DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

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.]

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 mammographers and other operators.

2.1.4 Applicability.

2.1.4.1 The requirements and provisions of this part apply 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(R)" . See "radiologic technologist" .

"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.

"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.

"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.

"Intercomparison" means the direct comparison, in accord with 2.4.4.4, of two instruments designed to measure the same physical quantity.

"Limited-scope operator" means an individual who has taken and passed a required test and has approval by the Department pursuant to 2.6.1 to operate x-ray systems and to conduct specified radiographic examinations of the chest, extremities, skull, hip/pelvis and spine/sacrum.

"LSO" means limited-scope x-ray machine operator, abbreviated by the ASRT as LXMO, limited x-ray machine operator.

“MQSA” means Mammography Quality Standards Act.

“NIST” means the National Institute of Standards and Technology.

“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 qualified inspector” (PQI) means an individual who meets the applicable requirements of Appendix 2I and has current Department approval in a designated specialty to perform, under the general supervision of a qualified inspector, evaluations of radiation machines, facilities, and operators for compliance with these regulations.

“QE(R)” means a qualified expert medical physicist designated for radiographic imaging.

“QE(S)” means a qualified expert physicist designated in other than the healing arts.

“QE(T)” means a qualified expert medical physicist designated for radiation therapy.

"Qualified expert" (QE) means an individual who as provided in 2.4.3 meets the applicable requirements of Appendix 2B or 2C and has current Department approval in a designated specialty to evaluate radiation shielding design and recommend radiation safety practices.

“Qualified inspector” (QI) means an individual who as provided in 2.4.4 meets the applicable requirements of Appendix 2I and has current Department approval in a designated specialty to perform evaluations of radiation machines, facilities, service providers and operators for compliance with these regulations.

“Qualified mammographer” means a mammographer who as provided in 2.4.5.4 meets the applicable requirements of Appendix 2M and has current Department approval.

“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 radiologic technology with the American Registry of Radiologic Technologists, designated ARRT(R).

“Registered medical physicist” (RMP) means an individual who meets the applicable requirements of Appendix 2B and has current Department approval to perform medical physics activities in a designated specialty, including to design shielding, measure ionizing radiation, and oversee radiation protection, 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, 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.

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 if the Department has received documentation, on Form R 61, "Disposition of a Radiation Machine" , signed by a service technician, or equivalent signed form, that 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.

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;

(2) Apply for registration of such facility with the Department prior to using a radiation producing machine at the facility;

(3) Complete and submit an application for registration on Department Form R-4, and include all of the information required by the form and any accompanying instructions, together with the required fee(s);

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

(b) Attest that a policy is in place for keeping up to date a written or electronic list of all operators who have demonstrated adequate radiation safety training and experience, as prescribed by 2.6.1 and the applicable appendices of parts of these regulations; and

(c) Attest that a written shielding design, if required, has been:

(i) Completed, or will have been completed, in accordance with 6.3.2 and Appendices 6A, 6B and 6C of these regulations, prior to any radiation machine installation; and

(ii) Placed and retained on file at the facility for the life of the facility.

2.4.1.2 As prescribed by 6.3.3.3 for a healing arts screening program, complete and submit Form R-300, "Application for Registration - Healing Arts Screening" , including all of the information required by Appendix 6F and/or Form R-300 and any accompanying instructions, together with the required fee(s).

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).

2.4.1.4 If radioactive materials are also present at the facility, the requirements of Part 2 apply as appropriate to coordination with the equivalent licensee or application for a license.

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, 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 furnishing or offering to furnish any such service.

2.4.2.2 Application for registration shall be completed on Form R-60, "Application for Registration - Radiation Machine Servicing and Services," and shall contain all of the information required by the Department as indicated on the form and all accompanying instructions, together with the required fee(s).

2.4.2.3 Each person applying for registration under 2.4.2 shall identify and provide:

(1) The specific services for which registration is being requested, including but not limited to:

(a) Engaging (or offering to engage) in selling, leasing, transferring, lending, assembling, installing, maintaining, repairing, trading out, or disposing of radiation machines and associated radiation machine components; and

(b) Servicing of radiation machines and associated radiation machine components; and

(c) Performance adjustment to or calibration of radiation machines, measurement instruments, and devices; and

(2) The name and qualifications of each service technician who will provide service, including:

(a) Documentation of the training and experience that demonstrate, as required by Appendix 2H, sufficient competence to provide the services for which registration is being requested; and

(b) Certification that each service technician has been instructed in the requirements of these regulations and of the Federal Performance Standard (21 CFR Chapter I, Subchapter J, April 1, 2010), and demonstrated an understanding thereof; and

(3) The type of personnel dosimetric monitoring supplied, frequency of reading, and replacement or exchange schedule as appropriate (see 4.17 and 4.18); and

(4) The type of measurement instruments that will be used to determine compliance with these regulations, including:

(a) The frequency of calibration; and

(b) The provider of calibration services; and

(c) A written commitment to meet the instrument calibration requirements specified in 2.4.4.4.

