In Confidence

Office of the Minister of Health

Chair, Cabinet Social Wellbeing Committee

Approval to Amend the Radiation Safety Regulations 2016

Proposal

1 This paper seeks approval for proposals to amend the Radiation Safety Regulations 2016 (the Regulations).

Relation to government priorities

2 These proposals are not directly related to Government priorities.

Executive Summary

3 In 2021, a Manatū Hauora, Ministry of Health (Ministry) review of the application fees for radiation safety authorisations found that the fees have never fully recovered the costs of verifying compliance with the radiation safety requirements. The Ministry then undertook a full review of the Regulations and consulted on proposals over a six-week period ending on 29 April 2022. While submitters did not want to pay higher fees, there was general acceptance that the proposals were fair.

4 The decisions sought by this paper are set out in appendices 1-3 of this paper. The proposed fees would also recover the shortfall in the fees taken since 2016. An amendment to the fee structure is also sought so that applications to renew existing authorisations become subject to a lower fee. In addition to the fees and fee structure further minor amendments are proposed, which were supported by submitters.

5 The proposed fee increases are significant, with a 111 percent increase to the overall fees taken proposed. While the percentage increase is high, the revised fees are still a very small proportion of the overall operating costs of safely providing services that are subject to the fees. In this respect, the increase in fees will have a low impact.

6 Subject to Cabinet decisions, I intend to present an Order in Council to Cabinet in December 2022, so that the amended Regulations can be made at the earliest possible time and the new fees can come into force 28 days later.

Background

7 The Radiation Safety Act 2016 (the Act) establishes a framework to protect the health and safety of people and protect the environment from the harmful effects of ionising radiation while allowing for the safe and beneficial use of ionising radiation.

8 The Act and the Regulations apply only to people and organisations that deal with radioactive material (for example, iodine-131 for thyroid treatments) and irradiating apparatuses capable of producing ionising radiation when they are operated (for example, X-ray machines and CT scanners). The proposals do not affect the regulation of non-ionising radiation such as: lasers, ultra-violet light (UV), WiFi, cellphone communication systems, microwave technologies, radio waves and other types of electromagnetic fields.

9 The Regulations set out the annual fees payable to the Ministry by people or organisations that apply for authorisations under the Act. Authorisations can be granted to manage and control radiation sources (source licences), use radiation sources (use licences) and import or export radioactive material (consents).

10 Just over half of the fees taken under the Act are paid by health service providers, including Te Whatu Ora – Health New Zealand, private hospitals and radiology services, primary healthcare providers (dentists, chiropractors), and breast screening providers. Outside of the health sector, fees are paid by universities, Crown Research Institutes, laboratories, veterinarians, engineering firms, construction, mining, oil and gas, manufacturing, and agricultural businesses. The Ministry for Primary Industries, the New Zealand Customs Service, and the Department of Corrections (among others) pay fees for their security screening programmes. The New Zealand Blood Service pays fees for its irradiators.

11 In addition to fees, the Regulations also set out exemptions for very low-risk situations (such as household smoke detectors) and authorise practices of people with appropriate knowledge and experience of radiation safety.

Consultation, submissions and response

12 On 9 February 2022, Cabinet approved the release of the public consultation document *Review of the Radiation Regulations 2016* [CAB-22-MIN-0021]. The six-week public consultation ended on 29 April 2022.

13 Twenty submissions were received. Eighteen submitters represented source licence holders and the other submitters were the Royal Australian and New Zealand College of Radiologists and the Civil Engineering Testing Association of New Zealand. A technical assessment was received from the Institute of Environmental Science and Research Ltd (ESR).

14 The majority of topics raised in the discussion document received full or majority support in the submissions. There were two topics in which submissions were split, the proposed significant increase in fees and the proposal to remove the term ‘inspection period’ from the Regulations.

Increase in fees

15 Some submitters said that the increased costs outlined in the discussion document were caused by inefficiency in administering the Act or inaccuracy

in calculating the fees. On this basis, some submitters argued that the Crown should fund (or write-off) the negative memorandum account balance.

16 The Ministry's view is that the cost increases have been necessary and unavoidable to administer the Act. The Ministry accepts the argument that the fees calculated in 2016 did not anticipate the extent of the cost increases that have occurred. However, it is also reasonable to argue that the people and organisations that pay fees under the Act have enjoyed the exclusive benefit of the undertake in fees. Also, no submitters identified a social or cultural goal, over and above the administration of the Act, that justifies Crown funding.

