MANATŪ HAUORA
MINISTRY OF HEALTH

Briefing

Minor and technical adjustments to the Cabinet policy decisions to amend the Radiation Safety Regulations 2016

Date due to MO:	3 March 2023	**Action required by:**	10 March 2023
Security level:	IN CONFIDENCE	**Health Report number:**	H2023020059
To:	Hon Dr Ayesha Verrall, Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

Name	Position	Telephone
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Keith Gardner	Principal Advisor, Office of Radiation Safety, Regulatory Services	

Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

Minor and technical adjustments to the Cabinet policy decisions to amend the Radiation Safety Regulations 2016

Security level:	IN CONFIDENCE	**Date:**	3 March 2023
To:	Hon Dr Ayesha Verrall, Minister of Health		

Purpose of report

1. This briefing seeks your approval for minor and technical policy adjustments to Cabinet's 21 November 2022 agreement to amend the Radiation Safety Regulations 2016 (the Regulations).
2. Cabinet has authorised the Minister of Health to make the adjustments under paragraph 7 of SWC-22-MIN-0207 – Appendix 1, (CAB-22-MIN-0513) - Appendix 2.
3. This report discloses all relevant information and implications.

Summary

4. The adjustments are required to address issues that have arisen during the drafting of the amended Regulations. Should you approve the adjustments, this briefing will be provided to the Parliamentary Counsel Office (PCO) to ensure that drafting can be completed.
5. Your approval would enable PCO to certify the amended Regulations as being in order for submission to Cabinet.
6. Manatū Hauora – the Ministry of Health (the Ministry) recommends the adjustments. The Ministry considers the adjustments to be minor and technical in nature and necessary to give full effect to the intent of Cabinet's decision to amend the Regulations.
7. The adjustments will not affect the information provided in the cost recovery impact statement (CRIS) that Cabinet considered when it agreed to amend the Regulations.
8. Once drafting of the amendments is complete you will be provided with a draft Order in Council, Cabinet Legislation Committee (LEG) paper, and cover briefing (with talking points) by 23 March 2023, in preparation for the LEG meeting of 13 April 2023.
9. The amended Regulations are required to be in force as soon as possible so that full cost recovery in administering the radiation safety requirements can be put in place. Currently, the fees payable under the Regulations are too low. This is responsible for a relatively large and increasing operating shortfall (a negative memorandum account balance) in administering the radiation safety requirements.
10. In addition to the decisions sought in this briefing is an outline of the radiation safety legislative framework and summary of the process to amend the Regulations.

Recommendations

a) **Note** that under paragraph 7 of SWC-22-MIN-0207 (confirmed CAB-22-MIN-0513 - appended) the Minister of Health is authorised by Cabinet to make minor and technical adjustments to the Cabinet decisions to amend the Radiation Safety Regulations 2016 as may be needed to give full effect to the intent of those decisions. **Noted**

b) **Note** that Cabinet's decisions set out in paragraphs 4.3 and 5.2 of SWC-22-MIN-0207 could enable application fees for new source licences and new use licences (higher fees) to be payable for a period of up to three years. This could give rise to concerns that the amended regulations would enable the over-recovery of the costs of administering the radiation safety requirements. **Noted**

c) **Approve** adjustments to the Cabinet decisions set out in paragraphs 4.3 and 5.2 of SWC-22-MIN-0207 so that the fees for new source licence applications and new use licence applications may only be charged for a period of one year (the shortest possible period). **Yes/No**

d) **Note** that Cabinet's decision set out in paragraph 6.4 of SWC-22-MIN-0207 to exempt a class of Micro-CT apparatus from authorisation requirements of the Radiation Safety Act 2016 (the Act) has proven technically difficult to achieve. **Noted**

e) **Approve** the removal of the exemption for a class of Micro-CT set out in paragraph 6.4 of SWC-22-MIN-0207. **Yes/No**

f) **Note** this briefing forms part of the Cabinet process to amend the regulations and therefore must be proactively released with all other relevant material within 30 days of Cabinet's final decisions as set out in Cabinet Office Circular, Practice Release of Cabinet Material: Updated Requirements (CO (18) 4). **Noted**

g) **Note** that for the purposes of meeting CO (18) 4, Manatū Hauora – The Ministry of Health sees no grounds on which to withhold or delay the release of any information in this briefing. **Noted**

h) **Approve** the proactive release of this briefing in accordance with CO (18) 4. **Yes/No**

Clare Perry
Deputy Director-General
Regulatory Services | Te Pou Whakariterite Ratonga
Date: 27/02/2023

Hon Dr Ayesha Verrall
Minister of Health
Date: 14/3/23

Dr Diana Sarfati
Te Tumu Whakarae mō te Hauora
Director-General of Health
Date: 01/03/23

