



This newsletter is on the MDE web site:

http://www.mde.state.md.us/programs/Air/RadiologicalHealth/InformationalMemos/Pages/Programs/AirPrograms/Radiological_Health/memos/index.aspx

Upcoming Meeting at the Maryland Department of the Environment (MDE)

The state licensed private inspector and registered service provider meeting will be held at MDE early next year. A date will be announced later. The Radiological Health Program is very interested in making this upcoming meeting a helpful and informational opportunity. If you have specific questions please email Mr. Ahsan Bhatti at ahsan.bhatti@maryland.gov or Ms. Mahala Thomas at mahala.thomas@maryland.gov to ensure that your questions are answered appropriately at the meeting.

Radiological Health Program (RHP) Announcement

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

Leteisha Hunt – Health Physicist Trainee in RMD’s Registration and Certification Section
Marsha Kennedy – RMD’s Office Secretary II

The Regulations and Radiation Exposure Strategies Section is proud to announce the filling of two positions:

James Ways – Health Physicist Trainee
Cydne McGuire – Health Physicist Trainee

Private Inspector License Requirement

All new and renewal applicants must disclose their Social Security Number on the application for a license to inspect radiation machines (RX32). 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. New and renewal applicants must submit a curriculum vitae with their application. A line has been added to the RX32 requesting your email address. This will help RHP disseminate information to you quickly. New applicants must submit official transcripts and provide accurate contact information of past employers for RHP verification. Please contact Mr. Ahsan Bhatti for further information.

Private Inspector Expectations

All inspection reports must be completed in their entirety and submitted to the RHP no later than 30 days after the beginning of each radiation machine inspection.

All facility information on the Radiation Machine Facility Registration Form (RX1) must be accurate and signed by the facility representative prior to submitting the inspection report.

Any cited inspection violations must be recorded in the inspection report and listed and properly cited on the Inspection Summary Form (RX2).

Preventive maintenance (PM) service reports must be reviewed during the inspection. The updated Inspection Data Facility Specific Form (RX4) requires specific PM information. Should the inspector find that the latest PM report date is not current (the manufacturer normally requires maintenance every 12 months), the facility may be subject to an enforcement action. The inspector should ask the facility representative if the PM report has been sent to the RHP.

Certification inspection forms have been updated and are posted on the website. Certification inspections **must** be submitted on the updated forms or they will be returned to the inspector causing a delay in approval by the RHP. The following is a link to the updated forms: http://www.mde.state.md.us/programs/Air/RadiologicalHealth/XRayApplicationFormsandGuidance/Pages/Programs/AirPrograms/radiological_health/xray_applications/index.aspx

Maryland Certification Inspections Facility Personnel Monitoring

All radiation machine facilities are required to have continuous personnel monitoring for all occupationally exposed workers. Podiatry and bone density facilities may be exempted after receiving RHP approval. In order to gain an exemption, the facility should submit a written request. The request should include 6 consecutive months or 4 consecutive quarters of dosimetry records. Upon review of the dosimetry records, the RHP may grant an exemption. A podiatry or bone density facility with a Fluoroscopy unit and/or other type of radiographic may not be eligible for an exemption. Approval letters should be available for review during inspections.

Exemptions remain 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. A radiation machine's operation or performance is such that RHP determines that monitoring is warranted again.

Machine Numbers

The RHP inspectors and state licensed private inspectors are authorized to assign unique machine numbers and place red stickers on each radiation machine. RHP inspectors, state licensed private inspectors, and service providers must use the assigned numbers on any documentation that is submitted to the RHP. Please contact Ms. Talya Langbaum or Ms. Shannon Page for assignment of machine numbers or red stickers.

Service Provider Expectations

Service companies providing x-ray services to a radiation machine facility must be registered with the RHP. It is the responsibility of the service company to maintain a current registration with the RHP. A facility, who utilizes the services of an unregistered service company, may be subject to enforcement action.

There have been significant changes to the training, requirements and paperwork submission expectations; specifically B.6 (e) and B.6 (f) of the regulations that were effective January 2014. The new regulations describe what is expected as sufficient content for preventive maintenance documentation, the length of time to submit final reports to the customer and to have those reports relayed to RHP. The radiation machine facility has 30 days to submit their PM reports to the RHP.

