EPA 1058/15: This report explains the review of the Radiation Protection and Control (Ionising Radiation) Regulations which includes the provisions to adopt aspects of the National Directory for Radiation Protection published by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) in July 2004 and other miscellaneous amendments.

Introduction

The Environment Protection Authority (EPA) has conducted a comprehensive review of the Radiation Protection and Control (Ionising Radiation) Regulations 2000 (IR Regulations) under the Radiation Protection and Control Act 1982 (the RPC Act). The Regulations provide the detailed requirements for protecting the health and safety of people and the environment from the harmful effects of radiation.

A driving factor for the review is the Subordinate Legislation Act 1978 requires regulations older than 10 years to be reviewed. The Regulations are due to expire on 1 September 2015, with no further extension possible.

Amendments to the Regulations are needed to implement requirements of the National Directory for Radiation Protection (National Directory). This directory provides a framework for national uniformity in radiation protection and adoption of its provisions is part of initiatives and commitments made by the South Australian Government at the Australian Health Ministers’ Conference, via the Council of Australian Governments (COAG) process. On 13 February 2011 the COAG resolved that nationally agreed legislative amendments should be given high priority.

The draft IR Regulations includes amendments to address the requirements of the National Directory relating to the adoption of:

- exemption Levels for radionuclides prescribed in Schedule 4
- national codes and standards
- the radiation incident reporting framework.

With the implementation of nationally agreed framework there will be a positive impact to business, with the reduction of regulatory burden associated with inconsistent regulations across jurisdictions.

Next steps

The revised IR Regulations will be drafted by Parliamentary Counsel with the EPA liaising and informing stakeholders, including licensees under the Act and relevant professional boards and industrial associations and the public.
Overview of the proposed amendments

The amendments will update the IR Regulations to include the most recent nationally agreed requirements for radiation regulation, provide for changes in radiation equipment technology and to make miscellaneous amendments stemming from the review of the current regulations.

The proposed changes include:

- Improving transparency and certainty by making provisions to accommodate many general exemptions that have been granted under section 44 of the RPC Act. The changes will reduce the regulatory burden for industry needing to apply for exemptions, including the:
  a. range of situations in which ‘specified employers’ (responsible persons) are not required to issue personal radiation monitoring devices to ‘radiation workers’ (occupationally exposed persons)
  b. classes of apparatus and persons not requiring a licence to operate radiation apparatus or to use or handle a radioactive substance
  c. classes of apparatus or sealed radioactive sources not requiring registration
  d. approval of exposure of people to ionising radiation for research purposes.

- Incorporating the exemption levels for quantities of radioactive substances prescribed in the National Directory into the regulations, and updating the classification of premises where radioactive substances are stored or handled. This will satisfy a requirement to adopt the exemption levels, and will bring South Australia into alignment with national and international recommendations.

- Replacing out-dated ‘special requirements’ relating to the registration and use of radiation apparatus and sealed radioactive sources, with regulations which are capable of keeping pace with changes in technology, and either reference the nationally agreed codes of practice published by ARPANSA, or reference specific codes of compliance published by the EPA that are listed in the Schedules of the regulations. This would enable business to access the required code and ensure its compliance with requirements stated in that code. For radiotherapy radiation apparatus/sealed radioactive sources, provisions have been proposed to enable a certified senior radiation oncology medical physicist to ensure safety of radiotherapy equipment and its installation. Currently the regulatory requirements for an apparatus or sealed radioactive source are cumbersome and difficult for business to assess.

- Updating the reporting provisions for radiation incidents, accidents and emergencies to include incidents listed in Schedule 13 in the National Directory that must be reported to ARPANSA for compilation in the Australian Radiation Incident Register (ARIR).

- Amend the provisions for a licence to carry out mining or mineral processing for the situations in which operations do not apply under section 24(1) of the RPC Act. The Regulations require a licence for mining or mineral processing based on the quantity of ore or mineral being processed. The proposed amendment would allow a risk-based approach to regulation and not require licensing where sufficient evidence can be provided to demonstrate that radiation exposures will be below ‘member of public’ limits, and there would be no adverse effects on the environment.

