#### In Confidence

Office of the Minister of Health

Chair, Cabinet Legislation Committee

## **Approval of the Radiation Safety Amendment Regulations 2023**

## **Proposal**

This paper seeks authorisation for submission to the Executive Council of the draft Radiation Safety Amendment Regulations 2023 (the Amendment Regulations).

## **Policy**

- On 21 November 2022, Cabinet agreed to amend the Radiation Safety Regulations 2016 [SWC-22-MIN-0207, CAB-22-MIN-0513].
- The amendments increase the application fees payable to Manatū Hauora the Ministry of Health (the Ministry) for authorisations (licences and consents) required by the Radiation Safety Act 2016 (the principal Act). The amendments also adjust some safety provisions so that the requirements for licenced people and organisations become more proportional to the risk that needs to be managed.
- The fees, originally set in 2016, have never achieved the intent of full cost recovery in administering the radiation safety legislation. The amendments will increase the fees by an average of 111 percent and include a 9.22 percent over-recovery for source licence application fees (for eight years) to recover the negative memorandum account balance (deficit) that has built up since 2016. The new fees are set out in clauses 7 (with reference to the table replaced by clause 15), 10 and 11 of the draft Amendment Regulations.

### Minor adjustments to policy

- I have approved two minor and technical adjustments to give full effect to the intent of Cabinet's decisions.
- The first adjustment limits the application of the proposed higher annual fees for new (first-time) source licence and use licence applicants to a period of one year (the shortest possible period). The adjustment would ensure that the higher fees are only payable in respect of the higher costs that are incurred in establishing first-time licences.
- The second adjustment removes the proposed exemption for a class of X-ray irradiating apparatus referred to as 'Micro-CT'. The Ministry advised that it has not been possible to adequately define the exempt apparatus.

Neither adjustment affects the assessments set out in the cost recovery impact statement (CRIS) that Cabinet considered when it agreed to the amendments.

## Timing and 28-day rule

The draft Amendment Regulations will comply with the 28-day rule as they will only come into force on 28 June 2023.

# Compliance

- 10 The draft Amendment Regulations comply with:
  - 10.1 the principles of the Treaty of Waitangi, noting that there are no Treaty of Waitangi provisions in the draft Amendment Regulations or in the principal Act
  - 10.2 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993
  - 10.3 the principles and guidelines set out in the Privacy Act 2020
  - 10.4 relevant international standards and obligations
  - 10.5 the Legislation Guidelines (2021 edition).
- 11 The principal Act requires:
  - 11.1 the responsible Minister to recommend regulations prescribing the fees payable by a person applying for an authorisation or renewal of authorisation, the method by which fees are calculated, and any refunds of the whole of any part of any fee (section 92(1))
  - 11.2 that before recommending any regulations for cost recovery, the responsible Minister must, as far as is reasonably practicable, have regard to the principles of equity, efficiency, justifiability, transparency, and ease of administration, in determining the most appropriate method of cost recovery (section 92(3))
  - that costs should not be recovered unless appropriate consultation takes place with people or organisations that the responsible Minister considers likely to be substantially affected, and that those people or organisations have sufficient opportunity to comment (section 92(4)).
- 12 I confirm that these requirements have been met.

## **Financial Implications**

The proposed changes are intended to address an historical shortfall in fees collected 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.

## **Regulations Review Committee**

There are no grounds for the Regulations Review Committee to draw the draft Amendment Regulations to the attention of the House of Representatives under Standing Orders.

# **Certification by Parliamentary Counsel**

The draft Amendment Regulations were certified by the Parliamentary Counsel Office as being in order for submission to Cabinet.

# **Impact Analysis**

A CRIS was prepared that met the quality assurance criteria. The CRIS was considered by Cabinet when it approved the proposed amendments [CAB-22-MIN-0513].

## **Publicity**

Approximately 3,690 authorisation holders (fees payers) will be advised by email following final Cabinet decisions on these proposals. Professional registration bodies (for example, the New Zealand Medical Radiation Technologists Board), professional associations and highly affected user groups will also be directly contacted at that time.

### **Proactive release**

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

## Consultation

- The following agencies and departments were consulted: the Treasury, the Ministries for Primary Industries, Pacific Peoples, the Environment, Foreign Affairs and Trade, Business, Innovation and Employment, Transport, Education, the Department of Corrections, National Emergency Management Agency, Te Puni Kōkiri, Worksafe New Zealand, Environmental Protection Authority, New Zealand Defence Force, Fire and Emergency New Zealand, Civil Aviation Authority of New Zealand, Maritime New Zealand, New Zealand Police, New Zealand Customs Service, Tertiary Education Commission, Waka Kotahi New Zealand Transport Agency and the Department of the Prime Minister and Cabinet.
- 20 Te Aka Whai Ora the Māori Health Authority was advised of the proposals.
- A six-week public consultation was conducted in accordance with the Cabinet approval [CAB-22-MIN-0021]. All fee payers were directly advised of the consultation as were professional registration bodies (for example, the New Zealand Medical Radiation Technologists Board), professional associations and highly affected user groups.

#### Recommendations

I recommend that the Cabinet Legislation Committee:

- note that on 21 November 2021, Cabinet agreed to amend the Radiation Safety Regulations 2016 [SWC-22-MIN-0207, CAB-22-MIN-0513], and to give effect to those decisions by making the Radiation Safety Amendment Regulations 2023 (the Amendment Regulations)
- 2 note that the Minister of Health, as authorised by SWC-22-MIN-0207, has approved minor and technical adjustments to give effect to the decisions under SWC-22-MIN-0207 and that those adjustments
  - 2.1 limit the application of the higher fees referred to in paragraphs 4.3 and 5.3 of SWC-22-MIN-0207 to a period of one year
  - 2.2 remove the exemption for Micro-CT referred to in paragraph 6.4 of SWC-22-MIN-0207
- note that section 92(1) of the Radiation Safety Act 2016 (the Act) requires the Minister of Health to recommend regulations prescribing
  - 3.1 the fees payable by a person applying for an authorisation or renewal of an authorisation
  - 3.2 the method by which the fees are to be calculated
  - 3.3 exemptions from or refunds of the whole or any part of the any fee
- 4 note that section 92(3) of the Act requires the Minister of Health, as far as reasonably practicable in determining the method of cost recovery, to have regard to the principles of; equity, efficiency, justifiability, transparency and ease of administration before recommending regulations that enable cost recovery
- note that section 92(4) of the Act requires appropriate consultation with people and organisations that the Minister of Health considers to be representative of the interests of people likely to be substantially affected by cost recovery and that those people and organisations have been given sufficient time and information to make an informed contribution
- 6 note that the advice of the Minister of Health is that the requirements of the principal Act have been met
- 7 authorise the submission to the Executive Council of the Amendment Regulations
- 8 note that the Amendment Regulations will come into force on 28 June 2023.

Authorised for lodgement

Hon Dr Ayesha Verrall Minister of Health