

Proposed Radiation Safety Regulations

A consultation document

Citation: Ministry of Health. 2016. *Proposed Radiation Safety Regulations: A consultation document*. Wellington: Ministry of Health.

Published in May 2016
by the Ministry of Health
PO Box 5013, Wellington 6140, New Zealand

ISBN 978-0-947515-09-6 (online)
HP 6404

This document is available at health.govt.nz



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We want your input

This consultation document and its accompanying submission form are being published to gather public input into the proposed Radiation Safety Regulations. The Regulations will be made under sections 91 to 93 of the Radiation Safety Act 2016.¹ The Regulations are required in order to give full effect to the Act, and they need to be in place before the Act comes into force on 7 March 2017.

This document outlines the options available for the proposed Regulations and identifies the Ministry of Health's preferred options. The preferred options are presented simply to promote discussion: no decisions have been made yet.

All the regulation-making provisions in sections 91 to 93 of the Act are discussed in this consultation document. However, discussion points are presented based on topic areas and do not follow the order of provisions in the Act. The regulation-making provisions of the Act are listed against a summary of the Ministry of Health's preferred options in the Index to this document.

The Ministry of Health is seeking public submissions on the proposed Regulations by Wednesday 22 June 2016. Submissions need to be on the topic of Regulations to be made under the Act in order to be considered within the scope of this consultation. All submissions that are in scope and received before the submission deadline will be considered.

Full guidelines for making a submission can be found in the submission form published alongside this consultation document. The submission form also lists the consultation questions found throughout this document to help submitters complete the submission process. Submitters do not have to use the submission form.

¹ Available on the New Zealand Legislation website:
www.legislation.govt.nz/act/public/2016/0006/latest/DLM6339517.html?src=qs

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Introduction

The Radiation Safety Act 2016

The Radiation Safety Act 2016 (the Act) repeals and replaces the Radiation Protection Act 1965, the Radiation Protection Regulations 1982 and the Radiation Protection (Appeals) Regulations 1974. Much of what is covered in the Radiation Protection (Appeals) Regulations has been carried over into the Appeals subpart (sections 48–52) of the Act. The main provisions of the Act will come into force on 7 March 2017.

The Act brings New Zealand radiation safety law into line with international recommendations and guidelines. In doing so, it establishes a framework for protecting the health and safety of people and protecting the environment from the harmful effects of ionising radiation while allowing for its safe and beneficial use. The Act also enables New Zealand to meet its international obligations on radiation protection, safety, security and nuclear non-proliferation.

The Act establishes fundamental requirements for safety, security, transport, storage and disposal (see sections 9–12) that must be complied with by every person who deals with a radiation source. The technical requirements specifying how to comply with the fundamental requirements may be outlined in codes of practice issued under section 86 of the Act and will therefore not be specified in Regulations. Codes of practice will be issued for each specific area of radiation practice, and consultation on their content is expected to start in the second half of 2016.

The Act and any Regulations made under the Act apply to the relatively small number of people who deal with ionising radiation. In almost all instances where people are dealing with radiation sources, the Act and its Regulations will apply alongside other applicable law that may have parallel and/or additional duties and requirements. Other applicable law may include the following:

- Health and Safety at Work Act 2015
- Resource Management Act 1991
- Customs and Excise Act 1996
- Medicines Act 1981
- Health Practitioners Competence Assurance Act 2003
- Terrorism Suppression Act 2012
- any Regulations made under these Acts.

In very limited situations the legislation mentioned in section 7 of the Act may also apply. Complying with New Zealand law will ensure the international obligations mentioned in section 3(b) of the Act are being met.

This consultation document discusses only the matters that can be covered in Regulations under sections 91–93 of the Act. Each discussion point begins with background information on the relevant regulation-making provision from the Act.

Definitions

This consultation document uses technical and scientific terms derived from the Act. To make the document more useful, these terms are signalled in the text using bold type on first mention, and they are also defined in Table 1. The definitions in Table 1 should be used only for the purposes of this consultation document.

Table 1: Definitions of technical and scientific terms used in this consultation document

Term	Definition	Use in the Act
Authorisation	A source licence, use licence or consent.	s5(1)
Codes of practice	These specify technical requirements that a person who deals with a radiation source must comply with in order to comply with the fundamental requirements.	s86
Compliance verification	The process of monitoring compliance with the radiation safety requirements in the Act.	s37
Consent	An authorisation to import or export radioactive material.	s5(1)
Controlled radiation source	Any irradiating apparatus, any sealed radioactive material, any nuclear material (whether sealed or unsealed), or any unsealed radioactive material of a kind that regulations require to be registered.	s30(2)
Deal with	Manufacture, possess, control, manage, use, transport, store, export, import, sell, supply or dispose of a radiation source or carry out any other activity or practice involving the radiation source.	s5(1)
Director	The person appointed as the Director for Radiation Safety under section 76 of the Act.	s76
Effective dose	The tissue-weighted sum of equivalent doses in all specified tissues and organs of the body.	s5(1)
Enforcement officer	A person appointed under section 36 to carry out compliance verification activities.	s36(1)
Equivalent dose	The radiation-weighted dose in a tissue or organ of the body.	s5(1)
Fundamental requirements	Every person who deals with a radiation source must ensure that people and the environment are protected, now and in the future, from the adverse effects of the radiation source by complying with the fundamental requirements set out in sections 9 to 12 of the Act.	s8
IAEA	The International Atomic Energy Agency.	s5(1)
Irradiating apparatus	Electrical equipment that is designed to generate ionising radiation such as X-rays, neutrons, electrons, or other charged particles; or that produces ionising radiation as a by-product resulting in a dose equivalent rate of or exceeding 1 microsievert per hour at a point 0.1 metres from any accessible surface and that has a maximum energy of or exceeding 5 kiloelectronvolts.	s5(1)
Nuclear material	Any source material or special fissionable material.	s5(1)
Radiation safety plan	A plan submitted under section 18 of the Act.	s5(1)
Radiation safety requirements	The requirements of the Act, its regulations, codes of practice, radiation safety plans, the conditions of authorisations, and the conditions of exemptions granted under section 86(3).	s5(1)
Radiation source	Radioactive material to which the Act applies or an irradiating apparatus.	s5(1)
Radioactive material	Any material that spontaneously emits ionising radiation, including any naturally occurring radioactive material or any nuclear material.	s5(1)
Radionuclides	Radioactive isotopes referred to in Schedule 2 of the Act.	Schedule 2
Sealed radioactive material	Radioactive material that is permanently sealed in a capsule or is closely bonded and in solid form.	s5(1)
Source licence	This authorises a person to manage and control a radiation source.	s17(1)

Term	Definition	Use in the Act
Source material	Uranium containing a mixture of isotopes occurring in nature, uranium depleted in the isotope 235, or thorium and any of that material that is in the form of metal, alloy, chemical compound, or concentrate, and any material prescribed under section 91(1)(c) of the Act.	s5(2)
Special fissionable material	Plutonium-239, uranium-233, or uranium enriched in the isotopes 235 or 233, or both or any combination of that material or any material prescribed under section 91(1)(c) of the Act.	s5(2)
Unsealed radioactive material	Radioactive material that is not a sealed radioactive material.	s5(1)
Use licence	This authorises the licence holder to use one or more radiation sources.	s21(1)
Warrant of appointment	A warrant issued to every person appointed as an enforcement officer.	s36(4)-(7)

1 Authorisations (source licences, use licences and consents)

(a) Application forms

Background

People or organisations that **deal with** radiation sources must obtain the appropriate **authorisation**. The requirements for authorisations are set out in sections 13–29 of the Act. These provisions specify the matters the Director must be satisfied with in order to grant authorisations. The provisions also allow the Director wide discretion in considering and setting conditions when granting authorisations. Section 29 specifically allows the Director to request further relevant information from an applicant.

Section 91(1)(g) allows for Regulations to prescribe the information that must be included in applications for the granting or renewal of authorisations.

Preferred option

No further information is prescribed in Regulations for inclusion in application forms.

This approach provides the most flexibility for obtaining the necessary information to consider an application and any conditions that may need to apply. In line with current practice of the Office of Radiation Safety, the information required for applications will continue to be available on the internet for use by applicants.

Alternative option 1

A single application form for each authorisation type is prescribed by Regulations.

The range of activities involved in use licences, source licences and consents is very wide and authorisations are considered on a case-by-case basis. This means that single application forms for each authorisation type would need to be very large, comprehensive documents in which most items would not apply to a particular applicant.

Alternative option 2

Many application forms are prescribed by Regulations.

