



MARYLAND DEPARTMENT OF THE ENVIRONMENT

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DATE: November 6, 2013

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

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)

SUBJECT: Information and Regulatory Interpretation Memo (IRI) 13-01, November 2013
Registered Service Provider Newsletter, November 2013

On July 26, 2013, a meeting was held with the state licensed private inspectors and the registered service providers. The following is a summary of the topics discussed during the meeting.

Registered Service Provider Expectations:

All service companies providing x-ray services to radiation facilities must be registered with the RMD. Unregistered service companies providing x-ray services are in violation of COMAR 26.12.01.01B(6) and radiation machine facilities that accept services from unregistered service companies are in violation of COMAR 26.12.01.01B(14)(c). Any x-ray services performed during a lapse in registration may subject the registrant of a facility to pay a financial penalty. Service companies are responsible for ensuring that their service registration is maintained according to regulations.

There have been facilities that are lodging complaints against certain registered service providers that have been slow to respond to inquiries about having their radiation machine undergo service or repair work. As a reminder, the MDE issues you a registration to ensure that you are providing x-ray services which should be your priority.

Service companies are required to submit all paperwork (RX24/FD2579) to the Department no later than 15 days after service is completed. The forms are to be completed in their entirety and legible.

Dental facilities that intend to acquire a cone beam computed tomography machine must have a plan review or area survey performed, prior to installation.

Hand held dental units are only approved for use in dental facilities that ALSO have a permanently mounted unit. Each registration application will be reviewed on its own merits to determine the need

for the device. Dental facilities must complete the hand held device log which is located on the MDE website. These machines must be FDA approved and have a non removable shield.

Service providers and preventative maintenance (PM) technicians are considered by occupation a Radiation Worker and are required to wear film badges. The RMD will conduct random audits in which service companies will have to submit their dosimetry reports for their employees.

The RMD does not interfere in the business relationship between the service provider and the registrant/client. The RMD does not endorse any particular service company for x-ray services, set the price for service work orders, or facilitate business agreements between the two entities.

State Licensed Private Inspector Expectations:

State licensed private inspectors must submit complete/signed certification inspection reports to the Department no later than 30 days after the beginning of an inspection. Cited violations are not considered corrected until they have been verified by the inspector in the form of an initialed/dated RX2. Updated inspection forms are available on the MDE website.

Any used or old radiation machine except for dental, veterinary, or mammography must be inspected by a State licensed private inspector prior to use. A certification inspection can be performed prior to registration of the facility. Denote “unreg” or “pending reg” for the field that asks for the registration number on the Radiation Machine Facility Registration Form (RX1) and the certification inspection forms. If violations are cited, those must be resolved prior to operation. Failure to comply with State regulations could result in the suspension, revocation, or termination of a license.

All new applicants and state licensed private inspectors are required to submit their social security number on the application to inspector radiation machines form. Your social security number will not be used for any purposes other than those described. Authority to collect your SSN is granted by the Family Law Article, Annotated Code of Maryland, § 10-119.3 (“FL 10-119.3”). Be advised that FL § 10-119.3 allows for certain licensing information, including your full name, address, SSN, and description of the license held by you, to be exchanged with the Maryland Department of Human Resources (“DHR”). The exchange of this information, including your SSN, is to assist in verification of your identity and to invoke the provisions of FL § 10-119.3 relating to child support obligations. Your SSN will NOT be given to the public, except as permitted by law. Please be further advised that FL § 10-119.3(e) allows MDE to suspend your license or deny your application for licensure upon notification by DHR.

Preventive Maintenance Requirement

Preventive maintenance (PM) is required on all radiation machines on the frequency recommended by the manufacturer. While it is the facility’s responsibility to send to the Department all PM service reports, the service provider should ensure that the facility has been given a complete report, which will:

- be completed on **the Department’s forms** for dental intraoral, dental pan/ceph, general purpose, or veterinary radiation machines

- provide identification of the **facility** and the **machine**, and the **date** the service was performed
- provide the **results of all tests** performed and indicate whether the machine **passed or failed** each test

Note: The facility and the service provider **must sign** each PM service report. The provider must give the facility the fully signed complete report for each machine on the date of service but in no case later than **seven days** after the service was performed. The provider must communicate the findings of the preventive maintenance check with the registrant.

Film Fog and Safelight Testing

There is a perception that the MDE inspectors and the service providers perform these tests in a different manner. The MDE inspector checks for visible light in the darkroom to determine light leakage and uses the densitometer and sensitometer device for actual measurements.

Instrument Review for the Piranha:

The Department is not advocating that service providers use this meter for dental PM but is relaying information on how the Piranha is being used by the MDE inspectors. The Piranha offers the following information:

- (1) Determination of Single phase vs. DC generator
- (2) Option of setting trigger level: 50% vs. 20%
- (3) Option of manually setting the default time from 200 msec to 100 msec
- (4) Option of manually evaluating HVL
- (5) Detector must be within +/- 5% with respect to x-ray tube

The ultimate goal is to have consistency among all registered service providers when performing a PM.

Plan Review and Area Survey Requirements

Submittal of a plan review or area survey must consist of the following items: the need for accurate ¼” scale drawings of the rooms, detailed exposure parameters, appropriate signatures, volume estimates, barrier construction detail, and completion of the form in entirety.

Accelerator plan reviews must consist of the following:

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

Testing Hand Held Units

The MDE inspectors test the dental hand held units the same as any other dental portable machine. The MDE inspector evaluates the output mR, kVp reproducibility and accuracy, and timer accuracy and reproducibility. The tube housing aperture is placed just in front of the piranha with the piranha set and braced by pillows. The MDE inspector wears an apron and gloves when taking an exposure.