



## **Information and Regulatory Interpretation Memo (IRI) 19-00**

### **Registered Service Provider and State Licensed Private Inspectors Newsletter**

**January 2019**

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**See Newsletter on the MDE website:**

<https://mde.maryland.gov/programs/Air/RadiologicalHealth/Pages/InformationalMemos.aspx>

**Updated RHP Radiation Machine forms are on the MDE website:**

<https://mde.maryland.gov/programs/Air/RadiologicalHealth/Pages/XRayApplicationFormsandGuidance.aspx>

### **Upcoming Meeting at the Maryland Department of the Environment (MDE)**

A state licensed private inspector and registered service provider meeting will be held at MDE Headquarters on March 7, 2019 from 8:30 a.m. to 12:00 noon. Please RSVP to the following email [mdexray.submission@maryland.gov](mailto:mdexray.submission@maryland.gov) by February 22, 2019. Directions are included and parking is available in the blue lot. If you have specific questions or concerns you would like addressed at the meeting, please email Mr. Ian Forrest at [ian.forrest@maryland.gov](mailto:ian.forrest@maryland.gov) to ensure that your questions are answered appropriately.

### **Radiological Health Program (RHP) Announcements:**

**The Radiation Machines Division is pleased to announce the filling of 8 positions:**

Shannon Page – Division Chief  
Ian Forrest - Health Physicist Supervisor for Inspection and Enforcement Section  
Michael Kurman - Health Physicist Supervisor for Registration and Certification Section  
Talya Langbaum – Health Physicist II  
Jeffrey Dickens – Health Physicist II  
Kiera Saleem - Health Physicist Trainee  
Matthew Sievers - Health Physicist Trainee  
Damika Gresham – Health Physicist Trainee

**The Radioactive Materials Division is Pleased to Announce the Filling of Five Positions:**

Charles Cox – Division Chief

Alan Goldey – Health Physicist Supervisor for Inspection Section

Cheryl Nitkowski – Acting Health Physicist Supervisor for Licensing Section

Umaru Ben-Tjan – Health Physicist II

Tishara Stewart – Administrative Specialist II

**Diagnostic Medical Radiation Events:**

A two-year study of Diagnostic Medical Radiation Events (DMRE) was conducted from November 1, 2016 through October 31, 2018.

Some of the major findings were as follows:

- An increase in reported DMREs after the moratorium on issuing penalties was instituted.
- A total of 327 DMREs were reported from 115 facilities, which indicates that the majority of facilities had more than one DMRE occur.
- Medical facilities that instituted procedural changes, such as enhanced patient identification and time-out requirements, had fewer subsequent DMREs than those facilities that provided counseling of employees and one-on-one re-education.

The MDE has elected to continue the study for one additional year, through October 31, 2019, in order to accumulate additional data to ensure that a stable pattern is demonstrated and a more informed decision can be made about addressing DMREs post study.

**New Regulations:**

Supplement 29 of COMAR 26.12.01.01 took effect May 21, 2018, which includes DMREs in Section F.4. A DMRE must be reported to the RHP and an occurrence log (RX-38) must be maintained at the physical location. This section differentiates such events from therapeutic misadministrations. If you have any questions about DMREs, contact Ms. Shannon Page or Mr. Michael Kurman.

**Regulations Under Development:**

Regulations are being developed to set requirements for the safe use of electronic brachytherapy radiation machines that treat skin cancer, cervical cancer, and intraoperative radiotherapy to the breast.

Regulations are being developed to control the use of full body scanners at correctional facilities. These scanners are used for detection of weapons, phones, drugs, and or other contraband in human beings. These regulations will provide for maximum annual and per screening dose, as well as operating requirements.

The RHP is currently amending x-ray control requirements as specified in COMAR 26.12.01.01 F.6(b)(2) for diagnostic x-ray machines other than fluoroscopic, dental intraoral, veterinarian, or computed tomography x-ray systems. This change will stipulate the incorporation of a deadman

exposure switch or a device that controls exposure using continuous pressure by the operator. A grandfather clause is anticipated for dental CBCT machines installed prior to August 2016 or as determined.

