Queensland Health

Radiation Safety Regulation 2021

Consultation Paper

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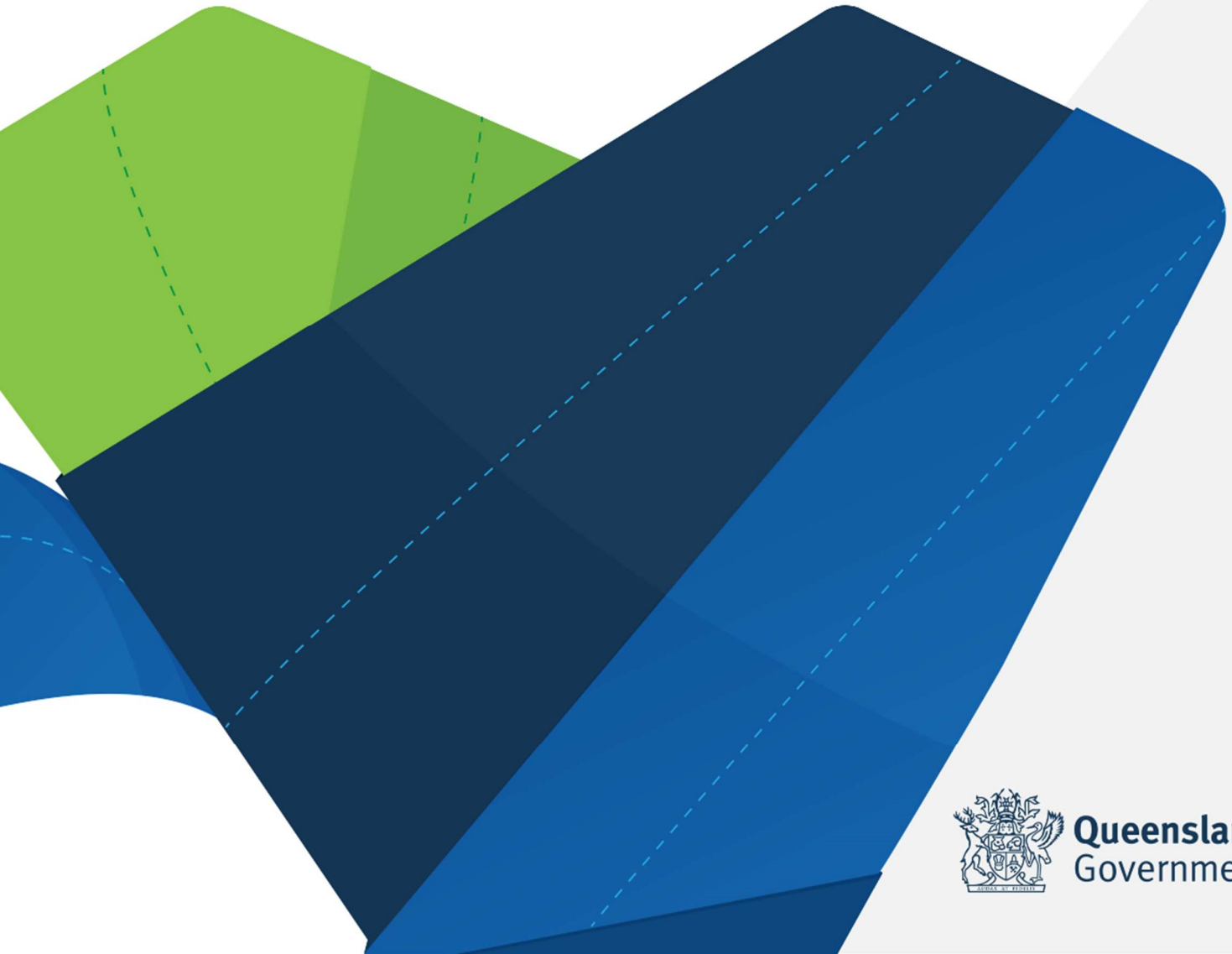

Queensland Government

Radiation Safety Regulation 2021 - Consultation Paper

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Contents

Background 1

Legislative framework 1
Overview of the Radiation Safety Regulation 1
Why is the Radiation Safety Regulation being remade? 2
Will the Radiation Safety Regulation change? 2

