



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 Dental Facilities Regarding Responsibility to Ensure Radiation Safety; use of Qualified Experts (QE's) (Updated November 2017)

Summary of Key Points:

- Dental facilities with x-ray machines must now hire Qualified Experts (QE's) in radiation safety, approved by the Missouri Radiation Control Program (MRCP) to perform initial and periodic surveys (inspections.)
- The QE will evaluate radiation safety of the facility, usually to include machine performance, shielding, and personnel monitoring. The QE will send evidence of the findings to the MRCP for any necessary follow up.
- These inspections must be done:
 - Whenever new facilities open or new x-ray rooms are added; **AND**, For existing facilities:
 - Prior to the **QE Due Date** assigned to your facility by MRCP. Most of these due dates will be from **2017-2022**, then every six (6) years thereafter. This due date was already mailed to your facility. **Your facility will also be sent a reminder notice 90 days prior to the Due Date.**
 - **2017 Update:** Cone Beam CT machines must be inspected every three (3) years per 192.500 RSMo (8/2017) and all non-CBCT dental equipment must be inspected every six (6) years.
- If a new x-ray room is added, in addition to the machine inspection, the facility must also demonstrate that radiation shielding is adequate. This can be done by following a shielding evaluation by a Qualified Expert, or at the time of an initial inspection on the new room prior to routine clinical usage.
- *Repairs* of existing equipment or *replacement* of dental equipment in existing rooms **do not** require a mandatory survey. However, facilities are encouraged to contact their QE to discuss if additional safety testing may be prudent.
- A QE list is maintained on the MRCP website: <http://health.mo.gov/safety/radprotection/pdf/QE-List.pdf>
- QE survey fees are not set or controlled by MRCP but by private arrangement between QE and facility. Type of equipment, numbers of machines, and distance of travel for the QE may all factor into the cost.

Detailed explanation

Per State Law 192.430, RSMo and state rule 19 CSR 20-10.050(1), it is ultimately the responsibility of the owner of x-ray machines to demonstrate that the equipment is installed and used in a safe manner. For many years, as a public health service, the Missouri Radiation Control Program (MRCP) was able to directly employ radiation safety professionals to perform inspections. However, due in part to changes in departmental priority and lack of staff, as of January 2014 responsibility for providing for these inspections has transitioned back to the equipment owners. This transition was originally announced by letter to all registered facilities in December 2012. To minimize impact, this transition is taking place incrementally over several years.

Effective 1/1/2014, it is again the responsibility of the owner of x-ray machines to provide for both initial and periodic inspection of x-ray machines, and to ensure radiation shielding is adequate, through use of MRCP-approved Qualified Experts in radiation safety (QE's.)

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All facilities are classified, and inspection periods determined, depending on the potential radiation hazard level of the x-ray machines used. Except for the relatively few dental facilities using Cone Beam CT machines (*discussion on CBCT to follow*), all other dental facilities in Missouri are currently Class D. This means that they represent the **lowest** radiation hazard level. Accordingly, most dental facilities will also have the **most lenient** mandatory inspection period. The vast majority of dental facilities will only need to be inspected every six years (72 months.)

What does this mean for your dental facility?

All existing dental facilities in Missouri that are properly and currently registered with the MRCP have been assigned a QE Due Date. This date was mailed to existing facilities in 2012, and is also noted in the paperwork each time your x-ray equipment is re-registered, which is required every two years. In addition, approximately three months (90 days) prior to the QE Due Date, you will be sent a reminder notice. Prior to the QE Due Date, you must make arrangements (including locating and paying for services) with an MRCP-approved Qualified Expert to perform a radiation safety survey on your x-ray equipment. The QE will send MRCP evidence that the inspection has taken place and the findings. If problems are identified, it will be your responsibility to provide MRCP with documentation of corrective action. The MRCP maintains a list of individuals approved to provide these services. ***As of 11/2017, there are over 70 individuals approved to conduct these dental inspections in Missouri.*** This number is likely to continue to increase over the next several years. A list of these approved Qualified Experts is available on the MRCP website: <http://health.mo.gov/safety/radprotection/pdf/QE-List.pdf>

MRCP has reviewed the education and credentials of these individuals (*and investigates any serious complaints regarding their qualifications*), but is not involved in scheduling or payment arrangements. You are allowed to shop around for an approved individual that best meets your needs. If you are in a rural area, you may wish to contact other nearby medical facilities with x-ray machines to see who they use, as the QE may be on a circuit through that region of the state, and inspecting several facilities in the area at one time may reduce costs.

How is the QE Due Date determined?

As mentioned above, the transition is being implemented incrementally over several years. Existing dental facilities that do not add new rooms, or use CBCT were randomly ***assigned a QE Due Date beginning in 2017, running through 2022.*** That means that your facility will not have to be inspected by these individuals until that date, unless your insurance or other outside entities require it, **or** you add new x-ray rooms.

New Dental Facilities or New X-ray Rooms/Operatory rooms: Shielding evaluation and initial inspections

New dental facilities beginning operation after 1/1/2014, or existing dental facilities that add additional rooms after 1/1/2014 must have those rooms evaluated for adequate radiation shielding, and the equipment itself inspected after installation. This is a separate requirement beyond the routine periodic QE due date. Qualified Experts can perform both a shielding evaluation and equipment inspection at the same time within 90 days from installation of the equipment (30 days for newly installed CBCT equipment.)

