



**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 *GB*

Date: December 2, 2014

Subject: **Rulemaking Hearing**  
Proposed Amendments to 6 CCR 1007-1, Radiation Control, Part 2, Registration of Radiation Machines, for the rulemaking hearing to occur in December 2014.

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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 Board of Health (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 the proposed changes at 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 national 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 25-1-108, C.R.S.

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**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, improved image quality, and fewer repeat imaging scans.

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

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 public comment period and during the August and October 2014 regular meetings. 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. E05 does not apply.

The following individuals and/or entities were notified that this rule-making was proposed for consideration by the Board of Health:

Through the notification of the opportunity to comment, all of the above individuals and entities were notified that this rule-making was proposed for consideration by the Board of Health. The notification included the website link (URL) to the radiation regulations website which included the tentative dates for the Board of Health request for rulemaking and final rulemaking hearings. The September 2014 presentation to stakeholders on the proposed changes also included the Board of Health request for rulemaking, and final rulemaking hearing dates.

A notice of final rulemaking hearing for Part 2, was sent to stakeholders via US Mail and/or email on November 6, 2014. All of the individuals who received notification of the opportunity to comment (identified above), were sent the formal rulemaking hearing notice which included the rulemaking date.

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 the comment.
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.

<p>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.</p>	<p>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.</p> <p>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).</p>
<p>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.</p>	<p>Changing the training criteria mid-stream may result in some individuals now in the process of becoming trained, to alter their training programs.</p> <p>No change was made to the rule as a result of the comment.</p>
<p><b>COMMENTS ASSOCIATED WITH THOSE OPPOSED TO THE PROPOSED CHANGES</b></p>	<p><b>RESPONSE / RESOLUTION</b></p>
<p>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)</p>	<p>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.</p> <p>No change was made to the rule as a result of the comment.</p>

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.

DRAFT 2 12/02/14

1 DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

2 Hazardous Materials and Waste Management Division

3 STATE BOARD OF HEALTH

4 RADIATION CONTROL - REGISTRATION OF RADIATION MACHINES, FACILITIES AND SERVICES

5 6 CCR 1007-1 Part 02

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

7 Adopted by the Board of Health ~~June 18~~December 17, 2014

8 PART 2: REGISTRATION OF RADIATION MACHINES, FACILITIES AND SERVICES

9 2.1 Purpose and Scope.

10 2.1.1 Authority

11 2.1.1.1 Rules and regulations set forth herein are adopted pursuant to the provisions of sections  
12 25 1 108, 25 1.5 101(1)(l), and 25-11-104, CRS.

13 2.1.2 Basis and Purpose.

14 2.1.2.1 A statement of basis and purpose of these regulations accompanies this part and  
15 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 (3) Registration of persons providing radiation machine services including assembly,  
21 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 2.1.4.1 The requirements and provisions of this part apply to each person who uses, operates,  
26 services or certifies radiation machines and to each registrant or applicant for registration  
27 subject to this part unless specifically exempted.

28 2.1.4.2 The provisions of this part are in addition to (and not in substitution for) other applicable  
29 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.

THESE COMMENTS ARE **NOT** 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 BODY OF THE RULE ARE FOR INFORMATION PURPOSES ONLY AND ARE NOT CONSIDERED PART OF THE RULE.

EDITORIAL NOTE 2: Yellow highlighting indicates modified wording since the request for rulemaking before the Colorado Board of Health on October 15, 2014.

**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 **“ARRT(N)” means an individual who is registered by the ARRT in Nuclear Medicine**  
37 **Technology.**

**Comment [JJ3]:** Definition added consistent with the use of the term in later sections of Part 2.

38 “ARRT(R)” . See “radiologic technologist” .

39 **“ARRT(T)” means an individual who registered by the ARRT in Radiation Therapy.**

**Comment [JJ4]:** Definition added consistent with the use of the term in later sections of Part 2.

40 “ASRT” means the American Society of Radiologic Technologists.

41 “Assembler” means any person engaged in the business of assembling, replacing, or installing  
42 one or more components into a radiation machine system or subsystem.

