



Protecting, Maintaining and Improving  
the Life of All Minnesotans



**JANUARY 2009**

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## ***New email address***

Our general email account has changed to [health.xray@state.mn.us](mailto:health.xray@state.mn.us). If you tried emailing us at our new address and experienced problems, we've corrected the issue and you shouldn't have any problems in the future. Please notify us immediately if you encounter errors, thank you!

## ***Registration Certificates***

Effective in 2008, facilities that register their x-ray equipment will receive a Registration Certificate. Certificates were not issued prior to 2008 and are mailed annually when a facility submits their Annual Registration forms and pays the appropriate fees. The rule states that the certificate SHOULD NOT be posted. It should be kept in your Quality Assurance (QA) Manual, and will be reviewed by our inspectors at the time of your inspection.

Bulletins are sent electronically only. This decreases printing and postage costs and it helps to keep your fees as low as possible. If you would like to receive these bulletins by email please submit your request to [Kelly.Sabanjo@state.mn.us](mailto:Kelly.Sabanjo@state.mn.us). You can visit our website at [www.health.state.mn.us/xray](http://www.health.state.mn.us/xray), click on Publications, to see our past Bulletins.



## ***CRNA's and Fluoroscopy***

The CRNA's can do fluoroscopy according to statute 141.121 subdivision, 5 b (2). They are exempt from the Limited Scope Exam requirement. To see who can take x-rays or fluoro, visit our website at [www.health.state.mn.us/xray](http://www.health.state.mn.us/xray), click on Frequently Asked Questions (X-ray FAQ) page.

## ***Limited Scope 1st Year Review***

Minnesota started the Limited Scope X-ray Testing program Jan. 1, 2008. In its first year in Minnesota, we have seen a 59% pass rate (minimum 70% score) on the Core (100 questions.) The positioning modules have been passed at a rate of 39-46% (20-25 questions per module.) There has been a downward trend in the pass rates, especially in the positioning modules. The last quarter of 2008 saw a pass rate of 26-38% in the positioning modules and a 51% pass rate in the Core. MDH is exploring ways to assist exam takers to better prepare them for taking the exam. If you have taken the Limited Scope exam and would like to give feedback on what would be helpful, your input is greatly appreciated. Please email MDH at [health.xray@state.mn.us](mailto:health.xray@state.mn.us).

## ***RSO Delegation Agreement***

A Radiation Safety Officer (RSO) Agreement must be kept on file for all registered facilities where the registrant is not the RSO:

- Agreement is available on our website on the Radiation Safety Officer page, or create your own
- After completed, file in your facilities Quality Assurance (QA) manual
- If you haven't already notified MDH of your designated RSO, download the Change of Facility information form on our Registration Forms page, and fax or mail to us
- Keep us informed of any changes to your RSO



[www.health.state.mn.us/xray](http://www.health.state.mn.us/xray)



## Temporary Equipment

If your facility is going to be using temporary equipment, please be aware of the following:

- If you are using the equipment for demonstration prior to purchasing it, you can do so for up to 14 days without notifying MDH.
- If the temporary usage is for a vendor training session or if its expected usage is going to extend beyond 14 days, then a reciprocity registration form is required. This form recognizes that it is registered in another state. The usage of the equipment continues to fall under Minnesota Rule 4732.
- The Reciprocity form is on our website at [www.health.state.mn.us/xray](http://www.health.state.mn.us/xray), on the Reciprocity page. It is the responsibility of the facility to fill out the form. Some out-of-state training programs may fill it in prior to the training session, but it is the facility's responsibility to have documentation on hand.

**Happy New Year!**  
from the Radiation Control Staff



## Federal Form 2579 is now online for Service Providers

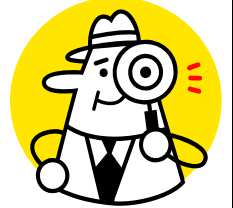
The FDA has gone paperless regarding the submission of 2579s. It will be up to the Service Provider to print off their electronic submission and supply it to the MDH. Please do the following if you are not already doing these electronically:

1. Download the free CDRH eSubmitter Software at <http://www.fda.gov/cdrh/cesub/>
2. Sign up to use the FDA electronic Submission Gateway (ESG): <http://www.fda.gov/esg/>
3. Information on how to get a digital certificate is available at [http://www.fda.gov/esg/userguide/WebHelp\\_10\\_2008/WebHelp\\_10\\_2008.htm](http://www.fda.gov/esg/userguide/WebHelp_10_2008/WebHelp_10_2008.htm)
4. Specific instructions for account setup are available at <http://www.fda.gov/esg/account.htm>



Chapter 4732 is available at the Minnesota Bookstore for \$13.95 plus shipping and tax . Call 651-297-3000 or 1-800-657-3757 or order online at [www.comm.media.state.mn.us/bookstore/bookstore.asp](http://www.comm.media.state.mn.us/bookstore/bookstore.asp)

## Inspector's Corner



### Fugi Go System

The digital Fugi portable x-ray unit, with instant display of the portable radiograph, has made its way into Minnesota. The collimator does not have the required field markings as required in the Code of Federal Regulations; 21 CFR 1020.31 (e) 2 states "The beam limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted." Fugi, not the facility, is responsible for providing this. If you have a Fugi Go System and cannot get the company to provide this, let MDH know. The FDA has been notified of the design error.

### Shielding Plan Requirements

New and remodel facilities only are required to submit a shielding plan for review by MDH:

- The shielding plan must be submitted to MDH prior to construction
- A placard will need to be posted upon completion of the project (see below)
- Turn around time for review is approximately 30 days
- Low-dose units (intraoral, mammography, podiatry and bone density) are exempt
- Replacement tubes of like output are also exempt, provided there is an existing shielding plan available to verify shielding
- The exempt facilities still need to have an overall shielding plan if they are making changes, but they will not need to submit it for review

### Placard Requirements

A permanent placard must be mounted in the room specifying the amount and type of shielding in all walls, doors, partitions, and if occupied, the spaces below or above the ceiling. If mounting the information is not practical, a registrant may post a notice in the room that describes where the document is located.

Visit our website shielding page to download the application form, verify shielding placard requirements and view our dental shielding presentation at [www.health.state.mn.us/xray](http://www.health.state.mn.us/xray), click on Shielding.