

Stage 2 Cost Recovery Impact Statement: Approval to Amend the Radiation Safety Regulations 2016

Purpose of Document	
Decision sought:	Approval to Amend the Radiation Safety Regulations 2016
Advising agencies:	Ministry of Health
Proposing Ministers:	Hon Andrew Little, Minister of Health
Date finalised:	19 September 2022
Problem Definition	
<p>Radiation safety fees</p> <p>The administration of radiation safety is operating a steadily growing negative memorandum account balance (deficit) that the current fees take cannot address.</p> <p>Categorisation of radiation safety practices</p> <p>Some ionising radiation practices are not in the correct (risk-based) compliance monitoring category and therefore, are not paying the appropriate fee for the level of inspection that is warranted.</p> <p>Inspection periods</p> <p>The use of inspection periods in the Radiation Safety Regulations 2016 (the Regulations) has inadvertently restricted some inspection practices that are desirable to better meet the purpose of the Act.</p> <p>Exemptions and authorisations</p> <p>Some exemptions and an authorisation require amendment to ensure technical accuracy and proportionality.</p>	
Executive Summary	
<p>A significant increase in the fees payable to the Ministry of Health (the Ministry) for authorisation applications made under the Radiation Safety Act 2016 (the Act) is proposed. The fees are set out in the Regulations.</p> <p>The proposed fees increase would ensure that the original intent for the Regulations to fully recover the direct and indirect costs of administering the Act can be met.</p>	

The proposed fees would also recover a shortfall in the fees taken since 2016 (the negative memorandum account balance). Supporting amendments are proposed for the refund provisions.

Re-categorising some practices set out in Schedule 2 of the Regulations is also proposed. Categorisation determines the fees that are payable for source licence applications (an authorisation type). This proposal would better allocate fees to the costs of inspections.

Replacing inspection periods with more suitable terminology is proposed to address unintended restrictions on inspection practices and scheduling. This proposal does not affect fees but is perceived to be removing some transparency. Addition reporting is proposed to add transparency. The proposal would improve the benefits available as a result of operating the inspection programme.

Additional minor amendments are proposed to the exemptions for very low-risk practices and to clarify the scope of an existing authorisation of a practice in Schedule 3 of the Regulations. These proposals do not affect the fees or cost recovery.

Limitations and Constraints on Analysis

Analysis was limited to the scope of matters that can be dealt with by the regulation making provisions set out in sections 91 to 93 of the Radiation Safety Act 2016 (the Act).

Analysis was further limited to evaluating the operation of the Radiation Safety Regulations 2016 (the Regulations) against the objectives set out in the 2016 regulatory impact statement (the 2016 RIS)¹ for the Regulations. The objectives of the 2016 RIS informed the policy approval for the Regulations [CAB-16-MIN-0417].

The 2021 public consultation document *Review of Radiation Regulations 2016 – a consultation document*² made the evaluation of the Regulations against the objectives of the 2016 RIS. The public consultation document substituted for an interim regulatory impact statement and the analysis reported in this document refers to the options outlined in the public consultation document.

Responsible Manager(s) (completed by relevant manager)

Clare Perry
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27 September 2022

¹ Ministry of Health, 4 October 2016 (accessed 10 September 2022) (www.health.govt.nz/about-ministry/information-releases/regulatory-impact-statements/radiation-safety-regulations)

² Ministry of Health, 16 March 2021 (accessed 10 September 2022) (www.health.govt.nz/publication/review-radiation-safety-regulations-2016-consultation-document)

Quality Assurance (completed by QA panel)	
Reviewing Agency:	Manatū Hauora, the Ministry of Health
Panel Assessment & Comment:	The Ministry of Health's Papers and Regulatory Committee has reviewed the CRIS and considers that it meets the quality assurance criteria.

Status quo

The Regulations were made in 2016 to fully implement the Radiation Safety Act 2016 (the Act).

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 the safe and beneficial use of ionising radiation. The Act also enables New Zealand to meet its international obligations relating to radiation protection, safety, security, and nuclear non-proliferation.

Regulations 15 to 20 (with reference to Schedule 2 for source licence applications only) set out the annual fees payable to the Ministry by people or organisations that apply for authorisations under the Act. Authorisations can be granted to manage and control radiation sources (source licences), use radiation sources (use licences) and import or export radioactive material (consents). Refund and GST provisions are included.

The fees are established in accordance with section 92 of the Act.

Regulations 15 and 16 and Schedule 2 of the Act use the term 'inspections period' to determine the source licence fee payable.

The Regulations also set out exemptions for very low-risk practices (such as using household smoke detectors) and authorise practices that can be performed by people with appropriate knowledge and experience of radiation safety. Exemptions are set out in regulations 10 to 14 and authorised practices are set out in Schedule 3 of the Regulations.

Exemptions and authorised practices are established in accordance with section 91 of the Act.

Reviews of cost recovery charges

The memorandum account balance process has identified that the fees taken under the radiation safety legislation are significantly short of achieving their intended goal of full cost recovery. A subsequent review of the fees against the objective of full cost recovery has confirmed that a shortfall in fees taken is creating steadily growing negative memorandum account balance that cannot be recovered at current fee levels.