43 “Calibration” means to adjust and/or determine the:

- 44 (1) Response or reading of an instrument relative to a series of conventionally true  
45 values; or
- 46 (2) Strength of a radiation source relative to a standard or conventionally true value.

47 “Certification Evaluation” (CE) means the evaluation of a radiation machine at a facility by a  
48 qualified inspector or the Department for the purpose of ascertaining the performance of the  
49 radiation machine system and/or facility in order to determine conformance with these  
50 regulations.

51 **“Certified Nuclear Medicine Technologist” means an individual who is currently registered**  
52 **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 in later sections of Part 2.

53 “Computed tomography” (CT) means the production of a tomogram by the acquisition and  
54 computer processing of x-ray transmission data. For the purposes of Part 2, the requirements  
55 stated for computed tomography machines do not apply to “Volumetric Dental Imaging Systems”.

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

- 58 (1) The direct supervisor is not required to be present in the room when the procedure is  
59 performed.
- 60 (2) Direct supervision during the performance of a mammography examination means  
61 that the supervisor is present to observe and correct, as needed, the  
62 performance of the individual being supervised who is performing the  
63 examination.

64 “Dual-energy X-Ray Absorptiometry” (DXA, previously DEXA) means an imaging technique using  
65 radiation machines for quantifying bone density, used in the diagnosis and management of  
66 osteoporosis.

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

69 “Facility” means, for purposes of Part 2, the location within one building (or vehicle, or under one  
70 roof, or at one address) and under the same administrative control, at which a radiation machine  
71 is or was installed, operated and/or located.

72 “FDA” means the United States Food and Drug Administration.

73 “Fluoroscopy” means a technique for generating x-ray images and presenting them  
74 simultaneously and continuously as visible images.

75 “Industrial Radiography” means an examination of the structure of materials by the  
76 nondestructive method of utilizing ionizing radiation to make radiographic images.

77 “Inter-comparison” means the direct comparison, in accord with 2.4.4.5, of two instruments  
78 designed to measure the same physical quantity.

79 “Limited-scope operator” (LSO) means an individual who has taken and passed a required test  
80 and has approval by the Department pursuant to 2.4.5.1 to operate x-ray systems and to conduct  
81 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.

87 “Performance adjustment” means the adjustment or repair of a function (not including the setting  
88 of operator-selectable functions, such as time, mA and/or kVp for an individual exposure) of an x  
89 ray machine or imaging system that is required to bring the machine into compliance with these  
90 regulations and the specifications.

91 “Provisional Mammographer” means an individual who meets the requirements of 2M.2 and has  
92 current department approval to perform mammograms under direct supervision in order to meet  
93 the requirements to become a Qualified Mammographer.

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

98 “QE(R)” means a qualified expert medical physicist approved to design or evaluate shielding for  
99 radiation machines used in the healing arts.

100 “QE(S)” means a qualified expert physicist approved to design or evaluate shielding for radiation  
101 machines used for non-healing arts purposes.

102 “QE(T)” means a qualified expert medical physicist approved to design or evaluate shielding for  
103 radiation machines used in radiation therapy.

104 “Qualified expert” (QE) means an individual who meets the applicable requirements of Appendix  
105 2B or 2C and has current Department approval as QE(S), QE(R), or QE(T) to evaluate radiation  
106 shielding design and recommend radiation safety practices, as provided in 2.4.3.

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

111 “Qualified mammographer” means a mammographer who meets the applicable requirements of  
112 Appendix 2M.

113 “Qualified trainer” (QT) means an individual whose training and experience adequately prepares  
114 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 ~~radiography~~radiologic technology with the American Registry of Radiologic Technologists,  
117 designated ARRT(R).

**Comment [JJ8]:** The definition language is modified slightly in accordance with the language used by the American Registry of Radiologic Technologists (<https://www.arrt.org/About-ARRT/Designation-Awarded>).

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.

