Radiation Safety Regulations 2016

Patsy Reddy, Governor-General

Order in Council

At Wellington this 12th day of December 2016

Present:
The Right Hon Bill English presiding in Council

These regulations are made under sections 91 to 93 of the Radiation Safety Act 2016—

(a) on the advice and with the consent of the Executive Council; and

(b) on the recommendation of the Minister of Health in accordance with sections 91(5) and 92(3) of that Act and after the requirements of section 92(4) of the Act have been satisfied.

Contents

Regulations

1 Title

These regulations are the Radiation Safety Regulations 2016.

2 Commencement

These regulations come into force on 7 March 2017.

3 Interpretation

(1) In these regulations, unless the context otherwise requires,—

Act means the Radiation Safety Act 2016

authorisation means—

(a) a source licence:

(b) a use licence:

(c) a consent

authorisation year, in relation to calculating the fees payable on an application for an authorisation or a renewal of an authorisation, means each 12-month period in the term of the authorisation that is requested by the applicant under regulation 6(2)(g) (*see also* subclause (2))

compliance monitoring category, in relation to a source licence or a renewal of a source licence, means a category set out in column 1 of Schedule 2

health practitioner has the same meaning as in section 5(1) of the Health Practitioners Competence Assurance Act 2003

high-activity radioactive material, in relation to any radioactive material listed in column 1 of Schedule 4, means material with an activity that equals or exceeds the corresponding activity in column 2 of that schedule

inspection period, in relation to calculating the fees payable on an application for a source licence or a renewal of a source licence, means the period determined under regulation 16

low-activity radioactive material means radioactive material that is not high-activity radioactive material

scope of practice has the same meaning as in section 5(1) of the Health Practitioners Competence Assurance Act 2003.

(2) For the purposes of regulations 15 to 19, if the term of the authorisation that is requested by the applicant under regulation 6(2)(g) includes a part of a 12-month period, the number of authorisation years must be rounded up to the nearest whole 12-month period.

Examples

Example 1

The applicant requests that a licence be granted for a period of 8 months. For the purposes of calculating fees, that period is treated as 1 authorisation year.

Example 2

The applicant requests that a licence be granted for a period of 2 years and 3 months. For the purposes of calculating fees, that period is treated as 3 authorisation years.

(3) In these regulations, a reference to the Chiropractic Board, Dental Council, Medical Council of New Zealand, or the Medical Radiation Technologists

Board is a reference to the body of that name that is continued or established under the Health Practitioners Competence Assurance Act 2003.

4 Status of examples

(1) An example used in these regulations is only illustrative of the provisions to which it relates. It does not limit those provisions.

(2) If an example and a provision to which it relates are inconsistent, the provision prevails.

5 Transitional, savings, and related provisions

The transitional, savings, and related provisions (if any) set out in Schedule 1 have effect according to their terms.

Authorisations

6 Information that must be included in applications

(1) This regulation applies to—

(a) an application for an authorisation; and

(b) an application for a renewal of an authorisation.

(2) The application must include the following information:

(a) the applicant's full name:

(b) the address of the applicant's principal place of business:

(c) the particulars of the radiation sources to which the application relates (*see* regulation 7):

(d) in the case of—

(i) a source licence or a renewal of a source licence, the locations (and, if required under regulation 16(4), the sub-locations) from which the applicant will manage or control radiation sources under the source licence:

(ii) any other authorisation or renewal of an authorisation, the places where the radiation sources referred to in paragraph (c) will be dealt with:

(e) in relation to the activities that the applicant will carry out with the radiation sources referred to in paragraph (c),—

(i) the nature of those activities; and

(ii) in the case of a source licence or a renewal of a source licence, the compliance monitoring category that applies under regulation 16 for each location or sub-location:

(f) the applicant's knowledge and experience of radiation safety and security:

(g) the requested period for the authorisation (*see* regulation 8 for the maximum periods for which an authorisation may be granted and regulation 3(2) for a provision that applies if the period includes a part-year).

