In Confidence

*Office of the Minister of Health*

Chair, Cabinet Social Policy Committee

**Proposed Radiation Safety Regulations: Policy Approval**

**Proposal**

1. This paper seeks policy approval for drafting instructions for the proposed Radiation Safety Regulations (the Regulations).

**Executive Summary**

1. In May 2016, Cabinet approved public consultation on proposals for the Regulations [Cab-16-MIN-0198]. Regulations are needed to implement the Radiation Safety Act 2016 (the Act) which comes fully into force on 7 March 2017. 142 submissions were received. Submissions supported most of the proposals but raised questions about fees and the activities that can be performed without the need to obtain a use licence.
2. Full cost recovery for authorisations (licenses and consents) and verifying compliance (‘inspections’) is proposed. Fees will be proportionate to the level of risk associated with the radiation source being managed. For an interim period of 6 years, a ‘discount’ on some fees is proposed to address an historical over recovery of fees under the current legislation.
3. Regulations authorising the groups that can perform activities without having to obtain a use licence are proposed. Only groups whose members have the radiation safety knowledge required to perform the specified activities would be authorised in this way. Some groups have already satisfied these requirements and are therefore included in the proposed Regulations. Other groups are still working to provide or develop the necessary verification. Groups that have not yet provided verification can continue to work with Ministry of Health officials to become authorised by Regulations at a later stage.
4. Other Regulations are also proposed including exemptions from provisions of the Act for temporary situations and for low-risk situations such as smoke detectors.
5. A number of other matters of detail that could be included in Regulations were also raised in submissions. Ministry of Health officials advise that these issues are best addressed in codes of practice and/or radiation safety plans and therefore are not included in the proposed Regulations.

**Background**

1. 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 its safe and beneficial use. The Act comes fully into force on 7 March 2017 and will replace the current Radiation Protection Act 1965. The new Act is broadly similar in scope to the current legislation. Regulations are needed for some of the Act’s provisions to operate.
2. On 9 May 2016, Cabinet approved public consultation on proposals for regulations [Cab-16-MIN-0198]. Consultation on *Proposed Radiation Safety Regulations: A consultation document* ran from 11 May until 22 June 2016.
3. The Act contains provisions for the Director (the regulator) to issue codes of practice and provides for radiation safety plans to support source licences (a type of authorisation). The proposed Regulations do not include any matters that can be included in such codes and plans. This is to ensure that the overall framework is as straightforward as possible and was the position favoured by the majority of submitters. Matters raised by other submitters, including the New Zealand Fire Service's preference for issues such as signage to be included in regulation, will therefore be addressed in codes of practice and/or radiation safety plans.

**Comment**

1. Approximately 4,500 current and recent licence holders under the existing legislation were informed of the consultation and invited to submit. All consultation information was publicly available on the Ministry of Health website.
2. 142 submissions where received. 90 submissions used largely identical pre-drafted text. This compares with the 14 public submissions received by the select committee on the Radiation Safety Bill in 2015. Submissions were received from across the radiation ‘sector’ including health service providers, district health boards, veterinarians, researchers and industrial users.
3. Submissions supported most of the preferred options outlined in the consultation document but raised questions about the proposed fees and the activities that can be performed without the need to obtain a use licence.

*Submissions on fees*

1. The consultation document proposed that the full cost of administering authorisations and inspections to verify compliance with radiation safety requirements should be met by the fees payable for authorisations. The proposals are consistent with the Treasury guidelines and the requirements for cost recovery established in the Act.
2. The principle of full cost recovery was supported by most submitters. However, some submitters questioned the costs associated with inspections (which is a more significant component of the total fee for higher risk situations). As a result of concerns expressed by some submitters, the proposed fee structure for compliance verification was reviewed. This confirmed that the proposed fees reflect the actual and reasonable costs of inspections and as a result no reduction in the proposed fees is warranted.
3. Current fees have not been adjusted since 1998. The intention to adopt a full cost recovery approach under the Act was outlined in the original 2004 regulatory impact statement prepared for the Radiation Safety Bill [CAB Min (04) 31/6].

