F.3, 2M.1 eff. 07/30/2010.

Part 02 entire rule eff. 08/14/2014.

Part 02 Rules 2.2.2, 2.4.5.1(2)(e)(i), 2.4.5.2, 2.6.1.7, Appendix 2E eff. 02/14/2015.

Part 02 Rules 2.4.1.1(2), 2.4.2.3(5), 2.4.2.4, 2.4.3.3, 2.4.4.5 – 2.4.4.6, 2.6.3.6, 2F.1.2 eff. 03/30/2015.