**Queensland**

**Explanatory Notes for SL 1999 No. 330**

***Radiation Safety Act 1999***

# RADIATION SAFETY REGULATION 1999

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**Short Title**

*Radiation Safety Regulation 1999.*

**Authorising law**

Details are contained in the regulatory impact statement.

**Policy objectives**

Details are contained in the regulatory impact statement.

**How policy objectives will be achieved**

Details are contained in the regulatory impact statement.

**Consistency with authorising law**

Details are contained in the regulatory impact statement.

**Options and alternatives**

Details are contained in the regulatory impact statement.

**Cost-benefit analysis**

Details are contained in the regulatory impact statement.

**Fundamental legislative principles**

Details are contained in the regulatory impact statement.

**Consultation**

In accordance with the requirements of the *Statutory Instruments Act 1992*, a regulatory impact statement (RIS) was prepared and released for public comment in September 1999. Advertisements about the availability of the RIS were placed in all major daily newspapers throughout Queensland. Direct advice about the publication of the RIS was provided to approximately 4 000 existing licensees.

Over 2 500 copies of the RIS were distributed to stakeholders and interested parties, including licensees and professional bodies, as well as individuals. In addition, the RIS was available on the internet and many people used this method to access it.

Over 90 written responses to the RIS were received. In addition, many people responded verbally in order to discuss their views.

Consultations were held with key stakeholders regarding specific aspects of the proposed regulation, for example—

- Consultations were held with representatives in the medical field with regard to a number of issues, such as: the proposed list of authorised persons who can prescribe a therapeutic procedure for another person, or request a diagnostic procedure for another person, if these procedures will involve the irradiation of the other person; and the requirement to mark images with certain information about the patient.
- The Queensland Mining Council raised concerns about the proposed thresholds at which materials are to be deemed to be radioactive substances, as well as the proposed maximum concentration limits to be prescribed for the disposal of radioactive material, and how this would affect the mining industry.

- The Department of Mines and Energy was consulted about the disposal of minerals where this takes place outside the boundaries of a mining lease, such as the disposal of material from a plant where the processing of minerals takes place.
- The Environmental Protection Agency was consulted about the point at which disposals into the sewerage system, water and air could be measured, and the appropriateness of the disposal criteria in Schedule 2 of the proposed regulation. The application of the legislation to domestic smoke detectors was also discussed.
- The Radiological Advisory Council, in its capacity as the Ministerial advisory body established under the *Radioactive Substances Act 1958*, was also consulted regarding the proposed regulation.

**Results of consultation**

Stakeholders generally responded favourably to the proposals being put forward as part of the RIS process.

Some respondents expressed concerns regarding specific aspects of the proposed regulation as follows:

- The time periods proposed for obtaining certificates of compliance were considered to be too short in some instances, particularly for persons in rural and remote areas of the State.
- Certain of the measures proposed for inclusion in radiation safety and protection plans were thought to be impractical for some businesses to comply with.
- Exemptions from licensing and disposal were suggested for some additional radioactive materials, such as minerals and bodily waste of persons who have been treated with a radioactive substance for diagnostic or therapeutic purposes.
- Changes were suggested for the list of authorised persons in order to adequately cover all fields of medicine where authorised persons will be required.

# SPECIFIC CHANGES

## Prescription of radioactive substances

The mining industry expressed concern that the proposed definition of what constitutes a radioactive substance would result in many of the products of mines and metal production facilities being classed as "radioactive" under the proposed regulation.

In response to this concern, and in the knowledge that such an amendment would have a minimal impact on radiation safety, the proposed prescription of a radioactive substance was varied for minerals in the mineral processing industries, by increasing the threshold concentrations in Column 2 of Schedule 1 of the proposed regulation. This variation was agreed to by the industry.

## Prescription of radiation apparatus

The Department of Employment, Training and Industrial Relations (Workplace Health and Safety Program) was consulted in relation to the prescription of non-ionising radiation apparatus (Class 4 lasers) for cosmetic purposes. The Department confirmed that it considered the application of the proposed regulation to these lasers was a suitable proposal.

## Certificates of compliance

The dental profession and rural doctors put forward the view that the periods proposed for obtaining certificates of compliance were too short and would result in unnecessary compliance costs for these businesses.

