## **Radiation Act 2005**

Annual report for the financial year ending 30 June 2024



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# Radiation regulation in Victoria in 2023–24: a snapshot

The 2023–24 financial year has seen transformational change in the way the Department of Health (the department) regulates radiation practices. In February 2024, the Health Regulator was established to bring together and align the regulatory functions of the department. The Health Regulator is the main regulatory oversight branch of the Department of Health. Our work includes administering permissions and licensing, monitoring compliance and enforcing the law, and regulatory reform and policy. This includes regulation of radiation practices under the Radiation Act 2005 (the Act).

The purpose of the Act is to protect the health and safety of Victorians and the environment from the harmful effects of radiation.

The Act requires the Secretary of the Department of Health to publish an annual report that describes the activities of the Secretary under the Act and summarises all authorities issued, renewed, suspended, cancelled, varied, transferred or surrendered during that year. The report must also detail all radiation incidents investigated and summarise all prosecutions for offences in that year.

At the end of the 2023–24 year there were just over 21,000 current licences or approvals issued to organisations or individuals to perform some form of radiation practice or for the use of a radiation source.

Over the 2023–24 financial year, a total of 64 individuals notified the department that they were intending to work in Victoria under new laws for automatic mutual recognition of their interstate licence.

Approximately \$4.453 million in licensing fees were paid during the 2023–24 financial year.

The department conducted 452 inspections in the 2023–24 financial year as part of its licensing compliance monitoring program. This was below the Victorian State Budget target of 480 inspections. Competing priorities resulted in an outcome just under target.

During the year, the department conducted a variety of regulatory actions. Three search warrants were obtained and executed in relation to suspected commercial tanning operations. This resulted in the seizure of three tanning units. Four diagnostic X-ray units were sealed – a general medical X-ray unit, a veterinary CT unit and two dental cone beam CT units. The two dental cone beam CT units remained sealed at the end of the 2023-24 financial year.

During 2023–24, 276 incidents were reported to the department compared to 268 in the previous year. All 276 incidents in 2023–24 were in the medical sector.

### Introduction

Diagnostic, therapeutic, industrial and other uses of radiation have contributed to the safety and quality of life for all Victorians. However, radiation does involve hazards if it is managed or used inappropriately or unnecessarily. For this reason, the department regulates the use of radiation to protect people and the environment from its harmful effects by licensing users of radiation sources and managers of radiation practices under the Act.

Section 134 of the Act requires that the Secretary of the Department of Health, in respect of each financial year, publish a report that:

- describes the activities of the Secretary under the Act
- includes a summary of all authorities issued, renewed, suspended, cancelled, varied, transferred or surrendered during that year
- includes all radiation incidents investigated in that year
- includes a summary of all prosecutions for offences against the Act or the Regulations commenced in that year
- includes any other prescribed matter.

  There are currently no prescribed matters.

This 2023–24 annual report describes the activities of the Secretary for the financial year from 1 July 2023 to 30 June 2024.

### Legislation

#### **Radiation Act**

The Radiation Act 2005 (the Act) commenced operation on 1 September 2007.

The Act gives effect to Victoria's commitment to the National Directory for Radiation Protection (NDRP) published by the Australian Radiation Protection and Nuclear Safety Agency. The NDRP outlines a common approach for Commonwealth, state and territory governments in regulating radiation practices.

The purpose of the Act is 'to protect the health and safety of persons and the environment from the harmful effects of radiation' and incorporates:

- the radiation protection principle
- a requirement for the Secretary of the department to have regard to both the radiation protection principle and the National Directory for Radiation Protection
- the concept of licensed activities. In particular, the licensing framework created by the Act features:
  - management licences that authorise the conduct of radiation practices (such as possessing a radiation source)
  - use licences that authorise a natural person to use a radiation source
  - radiation facility construction licences.
- the concept of approved testers and the testing of prescribed radiation sources against declared radiation safety standards
- the concept of approved assessors of security and transport security plans.

The Act creates significant offences, including:

- conducting a radiation practice without a management licence (the maximum penalty in the 2023–24 period for a body corporate for this offence was \$1,730,790)
- using a radiation source without a use licence (the maximum penalty in the 2023–24 period for an individual for this offence was \$230,772)
- non compliance with the conditions of a management licence (the maximum penalty in the 2023–24 period for a body corporate for this offence was \$1,153,860).

#### **Radiation Regulations**

The Radiation Regulations 2017 prescribe:

- licensing fees
- definitions of radioactive material
- radiation dose limits
- radiation sources that must be tested and issued with a certificate of compliance before use and at specified intervals afterwards.

The Regulations also:

- strengthen the security of high-consequence radioactive material
- implement changes to the occupational dose limit to the lens of the eye to reflect recent international and national developments.