*Proposed Content of Regulations*

Maximum periods for authorisations

1. A three-year maximum period for source licences (for the control or management of radiation sources) and use licences (for the use of radiation sources) is proposed. A one-year maximum period is proposed for consents to import and export radioactive material. This represents the time period within which the import/export must take place following the issuing of the consent. Maximum periods would allow the Director to opt for shorter durations where appropriate. These proposals were supported by most submissions.

Activities where a use licence is not required

1. Radiation risks are managed in a number of ways, including by requiring users to obtain a use licence. Where the Ministry of Health as the regulator is satisfied that the knowledge of radiation safety required to obtain a use licence has been demonstrated by another means (eg, users will operate under a vocational scope of practice that includes radiation safety), the need to obtain a use licence no longer adds materially to radiation safety. In these situations, Regulations can prescribe groups that can use radiation sources for specified activities without having to obtain a use licence. NB, under these circumstances, the Act’s fundamental safety requirements continue to apply and the owner of the radiation source will still be required to obtain a source licence.
2. The groups and the activities they can perform without a use licence proposed for inclusion in the Regulations are listed in Table 1 of the Appendix to this paper.
3. Submissions also identified groups that are currently unable to demonstrate that they have the required knowledge, but which may satisfy the requirements in the future. These groups are listed in Table 2 of the Appendix. Officials are working with representatives of these groups (mainly health sector registration bodies) and will advise if any of them are able to satisfy the criteria to operate without a use licence. In case any of these groups can meet the criteria, this paper seeks Cabinet’s delegated authority for the Minister of Health to instruct Parliamentary Counsel Office (PCO) to prepare regulations allowing any group in Table 2 to use radiation sources without having to obtain a use licence. Should any other group subsequently meet the requirements, a proposal to amend the Regulations would be prepared for Cabinet in the usual way.

Cost recovery

1. Full recovery of the costs of administering authorisations (licensing and consents) and verifying compliance (inspections) with radiation safety requirements is proposed. The cost (and total fees take) is expected to be approximately $1.44 million per year[[1]](#footnote-1). All other costs associated with radiation safety will continue to be funded from within Ministry of Health baselines.

Source licence fees

1. Source licences are a new type of licence created by the Act. This type of licence places responsibility for radiation safety with the legal entity that has control and management (‘ownership’) of the radiation source. Therefore, almost all of the compliance verification inspections associated with radiation safety will be conducted against source licences.
2. The consultation document outlined a graded scale of source licence fees to reflect the amount of risk being managed by the source licence. Higher risk situations require more complex and more frequent inspections and therefore, the inspection component of the source licence fee is higher. The proposed source licence fees cover the expected costs of both the licensing process and the inspection requirements. In some limited circumstances the Director may determine that no inspection fee will be payable (eg, where no inspection is necessary or radiation safety requirements can otherwise be satisfied).
3. A flat source licence processing fee of $145 per year is proposed as the costs of source licensing will not vary significantly depending on the radiation source. Graded compliance verification fees payable by applicants for source licences are proposed to be:
* $1,360 per year for entities on an annual inspection programme (highest risk)
* $680 per year for entities on a two-year inspection programme
* $455 per year for entities on a three-year inspection programme
* $340 per year for entities on a four-year inspection programme
* $270 per year for entities on a five-year inspection programme
* zero, as determined by the Director.

Use licence fees

1. A small number of submitters commented that the proposals to exclude some groups from having to obtain a use licence means that the cost of administering the use licence system would be met by a smaller number of license holders. Officials confirm that without the exclusions the number of such licences and the total cost of administering use licences would increase, but that any changes in the cost per licence, and therefore the fee, would be small.
2. As proposed in the consultation document, a flat use licence fee of $95 per year is proposed. A flat fee is appropriate because the costs of use licensing are not significantly affected by the amount of risk associated the radiation use.

Consent fees

1. Different fees for consents are proposed to reflect the costs associated with regulating various types of import and export situations. Import and export activity is also subject to specific requirements under international conventions and International Atomic Energy Agency (IAEA) recommendations. On this basis, the fees are proposed to be:
* $300 for each individual consent for IAEA category 1 and 2 (higher risk) sealed radioactive material
* $80 for each individual consent for IAEA category 3, 4 and 5 (lower risk) sealed radioactive material
* $80 for each individual consent for unsealed radioactive material
* $400 per year for a ‘general’ consent allowing multiple imports or exports of unsealed radioactive material over the course of a year (eg, short half-life unsealed sources often manufactured for medical applications).