Radiation Safety Regulation 2021 3

Overview of amendments 3
Certificates of compliance 3
Labelling and classification of lasers 4
Code of Practice for Radiation Protection in Dentistry (2005) 4
Requirements for the disposal of reverse osmosis concentrate 5
Training 5
Radiation sources exempt from licensing requirements under the Act 6
Persons authorised to request or prescribe diagnostic or therapeutic procedures 7
Dental cone beam computed tomography (CBCT) 8
Fees 8
Updating references to outdated documents 8
Plain diagnostic radiography 9
Updating various definitions for terms used in the Radiation Safety Regulation 9

Regulatory Impact Analysis 9

Purpose

The purpose of this document is to inform stakeholders about the remaking of the Radiation Safety Regulation 2010. This document should be read with the consultation draft of the Radiation Safety Regulation 2021.

The closing date for feedback is Friday 9 July2021.

Feedback can be provided in writing and forwarded to:

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Background

Legislative framework

The use of ionising and harmful non-ionising radiation is regulated in Queensland under the *Radiation Safety Act 1999* and *Radiation Safety Regulation 2010*. The main objective of the Radiation Safety Act is to protect the public and the environment from the harmful effects of particular sources of ionising radiation and harmful non-ionising radiation, while recognising the beneficial uses of radiation.

This objective is guided by a set of radiation safety and protection principles. These principles reflect the extensive body of research and development work that has been undertaken at national and international levels on the adverse health effects which may arise from exposure to different types of radiation, coupled with the measures that may be taken to prevent or minimise the detrimental effects arising from exposure to radiation.

The Radiation Safety Act provides a safety and protection framework which regulates how radiation sources can be used, establishes a licensing and compliance monitoring and enforcement regime, imposes restrictions and prohibits particular radiation sources. Any amendments to the Radiation Safety Act or Radiation Safety Regulation must align with the objective of the Act, as well as the guiding principles.

Overview of the Radiation Safety Regulation

The Radiation Safety Regulation prescribes matters necessary to support the Act. These include prescribing:

- radiation sources that are radioactive substances and radiation apparatus. This is important to determine which radiation sources are regulated by the Radiation Safety Act and Radiation Safety Regulation;
- standard conditions that apply to particular licences;
- requirements for the disposal of radioactive material;
- measures that a possession licensee's radiation safety and protection plan, security plan, or transport security plan must address;
- radiation dose limits for radiation exposures in different circumstances, including dose limit monitoring;
- persons authorised to request or prescribe diagnostic or therapeutic procedures;
- exemptions from the requirement to hold a use or possession licence for particular radiation sources in certain circumstances;
- labelling and classification requirements for lasers, including which lasers are radiation apparatus and therefore subject to the licensing requirements of the Act;
- fees to be paid for Act instruments, including applications for, and renewal of, Act instruments;
- relevant definitions for terms used in the Radiation Safety Regulation.

Why is the Radiation Safety Regulation being remade?

The Radiation Safety Regulation is classed as a statutory instrument under the *Statutory Instruments Act 1992*. Section 54 of the Statutory Instruments Act provides for the automatic staged expiry of subordinate legislation, such as the Regulation. This staged expiry provides for the review and remaking of subordinate legislation, thereby helping to ensure that all subordinate legislation is both current and relevant. The Radiation Safety Regulation 2010 (the 2010 Regulation) commenced on 1 September 2010. It was initially scheduled to expire on 1 September 20202010, however, due to the impacts of the COVID-19 pandemic, the expiry was extended by 12 months to 1 September 2021.

As the Radiation Safety Regulation is made under the Radiation Safety Act to support the operation of the Act, it is necessary that it continues to have effect beyond 1 September 2021. The two pieces of legislation operate together to form one set of rules. The regulation can give guidance about anything that is required or permitted by the Act. Any definition in the Act will also apply in the Regulation. Remaking the Regulation will ensure there are no disruptions to current practices involving radiation sources and will also help ensure consistency with national and international codes of practice and standards relating to radiation safety.

Will the Radiation Safety Regulation change?

