

# Compliance and Enforcement Policy

*Radiation Act 2005*

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## Scope

This document describes the policy that will be followed in respect of our approach to:

- monitoring of a regulated entity's compliance with the *Radiation Act 2005* (the Act)
- enforcing the ban on commercial tanning where required, taking action to bring about compliance with the Act.

In this context a regulated entity may be a:

- facility construction licence holder
- management licence holder
- use licence holder
- approved tester
- approved assessor
- a person or persons who are required by the Act to hold such an authority.

This document builds upon the department's 'Better Regulatory Practice Framework'<sup>1</sup>.

## Authorising environment

The authorising environment is the Act.

## The licensing framework

The Act establishes a licensing framework which regulates:

- companies, organisations and individuals which conduct 'radiation practices'. This licence is called a 'management licence' and authorises the conduct of a specific radiation practice such as possession of x-ray units or radioactive material for a specific purpose at a specified location. At the start of July 2020, there were 2,659 management licences authorised radiation practices to be conducted at in excess of 3,740 sites across Victoria.
- a company, organisation or individual which wishes to construct a radiation facility is required to hold a 'facility construction licence'. A radiation facility is a facility where it is intended to house or store or use high consequence radioactive material, specifically a high consequence sealed source or a high consequence group of sealed sources. At the start of 2021, one licence had been issued.
- individuals who use radiation sources such as x-ray units or radioactive material require a 'use licence'. At the start of July 2020, there were over 15,082 current use licences.
- individuals who have been approved by the department to issue certificates of compliance indicating that a particular medical diagnostic x-ray unit has been tested and met Victorian radiation safety standards are termed 'approved testers'. At the start of July 2020, there were 44 such testers.
- individuals who have been approved by the department to issue certificates of compliance indicating that a security plan or transport security plan meets Victorian security standards are termed 'approved assessors'. At the start of July 2020, there were 9 security assessors.

## Offence provisions

The Act describes a number of significant offences (Appendix 1).

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<sup>1</sup> <https://dhhs.vic.gov.au/publications/better-regulatory-practice-framework>

## What is regulated?

In practice, the department regulates the use of ionising radiation and non-ionising radiation (in the case of the ban on commercial tanning practices). This includes the regulation of both the public and private sector's use of radiation.

The Act does not apply to the use of radiation by Commonwealth agencies and their contractors. In these cases, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is the regulator.

Ionising radiation is used widely across Victoria in many quite different sectors and settings.

Some of these sectors include:

- the medical use of radiation:
- medical diagnostic radiography (e.g. CT's, fluoroscopy units, general X-ray units etc)
- diagnostic nuclear medicine
- medical radiotherapy to treat cancer (e.g. therapeutic nuclear medicine, brachytherapy, linear accelerators etc)
- research involving the irradiation of humans
- dental radiography (e.g. dental CT's, intra-oral dental X-ray units etc)
- industrial uses of radiation
- industrial radiography to check integrity of pipe welds
- industrial irradiation used to sterilise objects
- fixed radiation gauges used to control industrial processes e.g. thickness or flow of materials
- measurement of moisture or density
- oil and gas extraction through measurement of properties in a bore hole
- mining and processing of naturally occurring radioactive material
- veterinary use of radiation:
- diagnosis (e.g. general X-ray units and CT's etc)
- treatment of some cancers.

There are also a number of practices which occur in most sectors. These include the sale of radiation sources, disposal of radiation sources and the transport of radioactive material.

## Who administers the Act?

The Act is administered by the Department of Health (department).

Until approximately 1983/4, radiation safety was administered via the predecessors to the department (e.g. Health Department Victoria and Health Commission Victoria) through an Occupational Hygiene Branch.

From 1983/4 a specialist radiation safety team was created and this type of small specialist team has continued until today in various structures.

The Radiation Team, as it is now called, is a small, highly specialist team with team members drawn from a wide range of sectors with specialist skills. These specialist skills and experience include medical radiography, nuclear medicine technology, radiation safety consultancy, education, environmental health and the regulation of radiation safety.

The Radiation Team operates from the department's central Melbourne office. All members of the Radiation Team are authorised officers under the Act.

Whilst the Act refers to the powers of the Secretary of the department, in practice many of the powers are delegated by the Secretary to other officers of the department.

## Powers of authorised officers

An authorised officer under the Act is appointed by the Secretary of the Department of Health. An authorised officer is issued with an identity card by the Secretary of the department. The powers of an authorised officer are described in part 7, division 2 of the Act.

## Regulatory plan

The department has a published Radiation Safety Regulatory Plan<sup>2</sup>. The plan describes our focus as protecting the Victorian occupationally exposed persons, the public and the environment from the harmful effects of radiation.

