

Qualified Inspectors X-Rayport

From the desk of Brian Vamvakias, Unit Leader

Signing up for Regulatory Updates

Periodically, the Radiation Control Program will review and update the radiation regulations. Sometimes this is driven by changes in federal regulations, from updated Suggested State Regulations (SSR) from the Conference of Radiation Control Program Directors, Inc. (CRCPD) or from input from our various registered entities. To automatically receive notification of future regulatory changes, please complete the [Radiation Regulatory Change Notification Request form](#) online to register.



Qualified Expert categories and authorization

Qualified Expert (QE) registrations are authorizations by the X-ray Certification Unit for individuals to design or evaluate shielding for radiation machines. Additional information for the requirements of QE registration can be found in the [Colorado Rules and Regulations Pertaining to Radiation Control Part 2, Appendix 2B and Appendix 2C](#).

Registered medical physicists are granted a QE authorization along with their RMP registration. It will show as a category in their registrations. Applicants may also apply solely for QE registration. This may be individuals who offer shielding design services for facilities in Colorado but do not also wish to perform Certification Evaluations. *Anyone who provides shielding designs to radiation machine facilities in Colorado must be registered in Colorado as a QE.*

There are three registration categories for Qualified Experts:

QE(S), QE(R), QE(T). The following is a brief description of these three QE categories and the authorizations granted by the X-ray Certification Unit to perform shielding design services:

QE(S) is the designation for Qualified Experts who design or evaluate shielding for radiation machines **not used** in the healing arts. Individuals who are registered as QE(S) may only provide shielding designs for non-healing arts facilities such as analytical or industrial units;

QE(R) is the designation for Qualified Experts who design or evaluate shielding for radiation machines used in the healing arts as regulated by Part 6, but not used in radiation therapy. Individuals who are registered as QE(R) are authorized to provide shielding designs for healing arts facilities other than radiation therapy AND for radiation machines not used in the healing arts. In other words, QE(R) includes the authorization of the

QE(S) as well; **QE(T)** is the designation for Qualified Experts who design or evaluate shielding for radiation machines used in radiation therapy that are regulated by Part 24. Individuals who are registered as QE(T) are authorized to provide shielding designs for radiation therapy facilities, healing arts facilities AND for radiation machines not used in the healing arts. In other words, QE(T) includes the authorization of the QE(R) and

Also in this edition:

Registration submission	Page 2
Question of the month	Page 4
Get back issues	Page 4



COLORADO
Department of Public
Health & Environment



Registration submission timing

Time is of the essence!

Lewis' Carroll's March Hare said, "The time! The time! Who's got the time!?" Both our registrants and the X-ray Certification Unit are pressed for time. To have your registration applications processed promptly, time is of the essence when submitting your registration information to the Colorado X-ray Certification Unit. In 2015, we processed an average of 15 QI, QE, RMP and Service Company applications per month. Starting in April 2016, that number of renewals will at least double due to the new annual renewal frequency. However, we will not be adding any X-ray Certification staff members to process QI and Service Company applications. To help facilitate the timeliness of your registration renewal, please review the following tips for submitting your registration renewal on a timely basis:

Renewals:

Applications to renew are to be received by the X-ray Certification Unit 30 days prior to the registration expiration date, which is the last day of the renewal month. The minimum items that must be received 30 days in advance of the expiration date are the completed application form and the payment. Send these items to [Tracey Luty](#) in the X-ray Certification Unit. Applications received at least 30 days prior to the expiration date will allow the registration to stay active even past the expiration date should there be any delays in the processing on either your part or our part.

Applications or payments received in less than 30 days from the expiration date will be processed in the order they were received. That may mean that the renewal process will extend beyond the expiration date. If that is the case you must cease performing the tasks your registration authorizes you to do until and if the registration is completed. QIs must stop performing inspections after the registration expiration date. Service companies must stop selling, installing and servicing radiation producing machines after the registration expiration date.

New registration applications:

Please allow at least 30 calendar days for the processing of new applications. No inspections, sales, installations or service work should be scheduled in Colorado prior to the X-ray Certification Unit's approval of your initial application or an application to add technicians to a service company registration. Providing those services prior to your application's approval will subject you to action by the Department including fines. Any QI whose registration has expired will not be allowed to purchase certification evaluation labels.

Rush applications:

There is no provision in the X-ray Certification regulations nor policies to expedite or rush a registration application. The applications will be reviewed in the order they are received by the X-ray Certification Unit. Please plan accordingly.

Continued on Page 3

Registration submission timing

Continued from Page 2

Sending the application:

E-mail please! The preferred method of submitting your renewal or new application is by e-mail. You may e-mail directly to [Tracey Luty](mailto:Tracey.Luty). You may also send e-mail to the CDPHE_Xray_QISC@state.co.us address, but please be sure to copy Tracey Luty on the e-mail. You may mail a check separately or pay via credit card.

If you must mail the application, please be aware that there are hundreds of employees in the Colorado Department of Public Health and Environment receiving mail. In order for your application to get to the X-ray Certification Unit, you must address it properly. Send all QI, QE, RMP, Service Company applications to:

Tracey Luty
CDPHE - HMWMD - XRC
4300 Cherry Creek Drive South
Denver, CO 80246-1530

Tracking the status of the application once it has been received

Spreadsheets of the status of QI and Service Company applications are updated on a periodic basis on the [X-ray and Mammography webpage](#). There are two spreadsheets under the heading "Application Status." One for Qualified Inspectors (this will include RMPs and QEs) and one for Service Companies. These spreadsheets give you an idea of where your application stands in processing. Entries for completed applications are kept on the spreadsheets approximately one month after they are mailed or e-mailed to the registrant. If you do not see your application on this list, please contact [Tracey Luty](#) to see if it has been received.

These spreadsheets also list upcoming registration expirations. If your name or company name appears in an upcoming expiration, please feel free to submit your registration today.

Provide requested documentation promptly

If you are required to submit additional documentation to complete your application approval, you must submit it in 30 days from the request. If you do not, the application will be considered abandoned, your application will be denied and any fees submitted with the application will be forfeited. Should you not comply with the 30 day submission of data and you are notified that your application is abandoned, you will be required to submit a new application and fees to be given consideration for registration.



Question of the month

Serial Numbers

Q: Which X-ray machine Serial Number should I put on the Certification Evaluation when doing an inspection?

A: Part 2 requires that the department be notified within 15 calendar days of the full name and address of each person/facility that has received a radiation machine or component and specific information about the machine. That information includes: manufacturer, model and/or model number, **serial number** of each machine or component and the date of transfer, assembly or installation.

According to Part 6, 6.3.2.5(2)(a), the serial number submitted to the department for all correspondence, 59-1, 59-2, R-4, R-61, should be the same serial number found on the FDA Form 2579 for each particular machine, unless prior written approval is obtained from the department. If available, the serial number(s) from the manufacturer shall be clearly visible as a label or stencil on the control panel and the tube housing assembly.

When completing a Certification Evaluation during an inspection, QIs should use the serial number entered on the FDA 2579 or equivalent report of assembly and verify that the serial number present on the report of assembly matches the serial number present on the control panel or tube housing assembly. If the serial number has changed on the machine or has been recorded incorrectly with the Colorado X-ray Certification Unit, a notification of the change or correction must be made to the X-ray Certification Unit.

Missed an issue of the QI 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](#).



Jan 2015



Feb 2015



Mar 2015



Apr 2015



June/July 2015



Aug/Sept 2015



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Department of Public
Health & Environment

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