This approach is likely to produce a steady stream of updates to the Regulations, as particular applications forms would need to be updated to accommodate changes in radiation practices and authorisation requirements over time.

Alternative option 3

Minimum application requirements (the information to be included in all applications only) are prescribed by Regulations, leaving the Director to determine the final content of application forms.

Consultation questions

1. Do you think it would add value if application requirements were prescribed in Regulations?
2. If application requirements were prescribed in Regulations, would you prefer minimum requirements (requiring the Director of Radiation Safety to set additional requirements for specific situations) or should the full requirements be prescribed?
3. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

(b) Users and activities where a use licence is not required

Background

Section 13(b) of the Act requires users of **radiation sources** to obtain a **use licence**. However, section 16(a) allows for the use of radiation sources without a use licence for any activities prescribed by Regulations. The people and the activities they can perform without a use licence can be prescribed under section 91(1)(h) and (i). A person performing activities without having to meet the requirement to obtain a use licence under these Regulations will still be subject to the **fundamental requirements** of the Act and any **codes of practice** that apply.

Preferred option

Regulations list the groups of people and the activities they can perform without having to meet the requirement to obtain a use licence.

Groups will require a verifiable means of ensuring that all members who can perform activities under these Regulations have obtained radiation safety and security training and knowledge that would otherwise be required to obtain a use licence.

The proposed groups and the activities they can perform without having to meet the requirement of obtaining a use licence are listed in Table 2.

Table 2: Proposed groups and their activities that do not require a use licence

Authority	Group	Criteria	Activity
Medical Council of New Zealand	Vocational scope of practice: diagnostic and interventional radiology	Current registration and practising certificate	Use of irradiating apparatus for medical diagnostic purposes
Medical Council of New Zealand	Vocational scope of practice: radiation oncology	Current registration and practising certificate	Use of irradiating apparatus or radioactive material for medical therapeutic purposes
Dental Council	Vocational scope of practice: general dental practice	Current registration and practising certificate	Use of irradiating apparatus for dental diagnostic purposes
Dental Council	Vocational scope of practice: dental therapy practice	Current registration and practising certificate	Use of irradiating apparatus for the taking of periapical and bitewing radiographs for dental diagnostic purposes
Dental Council	Vocational scope of practice: dental hygiene practice	Current registration and practising certificate	Use of irradiating apparatus for taking of periapical, bitewing and extra-oral radiographs for dental diagnostic purposes
Dental Council	Vocational scope of practice: orthodontic auxiliary practice	Current registration and practising certificate	Use of irradiating apparatus for taking of intra-oral and extra-oral radiographs for dental diagnostic purposes
New Zealand Medical Radiation Technologists Board	Scope of practice: medical imaging technologist	Current registration and practising certificate	Use of irradiating apparatus for medical diagnostic purposes
New Zealand Medical Radiation Technologists Board	Scope of practice: nuclear medicine technologist	Current registration and practising 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 practising certificate	Use of radiation sources for the delivery of radiation treatment for medical therapeutic purposes
Veterinary Council of New Zealand	Veterinarian	Current registration and practising certificate	Use of irradiating apparatus for veterinary purposes

Alternative option

One of the purposes 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 its safe and beneficial use. Any groups (and activities) that do not meet the standards of radiation safety and security training and knowledge required to obtain a use licence would fall outside of the scope of the Act. Therefore, no alternative option is proposed.

Note

Radiation user groups that are not included under these Regulations when the new Act comes into force can work with the Office of Radiation Safety on the requirements to become included. If successful, a recommendation can be made to amend the Regulations to include further groups and the activities they can perform. The preferred option is designed to include the groups (and the activities they can perform) where verification of the required radiation safety and security training and knowledge can be easily demonstrated prior to the Act to coming into force.

Consultation questions

4. Do you think the proposed basis for exemptions is likely to maintain radiation safety and security?
5. Do you think there are any other areas of radiation practices that are likely to be able to meet the criteria for an exemption?
6. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

(c) Maximum periods for authorisations

Background

Section 91(1)(l) of the Act allows for Regulations to set the maximum periods for which authorisations may be granted. Different issues arise from the different types of authorisations, and provisions allow for different periods to be set for different authorisations. More information can be found in section 26.

Preferred option

Regulations stipulate that source licences and use licences can be issued for a maximum period of three years and consents can be issued for a maximum period of one year.

This does not prevent licences or consents being issued for shorter periods of time as determined by the **Director** under section 26(1). The nature of matters covered by licences and consents is significantly different, and therefore different maximum periods are justified.

Any risks associated with authorisation periods can be managed through other provisions in the Act, such as provisions to:

- monitor compliance (sections 37 and 38)
- suspend, vary or cancel authorisations (section 27)
- issue compliance orders (section 44)
- enforce offences (sections 62–75).

Alternative option

No maximum period is specified in Regulations.

This means that the duration of authorisations would be at the discretion of the Director.

Consultation questions

7. Do you think the proposed maximum period of three years for source and use licences is justified?
8. Do you think the proposed maximum period of one year for consents is justified?
9. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

(d) Radiation safety plans

Background

Section 91(1)(e) of the Act allows for Regulations prescribing further requirements for **radiation safety plans**. The Director may require **source licence** holders to maintain and update such plans. Plans relate to a specified radiation source or sources. The Act already specifies reasonably detailed requirements for plans in section 18.

Preferred option

Any requirements for plans that are in addition to those specified in section 18 of the Act are outlined in individual codes of practice rather than in Regulations. Therefore, no Regulations specifying further requirements for plans are proposed at this time.

The Ministry of Health's view is that this will allow the contents of plans to be more specifically tailored to the radiation sources and their intended use. The requirements for plans will vary widely depending on the nature of the radiation source and its intended use. Therefore, individual codes of practice offer a better means of specifying any additional requirements.

Alternative option

Additional requirements for plans could be specified by source type, use and application in Regulations. The Ministry of Health expects international recommendations on radiation safety and security to be updated on a reasonably regular basis. When international recommendations change, it is a more straightforward process to amend the relevant codes of practice as opposed to amending the relevant Regulations.

Consultation questions

10. Do you think additional requirements for radiation safety plans are best placed in individual codes of practice or in Regulations? Please provide reasons for your answer.
 11. Do you have any further comments, suggestions or alternative options?
- Please use the submission form to respond to these questions.

2 Fees for authorisation and compliance verification

(a) Scope of fees payable under the Act

Sections 14(c) and 28(1)(c) of the Act require applications for the issue and renewal of authorisations to be accompanied by the prescribed fee. The prescribed fees are set in Regulations made under section 92.

As well as cost recovery for issuing authorisations, section 92 also allows for the recovery of the direct or indirect costs of verifying compliance with the **radiation safety requirements**. This section also allows for different fees depending on authorisation type, establishes principles for calculating fees, and allows for exemptions and refunds from all or parts of fees.

For the purposes of this consultation, the term ‘verifying compliance’ refers to routine audit activities only. The costs associated with any case-by-case investigations into specific instances of potential non-compliance will not be recovered by fees set under section 92.

Section 92 also stipulates that only actual and reasonable compliance verification costs can be recovered in fees.

(b) Fees under the current radiation protection framework

The fees taken under the current radiation protection framework are reported against the costs of ‘licensing activities’, and they average \$783,125² per year. These costs (and fees) do not reflect the current costs of compliance verification activities. Because the fees proposed in this document will fully recover the cost of both authorisation (licensing) activities and compliance verification, the total fees payable under the Act will increase.

(c) Expected costs under the Act

Background

The Ministry of Health’s Office of Radiation Safety processes all applications for licences and consents, at a cost of approximately \$450,000 per year. The Office of Radiation Safety will also contract external science advice on aspects of regulation at a cost of approximately \$100,000 per year and audit services (compliance verification) at \$887,700 per year.

² Taken from Ministry of Health Annual Reports for the period 2007 to 2015 (inclusive) but excluding 2012. The annual reports (including 2012) are available on the Ministry’s website at www.health.govt.nz/about-ministry/corporate-publications/annual-reports. In the financial year ending in 2012 the National Radiation Laboratory was sold. As a result, revenue and expenses information for this year are not readily derived from the information presented in the Annual Report.

These arrangements will ensure that the functions of the Director, **enforcement officers**, assessing and granting authorisations, and the necessary science knowledge and experience are all available to meet the requirements of the Act.

The total operating cost is approximately \$1.44 million per year. A breakdown of these costs is provided in Table 3.