### How is the Act administered?

# Establishment of the Health Regulator

In December 2023, the Minister for Health announced the establishment of the Health Regulator to better protect Victorians and provide greater consistency to regulation across the health system.

The Health Regulator was formally established in February 2024, following a department restructure, and comprises teams focused on regulatory compliance and operations, permissions and licensing, regulatory strategy, intelligence, performance and capability and regulatory policy and reform. It regulates thousands of professionals, organisations and businesses across the State. The Health Regulator regulates radiation safety under the Act.

#### The Licensing Framework

The Act sets out a licensing framework combined with a series of significant offence provisions. The licensing framework involves:

- Facility construction licences, which authorise construction of a 'radiation facility', currently limited to premises where it is intended to store high consequence radioactive material (material with security requirements mandated, in addition to radiation safety requirements).
- Management licences, which authorise the conduct of a radiation practice. Radiation practices include:
  - Possession of radiation sources (such as X-ray units, CT scanners, radiopharmaceuticals used in nuclear medicine, radioactive sources used in industrial practices such as radiography of pipes and welds).
  - Transport of radioactive material.
  - Sale of radiation sources.
  - Research involving the exposure of persons to ionising radiation.
  - Disposal of radiation sources.
  - Mining or processing of radioactive material (in Victoria's case - mineral sands).

- Use licences, which authorise individuals to use a radiation source.
- Approved tester authorities, which authorise individuals to issue certificates indicating compliance with mandatory radiation safety standards for certain types of medical diagnostic X-ray units.
- Approved assessor authorities, which authorise individuals to issue certificates indicating compliance with mandatory security standards for high consequence radioactive material.

Technical matters are not dealt with in the Act or Regulations. These matters are likely to need frequent change to reflect international and national agreements. The omission of technical matters in the Act and Regulations necessitated a wide-ranging power to make and apply enforceable conditions of licence. The Act provides a wide power to make such conditions.

All licences issued by the department are subject to conditions. These conditions are increasingly focused on compliance with nationally agreed Codes specific to their type of practice.

#### **Automatic mutual recognition**

In late 2020, National Cabinet agreed to implement automatic mutual recognition (AMR). AMR allows a person who is licensed or registered for an occupation in one jurisdiction to be considered licensed or registered to perform the same activities in another jurisdiction, without the need to go through further application processes or pay additional fees. This makes it easier for workers who need to be licensed or registered for their job to work in another state and territory.

AMR for occupational licences became available from 1 July 2021 in certain states and territories. Victoria entered the scheme on this date with the scheme applying to the following types of authorities:

- Use licences.
- Approved testers.
- Approved assessors.

An interim declaration was made on 1 July 2021 by the Victorian Treasurer that required any worker coming into Victoria to work under these arrangements to have first notified the department, providing specific information.

Any worker wishing to work in Victoria under these arrangements must notify the department using a smart form available on the department's website before starting work.

In January 2022 the Victorian Acting Minister for Health extended the mandatory notification requirement of intention to work in Victoria until at least 2032.

During the 2022–23 financial year the department continued to liaise with other jurisdictions on the implementation of the system. The differences between jurisdictions' approaches and implementation timing have continued to make the implementation of AMR complex.

Over the 2023–24 financial year, a total of 64 individuals notified the department that they were intending to work in Victoria under these arrangements.

## Summary of authorities issued by the department

Section 12 of the Act creates an offence for a person to conduct a radiation practice unless the person holds a management licence or is exempted under s 16 of the Act.

The most common radiation practice requiring a management licence is possessing a radiation source. Other radiation practices include:

- transporting radioactive material
- selling radiation sources
- procuring or arranging research that involves exposing people to radiation
- mining or processing radioactive material.

Section 13 of the Act creates an offence for a person to use a radiation source unless the person holds a use licence or is exempted under s 16 of the Act.

The numbers of authorities issued, renewed, suspended, cancelled, varied, transferred and surrendered under the Act during 2023–24 are listed in Table 1.

Table 1: Number of authorities issued, renewed, suspended, cancelled, varied, transferred and surrendered under the Radiation Act, 1 July 2023 to 30 June 2024

Authority	Management licence	Use licence	Tester	Assessor
Issued	174	2855	8	0
Renewed	1783	6842	24	0
Suspended	0	0	0	0
Cancelled	0	0	0	0
Varied	554	460	6	0
Transferred	40	n/a	n/a	n/a
Surrendered	40	10	0	0

The numbers of current authorities under the Act as of 30 June 2024 are listed in Table 2.

Table 2: Number of authorities issued as of 30 June 2024

Authority	Number
Use licences	18153
Management licences	2920
Approved testers	51
Approved assessors	6

The estimate of the sectors in which these licences are held is listed in Table 3.

