

# Qualified Inspectors X-Rayreport

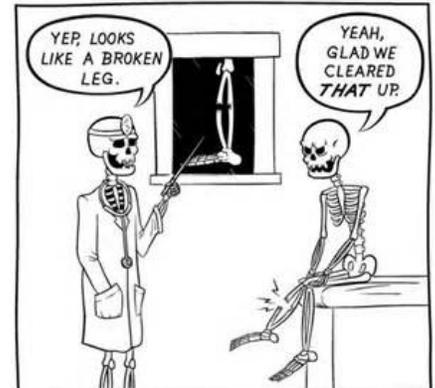
From the desk of Brian Vamvakias, Unit Leader

## X-ray machines on loan from a sales or service company

Occasionally, an x-ray machine supplier/service company will “loan” an x-ray machine to a facility for evaluation or during repair. These machines must be reported to the X-ray Certification Unit on a 2579 or report of assembly as a new install. The facility has 90 days to have the machine inspected by a Colorado registered qualified inspector. At the end of the 90 days, the machine must either be inspected or an R-61 Disposition of Radiation Machine form completed indicating the machine is disabled or no longer at that facility. If the machine is replaced with another machine, a report of assembly must be completed for the new machine.

In any case, all non-mammography x-ray producing machines must be inspected within 90 days from the installation date. Newly installed mammography machines may not be used for patient exams at all until a physicist’s survey is completed on that unit.

All companies loaning, leasing or selling machines to facilities in Colorado must be registered with the X-ray Certification Unit as an x-ray service company prior to any activity in the state.



## Shielding designs reviewed during machine installation

A shielding design is required to be completed prior to installation of many types of x-ray producing machines. For details about shielding design requirements, refer to the [Colorado Rules and Regulations Pertaining to Radiation Control part 6, section 6.3.2](#)

Service Company Registrant Responsibilities outlined in the Regulations state:  
**2.7.1** 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.

When completing a report of assembly for an installation of a

machine that requires a shielding design, the technician or engineering shall make a note in the comments section of the 2579 or Report of Assembly that says something like: “Unit installed based on shielding design completed on (insert date) by (insert QE name).”

The X-ray Certification Unit shall be notified in some fashion that the installation service technician or engineer reviewed the shielding design and who created the shielding design. The department does not maintain files of shielding designs. Therefore, the x-ray service company must ask the facility for the shielding design to complete the install, and the qualified inspector must verify that the shielding design is on site at the facility and was followed during the machine installation.

The shielding design is required to be kept at the facility site during the time that the x-ray machine is installed at that facility.

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**COLORADO**  
 Department of Public  
 Health & Environment

## X-ray Facility Registration Fees—FAQ's

### Q. What is the X-ray Facility Registration Fee?

- A. The x-ray facility registration fee is a new annual fee required by the *Colorado Rules and Regulations Pertaining to Radiation Control (6 CCR 1007-1)*. The rule was approved by the Colorado Board of Health in February 2015 and went into effect on March 30, 2015. This \$50 fee is charged to each x-ray machine facility in Colorado and is due by April 30 of each year. This fee is separate from the x-ray machine certification fee that is paid each time an x-ray machine is inspected.

### Q. Why are businesses using x-ray machines being charged this fee?

- A. Colorado x-ray machine certification fees have not changed since 2001 and the cost of registering over 5000 facilities and 15,000 x-ray machines has increased dramatically over 14 years. Prior to 2015, the only revenue received by the X-ray Certification Unit was from the radiation machine certification label fee. At the current rate, the X-ray Certification Unit requires an increase of revenue to continue to operate in compliance with state laws. An alternative fee structure that only increased the radiation machine certification label fees was determined to put an unacceptable burden on large facilities. The current fee structure allows a moderate increase in radiation machine certification label fees (from \$50 to \$60) with a \$50 x-ray facility registration fee that is the same for all facilities, regardless of how many x-ray machines are registered with that business.

### Q. What is my X-ray Facility Registration number?

- A. There are several places to find your registration number.

On the x-ray facility annual registration fee invoice the facility registration number can be found in two places:

- Following the “**Alt Cust#**” on the top portion of the invoice. The facility registration number is the number following “**XRAY**”; or

- In the center portion of the Invoice letter, following the words “**X-ray Annual Fee, Reg #**”

If you have a machine that has a blue/silver radiation machine certification label on it, your Registration number should be written in the box labeled “**Registration #**” at the top of the label.