123 “Service company” means a person who is engaged (or offers to engage) in the business of  
124 selling, leasing, transferring, lending, assembling, installing, maintaining, repairing, storing,  
125 trading out, disabling, or disposing of radiation machines and their related components, or is  
126 engaged in the business of furnishing or offering to furnish radiation machine servicing or  
127 services.

128 “Service technician” means an individual who is employed by a service company to perform  
129 radiation machine servicing or services.

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

140 **EDITORIAL NOTE: \*\*\*FOR BREVITY OF THE DOCUMENT, UNAFFECTED SECTIONS HAVE BEEN**  
141 **REMOVED FROM THE DRAFT. THERE ARE NO CHANGES PROPOSED FOR THESE SECTIONS\*\*\***  
142

**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 (1) Each individual operating an x-ray system on living humans in the State of Colorado,  
146 shall be registered as a Limited Scope Operator consistent with 2.4.5.1(2),  
147 except for:

148 (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,  
149 2.6.1.11, and 2.6.1.12, or

150 (b) Those individuals having current registration with the American Registry of  
151 Radiologic Technologists in radiography.

152 (2) Registration

153 (a) The applicant for LSO registration must complete the requirements of 2D.2.1,  
154 2D.2.2 and 2D.2.3 in a structured and documented training program in order to  
155 apply for registration as a Limited Scope Operator.

156 (b) Each Limited Scope Operator shall complete an application with all of the  
157 information required by the form and instructions, together with the fee required  
158 by Part 12, Category 24 and the fee required by the American Registry of  
159 Radiologic Technologists.

160 (i) The Form R-70 series application shall be used to initiate the  
161 registration process.

162 (ii) The Form R-71 series application shall be used to confirm the  
163 completion of the requirements of 2D.2.1, 2D.2.2 and 2D.2.3.

164 (c) Application for registration as a Limited Scope Operator shall be made within  
165 one year upon completion of the requirements of 2D.2.1 and within ninety (90)  
166 calendar days upon completion of the requirements of 2D.2.2 and 2D.2.3.

167 (d) If an applicant cannot achieve a passing score per 2D.2.4 within three  
168 attempts, the applicant must restart the training required by 2D.2.1, 2D.2.2, and  
169 2D.2.3.

170 (e) Registrants must meet the requirements of 2D.2.5 in order to renew the  
171 Limited Scope Operator approval.

172 (i) The Form R-95R-90 series application shall be used to renew the  
173 registration for a Limited Scope Operator.

174  
175 2.4.5.2 Computed Tomography Operator ~~Subject to Appendix 2E.~~

176 (1) Each individual operating a computed tomography system on living humans shall  
177 hold a current, valid registry in Radiography, Nuclear Medicine, or  
178 Radiation Therapy issued by ARRT, NMTCB, or where the individual has  
179 obtained written approval from the Department, another nationally  
180 recognized registry organization not listed herein, shall be registered  
181 with the Department as a Computed Tomography Operator, except for:

182 (a) Meet the requirements of 2E.1.1, 2E.1.2, 2E.1.3, or 2E.1.4 for the  
183 applicable use specified in 2.6.1.7;

**Comment [BNV10]:**  
The wrong application form was referenced in the last revision of Part2.  
This change corrects this error.

**Comment [JJ11]:**  
Following review by the Colorado Attorney General's Office, the language is modified here for clarity and understanding. The yellow highlight shows the modified wording since the request for rulemaking before the Colorado Board of Health on October 15, 2014.

**Comment [JJ12]:**  
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).

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.

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or

(b) Meet the requirements of Appendix 2E.2 and be registered with the Department as a Colorado Computed Tomography Operator;

or

(c) As a CT operator in training, be under the direct supervision of an individual who meets the requirements of 2.4.5.2(a) or 2.4.5.2(b).

~~(a) Those individuals having current registration with the American Registry of Radiologic Technologists in radiography and certification in computed tomography; or~~

~~(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~~

~~(c) those individuals having current registration with the American Registry of Radiologic Technologists in radiation therapy.~~

**Comment [JJ13]:** Language is added here based on stakeholder comment and discussions whereby 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.