17 On this basis, no changes have been made to the fees that were proposed in the preferred options outlined in the public consultation document.

Inspection periods

18 The term 'inspection period' is used in Schedule 2 of the Regulations to determine the source licence fee payable on a risk basis. An inspection period of one year is assigned to the highest risk categories and these source licence holders pay the highest fee. An inspection period of five years is assigned to the lowest risk categories which attract the lowest fee.

19 In addition to determining the source licence fee, the term inspection period has also inadvertently created interpretations that 'inspections' can only be conducted on site and can only be conducted within a specified 'period'. This was not the intention, and on this basis the public consultation document proposed removing the term inspection period from the Regulations.

20 Some submitters considered that this proposal would have the effect of removing transparency for the fees paid. In response, the proposal has been amended to ensure that off-site inspections methods and flexible risk-based inspection scheduling are available while also ensuring that a transparent connection between the fee paid and costs of inspection is retained in the Regulations.

Other matters raised in submissions

21 Submitters also raised technical matters and points of clarification that have been adopted in the proposals presented in this paper.

Proposed amendments

22 Appendices 1-3 of this paper set out the detailed changes proposed. The proposals are based on the public consultation document, incorporating changes in response to the submissions received during public consultation.

23 Appendix 1: *Proposed amendments to Schedule 2 of the Radiation Safety Regulations 2016* sets out: the proposals for new source licence fees, the re-categorisation of practices in Schedule 2, and the proposals on refunds in relation to source licences.

24 Appendix 2: *Proposed amendments to fees set out in regulation 17 and 18 of the Radiation Safety Regulations 2016* sets out the proposed new use licences application and consent application fees.

25 Appendix 3: *Proposed technical amendments to the Radiation Safety Regulations 2016* sets out all the other proposals that are not captured in appendices 1 and 2.

Next steps

26 If Cabinet agrees to the proposed amendments, I intend to:

- instruct the Parliamentary Counsel Office to draft the Order in Council to amend the Regulations
- present the proposed Order in Council to Cabinet in December 2022.

Financial Implications

27 The proposed changes are intended to address an historical shortfall in fees taken and to fully recover the direct and indirect costs of administering the Act. Therefore, there are no financial implications for the Crown arising from these proposals.

Legislative Implications

28 The proposals require an Order in Council to amend the Radiation Safety Regulations 2016. The Parliamentary Counsel Office has been consulted.

Impact Analysis

Regulatory Impact Statement

29 A Cost Recovery Impact Statement (CRIS) has been completed and is attached at Appendix 4 of this paper.

30 The Ministry of Health's Papers and Regulatory Committee has reviewed the CRIS and considers that it meets the quality assurance criteria.

Climate Implications of Policy Assessment

31 The Climate Implications of Policy Assessment (CIPA) team has been consulted and confirms that the CIPA requirements do not apply to these proposals as the threshold for significance is not met.

Population Implications

32 There are no additional gender, disability or ethnicity implications arising from the proposals outlined in this paper.

Human Rights

33 The proposals are consistent with the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.

Consultation

34 The following agencies have been consulted: The Ministry for Primary Industries, Pacific Peoples, the Environment, Foreign Affairs and Trade, Business, Innovation and Employment, Transport, and Education, Department of Corrections, National Emergency Management Agency, Te Whatu Ora – Health New Zealand, Te Puni Kōkiri, The Treasury, Worksafe New Zealand, Environmental Protection Authority, New Zealand Defence Force, National Emergency Management Agency, Fire and Emergency New Zealand, Civil Aviation Authority of New Zealand, Maritime New Zealand, New Zealand Police, New Zealand Customs Service, Tertiary Education Commission, and Waka Kotahi – New Zealand Transport Agency.

35 Te Aka Whai Ora – Māori Health Authority and the Department of the Prime Minister and Cabinet were advised of the proposals.

Communications

36 General communications are being conducted on the Ministry's website.

37 All licence and consent holders will be advised directly following final Cabinet decisions on these proposals. Professional registration bodies (for example, the Medical Council of New Zealand) and highly affected occupational representative organisations will also be directly advised. Officials will be available to meet affected parties on request.