Correcting historical over-recovery of costs

1. Since the current radiation licensing fees were last set in 1998, the Ministry of Health has over recovered the costs of administering the existing licensing regime (with the current surplus being approximately $970,000). Setting fees under the new Act provides an opportunity to move this balance toward zero.
2. To achieve this, a partial exemption of 13 percent from the full source licence fees (discussed in paragraph 23) is proposed for an interim period of six years.
3. It is therefore proposed that the source licence fee would become $126 per year for the first six years that such fees are payable. The graded compliance verification fees would also be adjusted for the first six years, to become:
* $1,183 per year for entities on an annual inspection programme (highest risk)
* $592 per year for entities on a two-year inspection programme
* $396 per year for entities on a three-year inspection programme
* $296 per year for entities on a four-year inspection programme
* $235 per year for entities on a five-year inspection programme
* zero, as determined by the Director.
1. All fees under the Act will be reviewed prior to the end of this six year period. Any proposals for changes to fees will be submitted to Cabinet for consideration.

Exemptions for temporary entry to New Zealand

1. Exemptions from the requirement to obtain an authorisation and to register controlled radiation sources are proposed for sources that temporarily enter New Zealand by ship or aircraft. These radiation sources are usually part of the normal operations of a vessel (such as X-ray equipment used on some cruise ships) or cargo *en route* to another country. Submissions were generally supportive of this approach but highlighted the need to specify the meaning of ‘temporary’ so that the usual requirements would be triggered if the definition is not met.
2. The Act prevents these exemptions from being applied to nuclear material (a subset of radiation sources defined in the Act).

Exemptions for low-exposure and low-probability situations

1. Exemptions from the requirement to obtain an authorisation and to register controlled radiation sources are also proposed for low-exposure and low-probability situations. These arise where radiation sources meet the definition of ‘radiation source’ established by the Act, but are of little regulatory concern because of the low probability of human or environmental exposure. For example, most household smoke detectors, providing they are used, labelled, and disposed of as prescribed, fall into this category. The Act also allows conditions to be imposed for these exemptions. The proposed exemptions and conditions are specified in Table 3 of the Appendix.

Warrants of appointment for enforcement officers

1. Additional information is proposed for inclusion on warrants appointing enforcement officers under the Act. The additional information is:
* the enforcement officer’s full name
* the enforcement officer’s place of work (warrant to expire if employment ceases)
* the period of appointment (warrant to expire at the end of period)
* any relevant conditions on the appointment the Director has imposed under section 36(3) of the Act.

Compliance orders

1. The Act requires compliance orders to be served in accordance with the procedures specified in Regulations. I propose that the Regulations refer to or incorporate relevant aspects of the District Court Rules for the service of documents.

**Consultation**

1. The government departments consulted on this paper were: Department of Corrections, Ministry of Foreign Affairs and Trade, Ministry for the Environment, Ministry of Justice, Ministry of Civil Defence and Emergency Management, Ministry of Transport, Ministry for Business Innovation and Employment, Department of Internal Affairs, Ministry for Women, Police, Ministry for Primary Industries, State Services Commission, PCO and the Treasury. The Department of the Prime Minister and Cabinet was informed.
2. The government agencies consulted on the consultation document, submissions template and this paper were: New Zealand Fire Service, NZDF, New Zealand Customs Service, New Zealand Transport Agency, Maritime New Zealand, Civil Aviation Authority and WorkSafe New Zealand.

**Financial Implications**

1. Full recovery of the costs of administering authorisations and verifying compliance with radiation safety requirements is proposed. Policy and enforcement costs will be covered from with baselines. The proposals are therefore cost-neutral. The proposal to move the over-recovered surplus toward zero by way of a time-limited partial exemption for source licence fees will provide a small benefit to the sector.

**Human Rights**

1. There are no human rights implications arising from the proposals in this paper.

**Legislative Implications**

1. Subject to Cabinet approval, drafting instructions for the proposed Radiation Safety Regulations will be issued to Parliamentary Counsel Office to be drafted and considered by Cabinet Legislation Committee prior to 7 February 2017.

