Dental industry

Issued February 2023

EPA 1135/23: This document provides information to those in the dental industry on the key changes of the new Radiation Protection and Control Regulations 2022 under the Radiation Protection and Control Act 2021.

1 Scope

The major changes that are relevant to dental industry include:

- Compliance testing of dental X-ray apparatus and introduction of cyclic testing to move towards national uniformity.
- Changes in the obligations of the owners and accredited compliance testers under the registration reform process.
- Published list of professionals in various streams who are authorised for exposure.
- Radiation management plan and personal dosimetry requirements.
- Published exemptions.
- Variations of conditions.

2 Compliance testing

As per Regulation 30 of the *Radiation Protection and Control Regulations 2022* (RPC Regulations) under the *Radiation Protection and Control Act 2021* (RPC Act), a radiation source must comply with the provisions of a relevant code that are expressed as mandatory provisions applying in respect of the radiation source. The EPA has published *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*. This code provides the mandatory requirements for the dental modalities and the shielding requirements for plain dental and panoramic/cephalometric apparatus**.** The shielding requirements for dental CBCT is covered under *Code of Compliance for facility design and shielding 2022* published by EPA.

The EPA is adopting cyclic compliance testing for all dental X-ray apparatus used on humans to move towards national uniformity. The frequency with which the compliance testing must be conducted for all types of dental X-ray apparatus, used on humans, is set at five years. Considering the low risk associated with dental modalities, the cyclic testing for dental apparatus will be introduced from February 2026.

Therefore, compliance testing must be done at the initial installation of the apparatus, and from February 2026 at intervals of five years and after major repairs such as X-ray tube change or software change that could affect radiation safety.

It is important to note that the cyclic compliance testing is only applicable for apparatus-specific tests and does not include shielding verification. When compliance testing is performed after major repairs the cyclic testing reset occurs from the date of compliance. From February 2026, with the introduction of cyclic testing, the annual servicing requirement will no longer be a requirement.

3 Registration reform process

A new process for the registration of ionising X-ray apparatus used for diagnostic purposes will commence on 11 February 2023.

From the commencement date, the owner must have submitted an application to register the apparatus prior to the conclusion of the installation phase and prior to clinical use. Then following an initial assessment, the EPA will issue the owner with a provisional registration.

Owners will be allowed a 60-day period under the provisional registration in which to have regulatory compliance verified. It will be the owner's responsibility to engage testers to ensure the ongoing compliance of X-ray apparatus with regulatory requirements. Clinical use is permitted during this 60-day period subject to the terms outlined.

This new process requires that the accredited tester must forward their test report and certificate of compliance, to the owner, rather than the EPA which has previously been the case.

