Owners of medical diagnostic X-ray equipment

Issued February 2023

EPA 1137/23: The Radiation Protection and Control (RPC) Act 2021 was assented to on 11 February 2022 and the subsequent Radiation Protection and Control (RPC) Regulations 2022 was published in October 2022. Changes to the legislation reflect a move toward national uniformity in radiation protection to meet current practices and standards.

1 Introduction

The legislation will be implemented on 11 February 2023, along with the introduction of seven EPA codes of compliance that further define the specifics of regulatory requirements in relevant areas of practice. The legislation is further supported by related ARPANSA codes listed within the RPC Regulations.

Additional changes to aspects of radiation protection regulation, to be phased in following the introduction of the new legislation, are:

- Introduction of cyclic testing of X-ray apparatus to confirm ongoing compliance with regulatory standards.
- Authorisation for diagnostic X-ray requests.
- Reform of the registration process for X-ray apparatus and introduction of critical failure limits to some compliance tests for X-ray apparatus.
- Changes to conditions attached to licences to possess and licences to operate.

2 Codes

As per Regulation 30 of the RPC Regulations under the RPC Act, a radiation source must comply with the provisions of a relevant code (outlined in Schedule 2 of the Regulations) that are expressed as mandatory provisions applying in respect of the radiation source.

Much of the technical detail outlined in the *Radiation Protection and Control Regulations 201*5 has been removed from the 2022 regulations allowing for a more responsive approach to regulating radiation safety as technology evolves. The technical detail now resides in codes that can be updated with greater ease.

Codes affecting the regulatory obligations of medical diagnostic X-ray apparatus are:

Code 1: Code of Compliance for radiation management plans 2022 − Provides the mandatory requirements for radiation management plans to be submitted and complied with by applicants for a radiation management licence.

Code 2: Code of Compliance for facility design and shielding 2022 − Provides the mandatory requirements for radiation apparatus, including diagnostic imaging apparatus used for medical, chiropractic or veterinary purposes, dental cone

beam CT, radiotherapy apparatus and non-medical apparatus. This code does not apply to plain dental or panoramic/cephalometric apparatus as their shielding requirements are stipulated in the Dental Code.

Rather than exposure rate limits for areas outside shielding to X-ray apparatus rooms, the new code requires the shielding design and verification methods of either the NCRP 147 or BIR 2012 to be used. A consequence of this means new dose constraints to workers and the public are required by the code. Effective dose to workers must not be greater than 5 mSv/year and for the public not greater than 1 mSv/year

Code 3: Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022 − Provides the mandatory radiation safety requirements for fixed, mobile, and portable apparatus used or designed to be used for, mammography or soft tissue radiography, medical or veterinary computed tomography, medical or veterinary fluoroscopy, medical, veterinary or chiropractic plain radiography, medical X-ray absorptiometry.

Code 4: Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022 − Provides the mandatory requirements for the dental modalities and the shielding requirements for plain dental and panoramic/cephalometric apparatus.

Code 7: Code of Compliance for labelling and signage of ionising radiation sources 2022 − Applicable to the labelling and signage requirements of all X-ray apparatus.

3 Test protocols

There are eight new test protocols derived from their relevant codes which describe the requirements of testing for regulatory compliance of X-ray apparatus:

- Dental – Plain radiography (intra oral).
- Dental – Panoramic & cephalometric.
- Dental – Cone beam CT.
- Medical, veterinary & chiropractic – Plain radiography.
- Medical, veterinary & chiropractic – Shielding.
- Medical & veterinary – Computed tomography.
- Medical & veterinary – Fluoroscopy.
- Mammography.

Changes in the new protocols are to bring apparatus testing requirements into line with national codes. Testing requirements for medical apparatus are derived from the ARPANSA draft *Multi-jurisdictional Radiation Apparatus Testing Requirements*. As this is a draft document, any future changes will be monitored for how this may affect test protocols in the future.

4 Dose constraint

The new concept of constraints has been introduced in the EPA *Code of Compliance for facility design and shielding 2022* to design and assess optimisation of protection.

Design constraints under planned exposure situations are:

1 For occupational exposure of a worker:

   a not greater than an effective dose of 5 (milliSievert) mSv in a year; or

   b not greater than an effective dose approved by the Minister and documented in an approved radiation management plan; and

2 For exposure of any other person, not greater than an effective dose of 1 mSv in a year.

5 Cyclic testing

Cyclic testing involves the complete compliance assessment of X-ray apparatus used for human diagnostic purposes at regular intervals to ensure the radiation safety and performance of the apparatus continues to comply over time. It will be the owner's responsibility to engage testers to ensure the ongoing compliance of X-ray apparatus with regulatory requirements.

Cyclic testing for the regulatory compliance of radiation apparatus is applicable to fixed, mobile and portable diagnostic X-ray apparatus used on humans only. The cyclic testing will be introduced in South Australia in a staged approach as listed in the following table.

As an example, any CT apparatus installed, and compliance tested prior to February 2024 will have its first cyclic compliance testing performed from February 2024 until February 2026. Cyclic testing will then need to be completed every two years from that date. If a new CT apparatus is installed sometime between February 2024 and February 2026 the due date for the first cyclic testing is two years from the date of initial compliance test when the apparatus was first registered.