- Amend the fee structure for mining or mineral processing licences under section 24 of the RPC Act to better define the types of operations and to align the fees with the EPA’s regulatory effort in administering the licences. The proposed fee structure is modular in format and identifies the components of operations, and the fees would apply to each part. They also provide for future operations where radioactive substances are present but not being significantly concentrated, and accommodate changes to operational status of mining or mineral processing operations, transition to care and maintenance, and rehabilitation. There will be no additional cost to business from the proposed changes.

- The Radiation Protection and Control (Transport of Radioactive Substances) Regulations 2003 (Transport Regulations) call up the ARPANSA Code of Practice for the Safe Transport of Radioactive Material (2001). The EPA proposes that the regulations for transport of radioactive substances will be updated and amalgamated with the IR Regulations.
It is further proposed that the Radiation Protection and Control (Non-Ionising) Radiation Regulations 2013 (Non-Ionising Regulations) be amalgamated with IR Regulations to become the Radiation Protection and Control Regulations 2015. Changes to the Non-Ionising Regulations that came into effect on 1 January 2015 will ban the use of cosmetic tanning units. Over time the regulations could be amended to include other controls on non-ionising radiation that may be required, for example through national agreements.

By amalgamating the IR Regulations, Transport Regulations and the Non-Ionising Regulations into one regulation would reduce the regulatory burden for business by having easily accessible regulations.

Draft Radiation Protection and Control Regulations

Part-by-part explanation

Part 1 – Preliminary

The main areas covered in this part are the short title, interpretation and application of the regulations to apparatus and radioactive substances.

Short title

It is proposed that the short title will be amended to Radiation Protection and Control Regulations 2015, if the Transport Regulations and Non-Ionising Regulations are amalgamated with the IR Regulations, otherwise it will be Radiation Protection and Control (Ionising Radiation) Regulations 2015.

Interpretation

The interpretation section has been reviewed to include definitions that are consistent with those in glossaries of the National Directory and relevant National Codes of Practice published by the Chief Executive Officer of ARPANSA, and to update definitions of professions named within the regulations. This is consistent with national consultation which included South Australia. The section has undergone a general revision of definitions of parameters, practices and equipment referenced in the regulations.

The following terms have been amended throughout the regulations:

a. ‘specified employer’ to be replaced with ‘responsible person’
b. ‘radiation safety officer’ to be replaced with ‘responsible person’
c. ‘radiation worker’ to be replaced with ‘occupationally exposed person’
d. ‘designated employee’ to be replaced with ‘occupationally exposed person’
e. ‘mining or milling of radioactive ore’ to be replaced with ‘mining or mineral processing’.

Application of regulations to apparatus

This section has been revised to be consistent with the exempt apparatus listed in Schedule 5 of the National Directory. This is in accordance with national consultation which included South Australia.

Application of regulations to radioactive substances

This section has been revised to adopt the exemption levels for radionuclides prescribed in Schedule 4 of the National Directory. This is consistent with national consultation which included South Australia. The exempt activity concentrations and exempt activities prescribed in the National Directory will be contained in a schedule. The current Schedule 1–Classification of radionuclides into groups will be deleted. The activities for registration of sealed radioactive sources and for registration of type B or C premises will be prescribed in the relevant regulations. The regulation defining radioactive ore has been combined with the application of regulations to radioactive substances section and will be defined in the interpretation section.
Part 2 – Radiation Control

There are currently seven divisions within this part.

Division 1 – General provisions

This division has a proposed new provision for the requirement that the responsible person, who is accountable for the overall radiation protection and safety of a practice under a licence, must implement a radiation management plan (RMP) and, in effect, ensure that a person is available with expert knowledge to perform the duties such as those of a Radiation Safety Officer (RSO). The requirement of an RMP replaces the requirement of a radiation safety manual. The requirements of the RMP are detailed in a new Schedule of the Regulations.

Division 2 – Radiation protection standards and limits

This division has been amended to state the limits consistent with the National Directory and also with national consultation which included South Australia.

Division 3 – Radiation safety officers

This division has been proposed to be removed from the regulations as an alternative provision under Division 1 will be introduced.