Minor and technical adjustments to the Cabinet policy decisions to amend the Radiation Safety Regulations 2016

Reason for this briefing

1. The Radiation Safety Regulations 2016 (the Regulations) are made under the Radiation Safety Act 2016 (the Act). You are the Minister responsible for the Act and the Ministry of Health – Manatū Hauora (the Ministry) administers the Act.
2. In February 2022, Cabinet agreed to public consultation on amendments to the Regulations [SWC-22-MIN-0001, CAB-22-MIN-0021], predominantly to set new fees to achieve full cost recovery in administering the radiation safety requirements.
3. Following consultation, Cabinet agreed in November 2022 to amend the Regulations with some minor adjustments to incorporate feedback received in submissions [SWC-22-MIN-0207; CAB-22-MIN-0513]. Copies of these Cabinet minutes are appended to this briefing for your reference.
4. The Ministry is working with the Parliamentary Counsel Office (PCO) to draft the Amendment Regulations in accordance with SWC-22-MIN-0207.
5. Two matters have arisen during the drafting process that require adjustments to Cabinet's decisions and your approval is required to make the adjustments.

Adjustments required to Cabinet's decisions to amend the Regulations

6. Cabinet has authorised the Minister of Health to adjust their decisions under paragraph 7 of SWC-22-MIN-0207.

Fee adjustment

7. An adjustment is required to ensure that Cabinet's decisions specifying higher application fees for new (first-time) source licenses and new use licences (set out in paragraphs 4.3 and 5.2 of SWC-22-MIN-0207) may only be charged for a period of one year (the shortest possible period). Cabinet's decisions do not specify a time limit. Without the adjustment, the amended regulations could (unintentionally) enable the higher fee to be applied for a period of up to three years.
8. This adjustment would ensure that the amended regulations would not enable a potential over-recovery of the costs of administering the radiation safety requirements.
9. This adjustment has no material effect on Cabinet's decisions. The additional costs associated with determining new applications (compared to applications to renew licences – ie, the lower fee) are fully incurred within the first year and the amended fees were calculated on this basis. Therefore, this adjustment would not affect the proposed fees or the information provided in the cost recovery impact statement (CRIS) that Cabinet considered when it agreed to amend the Regulations.
10. The Ministry's view is that this adjustment is minor.

Technical adjustment

11. A technical adjustment is required to ensure that Cabinet's decision to introduce an exemption from the authorisation requirements (source licences and use licences) for a class of 'Micro-CT' apparatus (set out in paragraph 6.4 of SWC-22-MIN-0207) does not proceed at this time.

12. In response to submissions received during public consultation, the Ministry assessed three models of small benchtop apparatus that use X-rays with computed tomography (CT) to produce very high-resolution, three-dimensional, images of small biological samples (Micro-CT). The assessment found that the models could meet the criteria set out in the Act for making exemptions if conditions could be applied. However, during drafting, the technical definitions required to isolate the proposed exemption from other technology has proven unworkable.

13. There is other apparatus that are not Micro-CT that are likely to also qualify for any exemption and conditions that could be drafted. However, at this time the Ministry has not been able to assess these devices to the standard required for making legislation. Excluding potentially qualifying apparatus raises an equity concern if the exemption were to proceed for Micro-CT only.

14. There are also practices that involve Micro-CT that do not warrant an exemption so that continued licensing (and inspections) remains in force. Because the drafting has not been able to succinctly define the legal boundaries of the exemption, radiation safety principles suggest that the exemption should not be applied until a solution is developed.

15. The Ministry advises that a reassessment of its approach to Micro-CT should be completed and (if still appropriate) sought through a separate amendment process later.

16. This adjustment would ensure that the amended regulations only contain considered safety measures that fully meet the purposes of the Act.

17. This adjustment would have minimal effect on the information Cabinet used to make its decisions. For the purposes of the CRIS that Cabinet considered, the overall impact of the proposed exemption was considered negligible. The proposed exemption would have removed licencing (and fees) for only a very small number of facilities. There are other facilities that have Micro-CT equipment that would not have been financially affected by the exemption because they have other radiation sources on-site that require licencing. This is because source licence fees are payable only for the highest-risk radiation practice conducted at each facility.

18. The Ministry will communicate directly with the submitters who proposed the exemption once Cabinet has made its final decisions on amending the Regulations.

How your approvals will be used

19. The Ministry recommends both adjustments and considers these necessary to give full effect to the intent of Cabinet's decision to amend the Regulations.

20. Your approval of the adjustments will be provided to PCO to ensure that drafting can be completed and enable certification of the draft Order in Council to amend the Regulations for submission to Cabinet.

