



Radiological Health Program

Radiation Machines Division Fact Sheet

This newsletter is on the MDE web site: <http://www.mde.state.md.us>

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REGULATION CHANGES TO COMAR 26.12.01.01

The Radiation Machines Division (RMD) will be informing the regulated community via a mass mailing about recent additions to COMAR 26.12.01.01 (Supplements 16 and 17), which are in effect as of June 15, 2009. The supplements include two new regulatory provisions that affect radiation machine facilities. Call the Division of State Documents at 1-800-633-9657 to order an official copy of "Code of Maryland Regulations" (COMAR) 26.12.01.01 Regulation for the Control of Ionizing Radiation or visit www.mde.state.md.us to obtain an un-official copy of the supplements.

An updated RX4 form for the State Licensed Private Inspectors, which is available on the Maryland Department of the Environment's website, is attached to this newsletter. A guidance document for the dental and veterinary facilities to aid in compliance to the regulations is included in this newsletter. This document does not guarantee violation free inspections, but it is designed to help the dental or veterinary facilities understand what is needed and to raise the level of awareness in areas most often cited as violation issues.

SECTION A.17 PUBLIC POSTING OF NOTICES

A notice of violation issued by the agency to a registered or licensed facility shall be conspicuously posted at the facility for public review within two (2) working days after receipt. A notice of violation shall remain posted for a minimum of 30 working days or until action correcting the violation has been completed and this correction has been verified by the agency.

Note: The regulation increases the posting time from its previous level of five days to thirty days.

SECTION F.3(D) MACHINE MAINTENANCE

A registrant shall maintain each radiation machine in accordance with the manufacturer's recommended specifications. A registrant shall maintain documentation, in the form of logs, service tickets, or work orders, that the machine manufacturer's recommended maintenance schedule has been met.

Note: The Department's main focus will be to check for documentation that the manufacturer's maintenance requirements have been met, so facilities should ensure that the appropriate records are on file. To facilitate the document review, having the machine manuals on file at the facility would be helpful, and we urge you to distribute the necessary manuals to facility owners.



PENALTY REMINDER

At the end of every inspection the facility will receive a Radiation Machine inspection summary form (RX2). If violations of regulatory requirements are found, they will be noted on the form and the form then serves as a NOTICE OF VIOLATION. Violations subject a facility owner to financial penalties as allowed under state Statute. All violations must be corrected and documentation of their resolution provided to the Department. Prompt correction will minimize the amount of any potential financial penalty, as penalties, if assessed, accrue from the date the violation occurred until corrected.

RADIOACTIVE MATERIALS CONFLICT OF INTEREST FOR RADIATION SAFETY OFFICER/CONSULTANT

The Radiological Health Program policy statement is specific to those facilities that hold a radioactive material specific license authorized under COMAR 26.12.01.01 Part G “Use of Radionuclides in the Healing Arts.”

The Radiological Health Program considers it a significant “conflict of interest” if a medical licensee’s private consultant (used to assist in the licensee’s compliance to license and regulatory requirements) is the same private consultant or private consultant company that is the licensee’s Radiation Safety Officer.

In other words, no medical licensee may have a private consultant as a Radiation Safety Officer who works for a private consultant who is responsible for conducting compliance reviews for the license. If you have any questions or require additional information concerning the above, please contact Ray Manley at 410-537-3301 or 1-800-633-6101, extension 3301.



RADIATION MACHINE COMPLIANCE AT DENTAL FACILITIES

“Succeeding in a Dental Inspection”

INSPECTION HOT SPOTS

❖ ADMINISTRATIVE PAPER WORK

- The “Notice to Employees” form must be posted in a gathering place for employees.
- Each Facility must be registered by the facility owner with the State--Evidence of this is a valid registration form hanging on a wall in a public place for the office customer/patient to review.
- If an NOV is issued following an inspection, the NOV is required to be posted within 2 days and is to remain posted for 30 days in a public viewing place.

❖ DARKROOM FOG (or white light leakage) TEST

(recommended every 6 months)

- The following seven-step process will help identify film fog issues
 1. In a dark darkroom with the safelight on, lay one film of panoramic/ceph film on top of processor or counter where film is routinely handled.
 2. Cover half of film with film box.
 3. Wait two minutes.
 4. Process film.
 5. If you can see a separation of light and dark on the film to show where the box was sitting, you have light leaking into darkroom.
 6. Repeat test with safelight off to determine how much comes from the safelight.
 7. Repair room and/or safelight light leaks when identified.

