

Review of Radiation Safety Regulations 2016

A consultation document

2022

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Introduction

We want your input

The Ministry of Health (the Ministry) is seeking public submissions on the review of the Radiation Safety Regulations 2016¹ (the Regulations) by 12 pm Friday 29 April 2022. Submissions must relate to the Regulations as outlined in sections 91 to 93 of the Radiation Safety Act 2016² (the Act) in order to be considered within the scope of this consultation. We will consider all submissions that are in scope and that we receive before the submission deadline.

You can find guidelines for making a submission in the submission form published alongside this consultation document. The submission form also repeats the consultation questions found throughout this consultation document to help submitters complete the submission process. Submitters do not have to use the submission form to make a submission, or if they do use it, they can choose to answer only those questions they wish to answer.

Radiation Safety Regulations 2016

The Regulations came into force on 7 March 2017. They are made in accordance with sections 91 to 93 of the Act.

The Regulations and the Act apply to organisations and people who **deal with** ionising radiation only. Ionising radiation sources are defined in the Act as being radioactive material that can produce ion pairs in biological material or irradiating apparatuses (electrical equipment) that can generate ionising radiation (such as X-ray machines). Therefore, this regulation review does not affect the regulation of non-ionising radiation, such as ultraviolet (UV) light, Wi-Fi, cell phone communication systems, microwave technologies, radio waves and other types of electromagnetic fields.

The Regulations set out the fees payable under the Act, the exemptions, prohibitions and restrictions that can be applied, as well as other administrative matters.

¹ Available on the New Zealand Legislation website:
www.legislation.govt.nz/regulation/public/2016/0303/latest/whole.html#DLM7049344.

² Available on the New Zealand Legislation website:
www.legislation.govt.nz/act/public/2016/0006/latest/whole.html#DLM6339517.

Relevant information on establishing the Regulations in 2016 is available from the original Ministry of Health consultation document *Proposed Radiation Safety Regulations: A consultation document*.³ The 2016 Regulatory Impact Statement for the Regulations (2016 RIS) provides further information on the Regulations.⁴

Fees and Regulations review 2021

The Regulations are being reviewed because the 2016 RIS identified a need for a review within six years. In particular, a review was required to consider the current 13 percent discount on source licence fees, which applies until March 2023 as a result of regulation 15(2) of the Regulations. The discount was originally applied to correct the historical over collection of fees under the previous radiation protection legislation. The review also aims to test the assumptions made about the costs of the regulatory framework and the level of licence fees when the 2016 RIS was prepared.

In addition, the Office of the Auditor-General's Good Practice Guideline *Charging Fees for Public Sector Goods and Services*⁵ advises that a review of fees set in the public sector should be conducted every three years. Further, in The Treasury publication *Guidelines for Setting Charges in the Public Sector [2017]*.⁶ The Treasury advises that 'cost-recovery frameworks should be 'living' regimes that are reviewed regularly to ensure that they are operating efficiently and that over-recovery or under-recovery is minimised'. The Treasury guidelines also recommend that fees be reviewed every three to five years.

About this document

In preparing this consultation document, the Ministry reviewed the objectives set out in section 19 of the 2016 Regulatory Impact Statement (RIS) and concluded that the objectives remain relevant in 2021. On this basis, the consultation document is designed to test whether the Regulations *continue* to meet the objectives of the 2016 RIS.

³ Ministry of Health. 2016. *Proposed Radiation Safety Regulations: A consultation document*. Wellington: Ministry of Health. URL: www.health.govt.nz/publication/proposed-radiation-safety-regulations-consultation-document (accessed 8 October 2021).

⁴ Ministry of Health. 2016. Regulatory Impact Statement – Radiation Safety Regulations. Wellington: Ministry of Health. URL: www.health.govt.nz/about-ministry/information-releases/regulatory-impact-statements/radiation-safety-regulations (accessed 8 October 2021).

⁵ The Office of the Auditor-General New Zealand. 2008. *Good Practice Guide: Charging Fees for Public Sector Goods and Services*. Wellington: Controller and Auditor-General. URL: www.oag.parliament.nz/2008/charging-fees/docs/charging-fees.pdf (accessed 8 October 2021).

⁶ The Treasury. 2017. *Guidelines for Setting Charges in the Public Sector [2017]*. Wellington: The Treasury. URL: www.treasury.govt.nz/publications/guidance/planning/charges (accessed 8 October 2021).

In summary, the 2016 RIS objectives are for the Regulations to:

- prescribe the operational necessities required to support the Act
- regulate the use of radiation sources in an appropriate way, by meeting the principles of:
 - proportionality – applying a graded approach so that the full range of risks and varying uses of ionising radiation can be managed appropriately
 - simplicity – creating a straightforward, usable framework that avoids the burden of unnecessary administrative or compliance requirements
 - certainty in cases where this is necessary – such as by including specifying requirements in appointment warrants and compliance orders
 - full cost recovery arising from administering authorisations and verifying compliance
 - ensuring fees recovered reflect the statutory principles of equity, efficiency, justifiability, transparency and ease of administration.

In testing whether the Regulations continue to support the Act adequately, we can confirm that the scope of the Regulations remains fit for purpose: no regulatory gaps have been identified, and no unnecessary or burdensome regulation has come to light. In this respect, no additional regulations or repeals are proposed in this consultation document. Therefore, we do not intend to make any changes to existing radiation safety policy.

In testing whether the Regulations continue to reflect the principle of proportionality, the consultation document outlines two areas where improvements could be made. Firstly, small changes could be made to better group radiation activities that present similar levels of risk into the same compliance monitoring category (and the same routine inspection period). This is discussed further in section 2.3 of this consultation document. Secondly, safety risks could be managed better by requiring a category of currently exempted, very-low-risk irradiating apparatuses to be registered under the Act. This would also require records to be kept and made available for inspection should this be required. Section 4.1 of this document discusses this further.

Section 2.4 discusses whether the Regulations continue to reflect the principles of simplicity and certainty and outlines that the means for determining the fees payable for source licences could be amended to make the Regulations easier to use. However, no changes to the existing approach to determining the source licence fee payable are being proposed.

Section 1 considers whether the Regulations continue to meet the objective of full cost recovery and present the findings of the Ministry's fees review. The fees review has found that the current fees significantly under-recover the current costs of regulating radiation safety. These sections also provide information on setting new fees to achieve full cost recovery. Every attempt has been made to provide full information on costs and fee distributions to demonstrate equity, efficiency, justifiability, transparency and ease of administration. The method used to calculate the proposed new fees has been reviewed by the accounting firm PricewaterhouseCoopers New Zealand (PwC).

Submitters can view PwC's report on the Ministry's website.⁷ The proposed new fees, compared to the existing fees, are set out in Appendix 1.

This consultation document presents only the matters identified in the review of the fees and the Regulations. It does not discuss all the matters that can possibly be dealt with in the Regulations – that is, any matters set out in sections 91 to 93 of the Act. Section 5 deals with the scope of other matters that can be dealt with in the Regulations.

While this consultation document sets out preferred options, it also includes status quo (no changes) and alternative options where feasible. This is a standard approach. The options are presented in this way to promote discussion: no decisions have been made at this stage of the process. Discussion points are presented based on topic areas and do not follow the order of provisions in the Regulations or in the Act.

The Ministry is satisfied that the fees and cost recovery information provided in this consultation document and PwC's report considers, as far as is reasonably practicable, the principles of equity, efficiency, justifiability, transparency and ease of administration as required under section 92(3) of the Act and provides sufficient information as required by section 92(4) of the Act.

The Ministry is satisfied that a six-week public consultation on the matters raised in this consultation document followed by due consideration of all in-scope submissions received would constitute appropriate consultation and provide sufficient time for submitters to provide their response as required by section 92(4) of the Act.

The Ministry has reviewed the consultation document and confirms that it can substitute for an interim RIS, can lead to effective consultation and can support the eventual development of a quality RIS.

All fees quoted in this consultation document are exclusive of goods and services tax (GST).

Definitions

This consultation document uses technical and scientific terms derived from the Regulations and the Act. To make the document more useful, these terms have been

⁷ PricewaterhouseCoopers New Zealand. 2021. *ORS Fees Model Test*. Wellington: Ministry of Health. URL: <https://www.health.govt.nz/publication/review-radiation-safety-fees-and-regulations> (accessed 16 March 2022).

highlighted in bold on their first mention and are also defined in Table 1 below. The definitions in Table 1 should be used only for the purposes of this specific consultation.