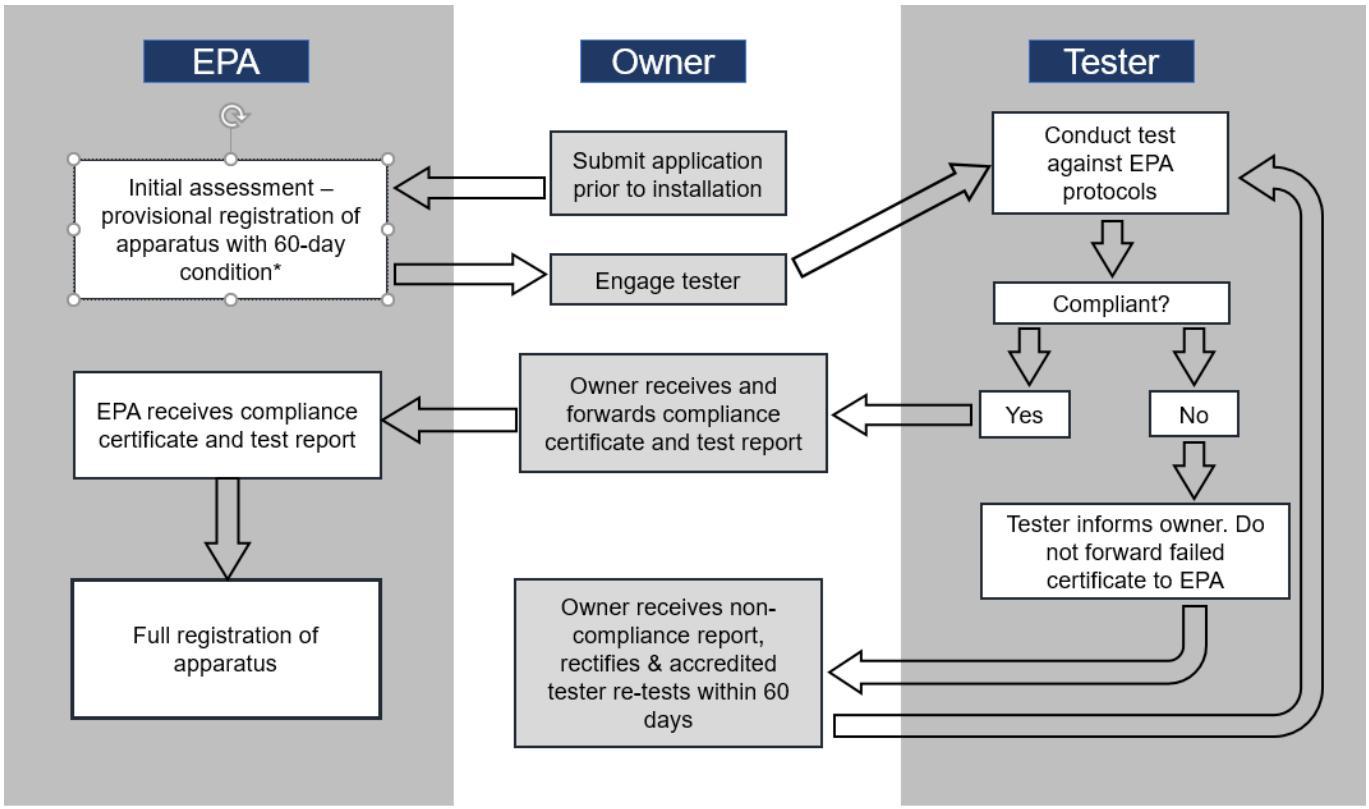
If compliant, the owner must then forward these documents to the EPA within the 60-day period and the apparatus then becomes fully registered with a new condition. The test report and certificate of compliance should be emailed to rpb.compliance@sa.gov.au

If the initial compliance test of the apparatus is found to be non-compliant, the owner is still permitted to operate the apparatus for clinical use but must ensure that the fault is rectified within the 60-day time period and retested by the accredited tester. Incomplete or not fully compliant certificates of compliance should not be submitted to the EPA.

If at any time the owner expects to not be able to fulfil their obligations to demonstrate apparatus compliance to the EPA within the 60-day allowance period, they must communicate this to the EPA via email and seek approval for further time if warranted.

The 60-day time period from the end of installation will be phased out over the next two years, meaning clinical use of apparatus will not be permitted prior to demonstrating compliance in the form of a finalised certificate of compliance and test report. In preparation of this reform the EPA recommends that an owner demonstrates compliance prior to clinical use. The EPA will continue to consult with licensees regarding the final implementation of this reform.

The following diagram outlines the new process.



*** In the event owner is unable to organise for initial compliance testing within the 60-day period, then the owner must communicate this to EPA and until further advice from EPA, apparatus is not permitted to be used clinically.**

4 Exposure authorisation

The new regulations (Regulation 106) require the EPA to publish through a Gazettal process, details of professionals that may authorise exposure to radiation.

With no national standard for exposure authorisation in Australia, the EPA has largely retained the current authorisation framework. The EPA plans to engage with licensees, State and National bodies to review the current authorisation framework and seeks input from stakeholders to assist with this process.