Table 3: Breakdown of annual costs for authorisations, renewals and compliance verification activities under the Act (exclusive of GST)

Item	Authorisation component	Compliance verification component	Total
Personnel expenses	\$244,000		\$244,000
Office and overheads	\$160,000		\$160,000
Miscellaneous costs	\$46,000		\$46,000
Contracted science advice	\$100,000		\$100,000
Contracted audit services		\$887,700	\$887,700
Total	\$550,000	\$887,700	\$1,437,700

Preferred option

Fees are set to recover the full costs.

The Ministry of Health's view is that these costs are both actual and reasonable.

Alternative option

Fees can be set to recover only part of the costs.

In some circumstances it may be appropriate to set charges below full cost recovery in order to achieve the purposes of legislation; for example, where the purpose of legislation is to provide social benefits or access to justice. The Ministry of Health's view is that there is not sufficient justification to set charges below full cost recovery in this case.

Consultation questions

12. Do you think the statement of costs is actual and reasonable?
13. If you think the statement of costs is not actual or reasonable, can you identify other information or another method for establishing costs?
14. Do you think it is reasonable to recover the full costs in fees?
15. If you think it is unreasonable to recover the full costs in fees, can you please identify who should meet the remaining costs.
16. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

(d) Distribution of fees across authorisation types

Background

The duties and obligations related to managing the majority of risks associated with radiation use under the Act rest with source licence holders. Almost all routine compliance verification activity will be conducted against source licence holders' obligations under the Act.

Preferred option

The costs of compliance verification are recovered in full from source licence holders, while the costs of licensing are recovered from all authorisation holders according to the time involved in administering those authorisations.

This distribution of fees closely follows costs. The proposed distribution of annual fees across authorisation types is outlined in Table 4.

Table 4: Proposed distribution of annual fees across authorisation types under the Act (exclusive of GST)

Authorisation type	Authorisation component	Compliance verification component	Total	Percentage
Source licence	\$360,000	\$887,700	\$1,247,700	87
Use licence	\$160,000		\$160,000	11
Consent	\$30,000		\$30,000	2
			\$1,437,700	100

Alternative option

The preferred option proposes fees based on the expected costs associated with each authorisation type. Any viable alternative option will need to justify the subsidisation of costs incurred in one authorisation type by fees recovered from another. The Ministry of Health is not aware of such a justification.

Consultation questions

17. Do you think the preferred distribution of fees across source licences, use licences and consents is justified?
 18. If you think the preferred distribution of fees is not justified, please suggest an alternative. Please provide a justification for your option.
 19. Do you have any further comments, suggestions or alternative options?
- Please use the submission form to respond to these questions.

(e) Proposed source licence fees and ‘compliance verification entities’

Background

The risks associated with each radiation source vary considerably. This risk is reflected in the frequency of compliance verification activities associated with each radiation source. As a result, the costs of compliance verification are closely related to the frequency of compliance verification activities.

Therefore, we propose that source licence fees be set to reflect the frequency of compliance verification activities associated with the sources being licensed. The frequency of compliance verification under the Act will be unchanged from the frequency of audits under the current radiation protection framework. These frequencies are set out in Table 5.

Table 5: Frequency of current and expected compliance verification inspections

Compliance verification frequency (years)	Compliance verification entities
1	Industrial irradiators
1	Research irradiators
1	External beam radiotherapy (includes high-dose rate where applicable)
1	Intraoperative radiotherapy
1	Blood irradiators
1	Industrial radiography
1	Cyclotrons
1	Storage of nuclear material
2	Waste conditioning
2	Industrial radiography (no source)
2	Industrial gauges (IAEA categories 1, 2 and 3 ³) and well logging
2	Security scanners using linear accelerators
2	Nuclear medicine
2	Complex radiology
2	Industrial laboratories and Crown Research Institutes
2	Universities
2	Vets using unsealed radioactive material
3	Industrial processing using linear accelerators
3	Nuclear density meters

³ See *IAEA Safety Standards: Categorization of radioactive sources, safety guide No. RS-G-1.9*, International Atomic Energy Agency, Vienna, 2005 (www-pub.iaea.org/MTCD/publications/PDF/Pub1227_web.pdf)

Compliance verification frequency (years)	Compliance verification entities
4	Calibration sources
4	Sentinel node biopsy
4	Low-dose-rate brachytherapy
4	Conventional radiology
4	Chiropractic
4	General practice
4	Podiatry
4	In-vitro testing laboratories
4	X-ray analytical equipment
4	X-ray inspection units
4	Veterinary
4	Industrial gauges (IAEA categories 4 and 5)
5	Other industrial (eg, static eliminators)
5	Dental
5	Installation and servicing
5	Demonstration/education
5	Bone densitometers

The costs associated with assessing applications for source licences are expected to be evenly distributed across all licence applications.

Preferred option

Source licence fees incorporate a component of compliance verification cost recovery that varies depending on the frequency of activities, and a component of application processing cost recovery that is evenly applied regardless of the frequency of compliance verification activities.

The preferred option is illustrated in Table 6, with the contribution of the compliance verification portion and the application assessment portion of the overall fee separated.

The preferred option from discussion point 1c of this document is that the Director can issue source licences up to a maximum period of three years. The fees information presented in Table 6 is for a one-year period. Fees for two- and three-year periods can be calculated on a *pro rata* basis.

Table 6: Proposed annual source licence fees under the Act (exclusive of GST)

Audit frequency (years)	Authorisation application portion of fee (annual)	Compliance verification portion of fee (annual)	Total annual fee	Anticipated number of licences	Annual fees take (authorisations)	Annual fees take (compliance verification)	Total annual fees take
1	\$145	\$1,360	\$1,505	46	\$6,670	\$62,560	\$69,230
2	\$145	\$680	\$825	179	\$25,955	\$121,720	\$147,675
3	\$145	\$455	\$600	246	\$35,670	\$111,930	\$147,600
4	\$145	\$340	\$485	785	\$113,825	\$266,900	\$380,725
5	\$145	\$270	\$415	1202	\$174,290	\$324,540	\$498,830
					\$356,410	\$887,650	\$1,244,060

Separate fees apply for each ‘compliance verification entity’ requiring an individual audit. The Ministry of Health does not expect any change to existing audit practices, including the practice of allowing a single audit for multiple radiation sources so long as those sources are within the same audit programme. This means that the total applicable fee under the preferred option can be determined based on current audit arrangements.

Alternative option

Fees are based on the expected costs associated with each audit frequency.

Any viable alternative option will need to justify the subsidisation of costs incurred in one audit frequency by fees recovered from another. The Ministry of Health is not aware of such a justification.

Consultation questions

20. Do you think the preferred option of varying fees on the basis of compliance verification frequency (see Table 5) is justified? Please provide your reasoning.
21. Do you think the preferred option of applying fees to ‘compliance verification entities’ is justified? Please provide your reasoning.
22. If you think the preferred options are unjustified, please outline an alternative option for assigning source licence fees. Please provide a justification for your method.
23. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

(f) Proposed use licence fees

Background

The costs associated with use licences will be in assessing whether the applicant meets the requirements to be granted a licence. These costs will be similar despite the differences in risk associated with using the source.

We expect the cost associated with use licensing to be approximately \$160,000 per year.

Under current legislation there are 4500 use licences. However, under the Act we expect this number to drop to approximately 1660. This is because we expect:

- 2800 fewer use licences if the proposals in discussion point 1b are adopted
- 380 fewer use licences for licensees who can be authorised to use a source under the source licence provision of section 17(2) of the Act
- 340 more use licences for those people currently using radiation sources under supervision or the instruction of a licensee but who will require a use licence under the modified rules relating to direct supervision and written instructions in section 21(4).

Preferred option

A single flat fee.

This option is preferred for use licences despite the differences in risks associated with the uses. Therefore, the annual cost per use licence is approximately \$95 per year (exclusive of GST).

The preferred option from discussion point 1c is that the Director will be able to issue use licences for periods up to a maximum of 3 years. Therefore, use licence fees, exclusive of GST, would be:

- \$95 for one year
- \$190 for two years
- \$285 for three years.

Alternative option

Fees are based on the expected total costs of use licensing.

Any viable alternative option will need to justify differential fees for use licences. The Ministry of Health's view is that differential use licence fees will cost slightly more to administer and that there is little to justify this option.

Consultation questions

24. Do you think the preferred use licence fee is justified?
25. If you think the preferred option is unjustified, please outline an alternative option for assigning use licence fees. Please provide a justification for your method.
26. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

(g) Proposed consent fees

Background

Consents will be issued for the import and export of **radioactive material** under section 24 of the Act. Currently, consents are issued for individual consignments of radioactive material and the costs of considering applications are dependent on the risk associated with the radiation source. The cost of administering the entire consent system is approximately \$30,000 per year. The operation and cost of regulating consents under the new Act is expected to remain unchanged.

