Information and Regulatory Interpretation Memo (IRI) 16-00

Registered Service Provider Newsletter

October 2016

This newsletter is on the MDE website:

http://mde.maryland.gov/programs/Air/RadiologicalHealth/InformationalMemos/Pages/Programs/AirPrograms/Radiological_Health/memos/index.aspx

Updated RHP forms are on the MDE website:
http://www.mde.state.md.us/programs/Air/RadiologicalHealth/XRayApplicationFormsandGuidance/Pages/Programs/AirPrograms/radiological_health/xray_applications/index.aspx

The Radiological Health Program (RHP) is very interested in keeping its state private licensed inspectors and registered service providers informed and up-to-date on any changes in the regulations and within the Radiation Machines Division (RMD) of RHP. To achieve this goal, RHP is releasing this IRI and newsletter which will discuss the expectations of RHP for its registered service providers and state licensed private inspectors so that optimal and consistent quality service can be provided to our regulated community.

Radiological Health Program (RHP) Announcement:

The RMD is proud to announce the filling of one position:
Shar'Dana Hugee- Office Secretary

The Radioactive Materials Division (RAM) is proud to announce the filling of one position:
Atnatiwos Meshesha- Health Physicist License Reviewer

The Regulations and Radiation Exposure Strategies Section is proud to announce the filling of one position:
Zachary Barthel-Health Physicist

Diagnostic Medical Radiation Event:

Effective November 1, 2016, the memorandum dated April 2015 entitled" Misadministration

Reporting Requirements" is superseded by the enclosed memo. This memo clearly depicts the registrant's responsibility for reporting a diagnostic medical radiation event. Also enclosed is the occurrence log which shall be used by all registrants. The memo and the occurrence log will be mailed to all medical registrants. If you have any questions about diagnostic medical radiation event reporting or the occurrence log, contact Ms. Eva Nair, Ms. Talya Langbaum, or Ms. Shannon Page.

State Licensed Private Inspector License Application Requirements:

The following are recurring issues with the submittal of the Application for License to Inspect Radiation Machines (RX32) which causes a delay in processing the application:

- All applicants are required to disclose their Social Security Number on the application (RX32) for a license to inspect radiation machines. This is pursuant to the provisions of Section 10-119.3 of the Family Law Article, Annotated Code of Maryland, which requires the Department to verify if the applicant has any child support obligations.
- All applicants must submit a Curriculum Vitae with their application.
- All applicants who want to conduct mammography inspections in Maryland must provide their Mammography credentials.
- All applicants must provide their e-mail address.
- New applicants must submit official transcripts of their education from the respective institutions and provide accurate contact information of past employers for RHP verification.

Maryland State Certification Inspection Requirements:

RHP will not process any incomplete certification inspection submittals. These certification inspections will be returned to the inspector. The following are issues that need to be addressed prior to submitting a certification inspection:

- Record inspection violations on the specific certification inspection forms and properly cite on the Inspection Summary Form (RX2).
- Submit the Certification Inspection Report to the RHP no later than 30 days after the completion of each radiation machine inspection.
- Submit a Radiation Machine Facility Registration Form (RX1), signed by a facility representative, that accurately reflects the facility and x-ray machine information.
- Utilize the updated certification forms that are located on the MDE website.
- Verify the preventive maintenance (PM) service reports during the inspection and enter the information on the Data Facility Specific Form (RX4). If the PM report(s) is not current or does not meet the manufacturer's recommendations, this needs to be cited on the RX2. Inform the facility representative to submit all PM reports to the RHP within thirty days of PM completion.

Enclosed is a bar graph (Appendix A) depicting certification inspection submission times by each inspector. Contact Ms. Talya Langbaum to determine if you are meeting the regulation submittal times.

