

Martin O'Malley
Governor
Shari T. Wilson
Secretary

Anthony G. Brown
Lieutenant Governor
Robert M. Summers, Ph.D.
Deputy Secretary

DATE: January 7, 2008

TO: All State Licensed Private Inspectors and Registered Service Providers

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

FROM: Eva Nair, Acting Division Chief, Radiation Machine Division

Jerry Adams, Section Head, Radiation Machines Division

SUBJECT: Information and Regulatory Interpretation Memo (IRI) 08-00, January 2008

On December 13, 2007 the Maryland Department of the Environment (MDE), Radiological Health Program hosted a meeting of State Licensed Private Inspectors and Registered Service Providers. The following is a summary of topics discussed during the meeting.

Introductions and Opening Remarks

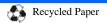
Roland Fletcher, Radiological Health Program (RHP) Manager opened the meeting welcoming the guests and describing the future direction MDE and the RHP will be taking to improve facility compliance. The RHP is redesigning its approach to violations and intensifying its focus on compliance and the expectation that the sites being reviewed are expected to be in full compliance with the regulations when the inspection begins. Violations will be tiered and Licensed Private Inspectors are expected to act on behalf of the State when performing their work. Licensed Private Inspectors who inspect therapeutic facilities will be expected to review the problem logs and to cite and report unreported misadministrations to the state. Unreported misadministrations are likely to receive very severe penalties.

Service Provider Paperwork Submission

The RMD is aware of service providers still not submitting documentation for the selling, leasing, transferring, lending, disposing, assembling, or installing of radiation machines within the 15 days required by COMAR 26.12.01.01, Section B.12. These mandatory forms are very important for the RMD to track machine types and locations. Be advised that this is a requirement of your company's registration with the State of Maryland to provide service to radiation machine facilities.

State Licensed Inspector requirements

On the MDE RX32, an applicant must indicate if they are interested in MQSA privileges, and/or Highenergy inspection privileges, and available for hire. Refer to COMAR 26.12.02 for qualifications and items that must be submitted with the application. The RMD conducts a thorough background check on



every applicant that applies for a license and has the right to ask for supporting documentation to ensure that COMAR 26.12.02 requirements are met.

Plan Reviews and Area Surveys

Effective January 1, 2008, the RMD is requiring e-mail addresses of the preparer and signature of the Owners/facility representatives on the RX21 and RX22. The RX21 and RX22 will be updated and available on the MDE Web page.

http://www.mde.state.md.us/Programs/AirPrograms/Radiological_Health/xray_applications/index.asp

Regulations

Proposed regulatory changes for Sections B and F were reviewed for the attendees. The lineout changes are available via e-mail for comment.

There are changes proposed for part B that add substantial new pieces of regulation for the design and reporting of plan reviews and area surveys for therapy vaults.

Digital Dental Program

The state is collecting data from dental offices to ascertain the depth of an anecdotal finding regarding poor use of the potential reduced techniques available for digital technologies. The RMD inspectors have been discovering offices using film techniques in a digital environment. This represents an unnecessary overexposure to the public. We will be developing educational information for the offices found to be using techniques in this manner.

Significant vs. Minor Violations

The RMD is in the process of reviewing its violation forms and making decisions as to what constitutes a significant or minor violation. Facilities are required to correct any violation cited immediately and submit the documentation within the requirements of the RX2.

The RMD reminds the State Licensed Private inspectors and the service providers that the expectation for sites being inspected is that the site will be in compliance at the beginning of each inspection. Administrative and/or civil penalties will be issued for violations found at the site.

The RMD is soliciting input on the review of violations, which is available by request. Submit any input by January 31, 2008 to Ms. Eva Nair or Mr. Jerry Adams.

Discussion of System vs. Subsystem

In response to several requests for clarification on what constitutes subsystems as compared to systems, The RMD has begun to develop a partial listing of subsystems that will required to be inspected by Medical Physicists prior to use on humans. The list is being developed and available for distribution and input.

