Radiological Health Program
X-RAY BULLETIN

December 1, 2010

Assembler and/or Manufacturer Transfer Obligation Requirements

The purpose of this guidance is to restate the notification responsibilities that dealers, manufacturers, installers and assemblers of X-ray equipment have in the Commonwealth of Virginia. As stated in the **Radiation Protection Regulations** (**12 VAC 5-481-350). Assembler or transfer obligation:**

A. Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines or upon significant service or modification thereof of any radiation machine (such as tube inserts, generators or collimators) in this state shall notify the agency within 15 days of:

1. The name and address of persons who have received these machines;

2. The manufacturer, model, and serial number of each radiation machine transferred; and

3. The date of transfer of each radiation machine.

B. No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used shall meet the requirements of these regulations.

This means all x-ray equipment used in the healing arts is required to be registered with the Virginia Department of Health, Division of Radiological Health and Safety Regulations. This includes, but is not limited to, medical and dental x-ray equipment, podiatric and veterinary x-ray equipment, bone densitometry equipment, and linear accelerators. If the FDA does not require the Report of Assembly, FDA Form 2579, this does not exempt you from filing notice with the Virginia Department of Health, Division of Radiological Health and Safety Regulations that an installation of equipment has occurred.

Once the equipment has been installed, the facility should contact a private inspector or state inspector to have the equipment inspected according to the Virginia Department of Health's **Radiation Protection Regulations**, effective November 1, 2008. If equipment has significant service or modification, such as replacements for tube inserts, generators, or collimators, or if the equipment is moved to another location, the equipment should be re-inspected to verify compliance.

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