2.4.3 Registration as a Qualified Expert.

2.4.3.1 Each individual who offers the service of designing and/or evaluating shielding to meet the requirements of 6.3.2 shall be registered with the Department as a qualified expert designated QE(R), QE(S) and/or QE(T).

(1) For a healing arts facility, each shielding design shall be completed as specified in Part 6 by a registered medical physicist who:

(a) Meets the criteria established in Appendix 2B; and

(b) Has a current Department “Notice of Registration” as a QE(R) for radiography and/or QE(T) for radiation therapy.

(2) For other than a healing arts facility, each shielding design shall be completed by a qualified expert who:

(a) Meets the criteria established in either Appendix 2B for a registered medical physicist or Appendix 2C for any other physicist, designated QE(S); and

(b) Has a current Department “Notice of Registration” as QE(R), QE(S) and/or QE(T).

2.4.3.2 Each individual who offers the service of calibration and compliance surveys for a radiation therapy unit shall be registered with the Department as a registered medical physicist who meets the criteria in Appendix 2B and has current Department approval as a registered qualified expert for radiation therapy, designated QE(T).

2.4.3.3 The application for registration shall be submitted on Form R-68, “Application for Registration - Qualified Expert,” and include all of the information required by the form and any accompanying instructions, together with the required fee(s).

2.4.4 Registration as a Qualified Inspector.

2.4.4.1 Each individual who offers the service of performing a certification evaluation of a radiation machine and/or facility evaluation shall be registered with the Department as a qualified inspector who meets the criteria established in Appendix 2I.

2.4.4.2 The application for registration shall be submitted on Form R-53, “Application for Registration - Qualified Inspector,” and include all of the information required by the form and any accompanying instructions, together with the required fee(s).

2.4.4.3 Department approval as a registered medical physicist consistent with Appendix 2B is considered also to be Department approval as a qualified inspector for any facility and/or machine.

2.4.4.4 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) Notwithstanding the requirement of 4.17.2, such equipment shall be calibrated 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.

(3) Calibrations shall be NIST-traceable where such traceability is feasible.

(4) In lieu of calibration, instrument accuracy may, with Department approval, be determined by (inter)comparison with a suitable and appropriately calibrated instrument.

(5) Each (inter)comparison protocol shall be submitted to the Department for review and approval.

(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.

(6) Instruments used for the certification evaluation report to measure the air kerma or air kerma rate of mammography machines shall be calibrated at least once every two (2) years and each time the instrument is repaired.

(a) The instrument calibration shall be NIST traceable; and

(b) The instrument shall be calibrated with an accuracy of ± six (6) percent (95 percent confidence level) in the mammography energy range.

2.4.5 Approval of an Operator.

2.4.5.1 X-ray Machine Operator Subject to Appendix 2D.

(1) Consistent with and governed by 2.6.1, prior to operating an x-ray system on living humans in the State of Colorado, each individual shall meet the x ray machine operator adequate radiation safety training and experience criteria established in Appendix 2D, in particular 2D.2.4 for a limited scope x-ray machine operator.

(2) Application for renewal as a limited scope x-ray machine operator, accompanied by the required fee(s) and evidence of 24 hours of continuing education as prescribed in Appendix 2D and not inconsistent with 2.6.1, shall be submitted at least thirty (30) calendar days prior to the expiration of each two year registration period.

2.4.5.2 Computed Tomography Operator Subject to Appendix 2E.

(1) Consistent with and governed by 2.6.1, prior to operating a computed tomography system on living humans, each individual shall at minimum meet the Computed Tomography Operator adequate radiation safety training and experience criteria established in Appendix 2E.

2.4.5.3 Bone Densitometry Equipment Operator (BDEO) Subject to Appendix 2F.

(1) Consistent with and governed by 2.6.1, prior to operating a bone densitometry x ray system on living humans, each individual shall at minimum meet the Bone Densitometry Equipment Operator adequate radiation safety training and experience criteria established in Appendix 2F, in particular 2F.2.4.

(2) Application for renewal, accompanied by the required fee(s) and evidence of 18 hours of continuing education as prescribed in Appendix 2F, shall be submitted at least thirty (30) calendar days prior to the expiration of each three year registration period.

2.4.5.4 Qualified Mammographer.

(1) Prior to performing any mammography examination in the State of Colorado, each individual operator shall be a qualified mammographer who meets the adequate radiation safety training and experience qualification criteria established in Appendix 2M.

DEPARTMENT NOTICE OF REGISTRATION

2.4.6 Requirements Applicable to Issuance and Maintenance of Department Registration.

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

2.4.6.2 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.

2.4.6.3 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.

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

(1) Each servicing and services registrant under 2.4.2 shall notify the Department each time the registrant adds a service technician (or several service technicians at the same time) to the list of service technicians authorized to provide radiation machine service(s).

(a) The registrant will be assessed an acceptance review fee as required by Part 12 for each list change.

(b) Changes made during renewal will not be assessed an acceptance review fee.