In response, the proposed period within which a certificate of compliance must be obtained for an ionising radiation apparatus used to carry out intra-oral dental diagnostic radiography, or plain film diagnostic radiography, involving the irradiation of a person has been increased from 2 to 3 years, and 1 to 3 years respectively.

These amended time periods are considered to be more acceptable. They will significantly assist with the level of compliance able to be achieved, and will particularly assist small or rural and remote businesses which may

experience difficulties in relation to the cost of compliance, as well as arranging for a suitable person to perform the compliance tests.

**Standard conditions of licence**

The proposed standard conditions of licence have been amended slightly to specify that the holder of a use licence to use an ionising radiation source for intra-oral dental diagnostic radiography, involving the irradiation of another person, must comply with the document entitled "Code of Practice for Radiation Protection in Dentistry 1987" published by the National Health and Medical Research Council (NHMRC).

The proposed requirement that the holder of a use licence to use a radioactive substance for a therapeutic procedure involving the irradiation of another person must comply with the document entitled "Recommendations Relating to the Discharge of Patients Undergoing Treatment with Radioactive Substances 1983" published by the NHMRC, has been removed. Persons involved in this practice were of the opinion that the key components of this document could be mentioned in the radiation safety and protection plan, and that the rest of the document is obsolete as it relies on superseded radiation protection recommendations.

**Disposals and exemptions**

*General comment on disposal*

Section 26(1)(a) of the Act specifies 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 maximum concentration or activity prescribed under a regulation.

The proposed regulation sets maximum concentrations for disposal of radioactive material, where the material is disposed of via a particular method: that is, into the air or water; into the sewerage system; or by another means. Where the radioactive material to be disposed of contains only one radionuclide, the maximum concentration has been set by referral to the concentrations listed in Schedule 2 of the proposed regulation. Where the radioactive material to be disposed of contains more than one radionuclide, the maximum concentration has been set by means of a calculation to be known as the "disposal factor". The disposal factor utilises

the concentrations of the radionuclides in the material, and the concentrations given in Schedule 2 for the relevant radionuclide.

*Respondents concerns*

A number of concerns were raised by respondents to the RIS, regarding the proposed maximum concentration limits for disposal of radioactive material. These are dealt with below—

**Smoke detectors**

- The Environmental Protection Agency agreed that, in certain circumstances, domestic smoke detectors could be exempted from the requirements of the legislation. The Agency had some concerns in relation to disposal of these smoke detectors and it was agreed that a policy should be developed by Queensland Health to specifically address the disposal of these items. The development of this policy is well advanced.

**Abrasive blasting material**

- The abrasive blasting industry expressed concerns with how the disposal of abrasive blasting material was to be achieved, given the technical elements of the proposed disposal criteria. Following consultation with members of the industry, these technical details were revised to reflect the consequences of more realistic usage conditions and to increase the variety of products available for abrasive blasting.

  When abrasive blasting material meets the criteria set by the proposed regulation, and when used in accordance with the Abrasive Blasting Industry Code of Practice 1999 issued by the Queensland Department of Employment, Training and Industrial Relations, abrasive blasters will be unlikely to receive a radiation dose in excess of the limit set for members of the public. Consequently, the abrasive blasting material will be exempt from the requirement for a person to obtain a possession licence, or a transport licence. Further, this material will also be able to be disposed of without the necessity for an approval under the Act.

**Minerals**

- Significant concerns were raised by the mining industry with regard to the disposal of minerals and mineral by-products from minerals processing. The mining industry expressed concern that, for some elements of the industry, there may be difficulty in achieving the specific disposal requirements proposed in the RIS. These requirements were seen as unnecessarily onerous and it was felt that acceptable levels of radiation safety could be achieved in a more acceptable way, by using critical hazard analysis methodology.

  In response to these concerns it is proposed that the person seeking to dispose of the material must demonstrate (using critical hazard analysis methodology), and continue to demonstrate (by ensuring the conditions of an approval to dispose of the material under the Act are complied with while the approval is in existence), that certain criteria are satisfied as a result of the disposal. A criterion that is commonly used in other jurisdictions is the demonstration, through modelling, that no person is likely to receive a radiation dose in excess of 300 $\mu$SV per annum as a result of the disposal. In practice, the person seeking to dispose of the material will provide a critical hazard analysis to the chief executive as part of their application for an approval to dispose. An assessment of the critical hazard analysis will be undertaken as part of the assessment of the application.