(3) Subclause (2)(g) does not limit the power of the Director to determine the period for which an authorisation is in force.

7 Particulars of radiation sources

The particulars required under regulation 6(2)(c) are the following particulars of the radiation sources to which the application relates:

(a) in the case of radioactive material,—

(i) the type of radionuclide:

(ii) whether the radiation source is sealed radioactive material or unsealed radioactive material:

(iii) the current activity of the radiation source (or the level of activity on a specified date of measurement):

(iv) the serial number on the radiation source (if any):

(v) the make, model, and serial number of the equipment in which the radiation source is housed (if any):

(vi) the intended use of the radiation source:

(b) in the case of irradiating apparatus,—

(i) the type of apparatus (for example, X-ray equipment, a linear accelerator, or a cyclotron):

(ii) the maximum kilovoltage of the apparatus:

(iii) the make, model, and serial number of the apparatus:

(iv) the intended use of the apparatus.

8 Maximum periods for which authorisations may be granted

(1) The maximum period for which a source licence or use licence may be granted is 3 years.

(2) The maximum period for which a consent may be granted is 1 year.

9 Use licence not required for certain persons when performing specified activities

A person specified in column 1 of Schedule 3 is authorised, for the purpose of section 16(a) of the Act, to perform the activity or class of activity specified for that person in column 2 of Schedule 3.

Exemptions

10 Exemption for dealing with americium-241 in smoke detectors

Every person who deals with americium-241 is, in accordance with section 91(1)(a)(iii)(A) of the Act, exempted from subparts 2 and 3 of Part 1 of the Act in respect of that radiation source if—

(a) the americium-241 is contained in an ionisation chamber smoke detector; and

(b) the level of activity of the americium-241 does not exceed 40 kilobecquerels; and

(c) the americium-241 is not readily accessible without dismantling the smoke detector; and

(d) the smoke detector is clearly labelled with a trefoil symbol and the word "Radioactive".

11 Exemption for dealing with nickel-63 or hydrogen-3 (tritium) in electron capture detectors or similar devices

Every person who deals with nickel-63 or hydrogen-3 (tritium) is, in accordance with section 91(1)(a)(iii)(A) of the Act, exempted from subparts 2 and 3 of Part 1 of the Act in respect of that radiation source if—

(a) the nickel-63 or hydrogen-3 (tritium) is contained in an electron capture detector or a similar device for use in gas chromatography; and

(b) the level of activity,—

(i) in the case of nickel-63, does not exceed 750 megabecquerels:

(ii) in the case of hydrogen-3 (tritium), does not exceed 20 gigabecquerels; and

(c) the source housing is clearly labelled with a trefoil symbol and the word "Radioactive".

12 Exemption for dealing with hydrogen-3 gaseous tritium light sources

Every person who deals with hydrogen-3 is, in accordance with section 91(1)(a)(iii)(B) of the Act, exempted from subparts 2 and 3 of Part 1 of the Act in respect of that radiation source if—

(a) the hydrogen-3 is contained in a gaseous tritium light source; and

(b) the level of activity of the hydrogen-3 does not exceed 74 gigabecquerels; and

(c) at least 98% of the total activity is in the form of elemental hydrogen gas.

13 Exemption for dealing with irradiating apparatus used for X-ray fluorescence or X-ray diffraction

Every person who deals with an irradiating apparatus is, in accordance with section 91(1)(a)(iii)(A) of the Act, exempted from subparts 2 and 3 of Part 1 of the Act in respect of that apparatus if—

(a) the irradiating apparatus is used for X-ray fluorescence or X-ray diffraction; and

(b) the irradiating apparatus is completely and permanently enclosed to prevent access of any part of the body to the primary X-ray beam; and

(c) the enclosure is interlocked with the X-ray generator so that disassembly of the enclosure would prevent the production of X-rays; and

(d) the source is shielded sufficiently to limit the instantaneous dose rate to 2.5 microsieverts per hour at a distance of 5 cm from any accessible point on the surface of the enclosure; and

(e) the enclosure is clearly labelled with a warning to the following effect:

"Do not disassemble. This unit produces ionising radiation when energised."