Proactive Release

38 I intend to proactively release this paper, subject to any withholding of information required in accordance with the Official Information Act 1982, within 30 business days following final Cabinet decisions on amended Regulations.

Recommendations

The Minister of Health recommends that the Committee:

1 note that in February 2022, Cabinet approved the release of a public consultation document about a proposal to amend the Radiation Safety Regulations 2016 (the Regulations) [CAB-22-MIN-0021];

2 note that the public consultation concluded in April 2022 and 20 submissions were received that have helped to inform the following proposals;

3 agree that fees be set to fully recover the direct and indirect costs of verifying compliance by authorisation holders with the radiation safety requirements in accordance with section 92(2)(b) of the Radiation Safety Act 2016 (the Act);

4 agree to adopt the proposals set out in Appendix 1 of this paper: *Proposed amendments to Schedule 2 of the Radiation Safety Regulations 2016* noting that agreement would;

4.1 set new source licence application fees giving effect to recommendation 3 above;

4.2 recover the negative memorandum account balance of $1.6 million over eight years through source licence fees in accordance with section 92(2)(a) of the Act;

4.3 establish, in accordance with section 92(2)(a) of the Act, different source licence fees for new applications considered under section 19 and renewal applications considered under section 28 of the Act;

4.4 move some practices into different compliance monitoring categories in Schedule 2 of the Regulations so that the inspections they receive will be proportionate to the risk that needs to be managed;

4.5 amend the refund provisions in regulation 19(3) for source licences granted where no inspection period applies;

5 agree to adopt the proposals set out in Appendix 2 of this paper as *Proposed amendments to fees set out in regulation 17 and 18* of the Regulations noting that agreement would;

5.1 set new use licence application fees to give effect to recommendation 3 above;

5.2 establish, in accordance with section 92(2)(a) of the Act, different use licence fees for new applications considered under section 22 or renewal applications considered under section 28 of the Act;

5.3 set new consent application fees to give effect to recommendation 3 above;

6 agree to adopt the proposals set out in Appendix 3 of this paper: *Proposed technical amendments to the Radiation Safety Regulations 2016* noting that agreement would:

6.1 establish new refund provisions for source licences;

6.2 replace or amend the operation of the term ‘inspection period’ used in the Regulations;

6.3 require X-ray fluorescence and X-ray diffraction apparatus subject to regulation 13 to be registered and compliance monitoring records to be kept;

6.4 add an exemption from authorisation requirements for a class of Micro-CT apparatus so that qualifying apparatuses only need to be registered and compliance monitoring records to be kept;

6.5 amend the veterinary practice authorisation in Schedule 3 of the Regulations to accurately describe the scope of activities that are authorised;

7 authorise the Minister of Health, without further reference to Cabinet, to make minor and technical adjustments to the above decisions as may be needed to give full effect to the intent of these decisions;

8 invite the Minister of Health to present a proposed Order in Council giving effect to these decisions to the Cabinet Legislation Committee in December 2022.

Authorised for lodgement

Hon Andrew Little

Minister of Health

Appendix 1:

Proposed amendments to Schedule 2 of the Radiation Safety Regulations 2016 - showing annual source licence application fees (excluding GST), new and renewal fees, amendments to compliance monitoring categories, and refund provisions.

