

COLORADO Department of Public Health & Environment

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To:	Members of the State Board of Health
From:	James Jarvis, Regulatory Coordinator, Hazardous Materials and Waste Management Division
Through:	Gary Baughman, Division Director 98
Date:	October 1, 2014
Subject:	Request for Rulemaking Hearing Proposed Amendments to 6 CCR 1007-1, Radiation Control, Part 2, Registration of Radiation Machines, with a request for the rulemaking hearing to occur in October 2014.

The Department is proposing minor revisions to the following parts of the *Rules and Regulations Pertaining to Radiation Control*: Part 2, *Registration of Radiation Producing Machines, Facilities, and Services.*

The proposed changes are being initiated to clarify and strengthen the training requirements for Computed Tomography (CT) Operators for specific types of use of CT systems based on a stakeholder comment and BOH discussions during the prior (June 2014) final rulemaking hearing for Part 2. Additionally, as a result of rulemaking outreach and comment during the current stakeholder discussions, the program is proposing to extend the expiration date for the Colorado CT Operator program beyond that approved by the BOH in June 2014. With the proposed change, the Colorado CT Operator program would end July 31, 2017 rather than the current 2015 date. The date extension is primarily based on the needs and request of rural hospital facilities who indicated a need for additional time so that individuals may complete their current training. The proposed extension will also allow the radiation program further time to evaluate the long term options and alternatives to the Colorado CT Operator program to more clearly address the needs of individuals in training and facilities who provide training.

Further details on the proposed changes are listed in a Statement of Basis and Purpose and Specific Statutory Authority for the proposed revised rule, which, along with a Regulatory Analysis and supporting information, is available at: http://www.colorado.gov/pacific/cdphe/radregs

The Radiation Program requests BOH approval for a final rulemaking hearing on December 17, 2014.

cc: Deborah Nelson, Administrator, State Board of Health

STATEMENT OF BASIS AND PURPOSE AND SPECIFIC STATUTORY AUTHORITY for Amendments to (6 CCR 1007-1, Radiation Control, Part 2, Registration of Radiation Machines)

Basis and Purpose.

The Colorado Radiation Control Act (the Act), Title 25, Article 11, Colorado Revised Statutes, Section 25-11-104, requires the State Board of Health (Board) to formulate, adopt and promulgate rules and regulations pertaining to radiation control.

Section 25-11-103 of the Act requires the Colorado Department of Public Health and Environment (Department) to develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing radiation, including hazards from radiation producing machines and to register or issue registrations pertaining to use of such devices.

Section 25-11-104 of the Act requires Colorado's radiation regulations to be compatible with the *Suggested State Regulations for Control of Radiation* (SSRCR) of the Conference of Radiation Control Program Directors, Inc., except when the Board concludes, that a substantial deviation from the SSRCR is warranted. The SSRCR Part B (last updated in 2009) - the basis for Part 2 - is written very broadly such that individual states typically use and shape the suggested rule to fit their needs and program structure. Therefore, the proposed amendment to Part 2 is written to follow Colorado's specific business processes rather than the generic requirements of the SSRCR.

This amendment is intended to make focused changes to Part 2, *Registration of Radiation Producing Machines, Facilities, and Services* previously adopted June 18, 2014 (and which became effective August 14, 2014). The proposed changes to Part 2 are being initiated primarily to address concerns about Computed Tomography (CT) Operator use and training by certain individuals. Below is a summary of the proposed changes.

The proposed changes focus on the following specific areas:

- Based on prior stakeholder comment and BOH concerns, the proposed changes place additional specific CT training requirements such that:

-CT Operators using a CT for general imaging purposes be specifically certified in CT by Colorado, or a nationally recognized registry board;

- CT Operators using a CT associated with hybrid or fusion imaging (procedures involving nuclear medicine), or uses associated with radiation therapy be specifically certified in their applicable nationally registry board (e.g., nuclear medicine or radiation therapy).

- The addition of clarifying language to ensure supervision of individuals who are in training to become CT Operators;

- The addition of two definitions to support and provide for consistency throughout the regulatory part (and at the suggestion of stakeholders);

- An extension of the date when the Program plans discontinue the Colorado CT Operators certification from the current date of July 2015 to July 2017; and

- Correction of a form reference error;

Editorial comments, notes, and information shown in the right side margin of draft proposed rule are for information only to aid the reader, and are not considered part of the regulation.

These will be removed from the final regulation prior to submission to the Colorado Secretary of State's office for publishing in the Colorado register.

Specific Statutory Authority.

These rules are promulgated pursuant to the following statutory provisions: 25-1.5-101(1)(k), 25-1.5(1)(l), 25-11-103, 25-11-104, and 25-11-108, C.R.S.

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

_____ Yes, the bill number is _____; rules are ___ authorized ___ required. ___X_ No

Is this rulemaking due to a federal statutory or regulatory change?

_____ Yes __X___ No

Does this rule incorporate materials by reference?

___X__ Yes _____ No

Does this rule create or modify fines or fees?

__X**_ Yes ____ No

** The proposed change in and of itself does not create or modify fees. However, as a result of the elimination of the Colorado Computed Tomography Operators certification program (extended to 2017 under the proposed rule amendment), there will be a slight reduction in fees collected beginning in August 2017. This is expected to have a minimal impact on radiation program revenue since 25 or fewer individuals apply for the Colorado CT certification in a typical year.

REGULATORY ANALYSIS for Amendments to (6 CCR 1007-1, Radiation Control, Part 2, Registration of Radiation Machines)

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

The classes of persons potentially affected by the proposed rule amendments are facilities using non-certified/registered Computed Tomography (CT) operators for general imaging on living humans. Additionally, persons operating CT imaging systems for use on living humans but who are not certified or registered by Colorado or by a national registry organization and who wish to continue operating such CT machines for general imaging on living humans will be potentially affected. These individuals (without CT certification) and who may now be operating a CT for general imaging purposes (not associated with nuclear medicine or radiation therapy) would no longer be able to perform such imaging activities except under the supervision of another qualified person until they become certified. These individuals would not benefit from the proposed change, as the proposed change would potentially either prohibit, or effectively limit their activities to performing only those CT imaging activities associated with their primary job roles (e.g., nuclear medicine or radiation therapy) related CT imaging).

The classes of persons that would potentially benefit from the proposed rule amendments are those who are specifically certified as CT Operators either through a national registry organization or the Colorado CT Operator certification process (while it remains in effect through 2017). Under the proposed rule language, there is no change to what these CT certified individuals may do with respect to operation of a CT machine. Individuals who operate CT machines as part of their job function in the performance of nuclear medicine or radiation therapy related activities would also see no change. Certified CT Operators may benefit from the proposed change by having additional job opportunities.