Table 3: Estimate of the sectors in which licences are held under the Radiation Act, 1 July 2023 to 30 June 2024

Sector	Management licence	Use licence
Dental	1549 (47.79%)	5884 (32.13%)
Veterinary	391 (12.06%)	2936 (16.03%)
Medical	240 (7.41%)	6904 (37.7%)
Industrial	237 (7.31%)	1532 (8.37%)
Sales	165 (5.09%)	n/a (%)
Chiropractic	67 (2.07%)	193 (1.05%)
Transport	52 (1.6%)	n/a (%)
Education	39 (1.2%)	89 (0.49%)
Mining	3 (0.09%)	n/a (%)
Other	498 (15.37%)	776 (4.24%)

#### Licence fees

Approximately \$4.453 million in licence fees was paid during the 2023-24 financial year. The fees are paid into the consolidated revenue.

#### Fee policy

The Victorian Guide to Regulation and general government policy require that regulatory fees and user charges should be set on a full cost recovery basis to ensure that both efficiency and equity objectives are met.

The department's aim is therefore to recover the full cost of the administration of the Act. This is done by setting fees based on the following principles:

- Applications for use licences attract a fee consisting of a non-refundable application fee plus a licence fee based on the time period of the licence, i.e., the longer the licence, the higher the fee but there is a small discount for longer licence periods to reflect the slight reduction of administrative burden associated with longer period licences.
- The fee for a use licence does not depend on the type of radiation source proposed to be used.
- Applications for a management licence attract a fee based on a non-refundable application fee plus a licence fee based on a combination of factors:
  - The types and numbers of radiation sources to be possessed. Sources deemed to represent a higher risk to workers, patients, or the environment attract a higher fee compared to sources considered to be of lower risk.
  - The time period of the licence the longer the period, the higher the fee.

- There is currently no fee for a facility construction licence because the old licensing database cannot process a fee for this type of licence at this time. When the database can process such fees, the department will seek to amend the regulations to require payment of a fee for this licence type.
- Applications for an approved assessor's authorisation do not currently attract a fee. This absence of a fee reflects the department's policy of removing disincentives to work in this area.

#### Fees for 2023-24

Licensing fees are defined by the Radiation Regulations in terms of the numbers of fee units that relate to the application or licence. The value of a fee unit is set by the Victorian Treasurer by a direction made under section 6 of the Monetary Units Act 2004. The direction is published in the Victorian Government Gazette.

For the 2023–24 financial year the value of a fee unit was \$15.90.

The licensing fees for each year are published on the department's website at: <a href="https://www.health.vic.gov.au/radiation/a-list-of-the-prescribed-fees-for-radiation-licences">https://www.health.vic.gov.au/radiation/a-list-of-the-prescribed-fees-for-radiation-licences</a>.

## Regulatory activities

The Health Regulator prioritises providing compliance support and assistance to duty holders to enable voluntary compliance with the Act and the Regulations. However, there may be some instances in which further regulatory action is required.

The Act provides the department with several regulatory tools in addition to the power to prosecute.

#### **Available regulatory actions**

#### Improvement notices

The Secretary, or a delegate of the Secretary, may issue an improvement notice if they believe that a person has contravened a provision of the Act or the Regulations in circumstances that make it likely that the contravention is continuing or will reoccur, or is likely to contravene a provision of the Act or the Regulations. If issued, the notice will require the person to remedy the contravention or likely contravention or the matters or activities causing the contravention or likely contravention.

#### **Prohibition notices**

Prohibition notices may be issued by the Secretary or a delegate under the same circumstances as improvement notices. The notice prohibits the person from carrying on the activity, or the carrying on of the activity in a specified way, until the Secretary or the delegate has certified in writing that the contravention has ceased or that the likelihood of the contravention occurring has passed.

#### Show cause notice

The Secretary or a delegate may issue a show cause notice notifying a licence holder of an action the Secretary or a delegate proposes taking in relation to a contravention of a requirement of the Act, with an invitation to the holder to show cause why the proposed action should not be taken.

#### **Executing a search warrant**

While the Act provides power for authorised officers to enter certain places to monitor compliance with the Act or the Regulations, under some circumstances it is necessary first to obtain a search warrant to authorise that access. An authorised officer of the department may apply to a magistrate to issue a search warrant if the authorised officer believes on reasonable grounds that there is, or may be within the next 72 hours, a particular thing (including a document) at the place that may afford evidence of an offence against the Act or the Regulations.

#### Seizure of articles

The Act gives certain powers to authorised officers, including the power to seize anything (including a radiation source or a document) if the authorised officer reasonably believes:

- the seized thing relates to an alleged contravention of the Act or the Regulations, or
- there is a serious risk to the health or safety of any person or the safety of the environment if the thing is not seized.

