

Part 6
“X-rays in the Healing Arts”

Part 2
“Registration of Radiation Machines,
Facilities and Services”

Stakeholder Engagement
Summer 2018

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Topics for discussion

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- Introductions and general information
- Where we've been - 2017 early stakeholder engagement
- Purpose and drivers for proposed rule changes
- Highlights of proposed changes by section
- Path forward / next steps
- Staying connected

Where we've been...

- Staff review and draft development
- 2017 early stakeholder engagement process
 - Draft of model regulation Part F posted
 - Series of stakeholder meetings held
 - Gathered information, data, and feedback from stakeholders on the impacts – positive or negative – of changes being considered;
 - Identification of particular challenges or limitations regarding changes being considered;
 - Use the information gathered to help guide Colorado's Part 6 rule
- Radiation Advisory Committee review
 - Initial discussions began in mid-2016
 - Drafts review over past 5 months/4 meetings

Why is CDPHE proposing changes to 6 and 2?

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- Colorado law (statute) requires radiation regulations “be consistent with” the model regulations of the CRCPD**.
- In 2015, the CRCPD [Part F model regulation](#) - the parallel rule to Colorado Part 6 - was significantly revised.
- The changes in F impact a wide variety of medical uses of x-ray systems

**CRCPD is the Conference of Radiation Control Program Directors, Inc.

What drove changes in Part F?

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- EPA Federal Guidance Report 14
- NEMA XR 29-2013
- FDA regulatory changes
- Recommendations of the International Commission on Radiological Protection, ACR, AAPM
- National attention and concerns over elevated exposures during some of the higher dose modalities (e.g., CT and Fluoroscopy/FGI)

What are the more significant changes being considered for Part 6?

Definitions (6.2)

- Deletion of a number of unused and perhaps outdated definitions found in current Part 6
- Updates and revisions to definitions for consistency with Part F and federal rules (CFR's)

- More significant new definitions added to the proposed rule include:
 - “Alert value” – a dose index set by user (registrant) to alert a CT or FGI operator that standardized protocols may be exceeded during a scan.
 - Brings attention to imaging procedures that are “out of the norm”
 - “Case review committee” or CRC – This term is a modification of the Radiation Protocol Committee definition (from Part F) but is specific to Fluoroscopically Guided Interventional procedures.
 - “Fluoroscopically-Guided Interventional (FGI) Procedures” – interventional or therapeutic procedure...using fluoroscopy to localize or characterize a lesion/diagnostic site/treatment site to monitor the procedure and control and document the therapy.
 - “Radiation Protocol Committee” – ...individuals at a CT facility responsible for... review/management of CT protocols to ensure...diagnostic image quality at the lowest radiation dose...

Additional definitions of note

- “Mammography”
- “Noise” (now specific to CT)
- “Notification value”
- “Size-specific dose estimate (SSDE)”
- “Substantial radiation dose level (SRDL)”
- “Hand-held x-ray equipment”

General Requirements (Section 6.3)

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- Supervision of x-ray machine use/ordering x-ray imaging
 - Proposed rule language (6.3.1.6, 6.3.3.5) defers to other licensing boards, licensing, regulations or laws and scope of practice to supervise the use of an x-ray machine or for ordering x-ray imaging studies
 - Intended to allow flexibility as more allied health and/or physician extenders are used for performing or supervising the performance of x-ray imaging studies
 - Limit the need for part 6 changes in the future
 - We need stakeholder feedback on this

Human research subjects

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- New proposed provisions/requirements in 6.3.3.6 are added and are applicable to those facilities using x-ray machines in human research
 - Requirements are modeled after similar requirements for radioactive materials facilities

Radiation safety

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- Enhancement of current Part 6 and Part 4 requirements, but specific details for x-ray are added
- Specifies limiting useful beam to clinical area of interest; use of techniques appropriate to patient size; limitations on holding of x-ray tube housing; methods to verify patient identity, etc.
- Annual evaluation of protective apparel (lead gloves, aprons, collars)
 - Visual/tactile inspection, x-ray inspection where available

Quality Assurance program

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- The current Part 6 rule contains QA requirements, but the proposed language expands some requirements and provides additional detail. Requirements include:
 - Designating a person to manage QA program
 - Written QA/QC procedures
 - Perform/document annual review of QA program
 - Check images for artifacts / take action as needed
 - Performing repeat / reject analysis of radiographic images quarterly in accordance with national organizations*
 - Performing preventative maintenance on machines*

*Excludes most dental, vet, and podiatry facilities

General Requirements (Section 6.4)

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- Limited changes in this section

Fluoroscopy Requirements (Section 6.5)

