

Qualified Inspectors X-Rayreport

From the desk of Brian Vamvakias, Unit Leader

You may have noticed that the slight change in the name of this publication. We took liberty and decided that it is ok to have a little fun while at the same time making sure we continue to provide timely and relevant information to our QI constituents.

Sometimes great ideas don't come to you until right after you hit the "Send" button.



Mammography equipment: Repairs, upgrades and training

Software Upgrades

The FDA requires that mammography equipment evaluations be performed after major repairs to mammography equipment. Software upgrades are considered to be major repairs. Mammography Quality Standards Act (MQSA) Alternative Standard #6 defines the conditions under which mammography equipment evaluations (MEE) must be performed after software upgrades to full field digital mammography (FFDM) units. Some evaluations must be performed by the medical physicist while others may be performed with medical physicist oversight. Click on the following link for detailed information in the [Policy Guidance Help System - MSQA Standard #6](#).

Major Repairs

There are a number of adjustments, changes and repairs to mammography equipment that the FDA considers major repairs that require the medical physicist

to conduct an onsite mammography equipment evaluation (MEE). The [Policy Guidance Help System - Major Repairs](#) includes a table that identifies some of the adjustments, changes and repairs that are considered major repairs and the level of involvement required by a medical physicist.

Training

The FDA requires that a medical physicist receive at least eight (8) hours of training in the surveying of units of the new mammographic modality prior to independently performing surveys of a new mammographic modality. The [Policy Guidance and Help System - Training](#) contains detailed information relating to this topic.

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Did you know that all web links and email addresses in this publication can be accessed by clicking on them?

New email address

The X-Ray Certification Unit recognizes that customer service can be improved by having a common email address that can be used by quality inspectors to submit CE reports, registration renewal applications and CE Label orders. To accommodate this, a new email address is now available.



cdphe_xray_qisc@state.co.us is the new email address to be used to submit CE reports, renewal applications and to order CE labels. Electronic submission is not required, however it is more timely and reliable and reduces the amount of paper used. It also can be accessed by multiple staff members and therefore decrease staff response time. All QI's are encouraged to submit correspondence using this new email address.

The following is the preferred method for submitting CEs:

1. Use email address cdphe_xray_qisc@state.co.us
2. Procedure
 - a) CE's must be attached as an Adobe pdf file
 - b) The file name must start with the Facility Registration Number
 - i) The QI may combine several CE's in one file. Only one facility ID per file, please.
 - ii) CE's must be legible and accurate
 - c) CE's must be delivered within 15 days of the inspection date
 - d) A receipt notification will be sent to the QI when the CE's are received

Using this method will help the X-Ray staff keep track of CE reports.

If you have questions about the status of your CE please contact Erin Woodd

Keeping up with the times

All forms that are required to submit to the X-Ray Unit for registrations, waiver requests and other regulatory requirements can be found on the X-ray and Mammography webpage at <https://www.colorado.gov/pacific/cdphe/x-ray-and-mammography-forms-and-applications>. Take a look at your inventory of CDPHE X-ray forms you print or e-mail to your clients. If they are not current, please replace them with the current version.

Due to regulation, contact and format changes, it is important to only use the most current forms. The X-ray unit cannot accept obsolete versions of forms.

Question of the month

How often is a facility required to scan their lead vests?

Answer: There is no regulations that requires a facility to scan their lead vests or aprons. It is recommended that protective equipment should be checked at least annually and replaced if an examination shows gaps in the protective shielding inside the vest.

Remember, vests should be hung on hangers or stored flat. Never fold a lead vest. The QI should verify that the facility has appropriate protection for their staff and patients. The QI should also verify that the facility has appropriate procedures for the care of lead vests and that the facility follows those procedures. Deficiencies in the availability of protective shielding for patients is a violation of regulation 6.3.3.6.



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