

In Confidence

Office of the Minister of Health

Chair, Cabinet Social Wellbeing Committee

Public consultation on proposals to amend the Radiation Safety Regulations 2016

Proposal

- 1 This Cabinet paper (the Paper) seeks approval to conduct public consultation on proposed amendments to the Radiation Safety Regulations 2016 (the Regulations).
- 2 The Regulations set out the fees payable under the Radiation Safety Act 2016 (the Act) and specify exemptions and other general safety requirements provided for by the Act. The Regulations and the Act apply only to people or organisations that deal with sources of ionising radiation.

Relation to government priorities

- 3 This is a routine matter that requires Cabinet approval and does not relate to a stated priority.

Executive summary

- 4 The Ministry of Health (the Ministry) has reviewed the fees payable under the Regulations and, based on the review, I am considering a significant fee increase to return the overall fees take to full cost recovery.
- 5 In addition, I am also considering a number of minor amendments to the safety provisions of the Regulations which may affect the fees payable for some people and organisations.
- 6 On this basis, I have asked the Ministry to run a six-week public communication and consultation process using the Ministry's website with the aim of commencing as soon as possible.
- 7 Following the consultation and consideration of feedback received, I further intend to seek Cabinet's agreement to:
 - instruct Parliamentary Counsel Office to draft amendments to the Regulations
 - agree the amended Regulations to come into force on 1 July 2022.

Background

- 8 One purpose of the Act is to establish 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.
- 9 Another purpose of the Act is to enable New Zealand to meet its international obligations relating to radiation protection, safety, security and nuclear non-proliferation.
- 10 The Regulations and the Act apply only to people or organisations that deal with sources of ionising radiation. Ionising radiation sources are defined in the Act as being radioactive material or apparatuses (devices) that can generate ionising radiation (such as X-ray machines). Therefore, these proposals do not affect the regulation of non-ionising radiation, such as ultra-violet light (UV), WiFi, cellphone communication systems, microwave technologies, radio waves and other types of electromagnetic fields.
- 11 The fees set out in the Regulations are payable by people who make applications for a licence or consent (an authorisation) or a renewal or variation of an authorisation under the Act.
- 12 The fees were first set in 2017 and were intended to achieve full cost recovery [SOC-16-SUB-0099; CAB-16-MIN-0417]. However, the costs of regulating radiation safety have risen far in excess of what was expected at that time. As a result, the fees taken since 2017 have been short of the costs incurred and the shortfall cannot be recovered at the current level of fees.
- 13 The increased costs have been generated to relieve cost pressures for contracted on-site compliance verification inspections (to ensure safety), improved staffing levels (to implement the new legislation) and a proposed new information technology (IT) system (to improve services). Based on the findings of the fees review, a significant fees increase would be required to meet the aim of achieving full cost recovery.
- 14 The Ministry has advised all people affected by the proposed fees increase about the fees review and the approximate scale of the issue. The Ministry has included professional registration bodies and occupational representative organisations in the radiation user sector in its communications on the fees review.
- 15 PricewaterhouseCoopers New Zealand (PwC) was engaged by the Ministry to review the method for establishing the proposed new fees. PwC's report is attached to this Paper.

Analysis

Why the Regulations require amending

- 16 The Ministry has reviewed the fees payable and found that a fees increase of approximately 111 percent would be required to return the overall fees take to

full cost recovery and to recover a shortfall in fees taken since 2017. This equates to an increase in the annual fees taken of approximately \$1.41 million spread over the approximately 3,690 authorisation holders who pay fees under the Act.

- 17 The fees structure is based on the cost of managing the radiation safety risks. The different fees, in line with international guidelines, are generated by the different costs associated with routine on-site compliance verification inspections. The proposed amendments would retain this structure.

Consultation

- 18 I have asked the Ministry to conduct a public consultation in relation to the proposed fee increase.
- 19 In addition, to better realise the purposes of the Act, I have also asked the Ministry to consult on other proposals to amend the Regulations to:
- partially remove the exemption from licencing, registration and record keeping for very low risk irradiating apparatuses
 - refine compliance monitoring categories and inspection periods to better align compliance monitoring with managing radiation risks. This will affect the fees that some entities with control or management of radiation sources must pay (some higher fees and some lower)
 - adjust the scope of activities that some people can perform without the need to obtain a licence to use radiation sources
 - amend the provisions on refunding fees so that the costs of assessing applications that require refunds are retained
 - set out the provisions on determining the source licence fees payable, as far as is possible, in table format to make the Regulations easier to use.