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

2.4.6.6 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.

2.4.6.7 The Department may not review or otherwise process a new application or application for renewal for which no remittance is received.

(1) An application that is incomplete or not accompanied by the prescribed fee(s) will not necessarily be returned to the applicant.

(2) All application fees are non-refundable.

2.4.6.8 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 Peremptory Registrant Obligations.

2.4.7.1 Whenever a business relationship exists between the qualified inspector and services and servicing provider, a "Notice of Registrant's Rights" Form R-65 shall be furnished to the registrant prior to beginning the service or evaluation, including:

(1) When a qualified inspector is also authorized 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.

2.4.7.2 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 and 2.4.4, 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 (section 2.5.1 is summarized in Table 2-1).

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

(2) Each certification evaluation is in addition to and not intended to replace the manufacturer(s) recommended equipment service and/or repair procedures or facility quality assurance programs.

(3) 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.

(4) 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.

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

2.5.1.2 Each non-healing-arts fixed industrial radiography, analytical, cabinet, or self contained airport or port of entry inspection x ray imaging machine or system shall be inspected at least every two (2) years.

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 or tomographic or computed tomographic system that is capable of a variable kilovoltage peak (kVp) or variable milliamperage (mA) or variable collimation and used in non-intraoral dentistry or podiatry 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 shall be inspected annually.

2.5.1.4 Each human use portable hand-held instrument used for any purpose 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 fixed industrial radiography or analytical, cabinet, airport or port-of-entry x ray machine or system	Every two years
Each bone densitometry, dental, podiatry or veterinary radiation machine, except as required below:	Every three years
Pursuant to 2.5.1.3(1), each radiographic x-ray machine or tomographic or computed tomographic system used with a variable setting (kVp, mA or collimation) in non-intraoral dentistry or podiatry	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	Every year
Pursuant to 2.5.1.4, each human use hand-held x-ray machine	Every year

2.5.1.5 Each new installation of a radiation machine system or replacement component that will affect or could potentially affect radiation output shall be evaluated within no more than ninety (90) calendar days of installation.

2.5.1.6 Each new installation of a mammography system shall be evaluated by a qualified inspector authorized in mammography prior to being used to perform any human examination.

2.5.1.7 Any radiation machine and/or facility not inspected in accordance with 2.5.1.1 through 2.5.1.6, or otherwise determined to be out of compliance with these regulations, shall be subject to a Department enforcement inspection and subject to the fees specified in Part 12.

2.5.2 Procedures for Certification Evaluations by Qualified Inspectors.

2.5.2.1 Each qualified inspector who performs a certification evaluation of a radiation machine and/or 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/or RSO designated pursuant to 2.4.1.1.

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 patient, 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 certify each determination of compliance and be responsible to 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 R 59 1, provided that it is in the same format and provides all of the information required by Form R 59 1.

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

(2) A qualified inspector shall provide to the registrant and Department a copy of the R-59-1 or R-59-2 Report.

(a) The Report shall indicate full or partial compliance and any specific violation of these regulations.

(b) The Report shall include recommendations for corrective actions by the registrant (if applicable) to assist in achieving full compliance and/or improving radiation safety and the quality of the imaging process.

(c) The Report shall be received by the Department no later than fifteen (15) calendar days after the inspection date, unless otherwise authorized by the Department.

(3) The qualified inspector shall personally affix, or personally direct the registrant exactly how and where to affix, a certification label issued by the Department in a location clearly visible to the machine operator and patient, if (and only if) and when it is determined that the requirements of these regulations, including manufacturer's required specifications, 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.

(4) Each qualified inspector shall ensure that the following closeout 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, signed by the qualified inspector as completed and including the number of the label that was affixed) 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 signed by the registrant as completed) shall be received by the Department no later than fifteen (15) calendar days after the date that full compliance was achieved.

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

(6) Repeated failure to affix certification labels and/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) Consistent with 2.4.1.1(3)(b), the registrant shall maintain a list of operators (or have a policy in place that specifies how such a list will be provided on request) who have been determined to be adequately trained in accordance with these regulations.

(a) For fluoroscopy equipment used in examination of a living human, a list of qualified individuals shall be maintained as required by 2.6.1.5.

(b) The list of all operators qualified for fluoroscopy 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 maintained 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 (not inconsistent 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 density or fluoroscopic equipment, 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 healing arts facility shall make a written determination that any individual who either supervises a fluoroscopy procedure or operates a fluoroscopy imaging system has adequate training in its safe operation, including documented training in 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 registration and/or other requirements of Appendix 2M.

2.6.1.7 For any computed tomography system used on a living human, "adequately trained" shall mean that the individual operator meets the registration and/or other requirements of Appendix 2E.

2.6.1.8 For any bone densitometry equipment used in examination of a living human, "adequately trained" shall mean that the individual operator meets the registration and/or other 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, "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 therefrom, 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 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.

