



Maryland Department of
the Environment

Information and Regulatory Interpretation Memo (IRI) 15-00

Registered Service Provider Newsletter

April 2015

This newsletter is on the MDE website:

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

The Radiological Health Program (RHP) is interested in keeping its licensed inspectors and registered service providers informed on any changes in the regulations or within the Radiation Machine Division (RMD) of RHP itself. If you have specific questions or concerns, 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.

Radiological Health Program (RHP) Announcement

The Radioactive Materials Division (RAM) is proud to announce the filling of one position:

Mr. Charles Cox- Health Physicist Supervisor for Licensing

State Licensed Private Inspector Application (RX32) Requirements

New and renewal applicants are required to 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 MDE to verify if the applicant has any child support obligations. New and renewal applicants must submit a curriculum vitae with their application. New and renewal applicants who want to provide medical physicist services to mammography facilities in Maryland must provide their mammography credentials with the RX32. Failing to do so will delay approval. If you have any questions, please contact Mr. Ahsan Bhatti.

State Licensed Private Inspector Responsibilities

Some private inspectors still continue to use outdated certification inspection forms. Last year the RMD updated all certification forms and placed them on MDE's website. 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

The following are recurring issues with a submission of a certification report:

1. Failure to submit a completed Radiation Machine Facility Registration Form (RX1) along with the certification report.
2. Failure to submit the correct number of tubes/machines located at the facility on the RX1.
3. Failure to denote an inspection violation(s) on the Inspection Summary Form (RX2).
4. Failure to use the correct COMAR citation on the Inspection Summary Form.
5. Failure to denote the latest preventive maintenance report date on the Inspection Data Facility specific Form (RX4).

Currently, the RMD staff contacts the private inspector to explain the missing items. Effective July 1, 2015, a deficiency letter will be mailed to the private inspector for an incomplete inspection report submittal. RMD will not process any certification inspection reports that are not complete.

The RMD will be sending a memo, which is enclosed, to all oncology and radiology supervisors reminding them of the reporting requirements for a misadministration.

According to COMAR 26.12.02.05, the inspection report must be submitted to the RMD no later than 30 calendar days after the beginning of each radiation machine inspection. Appendix A depicts the submission compliance rates for each active inspector. For your specific compliance rate, contact Ms. Talya Langbaum at talya.langbaum@maryland.gov or 410-537-3193.

Service Provider Expectations

Service providers who offer x-ray services to a radiation machine facility must maintain a current registration with the RMD. Service provider registrations expire every three years. To avoid a lapse in registration, submit your application for renewal ahead of your expiration date. The RMD does not send out reminder letters. A facility, who utilizes the services of an unregistered service company, may be subject to enforcement action.

The service providers must denote the physical address, not the mailing address of the facility, on the Report of Assembly Reassembly or Removal of a Radiation Machine form (RX-24) or FDA 2579 forms. The physical address is important because one facility may have multiple locations which makes it extremely difficult to determine where the change occurred if the mailing address is provided. Service companies should inform the facilities that submission of the RX24 does not absolve the facility from registering their radiation machines with the RMD. Any unregistered facility actively using a radiation machine will be subject to enforcement action. Facilities should contact Ms. Talya Langbaum, Ms. Shannon Page, or Ms. Leteisha Hunt at 410-537-3193 to inquire about the facility registration process.

The COMAR 26.12.01.01F.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 these reports to RMD. Some facilities have reported not having received the report (sometimes they only received an invoice) causing them to have to contact their provider for a copy. Facilities have only 30 days to provide these reports to RMD. Any delay in receipt of a complete report may affect their ability to comply with State regulations. The service providers must positively identify the RMD assigned machine number and the facility registration number on the preventive maintenance forms.

Some service providers continue to use their own forms to submit preventive maintenance findings. The preventive maintenance summary forms for intraoral, cephalometric, panoramic, general purpose, and veterinary are located on MDE's website. The following is a link to the forms:
http://www.mde.state.md.us/programs/Air/RadiologicalHealth/XRayApplicationFormsandGuidance/Pages/Programs/AirPrograms/radiological_health/xray_applications/index.aspx

According to COMAR 26.12.01.01B.12, any service paperwork must be submitted to the RMD no later than 15 calendar days after completion of service. Appendix B depicts the submission compliance rates for each service provider. For your specific compliance rate, contact Ms. Talya Langbaum at talya.langbaum@maryland.gov or 410-537-3193.

Demonstration X-Ray Devices

Radiation machines used for demonstration purposes on humans must be registered with the RMD prior to their use. The registrant must pay the registration fee, submit the RX1, payment transmittal form, plan review or area survey, and ensure that the machine is certified by a state licensed private inspector. Registration and certification approval can take up to 90 days, therefore, please contact the RMD 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 RMD 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.

Dental Cone Beam Computed Tomography (CBCT)

Service providers who sell and/or install a dental CBCT or 3D machines in a dental office should inform the facility that an application for plan review (RX21) is required for approval by RMD at least 30 days prior to installation of the machine.