Clarification of Specific Regulations:

COMAR 26.12.01.01F.5(n)(1)-the regulation states that only a licensed practitioner of the healing arts or a radiological technologist under the supervision/direction of a licensed practitioner may energize a fluoroscopic machine, and such personnel must comply with the training addressed in COMAR 26.12.01.01F.5(n)(2). A registered and licensed radiologist assistant or a radiological technologist may **NOT** independently energize or initiate a fluoroscopic exposure for clinical purposes.

All x-ray facilities, including radiology schools, vendors, and service providers are reminded that any exposure of individuals to x-rays for training or demonstration purposes is not permitted in Maryland based on COMAR26.12.01.01 F.3(a)(1)(viii), which states: *"**Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision also prohibits deliberate x-ray exposure for the purpose of training, demonstration or other non-healing-arts purposes."***

Updated Facility Area Survey (RX22):

The RX22 has recently been updated and now requires the signature of the facility representative and the date. This form must be used and completed in its entirety or it will not be processed by RHP and will be returned.

Service Provider Expectations:

Companies providing x-ray services to radiation machine facilities must maintain a current registration with the RHP. To avoid a lapse in registration, applications for renewal must be submitted ahead of the expiration date. RHP does not provide reminders. Facilities which utilize the services of an unregistered company may be subject to enforcement action.

The RX24/FDA 2579 forms are to be completed in their entirety. The Report of Assembly, Reassembly, or Removal (RX24) should be completed and submitted any time a radiation machine has been: installed, relocated, removed, disabled, or has had a major component replaced. These forms should be legible and accurately completed to include facility address, facility contact information, tube serial number, facility registration number (if assigned), and MDE machine number (if assigned there will be a red sticker located on the machine). Service providers must remember to use the actual physical address of the facility on the RX24/FDA 2579 forms rather than the facility's mailing address. It becomes extremely difficult to determine which facility has had a change in machines when there are multiple locations.

The submission of a Report of Assembly, Reassembly, or Removal (RX24/FDA2579) does not register a facility, and does not absolve the facility of its responsibility to register the radiation machines with the RHP. A radiation machine cannot be used until registration and/or certification approval from the RHP has been granted. Any unregistered facility actively using a radiation machine will be subject to enforcement action. Service providers should remind the facility to contact the RHP immediately to acquire all the necessary paperwork to apply for

registration. The registration process may take up to 90 days from the receipt of a complete application. Service provider paperwork must be submitted to the RHP no later than **15 calendar days** after the completion of a service. Many registered service providers continue to significantly exceed this time frame. Enclosed is a bar graph (Appendix B) depicting submission times by each service provider. Contact Ms. Talya Langbaum to determine if you are meeting the regulation submittal times.

Preventive Maintenance Expectations:

Effective November 1, 2016, the RHP will begin to enforce COMAR 26.12.01.01 B.6(e)(1), which requires that each preventive maintenance report shall be completed on the specific preventive maintenance form made available by the Agency applicable to the type of machine tested:

There are four such forms, which cover most common types of radiation machines:

Form RX33 Intraoral Dental Radiation Machine Preventive Maintenance Report
Form RX34 Cephalometric/Panoral Dental Radiation Machine Preventive Maintenance Report
Form RX16 General Purpose Radiation Machine Preventive Maintenance Report
Form RX36 Veterinary Radiation Machine Preventive Maintenance Report

If the machine is of a type different from these types for which specific PM Reports have been developed, a service-provider-produced form should be used. Such form should provide sufficient information for RHP to identify the radiation machine tested and confirm that the machine is operating in accordance with its manufacturer's specifications.

The Preventive Maintenance submission will be reviewed by a Health Physicist for completeness and for demonstration of compliance with manufacturer's specifications. Problems found during the review will be noted and the service company that performed the PM may receive follow-up questions for clarification.

Preventive Maintenance providers are expected to bring performance issues to the attention of the facility when found.

COMAR 26.12.01.01 F.3(d) requires facilities to have preventive maintenance performed based on the recommendation of the manufacturer. After performing preventive maintenance, service providers must give a complete preventive maintenance report to each facility. The facility is responsible for sending a copy of this report to RHP. Facilities have 30 days to provide these reports to RHP. Any delay in receipt by the facility of a complete report may affect their ability to comply with state regulations.