Preferred option

Different fees for individual consents are set to reflect the cost of regulation for each source.

Regulatory practice will be based on international convention requirements and International Atomic Energy Agency (IAEA) guidance.

The Ministry of Health also prefers to offer a ‘general consent’ to allow consent holders to make multiple imports under the same consent. This allows **unsealed radioactive material** (which usually has a short half-life) for use in medical applications to cross the border as efficiently as possible.

The preferred option from discussion point 1c of this document is that individual consents will be issued for the specific import/export event, and general consents will be limited to a duration of one year. The proposed consent fees are outlined in Table 7.

Table 7: Proposed consent fees under the Act (exclusive of GST)

Category	Approximate number of consents (per year)	Fee	Total
IAEA category 1 and 2 ⁴ sealed sources	7	\$300	\$2,100
IAEA category 3, 4 and 5 sealed sources	245	\$80	\$19,600
Unsealed radioactive material	Infrequent and on a case-by-case basis		
General	20	\$400	\$8,000
			\$29,700

Alternative option

Fees are based on the expected total costs of administering consents.

Any viable alternative option will need to justify the subsidisation of costs incurred in one consent type by fees recovered from another. The Ministry of Health is not aware of such a justification.

⁴ See IAEA Safety Standards: Categorization of radioactive sources safety guide No. RS-G-1.9, International Atomic Energy Agency, Vienna, 2005 (www-pub.iaea.org/MTCD/publications/PDF/Pub1227_web.pdf)

Consultation questions

27. Do you think the preferred consent fees are justified?
28. If you think the preferred option is unjustified, please outline an alternative option for assigning consent fees. Please provide a justification for your method.
29. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

(h) Historical fees take and the ‘memorandum account’

Background

The Office of Radiation Safety ‘memorandum account’ is reported in the Ministry of Health’s Annual Reports, and the current account balance is \$973,000.⁵ This balance indicates the amount by which the licence fees taken have exceeded the costs of licensing activities for the period 1998 to 2015.

The memorandum account balance can be attributed to the unanticipated and significant increase in the number of licences issued since the fees were last set in 1998. During the same period the Office of Radiation Safety has absorbed the increased licensing requirements without increasing its operating costs.

This review presents an opportunity to correct the historical over-recovery of costs through fees.

Preferred option

The memorandum account balance is moved towards zero by applying a partial exemption from the full fee for source licences, to be applied over the first six years of operation under the Act.

The Ministry of Health’s view is that the most significant contributors to the current memorandum account balance will fall into the category of source licence holders under the Act. Therefore, the proposed partial exemption from the full fee should be applied to source licence fees only.

A 13 percent partial exemption on the proposed annual source licence fees in Table 6 of this document will reduce the memorandum account balance by approximately \$162,000 per year. This partial exemption meets the aim of moving the memorandum account balance towards zero after six years. On this basis, the preferred partial exemptions for the first six years under the Act are outlined in Table 8.

⁵ See the section titled ‘Memorandum accounts’ in the Ministry of Health Annual Report for the year ended 30 June 2015 (p. 118 of the PDF version), which is available on the Ministry’s website at www.health.govt.nz/publication/annual-report-year-ended-30-june-2015.

Table 8: Proposed partial exemption from full source licence fees for first six years under the Act (exclusive of GST)

Audit frequency (years)	Proposed annual fee	Proposed annual fee with partial exemption	Amount of partial exemption per fee	Anticipated number of licences	Amount of partial exemptions: annual total
1	\$1,505	\$1,309	\$196	46	\$9,016
2	\$825	\$718	\$107	179	\$19,153
3	\$600	\$522	\$78	246	\$19,188
4	\$485	\$422	\$63	785	\$49,455
5	\$415	\$361	\$54	1202	\$64,908
					\$161,720

Alternative option

A slightly lower partial exemption is applied to all proposed fees to meet the aim of moving the memorandum account towards zero after six years.

The Act introduces new definitions for ‘direct supervision’ and ‘written instructions’ which means that some previously unlicensed users will need to obtain a use licence. Also, the Regulations proposed under discussion point 1(b) of this document could exempt significant numbers of previously licensed users from the need to obtain a use licence. Therefore, the group of use licence holders under the Act is likely to differ significantly from the group that contributed to the memorandum account balance. The Ministry of Health considers that it would be inequitable to apply the partial fee exemption to the new group of use licence holders.

Consent holders under the Act are likely to be a similar group to historical consent holders. However, historical consent fees have not met the full cost of administering the consent process and therefore, this group has not contributed to the memorandum account balance. The Ministry of Health considers that it would also be inequitable to apply the proposed partial fee exemption to consent holders.

Consultation questions

30. Do you think applying a partial exemption to full source licence fees is a fair way of returning historically over-recovered licence fees under the radiation protection framework?
31. Can you identify potential future authorisation holders under the new Act that have not incurred historical licence fees under the current radiation protection framework?
32. Do you have an alternative method for addressing the historical over-recovery of costs by partially exempting future fees?
33. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

3 Exemptions, restrictions and prohibitions

Limited and specified exemptions from the authorisation and registration requirements (see subparts 2 and 3 of Part 1 of the Act) can be made under section 91(1)(a). Conditions on these exemptions can also be made under section 91(1)(b). These exemptions cannot be applied to **nuclear material** (see section 91(4)).

(a) Radiation sources temporarily entering New Zealand by ship or aircraft

Background

Radiation sources may temporarily enter New Zealand and therefore become subject to the provisions of the Act, as well as other relevant New Zealand law. Temporary entry primarily occurs when a radiation source is either:

- part of the normal operations of a vessel (eg, X-ray equipment used in medical departments on cruise ships), or
- cargo that is destined for another country (which may stay on board while other cargo is loaded/unloaded or may be transferred to another vessel).

The Act does not allow for exemptions to the fundamental requirements (section 9–12), and therefore the fundamental requirements must be met while the radiation sources are temporarily in New Zealand.

Section 91(1)(a)(ii) of the Act allows for exemptions to the authorisation and registration requirements of the Act for radiation sources (other than nuclear material) temporarily entering New Zealand by ship or aircraft.

Preferred option

Exempt radiation sources (excluding nuclear material) that have temporarily entered New Zealand by ship or aircraft from the consent, licensing and registration requirements.

The radiation safety or security gain in requiring consents, licensing and registration in the temporary entry situations described above is highly marginal. Therefore, the Ministry of Health would prefer to exempt radiation sources (excluding nuclear material) that have temporarily entered New Zealand by ship or aircraft from the consent, licensing and registration requirements (that is, from all of subparts 2 and 3 of Part 1 of the Act).

Alternative option

Requiring licensing, consents and registration, or specifying some situations in which licensing, consents and registration would be required in this situation, would result in only a highly marginal gain in safety or security for the additional costs. Therefore, the Ministry of Health has not developed an alternative option.

Consultation questions

34. Do you think exemptions from the requirements to obtain an authorisation and to register radiation sources in the situations specified in discussion point 3(a) of the consultation document are justified?
35. Do you think there are situations that are not specified in discussion point 3(a) of the consultation document where radiation sources temporarily entering New Zealand by ship or craft should be exempted from the requirements to obtain an authorisation and registration?
36. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

(b) Low-exposure and low-probability scenarios

Background

Minimum threshold levels for radioactive material are set out for each individual **radionuclide** in Schedule 2 of the Act. Minimum requirements for **irradiating apparatus** are set out in the definition in section 5. There are situations where radiation sources may exceed the minimum requirements but the exposure arising from them is sufficiently low such that they can be exempted from some or all of the authorisation requirements of the Act. Section 91(1)(a)(iii) authorises Regulations to exempt radiation sources where the **effective dose** arising from them is less than the prescribed levels.

Preferred option

The radiation sources listed in Table 9 are exempted from the requirements of authorisations and registration.

