

DATE: February 4, 2010

TO: All State Licensed Private Inspectors and Registered Service Providers

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

FROM: Eva Nair, Chief, Radiation Machine Division (RMD)
Jerry Adams, Section Head, Radiation Machines Division (RMD)

SUBJECT: State Licensed Private Inspectors and Service Provider Newsletter, February 2010

Introduction

Roland Fletcher, Manager of the Radiological Health Program, welcomed all of the attendees and thanked everyone for their work over the last year and for their continued support in protecting the Maryland public from unnecessary radiation exposure. He encouraged the private inspectors and service providers to do more to ensure that the regulated community is aware of the increases in enforcement and penalties assessed to facilities who fail to maintain compliance at all times under the provisions of the Maryland Department of the Environment (the Department) Enforcement Policy. Mr. Fletcher conveyed his appreciation for their continued support and dedication to the Program and the regulated community.

Radiation Machines Division Announcement

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

Matthew Almes – Section Head and Supervisor of the Registration and Certification Section
Jacob Reinhert – Health Physicist Trainee in RMD’s Registration and Certification Section.

Update on Increased Enforcement

Eva Nair gave a presentation entitled, “Update on Enforcement”, providing data on how many enforcement cases have been pursued by RMD and the rates of compliance for the past three years. Ms. Nair discussed the new regulation changes and the effect on the regulated community. The State licensed inspectors and service providers need to ensure that the facilities are following their preventative maintenance schedule.

Penalty Reminder

At the end of every inspection, facilities will receive a Radiation Machine inspection summary form RX-2. This form serves as a NOTICE OF VIOLATION of the standards contained in Maryland Regulations COMAR 26.12.01.01. Violations subject registrants to the penalty provisions of Subtitle 5, "Enforcement" of title 8, "Radiation" of the Environmental Article, Annotated Code of Maryland which can result in a fine of up to \$50,000 or imprisonment of up to one year, or both. All violations must be corrected immediately, initialed and dated by a facility representative and returned to the Division. Any service work orders to resolve a violation must accompany the RX2 form.

New Regulation Changes Effective June 15, 2009

Public Posting of Notices of Violation

(a) A notice of violation issued by the Department to a registered or licensed facility shall be conspicuously posted at the facility for public review within two (2) working days after receipt.

(b) A notice of violation shall remain posted for a minimum of 30 working days or until action correcting the violation has been completed and this correction has been verified by the Department.

Interpretation: Notices of Violation must be posted within 2 days after receipt and stay up for 30 working days or until violation correction verified.

Machine Maintenance

A registrant shall maintain each radiation machine in accordance with the manufacturer's recommended specifications.

A registrant shall maintain documentation, in the form of logs, service tickets, or work orders, that the machine manufacturer's recommended maintenance schedule has been met.

Interpretation: Radiation Machines shall be maintained according to manufacturer's recommendation. Service tickets or work orders can be used to demonstrate compliance.

The expectation of the RMD on the service orders is that RMD inspectors when deciding on the acceptability of PM documentation will expect to see outcome numbers and indications that specific required tests were performed. The statement PM performed or completed without the documentation will not be accepted.

PM Requirement for Industrial Facilities

State licensed private inspectors need to ensure during their certification inspection that all industrial units are complying with COMAR 26.12.01.01E.5,E.31,E.73, and H.4 in terms of recordkeeping. The facility should be maintaining documentation to demonstrate that these regulations are being met such as annual surveys, interlock checks, light checks. The inspector shall cite the facility if the documentation can not be provided at the time of the inspection. COMAR H.4(b)(2) states that radiation survey measurements

may not be required if H.4(a) can be met. These units would include electron microscopes and X-Ray Fluorescence (XRF) Units.

Darkroom Evaluation

A review of darkroom procedures, fog testing, and processor preventative maintenance must be included as part of any quality review PM for Dental offices.

Licensing Process for State Licensed Private Inspectors

Ahsan Bhatti presented a review of what was required for a new applicant submitting an application to be licensed as a State Licensed Private Inspector. The requirements are stated in the Code of Maryland (COMAR) Regulations 26.12.02., Inspection and Certification, .03, Licensing of Inspectors. Mr. Bhatti reminded the inspectors to indicate interest in providing mammography services to facilities and have the relevant supporting documentation. Foreign degrees must be reviewed, translated, and validated by an outside agency prior to being accepted for our review.

Accelerator Plan Reviews

Randall Haack presentation entitled, "Consideration of Barrier Design for Accelerator Vaults", explained workload determination, use factors, occupancy factors, exposure/dose equivalent and the need to examine these closely. For further information or the presentation slides, please contact Mr. Haack..

Training on Dental Inspections

Yun Chong and Cynthia Pochan presented hands on training on performing a dental inspection utilizing the RTI Piranha. They explained the methods used to evaluate KVP and timer accuracy as well as the determination of half value layers and the need to check darkroom light levels and the processor. A detailed training session will be held on March 4, 2010 at the Department for the Dental Service Providers Meeting. If you did not receive a registration form and wish to attend, please contact Mr. Almes for further information.

Service Provider Audit

Christina Rowand provided a review of the data from the 2009 Service Provider Performance Report. According to COMAR 26.12.01.01 registered service companies are required to submit the RX-24 and/or FDA 2579 forms within 15 days of completion of the work.

The majority of service providers are within the mandated time specifications:

1st quarter – 25 days
2nd quarter – 20 days
3rd quarter – 21 days

Review of Dental Inspection Expectations

Noninvasive vs. Invasive determination of equipment values

The accepted method of measuring a radiation machines kVp is by reading the value as an output from the tube during an exposure using a non-invasive multimeter. Some service companies will use an internal diagnostic method to approximate the kVp level which can differ from the value determined by the RMD's measurement. Compliance determination is based on our measured results. As such, we strongly recommend that service companies performing these checks use a tool that reads kVp levels as an output. A service company may find similar issues with the measurements of timer accuracy.

30 Day Dental Inspection Notice

RMD provides at least a 30 day notice of our intent to inspect the dental offices. The dental office receives a call from a RMD inspector and will determine a date convenient to the facility. The RMD inspector provides a confirmation letter with the date and time agreed upon.

Frequently Documented Violations on Dental Systems

Panoral Systems

- Panoral systems cannot have untethered stretch cords. These cords and firing switches must be permanently fixed to the wall in a protected location.
- The patient must be viewable by the person making the exposure for the entire time the tube journeys around the patient. This must occur without the staff member leaving or leaning out of the protected area.
- The speed of the film and the screens in the cassettes must match.
- The cassette sleeve must be without tears or rips.

Intraoral Systems

- The tube head must be stable and remain in position when released and should not drift away from the release point.
- There cannot be a live exposure switch in the room
- The exposure switch must be behind a protective barrier or greater than six feet from the tube head.

RHP Web Page Update

The RHP has updated COMAR 26.12.01.01 so that it is fully searchable version. The dental checklist is located at http://www.mde.state.md.us/assets/document/air/Dental_Inspection_Checklist.pdf