Service providers are reminded that each preventive maintenance service report must positively identify the RHP-assigned tube number (or serial number if no RHP number has been assigned) and the facility registration number. Identification of room alone is not sufficient.

Demonstration X-ray Devices

Radiation machines used for temporary use at a facility for human examination purposes must be registered with the RHP prior to its use. The registrant must pay the registration fee, plan review/area, and ensure a certification inspection has been performed by a state licensed private inspector. Registration and certification approval can take up to 90 days, therefore, the registrant should contact the RHP in a timely manner.

Demonstration units not for human use do not need to be registered if they will be in the State for less than 20 days. While registration is not required, the Department must be notified in writing prior to the planned demonstration. Notification must include the type of unit, location and duration of the demonstration, as well as a description of how the unit will be used.

Hand-Held Dental X-ray Machines

The RHP reserves the right to deny a facility's request to use a dental hand-held x-ray unit. The service company should ask the facility if they have contacted the RHP prior to purchasing a dental hand-held unit since there are specific criteria that must be met by the facility. If a facility is approved by the RHP to use a hand-held unit, all personnel who use this hand-held x-ray unit must wear a personnel dosimetry device during use to record personal exposure levels and be able to document user training before first use.

Exposure Monitoring Reports

Exposure monitoring reports must be specific to the sites in which they were contracted. The badges cannot be shared between facilities or with several locations within an organization. New owners are required to initiate monitoring for their facilities. RHP allows only monthly or quarterly cycles for monitoring.

Personnel being shared on a temporary basis between office locations may wear the same badge as long as the readings are collectively read at their central location and a record is kept to determine where high readings may have occurred.

Dental schools are no longer required to furnish film badge monitoring to radiation staff and students on a continuous basis. Schools may follow the same policy as granted to other dental facilities by completing a minimum of six (6) consecutive months or four (4) consecutive quarters, provided doses are found to be negligible.

All dental facilities must provide continuous monitoring to operators of CBCT/3D machines and hand-held x-ray units. Dosimeters must be individually assigned and not shared. Film badge exposure reports are to be maintained at the facility indefinitely. Area radiation monitoring does not meet the regulatory requirement for personnel monitoring.

