Nuclear medicine

Issued February 2023

EPA 1133/23: This document provides information to those in the nuclear medicine industry on the key changes of the new Radiation Protection and Control Regulations 2022 under the Radiation Protection and Control Act 2021.

1 Relevant legislation

- *Radiation Protection and Control Act 2021* (RPC Act)
- *Radiation Protection and Control Regulations 2022* (RPC Regulations)

Relevant EPA Codes of Compliance and ARPANSA Codes can be found in Schedule 2 of the RPC Regulations.

2 Radioactive material

The definition of radioactive material has been updated to align with the standard set out by the International Atomic Energy Agency. As described in Regulation 8 radioactive material is defined as containing more than the prescribed concentration or more than the prescribed activity of a radioactive element or compound as specified in Table I.1 of the IAEA General Safety Requirements. As such the prior classification of radionuclides into Groups 1,2 ,3,4 has ceased and additionally a new category: prescribed low risk radioactive material has been established.

3 Registered premises

Registered premises in which unsealed radioactive materials are handled or kept will now be differentiated between laboratories and non-laboratories. Requirements associated with these premises are detailed in the EPA *Code of Compliance for facility design and shielding 2022*. Registered premises which are used as hot laboratories for the preparation of radiopharmaceuticals for diagnostic imaging or radiotherapy are considered laboratories. Other registered premises such as uptake rooms, camera rooms, radioactive waste storage rooms, etc are considered non-laboratory premises.

Laboratories: the classification of a laboratory (Type A, B, C) is determined using the *Australian/New Zealand Standard as specified in section 3.5 of* AS/NZS 2243.4:2018 Safety in Laboratories Part 4: Ionizing radiations. The standard details the radiotoxicity groupings and modifying factors used to determine the grading of a laboratory ie a low-level laboratory is determined to be a Type C premise, high-level laboratory is a Type A premise, etc.

The prescribed design and construction requirements correspond to the classification of the laboratory. It is important to note that these requirements are applicable to laboratory premise only, and do not affect non-laboratory premise. For example, an engineering workshop may not require a fume cupboard as it is considered a non-laboratory premise.

Non-laboratory premises: The classification of non-laboratory premises is primarily determined according to the associated risk of the operations being performed. The EPA *Code of Compliance for facility design and shielding 2022*

outlines in Schedule 1 common non-laboratory premises, details of operations, and the associated classification (see table).

Premises use	Type C	Type B	Type A
Laboratories			
Grading against section 3.5 of *AS/NZS 2243.4:2018 Safety in Laboratories Part 4: Ionizing radiations*	Low-level laboratory	Medium-level laboratory	High-level laboratory
Non-laboratory premises			
Storage of unsealed radioactive materials	Storage only		
Premises where radioactive materials are administered to animals, flora or humans	Premises where radioactive materials are applied to soil or flora or to animals which are incapable of escaping their enclosure	Premises where low dose radioactive materials are administered to humans or animals.	Premises where radioactive materials are administered to humans for high dose in-patient radionuclide therapy.
Non-laboratory premises (eg engineering workshops)	Non laboratory premises handling or keeping: • surface contaminated objects • NORM with a total activity concentration below 10 kBq/g • artificial radioactive materials classified by the transport code as LSA-I	All other non-laboratory premises	

Where a premises is used for more than one use then it will be classified as the highest applicable category − Type A = highest classification, Type C = lowest classification. Should a laboratory be a part of a premise which is used for more than one use, the laboratory requirements set out in in *AS/NZS 2243.4:2018 Safety in Laboratories, Part 4: Ionizing radiations* remain regardless of classification of the non-laboratory operations also being undertaken in that same premise.

Where a premises has multiple parts of the land, building or structure used for storage or handling of radioactive materials, the radiation management plan shall specify the classification of each part of the premises and its precise location within the building or area.

4 Radiation management licences − radiation facility vs licence to possess

A new category of radiation management licence is to be established. Known as a *Radiation management licence – radiation facility* this category of licence may be more suitable to nuclear medicine departments than the currently

established Radiation management licence – possession of a radiation source (commonly referred to as a 'Licence to Possess'). The holder of a radiation facility licence is exempt from registering all premises individually and instead is required to outline in the RMP a record of each premise including the classification, physical location, and associated operations of each premise. The EPA will be progressively implementing radiation facility licences and will advise those impacted in due course. In the meantime, all operations authorised by a current Radiation Management Licence – Possession of a Radiation Source continues as usual.

