

Regulatory Impact Statement

Radiation Safety Regulations

Agency Disclosure Statement

This Regulatory Impact Statement (RIS) has been prepared by the Ministry of Health. It analyses options to establish the regime supporting the newly enacted Radiation Safety Act 2016 (the Act) by Regulations.

The regulatory regime will apply to the relatively small number of people who deal with ionising radiation. It will also apply alongside other relevant legislation, such as the Health and Safety at Work Act 2015 and the Resource Management Act 1991.

Regulations must be in force by 7 March 2017 when the new Act comes into force.

The approach adopted in the proposed Regulations is both flexible for the various ionising radiation sources and uses and proportionate to the presenting radiation safety risk. The proposed Regulations do not:

- impose unnecessary costs on licence and consent applicants and holders;
- impose unnecessary administrative or compliance burdens; or
- create uncertainty.

The proposed authorisation fees for licences and consents are designed to reflect the following principles of equity, efficiency, justifiability, transparency and ease of administration, as required by s 92 of the Act.

The fees are proposed on a full cost recovery basis (in relation to applications for licences, consents and the compliance verification component of sources licences). This is on the basis that the costs of regulation will become largely cost neutral for the Crown, although policy and enforcement will continue to be funded separately through Vote Health. The total annual costings assume that costs are the same for both current and expected future costs. This is taking account of the new source licences and fees on the one hand, and the reduction in use licences resulting from exceptions on the other. The fees and assumptions will be reviewed before the end of the proposed six year 'interim' period.

The consultation with stakeholders, informing the proposed Regulations on fees and cost recovery, complies with the Act's requirement that it be with stakeholders who are representative of the interests of those likely to be substantially affected by the exercise of the powers before costs can be recovered.

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Executive summary

1. The Director for Radiation Safety (the Director) will be the Regulator responsible for implementing the Radiation Safety Regulations (the Regulations). The Director must be an employee of the Ministry of Health.
2. The issues and options analysed in the Regulatory Impact Statement traverse the degree of technical detail, rigor, certainty and flexibility, and proportionality necessary for the proposed Regulations. This is as well as aiming to satisfy the statutory principles (in section 92 of the Act, in the context of cost recovery). These are equity, efficiency, justifiability, transparency and ease of administration.
3. The Regulations would:
 - prescribe the maximum duration of source licences and use licences to be three years and consents (to import/export radioactive material) to be one year;
 - authorise some groups to perform prescribed activities without the requirement to obtain a use licence (listed in Table 1);
 - provide an exemption from the registration and authorisation¹ requirements for radiation sources that temporarily enter New Zealand on ships or aircraft;
 - provide conditional exemptions from the authorisation and registration requirements for low-exposure and low-probability scenarios, such as household smoke detectors (listed in Table 2);
 - specify the form of warrants appointing enforcement officers and the process for serving compliance orders;
 - authorise fees to fully recover the cost of administering authorisations and verify compliance with the radiation safety requirements;
 - provide that a 13 percent partial exemption would be applied to source licence fees for the first six years to return a surplus from historical over collection to users.

Status quo and problem definition

Legislative context

4. The new Radiation Safety Act 2016 (the Act) will come into force on 7 March 2017, and replaces the Radiation Protection Act 1965.
5. 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. It also enables New Zealand to meet its international obligations on radiation security and nuclear non-proliferation.

¹ "Authorisation" refers to the process of granting use and source licences and consents.

6. Like the Radiation Protection Act, the new Act continues to place safety responsibilities and duties on individual users (approximately 4,500). It additionally creates responsibilities and duties for the legal entities with control and management of radiation sources (such as District Health Boards, companies and research institutes). These entities have significant ability to determine radiation safety and security outcomes.
7. Radiation safety requirements comprise the requirements of the legislation, codes of practice, radiation safety plans, the conditions of authorisations which are required to deal with radiation sources, and the conditions of any exemptions or exceptions granted. Codes of practice will be issued for each specific area of radiation practice to deal with technical and operational radiation safety requirements. They are not regulations, but are disallowable instruments. Consultation on their content should start in the second half of 2016, and be completed by February 2017.