## Risk management framework

The risks associated with the more than 150 different types of radiation practices that are currently authorised in Victoria vary significantly. For example, the intrinsic risks associated with dental intra-oral X-ray units are extremely low compared to, for example, those associated with an industrial irradiator or a therapeutic dose of radiation. This risk variation necessarily guides much of the department's work in the regulation of radiation safety and security.

The department has a corporate risk management based on the AS/NZS ISO 31000 system. This identifies corporately identified risks that need to be addressed.

A specific risk management framework has been developed for the regulation of radiation safety and security which is consistent with the department's overall framework. This framework involves first focussing on the regulatory objectives that we are trying to achieve.

The next stage is to examine the corporately identified risks in light of these objectives to assess whether any of these risks have the potential to adversely impact on achievement of our objectives.

We capture each risk in a risk register. We then assess each identified risk against the department's risk assessment matrix. This involves an assessment of existing controls. Each risk is then assessed for cost effective treatments.

## Guidance and support

The department seeks to engage with key stakeholders to raise awareness of legal obligations, safety and security standards.

We maintain:

- A dedicated website as a repository of information relevant to different sectors and interests.
- A telephone hotline; currently only between 0900 and 1200 hours on business days but likely to be extended once a new licensing database is fully implemented.
- A dedicated email box for interactions with licence holders
- An email newsletter launched in 2018.

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<sup>2</sup> <https://dhhs.vic.gov.au/publications/better-regulatory-practice-framework>

## Monitoring compliance

Detecting non-compliance and solving compliance problems in the entities that the department regulates are essential elements of the department's regulatory role. Furthermore, the department has a significant licensing function that is also informed in part by the degree and nature of identified non-compliances.

Recognising trends in non-compliance, determining the potential or actual harms arising from non-compliance, and developing solutions to compliance problems are issues that challenge the department at analytical and resource levels.

For these reasons the department regards the efforts spent on monitoring compliance with the laws relating to radiation safety and security as a critical part of its activities.

## How will we monitor regulated entities compliance?

Monitoring of compliance by regulated entities will involve one or more of the following activities:

- the assessment of licence holders through monitoring activities such as inspections conducted directly by the department; or
- a mandatory self-audit conducted by licence holder and sent to the department. For example, the department also may use an audit function where either we conduct an audit of practices or documentation or request licence holders to complete a self-audit or supply evidence of certain things to provide evidence that a practice is being appropriately performed. An example of where this approach has been used is with the regulation of human research which uses ionising radiation.

Our inspections will focus primarily on management licence holders (i.e. those who are conducting the radiation practice) but in the course of these inspections we may also focus on the compliance with other licensing requirements such as the requirement for natural persons to hold a use licence prior to using a radiation source unless specifically exempted from holding such a licence.

There are several methods that underpin the way we will monitor compliance.

### Credible field presence

The department will be an active regulator of radiation safety and security with a credible field presence principally through its authorised officers conducting inspections at the sites where radiation practices are being conducted. This will predominantly occur in post-licensing inspections of the sites at which licence holders are conducting their radiation practices. It will at times also involve pre-licensing inspections, particularly of new, novel or significant radiation practices.

This field presence is critical to:

- enable the department to gain intelligence regarding the actual level of compliance with the Act across different sectors; and
- ensure the department maintains detailed knowledge of contemporary practices across different industries to enable it to identify problem areas. This is particularly relevant for radiation safety, where there is a myriad of different and evolving radiation practices used in various sectors and settings; and
- ensure that there is compliance with the government's radiation safety and security laws in these areas.

## Risk-based inspections

While random inspections of management licence holder's sites and practices plays a valid role in monitoring and regulation, inspections are most effective when focused on issues that create the greatest risk to public health.

Contemporary regulatory theory argues that no inspection should be conducted without good reason and that these reasons should be based on a solid base of evidence. The advantage of this approach is that it ensures that resources are allocated in the most effective way.

For this reason, inspections will be targeted and risk based.

In most cases, inspections of a regulated entity's sites will be pre-arranged with them to help minimise the adverse impacts of the visit on the regulated entity. However, it should be noted that there will be times when a pre-arranged inspection is either not feasible or could be counterproductive to investigation of the issue that is of concern.

The following factors are relevant to the selection of a particular regulated entity for a targeted inspection:

- data analysis
- regulated entity's history of compliance with their legal obligations
- investigation of reported incidents
- complaints
- time since last contact with the regulated entity
- regulatory priorities.