Table 9: Radionuclides 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 of the Act	No greater than 40 kilobecquerels Contained in a domestic ionisation chamber smoke detector Source is not readily accessible without dismantling the device Clearly labelled with a trefoil symbol and the word 'radioactive'	Emits alpha particles that are very easily shielded No external radiation dose so long as they remain in their manufactured containment 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 of the Act	No greater than 750 megabecquerels (Ni-63) or 20 gigabecquerels (H-3) Contained in an electron capture detector or similar device for use in gas chromatography Source housing clearly labelled with a trefoil symbol and the word 'radioactive'	These radiation sources emit low-energy beta particles These emissions are easily absorbed by the casing Satisfies the dose criteria in section 91(1)(a)(iii)A

Hydrogen-3	All of subparts 2 and 3 of Part 1 of the Act	No greater than 74 gigabecquerels Contained in gaseous tritium light source At least 98% of total activity in the form of elemental hydrogen gas	Emits low-energy beta particles These sources are encapsulated in a glass capsule that easily shields emissions Satisfies the dose criteria in section 91(1)(a)(iii)B
Benchtop X-ray analyser	All of subparts 2 and 3 of Part 1 of the Act	Used for X-ray fluorescence or X-ray diffraction Completely and permanently enclosed to prevent access of any part of the body to the primary X-ray beam Enclosure interlocked with the X-ray generator such that disassembly of the enclosure prevents X-ray production Shielded sufficiently to limit the instantaneous dose rate to 2.5 microsieverts per hour 5 cm from any accessible external surface Enclosure clearly labelled with suitable cautionary wording to the effect of: 'Do not disassemble. This unit produces ionising radiation when energised.'	Satisfies the dose criteria in section 91(1)(a)(iii)A

Alternative option

Further radiation sources and conditional exemptions are also exempted from the requirements of authorisations and registration.

The Ministry of Health has considered other possible exemptions from licensing and registration requirements, including Polonium-210 in static elimination devices and liquid scintillation counters. The Director has the power under section 17(2) to authorise the passive or limited use of radiation sources in a source licence. The Ministry of Health's view is that section 17(2) is the more appropriate way to deal with possible exemptions from use-licensing requirements for static elimination devices and liquid scintillation counters. The Ministry has therefore not developed an alternative option.

Consultation questions

37. Do you think the preferred exemptions outlined in Table 9 of the consultation document are justified?
38. Do you think there are other situations where the requirements to obtain an authorisation and to register the radiation source should be exempted because the radiation use presents a particularly low risk of exposure?
39. Do you agree that the best way to deal with static elimination devices and liquid scintilla counters is by using section 17(2) of the Act (source licence conditions) instead of section 91(1)(a)(iii) (exemptions)?
40. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

(c) Regulation is unlikely to be worthwhile

Background

There may be situations where justifiable exposures are above the specified levels but regulatory intervention is unlikely to result in a worthwhile reduction in individual doses or health risks. Section 91(1)(a)(iv) authorises the making of Regulations to specify any such situations.

Preferred option

No Regulations are made under section 91(1)(a)(iv) at this time.

The Ministry of Health has considered a number of possible sources for exemption under section 91(1)(a)(iv), including cabinet X-ray security and inspection systems and shielded gamma irradiators. In all the cases considered the exemption would only relate to use licence requirements where the use can be classified as ‘passive or limited’.

These situations can also be considered under section 17(2), which allows for the source licence to authorise the passive or limited use without requiring the operators to obtain a use licence. The Ministry of Health’s view is that section 17(2) provides a better way to deal with these situations. Therefore, the preferred option is to make no Regulations under section 91(1)(a)(iv) at this time.

Alternative option

Exempt cabinet X-ray security and inspection systems, shielded gamma irradiators and other sources that meet the criteria of section 91(1)(a)(iv), with appropriate conditions, under section 91(1)(a)(iv).

The Ministry of Health’s view is that section 17(2) provides the more appropriate means for dealing with these situations.

Consultation questions

41. Do you agree that it is appropriate to deal with the radiation sources mentioned in discussion point 3(c) as ‘passive or limited’ use situations under section 17(2) of the Act?
42. Do you think there are any radiation sources that exceed the threshold levels set by the Act but nevertheless should be exempted from the requirements to obtain an authorisation and to be registered because these regulatory interventions would not result in a worthwhile safety or security benefit? If you can identify such radiation sources, please indicate if you think dealing with them under section 17(2) or section 91(1)(a)(iv) is more appropriate.
43. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

(d) Prohibitions

Background

Section 91(1)(o) of the Act allows for Regulations to prohibit or restrict the general use of a radiation source. This provision allows the Act to adapt to any developments in scientific research and international recommendations and guidance on radiation sources and their use.

There are provisions throughout the Act that could be used to prohibit or restrict individual use in specific situations, including issuing compliance orders, seizing material, and varying, suspending or cancelling licences or consents.

Preferred option

No general prohibitions or restrictions on the use of radiation sources are included in Regulations at this time.

Alternative option

General prohibitions and restrictions on radiation sources are included in Regulations.

Other provisions of the Act, or the provisions of other Acts, are better suited to deal with the specific situations they are designed to regulate and the Ministry of Health is not aware of any further situations that warrant prohibitions or restrictions under this provision.

Consultation questions

44. Do you think there are any radiation sources that should be subject to a general prohibition or restriction?
45. Do you think there are situations where a general prohibition or restriction on a radiation source would be more effective in achieving safety or security benefits than applying case-by-case restrictions using other provisions in the Act, such as: issuing compliance orders, seizing material, and varying, suspending or cancelling licences or consents?
46. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

(e) Operations of the armed forces

Background

Section 91(1)(a)(i) of the Act allows for limited and specified Regulations to exempt the armed forces from the authorisation and registration requirements of the Act where this relates to armed forces operations. No section 91(1)(a) Regulations can be applied to nuclear material.

Regulations would enable the armed forces to continue to meet their duties in unexpected, time-critical and/or information-limited operating environments without having to first consider the licensing, consent and/or registration requirements of the Act. Regulations are not expected to be needed for the day-to-day, business-as-usual activities of the armed forces.

Preferred option

No regulations are proposed.

Alternative option

The Ministry of Health is not aware of any alternative options.

Note

Regulations under this provision are not essential for the implementation of the Act and do not have to be in place by the time the Act comes into force. After the Act comes into force, if required, a recommendation can be made to include Regulations to enable the armed forces to fully meet any operational duties they may have.

Consultation questions

47. Do you think Regulations are required to enable the armed forces to fully meet their operational duties?
48. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

4 Incidents and emergencies

Background

Sections 91(1)(d) and 91(1)(f) allow Regulations to prescribe further requirements for responding to incidents and emergencies. Several sections in the Act establish general requirements to appropriately manage incidents and emergency situations. For example, the fundamental requirements specified in section 10 require proper management of accidents, incidents and emergency situations.

Section 18 allows the Director to require radiation safety plans to be submitted. Radiation safety plans must (among other things) specify the steps to be taken to mitigate any adverse effects of accidents, incidents or emergencies.

Also, section 86(1)(a) provides for codes of practice to specify technical requirements in order to comply with the fundamental requirements, which include complying with section 10.

Preferred option

No Regulations are made to specify further general-level requirements for incidents and accidents.

Codes of practice will have to set out detailed requirements for responding to incidents and emergencies for each specific area of radiation practice. The Ministry of Health sees no benefit to setting further general-level requirements in Regulations.

Alternative option

General-level requirements for dealing with incidents and emergencies are specified in Regulations.

This option would separate the requirements for responding to incidents and emergencies (in Regulations) from the other technical requirements for complying with the fundamental requirements of the Act (in codes of practice). Because the specific requirements for each area of radiation practice will have to be included in codes of practice, the overall framework will be simpler if all the incident and emergency provisions are also included in codes of practice.

Consultation questions

49. Do you think setting detailed provisions for dealing with incidents and emergencies for each specific area of radiation practice in codes of practice is the best approach to achieving the required responses to incidents and emergencies?
50. If you think it is appropriate to have provisions for dealing with incidents and emergencies in Regulations, please identify what information should be in Regulations and what information should be in codes of practice.
51. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

5 Labelling, signage and other controls

Background

Requirements for labelling, signage and other controls are all necessary in order to satisfy the fundamental requirements of the Act. Section 86(1)(a) of the Act provides for codes of practice to specify the technical requirements in order to comply with the fundamental requirements. Accordingly, codes of practice will specify the labelling, signage and other controls for each specific area of radiation practice.

Preferred option

No Regulations are made to specify further general-level requirements for labelling, signage and other controls.

Codes of practice will set out detailed requirements for labelling, signage and other controls for each specific area of radiation practice. The Ministry of Health sees no benefit to setting further general-level requirements in Regulations.

Alternative option

General-level requirements for labelling, signage and other controls are specified in Regulations.

Specific requirements for each area of radiation practice will have to be included in codes of practice. Therefore, the overall framework will be simpler if all the labelling, signage and other controls provisions are included in codes of practice.