Approach to Regulations

8. The proposed Regulations discussed following were informed by extensive consultation with stakeholders summarised under [Consultation](#) later in this document.
9. The Act applies to a very broad range of uses for radiation, such as industrial, medical and research related. Radiation risk profiles vary widely within each of these categories and can change over time as new technologies develop. Therefore, the proposed framework maximises flexibility.
10. To ensure that the regulatory framework is as straightforward and workable as possible, the proposed Regulations do not include matters that can be addressed in codes of practice or radiation safety plans.
11. Technical details, specific to each area of radiation practice, will be addressed in codes. Such matters include signage, labelling, transport, record-keeping, contents of radiation safety plans and emergency response procedures.
12. Radiation safety plans will be attached to source licences and prepared at facility level or by category of source, setting out local rules and procedures to comply with the Act.
13. The proposed Regulations do not include all the matters authorised under section 91 to 93 of the Act (eg, labelling and signage). Instead, they include only those provisions necessary for the Act's effective operation. These provide:
 - maximum periods for authorisations
 - authorised groups that can perform prescribed activities without a use licence;
 - conditional exemptions for temporary, and low exposure and low probability, situations;
 - cost recovery and fees; and
 - the form of warrants of appointment for enforcement officers and process for serving compliance orders.

Proposed fees and cost recovery under the new Act

14. Everyone with control and management of a radiation source must obtain a source licence, and those who use a radiation source must obtain a use licence, with some statutorily prescribed exceptions. Consents will be required to import or export radioactive material. Fees will be payable for all three kinds of authorisation.
15. Costs cannot be recovered unless there has been appropriate consultation with people or organisations which the Minister considers representative of the interests of those likely to be substantially affected by the exercise of the power. Those consulted must have been given sufficient time and information to make an informed contribution.
16. Regulations can permit full cost recovery of both the direct and indirect costs. The Act also confirms that compliance verification costs can be recovered.

Issues affecting the Regulations

17. Two significant issues arising from consultation on the proposed Regulations were:
 - the nature and extent of Regulations authorising the use of radiation sources without having a use licence, thus avoiding application and fee paying requirements; and
 - fees payable for authorisations – including whether the Regulations should provide for full or partial cost recovery.
18. Ancillary issues discussed under [Options and impact analysis](#) are:
 - Should there be maximum durations for authorisations in the Regulations?
 - If yes, what should the maximum durations be?
 - What if any groups should be permitted to perform prescribed activities without a use licence?
 - Is an exemption from obtaining consents (etc) for temporary arrivals by ship or aircraft where that vessel has a radiation source on board appropriate?
 - How should the surplus funds due to historical over recovery of fees be treated?
 - Is full or partial cost recovery by way of fees preferred?
 - What exemptions from registration and authorisation should be provided for low-exposure and low-probability situations?

Objectives

19. The objectives of the proposed Regulations are:
 - (i) to prescribe operational necessities required to support the Act; and
 - (ii) to regulate the use of radiation sources in an appropriate way. To that end, we seek:

- proportionality - applying a graded approach so that the full range of risks and varying uses of ionising radiation will be appropriately managed;
- simplicity – creating a straightforward, usable framework avoiding unnecessary administrative or compliance burden;
- certainty in cases where this is necessary - such as by specifying requirements to be included in warrants of appointment and for the service of compliance orders; and
- full cost recovery arising from administering authorisations and verifying compliance, while ensuring fees recovered reflect the statutory principles of equity, efficiency, justifiability, transparency, and ease of administration.

20. There are timing constraints relating to when the Regulations must be in force. They must be in force in time for the Act's commencement on 7 March 2017.

Options and impact analysis

Should there be a maximum duration for authorisations in Regulations?

21. Section 91(1)(l) of the Act enables maximum periods for which authorisations may be granted to be prescribed by Regulations. Different periods may be prescribed for different radiation sources and purposes.