**Regulatory Impact Analysis**

1. A regulatory impact statement (RIS) is attached to this paper. The RIS shows full cost recovery is feasible. Following consideration of current owners and users of radiation sources and the existing and projected future licensing systems, an assumption is made that the proposed fees will fully recover the actual and reasonable costs of administering authorisations and compliance verification. The RIA will be published on the Ministry of Health and Treasury websites.
2. The Ministry of Health has reviewed the regulatory impact analysis (RIA) and considers that the disclosure of information is adequate and the level of analysis is appropriate for the scope of the proposals.

**Gender Implications**

1. There are no gender implications arising from this paper.

**Disability Perspective**

1. There are no implications for people with disabilities arising from this paper.

**Publicity**

1. A summary of submissions will be prepared for publication on the Ministry of Health website. Submitters will be informed of this publication and of the RIA. General publicity on the Regulations will occur at the time they are promulgated.

**Recommendations**

The Minister of Health recommends that the Committee:

* 1. **note** that Radiation Safety Regulations are needed to implement the Radiation Safety Act 2016 (the Act) when the Act comes fully into force on 7 March 2017;
	2. **note** that Cabinet agreed to a public consultation process on proposals for the Regulations [CAB-16-MIN-0198] and that the 142 submissions received have helped to inform the following proposals;

**Authorisations**

* 1. **agree** that Regulations prescribe that source licences and use licences have a maximum term of three years and that consents have a maximum term of one year, noting that the Director for Radiation Safety may specify shorter periods of time;
	2. **agree** that Regulations authorise the groups listed in Table 1 of the Appendix to this paper to perform the activities prescribed in that Table without the requirement to obtain a use licence;
	3. **note** that Table 2 of the Appendix lists groups that have not yet demonstrated the appropriate levels of knowledge of radiation safety to perform the activities specified in that Table without having to obtain a use licence;
	4. **authorise** the Minister of Health to instruct Parliamentary Counsel Office, without further reference to Cabinet, to prepare Regulations authorising any group listed in Table 2 of the Appendix to perform the activities prescribed in that Table without having to obtain a use licence;

**Fees**

* 1. **agree** that Regulations set fees to recover the full costs of administering authorisations and verifying compliance with radiation safety requirements and that such Regulations prescribe the method by which fees are to be calculated, and any exemptions from or refunds of the whole or any part of any fee;
	2. **note** that the establishment of new fees under the Act provides an opportunity to correct an historical over recovery of costs by way of a time-limited, partial exemption to the fees payable by applicants for source licences;
	3. **agree** that Regulations prescribe a source licence fee of $145 per year (excluding GST) and that a partial exemption is applied to this fee for the first six years that it is payable so that the fee during this period will be $126 per year (excluding GST);
	4. **agree** that Regulations prescribe a graded scale of compliance verification fees payable by source licence applicants and those fees will be (excluding GST):

 10.1 $1,360 per year for entities on a one year inspection programme (highest risk)

10.2 $680 per year for entities on a two-year inspection programme

10.3 $455 per year for entities on a three-year inspection programme

10.4 $340 per year for entities on a four-year inspection programme

10.5 $270 per year for entities on a five-year inspection programme

10.6 zero, as determined by the Director;

* 1. **agree** that Regulations prescribe partial exemptions to be applied to the graded scale of compliance verification fees for the first six years that the fees are payable so that the fees during this period will be (excluding GST):

11.1 $1,183 per year for entities on a one year inspection programme (highest risk)

11.2 $592 per year for entities on a two-year inspection programme

11.3 $396 per year for entities on a three-year inspection programme

11.4 $296 per year for entities on a four-year inspection programme

11.5 $235 per year for entities on a five-year inspection programme

11.6 zero, as determined by the Director;

* 1. **agree** that Regulations prescribe a use licence fee of $95 per year (excluding GST);
	2. **agree** that Regulations prescribe consent fees at different amounts and those fees will be (excluding GST):

13.1 $300 for each individual consent for International Atomic Energy Agency (IAEA) category 1 and 2 (higher risk) sealed radioactive material

13.2 $80 for each individual consent for IAEA category 3, 4 and 5 (lower risk) sealed radioactive material

13.3 $80 for each individual consent to import or export unsealed radioactive material