Consultation questions

52. Do you think setting detailed provisions for labelling, signage or other controls for each specific area of radiation practice in codes of practice is the best approach to achieving the desired outcomes?
53. If you think it is appropriate to have provisions for labelling, signage or other controls in Regulations, please identify what information should be in Regulations and what information should be in codes of practice.
54. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

6 Registration of controlled radiation sources

(a) Registration

Background

Sections 30–34 of the Act specify the requirements for the registration of **controlled radiation sources**. The purpose of registration is to help the Director establish the location of radiation sources and to support compliance and emergency response procedures.

Section 31 places a duty on persons who have management or control of a controlled radiation source to register that source.

Section 32 specifies the information that must be on the register. In specifying this information, this section determines the information required for registration. Section 32(f) provides for ‘other’ information to be included on the register. Other information can be required by either the Director or by Regulations.

Section 91(1)(q) allows for Regulations prescribing requirements for the registration process.

Preferred option

No Regulations prescribing requirements for the registration process are made.

This means that the information specified in section 32 must be provided and that only the Director may require ‘other’ information under section 32(f) of the Act. The Director may request other information depending on the risk profile of the radiation sources and their intended use. The Director will notify affected people of any other requirements for registration. Other requirements for registration are most likely to apply to radiation sources attracting higher safety and security requirements.

Alternative option

The general requirements of registration are specified in Regulations.

Consultation questions

55. Do you think registration requirements should be specified in Regulations rather than being published on a website by the Director of Radiation Safety?
56. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

(b) Unsealed radioactive material requiring registration

Background

Controlled radiation sources are defined in section 30 of the Act as requiring registration. Controlled radiation sources are irradiating apparatus, **sealed radioactive material**, nuclear material and 'any unsealed radioactive material of a kind that Regulations require to be registered'. Section 91(1)(p) allows for Regulations to specify unsealed radioactive material that must be registered.

People or organisations that deal with unsealed radioactive material must obtain the appropriate authorisations and comply with the fundamental requirements of the Act. Unsealed radioactive material often has a short half-life, meaning that it decays quickly.

The provision to specify certain unsealed radioactive material as requiring registration allows the Act to adapt to any developments in scientific research and international recommendations and guidance on radiation sources and their use.

Preferred option

No unsealed radioactive material is specified as requiring registration.

There is no unsealed radioactive material in use in New Zealand for which registration would add a safety or security benefit. Therefore, no unsealed radioactive material needs to be specified as requiring registration at this time.

Alternative option

Specify certain unsealed radioactive material as requiring registration.

The Ministry is not aware of any scientific research or international recommendations or guidance suggesting that registration of unsealed radioactive material would be significantly beneficial.

Consultation questions

57. Do you think there is any unsealed radioactive material that requires registration?
Please provide a justification.
58. Do you have any further comments, suggestions or alternative options?
Please use the submission form to respond to these questions.

7 Nuclear material

Background

Nuclear material is defined in section 5(1) of the Act as any **source material** or **special fissionable material**. These terms are further defined in section 5(2) and adopt the definition used by the IAEA.⁶ The IAEA definitions allow for ‘such other material as the Board of Governors shall from time to time determine’ to be added. To accommodate the possibility of IAEA additions, section 5(2) enables further material to be defined as nuclear material under the Act using the regulation-making power in section 91(1)(c).

Preferred option

No other material is prescribed as nuclear material at this time.

The IAEA has not added any other material to its definition of nuclear material. Therefore, no other material is required to be defined as nuclear material under the Act at this time.

Alternative option

The Ministry of Health has not considered an alternative option.

Consultation questions

59. Do you think any other material should be included in the definition of nuclear material under the Act, despite the International Atomic Energy Agency’s (IAEA’s) current position? Please provide a justification.

60. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

⁶ See paragraphs 4.4 and 4.5 of the *IAEA Safeguards Glossary, International Nuclear Verification Series No. 3*, International Atomic Energy Agency, Vienna, 2002.

8 Inspection, compliance and enforcement

(a) Record keeping

Background

Section 35 of the Act requires the keeping of records and sets out the information that must be kept and made available for inspection. Section 93(a) allows for Regulations to set out further requirements for the keeping and inspection of records.

Preferred option

All additional record-keeping requirements are specified for each area of radiation practice in codes of practice, to be issued under section 86 of the Act.

Codes of practice must specify how the fundamental requirements of the Act are to be met for each area of radiation practice. The record-keeping requirements should also be specified in codes of practice for ease of use.

Alternative option

Requirements for additional record keeping, by source type and use, are specified in Regulations.

Under this option, users will have to refer to both Regulations and to the codes of practice that apply to their particular area of radiation practice.

Consultation questions

61. Do you agree that any record-keeping requirements in addition to those specified in section 35 of the Act should be specified in codes of practice for each area of radiation practice?
62. If you think any additional requirements for record keeping should be specified in Regulations rather than in codes of practice, please provide a justification.
63. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

(b) Warrants of appointment

Background

Section 36 of the Act sets out the process for appointing enforcement officers. The section also specifies that a **warrant of appointment** must be issued, the functions, duties and powers of the holder must be specified, and a photograph and signature of the holder must be included. Section 93(b) allows for Regulations specifying further details that must be included in such warrants.

Preferred option

In addition to the information required under section 36, the warrant of appointment includes the:

- *full name of the enforcement officer*
- *place of work of the enforcement officer (the warrant to expire if employment ceases)*
- *date of commencement of the warrant of appointment*
- *date of expiry of the warrant of appointment.*

Alternative option

The Ministry of Health has considered the requirements of section 36 and its preferred content for Regulations under section 93(b) and no alternative options have been developed.

Consultation questions

64. Do you think there are any matters that should be included in warrants of appointment for enforcement officers in addition to those listed under discussion point 8(b) and those set out in section 36 of the Act?

65. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

(c) Compliance orders

Section 44 of the Act allows for compliance orders to be issued for breaches of the provisions of the Act. Section 45 specifies the form, content and method of serving compliance orders, including that compliance orders must be served in the manner prescribed in Regulations (section 45(2)). Section 93(d) allows for Regulations to prescribe the content of compliance orders, and section 93(e) requires compliance orders to be served in the manner prescribed in Regulations.

Preferred option

Only the requirements of section 45 of the Act are used to specify the content of compliance orders at this time.

Regulations will require compliance orders to be served in accordance with the court rules: primarily, Part 6 – *Service* (sections 6.1–6.32) of the District Court Rules 2014.

Alternative option

Additional requirements for the content of compliance orders and methods of serving compliance orders that vary from court rules are not considered necessary, and no alternative options have been developed.

Consultation questions

66. Do you think there is information in addition to that already required by section 45(1) of the Act that should be included in a compliance order?
67. Do you agree that serving radiation safety compliance orders in accordance with court rules, primarily in Part 6 – *Service* (6.1–6.32) of the District Court Rules 2014, is sufficient?
68. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

(d) Forms

Background

Section 93(c) of the Act allows for Regulations to prescribe the matters that must be included in any form required under the Act. This is a general provision, which applies in addition to more specific requirements for forms already discussed in this document: for example, applications for authorisations (section 14(b)) and for registering controlled radiation sources (section 31(c)(iv)).

Preferred option

No additional information is required to be included in forms for use under the Act at this time. Therefore, no Regulations are proposed under section 93(c) in this consultation.

Alternative option

The Ministry of Health has not developed an alternative option.

Consultation questions

69. Do you think there is further information to be included in any forms required by the Act that could be prescribed in Regulations?
70. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

9 Radiation Safety Advisory Council

Background

Section 80 of the Act establishes the Radiation Safety Advisory Council (the Council), and section 81 sets out its functions. Schedule 4 of the Act sets out rules for the Council. The Council will also be subject to Cabinet appointment processes, government financial and conduct requirements, and the internal policies of the department that provides the secretariat support for the Council. Subject to these rules, the Council may regulate its own procedures in any manner it sees fit.

Section 93(f) allows for Regulations to be made on the procedures of the Council.

Preferred option

No Regulations prescribing further procedures for the Council are proposed at this time.

Alternative option

The Ministry of Health has not developed any alternative options.

Consultation questions

71. Do you think there are any additional Radiation Safety Advisory Council procedures that should be set out in Regulations in time for the Act to come into force on 7 March 2017?
 72. Do you have any further comments, suggestions or alternative options?
- Please use the submission form to respond to these questions.

10 Other matters to give full effect to the Act or its administration

Background

Section 93(g) of the Act allows for Regulations to be made on any other matter contemplated by or necessary for giving full effect to the Act and for its due administration.

Preferred option

No Regulations prescribing other matters necessary to give full effect to the Act and its due administration are proposed at this time.

Alternative option

The Ministry of Health has not developed any alternative options.