  The disposal of minerals by this method does not constitute a radiation hazard, and, given that the volume of material to be disposed of may often be large, this approach is far more practical. Where the disposal of minerals would exceed the disposal limits set by the legislation, this will purely be a "trigger" (based on international standards) for the disposal of the material to come under regulatory scrutiny by way of an approval to dispose.

**Patients injected or administered with a radioactive substance**

- Concerns were raised by the medical profession in relation to the disposal of bodily waste from persons who have been treated with a radioactive substance as part of therapeutic or diagnostic

procedures. This material may at times be radioactive for a period after the person has been treated. In practice, a person's bodily waste will be carefully managed while they remain at the place where they were treated.

**Solids**

- The regulatory impact statement did not propose any maximum concentration limits for the disposal of radioactive material by any means other than as air or water borne material, or as sewerage. Consultations with respondents revealed that it would be preferable for there to be maximum concentration limits to cater for the disposal of solid materials, such as containers that had been contaminated by radionuclides, and general laboratory and other wastes. These materials, by their solid nature, cannot easily be disposed of through air, water or sewerage.

Compliance with the new criteria will ensure that the presence of radionuclides need not be considered further prior to disposal.

**Radiation safety and protection measures**

The Act requires possession licensees to develop radiation safety and protection plans as part of the process of obtaining a possession licence. A radiation safety and protection plan must be approved by the chief executive and must address a number of matters, including the radiation safety and protection measures and other particulars, which have been prescribed under a regulation.

The RIS proposed a number of radiation safety and protection measures for inclusion in the proposed regulation. Some of the proposed measures were the subject of comments and concerns as indicated below.

**Marking of images**

A number of radiographers and other health care professionals expressed concerns about the proposal to require marking of images with certain details, such as the operating parameters of the X-ray machine during the production of a radiograph. It was felt that this would be impractical and may have been too costly for some businesses to comply with.

Consequently, this criterion has been removed. In addition, the proposal has been amended to permit the marking of images with either the name or mark of the radiographer.

The proposal was also amended to permit the marking of images with adequate information to enable the correct interpretation of the image, rather than prescribing certain specific details which must be marked on the image.

**Record keeping**

Many respondents indicated their concerns with the amount of detail to be included in records kept by a possession licensee about a radiation practice. This matter has now been rationalised so that the details now required to be kept are those that such businesses would have to keep in order to receive the rebate from the Health Insurance Commission. This was seen by the industry as an acceptable revision.

**Authorised persons**

The Act permits only certain persons to prescribe a therapeutic procedure for another person, or request a diagnostic procedure for another person, if these procedures will involve the irradiation of the other person. The persons that may prescribe these therapeutic procedures or request these diagnostic procedures are to be known as authorised persons, and they must be specified as such in a regulation.

The RIS generated significant comment on the proposed list of persons to be specified as authorised persons for the legislation. As a consequence, this aspect of the proposal has required further consultation prior to finalisation. It is expected that this issue will be the subject of an amendment to the *Radiation Safety Regulation 1999* early in 2000.

**Radiation safety officers**

The Act requires a possession licensee to ensure that a radiation safety officer is appointed and carrying out the functions of a radiation safety officer, whenever a radiation practice is carried out with a radiation source possessed by the licensee. In most cases, the radiation safety officer must be a qualified person appointed as such by the chief executive. However, for some practices (such as small or single owner-operator practices), the

possession licensee may appoint themself as a radiation safety officer if they hold a qualification relevant to the practice, which has been prescribed under a regulation.

Rural doctors, chiropractors and the dental profession in particular held the view that the qualifications being proposed to enable a possession licensee to appoint him or herself as a radiation safety officer were too stringent. Following consultation, the proposed qualifications were expanded for the dental profession so that, for intra-oral diagnostic radiography of a person, any person registered under the *Dental Act 1971* may appoint themselves as a radiation safety officer for their practice. This expansion was mirrored for medical practitioners and chiropractors.