The website contains specific updated PM forms. These forms **MUST** be used by all service providers.

Service companies are required to submit all paperwork to the RHP no later than 15 days after service is completed. The forms are to be completed in their entirety and the machine number which is housed on the red sticker should be denoted.

The submission of the report of assembly reassembly or removal of a radiation machine (RX24) or FDA 2579 does not absolve the facility from registering their radiation machines with the RHP. The facility must contact the RHP to acquire all the necessary paperwork.

A plan review is required prior to installation of a dental cone beam computed tomography machine at a facility.

The RHP reserves the right to deny a facility from acquiring a dental hand held unit. The service company should ask the facility if they have contacted the RHP prior to selling a dental hand held unit since there are specific criteria that must be met.

Demonstration Devices

The RHP does NOT issue temporary registrations or reciprocity for radiation machines. Radiation machines used for demonstration purposes on humans must be properly registered with the RHP. This includes fees, inspections, and area survey/plan reviews if applicable. The registration may be done by the vendor or the facility where the demonstration will take place. The registrant will become the responsible party. Registration and certification approval can take up to 90 days; therefore, please contact the RHP in a timely manner.

Demonstration units not for human use do not need to register 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 should include the type of unit, location and duration of demonstration, as well as a description of how the unit will be used.

Regulations Update and Clarification of Specific Regulations

COMAR 26.12.01.01F.3(d) - The regulation requires facilities to have preventive maintenance performed based on the recommendation of the manufacturer. Compliance with this regulation is based on the number of months between PM visits as stipulated by the manufacturer in its paperwork, installation procedures, or user manual. The RHP continues to adjust PM periods as published by updates from the manufacturers. Please direct any newly found information that may impact the timing of preventive maintenance to Mr. James Ways or Ms. Cynthia Pochan.

In Supplement 24, which will be effective September 15, 2014 there are a series of changes too large for inclusion in a newsletter. A summary of some of the changes can be found below.

B.6 (g) Each person registered to provide services to radiation machine facilities including installation, assembly, calibration, repair, maintenance, disablement, or removal of radiation machines shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Part D of this regulation.

B.9 (b) Each application for renewal of registration of a radiation machine facility must be received by RHP at least 14 days prior to expiration of the facility's existing registration. Such application shall be made in accordance with the provisions of Section B.5. The RHP shall not grant re-registration unless all previously invoiced radiation machine fees are paid in full.

“Thyroid shielding” means a collar or shield consisting of ≥ 0.5 mm lead equivalent which is effective in protecting a patient's thyroid gland from direct exposure to the useful x-ray beam.

F.3(a)(7) states that thyroid shielding consisting of a ≥ 0.5 mm lead equivalent thyroid collar or shield shall be provided to and used for all patients upon request or whenever the useful beam is expected to or may strike the thyroid gland, so long as such shielding does not interfere with diagnostic x-ray procedures.

F.7(j) specifically for dental facilities states that thyroid shielding (as described above) shall be provided to and used for all patients, so long as such shielding does not interfere with diagnostic x-ray procedures.

F.(10)(d) and F.(10)(d)(3) discuss the allowed use of hand held radiographic devices in veterinary settings. These regulations are similar to the use of dental hand held machines.

Service Provider and Licensed Private Inspector Turn-Around Time and Submission Results

Enclosed are charts labeled Appendix A and B that provide information about your submission compliance rates that will help determine if you are meeting the specific regulations.

Appendix A refers to the private inspector submission time for certification inspections. Appendix B refers to the service company's submission time of the RX24/FDA forms. Unique identifiers have been assigned to all service providers and licensed inspectors as represented on the graph. For more information on the status of your compliance rate, please contact Ms. Talya Langbaum or Ms. Shannon Page.