Option one

22. Prescribe maximum durations for the various kinds of authorisations.

23. Advantages are that applicants will know in advance what is required of them and the possibility of open-ended authorisations is avoided. Applicants will be required to review their own arrangements, checking with the Office of Radiation Safety in tandem with making applications for licences and consents, which will help in meeting radiation safety requirements.

24. This option may be less flexible than option two. However, the Director has discretion to apply a shorter authorisation period if this is warranted; so option one has in-built flexibility.

Option two

25. Specify no time limits and these would be set administratively, on a case-by-case basis, by the Director when the authorisation is granted.

26. An advantage is maximum flexibility enabling tailoring to the range of applications and renewals, and the degrees of risk they present.

27. Disadvantages are that the time limits could be arbitrarily set, or perceived to be arbitrarily set, and applicants would not know in advance what is expected of them.

Analysis of options

Criteria	Option 1	Option 2
Proportionate	√	√
Simple	√√	√
Certain in cases where this is appropriate	√√	
Full cost recovery in keeping with statutory principles	N/A	N/A

Key = ticks indicate criteria met; blank spaces indicates they are not met

28. The Ministry prefers option one because it is simpler and more certain.

Maximum duration of authorisations

29. Under the outgoing Act use licences continue in force for one year (renewable). This is unless a shorter period is specified in the licence. There are no source licences mentioned in this Act. Consents are not legislatively time limited. Current practice is to specify a date on the face of the consent of up to one year.

Option one

30. Specify a maximum duration of one year for authorisations.

31. The current maximum for use licences of one year is not necessarily the best means of ensuring compliance with radiation safety requirements. The new Act provides a number of other proportionate mechanisms to achieve compliance (eg, information requiring powers, suspension, variation or cancellation of authorisations, compliance orders, powers of seizure, prosecution of offences), should this prove necessary.

32. Consents for importing and exporting radioactive material are different from source and use licences in that they usually apply to one-off events. In addition to the safety requirements, there are international obligations to meet on the movement of some of this material. Therefore, a maximum period of one year for consents is appropriate to achieve the Act's purposes.

Option two

33. Specify a three year maximum duration for authorisations.

34. Given the total range of mechanisms available to achieve compliance, a period of three years seems unlikely to unduly compromise radiation safety, bearing in mind the Director's discretion to grant a licence for a shorter period of time.

35. Again, these considerations do not apply to consents for importing and exporting radioactive material. A maximum period of one year for consents is appropriate to achieve the Act's purposes.

Option three

36. Specify a five year maximum duration for authorisations.
37. Five years between licence renewals would arguably be too long for applicants to be reviewing their procedures, and could compromise radiation safety unduly unless the Director frequently checks compliance. In this environment, the Director is likely to set different (lower than maximum) periods for a number of situations and this option is likely to be similar to setting licence durations on a case-by-case basis.
38. This option could have the perverse effect of adding to regulator cost and could be perceived as adding inconsistency to the system.

Analysis of options

Criteria	Option 1	Option 2	Option 3
Proportionate	√	√√	√
Simple	√√	√√	√
Certain in cases where this is appropriate	√√	√	
Full cost recovery in keeping with statutory principles	N/A	N/A	

Key = ticks indicate criteria met; blank spaces indicates they are not met

39. The Ministry prefers option two because it is more proportionate, simpler and more certain.

Groups that can perform prescribed activities without a use licence

40. The Act requires users of radiation sources to obtain a use licence. However, when the required radiation safety knowledge and experience can be demonstrated by another means, Regulations can authorise groups to perform prescribed activities without a use licence. These activities will still be subject to the fundamental safety and security requirements of the Act and any applicable codes of practice.

Option one

41. No Regulations are made excluding groups from obtaining a use licence. This option is equitable in the sense that all users are at least initially treated the same and the cost of licensing is spread over all users. However, it would add to regulator costs (additional licences) and add a compliance cost for those who already have radiation safety knowledge and experience and at no marked radiation safety gain.