The review of the Regulations also found that some of the practices listed in Schedule 2 of the Regulations are not in the correct compliance monitoring category.

As a result, the source licence fees payable are not ideally allocated to recovering the costs of inspections that are warranted for those practices.

The use of the term inspection period to determine the source licence fees payable, and the exemptions and authorisations, are part of the proposals to amend the Regulations. However, these proposals do not affect the fees or cost recovery under the Act.

Cost Recovery Principles and Objectives

The principles of cost recovery are established by section 92(3) of the Act (Regulations relating to fees), as:

- equity
- efficiency
- justifiability
- transparency
- ease of administration.

The objectives of the cost recovery proposals are set out in the 2016 RIS for the Regulations and include the principles set out in section 92(3) of the Act.

The 2016 policy approval for the regulations [SOC-16-SUB-0099; CAB-16-MIN-0417] included the objective of full cost recovery of the direct and indirect costs of verifying compliance by holders of authorisations with the radiation safety requirements.

The full cost recovery objectives were outlined in the 2016 RIS as ‘... *full cost recovery arising from administering authorisations and verifying compliance while ensuring fees recovered reflect the statutory principles [set out in section 92(3) of the Act] of equity [sometimes referred to as fairness] efficiency, justifiability, transparency, and ease of administration*’ (p4-5). Recovery of these costs is enabled by section 92(2)(b) of the Act.

The 2016 RIS objectives also included ‘... *to prescribe [the] operational necessities required to support the Act, and to regulate the use of radiation sources in an appropriate way [by] ... seek[ing]:*

- *proportionality, applying the graded approach so that the full range of risks 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 specifying the requirements to be included in warrants of appointment and for the service of compliance orders.*

Policy Rationale: Why a user charge? And what type is most appropriate?

The people and organisations that are authorised under the radiation safety legislation gain the exclusive benefit of being able to provide a service that involves

the safe and lawful use of ionising radiation. Unauthorised people and organisations are prevented from providing these services on highly justifiable safety grounds.

On this basis, authorisations under the radiation safety legislation have been considered a private good and therefore, full cost recovery by means of a fee is the appropriate regulatory approach.

There are grounds on which to consider that the level of fees may incentivise behaviour to avoid costs, and therefore, introduce safety risks. Considering this, and the purposes of the Act (to allow the safe and beneficial use of ionising radiation) it is prudent to consider authorisations under the radiation safety legislation to also be a merit good.

When the level of the proposed fees is compared to the level of capital and operating costs of providing safe and lawful services that use ionising radiation, the proportion of costs attributable to fees is so low that the risk of incentivising cost avoidance can be considered low.

Therefore, authorisations under the Act can be considered a merit good that requires no funding from general taxation while the fees remain at a low level relative to the other costs associated with providing services that use ionising radiation.

On this basis, the 2016 RIS objective of full cost recovery through fees remains entirely relevant.

The level of the proposed fee and its cost components (cost recovery model)

Table 1 sets out the costs of administering the Act compared to when the fees were first set in 2016.

Table 1: Annual costs of administering the Act: 2016 compared to projected costs for 2022

	2016	2022	Change (\$)	Change (%)
Direct costs of administering the Act	\$450,000	\$1,038,778	\$588,778	131%
Contracted compliance monitoring service (routine on-site inspections)	\$887,700	\$1,368,997	\$481,297	54%
Contracted technical evaluation service	\$100,000	\$82,670	-\$17,330	-17%
Total costs of regulation	\$1,437,700	\$2,490,445	\$1,052,745	73%

The direct and indirect costs of administering the Act have risen far in excess of the assumptions made when the fees were set. The increased costs have been generated to relieve cost pressures for contracted on-site inspections, meet the staffing levels required to implement the new legislation from 2016, and costs for operating a new information technology (IT) system.

The negative memorandum account balance is projected to be \$1.6 million as of 30 June 2022 (actual figure not yet reported). The memorandum account balance change since 2016 is set out in Table 2.

Table 2: Memorandum account balance: 2016 compared to projected balance for 2022

	2016	2022	Decrease (\$)	Decrease (%)
Memorandum account balance	\$973,000	-\$1,600,000	\$2,573,000	264%

On the basis of the costs of administering the Act and the memorandum account balance, the recoverable costs are outlined in Table 3.

Table 3: Annual recoverable costs of administering the Act

	2017	2022	Change (\$)	Change (%)
Total costs of regulation	\$1,437,700	\$2,490,445	\$1,052,745	73%
Memorandum account annual adjustment	-\$162,000	\$200,000	\$362,000	223%
Recoverable costs	\$1,275,700	\$2,690,445	\$1,414,745	111%

Table 4 sets out the proposed new fees and compares them to the existing fees. The proposed new fees would recover the annual recoverable costs of administering the Act, introduce a different fee for new source licence and new use licence applications compared to renewal applications, and adjust the refund amounts.

Because the current fees apply a 13 percent discount to source licence fees to address the historical over-take in fees that occurred prior to 2016, Table 4 also sets out a comparison to the current fees with this discount removed.

