

DATE: October 5, 2004
TO: All State Licensed Private Inspectors
THRU: Roland G. Fletcher, Manager III, Radiological Health Program
FROM: Renee Fizer, Chief, Radiation Machines Division
SUBJECT: Information and Regulatory Interpretation Memo (IRI) 04-03, October 2004

On September 21, 2004 a meeting was held with the State Licensed Private Inspectors. The following is a summary of topics discussed during the meeting.

Attendance at State Licensed Private Inspector Meeting

Attendance at Private Licensed Inspector Meetings is not optional for you or your company. These meetings are essential for the Radiation Machines Division (RMD) to provide you appropriate information regarding compliance and interpretation of COMAR regulations. Attendance at the September 21, 2004 meeting was unacceptable; 8 out of 72 licensed inspectors attended. You are required to notify Ms. Eva Nair if you or your company is not available to attend scheduled meetings.

Health Physicist II Inspector Vacancy

The RMD is advertising to fill a Health Physicist II inspector position to perform dental and veterinary radiation machine facility inspections. Interested applicants must submit a completed application (MS-100) to the Office of Human Resources at MDE no later than October 29, 2004. More information about the position is posted at www.mde.state.md.us.

Dental Inspection Backlog

The RMD continues to review options for acquiring qualified Health Physics assistance to help reduce the existing backlog of dental radiation machine facility inspections. Dental facilities must be inspected on a frequency stated in the statute. Options for the RMD include hiring a temporary inspector or submitting a proposal for bid. Once decided, qualified applicants must meet education and experience requirements stated in COMAR 26.12.02.02 for a state licensed private inspector. For more information on this, contact Ms. Renee Fizer.

Regulations

On August 16, 2004, **all** radiation user fees, except dental x-ray fees, increased. Call Division of State Documents at 1-800-633-9657 extension 3876 to order an official copy of COMAR 26.12.03 "Radiation Control Fund" or visit www.mde.state.md.us to obtain an un-official copy of the new fee structure. The radiation machine fee structure is as follows:

Machine Type	Biennial Fee Per Tube	Annual Installment
Group 1** or Group 2 (Accelerator)	\$1,000	\$500
Group 3 (Hospital)	200	100
Group 4 (General Medical)	200	100
Group 5 (Other Medical and Industrial)	200	100
Group 6 (Dental)	—	60*
Group 7 (Veterinary)	230	115
Group 8 (Mammography)	200	100

*The fee for tubes used for dental purposes must be paid annually. Annual Fee is \$70, effective June 30, 2004, and \$80 effective July 1, 2006.

**The term "group" refers to the classification established by COMAR 26.12.02.02B.

Bone Density Exemption from Personnel Monitoring

Effective September 21, 2004, radiation machines facilities that **solely** operate bone density units may apply for a **conditional exemption** from personnel monitoring. The facility must submit a request for exemption via letter and send six consecutive months or four consecutive quarters of dosimetry records. Upon review of the dosimetry records, the RMD may grant an exemption. If an exemption is granted, the RMD will mail an exemption letter to the facility. A bone density facility must have either the exemption letter or continuous monitoring records on site to satisfy requirements for State certification or it is a violation of COMAR 26.12.01.01D.1107 and D.502. The exemption remains 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 facility exhibits a behavior of non-compliance such that monitoring is again required.

Certification

Inspectors are required to verify that all medical staff at certification facilities working with a radiation machine have current licenses with the Department of Health & Mental Hygiene. The RX-4, "Inspection Data Facility Specific," requires verification of this information. COMAR 26.12.01.01F.3(a)(1)(vii) states that 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 regulation is interpreted to mean that the healthcare practitioner who prescribes x-rays must have a current license. This regulation also prohibits deliberate exposure of humans to x-rays for the purpose of training, demonstration, or other non-healing arts purposes. COMAR 26.12.01.01F.3(a)(1)(ii) states that individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in

the safe use of the equipment; the interpretation for this regulation, among additional requirements, includes the individual is licensed as a radiologic technologist or therapist. Bone density operators are exempted by the DHMH for any type of licensure. The above COMAR regulations should be cited on the RX-2, "Violation Summary Page" if you find expired or no licenses.

Draft Fluoroscopic Regulations

During the September 21, 2004 meeting, the draft fluoroscopic regulations were discussed in detail. Attached are the proposed fluoroscopic regulations. The proposed regulations are anticipated to become effective late Spring 2005. Contact Ms. Fizer for further information.

Digital Imaging

Currently Ms. Fizer is the chairperson of H-7, Committee on Quality Assurance in Diagnostic X-ray, for the Conference of Radiation Control Program Directors. The committee is drafting a guidance document for quality assurance on digital imaging by January 2005. Ms. Cynthia Pochan is gathering information from manufacturers concerning digital dental imaging systems.

Mid Atlantic States Radiation Program Meeting

On October 20-21, 2004, the Radiological Health Program (RHP) will host the 3rd Meeting of the Mid-Atlantic States Radiation Control Programs in Port Deposit, Maryland. If you are interested in attending this meeting, contact Ms. Fizer for additional information.

Licensing Criteria for State Licensed Private Inspectors

As a result of recent federal indictments against a member of the medical physics community, the RMD stresses the importance for state licensed private inspectors to follow regulations in COMAR 26.12.02 Inspection and Certification. For each new private inspector application, the RMD conducts a thorough background verification check of academic records and employment history. Renewal applicants must submit an RX-32 Application for License to Inspect Radiation Machines and an updated curriculum vitae. If the application states that there is a change in employment or additional training, the RMD conducts a verification check. If criteria in COMAR 26.12.02 is not followed, the process is halted pending results of an enforcement conference with the individual.

Reimbursement to State Licensed Private Inspectors

The MDE does not reimburse state licensed private inspectors for costs due to travel time, inspections, meals, equipment costs or calibration, or time/resources spent on enforcement cases. If an enforcement action is taken against a radiation machine facility that you or your company has inspected, you may be requested to testify or to provide documentation. Information may be subpoenaed, if deemed necessary.

Attachments (1): Proposed regulation changes for F.5, "Fluoroscopic X-ray Systems Except Computed Tomography X-ray Systems"