Compliance monitoring category	**Practice**	**New application fee**	**Renewal application fee**
Medical 1	Medical therapy	**$3,744**	**$3,508**
Medical 2	Medical **diagnosis (excluding use of radioactive material) ~~or dental diagnosis~~**	**$1,931**	**$1,695**
Medical 3	Nuclear medicine	**$1,931**	**$1,695**
Medical 4	Medical diagnosis (excluding interventional radiology, **interventional cardiology**, computed tomography and the use of **~~unsealed~~** radioactive material), **or dental diagnosis**	**$1,097**	**$861**
Medical 5	Dental diagnosis (excluding **~~cone beam~~** computed tomography)	**$993**	**$757**
Medical 6	Sentinel node biopsy, low-dose-rate-brachytherapy, and bone densitometry	**$993**	**$757**
Non-medical 1	Industrial radiography, **X-ray irradiation,** and any non-medical practice involving high-activity radioactive material	**$3,744**	**$3,508**
Non-medical 2	Production of unsealed radioactive material using a cyclotron	**$3,744**	**$3,508**
Non-medical 3	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**
Non-medical 4	Any non-medical practice involving irradiating apparatus or low-activity radioactive material that is sealed radioactive material, or both, (excluding industrial radiography, veterinary **practice**, well logging, **use of particle accelerators for non-medical purposes, X-ray irradiation,** and the production of unsealed radioactive material using a cyclotron	**$1,328**	**$1,092**
Non-medical 5	Veterinary diagnosis (excluding the use of radioactive material)	**$1,097**	**$861**
Non-medical 6	Any non-medical practice involving irradiating apparatus **~~or low-activity radioactive material that is sealed radioactive material, or both,~~** (excluding industrial radiography, veterinary **practice**, well logging, **use of particle accelerators for non-medical purposes, ~~nuclear density meters~~, human imaging for non-medical purposes, use of pulse generated portable security inspection systems, X-ray irradiation, ~~and the production of unsealed radioactive material using a cyclotron~~**	**$993**	**$757**
Application granted with no **~~inspection period~~ (replacement term)**	Amend regulation 19(3) to retain the following portion of the application fees	**$588**	**$353**
Applications declined	Replace regulation 19(4) to retain the follow portion of the application fees	**$405**	**$305**

Key: **Bold** – wording/figures to be added
~~Bold and strikethrough~~ – wording to be deleted
Normal text – wording to be retained

Appendix 2:

Proposed amendments to fees set out in regulation 17 and 18 of the Radiation Safety Regulations 2016 – showing annual use licence application fees and annual consent application fees (excluding GST), and new and renewal fees for use licence applications for the Radiation Safety Regulations 2016 (renewal applications do not apply to consents)

Authorisation	Type	New application fee	Renewal application fee
Use licence	Use of radiation source(s) for practice(s) specified in the licence	$408	$250
Consent	High-activity radioactive material on a single occasion	$233	N/A
Consent	Low-activity radioactive material on a single occasion	$163	N/A
Consent	Unsealed low-activity radioactive material on more than one occasion during a specified period	$163	N/A

Appendix 3:

Proposed technical amendments to the Radiation Safety Regulations 2016 - showing proposed additional amendments that are not are not specified in Appendix 1 or 2.

	Proposal	Existing regulations	Empowering provisions of the Act
Refunds	To specify the refund, or fee payable, when source licence applications are: 1. granted under section 19 or 28 of the Act for a compliance monitoring category that is different to that for which the application fee was paid, or; 2. varied under section 27 of the Act to a compliance monitoring category that is different to that for which the application fee was paid.	New provisions	Section 92(1)(c)
Inspection periods	Replace or amend the use of the term 'inspection period' in the Regulations to ensure that: 1. off-site methods of inspection are available for use, and; 2. meeting inspection period dates are not a legal obligation to retaining authorisation and monitoring compliance, and; 3. a transparent connection between the fee paid and costs of inspection is retained, and; 4. the existing method for determining the source licence fee payable is retained without alteration.	Regulation 3, 15, 16, 19, and Schedule 2	Section 92(2)(a)
X-ray fluorescence and X-ray diffraction	Remove the exemption from subpart 3 of Part 1 of the Act (register of controlled radiation sources and records), and; Retain the exemption from subpart 2 of Part 1 of the Act (activities that require authorisations), and; Amend regulation 13(b) so that the condition for the irradiating apparatus to be completely and permanently enclosed only applies when the primary X-ray beam is activated	Regulation 13	Section 91(1)(a)(iii)(A) and; Section 91(1)(b)
Micro-CT irradiating apparatus	Make an exemption from subpart 2 of Part 1 of the Act (activities that require authorisations), and; Include technical conditions, along the lines of regulation 13, to the exemption to ensure that the exemption criteria set out in the empowering provisions are met.	New provisions	Section 91(1)(a)(iii)(A) and; Section 91(1)(b)
Veterinary authorisation	Amend the authorisation for veterinarians so that the authorisation applies to the use of irradiation apparatus capable of plain radiography for veterinary diagnostic purposes as was intended when Schedule 3 was first approved	Schedule 3	Section 91(1)(h) and (i) and; Section 91(5)

Appendix 4:

Cost Recovery Impact Statement (CRIS) for proposals to amend the application fees for authorisations required by the Radiation Safety Act 2016