It is proposed the Radiation Safety Regulation 2010 (the 2010 Regulation) will be remade in its current form, with minor changes. Some parts of the Regulation have been re-structured or re-worded to improve clarity and readability, to reflect new drafting styles now being used by the Office of the Queensland Parliamentary Counsel, as well as to correct drafting anomalies.

A series of minor amendments are also being made to the 2010 Regulation to improve its operational effectiveness. These amendments are outlined in the following section.

Radiation Safety Regulation 2021

Overview of amendments

As noted above, the remaking process will see a number of operational amendments being made to the 2010 Regulation. These amendments are intended to strengthen the legislative framework and improve the operational effectiveness of the Regulation. These amendments include:

- amending the prescribed period for certificates of compliance where an apparatus is used under a quality assurance scheme approved by the chief executive;
- classifying all lasers above Class 1 as radiation apparatus, to help ensure all lasers are properly classified and labelled in accordance with the laser standard;
- clarifying that the *Code of Practice for Radiation Protection in Dentistry (2005)*, published by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) applies to both intra-and extra-oral dental diagnostic radiography;
- prescribing specific requirements for the disposal of reverse osmosis concentrate, to ensure appropriate regulation of purified water treatment facilities;
- simplifying the arrangements for recognising those training courses which will qualify a person for an exemption from the requirement to hold a use licence;
- providing that certain additional radiation sources are exempt from licensing requirements under the Radiation Safety Act;
- updating the list of persons allowed to prescribe or request therapeutic or diagnostic procedures so as not to impose undue restrictions on clinical practice;
- prescribing dental cone beam computed tomography (CBCT) imaging as a diagnostic procedure, including specifying who is authorised to request CBCT imaging;
- amending the schedule of fees to more accurately describe the licences for which fees are payable;
- updating references to outdated documents;
- amending references to 'plain film diagnostic radiography'; and
- updating various definitions for terms used in the Radiation Safety Regulation.

Certificates of compliance

The Radiation Safety Act imposes a number of obligations on possession licensees, including obligations for ensuring that a radiation source complies with all of the relevant radiation safety standards made by the Minister under the Act. These radiation safety standards are the minimum acceptable standards for equipment and premises. To demonstrate compliance with these radiation safety standards, a possession licensee must obtain a certificate of compliance for a radiation source or radiation apparatus.

The 2010 Regulation prescribes the different periods within which possession licensees must obtain certificates of compliance, after an initial certificate of compliance has been obtained. These periods vary between one year and five years, depending on whether the matter being assessed is a radiation source or a premises, and the practice for which it is being used.

In addition to compliance with the radiation safety standards, some possession licensees may participate in structured quality assurance schemes. The standards for some of these quality assurance schemes include equipment performance requirements that meet or exceed Queensland's radiation safety standards, resulting in duplication of testing and administrative processes.

The Radiation Safety Regulation 2021 will include provision to prescribe that, if a radiation source complies with the requirements of a quality assurance scheme approved by the chief executive, the prescribed period for obtaining another certificate of compliance for the radiation source (after the initial certificate of compliance is obtained before the radiation source's first use) is 10 years. The chief executive will only approve those schemes which duplicate or exceed the requirements of Queensland's radiation safety standards.

Labelling and classification of lasers

Currently, there is no obligation to label lasers to warn consumers of the hazards associated with laser use, other than for the Class 4 'laser apparatus' as defined in the 2010 Regulation. While lasers classed equal to or lower than Class 3B are not considered hazardous enough to require the imposition of licensing obligations under the Radiation Safety Act relating to possession and use, requiring all lasers to be correctly classified and labelled will help to reduce the risk of harm to consumers.

The Radiation Safety Regulation 2021 will provide that all lasers above Class 1 are radiation apparatus, regardless of their intended use. This amendment will ensure that all lasers are correctly classified and labelled in accordance with the *Australia/New Zealand laser standard* (AS/NZS IEC 60825.1-2014 Safety of laser products, Part 1: Equipment, classification requirements and user's guide). This amendment is intended to limit the public health and safety risk that may result from the use of lasers without a proper understanding of the harm that may be caused by them. The Radiation Safety Regulation 2021 will also make other consequential amendments to support this new requirement.

