State Licensed Private Inspectors & Registered Service Providers Wewsletter

D E P A R T M E N T O F T H E E N V I R O O L O G I C A L H E A L T H P R O G R A M I A T I O N M A C H I N E S D I V I S I O N

NEWS FLASH

- Eva Nair has been promoted to the Division Chief position of the Radiation Machines Division.
- We would like to welcome Austin Pardoe to the division.
 He will be working in the Registration & Certification
 Section.
- Special thanks to all of the State Licensed Private Inspectors and the Registered Service Providers who attended this years' meeting.

On December 11, 2008, the Maryland Department of the Environment (MDE), Radiological Health Program hosted the second annual combined State Licensed Private Inspectors and the Registered Service Providers Meeting.

INTRODUCTION

Mr. Roland G. Fletcher, Program Manager of the Radiological Health Program (RHP), welcomed all of the attendees and addressed increased enforcement and the need for the State to have their added eyes and ears that will help us gain compliance with the regulations. He went on to describe why RHP has undertaken this course of action and reiterated that it is expected that the private inspectors and the service providers will do their part to appropriately report violations observed. Mr. Fletcher thanked them for their continued support.

INCREASED ENFORCEMENT

Eva Nair, Division Chief presented a presentation entitled Increased Enforcement Action within the Radiation Machines Division (RMD). The RMD has increased its enforcement effort to gain better compliance to the regulations for all regulated communities. It is the intent of enforcement action taken by a regulator to ensure an activity that is non compliant returns to compliance. Reductions in cited violations may be addressed 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 private inspectors are expected to inform their clients that any citation found may be subject to a financial penalty**. The MDE has developed definitions for significant non-compliance and minor violations.

Minor

- Has not previously occurred;
- Poses minimal harm to health or the environment;
- Is promptly corrected; and
- Does not meet the criteria for significant Non-Compliance

Significant non-compliance violations

- Has caused actual adverse impact, or has the potential to cause substantial adverse impact to public health or the environment;
- Represents willful, chronic or recalcitrant behavior;
- Substantially deviates from the terms of a permit, order, settlement agreement, or from statutory or regulatory requirements or
- Warrants or requires public notification and/or penalty over \$50,000;
- Is not corrected within 60 days or the violator has not taken corrective action (s) as directed by the Department following the issuance of a Notice of violation, Site Complaint or Inspection Report by the department

STATE LICENSED PRIVATE INSPECTORS

Mr. Ahsan Bhatti stated that new applicants applying to become a State Licensed Private Inspector may be in receipt of a deficiently letter if the submission of an application is incomplete. Applicants must submit original transcripts from their University and not copies or faxes. Service providers must check on the application what type of x-ray services the company will be providing.

SERVICE PROVIDER AUDIT

Ms. Christina Rowand provided a review of the data from the 2008 Service Provider Performance Report. She collects the paperwork turn around times for the final paperwork from service providers for installations, deinstallations, repairs, disabling or replacement of radiation machines. It is expected that this information be turned in to the State within 15 days of completion of the work according to COMAR 26.12.01.01. This information is used to confirm the disposition of x-ray machines at these facilities. The availability of this information can affect the way in which we expect facilities to submit payment for registered tubes and machines.

The vast majority of Service Providers are within the mandated time specifications:

1st Quarter- 20.55 days 51% Compliance

2nd Quarter- 19.52 days 75% Compliance

3rd Quarter- 20.96 days 71% Compliance

4th Quarter- 16.34 days Compliance not calculated

REGULATIONS

In Supplement 18, there will be a requirement for preventative maintenance of radiation producing machines. Compliance for this regulation will be an inspection item for both state and private inspectors. Evidence of compliance will be in the form of invoices and worksheets, and other evidence of regularly scheduled maintenance. If there are questions or comments, please contact Mr. Jerry Adams.

In Supplement 18 there will be an increase in the number of days for which a Notice of Violation (NOV) is required to be posted in a public and conspicuous location as well as the methods by which the NOV posting may be resolved. It is now an expectation.

HAND HELD DENTAL UNITS

Hand Held Dental Units are not allowed to be used in the State of Maryland.

SERVICE PROVIDER EXPECTATIONS

- 1. Be able to support preventative maintenance recommendations of manufacturers for dental and veterinary units.
- Measuring KVP
- Measuring Timing
- Collimator light output
- Knowledge of inspection criteria of the State and act as resource for customers
- 2. Be able to support dark room services for Dental and Veterinary facilities.
- Safe light testing
- Knowledge of darkroom regulations
- Provide guidance to avoid operational issues.

RADIATION MONITORING FOR SERVICE TECHNICIANS

Service technicians by the nature of their work are considered Radiation Workers as described in the regulations and as such are expected to be monitored. The definition of a radiation worker is anyone who may in the course of their duties potentially receive 10% of the maximum permissible annual dose of 5 REM. RHP has had site reports come in that increasingly refer to service technicians not being appropriately monitored.

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, Bi-ennial, or Triennial inspections. The mammography, dental, veterinary, bone density, and podiatry facilities are exempt from plan reviews/ area surveys. Dental facilities utilizing FDA-approved dental CT devices, including the I-CAT, Cone Beam, 3-D Dental Imaging Systems, are required to submit a plan review/area survey performed by a State Licensed Private Inspector or Registered Service Provider.

Additionally, RHP will require a description of the make up of vault doors in future submissions of plan reviews for therapy vaults.

There will be additional 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.

MANUFACTURER SPECS FOR X-RAY MACHINES

RMD has worked closely with the registered service providers to obtain kVp and timer accuracy manufacturer specifications for certified medical radiation machines which includes dental, mammographic, and medical units. It is important to know the manufacturers specifications for kVp and timer accuracy in order to State certify and inspect radiation machines. For further information, please contact Mr. Jerry Adams at 410-537-3160.

UPDATE FOR THE 2008 MID-ATLANTIC STATES RADIATION CONTROL PROGRAMS

The Mid-Atlantic States Radiation Controls Programs meeting was held on September 24th & 25th, 2008 at the Embassy Suites Hotel in Hunt Valley. Certificates were issued at the end of the program, however some the certificates were missing dates of attendance. These certificates will be reissued, the target goal for new certificates is Mid-January of 2009. Our apologies for any problems this may have occasioned.

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