Qualitatively, medical patients may be positively affected by the proposed changes. The proposed changes help ensure that a CT operator performing general imaging procedures has met certain nationally accepted training and testing criteria. Such certifications may help to assure quality imaging among other things.

There are no specific additional or increased direct monetary costs with the proposed rule change.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

Quantitative:

As of August 2014, Colorado had approximately 329 facilities registered to use 192 CT machines. Since the Radiation Program does not require registration or licensing of individuals who are certified or registered by national organizations, general data is not available regarding the qualifications of CT Operators in the State. Since 2005, Colorado has registered approximately 230 individuals as Colorado Computed Tomography Operators. This number likely does not represent the current number of

individuals practicing in the field since the Colorado registration program does not have requirements for renewal and has no expiration date.

The quantitative impacts are that operators of CT machines on live humans for general imaging will, after 2017, be required to be registered by a nationally accepted registry organization in Computed Tomography rather than allow for a registration process through the Department. The Computed Tomography operators currently registered with the Department will be allowed to continue acting as CT operators as long as they maintain their registration with the American Registry of Radiologic Technologists (ARRT).

Qualitative:

The net qualitative effect of these changes is that some individuals currently operating CT machines for general imaging and who are not currently CT certified through a national registry organization or through the Colorado CT certification program, would no longer be authorized to perform such activities upon the effective date of the rule. Experienced, but non-certified individuals would need to document their training and experience and as applicable, formulate a training program necessary to obtain a national or Colorado certification.

Additionally, there may be a qualitative positive effect for patients who undergo CT exams for general imaging. Under the proposed changes, general imaging using CT systems will be required to be performed by certified CT operators. Requiring certified CT operators may potentially lead to reduced radiation dose and improved image quality.

The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

Over time, there will be a slight reduction in revenue to the X-Ray Certification program as the one-time \$50 registration fee for a Computed Tomography Operator certification application review would no longer be realized after July 31, 2017. For the past 5 year period 2009-2013, the maximum number of individuals applying for Colorado certification in any given year was 24. Based upon this value, the annual maximum revenue that would be lost as a result of terminating this program is approximately \$1,200. Although unknown at this time, the Department could receive a "surge" in applications, and consequently an increase in the amount of application fees received could be realized within the next 2.5 years as a result of the pending (2017) elimination of the program.

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

The Radiation Program believes that the benefit of requiring higher levels of certification for CT Operators outweighs the cost/eventual loss of fees to the program. The general consensus of stakeholders would appear to support this assessment as most stakeholders were in favor of more rigorous training criteria, while allowing for additional options for those individuals who are in-training.

As requested by stakeholders, the proposed changes will extend the expiration date of the Colorado CT Operator certification program by an additional 2 years, thus benefitting some facilities and individuals who need additional time to complete their CT certification. The proposed changes will also strengthen and clarify the requirements and certifications required for CT imaging as national accreditation organizations, insurance companies, and other quasi-regulatory entities generally encourage or require the use of certified individuals.

Inaction will not provide sufficient direction to the regulated community and will not be responsive to stakeholder comments made during the most recent Part 2 rulemaking hearing. Inaction would allow the status quo of not providing specific requirements for operators and specific uses of CT machines and is likely not in the best interest of public health.

The overall benefit will be to provide clear direction and options for those individuals and facilities that use CT machines for human imaging purposes. While the proposed changes, when effective, may result in limiting some individuals, the current and proposed language provides some alternatives. The majority of stakeholders that provided written and oral comments during the stakeholder process indicated they were in favor of more specific and explicit requirements for CT Operators.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

There are believed to be no less costly methods or less intrusive methods for achieving the purpose of the proposed rule in the allotted time. The rule changes are necessary to provide the regulated community with sufficiently detailed information and requirements necessary to comply with the requirements.

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

Alternative rules are not feasible as the proposed changes to this Part are intended to clarify and strengthen the existing requirements in a way that will be easier to understand by the regulated community. Additionally, concern by stakeholders and the BOH during the June 2014 rulemaking indicated that addressing the CT Operator training requirements sooner than later was a priority.

For future consideration and rulemaking, and as a result of the most recent stakeholder process, the Radiation Program has initiated conceptual discussions of the benefits and feasibility of a provisional CT certification process, that would in some respects replace the Colorado CT certification. Such a program would provide some additional, but limited measures and opportunities for those individuals on the path to national certification. Evaluation of such a program will take additional time and resources and if feasible would only be considered for future rulemaking processes.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

The consequences of the proposed changes will be that the facilities that use CT machines and individual operators of such machines will have an improved understanding of the regulatory requirements for operation, which are consistent with some other states and with other nationally accepted regulatory and non-regulatory

drivers and requirements. Based upon the stakeholder comments received, the regulated community, in general, appears to be in support of the proposed language of limiting the scope of work for those operators who are not specifically certified in the specialty of Computed Tomography but wish to perform general imaging using CT machines.

The long-term consequences of the proposed changes will be the extension and elimination (in 2017) of the Colorado CT Operators certification program and a slight reduction in fees received by the program. Elimination of this program will effectively require individuals to become CT certified through a national registry organization. Additional language developed as a result of the stakeholder process will also clarify the requirements for those individuals in training to become CT Operators. For those who are certified in Nuclear Medicine or Radiation Therapy, these individuals will continue to be allowed to perform those imaging procedures associated with their primary job roles in nuclear medicine and radiation therapy, so there is effectively no change or consequences for these types of use by such operators.

The Radiation Advisory Committee (RAC) reviewed the changes to Part 2 prior to the most recent public comment period and during the August, 2014 regular meeting. The RAC did not recommend any specific changes or express concerns over the proposed changes.

STAKEHOLDER COMMENTS for Amendments to (6 CCR 1007-1, Radiation Control, Part 2, Registration of Radiation Machines)

The following individuals and/or entities were included in the development of these proposed rules:

Notification of the opportunity to comment on the proposed changes to Part 2 was sent on August 13, 2014 to a total of approximately 3,050 email addresses/entities. Other notifications were sent in hardcopy form via US Mail.

The entities represented:

- Approximately 109 Qualified Inspectors/Qualified Experts;

- Approximately 16 radioactive materials licensees authorized for sources used hybrid/fusion imaging (PET/CT; SPECT/CT);

All 191 Registered CT facilities (hospitals, medical clinics, imaging centers, etc.);
Approximately 111 "other stakeholders" (individuals who have signed up to receive notification of any proposed radiation regulation changes) who represent a wide variety of interests, including: x-ray registrants, radioactive materials licensees; private citizens; private companies; professional organizations; and activist groups; and

 Seven professional healing arts related organizations including: Colorado Hospital Association; Colorado Medical Society; Colorado Radiological Society; Colorado Dental Association; Colorado Chiropractic Association; Colorado Veterinary Medical Association; and Rocky Mountain Oncology Society. These entities were also notified via U.S. mail.
 Approximately 2,711 Colorado based radiologic technologist members of the American Society of Radiologic Technologists (ASRT) professional organization.