14 Exemption for radiation sources that temporarily enter New Zealand

Every person who deals with a radiation source (other than nuclear material) is, in accordance with section 91(1)(a)(ii) of the Act, exempted from subparts 2 and 3 of Part 1 of the Act in respect of that radiation source if the source—

(a) temporarily enters New Zealand by a ship or an aircraft; and

(b) is destined to be taken to a place outside New Zealand; and

(c) stays on board the ship or aircraft or is transferred to another ship or aircraft for the purpose of leaving New Zealand.

Fees

15 Fee payable on application for source licence

(1) The fees payable under this regulation are payable for each location (or sublocation) from which the applicant will manage or control radiation sources under a source licence.

Example

On 1 March 2020, an applicant applies for a licence that will cover a location in Auckland and a location in Wellington. Under regulation 6(2)(g), the applicant requests that the licence be granted for 2 years (that is, there are 2 authorisation years). The fees in subclause (2) are payable for each of those authorisation years.

For the Auckland location, an inspection period of 2 years is determined under regulation 16. The fee for that location is $1,436 ($718 × 2).

For the Wellington location, 2 separate sub-locations need to be identified under regulation 16(4). For one of those sub-locations, an inspection period of 3 years is determined. The fee for that sub-location is $1,044 ($522 × 2). For the other sub-location, an inspection period of 4 years is determined. The fee for that sub-location is $844 ($422 × 2).

The total fee payable on applying for the source licence is $3,324 ($1,436 + $1,044 + $844) plus goods and services tax. Section 14 of the Act requires this fee to accompany the application for the source licence.

(2) The fee payable for each authorisation year by a person who applies for a source licence, or a renewal of a source licence, before 7 March 2023 is—

(a) $1,309, if the inspection period is 1 year:

(b) $718, if the inspection period is 2 years:

(c) $522, if the inspection period is 3 years:

(d) $422, if the inspection period is 4 years:

(e) $361, if the inspection period is 5 years.

(3) The fee payable for each authorisation year by a person who applies for a source licence, or a renewal of a source licence, on or after 7 March 2023 is—

(a) $1,505, if the inspection period is 1 year:

(b) $825, if the inspection period is 2 years:

(c) $600, if the inspection period is 3 years:

(d) $485, if the inspection period is 4 years:

(e) $415, if the inspection period is 5 years.

16 Determining inspection period for purpose of calculating fees for source licences

(1) This regulation must be applied to determine the inspection period for the purpose of calculating fees under regulation 15.

(2) This regulation must be applied for each location (or sub-location) from which the applicant will manage or control radiation sources under the source licence.

(3) If all practices carried out from the location are—

(a) fully described in only 1 compliance monitoring category, the inspection period is the period in column 2 of Schedule 2 that applies to that category:

(b) fully described in each of 2 or more compliance monitoring categories, the inspection period is the longest of the periods in column 2 of Schedule 2 that apply to the categories.

Example

The practices to be carried out under a particular licence are fully described in a category that has a 2-year inspection period under Schedule 2.

The practices are also fully described in a separate category with a 4-year inspection period.

The inspection period is 4 years for the purpose of calculating fees.

(4) If there is no single compliance monitoring category that fully describes all practices carried out from the location,—

(a) separate sub-locations must be identified and the practices must be assigned to those sub-locations so that at least 1 compliance monitoring category fully describes the practices carried out from each sub-location; and

(b) subclause (3) must be applied for each sub-location (as if it were a location) to determine the inspection period applicable to each sub-location.

Example

The practices to be carried out at a hospital under a particular licence cannot be fully described by any single category in Schedule 2.

The applicant identifies 2 sub-locations from which the practices are to be carried out (a radiotherapy sub-location and a radiology sub-location).