Table 1: Definitions of technical and scientific terms used in this consultation document

Term	Definition	Use in the Regulations and/or the Act
Authorisation	A source licence, use licence or consent	s5(1)
Authorisation year	In relation to calculating the fees payable on an application for an authorisation or a renewal of an authorisation, 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))	r3(1)
Codes of practice	These specify technical requirements that a person who deals with a radiation source must comply with in order to comply with the fundamental requirements	s86
Compliance monitoring category	In relation to a source licence or a renewal of a source licence, a category set out in column 1 of schedule 2 of the Regulations	r3(1)
Compliance verification	The process of monitoring compliance with the radiation safety requirements in the Act	s37
Consent	An authorisation to import or export radioactive material	s5(1)
Deal with	Manufacture, possess, control, manage, use, transport, store, export, import, sell, supply or dispose of a radiation source or carry out any other activity or practice involving the radiation source	s5(1)
Director	The person appointed as the Director for Radiation Safety under section 76 of the Act.	s76
Effective dose	The tissue-weighted sum of equivalent doses (the radiation-weighted dose in a tissue or organ of the body) in all specified tissues and organs of the body	s5(1)
High-activity radioactive material	In relation to any radioactive material listed in column 1 of schedule 4 of the Regulations, material with an activity that equals or exceeds the corresponding activity in column 2 of that schedule	r3(1)
Inspection period	In relation to calculating the fees payable on an application for a source licence or a renewal of a source licence, the period determined under regulation 16	r3(1)
Irradiating apparatus	Electrical equipment that is designed to generate ionising radiation, such as X-rays, neutrons, electrons or other charged particles, or that produces ionising radiation as a by-product that results in a dose-equivalent rate of or exceeding 1 microsievert per hour at a point 0.1 metres from any accessible surface and that has a maximum energy of or exceeding 5 kiloelectronvolts	s5(1)
Low-activity radioactive material	Radioactive material that is not high-activity radioactive material as defined above	r3(1)

1 Fees review and findings

1.1 Fees model, assumptions and methodology

The Ministry undertook a review of the fees payable under the Regulations in December 2020. The review aimed to test whether the objectives set out in the 2016 Regulatory Impact Statement (2016 RIS) for the Regulations⁸ were being met. As well as providing information for this consultation, section 1 can also be considered the report of the fees review.

The review found that the full cost recovery objectives of the 2016 RIS are not being met and have not been met at any time since the fees came into force in 2017.

On this basis, we propose new fees that are set out below. The fees model and methodology for calculating the proposed new fees have been reviewed by PricewaterhouseCoopers New Zealand (PwC). PwC's report is available on the Ministry's website.⁹

The proposals set out in this consultation document are made on the assumption that proposed new fees will be put in place in 2022.

1.2 Costs of regulating

The costs of regulating radiation safety have increased significantly since 2017. The projected direct costs of administering the Act from 2022 include higher staff costs and new operating costs associated with new information technology use. Projected contracted **compliance verification** activities (mostly on-site inspections) have increased due to staff costs. Contracted technical evaluation is projected to decrease slightly from 2022. The annual costs used to set fees in 2017 compared with the projected costs from 2020 are set out in Table 2.

⁸ Ministry of Health. 2016. *Regulatory Impact Statement – Radiation Safety Regulations*. Wellington: Ministry of Health. URL: www.health.govt.nz/about-ministry/information-releases/regulatory-impact-statements/radiation-safety-regulations (accessed 8 October 2021).

⁹ PricewaterhouseCoopers New Zealand. 2021. *ORS Fees Model Test*. Wellington: Ministry of Health. URL: <https://www.health.govt.nz/publication/review-radiation-safety-fees-and-regulations> (accessed 16 March 2022).

Table 2: Annual costs of regulating radiation safety: 2017 compared with projected costs from 2022

	2017	2022	\$ increase	% increase
Direct costs of administering the Act	\$450,000	\$1,038,778	\$588,778	131%
Contracted compliance verification (on-site inspections)	\$887,700	\$1,368,997	\$481,297	54%
Contracted technical evaluation	\$100,000	\$82,670	-\$17,330	-17%
Totals	\$1,437,700	\$2,490,445	\$1,052,745	73%

1.3 Fees take since 2017

The number of authorisations granted compared with the number of authorisations projected in 2017 (before the new legislation was put in place) is lower than was projected. The figures are set out in Table 3.

Table 3: Comparison of actual authorisations granted with projected authorisations

	2017 projected	2021 actual	Shortfall	% shortfall
Source licences	2,458	2,357	101	4%
Use licences	1,660	1,137	523	32%
Consents	272	196	76	30%

It took longer to move the existing licences from the previous radiation protection regime onto the new authorisations regime than was projected in 2017. As a result, fewer fees have been taken than was projected (see Table 4 below).

Table 4: Revenue and expenses for regulating radiation safety

Financial year ending 30 June	Projected fees take (discounted fees)	Revenue	Expenses	Deficit	Memorandum account balance
2016	–	–	–	–	\$1,019,000
2017	\$1,270,000	\$582,000	\$970,000	\$388,000	\$631,000
2018	\$1,270,000	\$1,126,000	\$1,359,000	\$233,000	\$398,000
2019	\$1,270,000	\$1,034,000	\$1,536,000	\$502,000	-\$104,000
2020	\$1,270,000	\$956,000	\$1,527,000	\$571,000	-\$675,000
2021	\$1,270,000	\$928,000	\$1,670,000	\$742,000	-\$1,417,000
Estimated 2022	–	–	–	–	-\$1,600,000

Expenses shown in Table 4 do not include the proposed information technology operating costs or funding uplift (increased costs) for on-site inspections proposed to take effect from 1 July 2022.

1.4 Memorandum account

Background

Currently, a 13 percent discount applies to the source licence fees payable, as set out in regulation 15(2). This discount applies until 7 March 2023, when source licence fees are due to increase as set out in regulation 15(3). The discount was applied to source licence fees in order to return to source licence holders a historical overtake in fees (a positive memorandum account balance) from the radiation protection regime that operated up until 2017.

In addition to the increased costs discussed in section 1.2 above, it took longer than expected to implement the new source licencing provisions of the Act in 2017 and 2018 and, as a consequence, less fees were taken. Also, a slightly lower than expected number of authorisations have been granted since 2017. All of these factors have combined to ensure that the memorandum account balance was very quickly refunded and now has an unrecoverable negative balance. The projected memorandum account for 30 June 2022 is negative \$1.6 million. The memorandum account balance in 2017 and the projected memorandum account balance for 2022 are set out in Table 5 below.

Table 5: Memorandum account balance 2017 and projected balance for 2022

	2017	2022	\$ decrease	% decrease
Memorandum Account	\$973,000	-\$1,600,000	\$2,573,000	264%

The memorandum account balance is projected to reach minus \$1.6 million by 30 June 2022 on current trends.

Status quo option

The status quo option is to continue operating a deficit in the annual fees take of around \$487,000 per year (on average). This annual operating deficit would grow if regulatory costs increased, and the memorandum account balance would also continue to grow. This is not recommended due to The Treasury's expectation in its *Guidelines for Setting Charges in the Public Sector [2017]*¹⁰ that '... the balance of each memorandum account will trend towards zero over a reasonable period of time ...'. Also, this option does not meet the principle of full cost recovery set out in the 2016 RIS prepared for the Regulations. Therefore, the status quo option is not viable if full cost recovery is to remain the aim of fees taken under the Regulations. On this basis, new fees must return the fees take to full cost recovery, and the proposals outlined in this consultation document assume full cost recovery is the aim.

¹⁰ The Treasury. 2017. *Guidelines for Setting Charges in the Public Sector [2017]*. Wellington: The Treasury. URL: www.treasury.govt.nz/publications/guidance/planning/charges (accessed 8 October 2021).

Arguments for retaining an ongoing deficit in fees take would, in effect, constitute adopting a partial fees recovery model. This matter is discussed more fully in section 1.6 of this consultation document.

Preferred option

To address the memorandum account balance, it is proposed that a \$200,000 per year premium be applied to the overall source licence fees take. This approach would recover the projected \$1.6 million (achieve a zero-memorandum account balance) by 2030.

The proposal to apply the premium to source licence fees only arises from the fact that the current 13 percent discount on fees applies only to source licence fees. In addition, source licence holders have been the only beneficiaries of the slower than expected issuing of source licences under the new regime. Therefore, source licence holders have benefited most from the undertake in fees since 2017.