Dental Hand-Held X-ray Machines

The RMD reserves the right to deny a registrant's request to use a dental hand held x-ray unit. The service company should ask the facility if they have contacted the RMD prior to selling a dental hand held x-ray unit since there are specific criteria that must be met by the registrant.

Personnel Monitoring Reports

Personnel monitoring reports must be maintained and specific to the physical location of the radiation machine. Personnel badges are not interchangeable between staff members, facilities or several locations within an organization. Contact Ms. Eva Nair or Mr. Jerry Adams at 410-537-3193 about specific personnel monitoring requirements.



MARYLAND DEPARTMENT OF THE ENVIRONMENT

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Larry Hogan
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Secretary

DATE: April 9, 2015

TO: All State Licensed Private Inspectors, Oncology and Radiology Supervisors

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

SUBJECT: Misadministration Reporting Requirements

RHP reminds all registrants with diagnostic and/or therapeutic radiation machines of mandatory reporting requirements for all alleged misadministrations as required by Code of Maryland Regulations (COMAR) 26.12.01.01 entitled "Regulations for the Control on Ionizing Radiation (1994)."

Misadministration of a **teletherapy radiation dose** or **dose from a radiation machine** is defined in COMAR 26.12.01.01 Sec.D1208b.iv to be the following:

1. Medical procedure involving the wrong individual, wrong mode of treatment, or wrong treatment site, or of a type other than the one intended; or
2. When the treatment consists of three or fewer fractions, a difference of the calculated total administered dose from the total prescribed dose by more than 10 percent of the total prescribed dose; or
3. A calculated weekly administered dose that is 30 percent greater than the weekly prescribed dose; or
4. A calculated total administered dose that differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

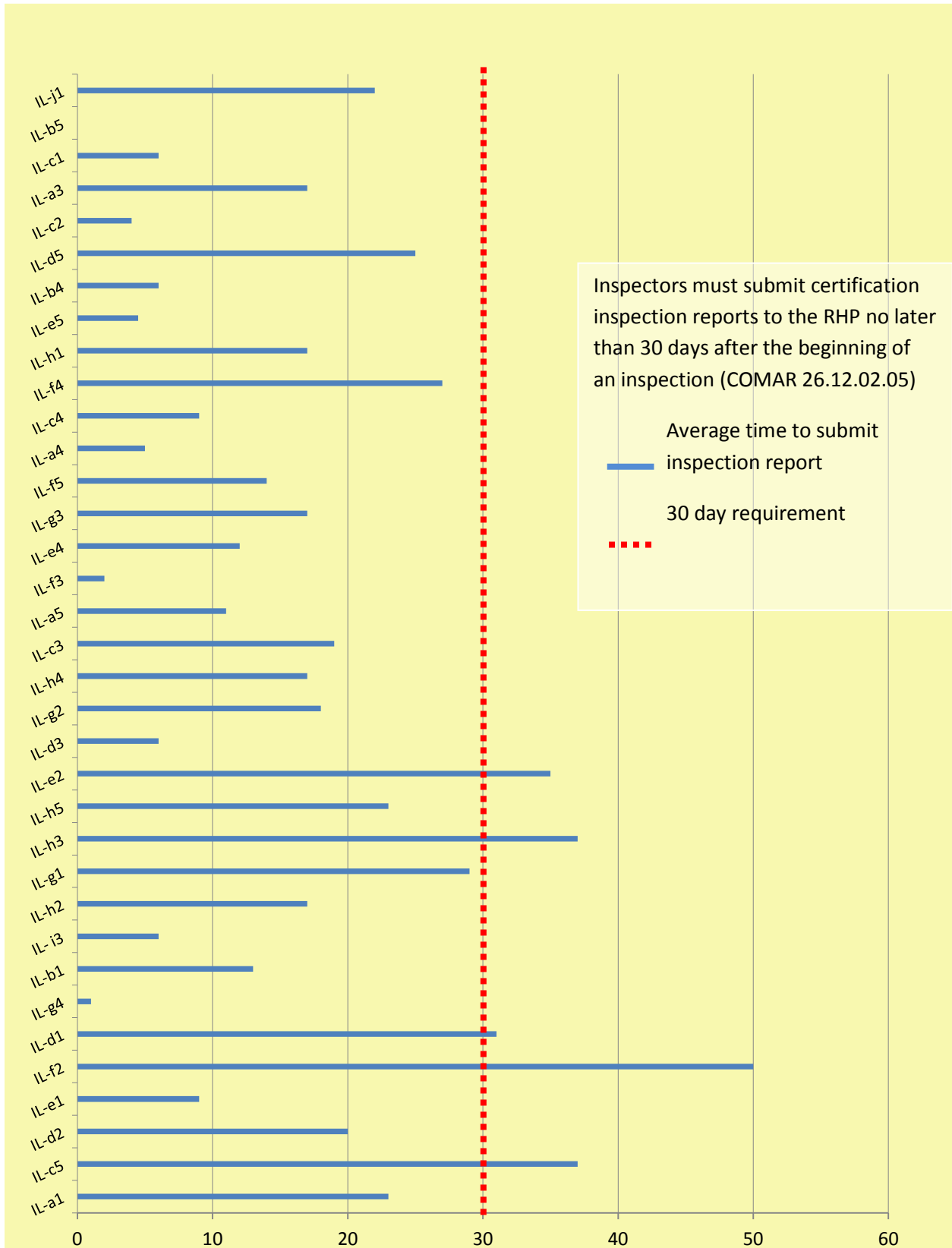
All alleged misadministrations must be reported by telephone to the RHP no later than the next calendar day after discovery according to COMAR 26.12.01.01.

