

DATE: November 4, 2010

TO: All State Licensed Private Inspectors

THROUGH: Roland G. Fletcher, Manager IV, Radiological Health Program

FROM: Eva Nair, Chief, Radiation Machines Division
Matthew Almes, Section Head, Radiation Machines Division
Jerry Adams, Section Head, Radiation Machines Division

SUBJECT: Information and Regulatory Interpretation Memo (IRI) 10-00, November 2010

Meeting Location at Maryland Department of the Environment (MDE)

The next meeting of the State Registered Service Providers will be held on December 17, 2010 at 10:00 a.m. in the Aeris, Aqua and Terra Conference Rooms on the 1st floor at the Maryland Department of the Environment, 1800 Washington Boulevard in Baltimore. **This is NOT a mandatory meeting for State Licensed Private Inspectors, although attendance is encouraged.** Please park in the visitor lot (marked Red Lot) or Blue Lot and come to the lobby area where someone will escort you to the meeting. A tentative agenda and directions are attached if you plan to attend.

Dental Law

Effective June 1, 2010, Maryland Senate Bill 664 became law. It requires a State inspector to provide a dental office or facility a written notice of violations found at the time of the inspection but prohibits the Department, with one exception, from imposing a fine on a dental office or facility for violations if they are corrected within 20 working days. The only exception to this prohibition is the Department may impose a fine if the violation (s) presents a serious hazard or potential danger to patients or employees. For more information please visit the Maryland General Assembly's Web site at www.mlis.state.md.us.

Regulations Update

Supplement (18) includes clarification of the radiation machine regulations and reflects upon new radiation machine types and safety considerations and is proposed to become effective in the fall of 2010. One of the major process changes is the following on preventative maintenance:

Preventative Maintenance:

F.3 (d) - The regulation will require each registrant to provide to the RMD written documentation to demonstrate that the preventative maintenance has been performed for each

radiation machine. Also, if documentation regarding the recommended maintenance schedule is not available from the manufacturer, then preventative maintenance must be performed on an annual basis.

Supplement 19 includes radioactive material changes to COMAR 26.12.01.01 and is proposed to become effective in the fall of 2010.

Changes to COMAR 26.12.01.02 clarify the due dates for certification of radiation machines and are proposed to become effective in the fall of 2010.

Supplement 20 includes radioactive material changes to COMAR 26.12.01.01 and is proposed to become effective in the spring of 2011.

Personnel Monitoring Requirements for Service Providers

Effective January 2011, the RMD will perform audits on service companies to review the personnel dosimetry records to ensure that COMAR 26.12.01.01D.502 is being met. Service technicians, by the nature of their work, are considered Radiation Workers under the regulations and are expected to be individually monitored for exposure. As stated in COMAR 26.12.01.01D.502, each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupation dose limits of Part D. It also states that adults who potentially may receive in one year a dose in excess of 10 percents of the limits in D.201a shall be monitored.

Adjustment Tolerances

Tolerances for reproducibility, accuracy, and linearity are based on the tolerance numbers posted and supplied by the radiation machine manufacturer. If the manufacturer does not specify tolerances then use a standard + or -10%.

Area Survey/Plan Reviews

Podiatry and Bone Density Facilities do not require Plan Reviews or Area Surveys before installation and operation of a machine.

Service Provider Requirements for Preventative Maintenance (PM)

As a service provider, you are required to follow the manufacturer's recommended intervals of inspection and the required evaluations of equipment performance. Tolerances allowed by the manufacturer will be honored if they have been published and are available to the RMD and the general service sector for use and evaluation.

Preventative Maintenance should include but not be limited to the following evaluations: HVL, reproducibility and accuracy for mA, KVP, and timer as appropriate. Service providers are required to put their documented numerical data/findings on their PM worksheets provided to the site. PM documentation that does not include details of final performance of the equipment could result in the PM being disallowed and the registrant potentially being subject to a penalty.

Private Inspector License Requirement

According to Subtitle 1, “Civil and Criminal Enforcement” of Title 10, “Support in General” of Family Law, Annotated Code of Maryland, a licensing authority shall require each applicant for a license to disclose the Social Security Number (SSN) and record the number on the application. To ensure that the Radiation Machines Division is complying with this statute, we are requesting that State licensed private inspectors denote their SSN on the RX32. If you need additional information about Article 10-119.3, please contact Ms. Eva Nair.

State Licensed Private Inspectors Audit

According to COMAR 26.12.01.03C(5), a State licensed private inspector has 30 days from the date of an inspection to submit the State certification paperwork to the RMD. Failure to comply with this regulation may lead the RMD to deny a license renewal application, or suspend or revoke an active license.

Maryland State Certification Inspections

All RX1 forms submitted to the RMD are to be complete in their entirety, especially the Federal Identification Number, a current Registration Number, an accurate Preventative Maintenance Schedule and active Machine Numbers. Any cited inspection violations must be recorded in the inspection report and listed and properly cited on the RX2 forms. Failure to adhere to this procedure affects decision making regarding potential enforcement action against facilities not meeting regulatory requirements.

Maryland State Certification Inspections must be conducted no later than 45 days prior to the facility’s expiration date. Facilities failing to comply with this regulation are subject to an enforcement action. Aside from the Certification Approval Letter and the Registration and Certification Certificate, the RMD does not mail reminder letters to certification facilities; however, the certification expiration date is on each annual invoice.

Maryland Certification Inspections Personnel Monitoring

All radiation machine facilities are required to have continuous personnel monitoring for all occupationally exposed workers. If a facility does not, this violates COMAR 26.12.01.01D.1107 and D.502. Bone density facilities and podiatry may be exempted after receiving Agency approval. They must submit a request for exemption via letter and send six consecutive months or four consecutive quarters of dosimetry records. Upon review of the dosimetry records, the RMD may grant an exemption. A bone density or podiatry facility must have either an exemption letter or continuous monitoring records **on site** during the State certification. Otherwise, it is a violation of the above mentioned regulations. This exemption remains valid **unless** any of the following occur:

1. The radiation machine facility changes ownership or the Federal Tax ID number changes;
2. The radiation machine facility relocates from its current location;
3. More radiation machines are added to the facility;
4. The radiation machine facility remodels its present location; or
5. The facility exhibits a behavior of non-compliance such that monitoring is again required.

Website Update

The RMD continues to update the Maryland Department of the Environment's (MDE) Radiological Health Program website to include revised x-ray forms; RX1, RX1A, RX2, RX2A, and RX24. The Registered Service Provider List and the State Licensed Private Inspector list have been updated. The Web section called Upcoming Events is updated frequently to reflect RHP informational meetings to be held at MDE. Please contact Mr. Matthew Almes or Ms. Christina Rowand to make changes to the Registered Service provider list or the State Licensed Private Inspector list posted on the website.

Important RHP web pages:

http://www.mde.state.md.us/PROGRAMS/AIR/RADIOLOGICALHEALTH/Pages/Programs/AirPrograms/Radiological_Health/index.aspx

http://www.mde.state.md.us/programs/Air/RadiologicalHealth/XRayApplicationFormsandGuidance/Pages/Programs/AirPrograms/radiological_health/xray_applications/index.aspx