Machines equipped with deadman exposure switches will ensure operator safety by preventing the operator from leaving the protected area during the entire exposure. Several manufacturers have equipped dental CBCT/panoral machines with automatic exposure acquisition through the machine operating software or remote scan switches that are momentarily depressed to start the exposure cycle. These machines free the operator to leave the protected area once the exposure has begun to cycle. A deadman exposure device will require the operator to apply constant pressure to the switch to maintain exposure while remaining in the protected area for the entire cycle.

The clarification of the regulation will also address machines which are remotely controlled with a permanent mounted exposure switch separate from the x-ray control itself, where the exposure switch on the x-ray control panel has been internally disabled. As such, the remote exposure switch must be located in a protected area, not the x-ray control.

The RHP has worked with x-ray manufacturers to convert dental CBCT's equipped without deadman switches to bring them into compliance with the intent of the current regulation. In some instances, modification to install a deadman switch is not practical or possible.

Until the revised regulation is approved and becomes effective, RHP will continue to request manufacturers modify machines not equipped with deadman exposure devices.

### **Temporary Radiation Machine Use:**

RHP does not issue temporary registrations for any radiation machine, nor is there reciprocity program for x-ray devices. Supplement 29 of COMAR 26.12.01.01B.15 requires the owner of a radiation machine that is to be used on patients on a temporary or demonstration basis to register the machine with RHP, pay the registration fee, utilize the machine in a shielded room, have a certification inspection performed by a state licensed private inspector (if not newly manufactured), and notify the RHP when use of the machine ends in Maryland. An RX-24 will be required for both installation and removal of the temporary machine.

### **Fluoroscopy:**

This is a reminder that registrants must adhere to COMAR 26.12.01.01F.5(n)(1), which states that only a licensed practitioner of the healing arts or a radiological technologist under the supervision/direction of a licensed practitioner may energize a fluoroscopic machine, and such personnel must comply with the training set forth in COMAR 26.12.01.01F.5(n)(2).

### **Training/Demonstration Use:**

All x-ray facilities, including radiology schools, vendors, and service providers are reminded that any exposure of individuals to x-rays for training or demonstration purposes is not permitted in Maryland based on COMAR 26.12.01.01F.3(a)(1)(viii), which states: ***“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 provision also prohibits deliberate exposure for the purpose of training, demonstration or other non-healing-arts purposes.”*

### **Service Provider Requirements:**

Pursuant to COMAR 26.12.01.01B.6, persons providing x-ray services to radiation machine facilities must maintain a current registration with the RHP. Facilities which utilize the services of an unregistered company may be subject to enforcement action. The application for registration of business providing services (RX-25) must be submitted before the renewal expiration date. A new field on the form requests that an e-mail address be provided.

### **MDE RX-24 Forms:**

The RX-24 forms are to be completed in their entirety and are used any time a radiation machine has been installed, relocated, removed, disabled, or has had a major component replaced.

The RX-24 forms should be legible and accurately completed to include facility address, facility contact information, tube serial number, facility registration number (if assigned), and MDE machine number (if assigned, there will be a red sticker located on the machine). Pursuant to COMAR 26.12.01.01B.12(a), all RX-24 forms must be submitted to RHP within 15 days of completion.

**NOTE:** The submission of a RX24 does not register a facility and does not absolve the facility of its responsibility to register the radiation machines with the RHP. A radiation machine cannot be used until a registration and/or certification approval from the RHP has been granted. Any unregistered facility actively using a radiation machine is subject to enforcement action. Service providers should remind the facility to contact the RHP immediately to acquire all the necessary paperwork to apply for registration. Preventive maintenance service alone **is not** an inspection of a facility.

### **State Licensed Private Inspectors Requirements:**

- Current inspectors must apply for renewal of their license prior to its expiration and must keep current with regulatory training requirements.
- You cannot perform inspections without an active license.
- All applicants are required to disclose their Social Security Number on the application, pursuant to the provisions of Section 10-119.3 of the Family Law Article, Annotated Code of Maryland, which requires the Department to verify if the applicant has any child support obligations.
- All applicants must submit a *Curriculum Vitae* with their application.
- All applicants who want to conduct mammography inspections in Maryland must provide their mammography credentials as required by COMAR 26.12.02.03B.(3)(c).
- All applicants must provide their e-mail address.
- New applicants must submit official transcripts of their education from the respective institutions and provide accurate contact information of past employers for RHP verification.
- The RHP reminds licensed inspectors to submit complete inspection reports for review within 30 days of the beginning of an inspection, in accordance with COMAR 26.12.02.05.
- Use the most current version of all inspection forms as they are updated to reflect any changes in regulations. All forms are available on the RHP website.

