



MARYLAND DEPARTMENT OF THE ENVIRONMENT

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Deputy Secretary

DATE: September 19, 2007

TO: All State Licensed Private Inspectors and Registered Service Providers

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

FROM: Eva Nair, Acting Division Chief, Radiation Machine Division
Jerry Adams, Section Head, Radiation Machines Division

SUBJECT: Information and Regulatory Interpretation Memo (IRI) 07-00, September 2007

Meeting Location at Maryland Department of the Environment (MDE)

A combined meeting of licensed private inspectors and service providers will be held on December 13, 2007 at 10:00 a.m. in the Aqua and Terra Room on the 1st Floor of the Montgomery Park Executive Office Building at 1800 Washington Boulevard. Please park in the visitor lot (marked Red Lot) and come to the lobby area where someone will escort you to the meeting. A tentative agenda and directions are attached.

Introduction

The RHP is proud to announce the filling of a position effective September 2007:

Mr. Andrew Hurst – Health Physicist Trainee

Ms. Renee Fizer has temporarily accepted a leadership assignment for the Regional Greenhouse Gas Initiative (RGGI). In the interim Ms. Eva Nair has been named Acting Division Chief.

2007 Mid-Atlantic States Radiation Control Program Regional Meeting

The 2007 meeting of the Mid-Atlantic States Radiation Control Programs will be held on October 16 and 17, 2007 at the Inn at Lambertville Station in Lambertville NJ. The meeting is hosted by the New Jersey Department of Environmental Protection's Radiation Protection Programs and co-sponsored by the New Jersey Chapter of the Health Physics Society. There will be MQSA training on October 16 and 6.5 MQSA CEU's will be offered. Agenda topics include Digital mammography Medical Physicist QC tests, MQSA compliance Overview, Access to MQSA for Women, among other topics. The States meeting will be held on October 17 and will cover new detection equipment technology, CBCT units, dental initiatives, nuclear medicine technology, ionizing radiation exposure, amount other topics. Please contact

Updated Area Survey and Plan Review Form

Effective October 1, 2007, the RHP will be introducing an updated Area Survey form (RX-22) and Plan Review Form (RX-21) which will be located on the MDE website. On the RX-22, you will be required to submit a facility signature and the facility registration number, and an email address for the inspector or service provider. On the RX-21, you will be required to submit an email address for the inspector or service provider. The RMD will be notifying inspectors or service providers via email as a temporary acknowledgment that the submission has been received and approved and a formal letter will follow in the mail. Contact Mr. Jerry Adams for further information.

Interpretation of COMAR 26.12.01.01E.5(b)

COMAR 26.12.01.01E.5(b)(3) states that the registrant shall perform an evaluation, at intervals not to exceed 1 year, to determine conformance with D.301 of these regulations. If such a system is a certified cabinet-x-ray system, it shall be evaluated at intervals not to exceed 1 year to determine conformance with 21CFR 1020.40. Records of these evaluations shall be maintained for inspection by the Agency for a period of 3 years after the evaluation. The RMD's interpretation of this regulation is that if a facility has film badges that will demonstrate an evaluation that the dose to the general public is less than the allowed amount of D.301. If you are interpreting this regulation differently, please let us know.

Submittal of the FDA's 2579 "Report of Assembly" and the MDE RX-24 "Report of Assembly"

The RMD notes continued deficiencies with registered service providers submitting required paperwork within the fifteen (15) day period stated in COMAR 26.12.01.01B.12. The RMD has a tracking system to determine which registered service providers are in compliance with this requirement. Escalated enforcement action will be considered for those service providers that do not comply. In order for the RMD to modify a radiation machine facility's number of invoiced x-ray tubes or to cancel a facility registration, it is necessary to have documentation from the service companies.

Manufacturer Specifications for Dental and Veterinarian X-Ray Machines

The State of Maryland continues to experience an increasing number of digital dental devices in Maryland. There is a need to establish a requirement that dentists use the recommended exposure technique ranges suitable to the new technology. The RMD's inspectors have noted that while many offices are using digital equipment, some are keeping their exposure time at or near pre digital installation levels. Beginning in August 2007, the RMD started collecting and compiling exposure ranges suggested or recommended by equipment manufacturers. An educational instrument will be developed to demonstrate to dental digital equipment users that reduction of exposure can be achieved with little or no impact to overall image quality. Any dental office found to be using film exposure settings in a digital environment would be appropriately educated as to the expectation of reduced exposures/doses.

Important RHP web pages:

http://www.mde.state.md.us/Programs/AirPrograms/Radiological_Health/index.asp

http://www.mde.state.md.us/Programs/AirPrograms/Radiological_Health/xray_applications/index.asp

Attachments: Agenda

Directions