The inspection period for the radiotherapy sub-location is 1 year because there is a single category (medical therapy) that fully describes all practices to be carried out within that sub-location. The inspection period for the radiology sub-location is 2 years because there is a single category (medical or dental diagnosis) that fully describes all practices to be carried out from that sub-location.

Fees are payable under regulation 15 in respect of both of those sub-locations.

(5) Nothing in these regulations limits the power of the Director to impose a condition on a source licence that provides for a different inspection period from the period that applies under Schedule 2.

17 Fee payable on application for use licence

The fee payable by a person who applies for a use licence, or a renewal of a use licence, is $95 for each authorisation year.

18 Fee payable on application for consent

The fee payable by a person who applies for a consent, or a renewal of a consent, is—

(a) $300, if the consent is for the import or export of high-activity radioactive material on a single occasion:

(b) $80, if the consent is for the import or export of low-activity radioactive material on a single occasion:

(c) $400, if the consent is for the import or export of unsealed radioactive material that is low-activity radioactive material on 2 or more occasions during the period of the consent.

19 Refunds

(1) The Director must refund the whole or a part of a fee that has been paid if—

(a) the Director imposes a condition on a source licence that provides for a longer inspection period than the period that applies under Schedule 2:

(b) the Director imposes a condition on a source licence that provides that no inspection period applies in relation to a location or sub-location:

(c) an application for an authorisation is declined.

(2) In the case of subclause (1)(a), the amount of the refund is the difference between the fee that was paid and the fee that would have been payable using the inspection period that applies under the condition.

(3) In the case of subclause (1)(b), the amount of the refund in respect of a location or sub-location is the difference between the fee that was paid in respect of the location or sub-location and the following amount that is applicable:

(a) $126, if the application is made before 7 March 2023:

(b) $145, if the application is made on or after 7 March 2023.

(4) In the case of subclause (1)(c), the amount of the refund is the whole amount of the fee that has been paid.

20 Fees exclusive of GST

The fees prescribed by these regulations are exclusive of goods and services tax.

Miscellaneous

21 Service of compliance orders

(1) A compliance order that is to be served on a person (**A**) must be served in accordance with Part 6 of the District Court Rules 2014 (applied with all necessary modifications).

(2) If A is an individual, the modifications under subclause (1) include that A's actual or last known postal or electronic address must be treated as an address under rule 6.1(1)(d) of those rules.

22 Form of warrant of appointment of enforcement officer

A warrant of appointment issued to an enforcement officer under section 36 of the Act must be in the form set out in Schedule 5.

Schedule 1
Transitional, savings, and related provisions

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Part 1
Provisions relating to these regulations as made

There are no transitional, savings, or related provisions relating to these regulations as made.

Schedule 2
Compliance monitoring categories and inspection periods

rr 3, 16

Column 1 Compliance monitoring category		Column 2 Inspection period (years)
	Medical	
Medical 1	Medical therapy	1
Medical 2	Medical or dental diagnosis	2
Medical 3	Nuclear medicine	2
Medical 4	Medical diagnosis (excluding interventional radiology, computed tomography, and the use of unsealed radioactive material)	4
Medical 5	Dental diagnosis (excluding cone beam computed tomography)	5
Medical 6	Sentinel node biopsy, low-dose-rate brachytherapy, and bone densitometry	5
	Non-medical	
Non-medical 1	Industrial radiography and any non-medical practice involving high-activity radioactive material	1
Non-medical 2	Production of unsealed radioactive material using a cyclotron	1
Non-medical 3	Any non-medical practice involving irradiating apparatus or low-activity radioactive material or both (excluding industrial radiography and the production of unsealed radioactive material using a cyclotron)	2
Non-medical 4	Any non-medical practice involving irradiating apparatus or low-activity radioactive material that is sealed radioactive material, or both (excluding industrial radiography, veterinary, well logging, and the production of unsealed radioactive material using a cyclotron)	3
Non-medical 5	Veterinary diagnosis (excluding the use of radioactive material)	4
Non-medical 6	Any non-medical practice involving irradiating apparatus or low-activity radioactive material	5