5 Radiation waste management plan

The requirement for regulatory approval to dispose of unsealed radioactive materials continues.

Approval to dispose of unsealed radioactive material for a period beyond 12 months may be granted as per Regulation 66. Should your organisation wish to apply for an approval period of longer than 12 months the following is to be detailed in your application: the exact period for which the application is sought, justification for the period being sought, as well as the typical information required such as the radionuclides and activities of unsealed radioactive materials purchased and disposed of by your organisation.

6 Registration of sealed radioactive sources

Sealed radioactive sources which are exempt from the requirement to be registered are prescribed by Regulation 20. This regulation differs somewhat to the previously prescribed classes of sealed radioactive sources, and as such some sealed radioactive sources which were previously exempt now require registration as per the 2022 Regulations.

The EPA will be publishing an exemption prior to 11 February 2023 which will allow classes of sealed sources that were prescribed from the registration requirement in the 2015 Regulations to continue to be exempted from the requirement to register. This will be an interim measure as the EPA reviews and makes changes to the fee structure for sealed sources and Category 5 low risk sources in particular. Once the fees have been amended, the exemption will be revoked and licensees will be required to register sources as per the requirements of Regulation 20. The EPA will continue to inform and advise of changes on this matter throughout 2023.

7 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 Act 2021. 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.

8 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.

9 Registration Reform Process of SPECT/CT and PET/CT apparatus

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 mailto:rpb.compliance@sa.gov.au

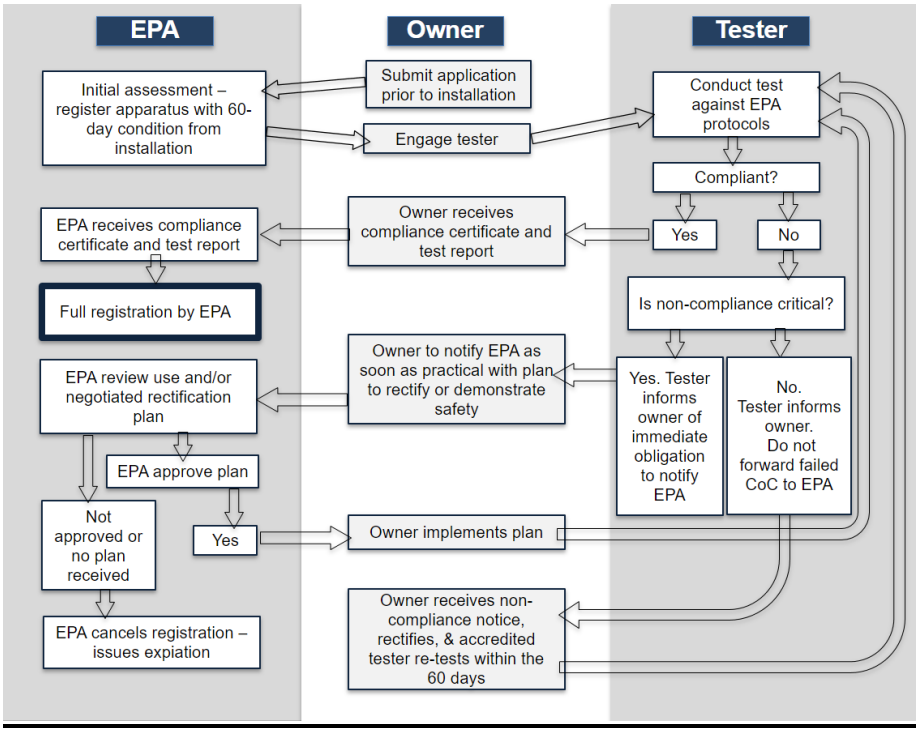
If the initial compliance test of the apparatus is found to be non-compliant but the fault not critical, as detailed in the relevant test protocol, the owner is still permitted to operate the apparatus for clinical use but must ensure that the fault is rectified within the 60-day time period and retested 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/enquiry/. 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.



10 Dose constraint

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

The design constraints under planned exposure situations are:

1 For occupational exposure of a worker:

   a not greater than an effective dose of 5 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.

11 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.

12 Feedback

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

Disclaimer

This publication is a guide only and does not necessarily provide adequate information in relation to every situation. 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

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