# Radiation Safety Amendment Regulations 2023

Rt Hon Dame Helen Winkelmann, Administrator of the Government

## Order in Council

At Wellington this 8th day of May 2023

Present:
Her Excellency the Administrator of the Government 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 made after complying with sections 91 and 92 of that Act.

### Contents

## Regulations

### 1 Title

These regulations are the Radiation Safety Amendment Regulations 2023.

### 2 Commencement

These regulations come into force on 28 June 2023.

### 3 Principal regulations

These regulations amend the Radiation Safety Regulations 2016.

### 4 Regulation 3 amended (Interpretation)

(1) In regulation 3(1), definition of **authorisation year**, delete "calculating the fees payable on an application for".

(2) In regulation 3(1), revoke the definition of **inspection period**.

(3) In regulation 3(2), replace "For the purposes of regulations 15 to 19, if" with "If".

(4) In regulation 3(2), examples 1 and 2, replace "For the purposes of calculating fees, that" with "That".

### 5 Regulation 6 amended (Information that must be included in applications)

(1) In regulation 6(2)(d)(i), delete "(and, if required under regulation 16(4), the sub-locations)".

(2) In regulation 6(2)(e)(ii), delete "or sub-location".

### 6 Regulation 13 amended (Exemption for dealing with irradiating apparatus used for X-ray fluorescence or X-ray diffraction)

(1) In the heading to regulation 13, after "**dealing with**", insert "**enclosed**".

(2) In regulation 13, replace "subparts 2 and 3 of Part 1" with "subpart 2 of Part 1".

(3) Replace regulation 13(b) with:

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

### 7 Regulation 15 amended (Fee payable on application for source licence)

(1) In regulation 15(1),—

(a) delete "(or sub-location)"; and

(b) revoke the example.

(2) Replace regulation 15(2) and (3) with:

(2) If a person applies for a source licence, the fee payable in respect of a location in a given compliance monitoring category is,—

(a) for the first authorisation year, the fee specified for the category in column 2 of Schedule 2; and

(b) for each of the second and third authorisation years, if any, the fee specified for the category in column 3 of Schedule 2.

(3) If a person applies for a renewal of a source licence, the fee payable in respect of a location in a given compliance monitoring category, and for each authorisation year, is the fee specified for the category in column 3 of Schedule 2.

**Example**

On 1 March 2024, an applicant applies for a new 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 3 years (that is, there are 3 authorisation years). For each location,—

- the fee under subclause (2)(a) is payable for the first authorisation year; and
- the fee under subclause (2)(b) is payable twice, once for each of the second and third authorisation years.

For the Auckland location, the compliance monitoring category determined under regulation 16 is a category in Schedule 2 that specifies a fee of $1,931 for the first authorisation year and a fee of $1,695 for each other authorisation year. The application fee as it relates to the Auckland location is $5,321 = $1,931 + ($1,695 × 2).

For the Wellington location, 2 separate sub-locations need to be identified under regulation 16(4). For one of those sub-locations, the category determined under regulation 16 has the same fees as for the Auckland location. The application fee as it relates to that sub-location is $5,321. For the other sub-location, the category

determined under regulation 16 is a category in Schedule 2 that specifies a fee of $993 for the first authorisation year and a fee of $757 for each other authorisation year. The application fee as it relates to that sub-location is $2,507 = $993 + ($757 × 2).

So the total fee payable on applying for the source licence is $13,149 ($5,321 + $5,321 + $2,507) plus goods and services tax. Section 14 of the Act requires the fee to accompany the application for the source licence.

## 8 Regulation 16 amended (Determining inspection period for purpose of calculating fees for source licences)

(1) In the heading to regulation 16, replace "**inspection period**" with "**compliance monitoring category**".

(2) In regulation 16(1), replace "inspection period" with "compliance monitoring category".

(3) In regulation 16(2), delete "(or sub-location)".

(4) Replace regulation 16(3) with:

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

(a) fully described in only 1 compliance monitoring category, the location is in that category:

(b) fully described in each of 2 or more compliance monitoring categories, the location is in whichever of those categories has the lowest fees specified in Schedule 2.

