

**DATE:** May 14, 2013

**TO:** All State Licensed Private Inspectors  
All State Registered Service Providers

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

**FROM:** Eva Nair, Chief, Radiation Machines Division (RMD)  
Jerry Adams, Inspection and Enforcement Section Head, RMD

**SUBJECT:** Information and Regulatory Interpretation Memo (IRI) 13-00, May 2013  
Registered Service Provider Newsletter, May 2013

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### **Meeting Location at the Maryland Department of the Environment (the Department)**

The next meeting of the State Registered Service Providers and Licensed Private Inspectors will be held on July 26, 2013 at 9:30 a.m. to 12 p.m. in the Aqua, Terra, and Aeris Conference Rooms on the 1<sup>st</sup> Floor of the Maryland Department of the Environment, 1800 Washington Boulevard in Baltimore. Please RSVP by June 19, 2013 to [Bonnie.Reynolds@maryland.gov](mailto:Bonnie.Reynolds@maryland.gov). This meeting is mainly geared to the registered service providers. Please park in the visitor Blue Lot. **If you have specific questions please email Ms. Eva Nair at [Eva.Nair@maryland.gov](mailto:Eva.Nair@maryland.gov) prior to the meeting to ensure that your questions are answered appropriately.**

### **Radiation Machines Division Announcement**

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

Talya Langbaum – Health Physicist I in RMD’s Registration and Certification Section  
Shannon Page – Health Physicist I in RMD’s Registration and Certification Section  
Mahala Thomas – Health Physicist I in RMD’s Inspection and Enforcement Section  
Hopele Rice – RMD’s Office Secretary II

### **Legislation Introduced at the Maryland General Assembly**

The dental community introduced Senate Bill 614/House Bill 625 entitled “Dental Radiation Machines - Maintenance and Inspections”. This bill proposed to eliminate the inspection of dental radiation machines performed by RMD inspectors as long as a dental facility complied with the manufacturer’s preventive maintenance requirements for each individual dental radiation machine. The Department would need to rely on the report submitted by the service providers as the sole means of determining a machine’s compliance status.

The podiatry and chiropractic community introduced Senate Bill 608/House Bill 798 entitled “Podiatry and Chiropractic Radiation Machines”. This bill proposed that a State inspector provide podiatry and chiropractic facilities a written notice of violations found at the time of the inspection but prohibited the Department, with one exception, from imposing a fine on a podiatry or chiropractic facility for violations if they are corrected within 20 working days. The only exception to this prohibition is that the Department may impose a fine if the violation(s) present(s) a serious hazard or potential danger to patients or employees.

**The General Assembly gave these two radiation bills an unfavorable report.**

### **Registered Service Provider Performance Expectations**

- Service Providers need to submit their completed Preventive Maintenance (PM) paperwork to the registrant QUICKLY since registrants have 30 days from service to submit PM reports. Service providers must also send these PM reports to the Department within the same time frame (30 days). PM reports may be sent via e-mail to [preventative.maintenance@maryland.gov](mailto:preventative.maintenance@maryland.gov). This is the preferred method of submission.
- Service Providers are mandated by regulation to submit MDE RX24 **and** FDA 2579 forms within 15 days of any activity.
- Service providers are required to submit an application for renewal of their registration prior to their expiration date. The application form for registration of a business providing services or servicing (MDE RX25) is available on the MDE website.
- The registrant or new owner is fully responsible for registering their facility and reporting any changes to the RMD. Instructions on how to register a radiation machine facility is on the MDE website or the registrant can contact Ms. Talya Langbaum or Ms. Shannon Page at 410-537-3193.
- Service Providers are to inform the registrant of the results of the PM. Failures found during a review must be conspicuously demonstrated and reported directly to the registrant. The RMD requests that the PM service report be clearly marked as “FAILS PM.” Subsequent correction of the failure must be documented and forwarded with the PM documentation to RHP, and the RHP asks that the service report then be marked “PASS.”

### **Preventive Maintenance (PM) Regulation**

All radiation machine facilities are required to have PM performed on their radiation machines at the interval recommended by the manufacturer for each machine. If an interval is not specified, the PM must be performed every 12 months. Tolerances allowed by the manufacturer will be honored if they are published and made available to the RMD.

Facilities are required to submit a copy of their PM Service report including test results to the Department no later than 30 days after the maintenance service has been performed on each radiation machine. In January 2013, the Department started issuing Notices of Violation to facilities who failed to submit their PM within the specified period.