21. This briefing will form part of the Cabinet process to amend the Regulations and must be proactively released, along with the other Cabinet papers, within 30 business days of final

Cabinet decisions being made unless there is good reason not to (Proactive Release of Cabinet Material: Updated Requirements (CO (18) 4)). The Ministry sees no reason to withhold or delay the release of any part of this briefing.

Background on the Radiation Safety Legislative Framework

22. The Act establishes a framework to protect the health and safety of people and to protect the environment from the harmful effects of ionising radiation while allowing for its safe and beneficial use.

23. The Act also enables New Zealand to meet its international obligations relating to radiation protection, radiation safety and security, and nuclear non-proliferation.

24. The Act does not affect or limit the application of the New Zealand Nuclear Free Zone, Disarmament, and Arms Control Act 1987 or other key legislation dealing with nuclear testing, atomic energy and the suppression of terrorism.

25. The legislative framework applies to 'radiation sources' which includes radioactive material and irradiating apparatus (devices capable of producing ionising radiation when operated).

26. The legislative framework includes the Regulations (specifying general provisions in detail) and Codes of Practice (specifying technical requirements for practices or activities, eg, the practice of diagnostic and interventional radiology or the practice of industrial radiography).

27. The Act itself requires licencing of the management and control of ionising radiation sources (source licences), the use of ionising radiation (use licences) and the export or import of radioactive material (consents). The Act also requires a register of most categories of radiation sources to be kept for the purpose of ascertaining the location of radiation sources (among other things).

28. Source licence holders receive scheduled on-site inspections to monitor compliance with the radiation safety requirements. Inspection frequencies vary depending on the risk that needs to be managed. The costs of inspections are included in the application fees paid for source licences. The frequency and complexity of inspections is the main reason for a large variation in source licence fees.

29. The fees proposed under paragraph 3 of SWC-22-MIN-0207 aim to achieve full cost recovery of the direct and indirect costs of verifying compliance with the radiation safety requirements.

Summary of the Development of the Amendment Regulations

30. In 2021, the Ministry reviewed the Regulations against the 2016 intent for the fees to fully recover the operating costs of the radiation safety legislative framework.

31. The review found that the fees have never achieved full cost recovery because the cost increases associated with administering the legislation have been considerably higher than was anticipated in 2016. Also, implementation of the new legislation was slower than anticipated.

32. The review concluded that an annual increase in the overall fees charged of approximately $1million (73 percent increase) was required to achieve full cost recovery, with an additional annual fees-take of $200,000 for eight years to recover the shortfall in the fees taken since 2016 (the negative memorandum account balance).

33. The review proposed the new fees be spread over approximately 3,690 licences and consents. The source licence fees are graded into 'compliance monitoring categories' which are assigned fees in proportion to the risks that need to be managed. The proposed new fees are set out SWC-22-MIN-0207 (attached). Amendments to the refund provisions were also proposed to support full cost recovery.

34. The report of the fees review was included in the public consultation document on amending the Regulations which is still available on the Ministry's website. PricewaterhouseCoopers New Zealand (PwC) was engaged to review the model used to set the new fees. PwC's report was released alongside the public consultation document and is also still available on the Ministry's website.

35. The public consultation set out proposals to adjust compliance monitoring categories for several radiation practices so that costs of higher frequency (or lower frequency) inspections can be recovered. The public consultation also included proposals to narrow the terms of an existing exemption and to improve the technical accuracy of some of language used in the Regulations (without changing the provisions).

36. Twenty submissions were received in response to the public consultation. Eighteen submissions were from source licence holders. Generally, submitters did not want to pay higher fees and some submitters wanted the Crown to meet the costs of recovering the deficit. No submitters identified a social goal that justified partial Crown funding of the legislative framework (such as safety or equity). No submitters identified faults or suggested improvements to the fees model.

37. Submitters supported (or did not comment on) the proposals that were not related to fees.

38. The fees set out in the public consultation document were approved by Cabinet unaltered. The other amendments agreed by Cabinet are in-line with the public consultation but incorporate several technical suggestions provided by submitters.

39. The Ministry's assessment of the impact of the proposals is fully disclosed in the CRIS that Cabinet considered when it approved the amendments set out in SWC-22-MIN-0207. The CRIS will be included in the documents proactively released after Cabinet makes its final decisions on the amended Regulations.

Equity

40. Your approval of the minor adjustments would not affect existing health equity programmes nor contribute to further health inequity.

41. However, approval of the adjustments would contribute to fairness (equity) in cost recovery and the application of exemptions.

Next steps

42. Your approval will be provided to PCO to ensure the required drafting and certification of the final draft Order in Council for submission to Cabinet.

43. The Ministry is preparing a Cabinet Legislation Committee (LEG) paper to accompany the draft Order in Council along with a cover briefing and talking points. These papers will be provided to your office by 23 March 2023, in preparation for the LEG meeting of 13 April 2023.

ENDS.

Minister's Notes