## Data analysis

The department holds a significant amount of licensing information related to radiation safety and security. This information includes the status of mandatory compliance elements. For example:

- testing of a medical diagnostic X-ray unit at prescribed intervals to ensure the unit meets mandatory standards before it may be used
- radiation management licence status
- radiation use licence status.

This data is rich in detail and helps the department identify regulated entities who prima facie appear to have failed to comply with a statutory obligation. Further investigation may reveal that this is not the case; however, it does enable limited department resources to be used efficiently to target an apparent non-compliance.

A regulated entity's failure to renew a licence is identified through data analysis tools.

## Regulated entity's prior history of compliance with their legal obligations

It is important that the prior history of compliance by a regulated entity is taken into consideration in allocating resources.

For example, a particular regulated entity may have been found to be non-compliant on a previous inspection where advice and education or further enforcement was provided to remedy the situation. In this case, the site may be targeted for re-inspection to confirm that the required actions have been taken.

Similarly, there may be evidence that a particular sector may be more at risk of non-compliance than another sector, resulting in a higher weighting given for inspection.

## Investigation of a reported incident

Some events may trigger the need for an urgent inspection, for example:

- a report of a significant medical maladministration of radiation might indicate significant systemic failures
- a report of an industrial incident involving radiation
- the report of a significantly higher than expected radiation dose to a worker.

Response to incidents will always focus on minimising harm to human health and the environment.

## Complaints

Complaints from workers, consumers or members of the public are extremely rare in the case of radiation practices (other than commercial tanning). However, where a complaint is received it may trigger the need for an inspection to investigate the complaint and assess compliance with licence conditions. Concerns are also often raised in other indirect ways such as through media coverage. This has occurred several times in relation to alleged breaches of the commercial tanning ban.

## Time since last contact with the regulated entity

Whilst some regulated entities are in regular contact with the department as a result of their operations, there are some regulated entities that the department may have limited or no contact with outside the licence renewal process. It is important that a small proportion of the inspection effort be allocated to proactively inspecting sites with limited contact with the department as part of the continued effort to gain intelligence regarding the actual level of compliance across all sectors. It also enables knowledge to be maintained of the detailed practices being performed in some sectors. However, as mentioned earlier there are over 3,740 sites where some form of radiation practice is authorised to be conducted. It is not feasible for the department to commit to inspecting all sites at a given frequency and still predominantly operate a risk based and targeted inspection program.

## Regulatory priorities

As discussed earlier, there are wide variations in the inherent risks associated with radiation practices.

The department will target the practices which represent the highest risks whether on an individual basis because of the nature of the radiation source or because of the overall contribution to the Victorian population.

Our regulatory activities will be based on a risk assessment. This will take the form of an annual process discussed earlier to re-evaluate our regulatory priorities i.e. to assess the risks posed by the people, companies and things that we regulate and to allow us to assess which of these represent higher risks than others. This information can then be used to determine the regulatory effort which we should allocate to particular areas.

Initially, in the case of radiation safety this will focus on an annual review of the radiation practices which we regulate to attempt to rate the relative risk posed by those practices. This can then inform the allocation of our resources.

The review of radiation practices will be conducted by scoring each of the radiation practices authorised at that time. Each practice will be assessed against a wide range of weighted criteria. The outcome of that process will be a small list of no more than ten types of radiation practices that we will endeavour to target during that year.

Where this process identifies a regulatory activity that is needed to mitigate an identified risk we will manage the implementation of that activity using a regulatory project approach. In this context, a regulatory project might be to develop and implement a new monitoring activity for a particular radiation practice.

The use of this process will ensure that our regulatory priorities are risk-based.

## How will we monitor compliance with the ban on commercial tanning?

We will use a variety of routine intelligence gathering techniques to identify potential breaches of the commercial tanning practice ban. We will also actively investigate any allegations which we receive from the public about a particular site that they suspect is conducting a commercial tanning practice.

## Enforce the law to achieve compliance

### Response to identified non-compliance

During an inspection, audit or an investigation of a complaint or report of suspected non-compliance, the department's authorised officers may form a view that there has been a contravention of the relevant legislation. This initial assessment will generally involve a preliminary examination by an authorised officer to confirm the facts and identify the seriousness and probable consequences of that contravention.

Further investigation may then be required to determine the appropriate level of response.

The department will use a variety of tools to gather evidence to inform a decision on whether to take enforcement action. This includes formal interviews, re-inspections, formal requests for information and even the use of search warrants. Search warrants permit, amongst other things, the entry of premises without consent, and the exercising of powers in certain circumstances. The department has used search warrants extensively regarding commercial tanning investigations.