In addition to the opportunity for written comment, stakeholders were provided with the opportunity to participate in two stakeholder meetings held in early September (prior to the conclusion of the comment period). A total of 11 stakeholders participated in these meetings either in-person or via conference call.

This rulemaking does not include a local government mandate. EO5 does not apply.

The following individuals and/or entities were notified that this rule-making was proposed for consideration by the Board of Health: N/A - the schedule for the request for rule-making is currently posted on the Department website. A formal notice will be sent at the time the final rulemaking is scheduled and approved by the BOH in October.

On or before the date of publication of the notice in the Colorado Register, the Division sent notice to persons and/or groups considered by the division to be interested parties to the proposed rule-making, and those who have requested notification/ information from the division regarding the proposed rule-making? ____ Yes _N/A_ No. The Division provided notice on ____(date) _____. The proposed rule has not yet been heard by the BOH and therefore the rulemaking hearing date has not yet been approved or finalized by the BOH. Once approved by the BOH, formal notice will be sent to stakeholders.

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

The major factual/policy issues encountered during the comment period and stakeholder process included:

- 1. The vast majority of comments received during the stakeholder process indicated that stakeholders were in favor of the proposed changes requiring specific CT Operator certification for performing general imaging.
- 2. A concern was expressed primarily by rural hospitals regarding the discontinuation of the Colorado CT certification program in 2015 under the current rule.

Background information: The Colorado CT certification program provides a mechanism to allow individuals who originally did not or currently do not intend to obtain national certification/registration in CT. At its initial inception in 2005, the Colorado CT certification program was intended to provide a "grandfathering" mechanism for those operators who were experienced in CT operation but were not necessarily seeking national (CT) certification or was for those who were unable to attend a more formal education based CT training program. While some requirements for the current Colorado certification process are similar to and partially based upon those of the national registry organizations, other certification criteria and requirements are not equivalent. The Program has recognized that certain elements are lacking with the current Colorado certification program, including the lack of a written exam as part of the certification process, the lack of ongoing training (e.g., continuing education) requirements, the lack of an expiration date for the certification, and, unlike a national certification, the fact that the Colorado certification may not be recognized outside Colorado.

Hospital/medical center facilities located in rural areas have expressed concern over the difficulty of attracting nationally registered CT Operators to their facilities and believe that the Colorado CT Operator program provides a mechanism for these facilities to train personnel "in-house" to become Colorado CT Operators. Additionally, both the Colorado and other national registry programs require a certain number and varying types of CT procedures be performed before an individual can become certified. Rural facilities have challenges with the number and variety of scans performed at their facilities that are needed to qualify an operator and complete the training requirements.

Proposed resolution: The expiration date of the Colorado CT Certification Program has been extended to July 31, 2017 in the proposed amendment to allow more time for the concerned facilities to train personnel to become CT Operators. Additionally, the program is exploring other long term options to address this concern, including consideration of a "provisional" CT certification. Other options will take time and further evaluation and will be deferred to a future outreach and rulemaking process. Multiple stakeholders provided comments during the comment period in writing or in person. The significant issues, comments, and responses are summarized below.

The individuals who participated in the stakeholder process represented individual radiologic technologists certified in Computed Tomography, Nuclear Medicine, and Radiation Therapy. Also represented were several medical physicists, and those representing educational programs, rural and regional medical facilities, and the Colorado Hospital Association.

Of the written comments received from 13 individuals:

- The majority (9) were in support of the changes.
- Two (2) of the stakeholders indicated that they were opposed to the proposed changes and believed that sufficient requirements were in place. Another commenter indicated that the proposed changes did not go far enough and that even more limited/focused applications of CT (including those associated with nuclear medicine and radiation therapy) should required full ARRT CT certification.
- Two (2) other commenters appeared to misunderstand the context of the proposed changes, with one believing that the proposed changes would prohibit individuals who were in training to become CT Operators. The proposed changes would not prohibit individuals who are in training.

Similar to the written comments, the majority of individuals present at the stakeholder meetings in person or via phone indicated support for the proposed changes, with the greatest concern expressed being associated with the ability of rural facilities to train, attract, and/or retain properly certified individuals.

COMMENTS ASSOCIATED WITH THOSE IN FAVOR OF THE PROPOSED CHANGES	RESPONSE / RESOLUTION
One commenter in favor of the proposed changes also commented that the Department should investigate other CT systems in use, such as those used/designed for a specific body part (e.g., head only scanners) and the associated training requirements.	As a result of this and other comments/discussion during the stakeholder meetings, the language was modified slightly to refer to CTs used for "general imaging" rather than use of the term "diagnostic imaging". The Department believes such specialized machines fall into the category of other general use CT machines which require CT specific certification.
One commenter in favor of the proposed change also commented that their experience was that individuals who had received on the job (OJT) training but had not become certified/passed a certification exam were less familiar with CT slice anatomy, CT physics, and proper dose adjustments.	The Department recognizes that less formal training programs may result in some training gaps compared with more structured programs. However, national registries or certifications can help to even this out, since many individuals successfully complete OJT training and ultimately pass the national registry. No change was made to the rule as a result of
One commenter in favor of the proposed change which would limit Nuclear Medicine (NM) certified individuals to performing only CT associated with NM also commented to that CT certified individuals should similarly not be allowed to perform nuclear medicine or radiation therapy procedures.	The Radiation Program believes that training requirements are adequately addressed in other regulatory Parts for NM's and Radiation Therapists. Colorado Parts 7, and 2 provide the specific training and experience requirements for individuals performing nuclear medicine and radiation therapy procedures, respectively. No change was made to the rule as a result of the comment.

Two commenters expressed concern that the proposed changes may prohibit on-the-job (OJT) training since hands-on performance of CT procedures is needed to learn and complete the necessary training requirements to achieve certification.	The Radiation Program believes that the language originally proposed in the rule would not prohibit OJT. The rule has however been, in some instances, silent with regard to training status versus those actively practicing in the field.
	As a result of this and other comments and discussion during the stakeholder process, clarifying language was added to the proposed rule to address individuals who are in training. The radiation program believes that this will make it sufficiently clear that trainees may perform procedures while under direct supervision of an individual who meets the CT training requirements specified (e.g., is CT certified) so that they may learn and practice. The added language may also negate the need for any future provisional CT operator program (discussed earlier).
One commenter in favor of the proposed change also commented that Colorado's training criteria should match the current and pending requirements of the ARRT.	Changing the training criteria mid-stream may result in some individuals now in the process of becoming trained, to alter their training programs.
	No change was made to the rule as a result of the comment.
COMMENTS ASSOCIATED WITH THOSE OPPOSED TO THE PROPOSED CHANGES	RESPONSE / RESOLUTION
One commenter opposed to the proposed change also commented that the reduction in radiation exposure is achieved at the protocol level and via use of improved software (rather than by CT certified individuals)	While it is realized that the control of the radiation exposure is most directly controlled by the CT software system, physical mechanisms should be in place to ensure the system is not tampered with or adjusted unless otherwise directed by a physician. The Department believes this is best addressed through proper training and certification.
	No change was made to the rule as a result of the comment.

Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradoans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?

- The Division believes there are no significant impacts on health equity and environmental justice (HEEJ).
- The proposed changes impact Coloradoans equally and equitably, consistent with the registration practices of the X-Ray Certification Unit, other states, and national accreditation organizations.
- The proposed changes are believed to be neutral with respect to advancing HEEJ.
- Other factors which influenced the proposed rules are the need to maintain Colorado regulations consistent with how the field is regulated in other states and through national registry organizations.

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DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

3	STATE BOARD OF HEALTH		
4	RADIATION CONTROL - REGISTRATION OF RADIATION MACHINES, FACILITIES AND SERVICES		
5 6	6 CCR 1007-1 Part 02 [Editor's Notes follow the text of the rules at the end of this CCR Document.]		
7	Adopted by the Board of Health June 18December 17, 2014		
8	PART 2: REGISTRATION OF RADIATION MACHINES, FACILITIES AND SERVICES		
9	2.1 Purpose and Scope.		
10	2.1.1 Authority		
11 12	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)(I), and 25-11-104, CRS.		
13	2.1.2 Basis and Purpose.		
14 15	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.		
16	2.1.3 Scope.		
17	2.1.3.1 This part provides for:		
18	(1) Registration of facilities;		
19	(2) Certification of radiation machines;		
20 21	 (3) Registration of persons providing radiation machine services including assembly, installation, maintenance and repair; 		
22	(4) Registration of qualified inspectors and qualified experts; and		
23	(5) Approval of radiation safety officers, mammographers and other operators.		
24	2.1.4 Applicability.		
25 26 27	2.1.4.1 The requirements and provisions of this part apply to each person who uses, operates, services or certifies radiation machines and to each registrant or applicant for registration subject to this part unless specifically exempted.		
28 29	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.		
30	2.1.5 Published Material Incorporated by Reference.		
31	2.1.5.1 Published material incorporated in Part 2 by reference is available in accord with 1.4.		
32	2.2 Definitions.		

Comment [JJ1]: EDITORIAL NOTE 1: ALL COMMENTS (SUCH AS THIS ONE) SHOWN IN THE RIGHT SIDE MARGIN OF THIS DRAFT RULE ARE FOR INFORMATION PURPOSES ONLY TO PROVIDE ADDITIONAL INFORMATION AND TO AID THE READER IN UNDERSTANDING THE PROPOSED CHANGE DURING THE DRAFT REVIEW PROCESS. DRAFT REVIEW PROCESS.

THESE COMMENTS ARE <u>NOT</u> PART OF THE RULE AND ALL COMMENTS WILL BE DELETED PRIOR TO FINAL SUBMISSION TO THE COLORADO SECRETARY OF STATE'S OFFICE FOR FINAL PUBLISHING IN THE COLORADO CODE OF REGULATIONS.

EDITORIAL NOTES WITHIN THE <u>BODY</u> OF THE RULE ARE FOR INFORMATION PURPOSES ONLY AND ARE NOT CONSIDERED PART OF THE RULE.

Comment [JJ2]: The date is modified to reflect the anticipated final rulemaking hearing date.

33	2.2.1 Definitions of general applicability to these regulations are in Part 1, section 1.2.	
34	2.2.2 As used in Part 2, each term below has the definition set forth.	
35	"ARRT" means the American Registry of Radiologic Technologists.	
36 37	"ARRT(N)" means an individual who is registered by the ARRT in Nuclear Medicine Technology	Comment [JJ3]: Definition added consistent with the use of the term in later sections of Part 2.
38	"ARRT(R)" . See "radiologic technologist" .	Comment [JJ4]: Definition added consistent with
39	"ARRT(T)" means an individual who registered by the ARRT in Radiation Therapy.	the use of the term in later sections of Part 2.
40	"ASRT" means the American Society of Radiologic Technologists.	
41 42	"Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into a radiation machine system or subsystem.	
43	"Calibration" means to adjust and/or determine the:	
44 45	 Response or reading of an instrument relative to a series of conventionally true values; or 	
46	(2) Strength of a radiation source relative to a standard or conventionally true value.	
47 48 49 50	"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.	
51 52	"Certified Nuclear Medicine Technologist" means an individual who is currently registered in nuclear medicine with the NMTCB or ARRT, designated CNMT or ARRT(N), respectively.	Comment [JJ5]: Definition added consistent with the use of the term
53 54 55	"Computed tomography" (CT) means the production of a tomogram by the acquisition and computer processing of x-ray transmission data. For the purposes of Part 2, the requirements stated for computed tomography machines do not apply to "Volumetric Dental Imaging Systems".	in later sections of Part 2.
56 57	"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.	
58 59	(1) The direct supervisor is not required to be present in the room when the procedure is performed.	
60 61 62 63	(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.	
64 65 66	"Dual-energy X-Ray Absorptiometry" (DXA, previously DEXA) means an imaging technique using radiation machines for quantifying bone density, used in the diagnosis and management of osteoporosis.	
67 68	"Examination" means performing a procedure, including selection of exposure settings, positioning the x-ray system and the patient, and initiating and terminating the exposure.	
69 70 71	"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.	
72	"FDA" means the United States Food and Drug Administration.	