The RHP created PM report forms for the following types of radiation machines: intraoral dental, cephalometric/panoral dental, and general purpose. MDE policy mandates that all registered service

providers use these MDE forms while performing PM. Complete the form in its entirety; if a section is not applicable, denote "N/A." Preventive maintenance, if specified by the manufacturer, should include but not be limited to the following evaluations: HVL, reproducibility and accuracy for mA, kVp, and timer accuracy as appropriate.

Service providers are required to put their documented numerical data/findings on the PM reports that they provide to the site. Documentation that does not include details of final performance of the equipment could result in the PM being disallowed and the registrant being subject to a penalty.

Service providers are required to denote the MDE machine number on the PM reports. If a machine number has not been assigned, the tube serial number and room number must be denoted.

The goal is to create PM report forms for each type of regulated radiation machine. Available forms are located on the MDE website on the [X-Ray Application Forms and Guidance](http://www.mde.state.md.us/programs/Air/RadiologicalHealth/XRayApplicationFormsandGuidance/Pages/Programs/AirPrograms/radiological_health/xray_applications/index.aspx) page ([http://www.mde.state.md.us/programs/Air/RadiologicalHealth/XRayApplicationFormsandGuidance/Pages/Programs/AirPrograms/radiological\\_health/xray\\_applications/index.aspx](http://www.mde.state.md.us/programs/Air/RadiologicalHealth/XRayApplicationFormsandGuidance/Pages/Programs/AirPrograms/radiological_health/xray_applications/index.aspx)) under the heading **Preventive Maintenance Summary Forms**.

### **Clarification of Preventive Maintenance**

There has arisen a need to differentiate RMD inspections from PM reviews performed by registered service providers. The RMD performs inspections of facilities that include items not covered or required by the radiation machine manufacturers. The RMD inspects facility operations such as occupational and patient radiation safety, compliance to posting regulations, licensing of facility employees, dark room, and equipment performance. The PM is specific to the functioning of the radiation machine and its performance relative to the manufacturer's standards, not the Department's regulatory standards.

### **Regulations Update**

COMAR 26.12.01.01 Supplement 21 includes updates to Section F. This supplement also includes updated information and clarification of dental hand held radiation machine regulations. An excerpt of the dental hand-held device regulations is provided:

#### **Additional Requirements Applicable to Systems Designed Specifically to the Hand-Held:**

F.7(i) - Each hand-held diagnostic x-ray device shall be FDA approved; the device shall not be operated if a person other than the patient, and operator, and others directly involved in providing care, is present in the room; **use of a hand-held device is allowed in dental offices as a replacement for or in addition to the use of permanent wall-mounted or free-standing portable dental x-ray machines, when it is determined by the authorized provider that it is not possible or is not safe to attempt to expose a radiograph using a wall mounted or portable stand mounted x-ray machine;** and the registrant shall keep a log of the hand-held device's usage on a form as provided by the Department

Supplement 22 includes clarification on registration notification requirements and the use of the alternative effective dose methodologies.

## **Personnel Monitoring Requirements for Service Providers**

In January of 2014, the RMD will be performing audits on random 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 percent of the limits in D.201a shall be monitored. An audit may include a visit to the service company to review records and procedures or require the company to send to the agency evidence of compliance.

## **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**

Plan Reviews or Area Surveys are not required for podiatry and bone density facilities before or after installation to operate these specific machines. Plan reviews are required for dental cone beam units (CBCT).

## **Report of Assembly/Reassembly or Removal of a Radiation Machine (MDE RX24)**

The MDE RX24 has been modified and updated and is available on the MDE website. The form must be neatly completed and filled out in its entirety. Incomplete or illegible forms may be returned to the service company for completion, which will cause a facility registration or cancellation to be delayed.

## **Tube Tracking Numbering System**

The RMD has initiated a numbering system as an identifier of radiation machine tubes within the State of Maryland. The machine number is denoted on a red sticker which is affixed to the radiation machine tube. Registered service providers are required to document the number on the MDE RX24 or FDA 2579, PM reports, and service work orders. The numbers are placed on the radiation machine tube by RMD inspectors or State licensed private inspectors.

## **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, RX3, RX4, RX5, RX6, RX7a, RX8, RX10, RX11, RX14, 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 Ms. Talya Langbaum or Ms. Shannon Page 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/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](http://www.mde.state.md.us/programs/Air/RadiologicalHealth/XRayApplicationFormsandGuidance/Pages/Programs/AirPrograms/radiological_health/xray_applications/index.aspx)