Column 1 Compliance monitoring category	Column 2 Inspection period (years)
that is sealed radioactive material, or both (excluding industrial radiography, veterinary, well logging, nuclear density meters, and the production of unsealed radioactive material using a cyclotron)	

Schedule 3
Use licence not required for certain persons when performing specified activities

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Column 1 Authorised persons	Column 2 Activity or class of activity that may be performed without a use licence
A health practitioner who— (a) is, or is deemed to be, registered with the Medical Council of New Zealand in the scope of practice of diagnostic and interventional radiology; and (b) holds a current practising certificate	Use of irradiating apparatus for medical diagnostic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Medical Council of New Zealand in the scope of practice of radiation oncology; and (b) holds a current practising certificate	Use of irradiating apparatus or radioactive material for medical therapeutic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Dental Council in the scope of practice of general dental practice; and (b) holds a current practising certificate	Use of irradiating apparatus for dental diagnostic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Dental Council in the scope of practice of dental therapy practice; and (b) holds a current practising certificate	Use of irradiating apparatus for taking periapical and bitewing radiographs for dental diagnostic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Dental Council in the scope of practice of dental hygiene practice (with no exclusion in taking extra-oral radiographs); and (b) holds a current practising certificate	Use of irradiating apparatus for taking extra-oral radiographs for dental diagnostic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Dental Council in the scope of practice of dental hygiene practice (with no exclusion in taking intra-oral radiographs); and (b) holds a current practising certificate	Use of irradiating apparatus for taking periapical and bitewing radiographs for dental diagnostic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Dental Council in the scope of practice of orthodontic auxiliary practice (with no exclusion in taking extra-oral radiographs); and (b) holds a current practising certificate	Use of irradiating apparatus for taking extra-oral radiographs for dental diagnostic purposes

Column 1 Authorised persons	Column 2 Activity or class of activity that may be performed without a use licence
A health practitioner who— (a) is, or is deemed to be, registered with the Dental Council in the scope of practice of orthodontic auxiliary practice (with no exclusion in taking intra-oral radiographs); and (b) holds a current practising certificate	Use of irradiating apparatus for taking periapical and bitewing radiographs for dental diagnostic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Dental Council in the scope of practice of endodontic specialist; and (b) holds a current practising certificate	Use of irradiating apparatus for dental diagnostic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Dental Council in the scope of practice of oral and maxillofacial surgery specialist; and (b) holds a current practising certificate	Use of irradiating apparatus for dental diagnostic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Dental Council in the scope of practice of oral medicine specialist; and (b) holds a current practising certificate	Use of irradiating apparatus for dental diagnostic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Dental Council in the scope of practice of oral pathology specialist; and (b) holds a current practising certificate	Use of irradiating apparatus for dental diagnostic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Dental Council in the scope of practice of oral surgery specialist; and (b) holds a current practising certificate	Use of irradiating apparatus for dental diagnostic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Dental Council in the scope of practice of orthodontic specialist; and (b) holds a current practising certificate	Use of irradiating apparatus for dental diagnostic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Dental Council in the scope of practice of paediatric dentistry specialist; and (b) holds a current practising certificate	Use of irradiating apparatus for dental diagnostic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Dental Council in the scope of practice of periodontic specialist; and	Use of irradiating apparatus for dental diagnostic purposes