A 9.22 percent premium added to the full fee for source licences, to be applied over the eight years to 2030, would add the required 200,000 per year.

The Ministry's view is that as source licence holders have benefited most from the fees undertake since 2017 and it is both justifiable and equitable that the memorandum account premium be applied to the fees payable by source licence holders.

Alternative option

A slightly lower percentage premium could be applied to all proposed fees to meet the aim of moving the memorandum account towards zero after eight years.

The Ministry's view is that this option would require some justification for recovering the memorandum account balance from all authorisation holders whether or not they received a discount on the fees payable from 2017. The Ministry is not aware of such a justification.

Consultation questions

- 1 Do you think the preferred option of recovering the negative memorandum account balance from source licence holders only over a period of eight years is justifiable and equitable?
- 2 If you think the preferred option of recovering the memorandum account deficit from source licence holders only over a period of eight years is **not** justifiable or equitable, please outline your reasons.
- 3 Do you think the alternative option of recovering the negative memorandum account balance from all authorisation holders is a better option? Please outline your reasons.
- 4 Do you think the negative memorandum account balance should be recovered over a longer or shorter period? If yes, please state whether it should be longer or shorter and outline your reasons.
- 5 Do you have an alternative method for addressing the positive memorandum account balance?
- 6 Do you have any further comments, suggestions or options for us to consider?

Please use the submission form to respond to these questions.

1.5 Recoverable costs

Background

The total costs of regulating and the memorandum account balance combine to determine the recoverable costs. The projected annual recoverable costs from 2022 are set out in Table 6.

Table 6: Projected annual recoverable costs under the Radiation Safety Act 2016

	2017	2022	\$ increase	% increase
Totals costs of regulating	\$1,437,700	\$2,490,445	\$1,052,745	73%
Memorandum account balance	-\$162,000	\$200,000	\$362,000	223%
Recoverable costs	\$1,275,700	\$2,690,445	\$1,414,745	111%

1.6 Cost recovery model

Background

Section 92(2)(b) of the Act provides for the recovery of direct or indirect Ministry costs in verifying authorisations holders' compliance with the radiation safety requirements. Also, section 92(3) of the Act requires that the principles of equity, efficiency, justifiability, transparency and ease of administration be considered, as far as is feasible, in determining the most appropriate method of cost recovery. The 2016 RIS for the Regulations identified full cost recovery as the model for setting fees, and the current fees were set on a full cost recovery basis.

Preferred option (the status quo option)

The preferred option is the status quo option, that is, a full cost recovery model be retained. The Ministry's view is that the recoverable costs are both actual and reasonable.

Alternative option

In some circumstances, full cost recovery can lead to a situation where the cost recovery regime undermines the policy objectives. In such circumstances, it may be appropriate to set charges below full cost recovery in order to achieve the purposes of legislation; for example, where the purpose of legislation is to provide social benefits (such as the safe use of radiation) or access to justice. The Ministry's view is that there is not sufficient justification in this situation to set charges below full cost recovery (that is, a partial cost recovery model). This view considers both the scale of the proposed new overall fees take and the implications of assigning the fees to individual authorisation types (in accordance with the associated costs) as proposed in the consultation document.

A partial fees recovery model would need to consider the principles of equity, efficiency, justifiability, transparency and ease of administration in the way that these matters are set out in section 92(3) of the Act. In addition, any arguments for partial fees model under the Regulations would also need to consider the needs to protect the health and safety of people and the environment and New Zealand's international obligations around radiation protection, safety, security and nuclear non-proliferation in the way that these matters are set out in section 3 (Purposes) of the Act.

An argument for a partial cost recovery model is within scope of this consultation and, therefore, we will consider any submissions received on this matter (including submissions on a zero-cost recovery model).

Consultation questions

- 7 Do you think it is reasonable to recover the full costs stated in fees?
 - 8 If you think it is unreasonable to recover the full costs stated in fees, please provide your reasons. Please also identify what costs should **not** be recovered and who should meet the unrecovered costs.
 - 9 Do you have any further comments, suggestions or options?
- Please use the submission form to respond to these questions.

1.7 Distribution of fees

Background

Assuming full-cost recovery, fees should be set to take \$2,690,445 annually. Table 7 sets out the proposed annual distribution fees based on where costs are generated.

Table 7: Proposed annual distribution of fees

Authorisation type	Projected numbers	Application assessment	Compliance monitoring	Technical evaluation	Memorandum account	Total	Percent
Source licence (new and variations)	117	\$53,070	\$67,902	\$10,382	\$12,242	\$143,596	5.34%
Source licence (renewals no variation)	2,240	\$683,063	\$1,301,095	\$39,451	\$187,758	\$2,211,367	82.19%
Use licence (new and variations)	114	\$36,336	\$0	\$10,016	\$0	\$46,352	1.72%
Use licence (renewals, no variation)	1,023	\$237,838	\$0	\$18,029	\$0	\$255,867	9.51%
Consents (high-activity)	19	\$2,760	\$0	\$1,674	\$0	\$4,434	0.16%
Consents (low-activity)	172	\$24,985	\$0	\$3,030	\$0	\$28,015	1.04%
Consents (unsealed multi-event)	5	\$726	\$0	\$88	\$0	\$814	0.03%
Totals	3,690	\$1,038,778	\$1,368,997	\$82,670	\$200,000	\$2,690,445	–

The projected costs on which fees were calculated in 2017 have been found to be slightly lower than expected for consents and slightly higher than expected for use licences. Source licence projected costs in 2017 have been found to be distributed as projected, as set out in Table 8.

Table 8: Current percentage distribution of fees compared with proposed percentage distribution

	2017 (current)	2022 (proposed)
Source licences	87%	87.53%
Use licences	11%	11.23%
Consents	2%	1.24%

Preferred option (and status quo option)

The preferred option for distributing fees across the authorisation types is to assign the fees based on where the costs are generated. This is the same method that was applied when the fees first came into force in 2017. Therefore, the preferred option is also the status quo option.

Alternative option

Any alternative option would require the distribution of fees to be altered from where the costs are generated. That is, one authorisation type would be subsidising another authorisation type (cross-subsidising).

Cross-subsidisation would need to be justified and follow the principles of equity, efficiency, justifiability, transparency and ease of administration as outlined in section 92(3) of the Act. In addition, any arguments for a cross-subsidised model under the Regulations would need to protect the health and safety of people and the environment and meet any international obligation New Zealand around radiation protection, safety, security and nuclear non-proliferation in the way that these matters are set out in section 3 (Purposes) of the Act.

An argument for a cross-subsidisation model is within scope of this consultation, and therefore, any submissions received on this matter will be considered.

Consultation questions

- 10 Do you think it is reasonable to distribute fees across the authorisation types based on where the costs are generated?
- 11 If you think it is unreasonable to distribute fees across the authorisation types based on where the costs are generated, please provide your reasons. Please also identify how the fees could be better distributed and provide your reasons.
- 12 Do you have any further comments, suggestions or alternative options?
Please use the submission form to respond to these questions.

2 Proposed changes to fees structure

2.1 Different fees for licence renewals

Background

Applications for renewing existing licences are processed under section 28 of the Act. Applications for variations to the scope or conditions of an existing authorisation are processed under section 27 and applications for new authorisations are processed under sections 19 (source licences), 22 (use licences) and 24 (consents).

Consents granted under the Act are considered to expire at the export or import for which they are granted or at the end of the period for which they are granted. Therefore, consents are not renewed and will always be processed as new applications.

The fees review has identified that there is a differential in the effort required to process applications for new licences and variations to existing licences compared with the effort required to renew an existing licence without variation. There is also a differential in the technical evaluation commissioned to assess applications for new or varied licences compared with renewals without variation.

A differential in technical evaluation required for different types of consent applications was also identified. Table 9 sets out the assessed differentials.

Table 9: Assessed differentials in effort required to administer applications

Application type	Application processing (minutes – average)	Technical evaluation (request volumes ratio)
Source licence (new and variations)	155	5
Source licence renewals (no variation)	105	1
Use licence (new and variations)	110	5
Use licence renewals (no variation)	80	1
Consents (high-activity)	50	5
Consents (low-activity)	50	1
Consents (low-activity unsealed multi-event)	50	1

The differences in effort arises from the fact that applications for renewals have received scrutiny, including consideration of any additional information required, when they were first granted (as new applications). Regulatory staff also have the benefit of compliance verification history to help them determine renewal applications.