(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 If and when an application to the Department is required, the application for adequate training review and approval or for an examination administered by the Department shall be:

(1) Submitted on forms prescribed by the Department; and

(2) Completed to contain all the information required by the form and all accompanying instructions; and

(3) Accompanied by the application fee(s) specified in Part 12; and

(4) Accompanied by evidence of continuing education, if and when required.

2.6.1.19 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."

2.6.3 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, in particular according to any of the criteria in 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 Upon correction of any radiation machine item of violation, confirm to the qualified inspector that indicated repairs have been completed.

(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 signed the original Form R-59-1.

(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 Upon correction of any item of violation identified on Form R-59-1, "X ray Machine Certification Evaluation Report," retain documentation that each indicated violation has been corrected to bring the machine into compliance.

2.6.3.6 Pay the fee required by Part 12 for each certification label issued to the registrant 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.

2.6.4.3 Pay any fee required by Part 12.

2.6.5 Record Retention and Reports.

2.6.5.1 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.

2.6.5.2 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.

2.6.5.3 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.

2.6.5.4 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 inspection certification evaluation reports;

(5) Facility compliance evaluation reports; and

(6) Notices of violation.

2.7 Service Company Registrant Responsibilities.

2.7.1 No person shall certify or declare that a radiation machine or component, or the supplies used in connection with such a machine or component, is ready for its intended use, unless and until:

2.7.1.1 The shielding design has been completed if and as required by 6.3.2, as documented (without exception after June 30, 2010) by a comment on Form FDA 2579 or a signed and dated notification to the Department.

2.7.1.2 The machine and/or component (and any associated equipment and supplies), after having properly been made operational, demonstrably meet the manufacturer specifications and the requirements of these regulations; and

2.7.1.3 The registrant has been provided, by the vendor, assembler and/or services and servicing personnel, as required by the Federal Performance Standard (21 CFR Chapter I, Subchapter J, April 1, 2010) and these regulations, 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 disposes any radiation machine, or component, which affects radiation output 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) in compliance with requirements of the Federal Performance Standard (21 CFR 1020.30(d), April 1, 2010) 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 If required by the Department on a Certification Evaluation Report, Form R-59-1, a service company that performs a radiation machine repair shall:

2.7.4.1 Sign, as the person providing service, the service repair certification section of a copy of the original Certification Evaluation Report, Form R-59-1;

2.7.4.2 Provide a copy to the qualified inspector who signed the original Certification Evaluation Report, Form R-59-1, with the service repair certification signed by the person providing service; and

2.7.4.3 Provide, upon request, a copy of any additional information about the details of the repair.

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 regarding inadequate action on any item of violation;

2.9.1.2 Determine a schedule for correction of each violation, specifying a date by which compliance must be achieved;

2.9.1.3 Confirm and verify by inspection a registrant’s corrective action(s) to assure compliance with these regulations; and/or

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 fails to fulfill the requirements in 2.5.1; 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 adequacy of servicing and services of each registrant, for example, on a frequency consonant with the type of radiation machine, as in 2.5.1.2;

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 evaluations; 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

The applicant, licensee, or registrant shall require each individual assigned to fulfill responsibilities as Radiation Safety Officer (RSO) to be an individual who:

2A.1 Has provided evidence of current credentials acceptable to the Department that demonstrate training and experience in the safe and effective use of radiation machines and the potential radiation hazards and emergency precautions applicable to the type(s) of activity or facility for which the individual is seeking to perform RSO duties, to include:

2A.1.1 For any healing arts facility, approval by the Department as a registered medical physicist (RMP), provided in addition that the RMP has:

2A.1.1.1 For radiation therapy, as provided by 2.4.3.2 and Part 6, current registration as a QE(T);

2A.1.1.2 For computed tomography, as provided by Part 6, current registration as either a QE(R) or QE(T); or

2A.1.2 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”), has current Department approval as a QE(R), QE(S), QE(T) or as having satisfactorily completed:

2A.1.2.1 A baccalaureate or higher degree in natural or physical science, health physics, radiological sciences, nuclear medicine, nuclear engineering, or other structured educational program that included classroom training in the responsibilities of an RSO, including but not limited to:

(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;

(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 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;

(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;

(5) Assuming control and having the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;

(6) Maintaining records as required by these regulations; and

(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; and

2A.1.2.2 Experiential training in radiation safety for the assigned type(s) of activity or facility, including emergency procedures and how to appropriately apply radiation regulations; or

2A.1.3 For a healing arts facility other than for radiation therapy or computed tomography, unless otherwise provided or prohibited by these regulations:

2A.1.3.1 Meets the applicable operator requirements of 2.6.1.2 through 2.6.1.14; and

2A.1.3.2 Has completed a structured educational program that includes ionizing radiation safety, for example, radiological sciences training as part of a professional course of study or a 40-hour radiation safety course; and

2A.1.3.3 Has completed at least two years of applicable supervised use of radiation machines; or

2A.1.4 For a healing arts facility other than for radiation therapy or computed tomography, or for a non-healing arts facility (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”), has:

2A.1.4.1 Prior Department approval pursuant to another part of these regulations as an authorized RSO; and

2A.1.4.2 Sufficient radiation safety experience, for example, as a qualified radiation machine operator (at least two years unless otherwise approved by the Department), commensurate with the type(s) of activity or facility for which the individual is seeking to perform RSO duties as, or under the supervision of, a certified health physicist, certified medical physicist, experienced RSO, or radiation protection professional recognized by the Department;

2A.2 And has also complied with each additional requirement applicable to the assigned type(s) of activity or facility that pertains to qualification or duties of a radiation safety officer under any other part of these regulations.

