MARYLAND DEPARTMENT OF THE ENVIRONMENT

1800 Washington Boulevard • Baltimore MD 21230
410-537-3000 • 1-800-633-6101

Martin O'Malley
Governor

Anthony G. Brown
Lt. Governor

Shari T. Wilson
Secretary

Robert M. Summers, Ph.D.
Deputy Secretary

DATE: August 5, 2008

TO: All State Licensed Private Inspectors and Registered Service Providers

THRU: Eva Nair, Acting Division Chief, Radiation Machines Division

Jerry Adams, Section Head, Radiation Machines Division

SUBJECT: Information and Regulatory Interpretation Memo (IRI) 08-01, August 2008

2008 Mid-Atlantic States Radiation Control Program Meeting:

The Mid-Atlantic States Radiation Control Program meeting will be held on September 24th and 25th 2008 at the Embassy Suites Hotel in Hunt Valley, Maryland. This meeting will be sponsored by the Maryland Department of the Environment Radiological Health Program. The annual meeting is two days of information exchange between state radiation control programs, federal agencies, and regional professional organizations to promote cooperative interaction with particular emphasis on regional radiation related issues and events. Mammography training will be offered on the 25th of September. If you are interested in attending this meeting, please call Ms. Bonnie Reynolds or Mr. Jim Lewis for more details. The registration form and agenda will be forthcoming.

Website Update

The RMD continues to update the Maryland Department of the Environment's (MDE) Radiological Health Program website to contain the most recent Information and Regulatory Interpretation memos through January 2008. The Registered Service Provider List and the State Licensed Private Inspector list have been updated. The Web section called Upcoming Events is updated frequently to reflect RHP informational meetings to be held at MDE. Please contact Ms. Eva Nair or Ms. Christina Rowand to make changes to the Registered Service provider list or the State Licensed Private Inspector list posted on the website.

Enforcement

MDE/RHP has increased its enforcement effort to assist Radiation Machines users in focusing on compliance to the regulations. If any violations are cited at a facility, even if they are corrected, the facility will receive a monetary penalty. The goal is to show an increase in initial compliance by all

institutions surveyed. A facility can reduce the number of violations by preventative maintenance for equipment, increased knowledge of staff and office management to the regulations, and conscientiously safer use of radiation machines by staff. State Licensed Inspectors are expected to inform facilities that a penalty will be forthcoming during the exit interview if violations are cited.

Service Provider Renewal

Service registrations must be current and all information updated in order for your company to provide radiation machine services in the State of Maryland. It is a violation of the Code of Maryland Regulations (COMAR) 26.12.01.01, Section B.6 to provide x-ray business services to a radiation machine facility. The RMD will cancel service registrations that have not renewed in a timely manner which is prior to expiration date of the registration. It is a violation of the Code of Maryland Regulations (COMAR) 26.12.01.01, Section B.6 to provide x-ray business services to a facility. Contact Ms. Christina Rowand at (410) 537-3193 in regards to questions pertaining to your service registration.

Radiation Monitoring for Service Technicians

Service technicians by the nature of their work are considered Radiation Workers as described in the regulations and are expected to be monitored. As stated in COMAR 26.12.01.01D.502 each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupation dose limits of Part D. It also states that adults how potentially may receive, in 1 year, a dose in excess of 10 percents of the limits in D.201a shall be monitored. Effective January 2009, the RMD will randomly come out to service companies to review personnel dosimetry records to ensure that this regulation is met.

Regulatory Changes: (Supplement 17)

Requirement for Preventative Maintenance

In the next supplement (Supplement 17) there will be a requirement for preventative maintenance of radiation producing machines. The draft regulations pertaining to how the expectation will be met is explained in the new regulations. Compliance to this regulation will be an inspection item for both service providers and State licensed private inspectors. Evidence of compliance will be in the form of invoices and worksheets, and other evidence of regularly scheduled maintenance.

Plan Review Submission Times

There will be increased submission for Plan reviews in the next supplement. Plan Review submission dates for systems equal to or less than 150 KEV device will increase from 15 to 30 days prior to installation and for systems greater than 150 KEV to no less than 45 days

Additionally there will be greater clarification of regulatory expectation as it applies to Plan review for System capable of 150 KEV or greater. These changes will reflect a need to collect more detail to allow us added information to review and validate the submission.

Posting Notices of Violation

In Supplement 17 there will be an increase in the number of days for which a notice of violation is required to be posted in public and conspicuous locations as well as the methods by which the NOV posting may be resolved.

Plan Reviews and Area Surveys

RMD expects to find all registrants who are required to have a Plan review or an Area survey at their site to be in possession of the appropriate documents at the time of their Annual or Biennial inspections. Currently the RMD follows the IRI policy that mammographic, dental, veterinary, and podiatry facilities are exempt from plan reviews/Area Surveys. For dental facilities, utilizing FDA-approved dental CT devices, including the I-CAT, Cone Beam, 3-D Dental Imaging Systems, the RMD requires facilities to submit a plan review/area survey performed by a State licensed Inspector or registered Service Provider.

New Radiation Machine Facilities

All radiation machine facilities that undergo certification inspections are expected to comply with the regulations in COMAR 26.12.01.01. Prior to an inspector performing the inspection, a facility is required to ensure that personnel monitoring is being performed, postings are posted, fluoroscopic out puts for fluoroscopic machines are performed and documented annually, area surveys and plan Reviews must be submitted to the RMD according to the Regulations.

Manufacturer Specs for X-Ray Machines

The RMD has worked closely with the registered service providers to obtain kVp and timer accuracy manufacturer specifications for certified medical radiation machines. This includes dental, mammographic, and medical. It is important to know the manufacturers specifications for kVp and timer accuracy in order to inspect radiation machines. The updated compilation is available on the Web site for downloading. For further information, contact Mr. Jerry Adams.

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