Status quo option and alternative option

Both the status quo option and the alternative option are to retain the current fee structure. This would retain the current single fee for source licences (in each compliance monitoring category) and a single fee for use licences regardless of whether the application is new, for a variation or for a renewal.

Preferred option

The preferred option is to adopt lower fees in proportion to the differential effort outlined in Table 9 above. The lower fee would apply only to applications to renew existing licences where no variation is sought in the application. Applications for new licences or variations to the scope or conditions of an existing licence would retain a fee proportionate to the (higher) effort required to process these applications. The difference in the effort required to process applications justifies differential fees. This option would help the Regulations better achieve the objectives set out in the 2016 RIS for proportionality, equity, efficiency and transparency.

Consultation questions

- 13 Do you agree that it is justifiable to charge differential application fees because of the difference in effort required to process applications?
 - 14 If you do not agree that differential fees are justifiable, please provide your reasoning.
 - 15 Do you have any further comments, suggestions or alternative options?
- Please use the submission form to respond to these questions.

2.2 Refunds

Background

Regulation 19 requires the Director for Radiation Safety (the Director) to refund the whole or a part of a fee that has been paid when:

- the Director imposes a condition on a source licence that provides for a longer inspection period than the period that applies under Schedule 2; or
- the Director imposes a condition on a source licence that provides that no inspection period applies in relation to a location or sub-location; or
- an application for an authorisation is declined.

Status quo option

The status quo option would mean that the retained portion of application fees set out in section 19(3) of the Regulations (\$126 or \$145), for situations where a source licence is granted with no inspection period, would remain in place. These fees relate to the assessed costs of processing the applications at the time they came into force in 2017. The assessed costs of processing applications for source licences are now higher. Also, the retained portion of application fees has never recovered the costs associated with any technical evaluation of the applications. Therefore, the status quo option does not recover the full cost of assessing applications in the case of a source being granted without an inspection period and, therefore, does not fully meet the objectives of the 2016 RIS for the Regulations.

This affects just four current source licence holders, and policy is in place to ensure that this number remains as low as practicably achievable.

The status quo option would also retain the existing provision for a full refund of source licence applications fees in the case of an application being declined. Declined applications must be assessed and therefore have associated costs. The status quo option has never recovered these costs and, therefore, this provision also does not fully meet the objectives of the 2016 RIS.

Preferred option

Refunds are amended as a consequence of the proposed new fees set out in Table 17 to follow.

Source licences

In the case of regulation 19(2) (licence granted with longer inspection period), no changes will be required as the formula to calculate the refund will continue to derive the correct amount of refund.

In the case of regulation 19(3) (licence granted with no inspection period), the amount of the application that is proposed to be retained by the Ministry will rise to:

- \$588 for a new source licence application or an application to vary an existing source licence granted without an inspection
- \$353 for a renewal application without a variation.

These amounts are an increase from \$126 (the discounted amount that applies to 7 March 2023) and \$145 (the full amount). This increase reflects the higher fees proposed in Table 13 and Table 14 to follow but also proposes that the Ministry retain the portion of the fee related to technical evaluation and the memorandum account balance.

In the case of regulation 19(4) (licence application declined), a refund of the whole application fee is required. When an application is declined, it is justifiable to retain the part of the fee that relates to the costs of determining the application but not the parts that relate to technical evaluation, inspections or the memorandum account. On this basis, it is proposed that the amount of refund be the full amount of the application fee but that the Ministry retain:

- \$450 for a declined source licence application that is new or a variation
- \$305 for a declined source licence application that is for a renewal (without variation).

It is proposed that retention of these amounts be applied regardless of the source licence application fee that has been paid. This is because the costs of determining the application have been assessed as very similar regardless of compliance monitoring category (that is, the risk) that applies to the source licence application.

Use licences and consents

Section 19 of the Act does not set out provisions for dealing with refunds in the situation where a use licence application or a consent is declined. The Ministry has provided full refunds in these situations to be consistent with the principles currently set out in regulation 19(4).

So that the regulations can be consistent between authorisation types, it is proposed that where use licence applications and consent applications are declined, the Ministry also retain the portion of the fees that relates to the costs of determining the application. On this basis, the amount of refund is the full amount of the application fee but the Ministry will retain:

- \$320 for a declined application that is new or a variation to an existing use licence
- \$232 for a declined application for a renewal (without variation) of a use licence
- \$145 for a declined application for consent to any type of import or export.

The change in refund approach would allow the Ministry to retain fees to cover costs incurred by activities that must be carried out when an application is received. Currently, costs where an application is declined are not recovered and, therefore, the cost of these activities is recovered from successful applicants.

The preferred option would help the Regulations better achieve the objectives set out in the 2016 RIS for proportionality, equity and efficiency.

Alternative option

In the case of applications that are declined, the portions of application fees that are proposed to be retained by the Ministry have a high degree of inequity compared with the application fee. Some examples are set out in Table 10 below.

Table 10: Examples of inequity in proposed preferred options for retaining fee portions for declined applications under regulation 19(4)

Authorisation type	Inspection period	Application fee	Proposed refunded portion	Proposed retained portion	% of fee retained
Source licence (new and variations)	1	\$3,744	\$3,294	\$450	12%
Source licence (renewals no variation)	1	\$3,508	\$3,203	\$305	9%
Source licence (new and variations)	5	\$993	\$543	\$450	45%
Source licence (new and variations)	5	\$757	\$452	\$305	40%
Use licence (new and variations)	–	\$408	\$88	\$320	78%
Use licence (renewals, no variation)	–	\$250	\$18	\$232	93%
Consents (high-activity)	–	\$233	\$88	\$145	62%
Consents (low-activity and unsealed multi-event)	–	\$163	\$18	\$145	89%

An alternative approach is to have the Ministry retain a flat percentage of the fee paid in situations where an application is declined. This fee would be in lieu of the costs associated with determining an application that has been declined so that declined applicants are contributing fees to the overall cost of regulating.

A nominal fee of 15 percent of the application fee could be retained in lieu of the costs associated with determining declined applications. This option introduces equity to refunds provided under the Regulations and makes a contribution to the costs of determining applications that are declined.

This approach does not necessarily assign costs to where they are generated.

Consultation questions

- 16 Do you think the preferred option to retain the portions of application fee set out in this section is justifiable?
 - 17 If you think the preferred option to retain the portions of application fee set out in this section is **not** justified, please outline your reasons.
 - 18 Do you think the alternative option to retain a nominal percent of 15 percent of the application fee when applications are declined is justified?
 - 19 If you think the alternative option to retain a nominal percent of 15 percent of the application fee when applications are declined is **not** justified, please outline your reasons.
 - 20 Do you have any further comments, suggestions or alternative options?
- Please use the submission form to respond to these questions.

2.3 Determining the source licence fee payable (compliance monitoring categories)

Background

Schedule 2 of the Regulations sets out (column 1) and describes (medical and non-medical) the **compliance monitoring categories** that apply to inspection periods (column 2). The compliance monitoring categories grade regulated activities with similar risk-management requirements so that those activities attract the same inspection periods commensurate with their risk (the graded approach).

The review of the Regulations offers the opportunity to reassess the compliance monitoring categories to ensure that, as far as can reasonably be achievable, each compliance monitoring category contains regulated activities that are comparatively similar in their risk-management requirements.

Status quo option

Further clarification on compliance monitoring categories would improve the application of the graded approach to managing radiation safety risk. This would help the Regulations better achieve the proportionality objective outlined in the 2016 RIS. Therefore, the status quo option is not justifiable.

Preferred option

Further distinction between compliance monitoring categories would improve the application of the graded approach to managing radiation safety risk. The preferred options are set out in Table 11 to follow.

No changes are proposed to the existing regulation 16(3)(a), which sets out that practices carried out be fully described in only one compliance monitoring category in column 1 of schedule 2, with the inspection period being the period listed in column 2 of schedule 2. This means that the status quo remains and that where two compliance monitoring categories apply, only the single, higher fee of the categories is payable.

One example of this is where a dental practice (at a single location) has control or management of both X-rays and cone beam computed tomography (CBCT). In such a case, the practice will continue to receive inspections and pay the fees that relate to CBCT only. Inspections will continue to cover both X-rays and CBCT.

