Missouri Department of Health and Senior Services
Bureau of Diagnostic Services
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Updated 8/18

Notice: To new radiation machine facilities, or existing facilities adding new equipment after 1/1/2014

The following information is provided to assist in outlining a facility's regulatory responsibility to ensure radiation safety. Missouri Radiation Control Program rules and policies require that the facility owner of radiation-producing machines demonstrate compliance with both radiation shielding and safe machine performance requirements, primarily through consultation with approved Qualified Experts in radiation safety. In most cases, if a new x-ray room is being added, **both** a written evaluation/shielding plan **and** an **onsite survey** by a Qualified Expert is required. After an initial survey, periodic surveys must be arranged every 1, 2, 3, 4, or 6 years, depending on the Class of the facility and its radiation equipment. See below for requirements. If you have additional questions please contact MRCP@health.mo.gov or by phone at 573-751-6083, or refer to our website at: http://health.mo.gov/safety/radprotection/

	New radiation facility	**New x-ray room(s)** (expansion → new radiation machine(s))	**Repairs/replacement equipment** in existing fixed location radiation/x-ray room.
Shielding plan or written evaluation by approved Qualified Expert. **Should** be done prior to clinical usage; **must** be done no later than the required QE survey.	**YES** --keep on file and provide to MRCP.	**YES** --keep on file and provide to MRCP.	NOT REQUIRED unless significant changes in room usage (going from radiographic to CT, etc.)
Initial onsite radiation safety survey by Qualified Expert if:			
→Equipment is: Mammography, Fluoroscopic, Radiation therapy, CT →Specific to CBCT (Cone Beam CT) used in dental offices:	**YES, PRIOR** to routine clinical usage **YES**, within thirty (30) days of installation with written statement from QE.	**YES, PRIOR** to routine clinical usage **YES**, within thirty days of installation of new CBCT when it replaces a panoramic or is completely new.	NOT MANDATORY, HOWEVER, it is ***recommended*** that the QE be contacted by the facility to determine if certain safety tests would be advisable. *Note MQSA requires QE evaluation for any "major component" change or repair of mammography equipment.
→Equipment is NOT one of the above (routine radiographic, dental [intra/oral or panoramic], non-medical, podiatric.	**YES**, but may be done within ninety (90) days of installation with written statement from QE.	**YES**, but may be done within ninety (90) days of installation with written statement from QE. **Medicare Certified portable x-ray suppliers→ new machines must be surveyed *prior* to use.	NOT MANDATORY, HOWEVER, it is ***recommended*** that the QE be contacted by the facility to determine if certain safety tests would be advisable.

Applicable rules

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].

Discussion: When does a facility need an inspection by a Qualified Expert in Radiation Safety (QE)

Missouri Radiation Control Program (MRCP) within the Bureau of Diagnostic Services (BDS) evaluates and approves the education/ training of individuals who wish to be considered Qualified to perform radiation safety surveys/inspections to demonstrate a facility is in compliance with applicable regulations. Once MRCP approves their application, the applicant becomes a QE (Qualified Expert). It is the regulatory responsibility of the facilities to make arrangements with (and pay for the services) of **only a DHSS-approved Qualified Expert**, and have the inspection done by the QE due date to demonstrate compliance. **Who needs a QE inspection**:

- All **new** x-ray facilities.
- Existing x-ray facilities that **move** to a new location.
  - New and relocated facilities need shielding evaluations by a QE (written statement) to ensure compliance with NCRP (National Council of Radiation Protection) standards. This ***should*** be done prior to usage, but ***must*** be done no later than the time of the survey/inspection by the QE noted below.
  - An equipment inspection by the QE.
    - **Prior to routine clinical usage** of the equipment is Class A (Mammography, Radiation Therapy, CT, Fluoroscopy [R/F, C-arm, Angio, Cardiac Cath, Interventional, etc.])
    - **For new CBCT (Cone Beam CT) machines used in dental offices,** inspection must be within 30 days of installation.
    - **For all other types of equipment not listed above (except TBD specifically-designated equipment),** inspection must be within 90 days of installation or beginning of routine clinical usage.

- Existing x-ray facilities that add **an additional x-ray room/machine** or different class of machine **(+1 to the facility inventory of x-ray machines)**—This requires a New Equipment inspection by a QE.
  - Note: New equipment inspection only has to be done on the new (+1) equipment.
  - The new room needs a shielding evaluation (written statement) from the QE regarding NCRP standards.
  - The new equipment inspection must be done on the new (+1) room/machine:
    - **Prior to routine clinical usage** of the equipment is Class A (Mammography, Radiation Therapy, CT, Fluoroscopy [R/F, C-arm, Angio, Cardiac Cath, Interventional, etc]).
    - **For new CBCT (Cone Beam CT) machines used in dental offices,** inspection must be within 30 days of installation.
    - **For all other types of equipment not listed above (except TBD specifically-designated equipment),** inspection must be within 90 days of installation or beginning of routine clinical usage.

- **Periodic inspections. All facilities with x-ray equipment still in use must be inspected by QE periodically. That period is based on the highest risk of equipment used by the facility. Note: no written shielding evaluations are required for existing facilities that were registered prior to 1/1/2014, unless significant changes in workload occur.**
  - Class A—inspection every 12 months (annually)
  - Class B—inspection every 24 months (2 years)
  - Class C—inspection every 48 months (4 years)
  - Class D—inspection every 72 months (6 years)
  - Class E—per state law 19.500 (8/28/17) these are dental facilities with CBCT units. The CBCT must be inspected every 36 months (3 years), the other dental equipment onsite must be inspected every 72 months (6 years).
  - **ALL equipment in use** at the facility must be included on the periodic inspection, at the facility classification period, regardless of the type of individual equipment (with the exception of CBCT per 192.500)
  - **In some cases, following a successful inspection by QE, some facilities—upon request and providing adequate documentation--may be eligible for an extension for their next QE due date.**
  - **In general, all equipment in use at the same physical location (same campus/premises) is on the same registration.** Only in very limited circumstances, when the facility requests it and provides adequate justification, (including distinct differences in ownership/control of the equipment) may the registration be split.
  - **Surveying more frequently than the standard period.** Some facilities may decide to have their equipment inspected more frequently due to accreditation (Joint Commission, etc.) standards, federal certification standards, insurance rules, or internal facility policy. This is acceptable but not mandated by MRCP.

When is a QE inspection NOT mandated:

- **Repair or replacement of previously registered equipment**. Facilities who are repairing an existing unit or replacing one with the same type of machine in the same location (except for Mammography). We ***recommend*** that a facility may wish to contact their QE to see if additional testing is advisable in this situation, but it is not required by MRCP regulation.
- **Temporary/loaner equipment.** 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 as part of their periodic inspections. We ***recommend*** that a facility may wish to contact their QE to see if additional testing is advisable in this situation, but it is not required by MRCP regulation.
- **Equipment brought into the state for temporary usage, if it has been inspected by another state radiation control program or a QE in another state.** The equipment must still be registered for temporary use in Missouri.

If you have additional questions not covered above, contact our program at MRCP@health.mo.gov or by phone at 573-751-6083.