Division 4 – Monitoring

This division has been amended to incorporate the exemptions that have been gazetted and to include the requirements for radiation monitoring and dose assessment of occupationally exposed persons.

A new clause has been proposed for the requirement that personal radiation monitoring devices are to be safely and securely stored.

Division 5 – Records, reports and investigations

This division has minor changes in relation to the alteration of personal records. These will only be made when the doses measured should not be attributed to a person’s personal dose record but due to inadvertent exposure of a personal monitoring device when it was not being worn by that person. In such a case the record may be altered and signed off by the responsible person and the occupationally exposed person involved.

A provision for the disclosure of information to ARPANSA for the purposes of the Australian National Radiation Dose Register has been introduced.

A new provision has been proposed for when a practice terminates, such that the responsible person must pass on to the Minister the records of radiation doses received by occupationally exposed persons employed by the responsible person.

A new clause has been proposed for a responsible person to review and investigate exposure of occupationally exposed persons or members of the public to certain doses from exposure to ionising radiation.

Division 6 – Radiation incidents, radiation accidents and radiation emergencies

It is proposed that this division will be re-titled Radiation incidents.

This division has been amended to incorporate the Incident Reporting Framework in the National Directory. A new schedule has been proposed to incorporate the requirements of the National Directory with timeframes for the reporting of radiation incidents. This is in accordance with national consultation which included South Australia.
Division 7 – Medical examinations

This division has a proposed amendment to the requirement for the Minister to direct a radiation worker to undergo a medical examination and remove the requirement for the employer of a designated employee to make arrangements.

Part 3 – Irradiation of humans for diagnostic, therapeutic or research purposes

There are currently two divisions within this part of the regulations.

Division 1 – Diagnostic or therapeutic purposes

In this division the table of persons who may authorise exposure to ionising radiation has been updated to include persons who have been permitted to authorise exposures via exemptions granted, and a review of the profession titles to be consistent with the Health Practitioner Regulation National Law. A new clause has been proposed to ensure the authorisation of diagnostic and therapeutic procedures are justified. This new clause is consistent with national consultation which included South Australia.

The definition of an emergency in regard to authorisations has been proposed, to be inserted in this division to describe the meaning of an emergency in relation to a diagnostic or therapeutic procedure.

Division 2 – Research purposes

This division has been amended to enable research to be conducted without the Minister’s approval, provided the research has been approved and conducted in accordance with the requirements of the Code of Practice for Exposure of Humans to Ionising Radiation for Research Purposes, Radiation Protection Series No. 8, May (2008) published by ARPANSA. This is in accordance with national consultation which included South Australia.

Part 4 – Ionising radiation apparatus

There are currently four divisions within this part of the regulations.

Division 1 – Sale or disposal of apparatus

Within this division there are two minor amendments proposed.

This first amendment is to regulation 51 to state that Form 12 of Schedule 5, Licence to Possess, must be served on the person making the order as well as the previous forms stated in this regulation.

The second amendment is a minor change to the wording of regulation 54 to ensure that if the tube housing or the housing is replaced in medical, dental or veterinary apparatus, a notice of this must be provided to the Minister.

Division 2 – Licence to operate apparatus

This division has been amended to account for the exemptions granted and to expand regulation 57(2)(a) to include a dentist.

The prescribed qualifications under regulation 58 are proposed to be removed and the pre-requisites document currently on the EPA website to be applied.

Division 3 – Registration of apparatus

This division has been amended to include demonstration ionising radiation apparatus as a prescribed class under regulation 60.
Division 4 – Special requirements for apparatus

This division has had significant changes proposed to accommodate new and emerging technology.

The requirements stated in this division for the different apparatus is proposed to be incorporated in EPA codes of compliance or using codes of practice prepared by ARPANSA. The code of compliance will be listed in a new schedule in the regulations. It is a requirement for national adoption of codes and standards under the National Directory and is consistent with national consultation which included South Australia.

The requirements of the code of compliance, prepared by the EPA, are proposed for the following apparatus:

1. Dental cone-beam computed tomography
2. Dental panoramic
3. Dental cephalometric
4. Dental plain radiography
5. Mammography
6. Computed tomography
7. Fluoroscopy
8. Plain Radiography
9. X-ray absorptiometry
10. Cabinet X-ray
11. Industrial radiography
12. Bore hole logging
13. X-ray fluorescence and or diffraction.

