



MARYLAND DEPARTMENT OF THE ENVIRONMENT

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DATE: April 5, 2005
TO: All State Licensed Private Inspectors
THRU: Roland G. Fletcher, Manager III, Radiological Health Program (RHP)
FROM: Renee Fizer, Chief, Radiation Machines Division (RMD)
SUBJECT: Information and Regulatory Interpretation Memo (IRI) 05-00, March 2005

On February 22, 2005, The Maryland Department of the Environment, Radiological Health Program hosted a meeting of the State Licensed Private Inspectors. The following is a summary of topics discussed during the meeting.

Temporary Inspector

Since September 2004, the RMD had been pursuing the option of hiring a temporary inspector or submitting a bid for proposal to reduce the existing backlog of dental radiation machine facility inspections. The RMD has decided not to pursue outsourcing because of cost restrictions. The RMD is in the process of hiring an individual to fill a Health Physicist II vacancy.

Maryland Certification Inspections

After much hard work by the private inspectors and the RMD, certification facilities appear to be aware of responsibilities relating to mandatory inspections and resolving violations. In order to further enhance the process, the RMD expects the private inspectors to comply with the following directives:

1. Cite as a violation of COMAR 26.12.01J.11(a), if a facility does not have a current Radiation Machine Facility Registration and Certification document posted in a public viewing location.
2. Ensure that the Radiation Machine Facility Registration Form (RX1) is filled out in its entirety.
3. Ensure that the correct regulation is referenced for the cited violation on the Inspection Summary Form (RX2).
4. Cited violations must be recorded on the inspection paperwork and the RX2.
5. Annotate on the RX2 as to whether a radiation machine has been removed or replaced,
6. When inspecting a new facility, you must assign the radiation machine a Machine Number. Modifications to the procedure on assigning a block of machine numbers to private inspectors will be implemented soon. The RMD will issue red stickers to the private inspectors with the assigned machine numbers already written on the stickers. When you issue a machine number to a radiation

machine, you must submit a RX1 which denotes the machine number. Please continue to contact Ms. Eva Nair for machine numbers and red stickers.

Radiation Machine Registration Change

The RMD has modified the registration process for new radiation machine facilities (non-hospitals) that own or operate a CT scanner, cardiac catheterization equipment, or linear accelerator(s). The facility must submit a copy of the Maryland Department of Health and Mental Hygiene (DHMH) Office of Health Care Quality (OHCQ) license along with the Radiation Machine Facility Registration Form and required fees. If a facility cannot provide a copy of this license, it will not be registered with the RMD and will be referred back to DHMH. Under "Instructions for Registering New Facilities with Radiation Machines," the RHP's website now includes a link to DHMH.

Maryland Certification Inspection Change

Inspectors are required to obtain a copy and to verify that all radiation machine facilities, excluding hospitals, with a CT, cardiac catheterization equipment or linear accelerators have a current license issued by Maryland Department of Health and Mental Hygiene (DHMH) Office of Health Care Quality (OHCQ). The RX-4, "Inspection Data Facility Specific," requires verification of this information. This license is required by DHMH to own and operate a Freestanding Ambulatory Care Facility which includes many types of surgical care facilities, including those containing Major Medical Equipment as referenced above. If a facility does not have a current DHMH license, cite COMAR 26.12.01.01B.5/B.9 on the RX-2, "Violation Summary Page". Please include a copy of the facility's DHMH license, if available, with the certification inspection paperwork.

Joint Commission on Accreditation Healthcare Organization (JCAHO) presentation on National Patient Safety Goals (NPSG)

On March 8, 2004, the RMD invited Richard Croteau, MD, Executive Director for Strategic Initiatives with JCAHO, to address hospital and oncology representatives and State licensed private inspectors on the NPSG. The NPSG's, among other topics, discusses improving the accuracy of patient identification, minimizing wrong site surgeries, and improving communication among caregivers and patients. After the JCAHO presentation, the RMD discussed with the medical community, especially the oncology community, the prevalence of wrong patient radiation treatments, including wrong patient misadministrations. In 2004, the Maryland oncology community reported eight misadministrations, of these, a majority involved wrong patient or wrong treatment site and root cause investigations by the RMD determined that human error and lack of communication led to breakdowns in following procedures.