Website Update

The following is the link to website:

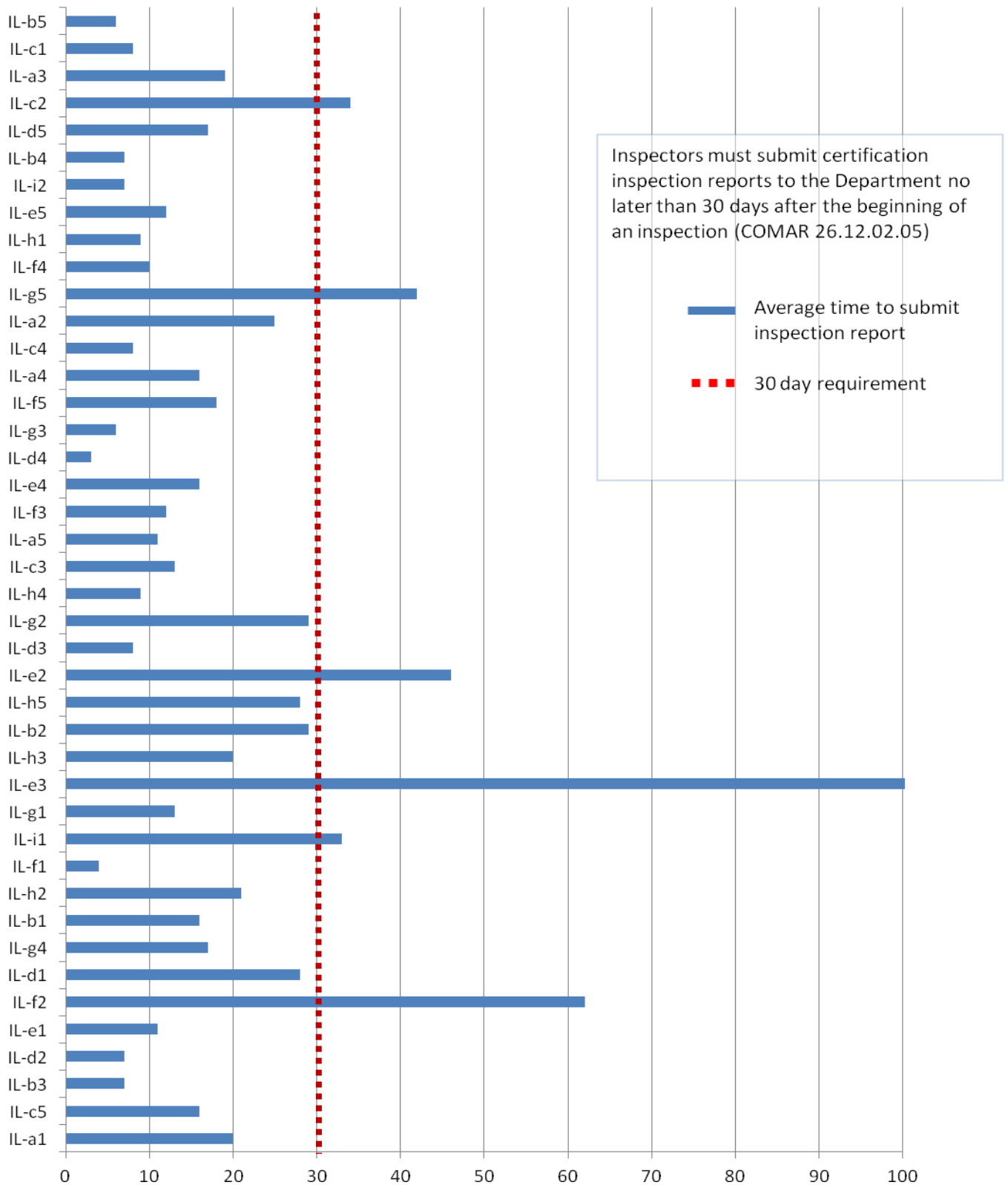
http://www.mde.state.md.us/programs/Air/RadiologicalHealth/Pages/Programs/AirPrograms/Radiological_Health/index.aspx

The RHP continues to post updated forms on the Department's Radiological Health Program Web page. All forms are periodically updated. Private inspectors and service providers are responsible for using the most current version of the documents, as they most accurately reflect the regulations set forth in the COMAR.

The Web section called Upcoming Events is updated frequently to reflect RHP informational meetings to be held at MDE.

Appendix A

Time Taken to Submit Certification Inspection Reports During FY14 (July 1, 2013 -June 30, 2014)



Appendix B

Time Taken to Submit RX24s/FDA25792 During FY14 (July 1, 2013 - June 30, 2014)

