



Missouri Radiation Control Program Guidance Document/Frequently Asked Question

See below for regulatory guidance on the following issue. If you have additional questions, you may contact the Missouri Radiation Control Program at MRCP@health.mo.gov or 573-751-6083

Guidance to X-ray Vendors/Service/Repair companies doing business in Missouri (updated November 2017)

If you sell new or used x-ray equipment in Missouri, or repair existing equipment, or disassemble equipment:

X-ray service company representatives are typically in contact with new facilities early in the planning stages, or existing facilities that are planning on renovating or adding additional x-ray rooms or machines, much earlier than the Missouri Radiation Control Program (MRCP). As such, equipment vendors have the opportunity to provide initial guidance to the facility as to their regulatory responsibility to ensure radiation safety. Note the following:

- **Registration with MRCP by the facility is required.** Be aware that FDA Form 2579, that installers are required to fill out and submit to the MRCP upon installation or repair of certified x-ray components is **NOT** a substitute for the facility's responsibility for registration. New facilities must still contact the MRCP and fill out registration paperwork, and facilities adding additional rooms must amend their registrations. Registration forms, as well as copies of the rules, and answers to many of the facility's potential questions, can be found on the MRCP website: <http://health.mo.gov/safety/radprotection/>
- **Shielding and equipment inspection required by Qualified Expert.** All new facilities and existing facilities adding additional x-ray rooms or adding additional x-ray machines to their total number must have a **radiation safety inspection** and **radiation shielding evaluation** performed by a DHSS-approved Qualified Expert in radiation safety.
- **Any equipment calibration tests performed by manufacturer representatives at the time of equipment installation is not typically sufficient to meet the inspection requirement,** unless the service company has a Qualified Expert on staff. After the facility's initial inspection by QE, a periodic inspection schedule will be established by MRCP based on the most hazardous type of radiation equipment in use at the facility. Periodic inspections are due every 12, 24, 48, or 72 months. Facilities adding rooms before their due date should have all equipment checked in order to "reset" the due date of the facility as a whole.
- **Written statement/evaluation of shielding** must be done prior to routine usage of the equipment. After the written statement/evaluation, the equipment may be used clinically up to ninety (90) days after installation until the QE performs an onsite inspection of the equipment. The shielding statement may be a formal shielding plan/evaluation (most common), or an onsite area survey after installation to demonstrate compliance with applicable NCRP shielding standards. For some smaller equipment, e.g., some mobile units or some self-contained units, the written statement could be as simple as an e-mail from the QE stating a formal shielding evaluation is not applicable or no additional shielding is necessary in the professional judgment of the QE. MRCP's expectation is that the facility has communicated with a QE as to the intended usage of the machine and the QE has provided some degree of consultation.

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- **Radiation safety inspection** must be performed by a Qualified Expert. This inspection must be done prior to clinical usage of some equipment: **CT, fluoroscopy [including C-arms], radiation therapy, and mammography** equipment. **Cone Beam CT (CBCT) equipment used in dental offices must be inspected within thirty (30) days from installation.** MRCP will make reasonable allowances for initial commissioning/applications visits by equipment vendors prior to the inspection. For other types of equipment not listed above, once a shielding evaluation is complete, the equipment can be used up to ninety (90) days after installation before the onsite inspection. An inspection summary report must be sent to the MRCP within thirty (30) days from the inspection. If the QE finds problems that need to be corrected, the facility must send MRCP evidence of corrective action.
- **No Current Machines Are Exempt from Survey Requirements.** There are no exempt radiation-producing machines. If a machine produces ionizing radiation, it needs a radiation safety inspection by a QE. That includes Dental intra/oral and panoramic units, DEXA, XRF, x-ray security machines, cabinet x-ray, electron microscopes, and specimen x-ray machines.
- **Repair/Replacement of x-ray equipment in existing rooms.** Note that the requirements for initial survey and shielding evaluation are for NEW ROOMS only, not for repairs or replacement with the same type of equipment. Surveys on repaired or replaced units would fall under routine/periodic survey timeframes, and would not require inspection or a shielding evaluation until the next QE due date. MRCP *recommends* (but does not require) facilities to contact their QE when making repairs or replacements of like equipment to get QE input as to whether additional testing is advisable (or required under MQSA or CMS requirements or accrediting body standards).
- **Loaner/temporary equipment usage; survey requirements?** In most cases loaner equipment is treated similarly to replacement equipment. If the loaner equipment is still in use after 90 days, the facility will be required to add the equipment to their registration and survey the equipment as normal. Beyond that, MRCP recommends that the facility should contact the QE and seek their professional judgment on any additional testing, if needed, but this decision for additional machine testing of loaner/temporary equipment are ultimately left between the facility and its QE.
- **Facilities removing/disposing of old x-ray equipment.** If a facility is closing down or ceasing to provide x-ray services, the MRCP must be updated as to the facility status. If the equipment is being removed, information on disposition of the equipment needs to be provided to MRCP.

Applicable rules

192.400(1), RSMo. It is unlawful for any person to produce radiation, or produce, use, store or *dispose of...radiation machines*, or to modify, extend or alter these activities unless he registers in writing with the department of health and senior services in accordance with the procedures prescribed by the department.

19 CSR 20-10.050 (1) The user shall provide for radiation surveys and monitoring sufficient to assure compliance....The *radiation survey and monitoring shall be performed by, or under the direction of, a qualified expert.*

19 CSR 20-10.050 (2) Until an actual radiation survey can be performed, a *written statement made by a qualified expert* based on his/her analysis of the situation shall be acceptable as evidence of the absence of radiation hazard in a given area.

19 CSR 20-10.190 (1) The *requirements for room shielding shall conform to* the requirements defined in...[*National Council on Radiation Protection {NCRP}, Reports 145, 147, 151*].

19 CSR 20-10.030 (1) ... *Any newly acquired source* shall be registered with the Department of Health within thirty (30) days after receipt. The registration shall be submitted on a form available from the department and shall describe each source, its location and use....The registration also shall give the name and address of the user(s) and the *name and address of the qualified expert* [used for the required surveys and monitoring].