5 Radiation management plan and personal dosimetry requirements

The EPA has developed the *Code of Compliance for radiation management plans* that provides the mandatory requirements for radiation management plan (RMP) to be submitted and complied with by applicants for a radiation management licence under Part 4 Division 1 of the RPC Act.

The protection and safety elements of the RMP are to be commensurate with the complexity of and the radiation risks associated with the licensed activity in a graded manner. Accordingly, risks will be considered sufficiently low where the effective dose expected to be incurred by any individual is demonstrated:

- under all reasonably foreseeable circumstances to not exceed 100 µSv (microSievert) in a year; and
- for low probability scenarios* to not exceed 1 mSv in a year; and
- for low probability scenarios that would not be classified as a notifiable radiation incident under Schedule 3 of the RPC Regulations.

* Unless otherwise specified, low probability scenarios are those where the probability of occurrence does not exceed 10^{-02} per year.

If the person holding the radiation management licence can demonstrate that the risks associated with the activities involved in their practice is sufficiently low, then the Regulation 86 requirement for an employer to provide radiation

monitoring devices for each of their radiation worker can be removed or exempted. It is up to the owners to find a suitable method with which they can demonstrate the low risks associated in their practice. The chosen methodology must be acceptable to the EPA.

For existing radiation sources, some of the possible methods, but not limited to, to estimate the doses could be:

- modelling of radiation sources;
- providing the personal dosimetry records of all the radiation workers from past five years;
- history of radiation incidents associated with each radiation sources and the doses received out of each incident.

For a new radiation source, some of the possible methods, but not limited to, to estimate the doses could be:

- modelling of radiation sources;
- shielding design report and survey measurements;
- providing the personal dosimetry records of radiation workers operating similar radiation apparatus (make and model) for at least 1−2 years;
- published data of personal dose values of radiation workers operating various dental modalities (such as from Australian Dental Association).

6 Published exemptions

Current exemptions as published in the South Australian Government Gazette under the RPC Act will continue to be valid for a period of 12 months following the commencement of the RPC Act. As such current exemptions will cease to be valid on 11 February 2024. Should a specific exemption be required past this date and is not addressed elsewhere in the RPC Act or RPC Regulations, please contact the EPA prior to 11 February 2024 to discuss further.

7 Variations of conditions

The condition attached to a Licence to Possess, Radiation Use Licence, Sealed Radioactive Source, Radiation Apparatus or Registered Premise may be varied to bring it into alignment with the RPC Act and RPC Regulations. Licensees will be notified of this change in February 2023.

8 Public register

Section 77 of the RPC Act requires the Minister to keep a publicly available register of accreditations, authorisations, registrations and permits. Regulation 125 sets out the information to be included on the register.

9 Feedback

The EPA encourages all questions and feedback on the implementation of the new legislation. Please email: EPARadiationProtectionBranch@sa.gov.au

10 Suggested readings

- *Radiation Protection and Control Act 2021*
- *Radiation Protection and Control Regulations 2022*
- *Code of Compliance for facility design and shielding 2022*
- *Code of Compliance for radiation management plan 2022*
- *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*

Disclaimer

This publication is a guide only and does not necessarily provide adequate information in relation to every situation. Information provided in this document is for general guidance and is not a substitute for relevant legislation. This publication seeks to explain your possible obligations in a helpful and accessible way. In doing so, however, some detail may not be captured. It is important, therefore, that you seek information from the EPA itself regarding your possible obligations and, where appropriate, that you seek your own legal advice.

Further information

Legislation

Online legislation is freely available on https://service.sa.gov.au/12-legislation

General information

Environment Protection Authority
GPO Box 2607 Adelaide SA 5001
Telephone: (08) 8204 2004
Facsimile: (08) 8124 4670
Freecall: 1800 623 445 (country)
Website: https://www.epa.sa.gov.au
Email: epainfo@sa.gov.au