#### Making a radiation source inoperative

The Act gives an authorised officer power to make a radiation source inoperative.

#### Sealing a radiation source

The Act gives an authorised officer the power to seal a radiation source. In practice, sealing a radiation source may be required where it is impractical to seize the source, but it is necessary to prevent its further use.

#### Suspending or cancelling an authority

The Act provides that the Secretary, or a delegate, may suspend or cancel an authority.

#### **Prosecution**

There are several significant offences contained within the Act and, under certain circumstances, the department may feel it is necessary to begin prosecutions for these offences.

# Regulatory activities undertaken in 2023–24

Table 4 summarises the regulatory actions the department took during the year.

Three search warrants were obtained and executed in relation to suspected commercial tanning operations. These resulted in the seizure of three tanning units.

Four diagnostic X-ray units were sealed – a general medical X ray unit, a veterinary CT unit and two dental cone beam CT units. The general medical X ray unit and veterinary CT unit were sealed as there was no licence authorising their possession. These two units were unsealed in the 2023 24 financial year when the licences were granted. The two dental cone beam CT units remained sealed at the end of the 2023–24 financial year – one because there was no licence authorising its possession and the other because shielding was not installed in accordance with the assessment of shielding required, provided by a radiation services contractor.

**Table 4: Regulatory actions** 

Regulatory action	Number
Improvement notice	0
Prohibition notice	1
Show cause notice	0
Execution of a search warrant	3
Sealing a radiation source	4
Seizure of commercial tanning unit	3
Prosecutions initiated	0
Licences suspended	0

# Representation on national committees

#### enHealth

The Environmental Health Standing Committee (enHealth) is a standing committee of the Australian Health Protection Principal Committee (AHPPC). EnHealth is responsible for providing agreed environmental health policy advice, consulting with key stakeholders, and developing and coordinating research, information and practical resources on environmental health matters at a national level. The development of national advice by enHealth is based on significant collaboration and consultation with federal, state and territory agencies, departments and organisations that deal with environmental health matters.

The department is represented on enHealth by Dr Evelyn E Wong, Deputy Chief Health Officer, Community & Public Health.

#### **Radiation Health Expert Reference Panel**

The Radiation Health Expert Reference Panel (RHERP) is a relatively new committee established in 2019 to provide advice to enHealth on specific radiation health issues as directed by enHealth. RHERP has a particular focus on implementation of national agreements and will develop a National Strategy for Radiation Protection.

The department is represented on RHERP by Andrea Hay, Manager Industrial Radiation and Legionella Regulation, Health Regulator.

#### **Radiation Health Committee**

The role of the Radiation Health Committee is to advise the chief executive officer of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) on matters relating to radiation protection, including formulating of draft national policies, codes and standards for consideration by the commonwealth, states and territories.

The department is represented on the Radiation Health Committee by Glenn Riley, Senior Policy Officer, Regulatory Strategy and National Reform, Health Regulator.

ARPANSA publishes the <u>minutes of these</u> <u>committee meetings at</u>: <a href="https://www.arpansa.gov.">https://www.arpansa.gov.</a> au/about-us/advisory-council-and-committees/radiation-health-committee/minutes>.

## National agreements and standards

## National Directory for Radiation Protection (2nd Edition, 2021)

The purpose of the National Directory for Radiation Protection (NDRP) is to provide an agreed framework for radiation safety, including both ionising and non-ionising radiation, together with clear regulatory statements to be adopted by the commonwealth, states, and territories. Replacing the first edition of the NDRP, approved by the Australian Health Ministers' Conference in July 2004, with subsequent amendments, the second edition (NDRP2), published in 2021, represents a modernisation and streamlined approach for the commonwealth, states, and territories to work towards to achieve the vision of a seamless regulatory framework for the safe use of radiation sources across Australia.

# Accreditation standards for radiation dosimetry service providers

The conditions placed on management licences usually include requirements to monitor radiation doses to individuals using personal radiation monitoring devices. Radiation dose monitoring is a cornerstone of radiation safety. However, there are no nationally agreed guidelines that personal radiation monitoring service providers need to follow to guide aspects such as quality assurance. Regulation of these service providers is inconsistent across Australia. There is currently no direct regulation in Victoria of the providers of personal radiation monitoring services. The current service providers include both internationally and locally based companies and organisations.

The department is leading a national project to develop a nationally agreed standard under which dosimetry service providers can be accredited. If a national agreement on the scheme can be reached, then Victoria will need to make minor amendments to the Act to incorporate a new regulatory scheme to regulate in this area and to support these accreditation standards.