PART 2, APPENDIX 2B: REGISTERED MEDICAL PHYSICIST ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

Each registered medical physicist shall be an individual who:

2B.1 Has provided evidence of:

2B.1.1 Current certification in a subfield of medical physics by:

2B.1.1.1 The American Board of Medical Physics; or

2B.1.1.2 The American Board of Health Physics; or

2B.1.1.3 The Canadian College of Medical Physics; or

2B.1.1.4 The American Board of Radiology in a radiological physics category; or

2B.1.1.5 American Board of Nuclear Medicine Science; or

2B.1.1.6 A recognized equivalent specialty board; and

2B.1.2 Written approval from the Department to design shielding or conduct specified medical physics activities as a qualified expert for:

2B.1.2.1 Radiography other than radiotherapy, designated QE(R), having met the applicable criteria in AAPM Report No. 42, "The Role of the Clinical Medical Physicist in Diagnostic Radiology" (January 1994), in particular page 12; or

2B.1.2.2 Radiation therapy, designated QE(T), with training and experience in the clinical applications of radiation physics to radiation therapy, having met the applicable criteria in AAPM Report No. 38, "The Role of a Physicist in Radiation Oncology" (1993), in particular page 7.

2B.2 Or, as an alternative to fully satisfying 2B.1, is approved by the Department as a provisional registered medical physicist to assist a registered medical physicist with assigned activities of specified duration, having provided to the Department:

2B.2.1 An application that includes the name and signature of each registered medical physicist for whom the applicant will be working under supervision; and

2B.2.2 Evidence that all training and experience requirements are met to become certified as prescribed by 2B.1.1, but full certification has not yet been received.

PART 2, APPENDIX 2C: QUALIFIED EXPERT FOR SHIELDING DESIGN FOR OTHER THAN A HEALING ARTS FACILITY – QE(S) – ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

As provided by 2.4.3.1(2), each qualified expert for shielding design (other than a registered medical physicist) shall be an individual who:

2C.1 Has provided evidence of:

2C.1.1 Current certification by a physics specialty board recognized by the Department; and

2C.1.2 Written approval from the Department as a qualified expert for shielding design, designated QE(S);

2C.2 Or, has provided written documentation that the individual:

2C.2.1 Holds a master or doctorate degree from an accredited college or university in physics, biophysics, radiological physics, health physics, or medical physics; and

2C.2.2 Has satisfactorily completed 2 years of training and work experience acceptable to the Department that include:

2C.2.2.1 One year of documented, full-time training in the appropriate field; and

2C.2.2.2 One additional year of documented, full-time practical experience, under the supervision of a qualified expert, including having designed shielding; and

2C.2.3 Has also satisfied 2C.1.2;

2C.3 Or, has adequate prior experience as an experienced qualified expert who has:

2C.3.1 Satisfied 2C.1.2 and 2C.2.1; and

2C.3.2 Demonstrated to the Department sufficient experience required of a qualified expert for shielding design.

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

The registrant shall require each x-ray system operator to be an individual at least 18 years of age who:

2D.1 Is certified or registered by:

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

2D.1.2 A specialty board that has been recognized by the Department, including or in combination with documentation accepted by the Department of the training required by 2D.2A through 2D.2F;

2D.2 Or, is accepted by the Department as a State of Colorado-registered limited scope x ray machine operator to conduct specified radiographic examinations of the chest, extremities, skull, hip/pelvis and spine/sacrum, having satisfactorily completed:

[Elements of the following are from the 2009 *Content Specifications for the Examination for the Limited Scope of Practice in Radiology* / and used with ARRT permission.]

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

RADIATION SAFETY (passing score on written test of 75% or higher on the radiation safety module)

2D.2A 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.2B 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.2C 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

RADIOGRAPHIC PROCEDURES (passing score on written test of 75% or higher on radiographic procedures module

2D.2D. 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.2E 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.2F 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 (in attendance during the procedure) 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.2A through 2D.2F); 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 Approval by the Department as having passed the ARRT Limited Scope Operator State Examination required by 2.4.5.1.

2D.2.4.1 The application to be registered in the State of Colorado as a Limited Scope Operator 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.

(1) The applicant shall complete Form R-70, "Application for Registration – Limited Scope Operator" and shall attach form R-71.

(2) The applicant shall verify didactic training and clinical experience on Form R-71, "Clinical Supervisory and Competency Statement – Limited Scope Operator."

2D.2.4.2 The application shall be accompanied by the required fee(s).