Note: Tests performed by the state inspectors are more sensitive than this test. The above process determines gross fog.

- Potential Sources of Fog:
 - Look for indicator lights and lamps
 - Look for safelight being too close to work Surface
 - Look for light under the door or from the ceiling
 - Tears in the sleeves of auto produces

❖ FILM BADGES

Each radiation machine facility **MUST** have records on site to demonstrate either six (6) consecutive months or four (4) consecutive quarters of personal film badge monitoring. If necessary, contact your monitoring company for copies of your records and keep them on site.



- Offices and Individuals cannot share badges
 - ~Badge reports must have names or an identifier of monitored staff.
 - ~Badges must be worn on the collar at the neck.
 - ~Badges must be exchanged on the schedule as contracted (monthly or quarterly).
 - ~Only Monthly (6 Readings) or Quarterly (4 Readings) badges are considered correct.
 - ~Monitoring once properly completed need not be redone unless one of the items below occurs.
- Monitoring must be redone if a facility:
 - ~increases the number of x-ray tubes,
 - ~relocates,
 - ~changes ownership; or
 - ~re-arranges the configuration of the radiation machines in the current location.

❖ LOGBOOK FOR CHEMISTRY CHANGES, SERVICE, AND CLEANING

- Each Facility must maintain a Log book that identifies and tracks the frequency of service, repair, chemistry changes, and cleansing of the film processing devices.
- Auto-processor and manual processor chemistry must be replaced per manufacturer's specifications which average every thirty (30) days.

Note: Your facility is required to maintain on site a QUALITY ASSURANCE LOGBOOK that tracks, as a minimum, cleaning and servicing of your processor and changing of chemicals.

❖ X-RAY EQUIPMENT – PM's

- Commonly cited technical deficiencies on x-ray equipment, including high or low tube potential (or kVp) and timer accuracy, can be identified and corrected prior to a State inspection with preventative maintenance by a registered service company. Appropriate levels for kVp or timer accuracy can best be determined during required preventative maintenance checks performed by an outside company.

Note: There are two primary ways to measure a machine's kVp level. The accepted method of checking this is by reading the value as an output from the tube during an exposure. Some service companies will use an internal diagnostic method to approximate the kVp level. This method can result in a kVp value that will differ from the value determined by the Department's inspector who is measuring a machine's kVp level as an output value. We will base our compliance determination on our measured results. As such, we strongly recommend that service companies performing these checks use a tool that reads kVp levels as an output. A similar issue can arise when measuring timer accuracy.

- According to COMAR 26.12.01.01F.3(d), Machines must be maintained per manufacturer's specs, and documentation of this maintenance must be maintained.

Note: It is important from a public health perspective to follow proper operating procedures and to properly maintain equipment in order to:

- Assure that radiation exposures remain at the lowest possible level by avoiding repeat filming and increases in the dosage level, as we do not know a patient's overall exposure to radiation prior to or after a visit to a dental facility
- Avoid unnecessary exposure to skin and surrounding tissues in the mouth and neck
- Avoid having poor work practices and certain machine deficiencies from escalating into more serious infractions
- Assure that everyone in the regulated community is performing at least at a minimum level of radiation safety for the protection of both the operators of the equipment and the patients.

❖ X-RAY EQUIPMENT SET-UP

Panoral Systems:

Panoral systems cannot have untethered stretch cords. These cords and firing switches must be permanently fixed to the wall in a protected location.

The patient must be viewable by the person making the exposure for the entire time the tube journeys around the patient. This must occur without the staff member leaving or leaning out of the protected area.

The speed of the film and the screens in the cassettes must match.

The cassette sleeve must be without tears or rips.

ID Systems:

The tube head must be stable and remain in position when released. It may not drift away from the release point.

There cannot be a live exposure switch in the room.

The exposure switch must be behind a protective barrier or greater than six feet from the tube head.

❖ UNDERPROCESSING FROM EQUIPMENT-PM's

Film under-processing violations often result from technical deficiencies with the processor, such as wrong replenishment rates and improper temperature. These problems will be identified and corrected with preventative maintenance recommended by your auto processor's owner's manual. You will need to reference your manufacturer manual to determine the preventative maintenance frequency. You must maintain copies of any service tickets.