Apparatus used or designed to be used for	**Frequency of testing**	**Year of introduction**
Computed tomography	2 years	Feb 2024
Fluoroscopy (including apparatus capable of both fluoroscopy and plain radiography)	2 years	Feb 2024
Mammography or soft tissue radiography	1 year	Feb 2025
Plain radiography	2 years	Feb 2025
X-ray absorptiometry apparatus	5 years	Feb 2026

6 Exposure authorisation

Classes of health practitioners that may authorise X-ray exposures will be published in the South Australia Government Gazette upon the commencement of the RPC Act and made available on the EPA website. Present allowances by gazette for certain health practitioners, such as registered nurses and nurse practitioners, will lapse in 12 months following the introduction of the new Act and Regulations (February 2024). Future gazettal of practitioners to authorise X-ray examinations is targeted to address previous allowances, where relevant, to maintain professional scope of practice.

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.

7 Registration reform and critical failures

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. 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

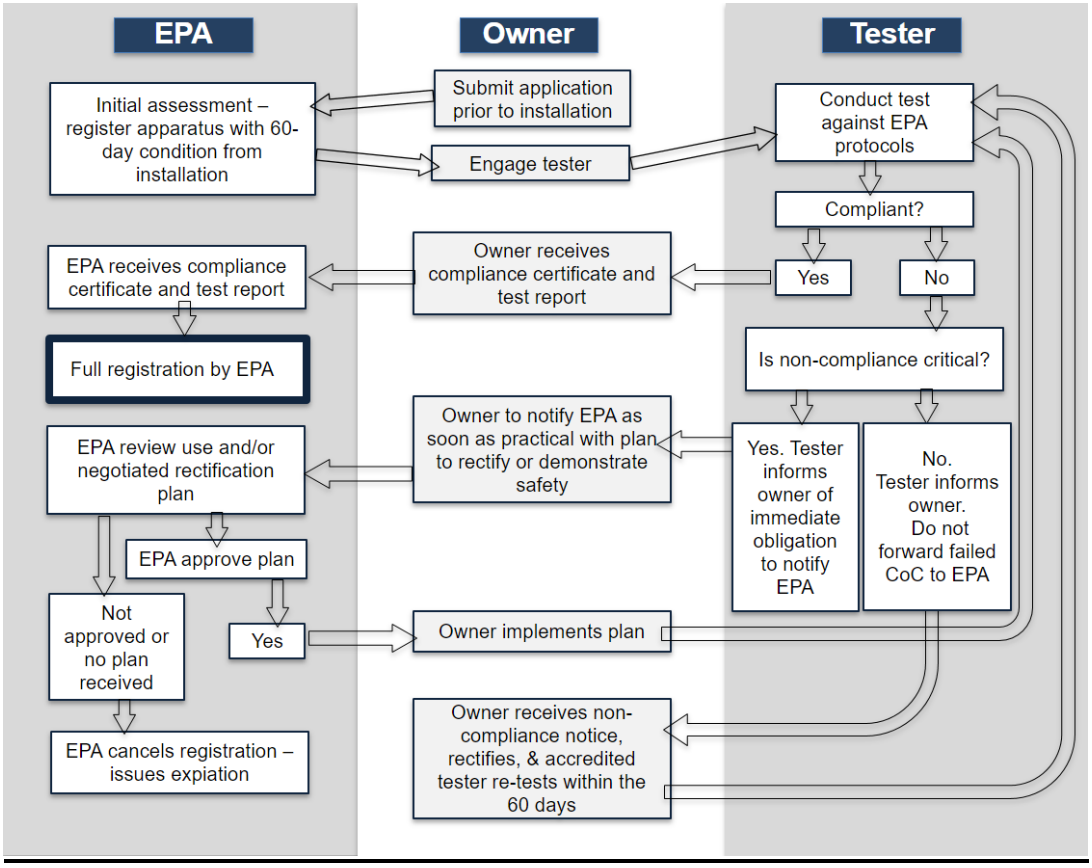
If the initial compliance test of the apparatus is found to be non-compliant but the fault not critical, the owner is still permitted to operate the apparatus for clinical use but must ensure that the fault is rectified within the 60-day time period and retested by the accredited tester. Incomplete or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

Critical failure limits are introduced on certain tests for medical apparatus where the significance of a non-compliance means the apparatus must not be clinically operated. Where the non-compliance is a critical failure, the tester must inform the owner who must immediately inform the EPA of the fault and ensure no clinical use of the apparatus is undertaken without the consent of the EPA and a rectification process is agreed to. The EPA should be notified of critical failures at https://ask.your.epa.sa.gov.au. The tester will provide the owner with further precise instructions regarding notifying the EPA of critical faults. Testers will also be required to place signage on the apparatus warning against operation of apparatus due to critical failure.

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.



8 Conditions

Once the new Act and Regulations come into effect, some conditions on current authorisations will need to be updated to reflect the new legislation. The majority of these updates will be limited to amendments to reflect the name and dates of the new legislation. From 11 February 2023, the EPA will notify relevant persons of updated conditions.

9 Published exemptions

Current exemptions to regulatory requirements, as published in the South Australian Government Gazette under the *Radiation Protection and Control Act 1982,* will continue to be valid for a period of 12 months following the commencement of the new RPC Act. These 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 this further.

10 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 of the RPC Regulations sets out the information to be included on the register.

Further information

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

General information

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