Table 11: Proposed amendments to compliance monitoring categories set out in schedule 2 of the Radiation Safety Regulations 2016

Affected activities	Affected current compliance monitoring categories	Preferred option	Aim of amendment	Impact of amendment
Interventional radiology, interventional cardiology	Medical 2, Medical 4	Amend medical 4 category so that the exclusion that applies to interventional radiology also applies to interventional cardiology.	To clarify that interventional radiology <u>and</u> interventional cardiology are both assigned to medical 2 category.	Clarification only, no change in practice (other than proposed new fees for medical 2).
Dental diagnosis	Medical 2, medical 4	Amend medical 2 and medical 4 so that dental cone beam computed tomography (CBCT) ¹ can become subject to medical 4.	Reduce inspection frequency for managing or controlling dental CBCT. No change is proposed to dental diagnosis without the use of CBCT in medical 5 (X-ray).	Reduced inspection frequency to every four years and proposed annual source licence fee of \$861 or \$1,097 for dental CBCT. When both dental CBCT and dental diagnosis without the use of CBCT are present, only the four-yearly inspection period applies and only the dental CBCT fee would be payable (but both modalities would be inspected).
Medical therapy, medical diagnosis and nuclear medicine	Medical 1, medical 2, medical 3	Amend medical 1, medical 2 and medical 3 to remove any implied overlap in the activities included in the categories.	Clarify existing situation – no change to inspection periods.	Clarification only, no change in practice (other than proposed new fees).
Industrial radiography	Non-medical 1, non-medical 3	Amend non-medical 3 and potentially non-medical 1 so that management or control of industrial radiography sources that use only X-ray techniques can become subject to non-medical 3.	Reduce inspections frequency to two-yearly for managing or controlling industrial radiography sources that use X-ray imaging techniques only. No change is proposed for industrial radiography that uses all other techniques, and inspection frequencies will remain annual. Management or control of industrial radiography involving a combination of both X-ray and other techniques will also remain unchanged on annual inspections.	Reduced inspection frequency to every two years and proposed annual source licence fee of \$1,695 or \$1,931 for X-ray only.

Affected activities	Affected current compliance monitoring categories	Preferred option	Aim of amendment	Impact of amendment
Nuclear gauges ² using low-activity sealed radioactive material	Non-medical 6, non-medical 4	Amend non-medical 6 category so that it applies only to irradiating apparatus, and amend non-medical 4, if required, so that it captures all nuclear gauges using low-activity sealed radioactive material (fixed and portable).	Increase inspections to three-yearly for the control or management of fixed nuclear gauges using low-activity sealed radioactive material. No change is proposed for irradiating apparatus, and portable nuclear gauges will continue to be inspected three-yearly.	Increased inspection frequency to every three years for the control or management of fixed nuclear gauges using low-activity sealed radioactive material (no change to portable nuclear gauges) and increased proposed annual source licence fee of \$1,092 or \$1,328.
Non-medical human imaging for security purposes	Non-medical 6, non-medical 4	Amend non-medical 6 (and non-medical 4 if necessary) so this activity is excluded from non-medical 6.	Non-medical human imaging for security purposes becomes only subject to the non-medical 4. The very high emphasis on justification required to obtain a source licence for this activity will remain.	Appropriate inspection frequency of every three years and proposed annual source licence fee of \$1,092 or \$1,328.
Control or management of linear accelerators ³ for non-medical use	Non-medical 6, non-medical 4 and non-medical 3	Amend non-medical 6 and non-medical 4 so that control or management of linear accelerators for non-medical use becomes subject to the non-medical 3 category.	Non-medical use of linear accelerators would become subject to the non-medical 3 category.	Increased inspection frequency to every two years and proposed annual source licence fee of \$1,695 or \$1,931.

Notes

1. Cone beam computed tomography (CBCT) is a subset of computed tomography (CT) scanners, which use a cone-shaped X-ray and two-dimensional digital flat-panel detector to yield a three-dimensional volumetric image in one rotation.
2. A nuclear gauge is a device that contains one or more sealed radiation sources for purposes other than well logging, such as a nuclear density meter or a fixed industrial gauge.
3. A linear accelerator is an apparatus where electrons are accelerated following straight trajectories in special evacuated structures called accelerating waveguides.

The preferred options improve the grading of activities so that the activities included in each compliance monitoring category contain similar levels of risk that require equivalent levels of risk management. These options would also assist the Regulations to better achieve the objectives set out in the 2016 RIS for proportionality and certainty.

Alternative option

No justifiable alternative options have been identified.

Consultation questions

- 21 Do you agree that the preferred options set out in Table 11 are justifiable?
- 22 If you do not agree that the preferred options set out in Table 11 are justifiable, please identify your reasons and/or provide an alternative option.
- 23 Do you have any further suggestions on grading the compliance monitoring categories so that they better reflect the radiation safety risk that needs to be managed?
- 24 Do you have any further suggestions on ways to make the Regulations clearer for applicants to determine the fees they must pay?

Please use the submission form to respond to these questions.

2.4 Determining the source licence fee payable (inspection periods)

Background

Schedule 2 of the Regulations sets out inspection periods in column 2. The Act requires control and management of the activities at each location (and sub-location) to be established before an application for a source licence (or a renewal) is granted. The inspection period is established by applying regulation 16. Regulation 15 also applies to the fees payable for a source licence.

The use of the term 'inspection period' and its application in regulation 16 and schedule 2 of the Regulations can be complicated. Further, the use of the term 'inspection' has been interpreted as meaning that on-site inspections are the only way of ascertaining compliance with the radiation safety requirements. The Regulations could be clearer in setting out the fees payable. Further use could be made of other provisions in the Act, such as the Director's powers to request information through applications (section 29(1) of the Act), registrations (section 32(f)) and record keeping

(section 35(1)), to gather information that may help ease the burden of on-site inspections where it can be ascertained that no (on-site) inspection can be put in place (see regulation 19(b) and section 19(3) of the Act) with little to no reduction in radiation safety.

The option of no inspection would continue to exist for exceptional situations, to be used when appropriate.

There are no significant cost savings in regulating without on-site inspections. Records, information and verification would still be required to a level equivalent to an on-site inspection, for which the source licence holder would still be required to produce and provide. Marginal reductions in inspectorate travel and accommodation costs may occur, but all other compliance verification costs would remain.

Regardless of any amendments made to determining the source licence fees payable, on-site inspections are expected to continue to be the cornerstone of verifying compliance with the requirements of the Act in accordance with international guidelines.

Status quo option

The Ministry is comfortable that the status quo option to retain the existing provisions for determining the source licence fee payable meets the objectives of the safety purposes of the Act. However, the ease of administration objective of the 2016 RIS on the Regulations could be better met by making the provisions on determining the source licence fees payable easier to use. Therefore, the status quo option is not justifiable.

Preferred option

The preferred option is to remove column 2 of schedule 2 of the Regulations ('Inspection period (years)') and replace the references with the fee payable. This would create a transparent table of fees and make the Regulations easier to use. This option would require suitable consequential amendments to regulations 15 and 16 so that the establishment of locations and sublocations from which control and management of radiation sources is achieved can remain intact and unaltered. This option would also help the Regulations better achieve the objectives set out in the 2016 RIS on certainty and ease of administration.

Alternative option

The existing Regulations effectively establish the fee payable. Therefore, an alternative option is to retain the current construction for determining the source licence fees payable. However, it is proposed that the term 'inspection period' be replaced with '**compliance verification** period' because this better allows all the Act's provisions to be used in ascertaining compliance with the Act.

Consultation questions

- 25 Do you agree with the preferred option to remove column 2 of schedule 2 of the Regulations ('Inspection period (years)') and replace the references with the fees payable (with suitable consequential amendments to ensure that the function of regulations 15 and 16 remain intact and unaltered)?
- 26 If you do not agree with the preferred option to remove column 2 of schedule 2 of the Regulations ('Inspection period (years)') and replace the references with the fees payable (with suitable consequential amendments to ensure that the function of regulations 15 and 16 remain intact and unaltered), please identify your reasons and/or provide an alternative option.
- 27 Do you agree with the alternative option to amend the term 'inspection period' to 'compliance verification period' in regulation 16 and Schedule 2 of the Regulations?
- 28 If you do not agree with the alternative option to amend the term 'inspection period' to 'compliance verification period' in regulation 16 and schedule 2 of the Regulations, please identify your reasons and/or provide an alternative option.
- 29 Do you prefer the status quo option of no change? If so, please explain your reasons.
- 30 Do you have any further suggestions on making the Regulations clearer for applicants to determine the fees they must pay?

Please use the submission form to respond to these questions.