(2) Registration

(a) The applicant for Colorado Computed Tomography Operator must complete the requirements of Appendix 2E, 2E.2 in a structured and documented training program.

(b) The application for registration as a Colorado Computed Tomography Operator shall contain all of the information required by the form and instructions, together with the fee required by Part 12, Category 24.

(i) The Form R-95 series shall be used to document the requirements of 2E.2.2, 2E.2.3 and 2E.2.4.

**Comment [JJ14]:** The modified language in this section is to clearly identify that the registration process is applicable only to the Colorado CT Operator training registration. (Individuals certified in CT by a national registry organization do not need to also have a Colorado registration).

(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 Computed Tomography Operators previously registered with the Department but will cease registration of new Colorado CT Operators.~~

**Comment [JJ15]:** 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.

The proposed change clarifies that the Department will continue to recognize those individuals previously "certified" under this program but will not register any new individuals after July 31, 2017.

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

**Comment [JJ16]:** EDITORIAL NOTE ONLY – NOT PART OF RULE.

217 **2.6 Facility Registrant Responsibilities.**

218 2.6.1 In any facility regulated by or requiring registration under these regulations, the registrant shall  
219 allow only individuals who are adequately trained in radiation safety and the safe and effective  
220 use of the machine to operate any radiation machine.

221 2.6.1.1 The facility registrant shall document evaluation of the qualifications of each individual  
222 permitted to operate any radiation machine at the facility.

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

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

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

231 (b) The list of all operators and supervisors shall be updated at least annually as  
232 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 (c) Be produced for examination upon request during any inspection conducted  
237 under the requirements of these regulations.

238 2.6.1.2 A physician, chiropractor, dentist, podiatrist, or veterinarian who has a current active  
239 license from the appropriate State of Colorado professional licensure board is considered  
240 to have demonstrated adequate training in radiation safety and the safe and effective use  
241 of the radiation machine (consistent with 2.6.1.5) and may operate radiation machines as  
242 part of medical, chiropractic, dental, podiatric or veterinary practice, respectively.

243 2.6.1.3 For a radiologist assistant "adequately trained" shall mean that the individual is qualified  
244 as provided in Appendix 2G.

245 2.6.1.4 For any radiographic x-ray system used on a living human (consistent with 2.6.1.2,  
246 2.6.1.3, and 2.6.1.5 through 2.6.1.14), "adequately trained" shall mean that the individual  
247 meets the requirements of Appendix 2D.