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- A number of technical requirements added based on FDA requirements/regulations
- Expansion/specificity of training for operators/supervising use of systems
 - All fluoroscopy use on living humans - Initial training
 - Users must meet appendix 2G requirements
 - No # hours specified for training
 - FGI use on living humans - Initial training
 - 1 hr hands on training
 - Periodic/ongoing training
 - Proposal for 2 hr refresher/in-service training required every 2 yrs
 - Implementation of training req's delayed until 2021



Requirement to establish a case review committee (CRC) for facilities performing FGI

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- Requires formation of a committee to review FGI procedures to lower dose/improve image quality
 - Requires written procedures, establishment of notification and alert values for procedures, establish methods to monitor patient dose
 - Requires records of radiation output (dose indices) sufficient to estimate radiation dose
 - Establish training procedures/processes for FGI use
 - Requires annual meeting and records of meetings

General Purpose Machine Req's (6.6)

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- Proposed requirement for the initial certification for digital systems be performed by a RMP
 - 90 day time period for initial certification maintained from current rule
- The technical requirements of this section are updated for consistency with FDA
- Added clarification for portable machines used in temporary locations
 - More than 5 days per month must meet stationary device requirements

Dental Machine Requirements (6.7)

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- Phase out of machines that operate below 51kVp
- QA requirements generally remain the same
- Clarification that CBCT systems used for dentistry would be required to follow applicable sections of 6.9 (w/exceptions)
- Consistent with model rule, proposal for annual evaluation of machine operators in 7 topic areas
- Thyroid shields specified for children but optional for adults for intraoral uses

Veterinary Requirements (6.8)

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- Minimal changes to this section
- Clarifying language to allow use of lead apron as alternate to other requirements

CT Requirements (Section 6.9)

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- Proposed language requires accreditation of CT facilities
 - 3+ yr phase-in period
 - Not applicable to CBCT machines, vet CT, treatment planning CT or SPECT/PET CT (used only for attenuation determination)
 - Use accreditations accepted by CMS
- Most technical and testing criteria remain the same or similar to current requirements but different wording

Requirement to establish a radiation protocol committee (RPC for CT)

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- Requires formation of a protocol committee to review CT procedures to lower dose/improve image quality
 - Review current CT protocols
 - Requires written procedures/protocols
 - Establishment of notification values, and alert values for procedures at the facility
 - Requires records of radiation output sufficient to estimate radiation dose
 - Establish procedures and training for CT use
 - Requires annual meeting and records of meetings
 - Can be integrated into other committee (e.g., a radiation safety committee)

Mammography Requirements (6.10)

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- Minimal changes that defer to the FDA MQSA requirements
- Updated definition for mammography (in 6.2) which resulted in removal of some parallel language in 6.10

Bone Densitometry Req's (6.11)

- New section that defers to federal rules and broad requirements

Part 2 Proposed Changes

Part 2

- A number of definitions have been updated or added, primarily with regard to the various certification bodies for operators
- The service company registration process has been streamlined a bit by reducing the documentation submitted
- Clarifying information added - registered technologists are not required to register with the Department
- The section for the Colorado CT operator qualification program was deleted as it expired in 2017

- A section is proposed to allow registration of Physician Assistants as fluoroscopy operators
 - Must meet certain training requirements, testing through ARRT via the state
 - Not effective until 2021
- Updates to the rule to defer and consolidate training requirements to Appendices or other licensing boards
- Updates to Appendix 2B (RMP) quals, 2E (CT operator), 2G (fluoro operator)

Next Steps

Where we're going...

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- Part 6 (&2) rulemaking process
 - Approximately 5,000 entities notified;
 - Draft of Parts 6 and 2 posted;
- ~90 day comment period through the end of August
- General stakeholder meetings
 - Scheduled for Denver, Colorado Springs, Grand Junction, and Loveland
 - Same format for all general stakeholder meetings
- “Focus group” stakeholder meetings
 - Purpose is to allow deeper review and discussion for specific sections of rules
 - Each meeting covers specific sections of the rule - see website for dates, times
 - Requires an RSVP
- Possible short comment period in fall
- Rulemaking before board of health in early 2019

- Stakeholders should review the proposed draft language of Part 6 and Part 2
- Provide written comments, by August 29, 2017 to: CDPHE_CORadRegs@state.co.us

- For more information:

- Visit

- <https://www.colorado.gov/pacific/cdphe/radiation-part-6-and-part-2-stakeholder-process>

- or-

- <https://www.colorado.gov/cdphe/radregs>

- [Click on “Stakeholder processes” link]

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Questions?