### **Inspection Reports Common Deficiencies:**

- Missing facility representative signatures.
- Missing information on the RX-1 (including facility contact information and Federal Tax ID).
- If there has been a change in Tax ID or ownership, the facility is **required** to apply for a new registration.
- Incorrect citation of violations on RX-2 and/or failing to list violations (for example, if a machine requires annual preventive maintenance and the last recorded date is greater than 12 months, this **MUST** be cited as a violation).
- A copy of the RX-1 and RX-2 should be left with the facility representative after the completion of the inspection.

### **Radiological Machine Facility Registration (RX-1) Revision:**

The RX-1 form has been updated (latest update 12/20/18). State licensed private inspectors are required to complete the fields listed below:

- E-mail Address
- Machine Manufacturer
- Machine Model (not Processor Model)
- Tube Head Serial Number (the only serial number needed is that on the tube head)
- Machine manufacturer's preventive maintenance schedule
- Date of last preventive maintenance on the radiation machine
- Check box if change of ownership and a date

### **Plan Reviews and Area Surveys:**

The RHP State licensed inspectors and State service providers must comply with the following requirements listed below:

- The plan reviews and area surveys submitted to the RHP for review must be on the RHP forms and legible.
- A correct scale for the floor plans or actual distance used in the evaluation must be provided and clearly readable.
- The signature of the facility representative, printed name of the facility representative, and the date must be on the form.
- The patient workload in terms of number of patients per week and occupancy factors must be provided.
- Detail of the barrier shielding material must be provided.

If plan review and area survey submissions are not completed in entirety, they will not be processed by the RHP. For further information, contact Mr. Yun Chong.

### **Dental Personnel Monitoring:**

- Personnel exposure monitoring reports must be specific to the facility location where the monitoring was performed. The personnel dosimeters ("film badges") cannot be shared

between persons, locations, or facilities. Facilities that use instant read-out dosimeters (Instadose) must record the readings on each such badge, at a minimum on a monthly basis.

- New dental facilities and/or new owners are required to initiate monitoring for their facilities. RHP requires machine operators to wear personnel dosimetry continuously for a period of six consecutive months (processed monthly) or four consecutive quarters (processed quarterly).
- If readings indicate no dose or negligible dose, operators may stop wearing badges. Dental schools are no longer required to furnish film badge monitoring to their radiation staff and students on an indefinite basis. Schools may follow the same policy as granted to other dental facilities by completing a minimum of six (6) consecutive months or four (4) consecutive quarters, provided doses are found to be negligible.
- However, any change in machines including their location in the office or change of machine type or addition of machine requires personnel monitoring to begin again for a new continuous six month or four quarter period. This does not apply to a machine replacement of the same type.
- All dental facilities must provide continuous monitoring to operators of CBCT/3D machines and hand-held x-ray units. Film badge exposure reports are to be maintained at the facility indefinitely. Area radiation monitoring does not meet the regulatory requirement for personnel monitoring.

### **Handheld X-Ray Machines:**

- Handheld x-ray machines presently approved for use at dental and veterinary facilities in Maryland are shown below. Prior to purchasing a handheld x-ray machine, contact the RHP to verify if it has been approved for use by meeting safety and regulatory requirements. The RHP will consider approval of other handheld x-ray machines and/or models as requested.

<b>Manufacturer</b>	<b>Model</b>	<b>PM Frequency</b>
Aribex	Nomad Dental Classic	N/A
Aribex	Nomad Dental Pro	N/A
Aribex	Nomad Dental Pro-Vet	N/A
Aribex	Nomad Dental Pro 2	Annual by trained operator or service provider w/ 5-Year return to MFR
Dexcowin	Dexcowin DX3000; iRay D3; Maxray DX3000	Annual user check; annual calibration
Dexcowin	Cocoon (DX7017/DX7020)	Annual user check; annual calibration
Dexcowin	ADX6000/ADX6000s; iRayA5 (medical use only-user must wear lead apron or mount on stand with hand-switch)	Annual user check; annual calibration
KaVo	Nomad Dental Pro 2	Annual by trained operator or service provider w/ 5-Year return to MFR.
Genoray	Zen PH-II	Annual