Option two

42. Prescribe the activities or classes of activities that groups can perform without obtaining a use licence. The Ministry has worked closely with potential groups to ensure that the required knowledge and experience has been gained (and will be maintained). These groups and the activities they can perform are set out in Table 1.

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 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	Scope of practice General Dental Practice	Current registration and practising certificate	Use of irradiating apparatus for dental diagnostic purposes
Dental Council	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	Scope of practice Dental Hygiene Practice	Current registration and practising 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 practising 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 practising certificate with no exclusion in taking extra-oral radiographs	Use of irradiating apparatus for taking of extra-oral radiographs for dental diagnostic purposes

Authority	Group	Criteria	Activity
Dental Council	Scope of practice Orthodontic Auxiliary Practice	Current registration and practising 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 practising certificate	Use of irradiating apparatus for dental 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
New Zealand Chiropractic Board	Scope of practice: Chiropractor	Current registration and practising certificate	Use of irradiating apparatus for chiropractic purposes

43. This option may not appear equitable as only a subset of radiation users will be excused from a use licence fee. However, without these exclusions the total cost of administering use licences would increase and any flow-on reduction in the use licence fee would be small. Further, the option is equitable in the sense that the same criteria for exclusions will be applied to all groups and their activities.

44. Other groups may be added to these Regulations over time. The Ministry will continue to work with groups that have indicated they may be able to meet the requirements to be included in these Regulations in the future.

Analysis of options

Criteria	Option 1	Option 2
Proportionate	√	√√
Simple	√	√
Certain in cases where this is appropriate	√√	√√
Full cost recovery in keeping with statutory principles	√	√√

Key = ticks indicate criteria met; blank spaces indicates they are not met

45. The Ministry prefers option two because it is more proportionate and more in keeping with full cost recovery principles.

Exemptions from authorisation for temporary arrivals by ship or aircraft

46. Conditional exemptions from the Act’s authorisation and registration requirements can be made by Regulations under section 91(1)(a). Radiation sources enter New Zealand temporarily as cargo or stores on ships or aircraft and also as part of their normal operations (eg, medical departments on cruise ships).

Option one

47. Provide an exemption from registration and authorisation requirements for radiation sources on ships or aircraft temporarily entering New Zealand, such as on the basis that they are leaving on the same or the next available vessel or scheduled time.

48. This option continues a practice that has operated under the outgoing Radiation Protection Act 1965.

49. The advantage is that this option prevents an onerous compliance and administrative burden. The inherent radiation safety risk is also comparatively small because there is a small temporal window for something to go wrong. In addition, the risk of a radiation safety incident occurring is lessened to some extent by the requirement that these sources will still be subject to all other requirements of the Act while in New Zealand. International Transportation Regulations will also apply.

Option two

50. Provide no exemption from the registration and authorisation requirements for radiation sources on ships and aircraft temporarily entering New Zealand.

51. While superficially simpler than option one, in reality this would involve significant compliance costs for cargo movers, tourism operators and others visiting New Zealand for short periods of time. It would also add significant regulator and compliance verification costs, would be difficult to enforce, and is likely to add to the cost of fees (eg, compliance verification costs would be significantly higher than average). So while this option would involve full cost recovery, the costs imposed would not meet the ease of administration and efficiency principles in the Act.

Analysis of options

Criteria	Option 1	Option 2
Proportionate	√	
Simple	√	
Certain in cases where this is appropriate	√√	√
Full cost recovery in keeping with statutory principles	√√	√

Key = ticks indicate criteria met; blank spaces indicate they are not met

52. The Ministry prefers option one because it is simpler and more workable than option two.

Exemptions for low-exposure and low-probability situations

53. There are situations where radiation sources are of little regulatory concern - because of the low probability of human or environmental exposure. Most household smoke detectors fall into this category (providing they are labelled, used and disposed of as recommended). Regulations can be made to exempt these sources from the requirements of licensing and registration where the effective dose arising from them is less than the prescribed levels.