13.4 $400 per year for a general consent to import or export unsealed radioactive material;

* 1. **note** that the fees set under these Regulations will be reviewed within the first six years that they are payable and any proposals for amendments will be submitted to Cabinet for consideration;

**Other matters**

* 1. **agree** that the Regulations provide for exemptions of radiation sources that temporarily enter New Zealand by ship or aircraft from the requirement to obtain an authorisation and to be registered as a controlled radiation sources;
	2. **agree** that Regulations provide exemptions for the low-exposure and low-probability radiation sources and situations (specified in Table 3 of the Appendix) from the requirement to obtain an authorisation and to be registered as controlled radiation sources;
	3. **agree** that Regulations specify the following details be included in warrants appointing enforcement officers: the officer’s full name, place of work, period of appointment, and any relevant conditions on the appointment the Director has imposed under section 36(3) of the Act;
	4. **agree** that, for the service of compliance orders, Regulations refer to or otherwise incorporate aspects of the District Court Rules;

**Drafting Instructions**

* 1. **invite** the Minister of Health to issue drafting instructions to Parliamentary Counsel Office for Radiation Safety Regulations to give effect to above decisions;
	2. **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 those decisions.

*Authorised for lodgement*

Hon Dr Jonathan Coleman

**Minister of Health**

**APPENDIX**

**Table 1:** Groups and the activities they can perform without having to obtain a use licence (refer sections 91(1)(h) and (i) of the Act)

|  |  |  |  |
| --- | --- | --- | --- |
| **Authority**  | **Group**  | **Criteria**  | **Activity**  |
| Medical Council of New Zealand  | Vocational scope of practice Diagnostic and Interventional Radiology | Current registration and practicing certificate | Use of irradiating apparatus for medical diagnostic purposes |
| Medical Council of New Zealand | Vocational scope of practice Radiation Oncology | Current registration and practicing certificate | Use of irradiating apparatus or radioactive material for medical therapeutic purposes |
| Dental Council  | Scope of practice General Dental Practice | Current registration and practicing certificate | Use of irradiating apparatus for dental diagnostic purposes |
| Dental Council  | Scope of practice Dental Therapy Practice | Current registration and practicing certificate | Use of irradiating apparatus for the taking of periapical and bitewing radiographs for dental diagnostic purposes |
| Dental Council  | Scope of practice Dental Hygiene Practice | Current registration and practicing certificate with no exclusion in taking extra-oral radiographs | Use of irradiating apparatus for taking of extra-oral radiographs for dental diagnostic purposes |
| Dental Council  | Scope of practice Dental Hygiene Practice | Current registration and practicing certificate with no exclusion in taking intra-oral radiography | Use of irradiating apparatus for taking of periapical and bitewing radiographs for dental diagnostic purposes |
| Dental Council  | Scope of practice Orthodontic Auxiliary Practice | Current registration and practicing certificate with no exclusion in taking extra-oral radiographs | Use of irradiating apparatus for taking of extra-oral radiographs for dental diagnostic purposes |
| Dental Council  | Scope of practice Orthodontic Auxiliary Practice | Current registration and practicing certificate with no exclusion in taking intra-oral radiography | Use of irradiating apparatus for taking of periapical and bitewing radiographs for dental diagnostic purposes |
| Dental Council  | Scope of practice The Twelve Dental Specialties requiring general dental training to be completed (NB: Regulations may list these specialties by name | Current registration and practicing certificate | Use of irradiating apparatus for dental diagnostic purposes |
| New Zealand Medical Radiation Technologists Board  | Scope of practice Medical Imaging Technologist | Current registration and practicing certificate | Use of irradiating apparatus for medical diagnostic purposes |

|  |  |  |  |
| --- | --- | --- | --- |
| New Zealand Medical Radiation Technologists Board | Scope of practice Nuclear Medicine Technologist | Current registration and practicing certificate | Administration of radiopharmaceuticals and use of irradiating apparatus and radioactive material for nuclear medicine purposes |
| New Zealand Medical Radiation Technologists Board  | Scope of practice Radiation Therapist | Current registration and practicing certificate | Use of radiation sources for the delivery of radiation treatment for medical therapeutic purposes |
| Veterinary Council of New Zealand  | Veterinarian | Current registration and practicing certificate | Use of irradiating apparatus for veterinary purposes |
| New Zealand Chiropractic Board | Scope of practice: Chiropractor | Current registration and practising certificate | Use of irradiating apparatus for chiropractic purposes |