2D.2.4.3 Application to take the ARRT LSO examination 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/or 2.D.2.3.

2D.2.4.4 Upon being contacted by ARRT to schedule the LSO examination, the applicant shall complete the Core Module and at least the Radiographic Procedure Modules for Chest, Extremities, Skull/Sinuses and Spine within ninety (90) calendar days.

2D.2.4.5 The Department will notify the applicant of ARRT LSO examination result upon receipt by the Department.

2D.3 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.3.1 Conform to guidelines equivalent to the August 1, 2008 ARRT *Continuing Education Requirements for Renewal of Registration* ; and

2D.3.2 Be documented by certificate(s) or other attestation(s) of satisfactory completion, submitted with an updated form R-90, “Application For Renewal – Limited Scope Operator” .

PART 2, APPENDIX 2E: COMPUTED TOMOGRAPHY (CT) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

The registrant shall require each computed tomography operator to be an individual at least 18 years of age who:

2E.1 Is certified:

2E.1.1 As ARRT(R) and also certified in computed tomography by ARRT; or

2E.1.2 As ARRT(N) or ARRT(T); or

2E.1.3 As CNMT by the Nuclear Medicine Technologist Certification Board; or

2E.1.4 By a specialty board that has been recognized by the Department, including or in combination with documentation accepted by the Department for the training required by 2E.2A through 2E.2L; or

2E.2 Is ARRT(R) and also has satisfactorily completed:

[Elements of the following are from the July 2008 *Content Specifications for the Examination in Computed Tomography* and used with ARRT permission.]

2E.2.1 At least 60 hours of didactic training providing the minimum hours of instruction in the specific subjects listed in 2E.2A through 2E.2L:

2E.2A 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.2B 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.2C Radiation Safety and Dosimetry—6 hours

(1) Technical factors affecting patient dose

(2) Radiation protection

(3) Dose Measurement

(4) Pediatric dose reduction

2E.2D Type of Study (24 hours; 1 hour for each topic—2E.2E, 2E.2F, 2E.2G and 2E.2H—for each type of study)

(1) Head

(2) Neck

(3) Chest

(4) Abdomen

(5) Pelvis

(6) Musculo-skeletal

2E.2E. Sectional Anatomy (for each type of study)

(1) Sagittal plane

(2) Transverse plane (axial)

(3) Coronal plane

(4) Off-axis (oblique)

(5) Landmarks

(6) Pathology recognition

2E.2F Contrast Media (for each type of study)

(1) Types of agents

(2) Indications

(3) Contraindications

(4) Dose calculation

(5) Administration route

(6) Scan/prep delay

2E.2G Scanning Procedures (for each type of study)

(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.2H Special Procedures (for each type of study)

(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.2I 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.2J 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.2K 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.2L 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 an ARRT(N), ARRT(R), ARRT(T) or CNMT computed tomography operator or other qualified trainer:

2E.2.2.1 "Direct supervision" means the supervisor must be present in the facility and immediately available to furnish assistance and direction throughout the performance of a procedure. The supervisor is not required to be present in the room when the procedure is performed.

2E.2.2.2 A signed statement by the individual(s) who provided supervision and evaluation shall be kept on file to document dates and locations of clinical training; and

2E.2.3 Documented performance under direct supervision of the following imaging procedures (at least 60 examinations in total, with record of each examination kept on file):

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 If the option is appropriate, Form R-95, "Application for Registration – Computed Tomography Machine Operator," to include all information required by the Department as indicated on the form and all accompanying instructions, plus payment of any fee.

2E.3 Or, meeting all requirements of 2E.2.1 and 2E.2.2, is allowed to be a computed tomography operator at a facility that performs only the particular procedure(s) for which record(s) document prior completion of the full number of examinations required in 2E.2.3;

2E.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 be a computed tomography operator only for the particular procedure(s) for which record(s) document prior completion of the full number of examinations required in 2E.2.3.

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

The registrant shall require each bone densitometry equipment operator (BDEO) to be an individual at least 18 years of age who:

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.2A, 2F.2B and 2F.2C; or

2F.1.3 A specialty board that has been recognized by the Department, in combination with documentation accepted by the Department for the training required by 2F.2A through 2F.2I; or

2F.2 Or, is accepted by the Department as having satisfactorily completed:

[Elements of the following are from the January 2003 *Content Specifications for the Bone Densitometry Equipment Operators Examination* and used with ARRT permission.]

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.2A through 2F.2I:

RADIATION SAFETY:

2F.2A 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.2B 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.2C 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

BONE DENSITOMETRY PROCEDURES

2F.2D 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.2E 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.2F 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.2G 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.2H 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.2I 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.2.2.1 "Direct supervision" means the supervisor must be present in the facility and immediately available to furnish assistance and direction throughout the performance of a procedure. The supervisor is not required to be present in the room when the procedure is performed.

2F.2.2.2 A signed statement by the individual(s) who provided supervision and evaluation shall be kept on file to document dates and locations of clinical training; and

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 Approval by the Department as having passed the Bone Density Equipment Operator State Examination required by 2.4.5.3.