The requirements of the code of practice, prepared by ARPANSA, are proposed to be adopted for the following apparatus:

1. Veterinary radiotherapy
2. Fixed radiation gauges.

It is proposed that the requirements for radiotherapy radiation apparatus to be checked for compliance by a certified senior radiation oncology medical physicist.

Part 5 – Radioactive substances

There are currently 13 divisions within this part of the regulations.

Division 1 – Sale of radioactive substances

Within this division there are four proposed amendments.

This first amendment is to regulation 116 to state that Form 12 of Schedule 5, Licence to Possess, must be served on the person making the order as well as the previous forms stated in this regulation.

The International Standards Organisation (ISO) publication has been updated to the most recent publication, ISO 2919:2012 (E). Details of what must be provided on the ISO certificate and a new clause is proposed to ensure the sealed radioactive source has ISO markings.

Regulation 123 has been updated to refer to the Australian Standard AS 3786-1993 Smoke Alarms.
Division 2 – Licence to use or handle radioactive substances

This division has been amended to incorporate the changes required for the adoption of the National Directory exemption levels, exemptions gazetted and other minor changes. This is consistent with national consultation which included South Australia.

Division 3 – Accounting for and storage and labelling of radioactive substances

This division has been amended to include the requirements in the Code of Practice for the Security of Radioactive Sources, Radiation Protection Series No. 11 (2007) published by ARPANSA. This is in accordance with national consultation which included South Australia.

Division 4 – Disposal of radioactive substances

One minor amendment to this division which involves the removal of radioactive ore under regulation 132.

Division 5 – Registration of sealed radioactive sources

This division has been amended to incorporate the changes required for the adoption of the National Directory exemption levels. This is consistent with national consultation which included South Australia.

Division 6 – Special requirements for sealed radioactive sources

This division has the ISO standard amended for the most recent publication.

It is proposed that the requirements for the different uses of sealed radioactive sources will be incorporated in the EPA codes of compliance or will be those contained in codes of practice published by ARPANSA. Both types of codes will be listed in a new schedule in the regulations.

The requirements of the code of compliance, prepared by the EPA, are proposed for the following sealed radioactive sources:

1. Bore hole logging
2. Industrial radiography.

It is proposed that the requirements of the codes of practice, prepared by ARPANSA, and is consistent with national consultation which included South Australia, for the following sealed radioactive sources will be adopted:

1. Radiation gauges
2. Veterinary radiotherapy
3. Density/moisture gauges.

It is proposed that requirements for radiotherapy sealed radioactive sources will be checked for compliance by a certified senior radiation oncology medical physicists.

Division 7 – Registration of premises

This division has been amended to incorporate the changes required for the adoption of the National Directory exemption levels and registrable activity levels for premises as listed within a new schedule of the regulations. This is in accordance with national consultation which included South Australia.
Division 8 – Special requirements for premises

This division has been amended with the premises activity levels for type B and C premises listed in a table within a new schedule of the regulations, Schedule 3–Classification of premises has been amended for the adoption of the National Directory. This is consistent with national consultation which included South Australia.

Division 8A – Licence to test for developmental purposes

This division has been amended with the interpretation under regulation 178A to be moved to the interpretation section and a new clause proposed for the renewal of a licences under Section 23A of the RPC Act.

Division 9 – Licence to carry out mining or mineral processing

This division has been amended for the situations in which operations do not apply under section 24(1) of the RPC Act. The Regulations require a licence for mining or mineral processing based upon an amount being processed. The proposed amendment would not require a licence where sufficient evidence has been provided to demonstrate that occupational radiation exposures would be below the member of public limits, and there would be no unacceptable adverse impacts on the environment.

The definition of a prescribed radioactive substance under regulation 180 will be moved to the interpretation section and Regulations 180A and 184 regarding forms for application for a licence under section 24 will be merged into a single clause.