Option one

54. Provide no exemptions from the authorisation and registration requirements.

55. This option would require householders to obtain a source licence and a use licence for their household smoke detectors, and to register their sources with the Director. While certain in application and initially simple, this would be disproportionate to the radiation safety risk and, therefore, overly cumbersome for administrators and radiation users.

Option two

56. Provide the exemptions listed in Table 2 subject to the listed conditions. Reasons for the exemptions are also provided.

57. This option would reduce applicant compliance costs and regulator costs, with negligible risk. It continues exemptions provided under the outgoing radiation protection legislative framework. However, the Ni-63 threshold of 750 megabecquerels has been raised from 500 megabecquerels as some research equipment sits at or around 500 megabecquerels and this options provides certainty for the owners of this type of equipment.

Table 2: Proposed Radionuclides exempted from authorisation and registration requirements

Radionuclide	Conditions	Reasons
Americium - 241	<p>No greater than 40 kilobecquerels</p> <p>Contained in a domestic ionisation chamber smoke detector</p> <p>Source is not readily accessible without dismantling the device</p> <p>Clearly labelled with a trefoil symbol and the word 'radioactive'</p>	<p>Emits alpha particles that are very easily shielded</p> <p>No external radiation dose so long as they remain in their manufactured containment</p> <p>Satisfies the dose criteria in s 91(1)(a)(iii)A</p>

Radionuclide	Conditions	Reasons
Nickel-63 or Hydrogen-3 (tritium)	<p>No greater than 750 megabecquerels (ni-63) or 20 gigabecquerels (H-3)</p> <p>Contained in an electron capture detector or similar device for use in gas chromatography</p> <p>Source housing clearly labelled with a trefoil symbol and the word 'radioactive'</p>	<p>These radiation sources emit low-energy beta particles</p> <p>These emissions are easily absorbed by the casing</p> <p>Satisfies the dose criteria in s 91(1)(iii)a</p>
Hydrogen-3	<p>No greater than 74 gigabecquerels contained in gaseous tritium light source</p> <p>At least 98% of total activity in the form of elemental hydrogen gas</p>	<p>Emits low-energy beta particles</p> <p>These sources are encapsulated in a glass capsule that easily shields emissions</p> <p>Satisfies the dose criteria in s 91(1)(a)(iii)B</p>
Benchtop x-ray analyser	<p>Used for x-ray fluorescence or x-ray diffraction</p> <p>Completely and permanently enclosed to prevent access of any part of the body to the primary x-ray beam</p> <p>Enclosure interlocked with the x-ray generator such that disassembly of the enclosure prevents x-ray production</p> <p>Shielded sufficiently to limit the instantaneous dose rate to 2.5 microsieverts per hour 5 cm from any accessible external surface</p> <p>Enclosure clearly labelled with suitable cautionary wording to the effect of: <i>'Do not disassemble. This unit produces ionising radiation when energised.'</i></p>	<p>Satisfies the dose criteria in s 91(1)(a)(iii)A</p>

Analysis of options

Criteria	Option 1	Option 2
Proportionate		√√
Simple	√	√
Certain in cases where this is appropriate	√	√√
Full cost recovery in keeping with statutory principles	√	√√

Key = ticks indicate criteria met; blanks space indicates they are not met

58. The Ministry prefers option two because it is simpler, easier, more in keeping with the statutory principles for cost recovery, and more proportionate in application.

Providing for full or partial cost recovery by way of fees

59. Under the Radiation Protection Act 1965, radiation users must renew their use licences annually, and pay a fee of \$190 - \$300 (incl GST), depending on the complexity of the licence. The Ministry must keep a register of licences and also maintains a register of radiation sources. The Ministry may suspend or cancel licences once granted, and the Regulations provide for exemptions or exceptions from all or some regulatory requirements, such as the requirement to hold a licence. The Act does not specify technical safety obligations that must be satisfied and these are imposed via licence conditions.