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

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

255 2.6.1.5 For fluoroscopy equipment used in examination of a living human, "adequately trained"  
256 shall mean that, in addition to meeting all applicable requirements in 2.6.1.1 through  
257 2.6.1.4, each individual who either supervises a fluoroscopy procedure or operates a  
258 fluoroscopy imaging system shall have adequate training in its safe operation. This  
259 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 2.6.1.6 For mammography equipment used in radiography of the human breast, "adequately
- 266 trained" shall mean that the individual operator meets the requirements of Appendix 2M.
- 267 2.6.1.7 For any computed tomography (CT) system used on a living human, **(excluding**
- 268 **Volumetric Dental Imaging Systems)** "adequately trained" shall mean that the
- 269 individual operator meets the **following requirements:**~~of Appendix 2E.~~
- 270 **(1) Individuals operating a CT system for general imaging purposes shall meet the**
- 271 **requirements of 2E.1.1, 2E.1.4, or 2E.2; or**
- 272 **(2) Individuals operating a CT system in conjunction with nuclear medicine**
- 273 **Positron Emission Tomography (PET-CT) or Single Photon Emission Computed**
- 274 **Tomography (SPECT-CT) systems (known as hybrid or fusion imaging machines)**
- 275 **shall meet the requirements of 2E.1.1, 2E.1.2, 2E.1.4, or 2E.2; or**
- 276 **(3) Individuals operating a CT system used in conjunction with radiation**
- 277 **therapy procedures (treatment simulation or tumor localization imaging) shall meet**
- 278 **the requirements of 2E.1.1, 2E.1.3, 2E.1.4, or 2E.2.**
- 279 **Individuals who are in-training to become a CT operator, shall not be considered**
- 280 **adequately trained until they have fully met the requirements of 2.6.1.7(1), or 2.6.1.7(2), or**
- 281 **2.6.1.7(3) and shall not operate such CT machines except under the direct supervision of**
- 282 **an individual who meets the requirements of 2.6.1.7(1), or 2.6.1.7(2), or 2.6.1.7(3).**
- 283 2.6.1.8 For any bone densitometry equipment used in examination of a living human,
- 284 "adequately trained" shall mean that the individual operator meets the requirements of
- 285 Appendix 2F.
- 286 2.6.1.9 For radiographic equipment used in the practice of medicine, "adequately trained" shall
- 287 mean that the individual operator meets all applicable requirements of the Colorado State
- 288 Board of Medical Examiners (in particular Rule 700, "State Board of Medical Examiners
- 289 Rules and Regulations Regarding Education and Training Standards for Unlicensed
- 290 Personnel Exposing Ionizing Radiation" of 3 CCR 713-16).
- 291 2.6.1.10 For radiographic equipment used in chiropractic, "adequately trained" shall mean that
- 292 the individual operator meets all applicable requirements of the Colorado State Board of
- 293 Chiropractic Examiners (in particular Rule 19, "Safety Training for Unlicensed
- 294 Chiropractic Personnel," of 3 CCR 707-1).
- 295 2.6.1.11 For radiographic equipment used in dentistry, including Volumetric Dental Imaging
- 296 Systems, "adequately trained" shall mean that the individual operator meets all
- 297 applicable requirements of the Colorado State Board of Dental Examiners (in particular
- 298 Rule X, "Minimum Standards for Qualifications, Training and Education for Unlicensed
- 299 Personnel Exposing Patients to Ionizing Radiation," of 3 CCR 709-1).
- 300 2.6.1.12 For radiographic equipment used in podiatry, "adequately trained" shall mean that the
- 301 individual operator meets all applicable requirements of the State of Colorado Podiatry
- 302 Board (in particular Rule 700 of 3 CCR 712-9).
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**Comment [JJ17]:**  
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.

**Comment [JJ18]:**  
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.  
  
Similar to other parts of the rule, this section also defers to the appendices (2E) for the applicable training requirements.

**Comment [JJ19]:** Following review by the Colorado Attorney General's Office, the word "someone" is changed to "an individual" for clarity and understanding. The yellow highlight shows the modified wording since the request for rulemaking before the Colorado Board of Health on October 15, 2014.

**Comment [JJ20]:**  
Language is added to more clearly delineate the requirements for individuals who are in-training to become fully qualified and registered CT Operators.

- 307 2.6.1.13 For radiographic equipment used in veterinary medicine, "adequately trained" shall
- 308 mean that the individual operator meets all applicable requirements of the State of
- 309 Colorado Board of Veterinary Medicine (in particular 4 CCR 727 1).
  
- 310 2.6.1.14 An individual, enrolled in an ARRT-recognized program or graduated from such a
- 311 program, may operate radiation machines so long as the individual works under the direct
- 312 supervision of a radiologic technologist or other qualified trainer and has documentation
- 313 of having completed education and experience equal to that specified in the program.
  
- 314 (1) A graduate from an ARRT-recognized program is granted ninety (90) calendar days
- 315 from the date of graduation to schedule, take and pass the ARRT radiologic
- 316 technology registry examination.
  
- 317 (2) During the 90-day period allowed by 2.6.1.14(1), the graduate is considered to satisfy
- 318 Appendix 2D requirements.
  
- 319 (3) A student or graduate who fails to pass the registry examination has not met the
- 320 requirements of Appendix 2D and shall not operate any radiation machine
- 321 system on a living human unless otherwise authorized by the Department.
  
- 322 2.6.1.15 For radiation machines used in non-healing-arts applications, "adequately trained" shall
- 323 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 (2) The requirements of 2N.2 apply to all non-healing-arts applications (including but not
- 326 limited to analytical, forensic, morgue, and homeland security uses) not subject
- 327 to Part 5.
  