**Example**

The practices to be carried out under a particular new licence are fully described in a category in Schedule 2 that specifies a fee of $1,931 for the first authorisation year.

The practices are also fully described in a separate category that specifies a fee of $1,097 for the first authorisation year.

So the location is in a category that specifies a fee of $1,097 for the first authorisation year.

(5) Replace regulation 16(4)(b) with:

(b) subclause (3) must be applied for each sub-location (as if it were a location) to determine which category each sub-location is in; and

(c) each sub-location must be treated as a location under the rest of these regulations.

(6) In regulation 16(4), replace the example with:

**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 radiotherapy sub-location is in the category of medical therapy because that is the single category that fully describes all practices to be carried out from that sub-location. The radiology sub-location is in the category of medical diagnosis (excluding the use of radioactive material) because that is the single category that fully describes all practices to be carried out from that sub-location.

The sub-locations are treated as locations under these regulations and so fees are payable under regulation 15 in respect of both of them.

(7) Replace regulation 16(5) with:

(5) To avoid doubt, this regulation does not limit the power of the Director to—

(a) impose conditions on a source licence as described by regulation 16A(1)(b) or 19(2)(a); or

(b) vary a source licence as described by regulation 19A(1).

### 9 New regulation 16A inserted (Additional fee payable for application for source licence)

After regulation 16, insert:

### 16A Additional fee payable for application for source licence

(1) This regulation applies if—

(a) a person applies for a source licence, or for a renewal of a source licence, in respect of a location in any compliance monitoring category (the **original category**); and

(b) the Director proposes to impose any conditions in relation to the location so that compliance with the radiation safety requirements is monitored on the same basis as for a higher compliance monitoring category.

(2) Before the Director may grant or renew the licence,—

(a) the Director must give written notice to the applicant requiring the payment of an additional fee; and

(b) the applicant must pay the additional fee.

(3) The additional fee is the difference between—

(a) the fee that would have been payable if the location were in the higher compliance monitoring category; and

(b) the fee that was paid in respect of the location.

(4) In this regulation, **higher compliance monitoring category** means a compliance monitoring category for which the fees specified in Schedule 2 are higher than those specified for the original category.

### 10 Regulation 17 replaced (Fee payable on application for use licence)

Replace regulation 17 with:

**17 Fee payable on application for use licence**

(1) The fee payable by a person who applies for a use licence is—

(a) $408, for the first authorisation year; and

(b) $250, for each of the second and third authorisation years, if any.

(2) The fee payable by a person who applies for a renewal of a use licence is $250 for each authorisation year.

**11 Regulation 18 amended (Fee payable on application for consent)**

(1) In regulation 18(a), replace "$300" with "$233".

(2) In regulation 18(b), replace "$80" with "$163".

(3) In regulation 18(c), replace "$400" with "$163".

**12 Regulation 19 replaced (Refunds)**

Replace regulation 19 with:

**19 Partial refund on application for source licence**

(1) This regulation applies if a person applies for the grant or renewal of a source licence in respect of a location in any compliance monitoring category (the **original category**).

(2) The Director must partly refund the fee paid for the application in respect of the location if they—

(a) grant or renew the source licence with any conditions so that compliance with the radiation safety requirements, in relation to the location,—

(i) is monitored on the same basis as for a lower compliance monitoring category; or

(ii) is not monitored; or

(b) decline the application.

*Lower compliance monitoring*

(3) For subclause (2)(a)(i), the amount of the refund is the difference between—

(a) the fee that was paid in respect of the location; and

(b) the fee that would have been payable if the location were in the lower compliance monitoring category.

*No compliance monitoring*

(4) For subclause (2)(a)(ii), the amount of the refund is the difference between—

(a) the fee that was paid in respect of the location; and

(b) either of the following:

(i) $588, if the application is for a source licence:

(ii) $353, if the application is for a renewal of a source licence.

*Declined application*

(5) For subclause (2)(b), the amount of the refund is the difference between—

(a) the fee that was paid in respect of the location; and

(b) either of the following:

(i) $405, if the application is for a source licence:

(ii) $305, if the application is for a renewal of a source licence.