Cost increases and the negative memorandum account balance

- 20 The proposed new fees take needs to be approximately \$2.69 million per year to achieve full cost recovery and to recover the shortfall in fees taken since 2017 (a negative memorandum account balance).
- 21 The current fees achieve an annual fees take of approximately \$1.28 million per year. Therefore, the proposed fees take would be an increase of approximately \$1.41 million per year on the current fees (an approximately 111 percent increase).
- 22 The increased fees take would be spread over approximately 3,690 authorisation holders. The recovery of the negative memorandum account balance would be spread over eight years.

- 23 Table 1 sets out the fees review’s projected annual costs from 2022 for the next eight years compared to the projected costs when the current fees came into force in 2017.

Table1: Changes in annual costs of regulating radiation safety

	Projected annual costs from 2022	Projected annual costs 2017	Cost changes	Percentage change
Routine on-site inspections	\$1,368,997	\$887,700	\$481,297	54%
Administration of applications	\$1,038,778	\$450,000	\$588,778	131%
Contracted technical evaluation	\$82,670	\$100,000	-\$17,330	-17%
Memorandum account	\$200,000	-\$162,000	\$362,000	223%
Total	\$2,690,445	\$1,275,700	\$1,414,745	111%

- 24 In line with the previous Cabinet decision [SOC-16-SUB-0099; CAB-16-MIN-0417], the draft consultation document has been prepared based on achieving full cost recovery.

Proposed fees

- 25 The proposed new fees, compared to current fees, are set out in Appendix 1 to this Paper. They are also discussed in full detail in section 3 (pages 24-28) and Appendix 1 of the draft consultation document attached to this Paper.
- 26 The draft consultation document provides information on the costs to be recovered, including the cost movements that have occurred since the current fees came into force in 2017.
- 27 The method used to calculate the proposed new fees has been reviewed by PwC to confirm that it is valid and justifiable. PwC’s review findings have been incorporated into the draft consultation document. PwC’s report is attached to this Paper and will be available on the Ministry website alongside the draft consultation document for the inspection of potential submitters.
- 28 The proposed new fees follow the existing fee structure. This structure assigns fees that are graded to the radiation safety risks that need to be managed. Higher-risk situations attract a higher frequency of inspections, are more complex and require higher degrees of inspector expertise.
- 29 For the large organisations paying the highest fees the proposed fees increase is unlikely to be significant compared to overall operating costs. Organisations in this category include district health boards, private hospitals and radiology providers, the New Zealand Blood Service, industrial irradiators, some research institutes and universities.
- 30 Sole charge operators and smaller organisations will experience the largest impact because fees (and the risks that need to be managed) do not

differentiate on the basis of business size. Organisations in these categories include many private dentists, small firms using industrial radiography techniques (high-risk) and a small number of veterinarians using radioactive material for treatments.

Other proposed amendments

- 31 The draft consultation document contains a proposal to partially remove an existing exemption for dealing with very low risk X-ray fluorescence or X-ray diffraction apparatuses (likely to result in effective dose of less than 10 microseverts per year). This proposal would make these apparatuses subject to the requirements of registration and record keeping under the Act.
- 32 This amendment would mean that registration and records information will become available for verifying compliance with the relevant radiation safety requirements. This proposal does not affect the existing exemption from the requirement to obtain a licence and therefore, no fees will become payable for this category of apparatuses.
- 33 Further, the draft consultation document proposes that the scope of some exemptions be narrowed and that some adjustments are made to the categories that determine the frequency of inspections required for the purposes of verifying compliance with the Act. Some of these proposals affect the fees that some entities with control or management of radiation sources must pay.
- 34 The draft consultation document also proposes amendments to the existing provisions on refunding fees so that the costs of assessing applications that require refunds are retained. These proposals would apply to applications that are either declined or varied to a lower inspection frequency and therefore, require a refund of a portion of the application fee.
- 35 Finally, it is also proposed that the provisions on determining the source licence fees payable are, as far as is possible, set out in table format to make the Regulations easier to use.

Consultation plan

- 36 In addition to the Cabinet Manual requirements on consultation, section 92(4) of the Act requires that:
 - any regulations relating to fees require appropriate consultation with persons or organisations that the Minister considers representative of the interests of persons likely to be substantially affected
 - the persons involved in the consultation be given sufficient time and information to make an informed contribution.
- 37 To meet these requirements, the Ministry has informed authorised people and other users of radiation sources as well as professional registration bodies and

occupational representative organisations (for example, the Medical Council of New Zealand) of the proposed consultation.

- 38 The purposes of the Act also make it appropriate that consultation is public so that people who may benefit from the use of ionising radiation, or who may have concerns about the potential harm of using ionising radiation, have the opportunity to make submissions.
- 39 The Ministry has also established a website to conduct ongoing communications with public consultation aiming to start as soon as possible and to run for a six-week period.

Next steps

- 40 If Cabinet agrees to the proposed amendments to the Regulations, I intend to seek Cabinet's agreement to:
- instruct Parliamentary Counsel Office to draft amendments to the Regulations
 - enable the Regulations to come into force on 1 July 2022.