Repairs to existing equipment (including replacement units) in existing rooms

Although MRCP encourages facilities to contact a QE to discuss any suggested additional testing whenever significant repairs are made to existing equipment, or replacement units are placed in existing x-ray rooms, no formal inspection by a QE is required in these circumstances, unless dental facilities are replacing routine pano equipment with CBCT.

Special guidance for dental facilities utilizing Cone Beam CT machines (CBCT)

Due to 2017 changes in state law, dental facilities that utilize CBCT machines (a small minority, around 10% of all registered dental facilities in Missouri) are Class E, indicating utilization of equipment with an increased radiation-safety risk. All CBCT equipment must be surveyed every 36 months/3 years. For the remaining non-CBCT equipment (I/O, panoramic,) this will only need to be surveyed every 72 months (6 years) following the first survey. Note: Any new rooms being added in these facilities would need to be surveyed to demonstrate compliance with shielding and operational requirements.

Some facilities have questioned the classification of facilities utilizing Cone Beam Computed Tomography (CBCT) equipment as Class E, which require more frequent radiation safety inspections. CBCT is a relatively new technological development, and extensive studies on the radiological impact, radiation dose, as well as detailed utilization and protocol optimization guidelines are still under development in the CBCT industry and health physics community. However, a current understanding of the technology and risk indicates that although the radiation exposure is less than a typical medical CT, on average it is well in excess of routine dental radiographic and panoramic x-rays. Moreover, CBCT is inherently prone to

artifacts and other technical issues than can negatively impact diagnostic quality and unnecessary exposure. Additionally, studies and surveys have indicated that that training and usage has not been consistently applied across the dental field.

Assessing the overall radiation safety risk of CBCT from a public health standpoint is a topic still being discussed and studied across the country, (as well as in other parts of the world like the European Union.) The Conference of Radiation Control Program Directors (CRCPD), which acts as an advisory body in setting national radiation safety regulatory policy, has an active Task Force (H-44) currently studying the question of CBCT on conjunction with the American Association of Physicists in Medicine (AAPM,) and expects to issue recommendations to the states in the near future. In addition, the National Council of Radiation Protection (NCRP) is currently updating national standards for radiation protection in dental facilities (update of NCRP Report 145). At present time, the consensus guidelines of these and most professional and technical advisory bodies (most pointedly the American Dental Association and American Association of Endodontists—two groups significantly affected) suggest CBCT be treated like medical CT, and similar radiation protection standards be applied. Relevant references include:

- Radiation doses and risks from dental CBCT are considerably higher than conventional dental radiography, although lower than typical conventional muscular-skeletal CT. Although specific radiation dose delivery will vary, CBCT dose is 10-450 times greater than a standard intraoral radiograph, and 5-50 times greater than a panoramic radiograph.— **Radiation Protection: Cone Beam CT for Dental and Maxillofacial Radiology, Evidence Based Guidelines (2011), Sedentex CT.**
- “[A]lthough CBCT technologies have advanced rapidly across time, concerns have been expressed about whether the information acquired with CBCT imaging warrants the additional exposure risk, as well as about the level of training, education and experience required to interpret the CBCT data set...Dentists must abide by applicable federal and state regulations in the provision of dental imaging modalities. This includes following regulations or guidance to ensure a safe working environment for both the staff and the public in relation to CBCT equipment and other sources of ionizing radiation...Facilities considering the installation of new CBCT devices should consult a health physicist (or other qualified expert) to perform a shielding analysis based on NCRP reports 145 and 147. Facilities using CBCT systems should consult a health physicist (or other qualified expert) to perform equipment performance and compliance evaluations initially at installation and then follow a schedule in compliance with local, state and federal requirements. The Council recommends that a performance evaluation be completed at least annually. The evaluations should include patient dose estimation to assist the facility with patient dose management.”-- **Use of cone-beam computed tomography in dentistry--An advisory statement from the American Dental Association Council on Scientific Affairs—8/1/12**
- “At this time, all CBCT equipment produce dose levels and beam energies that are higher than conventional dental radiography, requiring extra practical protection measures for office personnel. Appropriate qualified experts should be consulted prior to and after installation to meet state and federal requirements, and manufacturer’s recommended calibration routines should be conducted at the recommended intervals.”--**Joint Position Statement of the American Association of Endodontists and the American Academy of Oral and Maxillofacial Radiology—2010**
- [“A]ny practice undertaking medical exposure should have access to the advice of a qualified expert for advice on radiation protection and a medical physics expert for advice on patient dose optimization and equipment testing. ... the relative radiation dose implications of some CBCT systems [outline the need] to have a formal arrangement to obtain [qualified expert] advice...both when the equipment is first installed and then on a regular basis throughout the life of the equipment.” **[Maximum values for testing frequency for CBCT per the SEDENTEX Evidence based guidelines is 12 months.] --SEDENTEX CT, 2011**
- CBCT is prone to significant imaging artifacts (noise, scatter, motion, etc) that can negatively impact diagnostic quality and an accurate diagnosis. —**Dentomaxillofacila Radiology, July 2011, Vol 40:5, pp. 265-273**
- Although the radiation doses from dental CBCT exams are generally lower than other CT exams, dental CBCT exams typically deliver more radiation than conventional dental X-ray exams. Concerns about radiation exposure are greater for younger patients because they are more sensitive to radiation (i.e., estimates of their lifetime risk for cancer incidence and mortality per unit dose of ionizing radiation are higher) and they have a longer lifetime for ill effects to develop. — **fd.gov**