- "Fluoroscopy" means a technique for generating x-ray images and presenting them
 simultaneously and continuously as visible images.
- "Industrial Radiography" means an examination of the structure of materials by the
 nondestructive method of utilizing ionizing radiation to make radiographic mages.
- "Inter-comparison" means the direct comparison, in accord with 2.4.4.5, of two instruments
 designed to measure the same physical quantity.
- "Limited-scope operator" (LSO) means an individual who has taken and passed a required test
 and has approval by the Department pursuant to 2.4.5.1 to operate x-ray systems and to conduct
 specified radiographic examinations of the chest, extremities, skull, hip/pelvis and spine/sacrum.
- 82 "MQSA" means Mammography Quality Standards Act.
- 83 "NIST" means the National Institute of Standards and Technology.
- 84 "NMTCB" means the Nuclear Medicine Technology Certification Board, Inc.
- 85 "Operator" means an individual adequately trained in accordance with these regulations in the
 86 purpose and experienced in the practice of performing a radiographic examination.
- "Performance adjustment" means the adjustment or repair of a function (not including the setting
 of operator-selectable functions, such as time, mA and/or kVp for an individual exposure) of an x
 ray machine or imaging system that is required to bring the machine into compliance with these
 regulations and the specifications.
- Provisional Mammographer" means an individual who meets the requirements of 2M.2 and has
 current department approval to perform mammograms under direct supervision in order to meet
 the requirements to become a Qualified Mammographer.
- "Provisional qualified inspector" (PQI) means an individual who meets the applicable
 requirements of Section 2I.2 of Appendix 2I and has current Department approval in a designated
 specialty to perform evaluations of radiation machines, facilities, and operators for compliance
 with these regulations while under the supervision of a qualified inspector.
- "QE(R)" means a qualified expert medical physicist approved to design or evaluate shielding for
 radiation machines used in the healing arts.
- "QE(S)" means a qualified expert physicist approved to design or evaluate shielding for radiationmachines used for non-healing arts purposes.
- 102 "QE(T)" means a qualified expert medical physicist approved to design or evaluate shielding for103 radiation machines used in radiation therapy.
- 104"Qualified expert" (QE) means an individual who meets the applicable requirements of Appendix1052B or 2C and has current Department approval as QE(S), QE(R), or QE(T) to evaluate radiation106shielding design and recommend radiation safety practices, as provided in 2.4.3.
- "Qualified inspector" (QI) means an individual who meets the applicable requirements of
 Appendix 2I and has current Department approval in a designated specialty to perform
 evaluations of radiation machines, facilities, and operators for compliance with these regulations,
 as provided in 2.4.4.
- "Qualified mammographer" means a mammographer who meets the applicable requirements ofAppendix 2M.
- "Qualified trainer" (QT) means an individual whose training and experience adequately prepares
 the individual to carry out specified training assignments as illustrated in Appendix 2J.

Comment [JJ6]: A hard return (separation) is added to correct a typographical error and separate the two definitions ("Industrial Radiography", and "Inter-comparison") that were inadvertently merged into one definition during the prior amendment to Part 2.

There are no changes to either definition.

Comment [JJ7]: Definition added consistent with the use of the term in later sections of Part 2.

115	"Radiologic technologist" means an individual who is currently registered in
116	radiographyradiologic technology with the American Registry of Radiologic Technologists,
117	designated ARRT(R).
118	"Registered medical physicist" (RMP) means an individual who meets the applicable
119	requirements of Appendix 2I and has current Department approval to perform medical physics
120	activities, including shielding design, performing radiation surveys, and providing consultation for
121	radiation protection and quality assurance and clinical medical physics for radiation therapy,
122	computed tomography, mammography and/or other healing arts facilities.
122	
123	"Service company" means a person who is engaged (or offers to engage) in the business of
123	selling, leasing, transferring, lending, assembling, installing, maintaining, repairing, storing,
124	trading out, disabling, or disposing of radiation machines and their related components, or is
125	engaged in the business of furnishing or offering to furnish radiation machine servicing or
120	services.
127	Services.
100	Consistent and the second se
128	Service technician" means an individual who is employed by a service company to perform
129	radiation machine servicing or services.
100	
130	"Shielding design" means physical specifications, such as room layout, floor plan, construction
131	materials, and equipment configuration, to demonstrate compliance with the radiation limits set
132	forth in Part 4 of these regulations.
133	"Volumetric dental imaging system" means an x-ray machine that produces, for oral and
134	maxillofacial structures, a three-dimensional tomographic data set or a time sequence of three-
135	dimensional tomographic data sets. A dental x-ray machine only capable of producing a two-
136	dimensional image is not considered to be a volumetric dental imaging system. For the purposes
137	of Part 2, the requirements stated for "computed tomography" machines do not apply to
138	"Volumetric Dental Imaging Systems".
139	

EDITORIAL NOTE: ***FOR BREVITY OF THE DOCUMENT, UNAFFECTED SECTIONS HAVE BEEN REMOVED FROM THE DRAFT. THERE ARE NO CHANGES PROPOSED FOR THESE SECTIONS***

140

141 142 **Comment [JJB]:** The definition language is modified slightly in accordance with the language used by the American Registry of Radiologic Technologists (<u>https://www.arrt.org/About-ARRT/Designation-Awarded</u>).

Comment [JJ9]: EDITORIAL NOTE ONLY – NOT PART OF RULE.

143	2.4.5 Registration of specific radiation machine Operators.	
144	2.4.5.1 Limited Scope Operator.	
145 146 147	 (1) Each individual operating an x-ray system on living humans in the State of Colorado, shall be registered as a Limited Scope Operator consistent with 2.4.5.1(2), except for: 	
148 149	(a) Those individuals subject to 2.6.1.5, 2.6.1.6, 2.6.1.7, 2.6.1.8, 2.6.1.10, 2.6.1.11, and 2.6.1.12, or	
150 151	(b) Those individuals having current registration with the American Registry of Radiologic Technologists in radiography.	
152	(2) Registration	
153 154 155	 (a) The applicant for LSO registration must complete the requirements of 2D.2.1, 2D.2.2 and 2D.2.3 in a structured and documented training program in order to apply for registration as a Limited Scope Operator. 	
156 157 158 159	(b) Each Limited Scope Operator shall complete an application with all of the information required by the form and instructions, together with the fee required by Part 12, Category 24 and the fee required by the American Registry of Radiologic Technologists.	
160 161	(i) The Form R-70 series application shall be used to initiate the registration process.	
162 163	(ii) The Form R-71 series application shall be used to confirm the completion of the requirements of 2D.2.1, 2D.2.2 and 2D.2.3.	
164 165 166	(c) Application for registration as a Limited Scope Operator shall be made within one year upon completion of the requirements of 2D.2.1 and within ninety (90) calendar days upon completion of the requirements of 2D.2.2 and 2D.2.3.	
167 168 169	(d) If an applicant cannot achieve a passing score per 2D.2.4 within three attempts, the applicant must restart the training required by 2D.2.1, 2D.2.2, and 2D.2.3.	
170 171	(e) Registrants must meet the requirements of 2D.2.5 in order to renew the Limited Scope Operator approval.	
172 173	(i) The Form R-95 R-90 series application shall be used to renew the registration for a Limited Scope Operator.	Comment [BNV10]: The wrong application form was referenced in the last revision of Part2.
174		This change corrects this error.
175	2.4.5.2 Computed Tomography Operator Subject to Appendix 2E.	
176 177 178 179 180 181	(1) Each individual operating a computed tomography system on living humans shall hold a current, valid registry in Radiography, Nuclear Medicine, or Radiation Therapy issued by ARRT, NMTCB, or other nationally recognized registry organization accepted in writing by the Department, and shall: shall be registered with the Department as a Computed Tomography Operator, except for:	Comment [JJ11]: The proposed language helps to ensure that CT Operators must have a current, valid "base" registration in addition (as applicable) to any specialty certification (e.g., CT).
182 183	(a) Meet the requirements of 2E.1.1, 2E.1.2, 2E.1.3, or 2E.1.4 for the applicable use specified in 2.6.1.7;	This subsection is expanded in order to outline, but defer to the specific training requirements of Appendix 2E rather than hold the requirements within the body of the regulation, consistent with the approach used in the remainder of the rule.