## National radiation safety standards for medical diagnostic X-ray units

The department has been working with other jurisdictions on developing nationally consistent radiation safety standards for certain types of medical diagnostic X-ray units. The standards were endorsed by the Radiation Health Committee in December 2023. If adopted in Victoria, these standards would replace the current Victorian radiation safety standards for these types of X-ray units.

## **Compliance monitoring**

Monitoring the compliance of radiation practices with the requirements of the Act is primarily carried out through inspecting the practices. Where possible, the department works to promote compliance by providing advice and constructive guidance and by using technology and systems to help licence holders to interpret and comply with the laws and standards applicable to them.

The department conducted 452 inspections in the 2023–24 financial year as part of its licensing compliance monitoring program. This was below the Victorian State Budget target of 480 inspections. Competing priorities resulted in an outcome just under target.

The compliance monitoring program included inspections of specific types of radiation practices to monitor compliance with safety or security standards. The program also included inspections in relation to non renewal of management licences.

# Medical, veterinary and dental radiation practices

A total of 260 inspections were conducted of medical, dental and veterinary radiation practices over the reporting period.

#### **Medical Radiation Practices**

#### **Compliance monitoring**

An inspection program focusing on compliance with requirements pertaining to justification and approval of computed tomography (CT) procedures was continued in the 2023–24 year. The aim of the inspection program is to assess the quality of referrals for computed tomography procedures and to ensure compliance with the record keeping requirement pertaining to approvals of medical radiation procedures. The focus on requirements pertaining to justification and approval of computed tomography procedures will continue in the 2024–25 financial year.

The inspections of dual energy X-ray absorptiometry (DXA) practices were part of a compliance monitoring program commencing in 2022–2023 and this program was continued in the 2023–24 year. The inspections focussed on compliance with requirements pertaining to the use of DXA for the purpose of assessment of body composition. The department introduced these requirements in 2019–20 in response to growing evidence of DXA being used for assessment of body composition without reference to clinical indications, resulting in unnecessary exposure to radiation.

Other inspections within the medical sector relate to a variety of specific circumstance. Examples include pre-licencing construction inspections of new facilities, inspections relating to reported radiation incidents, overseeing the installation of area monitoring, or observing new technologies and assessing the impact on licencing requirements.

A total of 167 inspections were conducted of medical radiation practices over the reporting period. Ninety inspections were of practices using DXA, 40 inspections were of CT practices and 37 inspections were of other practices.

## Mandatory testing of medical diagnostic X-ray units

A prescribed radiation source may only be used for human diagnostic purposes if there is a current certificate of compliance in place. The department continued to monitor licensees for compliance with the testing requirements in 2023–24 and to monitor approved testers for compliance both with the conditions of their authorisation and with the provisions of the Act. A high level of compliance with the requirement to hold a current certificate of compliance (about 85%) was observed during the 2023–24 year.

#### Radiotherapy Special Interest Group

The Radiotherapy Special Interest Group (RSIG) was established by the department to ensure that relevant information is shared between different areas within the Health Regulator about this growing and complex rea of medical radiation. The RSIG comprises team members from the Health Regulator. The RSIG meets every 4 months with the aim of:

- fostering a collaborative network within the department for the sharing of information between groups
- promoting and improving radiation therapy within Victoria
- discussing developments that impact on best practice and safety for radiation therapy
- removing obstacles to the department's successful delivery of radiation therapy services
- providing the necessary transparency of information for licensing new radiation therapy facilities and providers.

#### The Justification of medical exposure

The principle of justification is a well-established fundamental principle in radiation protection. The principle recognises that there may be some harm from exposure to radiation and seeks to ensure that such harm is only accepted if the radiation exposure is likely to result in a net benefit to the exposed individuals and/or society. The principle of justification forms a cornerstone of the Act and the ARPANSA Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008) (Medical Code), which is applied as a condition of licence in respect of all radiation sources used for medical purposes.

The Radiation Medical Practitioner as defined in the Medical Code is the person responsible for the justification of procedures involving the exposure of patients to ionising radiation, either for each individual patient or by way of protocols specific for the procedure. In nuclear medicine, this person will normally be a Nuclear Medicine Specialist, in radiation oncology, this person will normally be a Radiation Oncologist, and in diagnostic or interventional radiology, this person will usually be a Radiologist, but might also be, for example, a Cardiologist or, for limited procedures, a General Practitioner.

Currently, the responsibilities of the Radiation Medical Practitioner as defined in the Medical Code are not imposed directly on the Radiation Medical Practitioner but rather indirectly by requiring the management licence holder to ensure that the responsibilities of the Radiation Medical Practitioner are met.