Based on the initial assessment conducted by the department, a further investigation into the contravention may be warranted.

An investigation will aim to:

- determine whether there is evidence that a law has been or may have been contravened
- determine whether there has been any harm to a person or the environment and provide advice or direction on stopping, mitigating or preventing such impacts
- collect evidence that could be used in subsequent compliance action by the department
- establish whether there is a need for improved controls to avoid reoccurrence of the contravention of the law
- deter further non-compliance
- achieve an appropriate outcome within a reasonable time and reasonable cost.

The nature, time taken, and method of investigation will depend on the circumstances of the incident or contravention. Where it is found that there was a contravention of the law, one of the enforcement tools described below will be selected based on the circumstances.

The department will generally take an escalating approach to the use of enforcement from the least to the most interventionist. However, where the non-compliance represents or could have resulted in a significant risk to health or the environment then the department will choose the enforcement tool with the most likelihood of mitigating those risks.

There are many offences prescribed in the legislation the department administers, with penalties ranging from 10 to 9000 penalty units<sup>3</sup>. There is an expectation from industry and the public that the department will ensure that these laws are complied with and public health and the environment are protected.

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<sup>3</sup> A penalty unit for the 2021 -2022 year is \$181.74. It is increased annually in line with a Treasurers' direction based on inflation rates.

We will address non-compliance with the law in a manner proportionate to the harm.

One of the complexities in the regulation of radiation safety and security is the high number of licence holders - over 17,794 at the start of July 2020.

This fact combined with the high variation in the inherent risks associated with different radiation practices creates a need for a quite sophisticated approach to the resolution of non-compliance.

We will not necessarily allocate the same level of resources to the resolution of non-compliance for different types of radiation practices. However, we are not able to completely ignore non-compliance even in a relatively low risk activity. For this reason, our response to identified non-compliance will consider several factors in deciding what type of enforcement action ought to be taken for a specific instance of non-compliance with the Act.

## **What are the considerations that will affect the department's response to a specific non-compliance?**

Once the department has decided to take enforcement action, the next question is which type of sanction ought to be applied from those available to the department in this area.

A sanction should:

- aim to change the behaviour of the offender;
- aim to eliminate any financial gain or benefit from non-compliance;
- be responsive and consider what is appropriate for the offender and regulatory issue;
- be proportionate to the nature of the offence and the harm caused;
- aim to restore any harm caused by regulatory non-compliance; and
- aim to deter future non-compliance.

In determining the appropriate response to a particular non-compliance scenario, the department will consider the following questions:

- what is the degree of the non-compliance?
- what are or were or could have been the consequences of the non-compliance?
- what is the scale of the non-compliance?
- what is or was the risk to human health associated with the non-compliance?
- what is or was the risk to the environment associated with the non-compliance?
- has there been previous enforcement action taken for the same non-compliance?
- what has been the department's experience with the licence holder including any inspection history?
- what has been the licence holder's response once the department informed the licence holder about the non-compliance?
- is there any evidence that the licence holder sought to make a financial advantage as a result of the non-compliance?
- whether the taking of the enforcement action serves the public interest?
- what will be the impact of the taking of specific types of enforcement action?
- is the non-compliance a breach of the commercial tanning practice ban?

### **What is the degree of the non-compliance?**

A non-compliance may relate to matters considered to be predominantly or superficially administrative in nature e.g. record keeping or a failure to renew a licence. It could be argued that a different approach ought to

be taken following an administrative non-compliance as compared to a non-compliance which resulted in an increased risk of harm or caused actual harm to people or the environment.

However, almost all regulatory requirements are intended to reduce risks in some way. For example, record keeping allows the licence holder to notice trends and importantly it is often critical to the investigation of incidents.

Offences such as failing to renew a radiation use licence or management licence prior to expiry may superficially seem administrative in nature and of low to trivial risk. However, these licences are the foundation of the regulatory scheme. Almost all the regulatory requirements relating to safety and security are applied through the application of licence conditions. These licence conditions cease to have impact if a licence expires. Furthermore, these types of breaches result in significant resource demands on the department and reduce the capacity for the department to spend time on monitoring other more high-risk activities.

This element will also consider the difficulty associated with achieving compliance e.g. in the case of renewal of a licence, it should be noted that the department provides several opportunities for regulated entities to renew their licences through multiple automated reminders and highly streamlined renewal processes.

### What are, were or could have been the consequences of the non-compliance?

The consequence of the non-compliance will be assessed based on the nature of the risk that has occurred or could have occurred but for an intervention. The types of consequences that will be considered include whether:

- the degree of the actual harm that was caused to a person or the potential harm that could have been caused to a person. The estimated radiation dose will be a major factor.
- the degree of the harm that was caused to the environment or the potential for harm to have been caused to the environment.