Also, most correspondence sent to you from the department lists your facility’s registration number on the letter.

### Q. Which R-4 Registration of Facility forms do I complete?

- A. There are two forms R-4 Registration of Facility for Healing Arts and R-4 Registration of Facility for Non-Healing Arts. If you use your x-ray machine to image living human beings or animals as a physician, chiropractor, podiatrist, dentist or veterinarian, you are a healing arts facility. If you use your x-ray producing machine to image inanimate objects, you are a non-healing arts facility.

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**Q. Who do I make a check for fee payment out to?**

- A. Make the check payable to “CDPHE” and put the invoice number on the check. The invoice number is located in the top section of the invoice, following “Inv#” and starts with the letters “INV”.

**Q. I sold my practice to someone years ago. Do I need to pay the facility fee?**

- A. If you received an invoice, the X-ray Certification Unit database currently has your facility registered as possessing a radiation machine. If the entire practice was sold with the x-ray machines, please forward the invoice to the new owner. If the machines were sold independently from an office, please complete an R-61 Disposition of Radiation Machine Form to notify the X-ray Certification Unit with regards to the x-ray machine transfer. If you still have an x-ray machine in your possession, even in storage, you are required to pay the facility fee.

**Q. I have the machine in my office in storage but have not used it in years. Do I need to pay the facility fee?**

- A. You are required to pay the facility fee if you have an x-ray machine in your possession, even if they are not currently in use. If you do not have the machines in your possession, you must complete an R-61 Disposition of Radiation Machine Form to notify the X-ray Certification Unit with regards to the x-ray machine transfer.

**Q. I have more than one X-ray machine in my office but I only received one invoice. Will I be receiving an invoice for each machine?**

- A. This is a “per-facility” fee. Whether there is one machine or many at a facility, the facility pays one x-ray facility registration fee. The definition of facility from the *Colorado Rules and Regulations Pertaining to Radiation Control* is as follows:

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

**Q. We received several invoices at one address for multiple facilities. Why?**

- A. Each invoice was sent to the facility mailing address present in our database. Some registered facilities that are part of a corporation have requested that mail for each facility under their management be sent to the corporate headquarter mailing address. Also, some registered facilities share the same street address, but our database does not have a suite number for a particular business. It is possible that your facility received an invoice intended for a neighboring business. You should check that each invoice you have received belongs to your company.

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**Q. Where do I mail the payment to?**

- A. Please use the business reply envelope to mail your payment. Payments will be automatically routed to the proper recipient.

If the business reply envelope is not available, please send your payment to:

**Colorado Department of Public Health and Environment  
Shawna Schmalholz - HMWMD-B2  
4300 Cherry Creek Drive South  
Denver, CO 80246-1530**

**Q. When I am completing the R-4 Facility Registration form, do I check New Application or Annual Facility Registration?**

- A. If you received an invoice from the department, please select “Annual Facility Registration”.

Additional information about these fees was presented in the January 2015 edition of the Qualified Inspectors Rayport. You can access that edition using the following link: [January 2015 Qualified Inspectors Rayport](#).



### Shipping Certification Evaluation labels

The X-ray Certification Unit encourages mailing Certification Evaluation (CE) labels to qualified inspectors in order to better streamline the process. Requests for CE labels should be sent by email to [cdphe\\_xray\\_qisc@state.co.us](mailto:cdphe_xray_qisc@state.co.us).

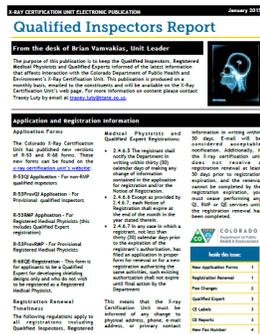
In April, the department began shipping all CE labels using FedEx. Each shipment will be tracked and a signature will not be required. The Qualified Inspector does not need to be present for the package to be delivered.

If a label order must be picked up in person, the QI must receive acknowledgement of the label purchase request from the X-ray Certification Unit a full 24 hours prior to the scheduled pick up time.

[www.colorado.gov/cdphe/xray](http://www.colorado.gov/cdphe/xray)

# 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



# COLORADO

## Department of Public Health & Environment

### X-Ray Certification Program

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Website: [www.colorado.gov/cdphe/xray](http://www.colorado.gov/cdphe/xray)

Radiation Regulations: [www.colorado.gov/cdphe/radregs](http://www.colorado.gov/cdphe/radregs)