Because of the seriousness of medical facilities failing to follow operational and emergency procedures, the RMD will continue working with oncology facilities to ensure all misadministrations are reported and to eventually reduce the number of misadministrations, particularly wrong patient and wrong treatment site. In addition, the RMD will review COMAR regulations pertaining to misadministrations. Attached is a memo to all Maryland oncology centers to remind all registrants with therapeutic radiation machines that Maryland Regulations require the reporting of all alleged misadministrations. The RMD looks forward to working closely with the oncology facilities and the State licensed inspectors. If you have any questions about the memo, please contact Ms. Eva Nair or Ms. Elina Toole.

Mobile C-arm Procedures

Effective February 22, 2005, any new radiation machine facility that owns or operates a mobile C-arm will be required to comply with the following procedures:

1. Immediately contact a State licensed private inspector to ensure that the shielding in the room(s) designated for use of the C-arm is adequate.
2. If the State licensed private inspector finds that the room(s) has adequate shielding, the facility should verify that the inspector records this information on the RX2.
3. If the State licensed private inspector finds that the room(s) does not have adequate shielding, the facility should verify that the inspector records this information on the RX2. The facility will be required to have a plan review performed.

For all existing facilities that install a mobile C-arm, an area survey for that room will be adequate. The facility must have an area survey conducted within 15 days of the installation of and prior to the operation of the machine.

Regulations

Supplement 12 of COMAR 26.12.01.01 will be published in the *Maryland Register* on April 1, 2005 for public comment and is scheduled to become effective by mid-May 2005. The supplement includes a rewrite of Section F.5, "Fluoroscopic X-ray Systems Except for Computed Tomography X-ray Systems." This also includes new regulations to ensure that all healthcare facilities performing fluoroscopic procedures establish and implement minimal radiation education and training for all personnel, including physicians, before they are permitted to energize or continue energizing fluoroscopic machines.

Supplement 13 of COMAR 26.12.01.01 is scheduled to become effective December 2005 and includes radioactive material changes, specifically new dosimetry technology requirements, financial assurance for materials licensee's requirements, skin dose limit, and the definition of license.

DHS's Transportation Security Administration (TSA)

With the U. S. Department of Homeland Security's TSA take-over of ownership for all radiation machines operated at BWI airport, the RMD has no knowledge of TSA's radiation safety policy regarding radiation machine installation, operator training, or equipment maintenance. The RMD has requested general information concerning TSA's ALARA program via a Freedom of Information Act (FOIA) request and will forward information as it becomes available.

For more information on the baggage screening devices at airports, please refer to the National Institute of Health and Safety's (NIOSH) study on Airport X-ray Study Update (<http://www.cdc.gov/niosh/topics/airportscreener/>) and NCRP SC 01-12 Presidential Report on Radiation Protections Advice: Screening of Humans for Security Purposes Using Ionizing Radiation Scanning Systems (<http://www.ncrp.com/prezrpts.html>).

CDC Video

On February 3, 2005, the Radiological Health Program staff members participated in a live web cast seminar given by the Center for Disease Control and Prevention. The title of the seminar was "The Role of Public Health in a Nuclear or Radiological Terrorist Incident." The seminar included training on radiation and possible radiation type terrorist incidents and roles of the local, state, and federal government emergency response programs. If you are interested in obtaining the video, email rsb@cdc.gov.

Mid Atlantic States Radiation Program Meeting

The 2005 Meeting of the Mid-Atlantic States Radiation Control Programs will be held in Delaware at a date not yet available during September or October. This meeting will be co-sponsored by the Mid-Atlantic

Chapter of the American Association of Physicists in Medicine. If you are interested in participating at this meeting, contact Ms. Fizer for additional information.

Presentations

Presentations were given by Mr. Randall Haack, Health Physicist III Advanced, on the Safelight Filter Fog Study and by Mr. Yun Chong, Health Physicist Supervisor, on Mammography Outreach. If you have questions, please contact Mr. Haack or Mr. Chong.

Conflict of Interest

The conflict of interest clause in COMAR 26.12.02.03C(1) states that the Department may deny a renewal application or suspend or revoke a license if it determines that the inspector has a financial arrangement with any business entity offering commercial sales or servicing of radiation machines. As a State licensed private inspector, be advised that it is inappropriate to limit the number of recommendations of registered service providers to your clients. A list of registered service providers is available on the MDE website (www.mde.state.md.us).

Attachment: Reporting Requirements for Misadministrations