Code of Practice for Radiation Protection in Dentistry (2005)

The 2010 Regulation prescribes a range of codes, protocols, standards or documents that a possession or use licensee is required to comply with as a standard condition of their licence. Currently, a possession licensee or a use licensee who possesses and/or uses an ionising radiation source for intra-oral dental diagnostic radiography involving the irradiation of a person is subject to the licence condition that the holder of the licence comply with the 'Code of Practice for Radiation Protection in Dentistry (2005)', published by ARPANSA (the Dental Code of Practice). However, the Dental Code of Practice applies to both intra- and extra-oral dental diagnostic radiography.

The 2010 Regulation does not currently require a possession licensee or use licensee who possesses or uses an ionising radiation source for extra-oral dental diagnostic radiography to comply with the Dental Code of Practice.

The Radiation Safety Regulation 2021 will amend the reference to *intra-oral dental diagnostic radiography to dental plain diagnostic radiography*. This amendment will reflect the requirement for both intra- and extra-oral dental diagnostic radiography licence holders to comply with the Dental Code of Practice.

Requirements for the disposal of reverse osmosis concentrate

The Radiation Safety Act provides that a person must not dispose of radioactive material unless the concentration or activity of a radionuclide in the material is not more than the amount prescribed under a regulation, or the person is the holder of an approval to dispose.

The 2010 Regulation sets out the maximum concentrations or activities of radionuclides for material disposed of into the sewerage system, as well disposal into the air or water. As it is currently drafted, the 2010 Regulation applies to entities that dispose of radioactive material into the sewerage system, such as hospitals and other health service providers that use nuclear medicine in the treatment of patients. It does not adequately regulate the effluent from advanced water treatment facilities, which use a process called 'reverse osmosis' to purify water.

The Radiation Safety Regulation 2021 will specify a point of disposal for reverse osmosis concentrate (a by-product of the reverse osmosis treatment process). This point of disposal is intended to be a point immediately outside an advanced water treatment facility where its effluent is released into the environment.

Training

The Radiation Safety Act provides that a person must not use a radiation source unless the person holds a use licence. All persons who use radiation sources are required to hold a use licence.

The only circumstance in which a person is not required to hold a use licence is where a person is using a radiation source in the presence and under the direct supervision of a use licensee who is allowed to use the source to carry out a radiation practice, and the use is for the purpose of either:

- helping the licensee to carry out a prescribed radiation practice; or
- the person is undergoing a course of training prescribed under a regulation.

The 2010 Regulation currently only prescribes two training courses:

- 'Compliance testing of diagnostic imaging equipment training course', conducted by the Department of Health; and
- 'Laser concepts in health care', conducted by the Australian Centre for Medical Laser Technology.

This means that a person completing a training course that is not prescribed must first complete theoretical training, then apply to the chief executive for a use licence to enable them to undertake their practical training. The chief executive may then grant a use licence with conditions limiting the licensee's use of the source to certain circumstances until the chief executive is satisfied the person is sufficiently competent to hold an unrestricted use licence.

The Radiation Safety Regulation 2021 will remove the list of prescribed training and, instead, enable the chief executive to approve training courses for the purpose of exempting a person from the requirement to hold a use licence while undertaking their practical training, and will provide that a list of approved courses be published on the Department of Health's website. The chief executive will only approve courses if he or she is satisfied that:

- training offered by an educational institution or other entity requires a person to use a radiation source;
- the educational institution or entity requires the person to undertake a reasonable period of practical training; and
- the practical training is of an acceptable standard.

Radiation sources exempt from licensing requirements under the Act

The Radiation Safety Act provides that a regulation may exempt a radiation source from the Act or a provision of the Act. Such an exemption must not be one that could reasonably be expected to pose any, or more than negligible health risks to any person or adverse effects on the environment. The ability to exempt a radiation source recognises that, under certain circumstances, the regulation of a particular type of radiation source or an activity involving radiation cannot be justified. The 2010 Regulation currently contains a number of exemptions from the requirement for licence for certain radiation sources.

