

Qualified Inspectors X-Rayport

From the desk of Brian Vamvakias, Unit Leader

Trade show policy

In general, the X-Ray Certification Unit does not allow the operation of any radiation equipment at trade shows because the regulations require registration of the facility, identification of a radiation safety officer and a radiation protection program; among many other requirements. This can be a large amount of work for the short time a company is present for a conference or trade show. Many companies are able to demonstrate their products without energizing the x-ray tube. If a company insists on energizing an x-ray machine at a trade show, the company must request a waiver from the various requirements present in the Regulations. For temporary use of an x-ray machine in Colorado, a facility may also request Reciprocity to use a machine under the regulations of another state. The state in which the x-ray machine is registered must have requirements very similar to Colorado otherwise the department will require additional conditions to ensure the safe use of the x-ray machine.



C-Arms and Shielding Designs

Colorado Rules and Regulations Pertaining to Radiation Control Part 6.3.2.1(2) requires that a shielding design be performed by a qualified expert based on the floor plan and equipment configuration of each radiation machine facility. The shielding design shall be completed prior to:

- construction of a new facility;
- any renovations or modifications that have the potential to alter the effectiveness of an existing shielding design;
- installation of new radiation producing equipment in an existing facility.

6.3.2.2.1(e) requires that a qualified expert review and modify a shielding design when mobile or non-handheld portable x-ray equipment is used regularly in the same location. Some

confusion exists concerning when a room requires a shielding design. If the facility has a policy or procedure that states a given room will be used to do x-ray exams, then that room must have a shielding design performed by a qualified expert or registered medical physicist. A facility that regularly uses a C-arm or portable x-ray in several different rooms must have a shielding design in each room. Exceptions are allowed for unusual circumstances or emergency situations.

2.7.1 states: No person shall certify or declare that a radiation machine or component is ready for its intended use until: (2.7.1.1) the shielding design has been completed as required by 6.3.2, as documented by a comment on Form FDA 2579, or a signed and

dated notification to the department. Service companies performing installations of x-ray producing machines shall indicate on the 2579 or equivalent form submitted to the x-ray certification department that the shielding design was complete and followed in the installation process.

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COLORADO
Department of Public
Health & Environment

Radiation regulation fee structure

The new Colorado Radiation Regulation fee structure was approved by the Colorado Board of Health on February 18, 2015. The new fee structure will go into effect March 30, 2015.

An updated Part 12 of the Colorado Rules and Regulations Pertaining to Radiation Control will be published on or about March 30, 2015.

The X-ray Certification Unit fees that are affected are outlined below.

Approved Fee Changes:

- Facility Registration Fee - A new fee created to cover the costs of doing our core business. Each facility will be required to pay an annual fee of \$50. Each x-ray facility will be mailed an invoice for this fee in the coming weeks. Instructions for paying the registration fee and updating the facility's registration will be included with the invoice.
- CE Label Fee - The Certification Evaluation (CE) label fee will change from \$50 to \$60.
- QI/Service Company/QE Registration Fee - The registration fees will change from \$160 for a two-year registration to \$100 for a one-year registration. All QIs, RMPs, and service companies due to renew in April 2015 and beyond will renew for a one-year period and pay \$100 per year. Registration changes made other than during the annual renewal will continue to incur a \$50 registration amendment fee.



You may see the changes to Part 12 as they were presented to the Colorado Board of Health on February 18, 2015 by clicking here: [Radiation Regulations Development—Part 12](#).

Additional information about these fees was presented in the January 2015 edition of the Qualified Inspectors and Service Company Rayports. You can access those editions using the link below:

[January 2015 Qualified Inspectors & Service Company Rayports](#)

Have you missed an issue of the Qualified Inspectors Rayport?

If you have missed the past issues or accidentally deleted the email that brought it to you, All past issues of the Qualified Inspectors Rayport are available on the x-ray unit's website: [Qualified Inspectors Rayports](#).

MQSA required annual survey vs. Colorado annual inspection

While the FDA allows for some flexibility in the timing for the required annual physics survey performed on a mammographic unit, the State of Colorado does not. The FDA will allow an occasional period of up to 14 months between surveys. The State of Colorado requires that each radiation producing machine be inspected annually by the end of the month in which the certification evaluation is due. Any mammographic unit that is inspected more than 12 months after the previous inspection would be considered past due and in violation of [Colorado Rules and Regulations Pertaining to Radiation Control Part 2.5.1](#).

Additional information: [Mammography Quality Standards Act Policy Guidance Help System](#)



COLORADO
Department of Public
Health & Environment

X-Ray Certification Program

4300 Cherry Creek Drive South
Denver, Colorado 80246



X-Ray Certification Unit Staff

Susan Quiet
Christine Irving
Tracey Luty
Erin Woodd
Brian Vamvakias, unit leader

Contact Information

Fax: 303-691-7841

Email: cdphe_xray_gisc@state.co.us

Comments: cdphe.hmxraycomments@state.co.us

Website: www.colorado.gov/cdphe/xray

Radiation Regulations: www.colorado.gov/cdphe/radregs



COLORADO
Hazardous Materials
& Waste Management Division
Department of Public Health & Environment