If you have any questions about misadministration reporting regulations, please contact Ms. Eva Nair, Mr. Jerry Adams, or Ms. Talya Langbaum at 410-537-3193.



Appendix A

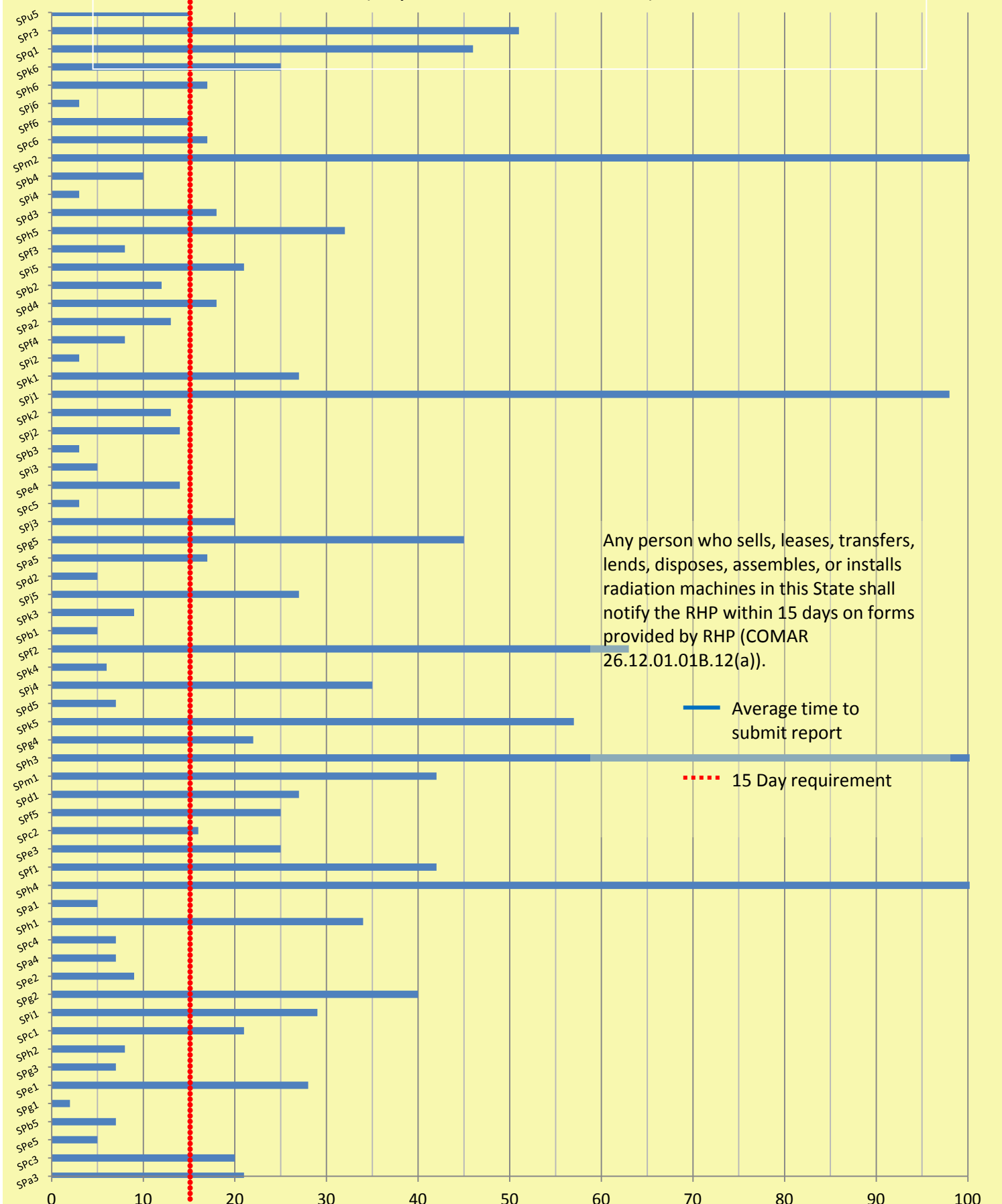
Time Taken to Submit Certification Inspection Reports During First Half of FY15 (July 1, 2014 -Dec. 31, 2014)



Appendix B

Time Taken to Submit RX24s/FDA2579s During First Half of FY15

(July 1, 2014 - Dec. 31, 2014)



Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines in this State shall notify the RHP within 15 days on forms provided by RHP (COMAR 26.12.01.01B.12(a)).

— Average time to submit report
..... 15 Day requirement