The Radiation Safety Regulation 2021 will make the following amendments to these exemptions:

- amend the definition of 'fully enclosed analytical radiation apparatus' to better describe the current technology, and thereby provide the benefits of using the technology to its users without requiring them to hold a use licence issued under the Radiation Safety Act;
- include americium-241 as a sealed radioactive substance as being exempt from the requirement for a possession licence, if it is incorporated in a sealed source apparatus used for gas chromatography or ion mobility spectrometry. Americium-241 used in this way will pose negligible health risks or adverse effects on the environment;
- include krypton-85 as a sealed radioactive substance that is exempt from the requirements of the Act when incorporated in an item to produce light (such as an energy saving light bulb). This change is consistent with the nationally agreed approach to exempt lighting products that contain krypton-85 from particular licensing requirements. This change will pose negligible health risks or adverse effects on the environment;
- change the activity amount specified for americium-241 as a sealed radioactive substance when used in teaching from 20 kilobecquerels (kBq) to 40 kBq. This amendment will ensure consistency with the nationally agreed position to exempt an americium-241 sealed radioactive substance from licensing requirements, provided the substance is being used for teaching the characteristics and properties of radiation or radiation sources. This change will pose negligible health risks or adverse effects on the environment;
- exempt a radioactive substance containing the radionuclide natural thorium from the definition of radioactive substance in particular circumstances, thereby removing the need for a possession licence, a use licence, or an approval to dispose under the Radiation Safety Act.

  The radiation source natural thorium is contained in alloys used in aircraft components and certain welding electrodes. The exemption will apply if:

  – the substance is incorporated in an alloy used in a component of an automotive or aircraft engine; or

- the substance is incorporated in a tungsten welding electrode and a person who is to use the electrode for tungsten inert gas arc welding is given a warning statement before using it.

A new exemption will be included regarding lasers. A laser will be exempt from the requirements of the Act if it is not a laser apparatus (defined in schedule 2 of the 2010 Regulation), and a compliant label is attached to the laser in accordance with the laser standard. For a laser that is not required to have the relevant safety information shown on a compliant or attached label under the laser standard, the laser will be exempt from the requirements of the Radiation Safety Act if the affected person has been given the information in another way allowed under the laser standard, or provided a label in another way allowed under the laser standard.

Persons authorised to request or prescribe diagnostic or therapeutic procedures

The Radiation Safety Act provides that a person must not prescribe a therapeutic procedure for another person, or request a diagnostic procedure for another person, unless the person is authorised to prescribe or request the procedure under a regulation. Schedule 6 of the 2010 Regulation lists the persons who are authorised, and the procedures they are authorised to request.

The Radiation Safety Regulation 2021 will make the following amendments to the list of authorised persons:

- remove the requirement for dental therapists to authorise intra-oral bitewing dental diagnostic radiography only if the procedure is to be performed under a protocol approved by the chief executive. Dental therapists are now considered to be adequately trained in terms of patient assessment and radiographic training, and have the requisite knowledge and skills to assess the risks of radiation exposure against clinical need such that a radiography protocol is no longer considered necessary;
- allow podiatrists to authorise the use of laser apparatus to perform procedures such as the treatment of onychomycosis and the ablation of warts. Podiatrists are currently authorised to request plain film diagnostic radiography of the foot, ankle, lower leg, knee, thigh and hip. Authorising the use of laser apparatus in certain circumstances will enable podiatrists to work to their full scope of practice, and improve access for patients to timely, cost effective care;
- authorise specialist paediatric nuclear medicine physicians to request and prescribe the same diagnostic therapeutic procedures as specialist nuclear medicine physicians. This amendment will correct an oversight occurring as a result of implementation of the Health Practitioner Regulation National Law;
- amend the references to ‘intra-oral’ and ‘extra-oral’ dental diagnostic radiography to clarify that these procedures relate only to plain diagnostic radiography and not to other types of diagnostic imaging, such as cone beam computed tomography (CBCT).

The Radiation Safety Regulation 2021 also makes minor amendments to update particular diagnostic and therapeutic procedures, for example, replacing references to ‘plain film diagnostic radiography’ with ‘plain diagnostic radiography’. The changes being made in the Radiation Safety Regulation 2021 may also result in Schedule 6 of the 2010 Regulation being renumbered.

Dental cone beam computed tomography (CBCT)

In addition to the above amendments to schedule 6 of the 2010 Regulation, the Radiation Safety Regulation 2021 will include dental CBCT as a diagnostic procedure. Only dentists who have written approval from the chief executive, stating the dentist is competent to carry out the procedure, will be permitted to authorise dental CBCT. This will ensure that only dentists who have the appropriate training are authorised to request dental CBCT imaging.

