

MARYLAND DEPARTMENT OF THE ENVIRONMENT

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DATE: December 7, 2006

TO: All State Licensed Private Inspectors

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

FROM: Renee Fizer, Chief, Radiation Machines Division (RMD)

SUBJECT: Information and Regulatory Interpretation Memo (IRI) 06-01, December 2006

On May 23, 2006, the Maryland Department of the Environment, Radiological Health Program hosted a meeting of State Licensed Private Inspectors. The following is a summary of topics discussed during the meeting.

Introduction

The RHP is proud to welcome Mr. Jerry Adams as Section Head of Inspections, Radiation Machines Division effective January 2006.

C-arms Used Exclusively for Extremities

Effective June 1, 2006, the RMD will exempt c-arms manufactured exclusively for imaging extremities from the annual exposure rate measurements which must be posted so that the fluoroscopist may readily have access to the results as stated in COMAR 26.12.01.01F.5(c)(2). These particular fluoroscopic machines are not exempt from any other part of the certification inspection requirements.

Replacement Component Certification Criteria

COMAR 26.12.02.02C(3) states that "Except for routine X-ray tube replacement, a person may not cause or permit the use of any radiation machine that has had any major component replaced or substantially rebuilt until the major component that has been affected has been re-inspected and the radiation machine has again been State certified." Radiation machines that have had major components rebuilt or replaced, with the exception of routine x-ray tube replacement must be inspected for certification, have all violations corrected and certification package submitted for Department review prior to use on humans.

Maryland State Certifications

After much hard work by the private inspectors and the RMD, certification facilities are aware of responsibilities relating to mandatory inspections and resolving violations. In order for the certification process to further improve, please comply with the following:

1. Unregistered radiation machine facilities acquiring a newly manufactured radiation machine do not need to undergo a State certification inspection prior to use.



- 2. Newly manufactured radiation machines installed at existing registered facilities do not need to undergo State certification prior to use but will be inspected on the facility's normal certification cycle.
- 3. Used, previously owned, or refurbished/rebuilt radiation machines installed at an unregistered radiation machine facility must undergo State certification, resolve all violations, and submit the certification package for Agency review prior to use of the radiation machine on humans.
- 4. Used, previously owned, or refurbished/rebuilt radiation machines installed at an existing registered facility must undergo State certification, resolve all violations, and submit the certification package for Agency review prior to use of the radiation machine on humans. After the initial inspection, the machine will be inspected on their normal certification cycle.
- 5. Denote on the RX1 the Federal Tax ID Number or if a change of ownership has occurred denote on RX2.

Mid Atlantic States Radiation Program Meeting

The 2006 Meeting of the Mid-Atlantic States Radiation Control Programs was held on October 4 and 5, 2006 in Mendenhall, Pennsylvania. The meeting was co-sponsored by the Mid-Atlantic Chapter of the American Association of Physicists in Medicine (MAC-AAPM). October 4, 2006 provided 6.5 Continuing Education Credits for Mammography Quality Standards Act (MQSA) inspectors and medical physicists. The Nuclear Regulatory Commission (NRC) provided half-day training on Brachytherapy while the MAC-AAPM presented for the second half. October 5 included presentations from the regional state programs, federal agencies, and other stakeholders. We offer special thanks to all private inspectors who participated in the regional meeting as presenters, supporters, or attendees.

Plan Reviews

The issuance of deficiency letters to facilities has continued to decrease. In order to keep up with this downward trend, the RMD State Licensed inspectors must comply with the following requirements:

- 1. The plan reviews that are sent into the State for review should be legible.
- 2. Include a scale for the floor plans and ensure that it is legible.
- 3. Describe any unusual features that might cause over or under compensation for presented readings.

The RMD inspectors who perform the reviews of the submissions use conservative numbers and make every effort to be as conservative as possible without being overly restrictive.

Draft Regulations for Particle Accelerators

If you are interested in reviewing the draft regulations for teletherapy radiation, please contact Ms. Renee Fizer for a copy. Modifications to Section F. and Section I. are in preliminary phases.