1		
184	or	
185 186	(b) Meet the requirements of Appendix 2E.2 and be registered with the Department as a Colorado Computed Tomography Operator;	
187	or	
188 189	(c) As a CT operator in training, be under the direct supervision of an individual who meets the requirements of 2.4.5.2(a) or 2.4.5.2(b).	Comment [JJ12]: Language is added here based on stakeholder comment and discussions whereby
190 191 192	(a) Those individuals having current registration with the American Registry of Radiologic Technologists in radiography and certification in computed tomography; or	individuals who are "in training" are specifically allowed to perform CTs as part of a training process. The current Part 2 does not clearly consider training situations.
193 194 195 196	(b) those individuals having current registration with the American Registry of Radiologic Technologists in nuclear medicine technology, or individuals registered with the Nuclear Medicine Technology Certification Board (NMTCB) as a certified nuclear medicine technologist; or	
197 198	 (c) those individuals having current registration with the American Registry of Radiologic Technologists in radiation therapy. 	
199	(2) Registration	Comment [JJ13]: The modified language in this section is to clearly identify that the registration process is applicable only to the Colorado CT
200 201 202	(a) The applicant for Colorado Computed Tomography Operator must complete the requirements of Appendix 2E, 2E.2 in a structured and documented training program.	Operator training registration. (Individuals certified in CT by a national registry organization do <u>not</u> need to also have a Colorado registration).
203 204 205	(b) AThe application for registration as a Colorado Computed Tomography Operator shall contain all of the information required by the form and instructions, together with the fee required by Part 12, Category 24.	
206 207	(i) The Form R-95 series shall be used to document the requirements of 2E.2.2, 2E.2.3 and 2E.2.4.	
208 209	(3) The state will no longer register Computed Tomography Operators under Appendix 2E.2 after July 30, 2015.After July 31, 2017, the Department will recognize	Comment [1]] (]: To Destruction being and
210 211	Computed Tomography Operators previously registered with the Department but will cease registration of new Colorado CT Operators.	Comment [JJ14]: The Department is phasing out the in-state program for CT certification as of July 31, 2017. The time extension from that in the current rule is based upon stakeholder comments.
212		The proposed change clarifies that the Department will continue to recognize those individuals
213 214	EDITORIAL NOTE: ***FOR BREVITY OF THE DOCUMENT, UNAFFECTED SECTIONS HAVE BEEN REMOVED FROM THE DRAFT. THERE ARE NO CHANGES PROPOSED FOR THESE SECTIONS***	previously "certified" under this program but will not register any new individuals after July 31, 2017.
215 216		Comment [JJ15]: EDITORIAL NOTE ONLY – NOT PART OF RULE.

217 **2.6 Facility Registrant Responsibilities.**

218 219 220	allow or	cility regulated by or requiring registration under these regulations, the registrant shall nly individuals who are adequately trained in radiation safety and the safe and effective he machine to operate any radiation machine.
221 222	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.
223 224 225		(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.
226 227		(2) The registrant shall maintain a list of all operators of any radiation machine used by the facility registrant.
228 229 230		(a) For fluoroscopy equipment used in examination of a living human, a list of operators and individuals providing technical supervision of operators shall be maintained.
231 232		(b) The list of all operators and supervisors shall be updated at least annually as part of the radiation safety program required by 4.5.
233		(3) Records of such evaluations shall:
234		(a) Include current certifications of qualification;
235		(b) Be updated annually by the facility; and
236 237		(c) Be produced for examination upon request during any inspection conducted under the requirements of these regulations.
238 239 240 241 242	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.
243 244	2.6.1.3	For a radiologist assistant "adequately trained" shall mean that the individual is qualified as provided in Appendix 2G.
245 246 247	2.6.1.4	For any radiographic x-ray system used on a living human (consistent with 2.6.1.2, 2.6.1.3, and 2.6.1.5 through 2.6.1.14), "adequately trained" shall mean that the individual meets the requirements of Appendix 2D.
248 249 250		 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.
251 252 253 254		(2) A limited-scope x-ray machine operator shall not perform radiologic procedures involving the administration or utilization of contrast media, bone densitometry, fluoroscopic, mammography, computed tomography, or radiation therapy procedures.
255 256 257 258 259	2.6.1.5	For fluoroscopy equipment used in examination of a living human, "adequately trained" shall mean that, in addition to meeting all applicable requirements in 2.6.1.1 through 2.6.1.4, each individual who either supervises a fluoroscopy procedure or operates a fluoroscopy imaging system shall have adequate training in its safe operation. This training shall be documented and include the following:

260	(1) Fundamental principles of radiation protection;	
261	(2) Biological effects of ionizing radiation;	
262	(3) Safe operation of fluoroscopy equipment for each mode of operation to be used;	
263	(4) Dose reduction techniques for fluoroscopy; and	
264	(5) Applicable radiation regulations.	
265 266	2.6.1.6 For mammography equipment used in radiography of the human breast, "adequately trained" shall mean that the individual operator meets the requirements of Appendix 2M.	
267 268 269 270	 2.6.1.7 For any computed tomography (CT) system used on a living human, (excluding Volumetric Dental Imaging Systems) "adequately trained" shall mean that the individual operator meets the following requirements: of Appendix 2E. (1) Individuals operating a CT system for general imaging purposes shall meet the 	Comment [JJ16]: The proposed change clarifies the exclusion of Volumetric Dental Imaging Systems (as defined in Section 2.2) from the CT requirements of 2.6.1.7.
271 272 273 274 275 276	requirements of 2E.1.1, 2E.1.4, or 2E.2; or (2) Individuals operating a CT system in conjunction with nuclear medicine Positron Emission Tomography (PET-CT) or Single Photon Emission Computed Tomography (SPECT-CT) systems (known as hybrid or fusion imaging machines) shall meet the requirements of 2E.1.1, 2E.1.2, 2E.1.4, or 2E.2; or	Comment [JJ17]: As a result of stakeholder comment during the previous Part 2 rulemaking process, the proposed changes of subsection (1), (2), and (3), clarifies the training requirements which are dependent upon the type of use of the machine.
277 278 279 280 281	(3) Individuals operating a CT system used in conjunction with radiation therapy procedures (treatment simulation or tumor localization imaging) shall meet the requirements of 2E.1.1, 2E.1.3, 2E.1.4, or 2E.2.	Similar to other parts of the rule, this section also defers to the appendices (2E) for the applicable training requirements.
282 283 284 285	Individuals who are in-training to become a CT operator, shall not be considered adequately trained until they have fully met the requirements of 2.6.1.7(1), or 2.6.1.7(2), or 2.6.1.7(3) and shall not operate such CT machines except under the direct supervision of someone who meets the requirements of 2.6.1.7(1), or 2.6.1.7(2), or 2.6.1.7(3).	Comment [JJ18]:
286 287 288 289	2.6.1.8 For any bone densitometry equipment used in examination of a living human, "adequately trained" shall mean that the individual operator meets the requirements of Appendix 2F.	Language is added to more clearly delineate the requirements for individuals who are in-training to become fully qualified and registered CT Operators.
290 291 292 293 294	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).	
295 296 297 298	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).	
299 300 301 302 303	2.6.1.11 For radiographic equipment used in dentistry, including Volumetric Dental Imaging Systems, "adequately trained" shall mean that the individual operator meets all applicable requirements of the Colorado State Board of Dental Examiners (in particular Rule X, "Minimum Standards for Qualifications, Training and Education for Unlicensed Personnel Exposing Patients to Ionizing Radiation," of 3 CCR 709-1).	
304 305 306	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).	