The department's compliance inspections and investigations have highlighted issues with this approach, and it will be reviewed as part of the implementation of the ARPANSA Code for Radiation Protection in Medical Exposure, Radiation Protection Series C-5.

#### **Veterinary radiation practices**

Two inspections were conducted of veterinary radiation practices over the reporting period.

#### **Dental radiation practices**

During the year, there has been a focus on compliance inspections of dental practices possessing 3D volumetric X-ray units.

There has been a significant growth in the number of licence holders being authorised to possess 3D volumetric X-ray units. This type of X-ray unit can generate detailed 3-dimensional images, which are useful to support complex orthodontic procedures. However, the radiation dose to a patient and operators is greater than for other types of dental radiographic examinations. Due to the widespread introduction of this type of unit, there was a concern that they may be used where alternate imaging methods with a lower corresponding radiation dose would be more appropriate.

Inspections of licence holders authorised to possess 3D volumetric X-ray units has confirmed that they are being appropriately used, with alternative radiographic methods being used as a preference.

A total of 91 inspections of dental radiation practices were conducted over the reporting period.

## Industrial radiation practices

During the year, there was a focus on compliance monitoring of industrial radiation practices involved in two separate sectors, firstly the transport of radioactive material and secondly the security of high consequence sealed sources.

An inspection program was continued to target all companies authorised within Victoria to transport radioactive material. Compliance with the ARPANSA Code for the Safe Transport of Radioactive Material which is a condition of the management licence issued by the department was assessed. The main area of focus being the transport companies' development and implementation of a Radiation Management Programme as required by the Code, which includes appropriate training of personnel, emergency response procedures and appropriate radiation monitoring during transport, among other things.

An inspection program was also continued to audit the approved security plans of all licence holders within Victoria authorised to possess high consequence sealed sources. The program of inspections was to ensure that the security plans associated with the licence holders' possession of high consequence sealed sources were up to date and were fully implemented with all the required physical security measures in place.

The department issued radiation management licences and radiation use licences authorising radiation practices involving self contained units that emit high intensity electron beams and secondary X rays. These units are used in such areas as the sterilisation of medical products and materials research. These novel devices are relatively new to the market, with only two known units currently in Australia. The department, in consultation with the suppliers of the unit and companies using the units, worked to understand the operation and safety risks associated with the apparatus to determine the appropriate regulatory regime to be applied under the Act. The department determined that new licence conditions specifying appropriate radiation

safety requirements were required, given the unique nature and risk profile of this type of apparatus. The new licence conditions were developed over several months and approved in March 2024. Two radiation management licences authorising possession of these units and two radiation management licences for overseas companies for the sale and installation of the devices were granted. Radiation use licences were granted to users of the units and overseas service technicians installing and testing the units. Compliance inspections, carried out during the installation process in March, of the two companies applying for a licence to possess these units, confirmed that the licence conditions were being complied with by the licence holders.

A total of 192 inspections was conducted of industrial radiation practices, including inspections of mineral sand mining and processing sites (see below), over the reporting period.

# Mining of mineral sands and rare earths

The department regulates the processing, storage, transport and disposal of the naturally occurring radioactive material associated with mineral sand mining and processing. The mining of mineral-rich sands within Victoria generally triggers the need to regulate the radiation safety aspects of the operations due to the presence of naturally occurring radioactive material in low concentrations. Mineral sands within Victoria are usually mined from ancient beaches, like those that existed in the Murray Basin. Mineral sands were deposited on shores where the large density of the mineral sand grains allowed them to settle close to the then existing shore and be concentrated there while lighter sands tended to be washed out to sea. There are currently two companies licensed under the Act to conduct mineral sand mining and processing in Victoria - Iluka Resources Limited and Donald Mineral Sands Pty Ltd.

Other projects have been proposed and are currently at varying stages of the required development assessment process, which typically includes a formal environmental effects assessment. Five mineral sands projects are in the Murray Basin and a sixth is in eastern Gippsland.

#### **Commercial tanning practices**

Under section 23D of the Act, it is an offence to conduct a commercial tanning practice.

During the year, the department commenced proceedings under section 23D after executing a search warrant and seizing five tanning units from a residential property in Doncaster. As a result of this investigation on 10 April 2024 a plea hearing proceeded in the Ringwood Magistrates' Court where a person was found guilty of four charges in relation to conducting a commercial tanning practice. They received a fine of \$15,000 with conviction and costs of \$10,000 were awarded to the department.

The department also obtained another three search warrants for three premises. These searches resulted in the seizure of three more tanning units.

Once the tanning beds are forfeited to the department, the components in the ultraviolet light tubes, including the glass and mercury, are safely removed and recycled and the tanning beds destroyed.