### What is the scale of the non-compliance?

The scale of the non-compliance will be assessed based on the nature of the hazard that has occurred or could have occurred but for an intervention. Relevant considerations will include:

- the number of individuals likely to have been affected or who could have been affected
- the likely or potential impact on the environment
- the length of time that the non-compliance has been occurring.

### What is or was the risk to human health associated with the non-compliance?

A significant number of regulatory decisions, which include decisions arising from compliance assessments, are related to the acceptability of radiation dose as a surrogate for risk. Numerical values of risk are usually expressed in respect of cancer fatalities. Cancer risk, cited as five percent per Sievert<sup>4</sup> ( $5 \times 10^{-2} \text{ Sv}^{-1}$ ), is calculated by using accepted bio-kinetic models, risk-per-unit-dose values for uniform whole-body radiation exposure, and linear energy transfer (LET) radiation.

Following an inspection, which, in the case of ionising radiation, involves the collection of information regarding ionising radiation hazards and the associated control measures, the risk assessment will be an analytical process which includes the methods, the assumptions, and the other considerations necessary to describe or quantify an actual or potential risk.

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<sup>4</sup> Annals of the ICRP. Publication 103.

### What is or was the risk to the environment associated with the non-compliance?

Harm to the environment is currently measured by an assessment of the impact on human health but the adoption in Australia of the '*Guide for Radiation Protection of the Environment (2015)*'<sup>5</sup> published by Australian Radiation Protection and Nuclear Safety Agency means that it will now be used to assess the impact on a theoretical organism as a proxy for environmental impact.

### Has there been previous enforcement action taken for the same non-compliance?

Any previous instances that required the department to take enforcement action will have a significant impact on the decision-making process for subsequent instances. It is likely to result in a decision to apply a sanction that has more impact than previous sanctions.

### What has been the department's experience with the licence holder including any inspection history?

The extent to which the licence holder has been inspected or audited previously will be a consideration in determining the level of previous compliance. This means that the fact that a site may never have been inspected by the department does not necessarily equate to that site or operation having a 'good' history.

### What has been the licence holder's response once the department informed the licence holder about the non-compliance?

The actions taken by the licence holder once the department informed them of the identification of the non-compliance are a relevant consideration.

### Is there any evidence that the licence holder sought to make a financial advantage as a result of the non-compliance?

Any evidence that a non-compliance has been a deliberate action taken to obtain a financial advantage over competitors will be a relevant and very significant consideration.

### Is the non-compliance a breach of the commercial tanning practice ban?

The offence related to conducting a commercial tanning practice is a special category in that it is the only practice explicitly banned by the Act. For this reason, breaches of the ban will be regarded as being in the highest category of non-compliances.

## What are the available enforcement tools?

There are many tools available to the department to achieve compliance in this area. These include:

- advice
- formal warning
- improvement notices
- prohibition notices
- penalty infringement notices; although not currently an option under this Act
- seizure or sealing a radiation source to prevent its use
- exercising the public health risk powers

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<sup>5</sup> <https://www.arpsa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/guides-andrecommendations/rpsg-1>

- varying a licence or authority condition
- prosecution
- licence suspension or cancellation.

Whilst this order approximates the escalating action that may be taken, there are circumstances in which this is not the case and these are discussed later.

## Advice

The department through an authorised officer may advise a licence holder about the non-compliance and the action that they may take to remedy the situation. A record will be kept of the advice given and the context in which it was given.

This is a suitable option for non-compliances that are of administrative in nature or considered to represent low risk to health or the environment AND where the regulated entity has not previously been the subject of enforcement action.

Authorised officers can issue such advice subject to any other applicable procedures covering the situation.

## Formal warning

The department may issue a formal warning that may warn of other enforcement action in the event of either a repetition of the non-compliance or where the non-compliance is not remedied by a due date. Failure to comply with a formal warning will lead to escalating enforcement action by the department.

This is a tool which is unlikely to be used given the availability of other tools but it does exist as an option. It may be suitable for non-compliances that are administrative in nature or considered to represent low risk to health or the environment AND where the regulated entity has not previously been the subject of enforcement action. The reason why it is less likely to be used is that if the regulated entity does not respond appropriately then the department must choose another tool which does have consequences for non-compliance such as the issue of an improvement notice.

## Improvement notices

Improvement notices may be issued under the Act in relation to radiation practices or users of radiation sources.

