Qualified Inspectors X-Rayport

From the desk of Brian Vamvakias, Unit Leader

It is a general requirement for all facilities using radiation machines to have a Radiation Protection Program that is reviewed at least annually by the Radiation Safety Officer. There is a guidance document available on our web site that is a generic radiation protection program and can be used by most of the facilities registered with us. The "X-Ray Radiation Protection Program Guidance" document is found under the "Guidance and Policy" link on the X-Ray and Mammography web page. This document goes through the general requirements of registration, inspections and training and provides a checklist for the facility to verify and document their compliance. For this to be considered a valid Radiation Protection Program for the facility, each facility must supplement this document with their own specific radiation safety procedures and policies. The Qualified Inspectors and Service Company engineers should encourage their customers to use this guidance to review the requirements of the Regulations.

Machine installation by non-registered service companies

Department Policy

- Facilities are required to use registered service companies for installation and repair of radiation machines (6.3.1.5) to ensure that the radiation machine meets both Colorado and FDA requirements and is safe to operate. Also, any person in the business of selling, installing, or repairing radiation machines must be registered with the Department to ensure that the person has adequate training and experience to safely service radiation machines (2.4.2.1). In order to ensure that radiation machines are installed safely and legally, it is the Department's policy to require an evaluation by a registered Service Company on any machine that has been serviced (installed or repaired) by an unregistered service company.

Qualified Inspectors

- QI's are required to evaluate both the radiation machine(s) and the facility radiation protection program when they are present at a facility.
- The QI must determine if the facility has added any radiation machines to their facility. If the facility has added machines, the QI must verify that a Report of Assembly (FDA Form 2579, Colorado Form 2579, or equivalent) is present in the facility records for the new machine (2.6.6.4(3)).
  - Companies selling/installing x-ray machines that are not FDA certified are not required to use a "2579" form to notify the Department about a radiation machine sale, but they are still required to meet 2.7.2 requirements by informing the Department of the sale or install within 15 days of the event.
- The QI shall verify that the service company performing the machine service or install is registered with the Department.
  - If the facility has a radiation machine installed by a service company not currently registered with the Department, the facility must be cited for violating 6.3.1.5 on a 59-2 Facility Certification Evaluation report.
  - If a facility owner installed a radiation machine themselves and did not notify the Department within 15 days of the installation, the facility must also be cited for violation of 2.7.2.Department within 15 days of the installation, the facility must also be cited for violation of 2.7.2.

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COLORADO Department of Public Health & Environment

Machine installation by non-registered service companies (continued from Page 1)

- Shielding design – The QI shall check for the presence of a shielding design if required by the type of x-ray producing machine installed. The shielding design must have been performed by a Qualified Expert registered with the Department according to Appendices 6A, 6B, and 6C in Part 6 or 8.6.1. The service company or individual who installed the machine must have noted on the 2579 or equivalent that the install was performed in accordance with the requirements held forth in the shielding design, especially the room floor plan.

- If the radiation machine was not "installed" by a company registered with the Department, the facility has two methods of corrective action:

  1. The facility must contact a registered Service Company to certify that the installation was done according to FDA and Colorado standards and before the QI will certify the machine.

     - If the QI is also a registered Service Company, then the QI may certify that the installation was done according to FDA and Department requirements.

     - A "2579" report or equivalent form will be presented by the registered service company that all instruction manuals, written instructions and regulations applicable to the newly installed radiation machine system or components have been delivered to the registrant to meet the requirements of 2.7.2.4.

  2. The unregistered service company and the service engineer responsible for the original installation must apply to become registered with the Department. If the unregistered service person or company can meet the registration requirement within a period allowed by the Department, then the original installation or sale may be approved without recertification. Each instance will be evaluated on a case-by-case basis.

Service Company

- When a registered Service Company suspects a radiation machine was installed or is being serviced by an unregistered person or company, the registered service company should contact the Department and provide any information they have about the facility, machine or the person or company who worked on the radiation machine. The Department will proceed with an investigation and work with the facility to achieve compliance.

Question of the month

What constitutes service?

The X-ray Certification Unit is frequently contacted by facilities, service companies and qualified inspectors questioning whether certain actions are considered radiation machine "service" and if they fall under the auspices of the *Colorado Rules and Regulations Pertaining to Radiation Control (further referred to as "the regulations").*

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The regulations state:

2.4.2.1 Each person who is engaged (or offers to engage) in the business of selling, leasing, transferring, lending, assembling, installing, maintaining, repairing, storing, trading out, disabling or disposing of radiation machines and their related components, or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this State, shall be registered with the Department prior to performing such activities.

There are three primary "tests" for service work being considered a regulated service activity:

1. The installation, relocation, component replacement or repair of a radiation machine may affect the amount of radiation present in that facility or from that machine.
2. The installation, relocation or removal of a radiation machine will change the shielding design compliance.
3. The installation or relocation of a radiation machine will invalidate the Dosimetry Waiver variance that a facility may have in place.

Examples:

Q. A service technician moved a dental intraoral x-ray machine from one operatory to another. Is that service technician required to be registered as a service company with the Department?

A. Yes, because the moving of this machine could meet the requirements of tests number 1, 2 and 3 above. Additionally, the Department should be notified on a Report of Assembly because that machine may be new to the facility, relocation of a machine may affect the dosimetry waiver variance provided to that facility and an inspection should be conducted to verify that the unit is functioning and positioned properly in the facility.

Q. I am a dentist who bought a hand held intraoral x-ray unit on the internet. Do I need to be registered with the Department?

A. No. However, a report of assembly/sale must be delivered to the Department in 15 days from the purchase/delivery of the unit.

Q. In the same scenario as the previous question, I am the company the dentist purchased the hand held unit from. Do I need to be registered with the Department?

A. Yes, if you are in the business of selling radiation machines and their related components in Colorado. Additionally, a report of assembly/sale must be completed by your company and include the information that fulfills the requirements of regulation 2.7.2.

Q. My company removed an x-ray machine from a veterinarian's office. Are we required to be registered with the Department?

A. Yes. Your company is involved in potentially storing, trading out or disposing of radiation machines.

Q. I am a chiropractor who purchased a clinic building including an x-ray machine from another

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chiropractor. The x-ray machine was not moved from its original location. Did the previous owner of this clinic need to be registered with the Department since he "sold" me his x-ray machine?

A. No, because that previous owner is presumably not in the business of selling x-ray machines. However, you are required to inform the Department in 30 days of this transaction of the changes to the ownership of this x-ray machine. Also, the previous owner must supply you with the owner/user manuals, the current shielding design for that unit's installation and each inspection (radiation survey) for the life of that unit.

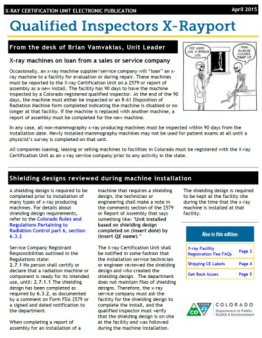
Have you missed a copy of the Qualified Inspectors Rayport?

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**.

January 2015

February 2015

March 2015



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COLORADO
Department of Public Health & Environment

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