# Regulatory policy and continuous improvement

#### Ionising radiation dose limits review

Work commenced during the latter part of the financial year on a review of the changes that will be required to the regulations to implement the ionising radiation dose limits contained in the ARPANSA Code for Radiation Protection in Planned Exposure Situations (2020). These dose limits are drawn from international standards but are often complex and difficult to implement. Work will continue during the 2024–25 financial year.

#### Radiation shielding assessments

Over the last few years, the department identified deficiencies in the quality of radiation shielding assessments and the adequacy of installed radiation shielding in three key areas:

- insufficient shielding being specified at the initial shielding design stage
- insufficient shielding being installed, or shielding being installed incorrectly
- lack of regular review to ensure the shielding parameter values (for example, workload, occupancy and distances from radiation sources) on which the shielding design was based have not changed from those used in the approved shielding assessment in such a way that the shielding assessment is no longer valid.

As a result of these concerns, the department drafted, during the financial year 2023–24, a shielding standard that prescribes the requirements for a shielding assessment. In conjunction with the standard, the department proposes to introduce an approval framework for shielding assessors. This framework would require assessments to be performed by an approved shielding assessor and approved shielding assessors to comply with the shielding design standard. Work in this area will continue in the 2024–2025 financial year.

#### Sewer Waste disposal project

Work is continuing on the development of a framework for the regulation of disposal of radioactive waste to sewer in preparation for the implementation of parts of the ARPANSA Code for the Disposal of Radioactive Waste by the User (2018). This code relates to the disposal and discharge of radioactive material containing relatively low levels of radioactivity, or radionuclides of short half-life, such as are generated by medical and research uses of radioactivity. The main changes resulting from the requirements imposed by the code are:

- the move to using an activity limit on the amount of radioactive waste that can be disposed of to sewer within a specified time period rather than specifying a radioactive concentration limit for the waste, and
- patient excreta no longer being excluded from the requirements.

# Secretariat support for the Radiation Advisory Committee

During the year, the department continued to provide secretariat services to the Radiation Advisory Committee, established under Part 10 of the Act. Read about the committee at: <a href="https://www.health.vic.gov.au/radiation/radiation-advisory-committee">https://www.health.vic.gov.au/radiation/radiation-advisory-committee</a>. A report of this committee's work is tabled in the Victorian Parliament each year and is available on the department's website. The annual reports of the Radiation Advisory Committee are available at: <a href="https://www.health.vic.gov.au/publications/radiation-advisory-committee-annual-report">https://www.health.vic.gov.au/publications/radiation-advisory-committee-annual-report</a>.

### **Radiation incidents**

Management licence holders must, by a condition of their licence, report incidents that are described in the department's document Mandatory reporting of radiation incidents located at: <a href="https://www.health.vic.gov.au/radiation/incident-reporting">https://www.health.vic.gov.au/radiation/incident-reporting</a>.

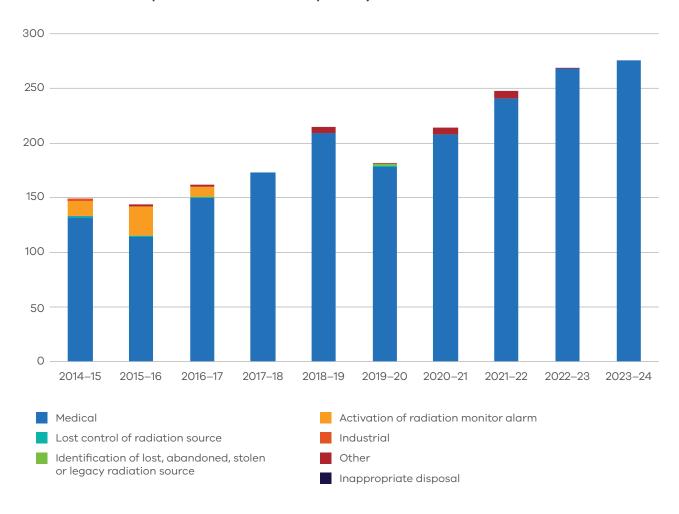
#### Incidents reported during 2023-24

During 2023–24, 276 incidents were reported to the department compared to 268 in the previous year.

All the 276 incidents in 2023-24 were in the medical sector. Most medical incidents involved unplanned exposure or additional exposure to patients because of errors in patient management. None of the incidents involved any compromise in security of high consequence sealed sources.