- 328 2.6.1.16 For assembly, installation and repair of radiation machines, "adequately trained" shall
- 329 mean that the individual service technician meets the requirements of Appendix 2H.
  
- 330 2.6.1.17 Department recognition of training as adequate pursuant to 2.6.1.3 through 2.6.1.16
- 331 shall pertain only to the areas of training and experience specifically identified in these
- 332 regulations.
  
- 333 2.6.1.18 The Department may, upon application or upon its own initiative, accept as being
- 334 adequate:
  
- 335 (1) Documented combinations of radiation safety training and experience; or
  
- 336 (2) Equivalent approval by another state or agency.

338 **EDITORIAL NOTE: \*\*\*FOR BREVITY OF THE DOCUMENT, UNAFFECTED SECTIONS HAVE BEEN**

339 **REMOVED FROM THE DRAFT. THERE ARE NO CHANGES PROPOSED FOR THESE SECTIONS\*\*\***

341 **PART 2, APPENDIX 2E: COMPUTED TOMOGRAPHY (CT) ADEQUATE RADIATION SAFETY**

342 **TRAINING AND EXPERIENCE**

343 Each operator of a computed tomography system shall hold a current, valid registry in Radiography,

344 Nuclear Medicine, or Radiation Therapy issued by ARRT, NMTCB, or, where the operator has

345 obtained written approval from the Department, another nationally recognized registry

346 organization not listed herein, shall meet the following experience and education requirements:

347 2E.1 ~~is certified~~ **Certification:**

**Comment [JJ21]:** EDITORIAL NOTE ONLY – NOT PART OF RULE.

**Comment [JJ22]:**  
Following review by the Colorado Attorney General’s Office, the language is modified here for clarity and understanding. The yellow highlight shows the modified wording since the request for rulemaking before the Colorado Board of Health on October 15, 2014.

**Comment [JJ23]:** The language added here is 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 use.

**Comment [JJ24]:**  
The proposed changes to 2E.1 clarify the types of certification(s) and training required depending upon the type of use.

The changes are made based on the stakeholder suggestion and concerns expressed during the last amendment of Part 2 before the Board of Health (June 2014).

348 2E.1.1 For general imaging computed tomography procedures, each operator is certified;

349 2E.1.1.1 As By the ARRT (R) and also certified in computed tomography by ARRT,  
350 ARRT(CT); or

351 2E.1.1.2 By the Nuclear Medicine Technology Certification Board (NMCTB) in  
352 computed tomography, CNMT(CT);

353 Or

354 2E.1.2 For nuclear medicine (hybrid or fusion imaging) computed tomography procedures  
355 such as PET-CT or SPECT-CT, is certified;

356 2E.1.2.1 by the ARRT in nuclear medicine As as ARRT(N) or

357 2E.1.2.2 by the NMTCB as CNMTARRT(T);; or

358 2E.1.2.3 in accordance with 2E.1.1.

359 orOr

360 2E.1.3 As CNMT by the Nuclear Medicine Technology Certification Board; For simulation or  
361 localization computed tomography procedures associated with radiation therapy,  
362 is certified;

363 2E.1.3.1 by the ARRT in Radiation Therapy, ARRT(T); or-

364 2E.1.3.2 in accordance with 2E.1.1.

365 Or

366 or2E.1.4 Is certified byBy a specialty board determined by the department to have substantially  
367 equivalent requirements for certification in computed tomography as the American  
368 Registry of Radiologic Technologists.

369 or

370 2E.2 Prior to July 3031, 201745, is certified as ARRT(R) and is also registered with the Department as  
371 a Computed Tomography Operator; by has satisfactorily completedcompleting the  
372 requirements of 2E.2.1 through 2E.2.3, inclusive.;

373  
374 2E.2.1 At least 60 hours of didactic training providing the minimum hours of instruction in the  
375 specific subjects listed in 2E.2.1.1 through E.2.1.12:

376 2E.2.1.1 Intravascular (IV) Procedures—2 hours

377 (1) Venipuncture

378 (a) Site selection

379 (b) Aseptic and sterile techniques

380 (2) Injection techniques

381 (a) Manual

382 (b) Automatic

**Comment [JJ25]:**  
The requirements of 2E.2 apply to those wishing to become a Colorado “certified” CT operator.  
  
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 NMTCB.