Consultation questions

73. Do you think there are other matters that should be included in the Regulations that cannot easily be included in other Regulations discussed in this consultation?
74. Do you have any further comments, suggestions or alternative options?

Please use the submission form to respond to these questions.

Index of regulation-making provisions in the Act and the discussion points in this consultation document

Section of Act	Discussion point in consultation document	Summary of proposal
Regulations		
91(1)(a)(i)	3e	No Regulations preferred at this time ∴ no exemptions apply
91(1)(a)(ii)	3a	Regulations preferred
91(1)(a)(iii)(A)	3b and Table 9	Regulations preferred
91(1)(a)(iii)(B)	3b and Table 9	Regulations preferred
91(1)(a)(iv)	3c	No Regulations preferred at this time ∴ no exemptions apply
91(1)(b)	3	Regulations preferred as part of s91(1)(a)
91(1)(c)	7	No Regulations preferred at this time ∴ only s5(1) definition applies
91(1)(d)	4	Codes of practice preferred ∴ no Regulations preferred at this time
91(1)(e)	1d	Codes of practice preferred ∴ no Regulations preferred at this time
91(1)(f)	4	Codes of practice preferred ∴ no Regulations preferred at this time
91(1)(g)(i)	1a	No Regulations preferred at this time ∴ only ss13–29 and Director's requirements apply
91(1)(g)(ii)	1a	No Regulations preferred at this time ∴ only ss13–29 and Director's requirements apply
91(1)(h)	1b and Table 2	Regulations preferred
91(1)(i)	1b and Table 2	Regulations preferred
91(1)(j)	5	Codes of practice preferred ∴ no Regulations preferred at this time
91(1)(k)	5	Codes of practice preferred ∴ no Regulations preferred at this time
91(1)(l)	1c	Regulations preferred
91(1)(m)	5	Codes of practice preferred ∴ no Regulations preferred at this time
91(1)(n)	5	Codes of practice preferred ∴ no Regulations preferred at this time
91(1)(o)	3d	No Regulations preferred at this time ∴ no further restrictions apply
91(1)(p)	7	No Regulations preferred at this time ∴ only s5(1) definition applies
91(1)(q)	6	No Regulations preferred at this time ∴ only ss30–34 apply
91(2)	7	No Regulations preferred under 91(1)(c) ∴ nothing applicable
91(3)	6	No Regulations preferred under 91(1)(q) ∴ nothing applicable
91(4)	3	Applies to Regulations preferred under s91(1)(a)
91(5)	1b and Table 2	Applies to Regulations preferred under s91(1)(h)

Section of Act	Discussion point in consultation document	Summary of proposal
Regulations relating to fees		
92(1)(a)	2	Regulations preferred
92(1)(b)	2	Regulations preferred
92(1)(c)	2	Regulations preferred
92(2)(a)	2	Applies to Regulations preferred under s92(1)
92(2)(b)	2	Applies to Regulations preferred under s92(1)
92(3)(a)	2	Applies to Regulations preferred under s92(1)
92(3)(b)	2	Applies to Regulations preferred under s92(1)
92(3)(c)	2	Applies to Regulations preferred under s92(1)
92(3)(d)	2	Applies to Regulations preferred under s92(1)
92(3)(e)	2	Applies to Regulations preferred under s92(1)
92(4)(a)	2	Applies to Regulations preferred under s92(1)
92(4)(b)	2	Applies to Regulations preferred under s92(1)
92(5)	2	Applies to Regulations preferred under s92(1)
92(6)	2	Applies to Regulations preferred under s92(1)
Other regulations		
93(a)	8a	Codes of practice preferred ∴ no Regulations preferred at this time
93(b)	8b	Regulations preferred
93(c)	8d	No Regulations preferred at this time ∴ no further specifications apply
93(d)	8c	No Regulations preferred at this time ∴ only s45 applies
93(e)	8c	Regulations preferred
93(f)	9	No Regulations preferred at this time ∴ only ss80–81 and Schedule 4 apply
93(g)	10	No Regulations preferred at this time ∴ no further specifications apply

References

Legislation, regulations and rules

District Court Rules 2014

(www.legislation.govt.nz/regulation/public/2014/0179/11.0/DLM6129567.html)

Radiation Protection Act 1965

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Radiation Protection (Appeals) Regulations 1974

(www.legislation.govt.nz/regulation/public/1974/0319/1.0/whole.html#DLM45668)

Radiation Protection Regulations 1982

(www.legislation.govt.nz/regulation/public/1982/0072/4.0/whole.html#DLM81126)

Radiation Safety Act 2016

(www.legislation.govt.nz/act/public/2016/0006/latest/DLM6339517.html?src=qs)

Radiation Safety Bill in Parliament, The

(www.parliament.nz/en-nz/pb/legislation/bills/00DBHOH_BILL61941_1/radiation-safety-bill)

Documents

International Atomic Energy Agency. 2002. *IAEA Safeguards Glossary: International nuclear verification series No. 3*. Vienna: IAEA. URL:

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Ministry of Health. 2016. *Radiation Safety Regulations: Submission form*. URL:

www.health.govt.nz/publication/proposed-radiation-safety-regulations-consultation-document

Ministry of Health Annual Reports

(www.health.govt.nz/about-ministry/corporate-publications/annual-reports)

Proposed Radiation Safety Regulations: Submission form

May 2016

Making a submission

This form is designed to assist submitters responding to the discussion points in *Proposed Radiation Safety Regulations: A consultation document* May 2016. The template is not intended to limit or constrain submissions. Submitters may wish to raise other matters or address the questions in this document in other ways. Also, submitters using this document do not have to provide responses to all questions.

All written submissions that fall within the scope of this consultation and are received before the closing date will be considered. The closing date for submissions is **5 pm, Wednesday 22 June 2016**.

The preferred method of receiving submissions is by email, at:

Radiation_Safety_Consultation@moh.govt.nz

Alternatively, submissions can be mailed to:

Radiation Safety Consultation
Ministry of Health
PO Box 5013
Wellington 6140

Submitter details

It is helpful when assessing submissions if submitters provide information about themselves. However, providing this information is not required for a submission to be considered, and you can choose to withhold this information if you wish.

This submission was completed by: (name) _____

Address: (street/box number) _____
(town/city and postcode) _____

Email: _____

Organisation (if applicable): _____

Position (if applicable): _____

Are you making this submission (tick one box only):

- as an individual?
- on behalf of a group or organisation?

Report

The Ministry of Health may publish a summary report on the submissions once the Government has made its decisions about the Regulations. No information identifying a person or an organisation will be released in this report.

Official Information Act 1982

The Official Information Act 1982 (the OIA) applies to any submission you make and to any personal information you provide. The OIA provides that information held (by the Ministry of Health) must be made available unless there is good reason to withhold it. Accordingly, if the Ministry of Health does receive a request under the OIA for your information, we will discuss that with you, where practicable, before responding to the request.

Consultation questions

Application forms – discussion point 1(a)

1. Do you think it would add value if application requirements were prescribed in Regulations?

- Yes
 No

Please provide reasons and comments below.

2. If application requirements were prescribed in Regulations, would you prefer minimum requirements (requiring the Director of Radiation Safety to set additional requirements for specific situations) or should the full requirements be prescribed?

- Minimum
 Full

Please provide reasons and comments below.

3. Do you have any further comments, suggestions or alternative options?

Users and activities where a use licence is not required – discussion point 1(b)

4. Do you think the proposed basis for exemptions is likely to maintain radiation safety and security?

Yes

No

Please provide reasons and comments below.

5. Do you think there are any other areas of radiation practices that are likely to be able to meet the criteria for an exemption?

Yes

No

Please provide reasons and comments below.

6. Do you have any further comments, suggestions or alternative options?

Maximum periods for authorisations – discussion point 1(c)

7. Do you think the proposed maximum period of three years for source and use licences is justified?

Yes

No

Please provide reasons and comments below.

8. Do you think the proposed maximum period of one year for consents is justified?

Yes

No

Please provide reasons and comments below.

9. Do you have any further comments, suggestions or alternative options?

Radiation safety plans – discussion point 1(d)

10. Do you think additional requirements for radiation safety plans are best placed in individual codes of practice or in Regulations?

Yes

No

Please provide reasons and comments below.

11. Do you have any further comments, suggestions or alternative options?

Expected costs under the Act – discussion point 2(c)

12. Do you think the statement of costs is actual and reasonable?

Yes

No

Please provide reasons and comments below.

13. If you think the statement of costs is not actual or reasonable, can you identify other information or another method for establishing costs?

14. Do you think it is reasonable to recover the full costs in fees?

Yes

No

Please provide reasons and comments below.