60. The Ministry can only recover the costs of licensing activities via use licence applications and renewals. The annual fees take from fees set in 1998, has averaged approximately \$785,000 in recent years. Since 1998 there has been higher than expected increase in the numbers of licences issued and the Ministry has absorbed the added workload without increasing its operating costs. This has generated a surplus of \$970,000, which the Ministry intends to return to users via discounts on fees.

61. The Ministry processes all applications for licences at a cost of approximately \$450,000 per year and contracts external science advice for its licensing activities and compliance verification services at a cost of \$987,700 per year. The current total operating cost is approximately \$1.44 million per year.

62. The new Act allows for the full or partial costs of both administering authorisations and compliance verification to be recovered in fees.

63. Adding recovery of the costs of compliance verification to fees will significantly increase fees.

64. The current and expected costs of administering authorisations and compliance verification activities are set out in Table 3 below.

Table 3: Expected costs of administering authorisations and compliance verification activities

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

Existing surplus funds through over recovery

65. Since the fees under the outgoing Act were last set in 1998, the Ministry has accumulated a surplus through over recovery for its partial cost-recovery licensing activities of \$970,000. Setting the fees under the new Act provides an opportunity to move this surplus towards zero.

Option one

66. Provide for partial cost recovery.

67. This is the current approach, which involves partial cost recovery, likely to be confined to the costs associated with processing licence fee applications. Even though this approach has led to over recovery, option one does not provide sufficient funds to operate the radiation safety framework in a cost neutral way over time.

68. The benefits to the Crown of choosing to subsidise these particular costs are likely to be marginal when set alongside the costs and revenues associated with activities using radiation and would not be targeted to any particular outcome (ie, marginal benefits would attribute to health service and research costs but would also attribute to the oil, gas, airline and construction industries).

Option two:

69. Recover full costs. This option is based on the current and expected costs outlined in Table 3 above. It enables the full costs of processing licences and consents, and of compliance verification in relation to source licences, to be met through imposition of fees.

70. This approach is justified cost recovery in that source licences apply to the legal entity with control and management of radiation sources, and these entities have significant influence on radiation safety and protection practices. Almost all compliance verification activities will be applied to source licence conditions. Therefore, fees will reflect the full cost of compliance verification costs which is the major component of overall cost of regulation. The costs of source licensing and compliance verification are expected to be approximately \$1.25 million per year or 87 percent of the total cost.

71. The advantages of this option are that it is clear, simple and the funding of regulation would be more closely associated with actual Regulator costs than option one. Put simply, fees reflecting this option are justifiable as meeting reasonable and actual expenses.

72. The disadvantages are that full cost recovery will be unpopular with some radiation users, particularly the compliance verification component of the fee. Also, there may be perceptions of inequity in that full cost recovery does not appear to take account of the surplus.

Option three - full cost recovery with initial, partial exemption for source licence holders

73. Provide an initial exemption from the full fees so that the balance of previously over-recovered costs under the current legislative framework would move towards zero over a six year period.
74. In this initial period a 13 percent partial exemption would apply to the full source licence fees. Applying this approach to the total expected cost (\$1.25 million per year), comes to \$1.09 million per year. This would reduce the surplus through over recovery by approximately \$160,000 per year or approximately \$960,000 over six years.
75. The proposal mentioned earlier, of adopting a three-year source licensing period, means that the Ministry's income from licensing is also likely to follow a three yearly cycle. Therefore, a meaningful analysis of the fees taken under these proposed Regulations would not be available until at least four years has past (one full cycle is complete). Under option three, the Ministry would review the fees (and costs) before the end of this six year period.
76. This option has been agreed by Cabinet as the basis on which the Ministry would consult with stakeholders and the public.
77. Option three has the advantage of giving the group most comparable to those who have contributed to the surplus funds in the past an initial, partial fees exemption. Put another way, this exemption would be appropriately applied to licence holders who have contributed most to the surplus, and best meets the statutory principles for cost recovery. It would also assist in initially keeping fees lower than option two.
78. A disadvantage is that the option is not as simple as either of the other options. Although there is a risk that the partial exemption may in reality result in a short fall of fees, compromising radiation safety compliance measures, the Ministry considers this risk to be slight.