**Fees**

Waiver provisions have been included in the proposed regulation as follows—

(a) persons who hold a current licence under the previous legislation and apply for the same type of licence under the new Act will not be required to pay the relevant application fee;

(b) persons who need to use a radiation source in the course of their study or training at an educational institution, and are required to hold a use licence to do so, will not be required to pay the application fee or the licence fee;

(c) a radiation safety officer under the previous legislation, who continues to be a radiation safety officer for the practice and applies for a radiation safety officer certificate under the new legislation, will not be required to pay the application fee;

(d) if a person who holds a use licence for a radiation source to carry out a diagnostic or therapeutic procedure involving the irradiation of another person, applies for a use licence of another type, the person will not be required to pay the application fee for that other licence; and

(e) the State will not be required to pay the application fee or the licence fee relevant to obtaining a possession licence, an approval to dispose, changing the conditions of a conditional Act instrument, changing an approved radiation safety and protection

plan, or issuing another instrument to replace one which has been lost, stolen, destroyed or damaged.

**Radiation safety standards**

The proposed Radiation Safety Standards were developed during a lengthy consultation process with industry. They were also the subject of comment and consultation on the RIS.

A number of respondents indicated that, because the proposed standards are so technical in nature, it would be desirable to include more explanatory detail to clarify how the various tests are to be undertaken and the criteria for passing the tests. The proposed standards have been amended accordingly.

A number of additional standards were also requested by industry to cover the use of radiation sources for radiotherapy, bone densitometry and sterilisation of materials (for example, blood products or imported stuffed toys). A standard has subsequently been developed for sterilisation. However, the development of other standards will be finalised following further consultation with professional bodies.

Listed below are the standards, which it is proposed will be made by the Minister for Health, for commencement on 1 January 2000, to coincide with the commencement of the proposed *Radiation Safety Regulation 1999*.

**Radiation sources—health care related**

- Standard for radiation apparatus used to carry out diagnostic radiography, excluding computed tomography, mammography, fluoroscopy and intra-oral dental diagnostic radiography.
- Standard for radiation apparatus used to carry out fluoroscopy.
- Standard for radiation apparatus used to carry out computed tomography.
- Standard for radiation apparatus used to carry out film-screen mammography.
- Standard for radiation apparatus used to carry out intra-oral dental diagnostic radiography.

- Standard for Class 4 lasers used to carry out cosmetic or health related procedures on human beings.

**Radiation sources—non-health care related**

- Standard for radiation apparatus used to carry out plain film radiography of inanimate objects.
- Standard for cabinet radiation apparatus used to carry out fluoroscopic or radiographic imaging of inanimate objects.
- Standard for radiation apparatus used to carry out diagnostic radiography of animals.
- Standard for radiation apparatus used to carry out industrial radiography.
- Standard for radiation apparatus used to carry out chemical analysis.
- Standard for radiation apparatus used to carry out industrial gauging.
- Standard for sealed radioactive substances incorporated in sealed source apparatus used to carry out industrial radiography.
- Standard for sealed radioactive substances incorporated in sealed source apparatus used to carry out chemical analysis.
- Standard for sealed radioactive substances incorporated in sealed source apparatus used to carry out industrial gauging.
- Standard for sealed radioactive substances incorporated in sealed source apparatus used to carry out borehole logging.
- Standard for sealed radioactive substances incorporated in sealed source apparatus used to carry out moisture/density measurements.
- Standard for radiation apparatus used to carry out sterilisation.
- Standard for sealed radioactive substances incorporated in sealed source apparatus used to carry out sterilisation.

**Premises**

- Standard for premises at which radiation sources are used to carry out a radiation practice.
- Standard for premises at which radioactive substances are stored.
- Standard for premises at which radiation sources are used to carry out industrial radiography, excluding open sites.
- Standard for premises at which radiation apparatus is used to carry out health related diagnostic radiography or radiation therapy.
- Standard for premises at which radiation apparatus is used to carry out veterinary diagnostic radiography or veterinary radiation therapy.
- Standard for premises at which radiation sources are used to carry out industrial gauging.
- Standard for premises at which radiation apparatus is used to carry out chemical analysis.
- Standard for premises at which Class 4 lasers are used to carry out cosmetic or health related procedures.
- Standard for premises at which radiation sources are used to carry out sterilisation.

ENDNOTES

1. Laid before the Legislative Assembly on . . .
2. The administering agency is the Department of Health.