15. If you think it is unreasonable to recover the full costs in fees, can you please identify who should meet the remaining costs.

16. Do you have any further comments, suggestions or alternative options?

**Distribution of fees across authorisation types –
discussion point 2(d)**

17. Do you think the preferred distribution of fees across source licences, use licences and consents is justified?

Yes

No

Please provide reasons and comments below.

18. If you think the preferred distribution of fees is not justified, please suggest an alternative. Please also provide a justification for your option.

19. Do you have any further comments, suggestions or alternative options?

Proposed source licence fees and ‘compliance verification entities’ – discussion point 2(e)

20. Do you think the preferred option of varying fees on the basis of compliance verification frequency (see Table 5) is justified?

Yes

No

Please provide reasons and comments below.

21. Do you think the preferred option of applying fees to ‘compliance verification entities’ is justified?

Yes

No

Please provide reasons and comments below.

22. If you think the preferred options are unjustified, please outline an alternative option for assigning source licence fees. Please provide a justification for your method.

23. Do you have any further comments, suggestions or alternative options?

Proposed use licence fees – discussion point 2(f)

24. Do you think the preferred use licence fee is justified?

- Yes
 No

Please provide reasons and comments below.

25. If you think the preferred option is unjustified, please outline an alternative option for assigning use licence fees. Please provide a justification for your method.

26. Do you have any further comments, suggestions or alternative options?

Proposed consent fees – discussion point 2(g)

27. Do you think the preferred consent fees are justified?

Yes

No

Please provide reasons and comments below.

28. If you think the preferred option is unjustified, please outline an alternative option for assiging consent fees. Please provide a justification for your method.

29. Do you have any further comments, suggestions or alternative options?

Historical fees take and the ‘memorandum account’ – discussion point 2(h)

30. Do you think applying a partial exemption to full source licence fees is a fair way of returning historically over-recovered licence fees under the radiation protection framework?

Yes

No

Please provide reasons and comments below.

31. Can you identify potential future authorisation holders under the new Act that have not incurred historical licence fees under the current radiation protection framework?

32. Do you have an alternative method for addressing the historical over-recovery of costs by partially exempting future fees?

33. Do you have any further comments, suggestions or alternative options?

Radiation sources temporarily entering New Zealand by ship or aircraft – discussion point 3(a)

34. Do you think exemptions from the requirements to obtain an authorisation and to register radiation sources in the situations specified in discussion point 3(a) of the consultation document are justified?

- Yes
 No

Please provide reasons and comments below.

35. Do you think there are situations that are not specified in discussion point 3(a) of the consultation document where radiation sources temporarily entering New Zealand by ship or craft should be exempted from the requirements to obtain an authorisation and registration?

- Yes
 No

Please provide reasons and comments below.

36. Do you have any further comments, suggestions or alternative options?

Low-exposure and low-probability scenarios – discussion point 3(b)

37. Do you think the preferred exemptions outlined in Table 9 of the consultation document are justified?

Yes

No

Please provide reasons and comments below.

38. Do you think there are other situations where the requirements to obtain an authorisation and to register the radiation source should be exempted because the radiation use presents a particularly low risk of exposure?

Yes

No

Please provide reasons and comments below.

39. Do you agree that the best way to deal with static elimination devices and liquid scintilla counters is by using section 17(2) of the Act (source licence conditions) instead of section 91(1)(a)(iii) (exemptions)?

Yes

No

Please provide reasons and comments below.

40. Do you have any further comments, suggestions or alternative options?

Regulation is unlikely to be worthwhile – discussion point 3(c)

41. Do you agree that it is appropriate to deal with the radiation sources mentioned in discussion point 3(c) as ‘passive or limited’ use situations under section 17(2) of the Act?

Yes

No

Please provide reasons and comments below.

42. Do you think there are any radiation sources that exceed the threshold levels set by the Act but nevertheless should be exempted from the requirements to obtain an authorisation and to be registered because these regulatory interventions would not result in a worthwhile safety or security benefit? If you can identify such radiation sources, please indicate if you think dealing with them under section 17(2) or section 91(1)(a)(iv) is more appropriate.

Yes

No

Please provide reasons and comments below.

43. Do you have any further comments, suggestions or alternative options?

Prohibitions – discussion point 3(d)

44. Do you think there are any radiation sources that should be subject to a general prohibition or restriction?

Yes

No

Please provide reasons and comments below.

45. Do you think there are situations where a general prohibition or restriction on a radiation source would be more effective in achieving safety or security benefits than applying case-by-case restrictions using other provisions in the Act, such as: issuing compliance orders, seizing material, and varying, suspending or cancelling licences or consents?

Yes

No

Please provide reasons and comments below.

46. Do you have any further comments, suggestions or alternative options?

Operations of the armed forces – discussion point 3(e)

47. Do you think Regulations are required to enable the armed forces to fully meet their operational duties?

Yes

No

Please provide reasons and comments below.

48. Do you have any further comments, suggestions or alternative options?

Incidents and emergencies – discussion point 4

49. Do you think setting detailed provisions for dealing with incidents and emergencies for each specific area of radiation practice in codes of practice is the best approach to achieving the required responses to incidents and emergencies?

Yes

No

Please provide reasons and comments below.

50. If you think it is appropriate to have provisions for dealing with incidents and emergencies in Regulations, please identify what information should be in Regulations and what information should be in codes of practice.

51. Do you have any further comments, suggestions or alternative options?

Labelling, signage and other controls – discussion point 5

52. Do you think setting detailed provisions for labelling, signage or other controls for each specific area of radiation practice in codes of practice is the best approach to achieving the desired outcomes?

Yes

No

Please provide reasons and comments below.

53. If you think it is appropriate to have provisions for labelling, signage or other controls in Regulations, please identify what information should be in Regulations and what information should be in codes of practice.

54. Do you have any further comments, suggestions or alternative options?

**Registration of controlled radiation sources –
discussion point 6(a)**

55. Do you think registration requirements should be specified in Regulations rather than being published on a website by the Director of Radiation Safety?

Yes

No

Please provide reasons and comments below.

56. Do you have any further comments, suggestions or alternative options?

Unsealed radioactive material requiring registration – discussion point 6(b)

57. Do you think there is any unsealed radioactive material that requires registration?

Yes

No

Please provide reasons and comments below.

58. Do you have any further comments, suggestions or alternative options?

Nuclear material – discussion point 7

59. Do you think any additional material should be included in the definition of nuclear material under the Act, despite the International Atomic Energy Agency's (IAEA's) current position?

Yes

No

Please provide reasons and comments below.

60. Do you have any further comments, suggestions or alternative options?

Record keeping – discussion point 8(a)

61. Do you agree that any record keeping requirements in addition to those specified in section 35 of the Act should be specified in codes of practice for each area of radiation practice?

- Yes
- No

Please provide reasons and comments below.

62. If you think any additional requirements for record keeping should be specified in Regulations rather than in codes of practice?

- Yes
- No

Please provide reasons and comments below.

63. Do you have any further comments, suggestions or alternative options?

Warrants of appointment – discussion point 8(b)

64. Do you think there are any matters that should be included in warrants of appointment for enforcement officers in addition to those listed under discussion point 8(b) and those set out in section 36 of the Act?

- Yes
- No

Please provide reasons and comments below.

65. Do you have any further comments, suggestions or alternative options?

Compliance orders – discussion point 8(c)

66. Do you think there is information in addition to that already required by section 45(1) of the Act that should be included in a compliance order?

Yes

No

Please provide reasons and comments below.

67. Do you agree that serving radiation safety compliance orders in accordance with court rules, primarily in Part 6 – *Service* (6.1-6.32) of the District Court Rules 2014, is sufficient?

Yes

No

Please provide reasons and comments below.

68. Do you have any further comments, suggestions or alternative options?

Forms – discussion point 8(d)

69. Do you think there is further information to be included in any forms required by the Act that could be prescribed in Regulations?

Yes

No

Please provide reasons and comments below.

70. Do you have any further comments, suggestions or alternative options?

Radiation Safety Advisory Council – discussion point 9

71. Do you think there are any additional Radiation Safety Advisory Council procedures that should be set out in Regulations in time for the Act to come into force on 7 March 2017?

Yes

No

Please provide reasons and comments below.

72. Do you have any further comments, suggestions or alternative options?

Other matters to give full effect to the Act or its administration – discussion point 10

73. Do you think there are other matters that should be included in the Regulations that cannot easily be included in other Regulations discussed in this consultation?

Yes

No

Please provide reasons and comments below.

74. Do you have any further comments, suggestions or alternative options?