2F.2.4.1 The application to be registered in the State of Colorado as a Bone Density Equipment Operator 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.

(1) The applicant shall complete Form R-80, “Application for Registration – Bone Densitometry Equipment Operator” ; or

(2) The applicant shall verify clinical experience on Form R-81, “Clinical Supervisory and Competency Statement – Bone Density Equipment Operator” ; and

2F.2.4.2 The application shall be accompanied by the required fee(s).

2F.2.4.3 Application to take the BDEO examination 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/or 2.F.2.3.

2F.2.4.4 Upon being contacted to schedule the BDEO examination, the applicant shall complete the examination within ninety (90) calendar days.

2F.2.4.5 The Department will notify the applicant of a BDEO examination result upon receipt by the Department.

2F.3 Has maintained a minimum of eighteen (18) hours continuing education every three years, documented by certificate(s) or other attestation(s) of satisfactory completion, submitted with an updated Form R-82, “Application for Renewal – Bone Density Equipment Operator” .

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

The registrant shall require each radiologist 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;

2G.2 Or, 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

The registrant shall require each individual who independently performs radiation machine assembly, installation or repair to obtain and retain evidence demonstrating that the individual is registered with the Department in accord with Appendix 2B or 2C or that the following requirements are met:

2H.1 Completion of a structured educational program that includes training in radiation-producing device safety, assembly, installation and repair, such as:

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 factory, military or other technical school training; and

2H.2 For each type of equipment to be serviced:

2H.2.1 Education and/or experience providing familiarity with the equipment, including protective measures to reduce potentially hazardous conditions; and

2H.2.2 Completion of six months of supervised equipment assembly and repair.

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

As provided by 2.4.4, each qualified inspector shall be an individual who:

2I.1 Has provided written documentation as evidence of:

2I.1.1 Current certification by:

2I.1.1.1 The American Board of Radiology in diagnostic radiologic physics or radiological physics;

2I.1.1.2 The American Board of Radiology in therapeutic or nuclear medicine radiological physics; roentgen ray and gamma ray physics; x-ray and radium physics; or equivalent specialty;

2I.1.1.3 The American Board of Medical Physics in Diagnostic Imaging Physics or Therapeutic Radiological Physics;

2I.1.1.4 The American Board of Health Physics (comprehensive certification);

2I.1.1.5 The Canadian College of Medical Physics;

2I.1.1.6 American Board of Nuclear Medicine Science; or

2I.1.1.7 A recognized equivalent specialty board.

2I.2 Or, for a qualified inspector of mammography facilities, has provided evidence of:

2I.2.1 Current certification as provided in 2I.1.1.1, 2I.1.1.2, or an equivalent specialty of the American Board of Radiology or another certifying body recognized by the American College of Radiology;

2I.2.2 Or the following combination of training and experience:

2I.2.2.1 A master of science, master of arts, or higher degree in physics, applied physics, biophysics, radiological physics, health physics, medical physics, or equivalent, from an accredited college or university; and

2I.2.2.2 At least two years of training in medical physics in the area of clinical diagnostic radiologic physics; and

2I.2.2.3 At least three (3) years of experience in conducting mammography equipment performance evaluations;

(1) Twenty (20) contact hours of documented specialized training in conducting surveys of mammography facilities;

(2) Experience of conducting surveys of at least one mammography facility and a total of at least ten (10) mammography units;

(a) No more than one survey of a specific unit within a period of sixty (60) calendar days can be counted towards the total mammography unit survey requirement;

(b) This experience must be accomplished under the direct supervision of a currently registered qualified inspector in mammography;

2I.2.3 And sufficient continuing education and experience, including:

2I.2.3.1 A minimum of fifteen (15) documented hours of continuing education in mammography which are no more than thirty-six months old;

2I.2.3.2 Surveys of at least two (2) mammography facilities and a total of at least six (6) mammography units within the immediately previous twenty-four (24) months;

2I.2.3.3 If performing a certification evaluation including a new modality of mammography imaging, a minimum of eight (8) hours of training in the new modality prior to performing such a certification evaluation independently;

2I.2.3.4 If the applicant fails to meet the continuing education requirement, sufficient additional continuing education hours, prior to performing any certification evaluation; and

2I.2.3.5 If the applicant fails to meet the continuing experience requirement, a sufficient number of certification evaluations under the supervision of a currently registered qualified inspector in mammography or a MQSA-approved medical physicist to bring the applicant's total certification evaluations up to the required two (2) facilities and six (6) units in the previous twenty-four (24) months.