Financial Implications

- 41 There are no financial implications as a result of this paper.

Legislative Implications

- 42 A proposal to amend the Regulations will be presented for Cabinet consideration once submissions on the draft consultation document have been considered and the proposals have been finalised.

Impact Analysis

Regulatory Impact Statement

- 43 The Ministry has reviewed the draft consultation document and confirms that it is a suitable substitute for an interim Regulatory Impact Statement.

Population Implications

- 44 The benefits of the safe use of ionising radiation are available to all New Zealanders through publicly funded health services provided by district health boards, the New Zealand Blood Service, and breast screening providers. Partly-subsidised and private health services in primary health care, dentistry, and in private hospital services also make use of ionising radiation.
- 45 Infrastructure projects (for example, road building), other construction, crown research institutes and universities also use ionising radiation to benefit New Zealand as whole. The primary sector benefits because veterinary, animal products and screening services use ionising radiation. A range of industries benefit from the use of ionising radiation technologies. Security services (such

as baggage screening) also use ionising radiation to the benefit of New Zealanders.

- 46 There are no additional gender implications or implications for the disability sector arising from the proposed consultation. There are also no additional implications for Māori and Pacific populations arising from the proposed consultation.

Human Rights

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

Consultation

- 48 The following agencies have been consulted: The Ministries for: Primary Industries; Pacific Peoples; the Environment; and Women. The Ministries of: Foreign Affairs and Trade; Justice; Business, Innovation and Employment; Transport; and Education. The Departments of: Corrections; Internal Affairs; and the Department of the Prime Minister and Cabinet. Fire and Emergency New Zealand. Te Puni Kōkiri. The Treasury. Worksafe New Zealand. Environmental Protection Authority. New Zealand Defence Force. Civil Aviation Authority of New Zealand. Maritime New Zealand. New Zealand Police. New Zealand Customs Service. Tertiary Education Commission. Waka Kotahi NZ Transport Agency.

Communications

- 49 Communications and the public consultation will be run on the Ministry's website. Meetings with professional registration bodies and occupational representative organisations (for example, the Medical Council of New Zealand) have been offered and will remain available on request.

Proactive Release

- 50 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

I recommend that the Committee:

- 1 **note** that the fees set out in the Radiation Safety Regulations 2016 (the Regulations) require amending to achieve full cost recovery in administering the Radiation Safety Act 2016 (the Act)
- 2 **note** that the current fees level is creating an increasing negative memorandum account balance (shortfall in fees taken against costs) in administering the Act
- 3 **note** that the draft consultation document attached to this Paper has been prepared for public consultation on proposed new fees to achieve full cost

recovery and to decrease the negative memorandum account balance to zero over eight years

- 4 **note** that the draft consultation document also contains proposals to amend the Regulations to:
 - 4.1 align the existing refund provisions with the new fees and the principles of cost recovery
 - 4.2 as far as possible, set out the existing provisions on determining the source licence fees payable in table format to make the Regulations easier to use
 - 4.3 partially remove an existing exemption for very low risk irradiating apparatuses
 - 4.4 better align exiting compliance monitoring categories and inspection periods with the radiation risks that need to be managed
 - 4.5 adjust the scope of some existing activities that can be performed without the need to obtain a licence to use radiation sources.
- 5 **note** that section 92(4) of the Act requires the Minister of Health to consult on changes to the fees and to give potential submitters sufficient time and information to make an informed contribution
- 6 **note** that the Ministry of Health (the Ministry) will publish the draft consultation document attached to this Paper on its website for a six-week period of public consultation
- 7 **note** that PricewaterhouseCoopers New Zealand's report on the method used to calculate the proposed fees (attached to this Paper), will be available alongside the draft consultation document for the inspection of potential submitters
- 8 **note** that the Ministry will inform the people who pay fees under the Act, other users of radiation sources, professional registration bodies and occupational representative organisations when the consultation is open
- 9 **agree** to conduct public consultation on the proposed amendments to the Regulations set out in the draft consultation document attached to this Paper
- 10 **authorise** the Minister of Health to make minor editorial or technical amendments to the attached draft consultation document before it is published.

Authorised for lodgement

Hon Andrew Little

Minister for Health

Appendix 1: Cabinet paper: Public consultation on proposals to amend the Radiation Safety Regulations 2016 - Proposed new annual fees compared to current fees (discount until 7 March 2023 applied) and full current fees (discount removed from 7 March 2023)

Source licences (new and variations)	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
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 (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	\$997	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%

The report relating to the Review of Radiation Safety Regulations 2016 can be found here: www.health.govt.nz/publication/review-radiation-safety-regulations-2016-consultation-document