

Facts About...

December 21, 2011

Information and Regulatory Interpretation Memo (IRI) 11-00 Newsletter

TO: All State Licensed Private Inspectors

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

FROM: Eva Nair, Chief, Radiation Machines Division (RMD)

Jerry Adams, Section Head, Radiation Machines Division (RMD)

Introduction

The Maryland Department of the Environment (MDE), Radiological Health Program wishes to thank you for your active participation and continued support in the forward movement of the Division during this past year. This year has been particularly challenging for the RMD with the loss of three individuals in the Registration and Certification Section. Currently we are in the process of rebuilding that Section and hopefully will be fully staffed and operational by the end of the year.

Radiation Machines Division Announcement

The Radiation Machines Division (RMD) is proud to announce the filling of three positions:

Talya Langbaum – Health Physicist Trainee in RMD's Registration and Certification Section.

Mahala Thomas – Health Physicist Trainee in RMD's Registration and Certification Section.

Adedotun Odegbile – Health Physicist Trainee in RMD's Registration and Certification Section.

To fulfill the need for direct oversight of new staff on a temporary basis, effective October 26, 2011, Ahsan Bhatti is the Acting Section Head for the Registration and Certification Section.

Preventive Maintenance Regulation

Effective January 1, 2012, the RMD will be enforcing COMAR 26.12.01.01F.3(d)(4) which states that registrants must submit written documentation, a service report, demonstrating that the preventative maintenance has been performed for their radiation machine(s). The documentation must be received by the RMD 30 days after the preventative maintenance has been performed. As a registered service provider, ensure that your clients are made aware of this change in procedure. For registrants failing to comply with these regulations, enforcement action will be taken against the facility. Enclosed is the memo that will be mailed to all stakeholders informing them of the change in procedure.



Update of enforcement within the Radiation Machines Division

The number of enforcement cases has decreased since most of the enforcement actions were taken on dental facilities. Since the Maryland Senate Bill 664 went into effect June 1, 2010, the majority of the dental facilities have been able to correct their cited violations within 20 working days. The certification facilities have on the average a 95 percent initial compliance rate. The RMD believes that one of the reasons for the high compliance rate is due to the preventative maintenance being performed on the radiation machines according to the manufacturer specifications. As a reminder, at the end of the certification inspection, the facility should receive an Inspection Summary Form (RX2). An inspector needs to ensure that all violations cited during the inspection with proper citations are transposed onto the RX2. The facility representative also needs to be told that that the violations must be corrected immediately.

Regulations Update

Supplement 20 which includes radioactive material changes to COMAR 2.12.01.01 was effective on September 19, 2011. The updated information can be found on the MDE's website.

Service Provider Requirements for Preventative Maintenance (PM)

A service provider is required to follow the manufacturer's recommended intervals of inspection and the required evaluations of equipment performance. If the service provider performs extra services, beyond the manufacturer's specifications, that is between the provider and the registrant. The RMD has reviewed the incoming preventive maintenance documentation and it reveals that there are service companies that are not reporting potential violations to the registrants. If the inspector should come upon this situation, the radiation machine should be cited and it should be brought to the attention of the facility representative.

State Licensed Private Inspectors

There have been facilities that are lodging complaints against certain State licensed private inspectors stating that inspectors have been slow to respond to inquiries about having their radiation machine undergo State certification. As a reminder, the MDE issues you a license to inspect certification facilities which should be your priority.

Accelerator Plan Reviews

If an oncology facility is replacing their medical accelerator but not undergoing any structural changes, the registrant must submit the following:

- 1. The location of the machine
- 2. The design and anticipated power use
- 3. Workload and occupancy factors
- 4. Modality change and addressing scatter radiation

The RMD staff will perform an area survey after installation of the radiation machine. If there are questions or you need to schedule an area survey, please contact Mr. Randall Haack.

Handheld Dental Radiation Machines

The handheld dental radiation machines are only approved to be used at the following settings: nursing homes, home health care, special needs patients, hospitals, or sedated patients. The devices <u>will not</u> be allowed in dental offices where stabilized/stationary conventional units are utilized or in a school environment for screening purposes. The applicants must complete the registration form, conditions form, and operator training records. If you have questions about the registration process, please refer to the MDE website.

Weighting Factor Policy: Alternative Effective Dose Methodologies

Effective January 1, 2012, the weighting factor policy will supersede the April 5, 2001 guideline for evaluating ALARA Program for use of Alternative Effective Dose Methodologies. The new policy will only be applicable to interventional radiology, cardiac catheterization, and pain management facilities. A regulation change will be forthcoming to incorporate the policy and the double badge methodology. The policy is enclosed for your purposes and to share with your clients. If there are questions, please contact Ms. Eva Nair or Mr. Jerry Adams.

Website Update

The Maryland Department of the Environment's (MDE) Radiological Health Program website continues to update and to create a user friendly version of the Regulations for the Control of Ionizing Radiation (COMAR 26.12.01.01)

Important RHP web pages:

 $\underline{http://www.mde.state.md.us/programs/Air/RadiologicalHealth/Pages/Programs/AirPrograms/Radiological_Health/index.aspx}$

http://www.mde.state.md.us/programs/Air/RadiologicalHealth/XRayApplicationFormsandGuidance/Pages/Programs/AirPrograms/radiological health/xray applications/index.aspx

Enclosure: Preventive Maintenance Memo