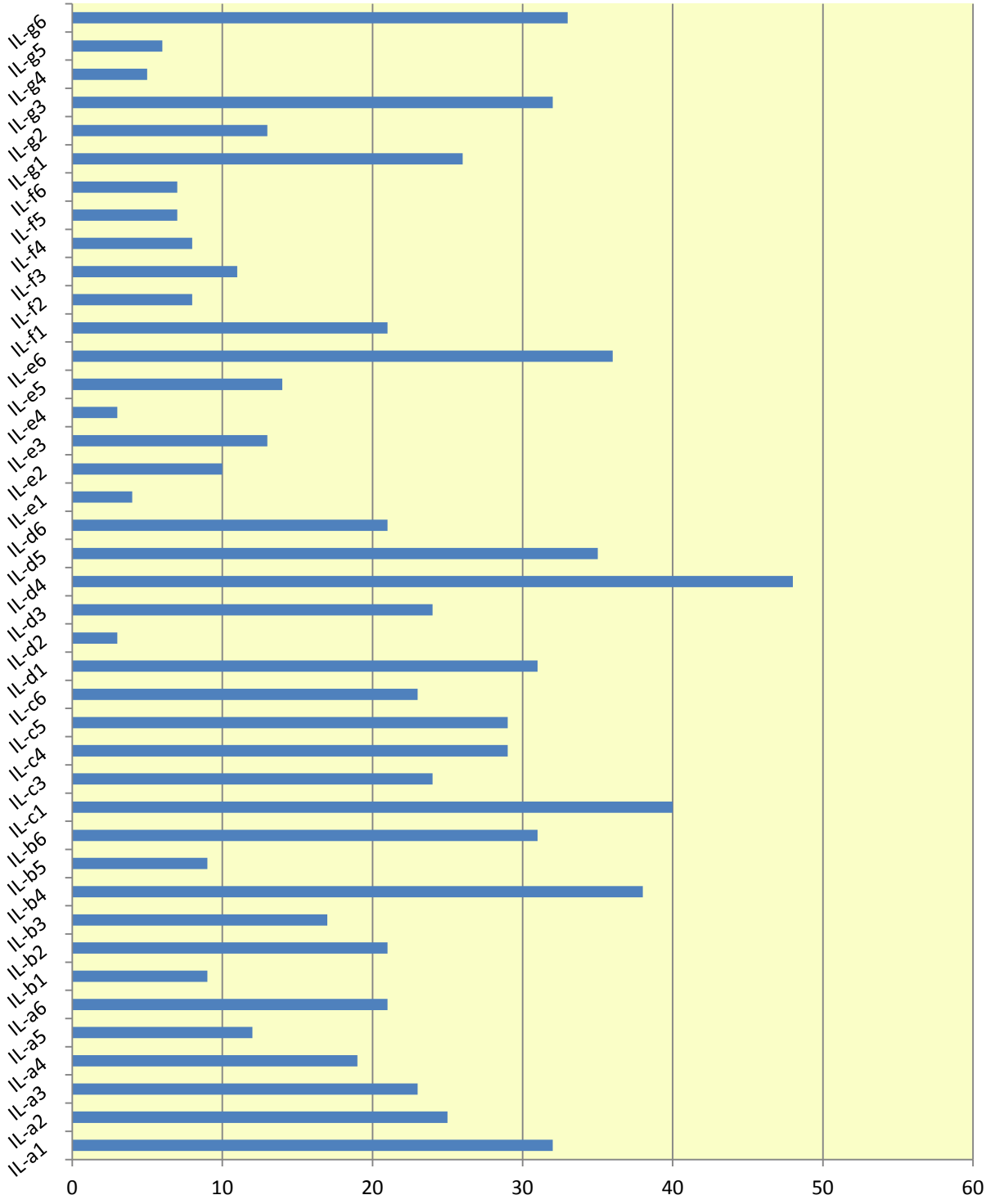
Dental Cone Beam Computed tomography (CBCT) and Panoramic X-ray Machines equipped with Automatic Exposure Controls that do not comply with Maryland Radiation Safety Regulations

Some dental x-ray manufacturers are designing dental CBCT and panoral machines that allow the operator to leave the protected area once the exposure has started. These machines typically require the operator to select an acquisition prompt in the software or briefly press a scan button to start the exposure. Once the exposure is initiated, the operator is free to leave the protected area. There are also machines equipped with automatic exposure delay, where the operator selects a prompt on the control panel of the machine to ready the exposure. The operator is then cued to move to a protected area before the delay lapses and the exposure starts. Currently, the designed machines do not comply with COMAR 26.12.01.01 F.6(b)(2)(ii)(a) which states: "***stationary x-ray systems shall be required to have the x-ray control mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure."*** To guarantee the radiation safety of the operator, it has been MDE's policy to restrict the operator to a protected area by using a permanently mounted dead-man exposure switch installed at least six (6) feet from the tube/patient or behind an adequate barrier. The operator controls the exposure by keeping continuous positive pressure on the switch or releasing it to cause the exposure to stop. Any modifications to bring machines already using automatic exposure acquisition into compliance must ensure the operator remains in the protected area during the full exposure. From the protected area, the operator must have the ability to both terminate the exposure at any time and to view the patient during the entire exposure.

cc: Memorandum Regarding Diagnostic Medical Radiation Exposure
Diagnostic Medical Event Occurrence Log RX38

Appendix A

Time Taken to Submit Certification Inspection Reports - 2015



Appendix B

Time Taken to Submit RX24s/FDA2579s - 2015