Column 1 Authorised persons	Column 2 Activity or class of activity that may be performed without a use licence
(b) holds a current practising certificate	
A health practitioner who— (a) is, or is deemed to be, registered with the Dental Council in the scope of practice of prosthodontic specialist; and (b) holds a current practising certificate	Use of irradiating apparatus for dental diagnostic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Dental Council in the scope of practice of public health dentistry specialist; and (b) holds a current practising certificate	Use of irradiating apparatus for dental diagnostic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Dental Council in the scope of practice of restorative dental specialist; and (b) holds a current practising certificate	Use of irradiating apparatus for dental diagnostic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Medical Radiation Technologists Board in the scope of practice of medical imaging technologist; and (b) holds a current practising certificate	Use of irradiating apparatus for medical diagnostic purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Medical Radiation Technologists Board in the scope of practice of nuclear medicine technologist; and (b) holds a current practising certificate	Administration of radiopharmaceuticals and use of irradiating apparatus and radioactive material for nuclear medicine purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Medical Radiation Technologists Board in the scope of practice of radiation therapist; and (b) holds a current practising certificate	Use of radiation sources for the delivery of radiation treatment for medical therapeutic purposes
A veterinarian within the meaning of the Veterinarians Act 2005	Use of irradiating apparatus for veterinary purposes
A health practitioner who— (a) is, or is deemed to be, registered with the Chiropractic Board in the scope of practice of chiropractor; and (b) holds a current practising certificate	Use of irradiating apparatus for chiropractic purposes

Schedule 4
Activity levels

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Column 1 **Radioactive material** **radionuclide**	**Column 2** **Activity level (Bq)**
Am-241	6×10^{11}
Am-241/Be	6×10^{11}
Cf-252	2×10^{11}
Cm-244	5×10^{11}
Co-60	3×10^{11}
Cs-137	1×10^{12}
Gd-153	1×10^{13}
Ir-192	8×10^{11}
Pm-147	4×10^{14}
Pu-238	6×10^{11}
Pu-239/Be	6×10^{11}
Ra-226	4×10^{11}
Se-75	2×10^{12}
Sr-90 (Y-90)	1×10^{13}
Tm-170	2×10^{14}
Yb-169	3×10^{12}
Au-198	2×10^{12}
Cd-109	2×10^{14}
Co-57	7×10^{12}
Fe-55	8×10^{15}
Ge-68	7×10^{12}
Ni-63	6×10^{14}
Pd-103	9×10^{14}
Po-210	6×10^{11}
Ru-106 (Rh-106)	3×10^{12}
Tl–204	2×10^{14}

Schedule 5
Form of warrant

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Warrant of appointment of enforcement officer

Section 36, Radiation Safety Act 2016

(Front of warrant)

Enforcement officer
Warrant of appointment

Full name:

Identification number:

Place of work:

Period of appointment:

[*Photo of warrant holder*]

Signature:

(Back of warrant)

Warrant of appointment issued under section 36 of Radiation Safety Act 2016

This is to certify that the person whose name, photograph, and signature appear on this warrant—

(a) is an enforcement officer appointed under section 36 of the Radiation Safety Act 2016; and

(b) may perform or exercise the following functions, duties, and powers: [*specify*]

The warrant is subject to the following conditions: [*specify conditions imposed under section 36(3) of the Act*]

Date:

Signature:

Director for Radiation Safety

Michael Webster,
Clerk of the Executive Council.

Explanatory note

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations, which come into force on 7 March 2017, prescribe certain matters for the purposes of the Radiation Safety Act 2016 (the **Act**).

The matters include providing for—

- the information that must be included in an application for an authorisation or a renewal of an authorisation under the Act (*see regulations 6 and 7*):
- the fees that are payable when making an application (*see regulations 15 to 20*):
- the maximum periods for which an authorisation may be granted (*see regulation 8*):
- certain persons to perform specified activities without requiring a use licence (*see regulation 9*):
- exemptions from subparts 2 and 3 of Part 1 of the Act. Those subparts relate to the activities that require an authorisation and the register of controlled radiation sources and records (*see regulations 10 to 14*):
- the service of compliance orders (*see regulation 21*):
- the form of warrant of appointment of an enforcement officer (*see regulation 22*).

Regulatory impact statement

The Ministry of Health produced a regulatory impact statement on 1 August 2016 to help inform the decisions taken by the Government relating to the contents of this instrument.

A copy of this regulatory impact statement can be found at—

- http://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-impact-statements/radiation-safety-regulations
- http://www.treasury.govt.nz/publications/informationreleases/ris

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