*Meaning of lower compliance monitoring category*

(6) In this regulation and regulation 19A, **lower compliance monitoring category** means a compliance monitoring category for which the fees specified in Schedule 2 are lower than those specified for the original category.

### 19A Partial refund on variation of source licence

(1) This regulation applies if—

(a) the Director varies a source licence in respect of a location in any compliance monitoring category (the **original category**); and

(b) as a result of the variation, the location is in a lower compliance monitoring category.

(2) If there are 1 or more remaining authorisation years, the Director must partly refund the fee paid for the application, in respect of the location, for the most recent grant or renewal of the source licence.

(3) The amount of the refund is the difference between—

(a) the fee that was paid in respect of the location and the remaining authorisation years; and

(b) the fee that would have been payable in respect of the remaining authorisation years if the location were in the lower compliance monitoring category.

(4) In this regulation, **remaining authorisation year** means each of the licence's authorisation years (if any) that has not started when—

(a) the holder requests a variation of the source licence, if the variation results from the request; or

(b) the licence is varied, if the variation is made without a request.

**Example**

A new source licence is granted for a single location for 3 authorisation years. The application fees were $1,931 for the first authorisation year and $1,695 for each other authorisation year. The licence is varied during the first authorisation year, so there are 2 remaining authorisation years. As a result of the variation, the location is in a lower compliance monitoring category. The fees that would have been payable for the second and third years of the lower compliance monitoring category are $861 for each year. The amount of the refund is $1,668, which is the difference between—

- $3,390 = $1,695 × 2; and
- $1,722 = $861 × 2.

The $1,931 fee paid for the first authorisation year is not refunded.

### 19B Refund on application for use licence or consent

The Director must fully refund the fee paid for an application for the grant or renewal of a use licence or a consent if they decline the application.

### 13 Regulation 20 amended (Fees exclusive of GST)

In regulation 20, after "The fees", insert "or other amounts".

### 14 Schedule 1 amended

In Schedule 1,—

(a) insert the Part set out in Schedule 1 of these regulations as the last Part; and

(b) make all necessary consequential amendments.

### 15 Schedule 2 replaced

Replace Schedule 2 with the schedule set out in Schedule 2 of these regulations.

### 16 Schedule 3 amended

In Schedule 3, item relating to a veterinarian within the meaning of the Veterinarians Act 2005, replace "Use of irradiating apparatus for veterinary purposes" with "Use of irradiating apparatus in general radiography for veterinary diagnostic purposes".

# Schedule 1
# New Part 2 inserted into Schedule 1

r 14

## Part 2
## Provisions relating to Radiation Safety Amendment Regulations 2023

### 1 Existing applications

If, before 28 June 2023, a person applied for anything for which a fee was payable under these regulations, the application must be dealt with in accordance with these regulations as they were when the application was made (including in respect of any fees payable or to be refunded).