- Handheld x-ray radiation machines must have a permanently mounted backscatter shield attached to the x-ray cone or beam limiting device (BLD). The machine must also be Food and Drug Administration (FDA) certified for use in the United States of America.
- Prior to sale of any handheld device by a service provider, a facility is required to submit an application to the RHP for approval to use. The facility must provide a written application, statement of reason for use, and agree to specific conditions for its use. The facility must have a permanent wall mounted unit for use under normal conditions. All users are required to complete and document operator training from the machine manufacturer.
- Upon approval by the RHP for use of the machine, the facility must provide continuous film badge exposure monitoring for each operator. All patient radiographs must be logged with justification for using the unit. The unit must be stored in a locked cabinet or equivalent locked area when not in use.
- Facilities are not permitted to operate a handheld unit as a substitute or replacement in an operatory where a permanent machine is not installed or is absent.
- You are advised that dental machine operators have expressed difficulty in positioning the handheld machine to digital sensor/film when using an aiming ring device extension cone paralleling (XCP) to take intraoral patient images.
- Interference between the metal shaft or rod of the XCP and the backscatter shield does not allow the end of the x-ray cone to be positioned against the ring of the XCP on the patient's cheek.
- The permanently attached backscatter shield on the handheld unit should be positioned at the end of the x-ray cone to minimize exposure to the operator. XCP devices are now available from suppliers suitable for use with handheld units.
- XCP's with shortened rods enable the x-ray cone to be placed against or closer to the ring of the XCP at the patient's cheek. Facilities may also manually trim the rod on the XCP to accommodate the backscatter shield.

### **Preventive Maintenance Expectations:**

- Use the RHP forms on the MDE Website for intraoral (RX-33), pan/ceph (RX-35), general purpose (RX-16), and veterinary (RX-36) machines.
- If you are using your own preventive maintenance form for a type of machine for which there is no RHP form, be sure to identify the facility by **Registration Number** and the machine by **MDE Machine Number**. Always date the report.
- It is the responsibility of the provider to supply the facility with preventive maintenance reports that contain the information requested on the form. Preventive maintenance reports should be submitted electronically as .pdf files to **preventive.maintenance@maryland.gov**. Pictures taken of the reports are fine as long as the RHP can read the entire report.
- Remind facilities that it is their responsibility to submit your complete preventive maintenance reports to the RHP. A certificate or an invoice alone will not suffice. Facilities have 30 days to provide these reports to Department.
- Remind each facility of the maintenance frequency their machines must follow based on the manufacturer's recommendation and when their next maintenance service is due.
- Failure to comply will cause RHP to issue a Notice of Violation for a late PM report and may subject the owner to a monetary policy.

**Contact Information:**

- RHP's telephone number is 410-537-3193 and fax is 410-537-3198.
- Preventive maintenance reports may be scanned and attached to an e-mail to **[preventive.maintenance@maryland.gov](mailto:preventive.maintenance@maryland.gov)**.
- Registration applications, registration renewals, certification, service provider registration, or private inspector licensing, and all supporting materials, may be scanned and attached to an e-mail to **[mdexray.submission@maryland.gov](mailto:mdexray.submission@maryland.gov)**.
- Guidance on a variety of x-ray topics can be found on the MDE Website at:  
**<https://mde.maryland.gov/programs/Air/RadiologicalHealth/Pages/XRayApplicationFormandGuidance.aspx>**.
- The current version of the Regulations for the Control of Ionizing Radiation can be found on the MDE Website at:  
**[https://mde.maryland.gov/programs/Air/RadiologicalHealth/Documents/www.mde.state.md.us/assets/document/air/RH\\_comar/regs\\_final\\_new.pdf](https://mde.maryland.gov/programs/Air/RadiologicalHealth/Documents/www.mde.state.md.us/assets/document/air/RH_comar/regs_final_new.pdf)**.
- COMAR 26.12.02.02, which deals with State certification and Licensing of Inspectors, may be found on the Division of State Documents Website at:  
**[http://www.dsd.state.md.us/comar/subtitle\\_chapters/26\\_Chapters.aspx](http://www.dsd.state.md.us/comar/subtitle_chapters/26_Chapters.aspx)**. Chapter 12 contains Radiation Management regulations.