

Service Company X-Rayport

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 service company constituents.

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



Mammography equipment: Repairs, upgrades and service authorization

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 mammogra-

phy 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.

Service Authorization

The Colorado X-ray Certification Unit requires any service technician or engineer who performs installation, services or maintenance to mammography units in the State of Colorado must be specifically authorized to do so. Mammography services authorization will be granted to technicians/engineers who provide evidence of training in mammography unit services. Technicians with the Colorado mammography services authorization will have an "M" following their names on the Service Company registration certification document.

Also in this edition:

New email address	2
Keeping up with the times	3

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



COLORADO
Department of Public Health & Environment

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 service companies to submit Reports of Assembly, registration renewal applications and to contact our agency with questions. 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 Reports of Assembly, registration renewal and general correspondence. Electronic submission of Reports of Assembly and renewal applications is not required, however it is more timely and reliable and reduces the amount of paper used. This new email address can be accessed by multiple staff members and therefore decrease staff response time.

The following is the preferred method for sending Reports of Assembly (2579s):

1. Use email address cdphe_xray_qisc@state.co.us
2. Procedure:
 - a) Reports of Assembly must be attached as an Adobe PDF file.
 - b) The file name must start with the Facility Name. Only one facility per file, please.
 - c) Reports of Assembly must be delivered within 15 days of the installation date.
 - d) A receipt notification will be sent to the service company when the reports are received.

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

If you have questions about the status of your notification please contact Christine Irving at 303-692-3448 or by email at Chris.Irving@state.co.us.

Remember: Sales or installation of any x-ray machine must be reported to the Colorado X-Ray Certification Unit within 15 days of the date of sale or installation.

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.



COLORADO

Department of Public Health & Environment

X-Ray Certification Program

4300 Cherry Creek Drive South
Denver, Colorado 80246



X-Ray Certification Unit Staff

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

Contact Information

Fax: 303-691-7841

Email: cdphe_xray_qisc@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