CBCT is a form of computed tomography, and currently, only specialist radiologists can request computed tomography imaging. However, it is considered that dentists are best placed to determine whether dental CBCT imaging is the appropriate diagnostic imaging methodology, and to interpret the images produced from this procedure.

Enabling approved dentists to request dental CBCT imaging will align the Radiation Safety Regulation 2021 with clinical expectations.

Fees

As noted above, the objective of the Radiation Safety Act is to protect people and the environment from the harmful effects of particular sources of radiation. This objective is achieved through the establishment of a licensing regime to regulate the possession and use of radiation sources, and the transportation of radioactive substances, as well as imposing restrictions on the acquisition and relocation of radiation sources, and the disposal of radioactive substances. These licences and approvals are collectively referred to as 'Act instruments'.

To apply for an Act instrument, a person must apply to the chief executive in the approved form with the accompanying fees and documentation prescribed under a Regulation. The relevant fees are prescribed in Schedule 8 of the 2010 Regulation.

The Radiation Safety Regulation 2021 will amend the table of fees to more closely align with the categories of Act instruments for which a person may apply. Consequential amendments will also be made to the description of how these fees are calculated.

Updating references to outdated documents

The 2010 Regulation makes reference to a number of external reference materials to guide and assist regulated persons in complying with their obligations under the Radiation Safety Act. Over time, these documents themselves are reviewed and updated, and new editions published.

The Radiation Safety Regulation 2021 will update references to outdated external reference materials including, for example, updating the reference to the laser standard (AS/NZS 2211.1:2004 (Safety of laser products, Part 1: Equipment classification, requirements and user's guide) to refer instead to the 2014 edition of this standard. Updating the references to external reference materials will ensure stakeholders are relying on the most recent versions of these documents to assist them in complying with their legislative obligations.

Plain diagnostic radiography

The 2010 Regulation makes a number of references to 'plain film diagnostic radiography'. In general terms, plain film diagnostic imaging is an X-ray image.

The use of 'plain film diagnostic radiography' is historical, and the use of X-ray film is becoming obsolete as digital techniques replace old equipment which uses film. As such, using the phrase 'plain film diagnostic radiography' is outdated. While the definition in the 2010 Regulation includes new and current technology, it is considered more appropriate to amend the phrase itself and provide a more concise meaning to clearly describe the regulatory intent.

The Radiation Safety Regulation 2021 will remove the word 'film' from the phrase 'plain film diagnostic radiography' so the Regulation instead simply refers to 'plain diagnostic radiography', and a clear definition for this phrase provided. That is, 'plain diagnostic radiography' will be defined to mean single projection imaging using X-ray transmission. Consequential amendments will also be made throughout the Regulation to replace references to 'plain film diagnostic radiography' with references to 'plain diagnostic radiography'.

Updating various definitions for terms used in the Radiation Safety Regulation

The Radiation Safety Regulation 2021 updates various definitions used in the Regulation including, for example, laser apparatus and podiatrist. The relevant definitions have been updated to reflect the amendments outlined above.

New definitions have also been included, where necessary. For example, a definition for computed tomography has been included. Defining terms used in the regulation assists regulated persons in more clearly understanding what is within scope of the legislative framework and its application.

Regulatory Impact Analysis

The Radiation Safety Regulation 2021 supports the Act, the benefits of which include the protection of Queenslanders from health risks associated with exposure to certain radiation sources.

It is not expected the Radiation Safety Regulation 2021 will impose significant costs on the persons or organisations to which they apply. The amendments requiring lasers to be classified and labelled will impact some businesses. The vast majority of lasers available for purchase are labelled. Provided these lasers have been correctly labelled, there should be no impact on affected businesses. However, if a business is incorrectly labelling its lasers or a laser has not been labelled, the amendment will provide the means by which the regulatory authority can require the situation to be remedied.

The Office of Best Practice Regulation within Queensland Treasury was consulted on the remaking of the 2010 Regulation and each of the amendments it contains, and its assessment was that a Regulatory Impact Statement was not required.