These notices are not sanctions or punishments. They require certain actions to be taken or not to be taken. They also ensure that there is a formal record that the department has required action to remedy a risk or require compliance with a law to ensure that all regulated entities are treated consistently. Notices will usually hold recipients to a specified time frame within which to comply with the requirements. Failure to comply with an improvement notice is a serious offence which will lead to escalating enforcement action by the department.

This is a tool which has application in many circumstances but primarily where there is a clear path of action that the regulated entity can take which will 'fix the problem'.

## Prohibition notices

Prohibition notices may be issued under the Act in relation to radiation practices or users of radiation sources.

These notices are not sanctions or punishments. They require certain actions not to be taken. They also ensure that there is a formal record that the department has required action to remedy a risk or require compliance with a law to ensure that all regulated entities are treated consistently. Notices will usually hold

recipients to a specified time frame within which to comply with the requirements. Failure to comply with a prohibition notice is a serious offence which will lead to escalating enforcement action by the department.

This is a tool which may have application in certain circumstances, but its use should be limited to clearly defined matters where the cessation of the activity can be achieved by the regulated entity.

## Penalty infringement notices

Infringement notices are a way of dealing with more common breaches of the law where the impacts are not considered serious enough to warrant prosecution.

A penalty infringement notice (PIN) imposes a financial penalty and can be issued by an authorised officer.

Typically, the offences for which infringement notices may be applied are very well defined.

They will not be used where:

- advice and education can be used to remedy the offence
- an improvement or prohibition notice is more appropriate
- a prosecution is more appropriate according to the criteria in this policy
- the penalty for a PIN would be inadequate for the severity of the offence and would not act as a sufficient deterrent.

The recipient of a PIN has the option of paying the penalty by the given date, seeking an internal review or appearing in court to answer the charges.

At the time of writing of this policy, there are no offences under the Act where a penalty infringement notice can be issued but this is subject to change over time. To do this a regulation must be made to prescribe the specific offence and the penalty.

## Seizure or sealing of a radiation source

This enforcement tool is most likely to be used in relation to issues relating to radiation sources.

The Act gives power<sup>6</sup> to an authorised officer to seize any thing (including a radiation source) at a place accessed by the authorised officer in accordance with his/her powers under the Act if the authorised officer reasonably believes that:

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

Whilst, seizure or sealing of items other than a radiation source may be needed to assist with an investigation, the power to seize or seal a radiation source is more likely to be exercised when there is a serious risk to the health or safety of any person or the environment.

Seizure of commercial tanning units has been an important enforcement tool since the 2015 ban on commercial tanning practices.

Considerations that may be taken into account when deciding whether to use this power will include:

- Whether there is evidence that the possession of the radiation source constitutes an offence;
- The implications for health or safety as a result of sealing or seizing the source. For example, a radiation source used for radiation therapy provides great health benefits to patients. Sealing or seizing the item would probably only be reasonable where the loss of the use of the source is outweighed by the serious risks to the health and safety of a person if the action was not taken;

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<sup>6</sup> Section 77 Radiation Act 2005

- What other enforcement options exist? For example, in the radiation therapy example, issue of an improvement notice, a licence variation or prosecution may be more appropriate to deal with the contravention where there is no immediate serious health risk.
- Sealing (as opposed to seizing) a radiation source may be appropriate because of the logistic difficulties of seizing a very large item. Where this occurs, the department will use tamper evident tape. It should be noted that tampering with a seal is a serious offence under the Act.
- Sealing a radiation source may also be an appropriate enforcement tool where there has been a failure to renew a management licence but only after considering the implications for health or safety as a result of the potential action.

## Variation to a licence

The Act provides power for the Secretary to vary a licence once it has been issued. Whilst this is normally used to periodically change licence conditions to update a class of licences or approvals to reflect changed standards, it can also be used to restrict the scope of the specific licence or alter the conditions of the licence to impose new obligations to, for example, mitigate an identified safety risk.

This tool is useful where the department's assessment is that additional controls are required on this class of radiation practice or even on a particular licence holder. The latter use of the power needs to be carefully considered to avoid creating unnecessary complexity in the licensing system, but it remains a valid option.

## Prosecutions

Prosecutions seek to have an appropriate sanction imposed on the offender, act as a deterrent for future noncompliance and improve public confidence in the integrity of the regulatory system.

The department's general prosecution policy will guide the overall considerations on the use of this sanction.