3 Proposed new fees

3.1 Proposed new source licence fees

Background

The fees payable for each location (or sub-location) from which the applicant will manage or control the radiation sources under a source licence are set out in regulations 15 and 16. Schedule 2 of the Regulations also applies.

Status quo option

The status quo option to retain the existing fees and fees structure does not meet most of the objectives outlined in the 2016 RIS on the Regulations and therefore is not viable.

Preferred option

This consultation proposes to retain the existing approach set out in regulations 15 and 16 and schedule 2 of the Regulations. In proposing a differential fee for applications renewals, the proposed fees (exclusive of GST) are set out in Table 12 and Table 13 to follow.

The proposed fees for source applications that are new or variations to existing licences are set out in Table 12 below.

Table 12: Proposed source licence fees (exclusive of GST) for new and variation applications

Inspection period (year)	Proposed annual fee	Current fee (before 7 March 2023)	Fee from 7 March 2023	\$ increase on current fee	% increase on current fee
1	\$3,744	\$1,309	\$1,505	\$2,435	186%
2	\$1,931	\$718	\$825	\$1,213	169%
3	\$1,328	\$522	\$600	\$806	154%
4	\$1,097	\$422	\$485	\$675	160%
5	\$993	\$361	\$415	\$632	175%

Table 13: Proposed source licence fees (exclusive of GST) for source renewal applications (with no variations)

Inspection period (year)	Proposed annual fee	Current fee (before 7 March 2023)	Fee from 7 March 2023	\$ increase on current fee	% increase on current fee
1	\$3,508	\$1,309	\$1,505	\$2,199	168%
2	\$1,695	\$718	\$825	\$977	136%
3	\$1,092	\$522	\$600	\$570	109%
4	\$861	\$422	\$485	\$439	104%
5	\$757	\$361	\$415	\$396	110%

The proposed increases are based on a reassessment of the effort employed to regulate rather than applying a percentage increase to the current fee.

The reassessed fees comprise costs attributed to regulating as set out in Table 14 and Table 15 below.

Table 14: Proposed source licence fee components new and variation applications

Inspection period	Projected authorisations	Application fee component (annual)	Compliance verification (inspections) fee component (annual)	Technical evaluation fee component (annual)	Memorandum account adjustment fee component (annual)	Proposed fee (annual)
New and variations						
1	2	\$450	\$2,888	\$88	\$318	\$3,744
2	16	\$450	\$1,228	\$88	\$165	\$1,931
3	10	\$450	\$677	\$88	\$113	\$1,328
4	25	\$450	\$465	\$88	\$94	\$1,097
5	64	\$450	\$370	\$88	\$85	\$993
No inspection	0	\$450	\$0	\$88	\$50	\$588
Totals	117					

Table 15: Proposed source licence fee components renewal applications

Inspection period	Projected authorisations	Application fee component (annual)	Compliance verification fee component (annual)	Technical evaluation fee component (annual)	Memorandum account adjustment fee component (annual)	Proposed fee (annual)
Renewals (no variation)						
1	41	\$305	\$2,888	\$18	\$297	\$3,508
2	310	\$305	\$1,228	\$18	\$144	\$1,695
3	194	\$305	\$677	\$18	\$92	\$1,092
4	476	\$305	\$465	\$18	\$73	\$861
5	1,215	\$305	\$370	\$18	\$64	\$757
No inspection	4	\$305	\$0	\$18	\$30	\$353
Totals	2,240					

Alternative option

The Ministry has not identified a justifiable alternative option.

Consultation questions

- 31 Do you think the preferred option of retaining the existing graded approach to source licence fees based on the assessed cost components set out in Table 14 and Table 15 is justified?
 - 32 If you think the preferred option of retaining the existing graded approach to source licence fees based on the assessed cost components set out in Table 14 and Table 15 is **not** justifiable, please outline an alternative option for assigning source licence fees. Please provide reasons for your option.
 - 33 Do you have any further comments, suggestions or alternative options?
- Please use the submission form to respond to these questions.

3.2 Proposed new use licence fees

Background

The fees payable on application for a use licence are set out in regulation 17.

Status quo option

The status quo option to retain the existing flat fee does not meet most of the objectives outlined in the 2016 RIS on the Regulations and therefore is not viable.

Preferred option

Retain the existing approach set out in Regulation 17 of a fee payable for each **authorisation year**. Different fees are proposed for applications for new use licences and applications for renewals of existing use licences. The proposed fees (exclusive of GST) are:

- \$408 for each authorisation year for an application for a new-use licence or to vary an existing-use licence
- \$250 for each authorisation year for an application to renew an existing-use licence without variation.

The proposal is a significant increase on the current fee of \$95 for each authorisation year. The size of the increase arises from a reassessment of the effort required to determine licence applications. This option would help the Regulations better achieve the objectives set out in the 2016 RIS for proportionality and equity. The fees review information is set out in Table 16 below.

Table 16: Reassessment of effort devoted to assessing applications for use licences

	Projected authorisations	Average time per application (minutes)	Application fee component	Technical evaluation (assessed relative effort)	Technical evaluation fee component	Total fee
Use licences (new or variations)	114	110	\$320	5	\$88	\$408
Use licences (renewals only)	1,023	80	\$232	1	\$18	\$250
Totals authorisations	1,137	–	–	–	–	–

Alternative option

The percentage increase for use licence fees is the highest identified in this consultation document. The fees are based on the time spent administering this licence type. Alternative options to reduce the relative size of this increase would involve another authorisation type (source licences or consents) subsidising the price (cross-subsidisation) or identifying another party to meet the costs so that the fees recover only part (or none) of the costs. The Ministry's view on this matter, as set out in section 1.6 (Cost recovery model) of this document, is that these options are not justifiable at this level of proposed new fees.

Consultation questions

- 34 Do you think the preferred option of setting use licence fees based on the assessed cost components, as set out in Table 16, is justifiable?
 - 35 If you think the preferred option of setting use licence fees based on the assessed cost components, as set out in Table 16, is **not** justifiable, please outline an alternative option for assigning use licence fees. Please provide reasons for your option.
 - 36 Do you have any further comments, suggestions or alternative options?
- Please use the submission form to respond to these questions.

3.3 Proposed new consent fees

Background

The fees payable on application for a consent to import or export radioactive material are set out in regulation 18.

Status quo option

The status quo option to retain the existing fees and fees structure does not meet the proportionality, equity, efficiency or transparency objectives outlined in the 2016 RIS on the Regulations, and therefore, the status quo option is not viable.

Preferred option

Retain the existing approach to consent categories set out in regulation 18. This option would help the Regulations better achieve the objectives set out in the 2016 RIS for proportionality and equity.

The proposed fees (exclusive of GST) are set out in Table 17 below.

Table 17: Proposed new consent fees by existing consent type

	Projected annual applications	Application fee component	Technical evaluation	Total fee
Consents under regulation 18(a) for import or export of high-activity radioactive material on a single occasion	19	\$145	\$88	\$233
Consents under regulation 18(b) for import or export of low-activity radioactive material on a single occasion	172	\$145	\$18	\$163
Consents under regulation 18(c) for import or export of unsealed radioactive material that is low-activity radioactive material on two or more occasions during the period of the consent	5	\$145	\$18	\$163
Total	196	–	–	–

Alternative option

Any viable alternative will need to justify the cross-subsidisation of costs incurred in one consent type by fees recovered from another authorisation type or justify a partial (or zero) cost recovery approach. Such a justification has not yet been identified.

Consultation questions

- 37 Do you think the preferred option of setting consent fees based on the assessed cost components set out in Table 17 is justifiable?
- 38 If you think the preferred option of setting consent fees based on the assessed cost components set out in Table 17 is **not** justifiable, please outline an alternative option for assigning use licence fees. Please provide reasons for your option.
- 39 Do you have any further comments, suggestions or alternative options?

4 Amendments to existing exemptions, prohibitions and restrictions

4.1 Exemption for dealing with irradiating apparatuses used for X-ray fluorescence and X-ray diffraction likely to result in very low effective doses

Background

Regulation 13 currently provides an exemption from the requirements of authorisations, registration and record keeping (subparts 2 and 3 of the Act) for **irradiating apparatuses** used for X-ray fluorescence and X-ray diffraction that, in reasonably foreseeable circumstances, are likely to result in an effective dose of less than 10 microsieverts per year.

