

Cone-Beam Computed Tomography

Cone-beam computed tomography (CBCT) is a medical imaging technique consisting of X-ray computed tomography where the X-rays are divergent, forming a cone. The beam is used to create a three-dimensional image of a body region, usually the mouth or head. CBCT was developed by Dr. Piero Mozzo and Dr. Yoshinoro Arai in the mid-1990s.

Dental CBCT is a non-invasive way for dental professionals to get a complete picture of a patient's mouth and can be used to diagnose mouth and jaw issues, make bone grafts, or install dental implants. Unlike X-rays, CBCT images both soft tissue and bone. Compared to conventional computed tomography (CT) scans, CBCT produces lower radiation exposure. CBCT scans are fast, painless, and noninvasive.

Registration of X-ray Equipment

By regulation under [25 Pa. Code § 216.2](#), CBCT units must be registered as a radiation-producing machine with the Department of Environmental Protection's (DEP) Bureau of Radiation Protection within 30 days of acquisition.

FDA Requirements

U.S. Food and Drug Administration regulations at [21 CFR Part 1020](#) contain performance standards for ionizing radiation emitting products. [21 CFR § 1020.33](#) covers CT equipment. [21 CFR § 1020.33\(d\)](#) (relating to Quality assurance), provides, in part, that the manufacturer of a CT unit shall provide the end user with a phantom and instructions on use of the phantom, including a testing schedule, allowable parameter variations, and a method to store quality assurance data.

25 Pa. Code 25 § 221.64 - CBCT

[25 Pa. Code § 221.64](#) requires a performance evaluation be performed by or under the direct supervision of a Qualified Medical Physicist (see [25 Pa. Code § 221.2](#)) or Qualified Expert (see [25 Pa. Code § 215.2](#)). The evaluation shall be performed within 30 days of installation, at intervals not to exceed 14 months, and within 30 days after any change or replacement of components which could cause a change in the radiation output or image quality.

In addition to the requirements of [25 Pa. Code § 221.16](#) (relating to training, competency and continuing education), the CBCT system should only be operated by an individual who has been specifically trained in its operation.

For More Information

For more information, visit www.dep.pa.gov or call 717-787-3720. You can also use the DEP Bureau of Radiation Protection email resource account RA_EPRPControl@pa.gov with "Regulation Question/[Your Registration Number]" as the title of your subject line.

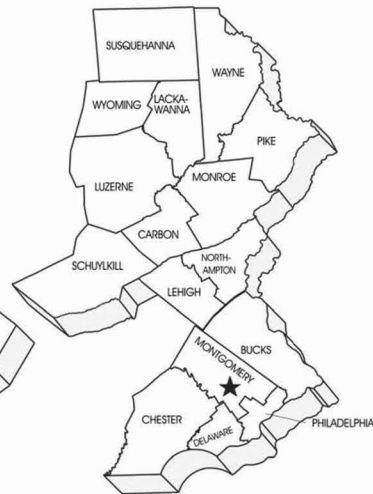
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