Analysis of options

Criteria	Option 1	Option 2	Option 3
Proportionate		√√	√√
Simple	√√	√√	√
Certain in cases where this is appropriate	√	√√	√√
Full cost recovery in keeping with statutory principles		√√	√√√

Key = ticks indicate criteria met; blank spaces indicates they are not met

79. The Ministry prefers option three, since it at least initially off-sets some of the cost of source licence fees, and assists in reducing surplus funds.

Consultation

Mode and timing of consultation

80. On 11 May 2016, a consultation document, *Proposed Radiation Safety Regulations*, was published on the Ministry of Health's website. Every current licence holder was alerted twice by email. All relevant departments, DHBs and some health related registration bodies and engineering professional bodies, were advised.
81. In total, more than 4,500 current owners and licensed users of radiation sources were consulted, as well as the professional registration bodies and other organisations representing potential users (eg, the Medical Council of New Zealand). Members of the public have also been consulted to enable people who may benefit from or be concerned about potential harm from using ionising radiation have an opportunity to be heard.
82. Stakeholders were consulted on the basis that the proposed Regulations may include authorisations, exemptions, categorisation of radioactive material, safety plans, fees which must be submitted with applications for authorisations and renewals, record-keeping and enforcement matters.
83. The consultation period was for six weeks and a submissions template was published with the consultation document to facilitate feedback. The Ministry considers that the consultation satisfies the Act's requirements where Regulations relate to fees.

Tenor of submissions

84. The Ministry received 142 submissions. The majority were on the fees and increases proposed and the activities which can be performed without obtaining a use licence.
85. Ninety almost identical submissions were nearly all from chiropractors seeking to come within the use licence exceptions, itemised in Table 1 above. After follow up meetings between the Office of Radiation Safety and the New Zealand Chiropractic Board (the profession's registration body), the Ministry considers chiropractors should be one of the occupational groups avoiding having to apply for a use licence for the activities shown in Table 1. They were able to demonstrate the competency and registration requirements asked of them.
86. In addition, 12 dental specialities have been added to the Table.
87. Although a lot of detailed matters were raised by submitters, the majority supported the bulk of the proposals in the consultation document, including the appropriateness of full cost recovery.
88. Submitters particularly supported:
 - dealing with radiation safety plans in codes of practice rather than in Regulations;

- user exceptions to licensing;
- the detail of the dose limit exemption tables; and
- taking a lean approach to Regulation, with most of the detail being included in codes of practice.

Conclusions and recommendations

89. The proposed Radiation Safety Regulations supporting the Radiation Safety Act 2016 would:

- specify maximum time limits for the duration of authorisations (use and consent licences and consents to import and export radioactive sources);
- provide that the maximum time limits for use and source licences are three years and for consents are one year;
- provide exceptions from the requirement to have a use licence for people who can demonstrate by another means that they are safe to use radiation sources – so far the people and activities set out in Table 1 of the RIS;
- provide an exemption from the registration and authorisation requirements in subparts 2 and 3 of Part 1 of the Act for aircrafts and ships temporarily entering New Zealand, such as on the basis that they are leaving on the same or the next available vessel;
- exclude radiation sources from the authorisation and registration requirements in the Act when the effective dose arising from them is less than the prescribed levels, as set out in Table 2 of the RIS;
- provide for full cost recovery of costs arising from processing authorisations and compliance verifications, except that a partial exemption to the full source licence fee would apply over the first six years of the new Act's operations, moving the surplus towards zero over that period.