The people who deal with these apparatuses are currently subject to the *Code of Practice for Irradiating Apparatus: ORS C10*.¹¹

Status quo option

This exemption does not provide an appropriately graded level of regulation for this category of apparatus, and therefore, further controls are required. This means that the proportionality objectives of the 2016 RIS for the Regulations are not being fully met. On this basis, the status quo option is not viable.

¹¹ Ministry of Health. 2020. *Code of Practice for Irradiating Apparatus: ORS C10*. Wellington: Ministry of Health. URL: www.health.govt.nz/system/files/documents/publications/code-of-practice-irradiating-apparatus-ors-c10-30june2020.pdf (accessed 11 October 2021).

Preferred option

The preferred option is that these apparatuses also become subject to the requirements of registration and record keeping (subpart 3 of the Act). This means that the purposes of registration (section 30(3) of the Act) and records of the specified information (section 35(2) of the Act) will become available for achieving the purposes that are specified in the Act. Principally, the location and movement of the apparatus can be recorded and used for emergency preparedness and response. Also, compliance with the radiation safety requirements can be determined using this information.

This option does not propose to require authorisation (licencing) for these apparatuses. The existing exemption from subpart 2 of the Act would remain. Because fees are only payable on application for authorisation, no fees would be payable by people who manage and control these apparatuses under this option.

Alternative option

An alternative option is to remove the exemption provided by regulation 13 altogether. This option would require people who deal with these apparatuses to obtain a source licence and potentially a use licence (in most cases, unlikely).

This option would be disproportionate to the radiation risk that needs to be managed.

Consultation questions

- 40 Do you think that the preferred option of requiring registration and record keeping for people who deal with irradiating apparatuses used for X-ray fluorescence and X-ray diffraction that, in reasonably foreseeable circumstances, is likely to result in an effective dose of less than 10 microsieverts per year, is proportionate to the additional radiation safety that will be achieved?
 - 41 If you think the preferred option is disproportionate, please provide comment to support your view.
 - 42 Do you have any further comments, suggestions or alternative options?
- Please use the submission form to respond to these questions.

4.2 Proposed changes to veterinarian exemption and Medical Imaging Technologists exemption under schedule 3

Background

Schedule 3 of the Regulations sets out situations where a use licence is not required for groups of people when they are performing specified activities. The provisions that enable schedule 3 are sections 91(h) and (i) of the Act.

Schedule 3 is achieving its purpose of permitting the uses set out in the schedule where appropriate radiation safety training, qualifications and the experience of all members of the specified groups can be verified by a means other than requiring a use licence.

Status quo option

The status quo option would see no changes to schedule 3 of the Regulations. However, the preferred options have identified two minor amendments that would improve the certainty objective of the 2016 RIS for the Regulations, and therefore, the status quo option is not recommended.

Preferred option

Two amendments to the existing provisions set out in schedule 3 are proposed.

For column 2 (Activity or class of activity that may be performed without a use licence) of schedule 3, on the row 'A veterinarian within the meaning of the Veterinarians Act 2005', the preferred option is to tighten the scope of activity to become 'the use of fixed or mobile irradiating apparatuses for veterinary diagnostic purposes'. This would require a use licence in situations where veterinarians are using computed tomography, fluoroscopy and radiation therapy. This complements the current situation in which veterinarians are required to obtain a use licence in situations where they are using radiopharmaceuticals for veterinary purposes.

For column 2 (Activity or class of activity that may be performed without a use licence) of schedule 3, on the row 'A health practitioner who is, or is deemed to be, registered with the Medical Radiation Technologists Board in the scope of practice of medical imaging technologist' the preferred option is to broaden the scope of activity to become 'use of irradiation apparatuses for medical diagnostic or veterinary diagnostic purposes'. The registration and updating requirements for this group have been assessed as satisfactory for all members to perform the additional radiation safety activities without the need to obtain a use licence.

Alternative option

No viable alternative option has been identified.

Consultation questions

- 43 Do you agree with the preferred option to tighten the scope of activities that veterinarians can perform without the need to obtain a use licence?
- 44 If you do not agree with the preferred option to tighten the scope of activities that veterinarians can perform without the need to obtain a use licence, please outline your reasons and/or suggest an alternative approach.
- 45 Do you agree with the preferred option to broaden the scope of activities that medical imaging technologists can perform without the need to obtain a use licence?
- 46 If you do not agree with the preferred option to broaden the scope of activities that medical imaging technologists can perform without the need to obtain a use licence, please outline your reasons and/or suggest an alternative approach.
- 47 Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

5 Other matters that can be dealt with under the Regulations

Background

The scope of matters that can be dealt with in the Regulations is set out in sections 91–93 of the Act. This scope is wider than the matters raised in this consultation document. Unless identified in this document as a proposed amendment, the Ministry is recommending that all other existing regulations remain unaltered. Also, it follows that the Ministry is only recommending the amendments discussed in this document.

Preferred option and status quo option

Any matters that are not discussed in the consultation document but that are matters that can be dealt with under sections 91–93 of the Act can be raised by submitters for consideration. Submissions should aim to improve the Regulations' ability to meet the purposes of the Act (radiation safety and international obligations) or better achieve the principles set out in section 92(3) of the Act in relation to the cost-recovery principles of: equity, efficiency, justifiability, transparency or ease of administration. Also, submissions should aim to improve the ability of the Regulations to meet the objectives set out in the 2016 RIS for the Regulations (see 'We want your input' under Introduction above).

Alternative option

No alternative options have been identified.

Consultation question

48 Do you think there are any other matters that should be included in or removed from the Regulations? Please provide justification for your view.

Please use the submission form to respond to this question.

Appendices

Appendix 1: Proposed new annual radiation safety fees compared with current fees

Table 18: Proposed new annual fees compared with current fees (discount until 7 March 2023 applied) and full current fees (discount removed from 7 March 2023)

Source licences	Inspection period	Proposed new fee	Current fee (discount applied)	Current full fee (no discount)	Change from current discounted fee	Percentage change from current discounted fee
New and variations						
Medical 1, non-medical 1, non-medical 2	1	\$3,744	\$1,309	\$1,505	\$2,435	186%
Medical 2, medical 3, non-medical 3	2	\$1,931	\$718	\$825	\$1,213	169%
Non-medical 4	3	\$1,328	\$522	\$600	\$806	154%
Medical 4, non-medical 5	4	\$1,097	\$422	\$485	\$675	160%
Medical 5, medical 6, non-medical 6	5	\$993	\$361	\$415	\$632	175%
No inspection	0	\$588	\$126	\$145	\$462	367%

Source licences	Inspection period	Proposed new fee	Current fee (discount applied)	Current full fee (no discount)	Change from current discounted fee	Percentage change from current discounted fee
Renewals without variation						
Medical 1, non-medical 1, non-medical 2	1	\$3,508	\$1,309	\$1,505	\$2,199	168%
Medical 2, medical 3, non-medical 3	2	\$1,695	\$718	\$825	\$977	136%
Non-medical 4	3	\$1,092	\$522	\$600	\$570	109%
Medical 4, non-medical 5	4	\$861	\$422	\$485	\$439	104%
Medical 5, medical 6, non-medical 6	5	\$757	\$361	\$415	\$396	110%
No inspection	0	\$353	\$126	\$145	\$227	180%
Use licences						
Use licence (new and variations)	0	\$408	\$95	\$95	\$313	329%
Use licence (renewals without variation)	0	\$250	\$95	\$95	\$155	163%
Consents						
Consents (high-activity)	0	\$233	\$300	\$300	-\$67	-23%
Consents (low-activity)	0	\$163	\$80	\$80	\$83	104%
Consents (unsealed multi)	0	\$163	\$400	\$400	-\$237	-59%