307 308 309	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).	
310 311 312 313	2.6.1.14 An individual, enrolled in an ARRT-recognized program or graduated from such a program, may operate radiation machines so long as the individual works under the direct supervision of a radiologic technologist or other qualified trainer and has documentation of having completed education and experience equal to that specified in the program.	
314 315 316	(1) A graduate from an ARRT-recognized program is granted ninety (90) calendar days from the date of graduation to schedule, take and pass the ARRT radiologic technology registry examination.	
317 318	(2) During the 90-day period allowed by 2.6.1.14(1), the graduate is considered to satisfy Appendix 2D requirements.	
319 320 321	(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.	
322 323	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.	
324	(1) For industrial radiography, the requirements in Part 5 apply, as stated in 2N.1.	
325 326 327	(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.	
328 329	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.	
330 331 332	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.	
333 334	2.6.1.18 The Department may, upon application or upon its own initiative, accept as being adequate:	
335	(1) Documented combinations of radiation safety training and experience; or	
336	(2) Equivalent approval by another state or agency.	
337		
338 339	EDITORIAL NOTE: ***FOR BREVITY OF THE DOCUMENT, UNAFFECTED SECTIONS HAVE BEEN REMOVED FROM THE DRAFT. THERE ARE NO CHANGES PROPOSED FOR THESE SECTIONS***	Comment [JJ19]: EDITORIAL NOTE ONLY –
340		NOT PART OF RULE.
341		
342		
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345		

346 347	PART 2, APPENDIX 2E: COMPUTED TOMOGRAPHY (CT) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE	
348 349 350 351	Each operator of a computed tomography system shall hold a current, valid registry in Radiography, Nuclear Medicine, or Radiation Therapy issued by ARRT, NMTCB, or other nationally recognized registry organization accepted in writing by the Department, and shall meet the following experience and education requirements:	Comment [JJ20]: The language added here is
352	2E.1 Is contifiedCertification	similar to that in 2.4.5.2 to ensure that individuals have a current, valid "baseline" registry in addition to a CT specific registry, applicable to the type of
353	2E.1.1 For general imaging computed tomography procedures, each operator is certified;	use.
354 355	2E.1.1.1 As By the ARRT (R) and also certified in computed tomography by ARRT, ARRT(CT); or	Comment [JJ21]: The proposed changes to 2E.1 clarify the types of certification(s) and training required depending upon the type of use.
356 357	2E.1.1.2 By the Nuclear Medicine Technology Certification Board (NMCTB) in computed tomography, CNMT(CT);	The changes are made based on the stakeholder suggestion and concerns expressed during the last amendment of Part 2 before the Board of Health
358	Or	(June 2014).
359 360	2E.1.2 For nuclear medicine (hybrid or fusion imaging) computed tomography procedures such as PET-CT or SPECT-CT, is certified;	
361	2E.1.2.1 by the ARRT in nuclear medicine As as ARRT(N) or	
362	2E.1.2.2 by the NMTCB as CNMTARRT(T);; or	
363	2E.1.2.3 in accordance with 2E.1.1.	
364	orOr	
365 366 367	2E.1.3 As CNMT by the Nuclear Medicine Technology Certification Board; For simulation or localization computed tomography procedures associated with radiation therapy, is certified;	
368	2E.1.3.1 by the ARRT in Radiation Therapy, ARRT(T); or-	
369	2E.1.3.2 in accordance with 2E.1.1.	
370	Or	
371 372 373	er2E.1.4 Is certified by By a specialty board determined by the department to have substantially equivalent requirements for certification in computed tomography as the American Registry of Radiologic Technologists.	
374	or	
375 376 377	2E.2 Prior to July 303 1, 2017 15 , is certified as ARRT(R) and is also registered with the Department as a Computed Tomography Operator- by has satisfactorily completedcompleting the requirements of 2E.2.1 through 2E.2.3, inclusive.:	Comment [JJ22]:
378		The requirements of 2E.2 apply to those wishing to become a Colorado "certified" CT operator.
379 380	2E.2.1 At least 60 hours of didactic training providing the minimum hours of instruction in the specific subjects listed in 2E.2.1.1 through E.2.1.12:	The Department will continue to recognize but will be phasing out this registration program as of July 31, 2017, after which the Department will defer to nationally recognized certifications by ARRT or
381	2E.2.1.1 Intravascular (IV) Procedures—2 hours	NMTCB.
382	(1) Venipuncture	

383	(a) Site selection
384	(b) Aseptic and sterile techniques
385	(2) Injection techniques
386	(a) Manual
387	(b) Automatic
388	(i) Single phase
389	(ii) Multi-phase
390	(iii) Flow rate
391	2E.2.1.2 Contrast Agent—6 hours
392	(1) Types
393	(a) Ionic
394	(b) Non-ionic
395	(c) Water soluble
396	(d) Air
397	(e) Water
398	(2) Administration route and dose calculations
399	(a) IV (angiocatheter or butterfly)
400	(b) Oral
401	(c) Rectal
402	(d) Intrathecal
403	(e) Catheters
404	(3) Special considerations
405	(a) Allergy preparation
406	(b) Pathologic processes
407	(c) Contraindications
408	(d) Indicators
409	(4) Adverse reactions
410	(a) Recognition and assessment of symptoms
411	(b) Treatment (e.g., compresses, medications)
412	(c) Documentations