# Schedule 2
# Schedule 2 replaced

r 15

## Schedule 2
## Source licences: compliance monitoring categories and fees

rr 3, 15, 16, 16A, 19

| Column 1<br>Compliance monitoring category | Column 2<br>Fee for first authorisation year of new authorisation ($) | Column 3<br>Fee for each other authorisation year ($) |
|---|---|---|
| **Medical** | | |
| Medical therapy | 3,744 | 3,508 |
| Medical diagnosis (excluding the use of radioactive material) | 1,931 | 1,695 |
| Nuclear medicine | 1,931 | 1,695 |
| Medical diagnosis (excluding interventional radiology, interventional cardiology, computed tomography, and the use of radioactive material) or dental diagnosis | 1,097 | 861 |
| Dental diagnosis (excluding computed tomography) | 993 | 757 |
| Sentinel node biopsy, low-dose-rate brachytherapy, and bone densitometry | 993 | 757 |
| **Non-medical** | | |
| Industrial radiography, the practice of X-ray irradiation, and any non-medical practice involving high-activity radioactive material | 3,744 | 3,508 |
| Production of unsealed radioactive material using a cyclotron | 3,744 | 3,508 |
| Any non-medical practice involving irradiating apparatus or low-activity radioactive material, or both (excluding industrial radiography using radioactive material, X-ray irradiation, and the production of unsealed radioactive material using a cyclotron) | 1,931 | 1,695 |
| Any non-medical practice involving irradiating apparatus or low-activity radioactive material that is sealed radioactive material, or both (excluding industrial radiography, X-ray irradiation, the production of unsealed radioactive material using a cyclotron, veterinary diagnosis or practice, well logging, and the use of particle accelerators) | 1,328 | 1,092 |
| Veterinary diagnosis (excluding the use of radioactive material) | 1,097 | 861 |
| Any non-medical practice involving irradiating apparatus (excluding industrial radiography, X-ray irradiation, veterinary diagnosis or practice, well logging, the use of particle accelerators, human imaging, and the use of pulse-generated portable security inspection systems) | 993 | 757 |

Rachel Hayward,
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 amend the Radiation Safety Regulations 2016 (the **principal regulations**). The amendments come into force on 28 June 2023. This note refers to the numbered regulations and other parts of the principal regulations.

## *Exemption for enclosed irradiating apparatus used for X-ray fluorescence or X-ray diffraction*

In regulation 13, the exemption for dealing with enclosed irradiating apparatus used for X-ray fluorescence or X-ray diffraction is amended—

- so that a person is exempted from only subpart 2 of Part 1 of the Radiation Safety Act 2016 (activities that require authorisation), not also subpart 3 (register of controlled radiation sources and records); and
- to require the irradiating apparatus to be enclosed only while the primary X-ray beam is activated.

## *Fees for source licences*

In regulations 15 and 16 and *new Schedule 2*, the fee payable on application for a source licence (including a renewal) is now based on the fees specified for the relevant compliance monitoring category, with no reference to an inspection period. Some of the compliance monitoring categories are changed. The fee for the first authorisation year of a new source licence is now greater than the fee for—

- its second and third authorisation years, if any; or
- any authorisation year of a renewed source licence.

All of those fees are increased.

*New regulation 16A* imposes an additional fee for an application for a source licence (including a renewal) if conditions are to be imposed so that compliance is monitored on the same basis as for a higher compliance monitoring category.

## *Partial refunds of fees for source licences*

*New regulation 19*, like the former regulation 19, deals with the refund of the application fee for a source licence (including a renewal). If the licence is granted or renewed with conditions so that compliance—

- is monitored on the same basis as for a lower compliance monitoring category, the partial refund is now based on the fee specified for that category, with no reference to an inspection period; or
- is not monitored, the partial refund is based on retention of an increased amount.

If the application is declined, the refund is now partial.

*New regulation 19A* provides for the partial refund of the fee paid for the application for a source licence (including a renewal) if—

(a) the licence is varied and a lower compliance monitoring category applies; and

(b) the licence still has 1 or more full authorisation years to run.

### *Use licences and consents*

In *new regulation 17*, the fee for the first authorisation year of a new use licence is now greater than the fee for—

- its second and third authorisation years, if any; or
- any authorisation year of a renewed use licence.

All of those fees are increased.

In regulation 18, the fees payable on application for a consent (including a renewal) are—

- increased for the import or export of low-activity radioactive material on a single occasion; but
- decreased otherwise.

*New regulation 19B* continues the effect of former regulation 19 on use licences and consents. There is still a full refund if the relevant application is declined.

### *Activity for which veterinarian does not require use licence*

In Schedule 3, the activity for which a veterinarian does not require a use licence is further confined.

### *Existing applications*

*New Part 2 of Schedule 1* applies the principal regulations, without the amendments made by these regulations, to any existing applications.

## Regulatory impact statement

The Ministry of Health produced a regulatory impact statement on 19 September 2022 to help inform the decisions taken by the Government relating to the contents of this instrument.

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

- https://www.health.govt.nz/about-ministry/information-releases/regulatory-impact-statements
- https://treasury.govt.nz/publications/informationreleases/ris

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