

# Radiotherapy industry

Issued February 2023

*EPA 1136/23: This document provides information to those in the radiotherapy 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 radiotherapy industry include:

- Compliance testing.
- Published list of professionals who are authorised for exposure.
- Radiation management plan and personal dosimetry requirements.
- Registration of sealed radioactive sources.
- Dose constraints
- Published exemptions.
- Variations of conditions.

## 2 Compliance testing

With the new regulations, much of the prescriptive requirements have been removed and included in Codes of compliance. With regard to radiation therapy, the EPA has published a [Code of Compliance for radiation therapy apparatus 2022](#) which provides the mandatory requirements for the radiation therapy modalities including radiation treatment image guidance and superficial therapy apparatus. The shielding requirements for these modalities are covered under [Code of Compliance for facility design and shielding 2022](#).

## 3 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.

## 4 Radiation management plan and personal dosimetry requirements

Part 4 Division 1 of the Act requires development of a radiation management plan (RMP) to demonstrate appropriate systems are in place to assure radiation safety. To assist licence holders to understand the mandatory requirements that an RMP must address, the EPA has developed a [Code of Compliance for radiation management plans](#).

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 the 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;
- area monitoring records of locations where radiation workers will be present, such as control console for at least one year.

## 5 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 to the previously prescribed classes of sealed radioactive sources, and as such some sealed radioactive sources which were previously exempt now require registration under the 2022 regulations.

However, the EPA will be publishing an exemption prior to 11 February 2023 that 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 beyond 11 February 2023. 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 of the 2022 Regulation. The EPA will continue to inform and advise of changes on this matter throughout 2023.

## 6 Dose constraint

The concept of new dose constraint 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 mSv (millisievert) 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.

## 7 Published exemptions

Current exemptions 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 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 Act 2021 or the Regulations 2022, please contact the EPA prior to 11 February 2024 to discuss further.

## 8 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.

## 9 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.

## 10 Feedback

The EPA encourages all questions and feedback on the implementation of the new legislation. Please email at [EPARadiationProtectionBranch@sa.gov.au](mailto:EPARadiationProtectionBranch@sa.gov.au)

## 11 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 radiation therapy apparatus 2022\*](#)
- [\*Code of Compliance for labelling and signage of ionising radiation apparatus 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

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