- 383 (i) Single phase
- 384 (ii) Multi-phase
- 385 (iii) Flow rate
- 386 2E.2.1.2 Contrast Agent—6 hours
- 387 (1) Types
- 388 (a) Ionic
- 389 (b) Non-ionic
- 390 (c) Water soluble
- 391 (d) Air
- 392 (e) Water
- 393 (2) Administration route and dose calculations
- 394 (a) IV (angiocatheter or butterfly)
- 395 (b) Oral
- 396 (c) Rectal
- 397 (d) Intrathecal
- 398 (e) Catheters
- 399 (3) Special considerations
- 400 (a) Allergy preparation
- 401 (b) Pathologic processes
- 402 (c) Contraindications
- 403 (d) Indicators
- 404 (4) Adverse reactions
- 405 (a) Recognition and assessment of symptoms
- 406 (b) Treatment (e.g., compresses, medications)
- 407 (c) Documentations
- 408 2E.2.1.3 Radiation Safety and Dosimetry—6 hours
- 409 (1) Technical factors affecting patient dose
- 410 (2) Radiation protection
- 411 (3) Dose Measurement
- 412 (4) Pediatric dose reduction

- 413 2E.2.1.4 Type of Study
- 414 (1) Head
- 415 (2) Neck
- 416 (3) Chest
- 417 (4) Abdomen
- 418 (5) Pelvis
- 419 (6) Musculo-skeletal
- 420 2E.2.1.5. Sectional Anatomy (for each type of study listed in 2E.2.1.4)
- 421 (1) Sagittal plane
- 422 (2) Transverse plane (axial)
- 423 (3) Coronal plane
- 424 (4) Off-axis (oblique)
- 425 (5) Landmarks
- 426 (6) Pathology recognition
- 427 2E.2.1.6 Contrast Media (for each type of study listed in 2E.2.1.4)
- 428 (1) Types of agents
- 429 (2) Indications
- 430 (3) Contraindications
- 431 (4) Dose calculation
- 432 (5) Administration route
- 433 (6) Scan/prep delay
- 434 2E.2.1.7 Scanning Procedures (for each type of study listed in 2E.2.1.4)
- 435 (1) Positioning
- 436 (2) Scout
- 437 (3) Acquisition methods (e.g., spiral, non spiral, dynamic, multi-row detector)
- 438 (4) Parameter selection (e.g., slice thickness, mA, time, algorithm, pitch)
- 439 (5) Protocol modification for pathology or trauma
- 440 (6) Cardiac gating
- 441 2E.2.1.8 Special Procedures (for each type of study listed in 2E.2.1.4)
- 442 (1) 3-D studies

- 443 (2) Biopsies
- 444 (3) Radiation therapy planning
- 445 (4) Drainage and aspiration
- 446 (5) Post-myelography
- 447 (6) CT arthrography and angiography
- 448 (7) Cardiac gating
- 449 2E.2.1.9 Systems Operation and Components—4 hours
- 450 (1) Tube
- 451 (2) Generator and transformers
- 452 (3) Detector configuration
- 453 (4) Data Acquisition Systems (DAS)
- 454 (5) Collimation
- 455 (6) Computer and array processor
- 456 (7) Equipment maintenance
- 457 2E.2.1.10 Image Processing & Display—10 hours
- 458 (1) Image reconstruction
- 459 (a) Filtered back projection reconstruction
- 460 (b) Reconstruction filters (algorithms)
- 461 (c) Raw data vs. image data
- 462 (d) Prospective / retrospective reconstruction (single and multi-row)
- 463 (e) Effective slice thickness
- 464 (f) Reconstruction interval
- 465 (2) Image display
- 466 (a) Pixel, voxel
- 467 (b) Matrix
- 468 (c) Image magnification
- 469 (d) Field of view (scan, reconstruction and display)
- 470 (e) Attenuation coefficient
- 471 (f) Window level, window width
- 472 (g) Plane specification (X, Y, Z coordinates)