Implementation plan

Steps towards implementation

89. The Act has a 12 month transitional period between enactment and implementation, enabling the proposed Regulations to be ready in time for commencement.
90. An Implementation Steering Group has responsibility for overseeing the implementation plan. One of the key priorities identified is appointing a Director for Radiation Safety, with the incumbent Team Leader of the Office of Radiation Safety effectively acting in the role until the permanent appointment has been made. Another is to appoint the members of the Radiation Safety Advisory Council which has advisory powers to the Minister of Health, Director-General of Health and the Director.

91. Drafting codes of practice is another key priority identified on the Plan, although existing codes of safe practice can be used in the interim to some extent. The codes need updating across the board to ensure they meet the requirements of s 86 of the Act (eg, codes must state the fundamental requirement/s to which they relate, the scope of the code of practice, and not be inconsistent with the Act). The codes must be available on the Office of Radiation Safety part of the Ministry's website and have been consulted on.
92. A new security code of practice must be drafted, although the substance is currently contained in licensing conditions of it. The Implementation Steering Group will monitor progress in updating the codes of practice, for planned completion of them by February 2017, in time for the Act's commencement.

Steps taken to minimise compliance costs

93. The Ministry's cost recovery proposals recognise that segments of the radiation sector have disproportionately carried the brunt of licensing costs under the old legislation, and the surplus will to some extent be returned to those segments in the first six years of the Act's operation.
94. Exceptions to obtaining authorisations proposed in the Regulations for some radiation safety users and activities, based on the availability of demonstrably robust training requirements, enable them to avoid the payment of fees.
95. Compliance verification audit frequency is also geared to the presenting radiation safety risk (eg, three year licence holders could in some instances be subject to an audit every five years, and the fees will be comparative low as a result).
96. The proposed cost recovery Regulations have been developed taking into account the cost recovery principles in s 92 of the Act – including equity, efficiency, justifiability, transparency, and ease of administration.
97. The consultation requirements in the Act which apply before cost recovery can be embarked on are another means of checking burgeoning costs.

Impact of the proposals on existing Regulations

98. The Radiation Protection Regulations 1982 and the Radiation Protection (Appeals) Regulations will be revoked by the Radiation Safety Act 2016 when it comes into force on 7 March 2016.

Enforcement strategy

99. The new Act allows for enforcement officers which will be appointed by the Ministry, as recognised in the Implementation Plan. The Office of Radiation Safety will be continuing the audits of compliance and responding to any incidents coming to its notice. An Incidents Responders' Handbook (March 2009) is being revised to meet the requirements of s 60 of the Act - which necessitates a Radiation Response Plan for events that may involve radiation safety and containing "appropriate operational arrangements". Website material will also be updated to reflect the legislative changes, including enforcement changes.

Monitoring, evaluation and review

100. Within six years, fees will be reviewed in light of the surplus, and our assumptions on costs of the regulatory framework and the level of licence fees. A review at the three year mark would be premature in the Ministry's view given this and the three year maximum duration of most authorisations. Transitional arrangements in the Act mean the current licences that are all one year licences will be expiring within the first year of operation and then will move on to source and user licences of up to three years' and to consents of up to one years' duration. After only three years there is unlikely to be sufficient data to conduct a meaningful review.
101. In terms of other features— such as duration of authorisations and exceptions and exemptions, some occupational groups will continue to work with the Office of Radiation Safety for possible future avoidance of fees. This would only arise when the Director is satisfied that the training and competency requirements of the people performing the radiation user activities are robust enough to ensure radiation safety without additionally going through the use licensing requirements.
102. Section 94 of the Act provides for revision by Order in Council of Schedules 2 (lower limits for radioactive material subject to the Act) and 3 (upper dose limits for ionising radiation which cannot be exceeded). These review mechanisms reflect the Office's broader responsibilities for monitoring and acting on International Atomic Energy Agency Guidance issued from time and relating to radiation safety.
103. Finally, the Radiation Safety Advisory Council has powers to communicate with the Minister and vice versa. They could conceivably provide advice on matters coming within the scope of monitoring, evaluation and review of the Regulatory framework.