

ADIA Policy Statement P11 – Dental Product Regulation (CBCT/CBVT Ownership)

Statement

That the regulations for the ownership of Cone Beam Computed Tomography (CBCT) / Cone Beam Volumetric Tomography (CBVT) should provide a framework for correct installation and operation; and that matters associated with its use on patients and image interpretation / patient diagnosis are matters of professional practice.

Principle/s

- CBCT / CBVT digital imaging equipment that complies with the regulatory standards for the approval of medical devices presents no risk (i.e. the equipment is not itself dangerous) thus there should be no restrictions on the ownership of the equipment.
- Insofar as CBCT / CBVT digital imaging presents a risk to patients, these relate to ionising radiation exposure and image interpretation / diagnosis thus are matters of healthcare professional competency and registration.

Background

CBCT / CBVT digital imaging equipment in dentistry is used for various clinical applications including dental implant planning, visualisation of abnormal teeth, evaluation of the jaws and face, cleft palate assessment, diagnosis of dental caries (cavities), endodontic (root canal) diagnosis, and diagnosis of dental trauma.

The regulatory standards for the ownership of CBCT / CBVT digital imaging equipment vary between state / territory governments. The regulatory body is typically the government agency responsible for radiation safety.

As with any x-ray exposure, CBCT / CBVT use poses potential risks to the patient thus widespread acceptance of the ALARA principle (As Low as Reasonably Achievable) to reduce radiation exposure to their patients by: determining the need for and type of radiographs to take; using "best practices" during imaging, including the application of quality control procedures; and, interpreting the images completely and accurately. Regulation of this type of activity falls clearly within the domain of the Australian Health Practitioner Regulation Agency (APRAH) and national Boards including the Dental Board of Australia (DBA) and the Medical Radiation Practice Board of Australia (MRPBA).

Engagement & Advocacy Partners

- Internal: ADIA Reference Group – WA Digital Imaging
- Stakeholder: N/A
- Government: State / Territory Governments

Endorsement

ADIA-DRC Dental Regulation Committee: 4/5/2017

ADIA Board: 23/5/2017

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