Appendix 2: Radiation licencing fees comparison, New Zealand–Australia

Table 19: Radiation licencing fees comparison, New Zealand/Australia¹

Authorisation type	Current NZ fee	Proposed NZ fee	Australia (federal) fee ²	Australia (Vic) fee ³	Australia (NSW) fee ⁴	Australia (Qld) fee ⁵	Australia (WA) fee ⁶	Australia (SA) fee ⁷	Australia (Tas) fee ⁸
Source licence ⁹	\$NZD	\$NZD	\$AUD	\$AUD	\$AUD	\$AUD	\$AUD	\$AUD	\$AUD
Medical 1, non-medical 1 and non-medical 2	1,309–1,505	3,508–3,744	Group 3: 14,862 (0–3) 29,720 (4–10) 54,489 (>10) Production of unsealed: 27,130	296.20–592.40	258.00–495 + 35.00–1490.00 per unit	280 + 112.50 for each sealed radioactive substance or type of unsealed radioactive substance + 84 for each radiation apparatus (< 1 year) OR 561 + 225 for each sealed radioactive substance or type of unsealed radioactive substance + 168 for each radiation apparatus (1–2 years) OR 841.50 + 337 for each sealed radioactive substance or type of unsealed radioactive substance + 252 for each radiation apparatus (>2 but < 3 years)	Irradiating apparatus: 210.00 (1–2) 420.00 (3–5) 840.00 (6–10) 1325.00 (>10) and radioactive material: 210.00 (<40GBq) 420.00 (40–400GBq) 840.00 (0.4–4TBq) 1325.00 (>4TBq)	Irradiator/ Accelerator: 38,519.00, or possession: 536.00 (<6) 1460.00 (6–10) 2625.00 (>10) and Unsealed: 1,710.00 and 1st RM source: 1,710.00 (1,496.00 each additional) and 847.00–1,147.00	333.72–1247.40 (1–5 sources) or 228.42 per source (>5 sources)
Medical 2, medical 3 and non-medical 3	718–825	1,695–1,931	Group 2: 4,954 (0–3) 9,907 (4–10) 18,622 (>10)	296.20–592.40	258.00–495 + 35.00–69.00 per unit	As above	Irradiating apparatus: 210.00 (1–2) 420.00 (3–5) 840.00 (6–10) 1,325.00 (>10) and radioactive material: 210.00 (<40GBq) 420.00 (40–400GBq) 840.00 (0.4–4TBq)	Unsealed: 1,710.00 possession: 536.00 (<6) 1,460.00 (6–10) 2,625.00 (>10) and 1st RM source: 1,710.00 (1,496.00 each additional) and 847.00–1,142.00	Nuc. med.: 1,282.00 unsealed lab 137.00 per area and 333.72–1,247.40 (1–5 sources) or 228.42 per source (>5 sources)

Authorisation type	Current NZ fee	Proposed NZ fee	Australia (federal) fee ²	Australia (Vic) fee ³	Australia (NSW) fee ⁴	Australia (Qld) fee ⁵	Australia (WA) fee ⁶	Australia (SA) fee ⁷	Australia (Tas) fee ⁸
Source licence ⁹	\$NZD	\$NZD	\$AUD	\$AUD	\$AUD	\$AUD	\$AUD	\$AUD	\$AUD
Medical 4 and non-medical 5	422–485	861–1,097	Group 1: 1,238 (0–3) 3,216 (4–10) 6,192 (>10)	148.10–296.20	258.00–495.00 + 17.00–35.00 per unit	As above	Irradiating apparatus: 210.00 (1–2) 420.00 (3–5) 840.00 (6–10) 1,325.00 (>10)	Possession: 536.00 (<6) 1,460.00 (6–10) 2,625.00 (>10) and 1st RM source: 1,710.00 (1,496.00 each additional) and each apparatus 791.00–1,142.00	333.72–1,247.40 (1–5 sources) or 228.42 per source (>5 sources)
Medical 5, medical 6 and non-medical 6	361–415	757–993	Group 1: 1,238 (0–3) 3,216 (4–10) 6,192 (>10)	148.10–592.40	258.00–495.00 + 17.00–69.00 per unit	As above	Irradiating apparatus: 210.00 (1–2) 420.00 (3–5) 840.00 (6–10) 1,325.00 (>10) and radioactive material: 210.00 (<40GBq) 420.00 (40–400GBq) 840.00 (0.4–4TBq)	Possession: 536.00 (<6) 1,460.00 (6–10) 2,625.00 (>10) Unsealed: 1,710.00 and 1st RM source: 1,710.00 (1,496.00 each additional) and each apparatus 791.00–847.00	1,101.60 per linac and 333.72–1,247.40 (1–5 sources) or 228.42 per source (>5 sources)
Non-medical 4	522–600	1,092–1,328	Group 2: 4,954 (0–3) 9,907 (4–10) 18,622 (>10)	148.10	258.00–495.00 + 35.00–69.00 per unit ¹⁰	As above	210.00 (<40GBq) 420.00 (40–400GBq)	Possession: 536.00 (<6) 1,460.00 (6–10), 2,625.00 (>10) and 1st RM source: 1,710.00 (1,496.00 each additional) and each apparatus 791.00	333.72–1,247.40 (1–5 sources) or 228.42 per source (>5 sources)

Use licence	\$NZD	\$NZD	\$AUD	\$AUD	\$AUD	\$AUD ¹¹	\$AUD	\$AUD	\$AUD
1 year	109	250–408	–	74.10	191.00–254.00 ¹²	168.00	85–170	408–412 ¹³	335.36 ¹⁴ –411.00
2 year	218	500–816	–	140.70	–	238.00	–	–	–
3 year	327	750–1,224	–	199.90	333.00–523.00	308.00	–	–	–

Notes

- This list is not exhaustive and does not include all fees relating to radiation licensing; fees are based on a single-year licence period – where a discount is available for multiple years, this is indicated.
- For more information, see Australian Radiation Protection and Nuclear Safety (Licence Charges) Regulations 2018 on the Australian Government’s Federal Register of Legislation website at: www.legislation.gov.au/Details/F2018L01697.
- Radiation Regulations 2017, available at: https://content.legislation.vic.gov.au/sites/default/files/0174274d-2f5a-3f7d-a7b0-bd3610dc74a3_17-83sra001%20authorised.pdf. Fees are calculated based on fee units set by the Treasurer of Victoria each year. Management licence fees are discounted for licence periods of two and three years. The fee unit rate for the 2020/21 financial year is \$AUD14.81.
- Radiation Control Regulation 2013, available at: www.legislation.nsw.gov.au/view/html/inforce/current/sl-2013-0052#sch.4.
- Radiation Safety Regulation 2010, available at: www.legislation.qld.gov.au/view/html/inforce/current/sl-2021-0125. Security enhanced sources are \$AUD1,244.50 + \$AUD110.00 per source, first year includes application fee.
- Radiation Safety (General) Regulations 1983, available at: www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_1969_homepage.html. A licence period is either one or three years – the fee for three years is double the annual fee. WA has a separate schedule of fees for temporary permits for periods not exceeding three months.
- Radiation Protection and Control (Ionising Radiation) Regulations 2015, available at: [www.legislation.sa.gov.au/LZ/C/R/Radiation%20Protection%20and%20Control%20\(Ionising%20Radiation\)%20Regulation%202015.aspx](http://www.legislation.sa.gov.au/LZ/C/R/Radiation%20Protection%20and%20Control%20(Ionising%20Radiation)%20Regulation%202015.aspx). SA licence fees and registration fees are made up of a non-refundable application fee and an annual fee.
- Radiation Protection Regulations 2016, available at: www.legislation.tas.gov.au/view/html/inforce/current/sr-2016-032. All fees are calculated using a fee unit of \$AUD1.62 (supplied by the Tasmanian Government’s Department of Treasury and Finance for the 2019/2020 financial year). Lower fees apply if sources are in storage and not used. An additional \$AUD207.36 licence application fee applies, and there is an \$AUD333.72 registration fee for each radiation place.
- In New Zealand, a source licence fee is annual and risk based. Broadly similar, it is known as a ‘Management licence’ in Victoria, where it can vary from one to three years’ duration. There are also additional application fees not listed here. In Queensland, this is known as a ‘Possession licence’. In NSW, it is also known as a ‘Management licence’. In South Australia, it is called a ‘Source Licence’, and in Western Australia and Tasmania, it is simply a ‘licence’ to deal with radiation.
- Calculation of fee unit for purposes of the regulation in NSW:
 - A fee unit is: (a) \$AUD100 for the 2018/19 financial year, and (b) in each subsequent financial year, it is the amount calculated as follows:

$$\$100 \times \frac{A}{B}$$

where:

A is the public sector wage price index number for the March quarter in the financial year immediately preceding the financial year for which the amount is calculated.

B is the public sector wage price index number for the March quarter of 2018.

- (2) The amount of a fee unit is to be rounded up to the nearest cent.
 - (3) However, if the amount of a fee unit calculated for any financial year is less than the amount that applied to the previous financial year, then the amount for that previous financial year applies instead.
- 11. Includes a non-refundable \$AUD96.50 application fee.
 - 12. This fee is for a new use licence; a lower fee applies for a renewal.
 - 13. This fee is for a new use licence; a lower fee applies for a renewal.
 - 14. This fee includes a non-refundable \$AUD128.00 application fee.