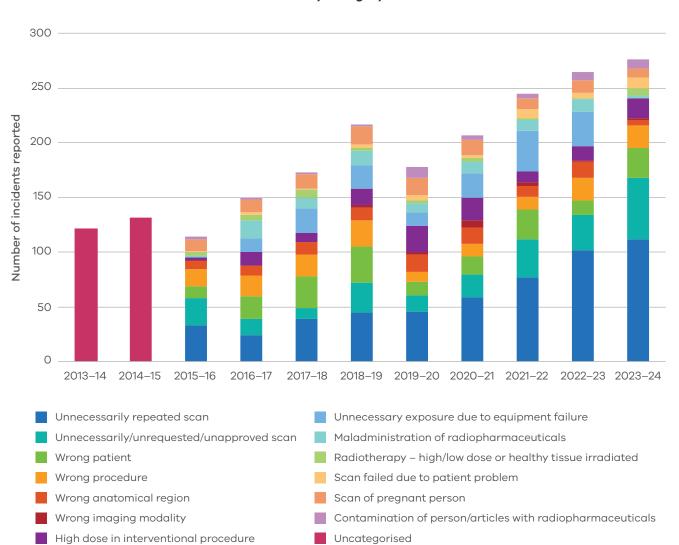
The incidents reported in 2023-24 are summarised in Table 6. Chart 1 below presents an overview of reported incidents over the past 10 years.

Chart 1: Overview of reported incidents over the past 10 years



The number of incidents reported to the department has increased over the last 10 years with most reported incidents occurring in the medical sector. The numbers of incidents in the various medical radiation incident categories per financial year from 2013–14 to 2023–24 are shown in Table 5 below. The total number of medical incidents is also represented in Chart 2. Data have been included for the 2013–14 and 2014–15 financial years although the incidents in these years are uncategorised.

Chart 2 Number of medical radiation incidents by category



The number of reported medical incidents in 2023–24 continues the trend of increasing numbers of such incidents over the past 10 years. The number of medical imaging procedures that involve ionising radiation has also increased over the same period of time. It is therefore to be expected that the number of incidents occurring would also increase if the incident rate per procedure did not vary over time. It is important to determine whether the observed increase in the number of reported incidents is attributable solely to the increase in the number of medical procedures performed or whether the increase in reported incidents is due to an increase in the incident rate per procedure.

Table 5 summarises the number of medical incidents reported since the 2013–2014 financial year along with the number of nuclear medicine and CT medical imaging procedures performed and the incident frequency, expressed as the number of incidents per 100,000 procedures. The number of medical imaging procedures

performed was obtained from Medicare Australia statistics. It should be noted that the Medicare Australia procedural data:

- are not a complete representation of all medical radiation procedures performed as they exclude procedures that are not covered by Medicare. However, the data are considered to be sufficiently representative of the relative increase in total number of procedures performed; and
- only include CT and nuclear medicine imaging procedures because most of the reportable incidents occur with CT and nuclear medicine imaging modalities. Procedures performed with these modalities almost always result in doses to patients of 1 mSv or greater. Consequently, the dose to a patient because of an incident involving one of these modalities is much more likely to exceed the 1 mSv threshold for reportable incidents than for incidents involving other modalities (e.g. general X ray and mammography).

Table 5 Medical radiation incidents by categories per financial year

Financial year	No. of medical incidents reported	No. of diagnostic imaging services (CT and nuclear medicine only)	Incident frequency (per 100,000 CT and nuclear medicine diagnostic imaging procedures)
2013/2014	122	675,981	18.0
2014/2015	132	815,525	16.2
2015/2016	114	819,462	13.9
2016/2017	150	887,298	16.9
2017/2018	173	946,310	18.3
2018/2019	217	993,218	21.8
2019/2020	178	1,018,872	17.5
2020/2021	207	1,126,448	18.4
2021/2022	245	1,149,761	21.3
2022/2023	265	1,228,582	21.6
2023/2024	276	1,293,875	21.3
Average			19.0

Table 6 shows that the total number of CT and nuclear medicine procedures has steadily increased since 2013–2014. The incident frequency per 100,000 CT and nuclear medicine diagnostic

imaging procedures seems to show a small upward trend over time, although the frequency appears to have steadied in the last three years.

Table 6 Radiation Act incident summary, 2023–2024

Incident Type	Number
Unnecessarily repeated medical imaging procedures	85
Unnecessary, unrequested or unapproved medical procedures	49
Wrong patient underwent a medical procedure	27
Patient underwent incorrect medical procedure	17
Patient underwent a medical procedure on the wrong anatomical region	11
Patient underwent a medical procedure using the wrong modality	4
High patient dose during an interventional or fluoroscopic procedure	18
Unnecessary radiation exposure due to equipment failure	27
Maladministration of radiopharmaceutical	4
Radiotherapy - unintended irradiation of healthy tissue or over/underdose to target tissue	6
Medical procedure failed due to patient non-cooperation or other patient problem	11
A pregnant person was exposed to radiation	9
Contamination of persons or articles with a radiopharmaceutical	8