Specific factors that the department may consider when deciding to proceed with a particular prosecution in relation to the Radiation Act may include whether:

- consequence: these may include the harm or potential harm associated with the alleged breach. For example, serious harm to a person or the environment may warrant prosecution regardless of the previous history
- culpability, including whether:
  - there is evidence that the alleged breach was deliberate
  - there is evidence of financial benefits obtained through the delaying or avoiding of compliance
  - there is evidence of a breach of the ban on commercial tanning practices
  - there is evidence that the regulated entity was operating well below acceptable standards
  - in the case of radioactive material, there is evidence of environmental impacts which have not yet been remedied
  - there has been a past history of previous incidents or non-compliance
  - there was any evidence of recklessness that contributed to the alleged breach
  - the alleged breach occurred in a sector targeted in the department's risk assessment process
  - the alleged breach involved a breach of a statutory notice
  - other enforcement measures are inadequate. For example, in the case of the radiotherapy example provided earlier, prosecution may be a viable and appropriate alternative.
  - other enforcement measures are unlikely to ensure ongoing compliance. For example, improvement notices may have been issued in the past, but the non-compliant behaviour has been repeated.
  - the non-compliance involves a significant falling short of accepted standards

- there has been permanent or long-term harm or potential harm to health or environment
- risk to safety has given rise to a high level of public concern – whether the decision to prosecute is in the public interest.

## Public interest test

To help assess whether the decision to prosecute is in the public interest, the Radiation Team will perform a public interest test which involves documenting an assessment informed by the Policy of the Director of Public Prosecutions for Victoria<sup>7</sup>.

## Licence suspension and cancellation

The Act gives the Secretary of the department power to suspend an authority issued by the Secretary under the Act in circumstances where the Secretary reasonably believes that:

- the authority holder is no longer a fit and proper person
- the authority was issued on the basis of information that was false or misleading
- the authority holder has breached a condition of their authority; or
- there is a risk to health and safety of persons or the safety of the environment if the authority is not suspended.

Suspension of a radiation management licence, a radiation use licence, an approved tester of radiation sources approved assessor of security or transport security plans removes the ability of the person or company concerned to operate some or all of their business.

The Act details a mandatory process for a show cause notice to be issued to the authority holder prior to the suspension occurring to provide an opportunity for the person to make a representation as to why the authority should not be suspended or cancelled.

A decision by the Secretary to suspend or cancel an authority is reviewable by the Victorian Civil and Administrative Tribunal.

There is also a power for the Secretary to immediately suspend or cancel an authority in urgent circumstances to protect the health or safety of persons or the environment from the harmful effects of radiation until the full suspension or cancellation process described above has been completed.

It should be noted that as with the power of seizure and sealing of radiation sources, the use of the power to suspend or cancel a management licence authorising a radiation practice should involve consideration of the impact of the licence being suspended or cancelled. For example, suspending the licence held by a radiographer is likely to have a significant impact because it is likely that most of their work involves use of a radiation source whilst suspending the licence of a dentist is unlikely to have a significant impact if the dentist works in a practice with other dentists licensed to use radiation sources.

In the radiation therapy example provided earlier, cancellation of the licence might have unintended consequences of preventing people from receiving cancer therapy. In such situations, other enforcement options such as the issue of an improvement notice or prosecution may be considered by the department to be more appropriate.

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<sup>7</sup> <http://www.opp.vic.gov.au/Resources/Policies>

## Appendix 1: Offences – Radiation Act 2005

| Radiation Act 2005 - Contraventions |  |  |   |                        |
|-------------------------------------|--|--|---|------------------------|
| Section                             | Provision  | Penalty<br>(penalty units)<br>Natural person | Penalty<br>(penalty units)<br>Body<br>Corporate | Indictable<br>offence? |
| 12                                  | Conduct of radiation practice prohibited unless licensed   | 1800   | 9000  | Yes                    |
| 13                                  | Use of a radiation source prohibited unless licensed   | 1200   | NA  | Yes                    |
| 14                                  | Construction of radiation facilities prohibited in certain cases                                     | 600  | 3000  | Yes                    |
| 15                                  | Licence holders must comply with conditions of licence   | <b>Management</b><br>1200                    | <b>Management</b><br>6000                       | Yes                    |
|                                     |  | <b>Use</b><br>600                            | NA  |                        |
|                                     |  | <b>Facility construction</b><br>600          | <b>Facility construction</b><br>3000            |                        |
| 17                                  | Persons must not falsely represent that they are licence holders                                     | 60   | 300   | -                      |
| 18                                  | Offence to allow persons who do not hold a use licence to use a radiation source                     | 1200   | 6000  | Yes                    |
| 19                                  | Offence to allow a use licence holder to use a radiation source in a manner not permitted by licence | 1200   | 6000  | Yes                    |
| 20                                  | Secretary to be notified of loss or theft of radiation source  | 600  | 3000  | -                      |

