

Missouri Department of Health and Senior Services Bureau of Diagnostic Services Missouri Radiation Control Program

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Missouri Radiation Control Program Facility Classification for Cone-Beam CT outside of dental facilities [Revised Jan 2024]

- Both the US Food and Drug Administration (FDA) and MO DHSS MRCP consider Cone Beam Computed Tomography (CBCT) a variation of traditional computed tomography systems.
- CBCT generally represents a lower radiation hazard risk than traditional CT, but in many cases is significantly higher than conventional radiology of a similar area of interest. MRCP has by convention (based on a preponderance of generally-agreed upon health physics information) classified CBCT by default as Class A equipment, requiring annual radiation safety inspections (every 12 months.) However, there are various factors that can impact or mitigate CBCT hazards and/or classification.
- The most common utilization of CBCT is in dental radiography. In 2017, the MO Dental Association supported legislation to limit most CBCT dental facilities in Missouri to routine inspection no more than every three (3) years. (192.500 RSMo) However, some high output dental CBCT units are still be required to be inspected annually. In addition, 192.500 only impacts dental CBCT, not CBCT used outside dental facilities.
- For non-dental facilities using CBCT, barring submission of additional information, MRCP will by default continue to initially classify non-dental CBCT as Class A (requiring annual inspection by Qualified Expert.) However, we will also evaluate on a case-by-case basis, consideration of factors in use by a given facility that may allow a reduction in the required inspection frequency.

•	For non-dental facilities using CBCT that request a reduction in mandatory inspection frequency, please indicate which of
	the following mitigation factors (indicate all that apply) should be considered for your facility:

	At least two quarters (six months) of facility personnel dosimetry following installation of the CBCT is available,
	indicating minimal or low exposure to facility staff. Provide documentation of dosimetry reports to MRCP.
	CBCT is used exclusively on non-human subjects (veterinary or imaging phantom [teaching] use only.)
	CBCT is limited only to head/neck/cervical spine studies only, no torso or below imaging.
	Limited clinical technique. Indicate the maximum kVp setting your facility's machine is capable of, and/or the
	maximum technique ever to be used at your facility: IndicateMax kVp possible;Max kVp used clinically.
	Limited CBCT exposures: Facility limits the number of exposures to the patient to a max of two (2) per exam.
	Operator control location for the CBCT is at least six (6) feet away from the unit, there is a barrier between the unit
	and the exposure switch, and facility staff are never in the same room as the patient and never used to hold/support
	the patient.
	Facility has an active QC/QA program in place for CBCT unit (routine periodic phantom image review, etc.)
	Describe the QC/QA program in writing and provide evidence.
	Facility's Qualified Expert can provide a statement based on their professional expertise that, upon QE review, this unit and the facility's use thereof represents a lower-risk case and should be reclassified. Provide QE statement .

Upon review of any submitted information, MRCP will review and communicate back to your facility if the Classification will change. If you have additional questions, please call 573-751-6083 or email MRCP@health.mo.gov

Sincerely,

Missouri Radiation Control Program, Bureau of Diagnostic Services

Resources/References:

 $\underline{https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/dental-cone-beam-computed-tomography}$

https://pubmed.ncbi.nlm.nih.gov/25805884/

https://www.researchgate.net/publication/260716130_Cone_beam_CT_Non-dental_applications

 $\underline{https://www.entnet.org/resource/position-statement-point-of-care-imaging-in-otolaryngology/}$

 $\underline{https://todays veterinary practice.com/dentistry/cone-beam-computed-tomography-in-veterinary-dentistry/cone-beam-computed-tomography-in-veterinary-dentistry/cone-beam-computed-tomography-in-veterinary-dentistry/cone-beam-computed-tomography-in-veterinary-dentistry/cone-beam-computed-tomography-in-veterinary-dentistry/cone-beam-computed-tomography-in-veterinary-dentistry/cone-beam-computed-tomography-in-veterinary-dentistry/cone-beam-computed-tomography-in-veterinary-dentistry/cone-beam-computed-tomography-in-veterinary-dentistry/cone-beam-computed-tomography-in-veterinary-dentistry/cone-beam-computed-tomography-in-veterinary-dentistry/cone-beam-computed-tomography-in-veterinary-dentistry/cone-beam-computed-tomography-in-veterinary-dentistry/cone-beam-c$

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3232399/

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6404553/

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