- 473 (h) Cine
- 474 (i) ROI (single and multiple image)
- 475 (3) Post-processing
  - 476 (a) Multiplanar reformation
  - 477 (b) 3-dimensional rendering (MIP, SSD, VR)
  - 478 (c) Quantitative measurements (volume, distance, diameter)
- 479 (4) Data management
  - 480 (a) Hard/soft copy
  - 481 (b) Storage / archive
  - 482 (c) PACS
  - 483 (d) Security and confidentiality
  - 484 (e) Networking
- 485 2E.2.1.11 Image Quality—4 hours
  - 486 (1) Spatial resolution
  - 487 (2) Contrast resolution
  - 488 (3) Temporal resolution
  - 489 (4) Noise and uniformity
  - 490 (5) Quality assurance procedures
  - 491 (6) CT number
  - 492 (7) Linearity
- 493 2E.2.1.12 Artifact Recognition and Reduction—4 hours
  - 494 (1) Beam hardening
  - 495 (2) Partial volume averaging
  - 496 (3) Motion
  - 497 (4) Metallic
  - 498 (5) Edge gradient
  - 499 (6) Patient positioning
  - 500 (7) Equipment-induced
    - 501 (a) Rings
    - 502 (b) Streaks

503 (c) Tube arcing

504 (d) Cone beam; and

505 2E.2.2 At least 480 hours of clinical training during which time computed tomography  
506 examinations are performed only under direct supervision of ~~an ARRT(N), ARRT(R),~~  
507 ~~ARRT(T) or CNMT~~ **a qualified** computed tomography operator or other qualified trainer  
508 **who meets the requirements of 2E.1.1, 2E.1.4, or 2E.2; and:**

509 2E.2.3 ~~Documented performance~~ **Has performed**, under direct supervision, ~~of the following~~  
510 **computed tomography** imaging procedures ~~(at least 60 examinations in total, with~~  
511 ~~record of each examination kept on file):~~

512 2E.2.3.1 Head—10 examinations;

513 2E.2.3.2 Neck—10 examinations;

514 2E.2.3.3 Chest—10 examinations;

515 2E.2.3.4 Abdomen—10 examinations;

516 2E.2.3.5 Pelvis—10 examinations; and

517 2E.2.3.6 Musculo-skeletal—10 examinations; ~~and~~

518  
519 ~~2E.2.4 Or, meeting all requirements of 2E.2.1 and 2E.2.2, is allowed to be a computed~~  
520 ~~tomography operator at a facility that performs only the particular procedure(s) for which record(s)~~  
521 ~~document prior completion of the full number of examinations required in 2E.2.3;~~

522  
523 2E.2.45 Or, having completed didactic training in accord with Section 2E.2.1, is allowed under  
524 general supervision during the clinical training required by 2E.2.2 to **perform the individual**  
525 **procedure(s) outlined in 2E.2.3.1 through 2E.2.3.6 for which the individual has documented the**  
526 **completion of the number of examinations required in 2E.2.3.** ~~be a computed tomography operator~~  
527 ~~only for the particular procedure(s) for which record(s) document prior completion of the full number of~~  
528 ~~examinations required in 2E.2.3;~~

**Comment [BNV26]:** 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 [JJ27]:** 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 [JJ28]:** EDITORIAL NOTE ONLY – NOT PART OF RULE.

529 **EDITORIAL NOTE: \*\*\*FOR BREVITY OF THE DOCUMENT, SUBSEQUENT UNAFFECTED**  
530 **SECTIONS HAVE BEEN REMOVED FROM THE DRAFT. THERE ARE NO CHANGES PROPOSED**  
531 **FOR THESE SECTIONS\*\*\***  
532

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534  
535