DATE: March 29, 2006

TO: State Licensed Private Inspectors

THRU: Roland G. Fletcher, Radiological Health Program (RHP) Manager III

FROM: Renee L. Fizer, Chief, Radiation Machines Division, (RMD)

SUBJECT: Information and Regulatory Interpretation Memos (IRI) 06-00 March 2006

Meeting Location at Maryland Department of the Environment (MDE)

The next meeting of the licensed private inspectors will be held on May 23, 2006 at 10:00 a.m. in the Aeris and Aqua Conference Room on the 1st Floor of the Montgomery Park Executive Office Building at 1800 Washington Boulevard. Please park in the visitor lot (marked Red Lot) and come to the lobby area where someone will escort you to the meeting. A tentative agenda and directions are attached.

Plan Reviews

As of September 2005, the RMD only accepts plan reviews utilizing the methodology in the National Council on Radiation Protection and Measurements (NCRP) 147. Issues have been raised as to whether dental, veterinary, podiatry, mammographic, and bone density facilities should have a plan review performed. Though the RMD has not changed its previous position in regards to plan reviews for these facilities, this may be an issue that warrants further discussion. The RHP follows the policy stated in IRI-96-2 and IRI-97-3 (attached), which is that mammographic, dental, veterinary, and podiatry facilities are exempt from plan reviews.

For dental facilities utilizing FDA-approved dental CT devices, including the i-CAT Cone Beam 3-D Dental Imaging System, the RMD is requiring facilities to submit a plan review performed by a State licensed Inspector or registered Service Provider. Currently dental CT machines are regulated as CT devices. The RMD is working in conjunction with the Maryland State Dental Association and various organizations to determine appropriate courses of action in regards to regulations and training of operators for this device.
Fluoroscopic Privileging Regulations

The following are interpretations of the fluoroscopic privileging regulations:

Initial Training: The intent of the regulation is to ensure that users who energize fluoroscopic radiation machines have had, at some point in time prior to December 31, 2005 or prior to a user new to a facility energizing fluoroscopic machines, a minimal amount of training on the equipment and radiation safety. Documented training can have occurred in previous years and does not have to be in a block 4-hour period. Required initial training of healthcare practitioners and radiological technologists does not expire on December 31, 2005.

Refresher Training: The intent of the regulations is to ensure refresher training within twenty-four month cycles for users who energize fluoroscopic radiation machines. A regulatory two-year cycle was chosen to meet biennial State certification requirements. The Agency’s interpretation is that users who energize fluoroscopic radiation machines have 24 months to acquire refresher training after either December 31, 2005 or, if a new user at a facility, the date initial training was documented; however, registrants may choose a more strict timeline or cycle, such as, but not limited to, employment anniversary or birth date.

C-arms used Exclusively for Extremities

The RMD is soliciting input by April 30, 2006, from the private inspectors, as to whether C-arms used exclusively for imaging extremities should be exempt from annual exposure rate measurements which must be posted so that the fluoroscopist may readily have access to the results stated in COMAR 26.12.01.01F.5(c)(2). The RMD will evaluate the responses posed by this question and make a determination of whether an exemption should or should not be granted.

Laser printers or digital processors

This is a reminder to assign machine numbers to laser printers or digital processor while conducting a State certification inspection. Also please denote on the RX2 as to whether a facility has a laser printer or digital processor. At this time, the Department is not requiring fees for these processing machines but is keeping an inventory of what types of processing methods facilities are utilizing.

Enclosures: Attachment IRI 96-2 and IRI 97-3

Agenda
Directions