4	413 2E.2.1.3 Ra	diation Safety and Dosimetry—6 hours
4	414 (1)	Technical factors affecting patient dose
4	415 (2)	Radiation protection
4	416 (3)	Dose Measurement
4	417 (4)	Pediatric dose reduction
4	418 2E.2.1.4 Ty	pe of Study
4	419 (1)	Head
4	420 (2) 1	Neck
4	421 (3)	Chest
4	422 (4)	Abdomen
4	423 (5)	Pelvis
4	424 (6) 1	Musculo-skeletal
4	425 2E.2.1.5. Se	ectional Anatomy (for each type of study listed in 2E.2.1.4)
4	426 (1) \$	Sagittal plane
4	427 (2)	Transverse plane (axial)
4	428 (3) (Coronal plane
4	429 (4) (Off-axis (oblique)
4	430 (5) 1	Landmarks
4	431 (6)	Pathology recognition
4	432 2E.2.1.6 Co	ntrast Media (for each type of study listed in 2E.2.1.4)
4	433 (1)	Types of agents
4	434 (2)	Indications
4	435 (3) (Contraindications
4	436 (4) 1	Dose calculation
4	437 (5)	Administration route
4	438 (6) \$	Scan/prep delay
4	439 2E.2.1.7 Sc	anning Procedures (for each type of study listed in 2E.2.1.4)
4	440 (1) 1	Positioning
4	441 (2) \$	Scout
4	442 (3)	Acquisition methods (e.g., spiral, non spiral, dynamic, multi-row detector)

443	(4) Parameter selection (e.g., slice thickness, mA, time, algorithm, pitch)
444	(5) Protocol modification for pathology or trauma
445	(6) Cardiac gating
446	2E.2.1.8 Special Procedures (for each type of study listed in 2E.2.1.4)
447	(1) 3-D studies
448	(2) Biopsies
449	(3) Radiation therapy planning
450	(4) Drainage and aspiration
451	(5) Post-myelography
452	(6) CT arthrography and angiography
453	(7) Cardiac gating
454	2E.2.1.9 Systems Operation and Components—4 hours
455	(1) Tube
456	(2) Generator and transformers
457	(3) Detector configuration
458	(4) Data Acquisition Systems (DAS)
459	(5) Collimation
460	(6) Computer and array processor
461	(7) Equipment maintenance
462	2E.2.1.10 Image Processing & Display—10 hours
463	(1) Image reconstruction
464	(a) Filtered back projection reconstruction
465	(b) Reconstruction filters (algorithms)
466	(c) Raw data vs. image data
467	(d) Prospective / retrospective reconstruction (single and multi-row)
468	(e) Effective slice thickness
469	(f) Reconstruction interval
470	(2) Image display
471	(a) Pixel, voxel
472	(b) Matrix

473	(c) Image magnification
474	(d) Field of view (scan, reconstruction and display)
475	(e) Attenuation coefficient
476	(f) Window level, window width
477	(g) Plane specification (X, Y, Z coordinates)
478	(h) Cine
479	(i) ROI (single and multiple image)
480	(3) Post-processing
481	(a) Multiplanar reformation
482	(b) 3-dimensional rendering (MIP, SSD, VR)
483	(c) Quantitative measurements (volume, distance, diameter)
484	(4) Data management
485	(a) Hard/soft copy
486	(b) Storage / archive
487	(c) PACS
488	(d) Security and confidentiality
489	(e) Networking
490	2E.2.1.11 Image Quality—4 hours
491	(1) Spatial resolution
492	(2) Contrast resolution
493	(3) Temporal resolution
494	(4) Noise and uniformity
495	(5) Quality assurance procedures
496	(6) CT number
497	(7) Linearity
498	2E.2.1.12 Artifact Recognition and Reduction—4 hours
499	(1) Beam hardening
500	(2) Partial volume averaging
501	(3) Motion
502	(4) Metallic

504 (6) Patient pos 505 (7) Equipment 506 (a) Rin 507 (b) Strutt 508 (c) Tut	induced gs	
506 (a) Rin 507 (b) Stress	gs eaks be arcing ne beam; and	
507 (b) Str	eaks be arcing ne beam; and	
	be arcing ne beam; and	
508 (c) Tub	ne beam; and	
509 (d) Co	nical training during which time computed tomography	
511examinations are perfor512ARRT(T) or CNMTa que	med only under direct supervision of an <u>ARRT(N), ARRT(R),</u> alified computed tomography operator or other qualified trainer ments of 2E.1.1, 2E.1.4, or 2E.2; and.	
	ce Has performed, under direct supervision, of the following y imaging procedures (at least 60 examinations in total, with tion kept on file):	
517 2E.2.3.1 Head—10 exa	aminations;	
518 2E.2.3.2 Neck—10 exa	minations;	
519 2E.2.3.3 Chest—10 ex	aminations;	
520 2E.2.3.4 Abdomen—10) examinations;	
521 2E.2.3.5 Pelvis—10 ex	aminations; and	
522 2E.2.3.6 Musculo-skele	etal—10 examinations ; and	
523		
525 tomography operator at a facility	ents of 2E.2.1 and 2E.2.2, is allowed to be a computed / that performs only the particular procedure(s) for which record(s) e full number of examinations required in 2E.2.3;	Comment [BNV : section was to allow
529general supervision during the of530procedure(s) outlined in 2E.2.531the completion of the number532tomography operator only for the	didactic training in accord with Section 2E.2.1, is allowed under clinical training required by 2E.2.2 to perform the individual 3.1 through 2E.2.3.6 for which the individual has documented of examinations required in 2E.2.3. be a computed e particular procedure(s) for which record(s) document prior examinations required in 2E.2.8.	facility that does no listed in 2E.2.2.1 to CT certified individ have a method to er requirements of 2E. This section is being effectiveness of the Comment [JJ24 is clarified to more training may perfor
	OF THE DOCUMENT, SUBSEQUENT UNAFFECTED ROM THE DRAFT. THERE ARE NO CHANGES PROPOSED	they have been spec completed the minin procedures/exams s Individuals in trainifully qualified CT of the specified require
540		Comment [JJ25 NOT PART OF RU

Comment [BNV23]: The original intent of this section was to allow an applicant who trains at a facility that does not perform all of the procedures listed in 2E.2.2.1 to 2E.2.3.6 to become a Colorado CT certified individual. The Department does not have a method to ensure these persons complete the requirements of 2E.2.3 if they change employment. This section is being deleted as it reduces the effectiveness of the requirements.

Comment [JJ24]: The language in this paragraph is clarified to more clearly state that operators in training may perform certain procedures for which they have been specifically trained and have completed the minimum number of procedures/exams specified in 2E.2.3.

Individuals in training are not considered to be a fully qualified CT operator, until they have met all of the specified requirements.

Comment [JJ25]: EDITORIAL NOTE ONLY – NOT PART OF RULE.