

**Radiation Machine Registration Unit
Radiation Safety Section
Michigan Department of Consumer & Industry Services**

State Reporting and X-Ray Machine Registration Issues

A. Responsibilities of the Radiation Machine Registration Unit

1. Registration of all radiation machines in Michigan.

Currently there are over 25,000 radiation machines registered at approximately 9,200 facilities in the state.

2. Authorization of x-ray machines used for mammography.

Currently, approximately 550 x-ray machines are authorized for use for mammography in 330 facilities in the state.

B. Regulatory basis for Radiation Safety Section program functions, including Radiation Machine Registration Unit registration and mammography authorization activities.

1. Act 368 of the Public Acts of 1978, as amended (also known as the Public Health Code).

The most recent amendments to the Public Health Code occurred in 1989, 1992, and 1994, which affected mammography machine authorization, and established the current schedule of registration and inspection fees.

2. Michigan's Ionizing Radiation Rules.

Part 4 of the Rules which addresses the registration of radiation machines was revised to its present form in March 1979. Part 14 of the Rules, which includes mammography authorization criteria, was added in November 1993.

C. Radiation machine registration process.

- 1. A unique facility registration record is created in the Radiation Safety Section database for each initial registration application sent.**
- 2. A follow-up date is established to contact facilities whose completed application has not been received by that date.**

NOTE: Because we maintain a registration database and a registration application follow-up protocol, suppliers and installers of x-ray machines may not provide registration applications directly to registrants.

- 3. Upon receipt of a completed registration application with appropriate registration fee, a Radiation Machine Registration Certificate is sent to the registrant, together with a machine tag for each machine registered on the Certificate (show examples).**
- 4. The registrant is expected to post the registration certificate at the facility where x-ray equipment is located, and to affix machine tags to the control consoles of all x-ray machines registered.**

D. Vendor requirements as contained in Part 4 of Michigan's Ionizing Radiation Rules.

- 1. Registration of radiation machines by vendors themselves is required for:**
 - a. Machines used for demonstration purposes.**
 - b. Machines used for testing or servicing of other x-ray equipment or equipment components.**
- 2. Pursuant to Rule 195, all vendors are required to submit quarterly reports of sales and installations of radiation machines, even if no sales or installations are made in any given quarter (show example). Submission of the State of Michigan**

copy of the FDA's Report of Assembly is not currently accepted in lieu of filing quarterly installer reports.

- 3. Pursuant to Rule 195, all vendors are responsible for installing radiation machines so that the machines meet the requirements of Michigan's Ionizing Radiation Rules.**

E. Recommended vendor actions to ensure that registrants meet Michigan's registration requirements.

- 1. Prior to installation, inform the registrant that it is the facility's obligation to register radiation machines with the Department. Provide our Lansing telephone number, (517) 241-1989, to the registrant to call regarding registration. We will instruct the registrant regarding appropriate registration procedures to be followed.**
- 2. When installing or servicing x-ray equipment, request to see a facility's current Radiation Machine Registration Certificate, and look for machine tags on control consoles. If a valid registration certificate or machine tag is not observed, inform the registrant of their need to contact our office regarding registration posting and labeling requirements.**
- 3. If any of a facility's registration information is suspected to be inaccurate (e.g., incorrect owner, inappropriate Radiation Protection Supervisor designation, inaccurate x-ray machine information), inform the registrant of the need to contact our office.**
- 4. Installers of x-ray equipment who are also responsible for the design and construction of the x-ray room need to be aware that Rule 331(2) of Michigan's Ionizing Radiation Rules requires that x-ray room shielding and design are subject to Department approval. Don Parry of our Section will elaborate on shielding and design issues later in the program.**

F. Questions