Division 10 – Facilities licence

This division requires amendments to remove typographical errors in regulation 180B, ie the removal of ‘Bq’ in Regulations 180B(2)(a) and (2)(b).

Division 11 – Licence to possess a radiation source

There are no amendments to be made to this division.

Division 12 – Accreditation of third party service providers

There are no amendments to be made to this division.

Part 6 – Miscellaneous

There are currently two divisions within this part of the regulations.

Division 1 – Use of ionising radiation in schools

This division is proposed to be removed from the regulations as the code of practice has been superseded with a Safety Guide. This is consistent with national consultation which included South Australia. An information sheet will be prepared and placed on the EPA website.

Division 1 – Miscellaneous

Minor amendments within this division include new clauses for Registers of Licences under sections 23A, 29A and 33A of the RPC Act.
Schedules

Schedule 1 – Classification of radionuclides into groups

The existing Schedule 1 will be deleted and replaced by a schedule of Exemption Levels adopted from the National Directory. This is in accordance with national consultation which included South Australia. The schedule will also contain levels for registration of type B and C premises.

Schedule 2 – Radiation Symbol

The radiation symbol in this schedule has been modified to accurately display the angles and dimensions required in the trefoil.

Schedule 3 – Classification of premises

This schedule has been amended due to the proposed changes in Schedule 1 for the adoption of the National Directory exemption levels. This is consistent with national consultation which included South Australia.

Schedule 4 – Fees

The fees for licences to carry out mining or mineral processing (section 24 of the RPC Act) have been amended to a more modular form to include the components of operations and provisions for care and maintenance, and rehabilitation stages, and for future operations where radioactive substances are present but not being significantly concentrated. The current fees do not accommodate changes to operational status including care and maintenance, and rehabilitation.

Schedule 5 – Forms

There has been no change to this schedule.

Schedule 7 – Minimum half value layers for diagnostic apparatus

This schedule is to be removed from the regulations and instead placed in the relevant code of compliance prepared by the EPA.

Schedule 8 – Error distances for automatic collimation to a spot film device

This schedule is to be removed from the regulations and instead placed in the relevant code of compliance prepared by the EPA.

Schedule 9 – Error distances for automatic collimation to an image intensifier

This schedule is to be removed from the regulations and instead placed in the relevant code of compliance prepared by the EPA.

Schedule New – Radiation management plan

The requirements in this schedule have been adapted from the Radiation Protection in Planned Exposure Situations currently in draft form by ARPANSA. This is consistent with national consultation currently in progress including South Australia.

Schedule new – Incident reporting framework

This schedule has been adapted from Schedule 13 of the National Directory and has proposed time levels incorporated for reporting. This is in accordance with national consultation which included South Australia.
Schedule New – List of code of compliance documents

This schedule lists the code of compliance documents prepared by the EPA to stratify the requirements under Part 4 Division 4 and Part 5 Division 5 of the regulations.

Other comments

New part

A new part is proposed for requirements in the regulations that are for both apparatus and radioactive substances. These include:

1. Division 10 – Facilities licence
2. Division 11 – Licence to possess a radiation source
3. Division 12 – Accreditation of third party service.

Transport Regulations

The Transport Regulations are proposed to be amalgamated into the IR Regulations and placed as a new division under radioactive substances. The Transport Regulations will be amended to incorporate the latest Code of Practice published by ARPANSA. This is consistent with national consultation which included South Australia.

Non-Ionising Regulations

The Non-Ionising Regulations are proposed to be amalgamated and placed under a new part in the IR Regulations.

Further information

Legislation

Online legislation is freely available. Copies of legislation are available for purchase from:
Service SA Government Legislation Outlet
Adelaide Service SA Centre
108 North Terrace
Adelaide SA 5000

Telephone: 13 23 24
Facsimile: (08) 8204 1909
Website: <shop.service.sa.gov.au>
Email: <ServiceSACustomerservice@sa.gov.au>

General information

Environment Protection Authority
GPO Box 2607
Adelaide SA 5001

Telephone: (08) 8204 2004
Facsimile: (08) 8124 4670
Freecall: 1800 623 445 (country)
Website: <www.epa.sa.gov.au>
Email: <epainfo@epa.sa.gov.au>