**Table 2:** Groups that have not yet satisfied the requirements to perform activities without having to obtain a use licence (per sections 91(1)(h) and (i) of the Act) *and for which delegated authority to instruct PCO is sought*

|  |  |  |  |
| --- | --- | --- | --- |
| **Authority**  | **Group**  | **Criteria**  | **Activity**  |
| Dental Council | Scope of practice: oral health therapy | Current registration and practising certificate | Use of irradiating apparatus for dental diagnostic purposes |
| Medical Council of New Zealand | Vocational scope of practice: diagnostic and interventional radiology | Current registration and practicing certificate | Use of unsealed radioactive material for medical diagnostic purposes |
| Medical Council of New Zealand | Vocational scope of practice: ophthalmology | Current registration and practicing certificate | Use of sealed radioactive material for medical therapeutic purposes |
| Medical Council of New Zealand | Vocational scope of practice: general practice | Current registration and practicing certificate | Use of irradiating apparatus for medical diagnostic purposes |
| Medical Council of New Zealand | Vocational scope of practice: vascular surgery | Current registration and practicing certificate | Use of image intensifiers for medical diagnostic purposes |
| Medical Council of New Zealand | Vocational scope of practice: orthopaedic surgery | Current registration and practicing certificate | Use of image intensifiers for medical diagnostic purposes |
| Australasian College of Physical Scientists and Engineers in Medicine | Medical physics specialist | Current certification and registration | Use of radiation sources for the purposes of the role of a medical physics expert |

**Table 3**. Exemptions for low-exposure and low probability situations

(Radionuclides and apparatus exempted under section 91(1)(a)(iii) of the Act)

|  |  |  |  |
| --- | --- | --- | --- |
| **Radionuclide** | **Exempted from** | **Conditions** | **Reasons** |
| Americium-241 | all of subparts 2 and 3 of Part 1 | 1. no greater than 40 kilobecquerels
2. contained in a domestic ionisation chamber smoke detector
3. source is not readily accessible without dismantling the device
4. clearly labelled with a trefoil symbol and the word “radioactive”
 | 1. emits alpha particles that are very easily shielded
2. no external radiation dose so long as they remain in their manufactured containment
3. satisfies the dose criteria in section 91(1)(a)(iii)A
 |
| Nickel-63 or Hydrogen-3 (tritium) | all of subparts 2 and 3 of Part 1 | 1. no greater than 750 megabecquerels (Ni-63) or 20 gigabecquerels (H-3)
2. contained in an electron capture detector or similar device for use in gas chromatography
3. source housing clearly labelled with a trefoil symbol and the word “radioactive”
 | 1. these radiation sources emit low energy beta particles
2. these emissions are easily absorbed by the casing
3. satisfies the dose criteria in section 91(1)(a)(iii)A
 |
| Hydrogen-3 | all of subparts 2 and 3 of Part 1 | 1. no greater than 74 gigabecquerels
2. contained in gaseous tritium light source
3. at least 98% of total activity in the form of elemental hydrogen gas
 | 1. emits low energy beta particles
2. these sources are encapsulated in a glass capsule that easily shields emissions
3. satisfies the dose criteria in section 91(1)(a)(iii)B
 |
| Benchtop x-ray analyser | all of subparts 2 and 3 of Part 1 | 1. used for x-ray fluorescence or x-ray diffraction
2. completely and permanently enclosed to prevent access of any part of the body to the primary x-ray beam
3. enclosure interlocked with the x-ray generator such that disassembly of the enclosure prevents x-ray production
4. shielded sufficiently to limit the instantaneous dose rate to 2.5 microsieverts per hour 5 cm from any accessible external surface.
5. Enclosure clearly labelled with suitable cautionary wording to the effect of: “Do not disassemble. This unit produces ionising radiation when energised.”
 | 1. satisfies the dose criteria in section 91(1)(a)(iii)A
 |

1. All monetary amounts related to fees are exclusive of GST [↑](#footnote-ref-1)