2I.3 Or, for a qualified inspector other than for mammography facilities, has provided written documentation as evidence that the individual:

2I.3.1 Holds a degree in physics, applied physics, biophysics, biophysical engineering, medical physics, radiologic physics, health physics, or equivalent, from an accredited college or university; and

2I.3.2 Has satisfactorily completed appropriate, acceptable, documented, full-time work experience:

2I.3.2.1 One year with a master or doctorate degree; and

2I.3.2.2 Two years with an arts or sciences baccalaureate degree;

2I.3.2.3 Three years with an Associate Degree; and

2I.3.3 Has experience with each category of radiation machine for which approval is requested, including but not limited to:

2I.3.3.1 Measuring ionizing radiation;

2I.3.3.2 Evaluating radiation machines and components;

2I.3.3.3 Film processing;

2I.3.3.4 The applicable requirements of the radiation regulations; and

2I.3.3.5 Specialized training with the x-ray imaging and image processing system software and hardware, if and when applicable and available; and

2I.3.4 Has obtained training and experience required by Appendix 2I:

2I.3.4.1 Within the 7 years preceding the date of application; or

2I.3.4.2 Through documented subsequent continuing education and experience.

2I.4 Or, has adequate prior experience as an experienced qualified inspector who has satisfied 2I.3.3 and 2I.3.4 and demonstrated to the Department sufficient experience in the tasks required of a qualified inspector for which the individual is requesting authorization to be a qualified inspector;

2I.5 Or, is approved by the Department as a provisional qualified inspector, fully meeting the requirements of 2I.3.1 but as an alternative to fully satisfying 2I.3.2, 2I.3.3 and 2I.3.4, having:

2I.5.1 Submitted to the Department an application that includes the name and signature of each approved qualified inspector for whom the applicant will be working under general supervision in order to meet the requirements of 2I.3.2, 2I.3.3 and 2I.3.4; and

2I.5.2 Provided written documentation of having assisted with certification evaluation of at least five (5) radiation machines under the direct supervision of an approved qualified inspector.

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

The registrant shall require each qualified trainer to 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

The applicant, registrant, or licensee for any therapeutic radiation machine subject to 24.7 or 24.8 shall require an authorized user of therapeutic radiation machines to 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

The applicant, registrant, or licensee shall require the operator of a therapeutic radiation machine for human use to 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:

2L.2.1 Conform to guidelines equivalent to the August 2008 ARRT *Continuing Education Requirements for Renewal of Registration* ; and

2L.2.2 Be documented by certificate(s) or other attestation(s) of satisfactory completion.

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

The registrant shall require each mammographer to be an individual who:

2M.1 Has provided evidence that the individual is certified in mammography as ARRT(M), meeting the requirements of 21 CFR 900, in particular 900.12(a)(2), April 1, 2010;

2M.2 Or, is an ARRT(R) accepted by the Department as an experienced mammographer who has provided evidence demonstrating to the Department mammography training and experience equivalent to the Content Specifications for the Examination for the ARRT Mammography Certification (July 2009), including at a minimum:

2M.2.1 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.2.2 Eight (8) hours or more documented training in each mammography modality to be used by the technologist in performing mammography examinations; and

2M.2.3 Performance, under the direct supervision of a mammographer, of a minimum of 25 examinations;

2M.3 Or, is a radiologic technologist (mammographer in training or provisional mammographer), who:

2M.3.1 Is enrolled in or has completed a structured training program that includes a minimum of 40 contact hours of documented training specific to mammography;

2M.3.2 Is completing or has completed, at all times during examination procedures under the direct supervision of a mammographer present on the premises and available for prompt consultation, the tasks in 2M.2.1, 2M.2.2 and 2M.2.3; and

2M.3.3 Has applied for a provisional certificate on Form R-64, “Criteria for a Structured Training Program in Mammography,” including all information required by the form and by all accompanying instructions, accompanied by the fee specified in Appendix 12A;

2M.3.4 Has obtained from the Department a provisional certificate valid for one year from the date of issuance or a one-time renewal certificate valid for one additional year only.

2M.4 Continuing training and experience required by Appendix 2M shall have been obtained:

2M.4.1 Within the 7 years preceding the date of application, except when an attestation of adequate training and experience prior to October 1, 1994 has been provided; or

2M.4.2 Through documented subsequent continuing education and experience:

2M.4.2.1 The mammographer shall document fifteen (15) hours of continuing education completed within the immediate prior 36 months.

(1) A mammographer who fails to meet this continuing education requirement shall obtain a sufficient number of continuing education units (CEU) in mammography to bring their total up to at least fifteen (15) CEU.

(2) A mammographer who fails to meet this continuing education requirement shall work only under direct or personal supervision.

2M.4.2.2 The 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 mammographer before resuming the performance of unsupervised mammography examinations.

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

The registrant shall require each operator of an analytical, industrial or other non-healing-arts radiation generating machine to 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 Four (4) hours 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 Successful completion of 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 smaller sections for ease of use. Versions prior to 4/1/07 and rule history are located in the first section, 6 CCR 1007-1. Prior versions can be accessed from the History link that appears above the text in 6 CCR 1007-1. To view versions effective on or after 4/1/07, Select the desired part of the rule, for example 6 CCR 1007-1 Part 1 or 6 CCR 1007-1 Parts 8 - 10.

History

[For history of this section, see Editor's Notes in the first section, 6 CCR 1007-1]