|    |                                     |      |      |     |
|----|-------------------------------------|------|------|-----|
| 21 | Offence to abandon radiation source | 1800 | 9000 | Yes |
|----|-------------------------------------|------|------|-----|

| Radiation Act 2005 - Contraventions |  |  |   |                        |
|-------------------------------------|--|--|---|------------------------|
| Section                             | Provision  | Penalty<br>(penalty units)<br>Natural person | Penalty<br>(penalty units)<br>Body<br>Corporate | Indictable<br>offence? |
| 22                                  | Offences to cause another person to receive a higher radiation dose than is prescribed | Conducting a radiation practice<br>600       | Conducting a radiation practice<br>3000         | Yes                    |
|                                     |  | Using a radiation source<br>240              | NA  | -                      |
| 23                                  | Offences to cause serious harm to the environment                                      | Conducting a radiation practice<br>1800      | Conducting a radiation practice<br>9000         | Yes                    |
|                                     |  | Using a radiation source<br>1200             | NA  | Yes                    |
| 23A                                 | Offence to permit use of high consequence sealed sources by unverified person          | 1200   | 6000  | -                      |
| 23B                                 | Offence to permit transport of high consequence sealed sources by unverified person    | 1200   | 6000  | -                      |

|            |  |      |      |   |
|------------|--|------|------|---|
| <b>23C</b> | Offence to permit access to high consequence sealed sources by unverified person                         | 1200 | 6000 | - |
| <b>23D</b> | Offence to conduct a commercial tanning practice   | 60   | 300  | - |
| <b>26</b>  | Approved testers must comply with conditions of tester's approval  | 600  | NA   |   |
| <b>27</b>  | Only approved testers who hold testers' approvals that are in force may issue certificates of compliance | 60   | NA   | - |

| <b>Radiation Act 2005 - Contraventions</b> |  |   |   |                                |
|--|--|---|---|--------------------------------|
| <b>Section</b>                             | <b>Provision</b>   | <b>Penalty<br/>(penalty units)<br/>Natural person</b> | <b>Penalty<br/>(penalty units)<br/>Body<br/>Corporate</b> | <b>Indictable<br/>offence?</b> |
| <b>28</b>                                  | Offence to impersonate approved tester   | 60  | NA  | NA                             |
| <b>35</b>                                  | Approved tester must not knowingly issue a certificate of compliance that is false                       | 600   | NA  | Yes                            |
| <b>36</b>                                  | Use of prescribed radiation sources prohibited unless there is a certificate of compliance               | 1200  | 6000  | Yes                            |
| <b>61</b>                                  | Return of cancelled authority to Secretary   | 20  | 20  | NA                             |
| <b>67D</b>                                 | Management licence holders who possess high consequence sealed sources must have approved security plans | 1200  | 6000  | Yes                            |

| 67E  | Approved security plan to be provided to Secretary  | 60  | 300                                       | NA                  |
|--|---|---|---|---------------------|
| 67F  | Review of approved security plans   | 60  | 300                                       | NA                  |
| 67I  | Review of transport security plan   | 60  | 300                                       | NA                  |
| 67J  | Offence to transport high consequence sealed source without transport security plan   | 1200                                      | 6000                                      | NA                  |
| 67M  | Offence to fail to comply with security plan or transport security plan   | 1200                                      | 6000                                      | NA                  |
| 78   | Power to direct persons to produce documents, operate equipment, answer questions etc.  | 60  | 300                                       | NA                  |
| <b>Radiation Act 2005 - Contraventions</b> |   |   |   |                     |
| Section                                    | Provision   | Penalty (penalty units)<br>Natural person | Penalty (penalty units)<br>Body Corporate | Indictable offence? |
|  | <b>A person must not refuse or fail to comply with direction under subsection (1) unless the person has a reasonable excuse</b> |   |   |                     |
| 90B  | Person must comply with improvement notice or prohibition notice  | <b>Contravention of Act</b><br>120        | <b>Contravention of Act</b><br>600        | NA                  |

|            |  | <b>Contravention<br/>of<br/>Regulations</b> | <b>Contravention<br/>of<br/>Regulations</b> |     |
|------------|--|---|---|-----|
|            |  | 20  | 20  | NA  |
| <b>91</b>  | Offence to impersonate an authorised officer                   | 60  | NA  | NA  |
| <b>115</b> | Tampering with radiation sources sealed by authorised officers | 600   | 3000  | Yes |
| <b>116</b> | False and misleading information                               | 1200  | 6000  | Yes |
| <b>117</b> | Offence to hinder or obstruct an authorised officer            | 60  | NA  | NA  |

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