The fees set out in Table 4 are unaltered from those outlined in the public consultation document.

Table 4: Proposed new annual fees compared with current fees (discount applied until 7 March 2023) and full current fees (discount removed from 7 March 2023)

Source licences compliance monitoring category (new applications)	Proposed new fee	Current fee (discount applied)	Current fee (no discount)	Change from current discounted fee	Percentage change from current discounted fee
Medical 1, Non-medical 1, Non-medical 2	\$3,744	\$1,309	\$1,505	\$2,435	186%
Medical 2, Medical 3, Non-medical 3	\$1,931	\$718	\$825	\$1,213	169%
Non-medical 4	\$1,328	\$522	\$600	\$806	154%
Medical 4, Non-medical 5	\$1,097	\$422	\$485	\$675	160%
Medical 5, Medical 6, Non-medical 6	\$993	\$361	\$415	\$632	175%
No inspection (refund)	\$588	\$126	\$145	\$462	367%
Source licences (renewals)					
Medical 1, Non-medical 1, Non-medical 2	\$3,508	\$1,309	\$1,505	\$2,199	168%
Medical 2, Medical 3, Non-medical 3	\$1,695	\$718	\$825	\$997	170%
Non-medical 4	\$1,092	\$522	\$600	\$570	109%
Medical 4, Non-medical 5	\$861	\$422	\$485	\$439	104%
Medical 5, Medical 6, Non-medical 6	\$757	\$361	\$415	\$396	110%

No inspection	\$353	\$126	\$145	\$227	180%
Use licences					
Use licence (new applications)	\$408	\$95	\$95	\$313	329%
Use licence (renewals)	\$250	\$95	\$95	\$155	163%
Consents					
Consents (high-activity)	\$233	\$300	\$300	-\$67	-22%
Consents (low-activity)	\$163	\$80	\$80	\$83	104%
Consents (unsealed multi)	\$163	\$400	\$400	-\$237	-59%

The level of projected authorisation applications and an analysis of the cost components are set on in Table 5

Table 5: Cost components of administering the Act

Authorisation type	Projected applications	Application assessment	Compliance monitoring	Technical evaluation	Memorandum account	Total	Percent
Source licence (new)	117	\$52,692	\$67,902	\$10,312	\$12,113	\$143,019	5.32%
Source licence (renewals)	2240	\$683,386	\$1,301,095	\$39,484	\$187,887	\$2,211,852	82.21%
Use licence (new)	114	\$36,436	\$0	\$10,047	\$0	\$46,483	1.73%
Use licence (renewals)	1023	\$237,790	\$0	\$18,032	\$0	\$255,822	9.51%
Consents (high-activity)	19	\$2,760	\$0	\$1,675	\$0	\$4,435	0.16%
Consents (low-activity)	172	\$24,988	\$0	\$3,032	\$0	\$28,020	1.04%
Consents (unsealed multi-event)	5	\$726	\$0	\$88	\$0	\$814	0.03%
Totals		\$1,038,778	\$1,368,997	\$82,670	\$200,000	\$2,690,445	

The proposed new fees are expected to generate the annual recoverable costs from Table 3 for the financial year beginning 1 July 2023 and outyears. Total revenue for the three-year period to 30 June 2026 is expected to be \$8,071,335.

The proposed new fees would also lift revenue slightly for the current financial year ending 30 June 2023.

The costs of administering the Act (direct and indirect) have assumed a year-on-year increase in costs of 1.5% on current budgets. It is too soon to evaluate the effect of this assumption.

The direct costs of administering the Act includes costs of operating a new IT system which is due to come into operation in 2023. Any delay in this project would result in an over-take in fees for the delay period. The effect of any delay can be dealt with using the memorandum account process.

The effects of operating a new IT system on costs associated with processing applications are unknown. Once the new IT system is fully implemented and operating processes are settled, a further review of the fees is warranted.

Options and Impact analysis

The options for the proposals were limited to evaluating the operation of the Radiation Safety Regulations 2016 (the Regulations) against the objectives set out in the 2016 RIS³ for the Regulations.

The options were set out in the public consultation document in five sections as being:

- fees review and findings
- proposed changes to fees structure
- proposed new fees
- amendments to existing exemption, prohibitions and restrictions
- other matters that can be dealt with under the Regulations.

Fees review and findings

Memorandum account balance

The option of recovering the memorandum account balance over eight years from source licence fees only has been chosen.

The status quo option was not considered because it would maintain a steadily increasing negative memorandum account balance against the expectation that memorandum account balances should trend toward zero over a period of time.

The alternative option of recovering the memorandum account balance from all authorisation types was rejected. Source licence holders are the main beneficiaries of the undertake in fees since 2016. Source licence holders have also been the exclusive beneficiaries of a 13 percent discount in fees since 2016 to address what was a positive memorandum account in 2016.

Some submitters proposed that the Crown should fund (or write-off) the negative memorandum account balance. They argued that the increased costs outlined in the public consultation document were caused by inefficiency in administering the Act or inaccuracy in calculating the fees.

The cost increases have been necessary and unavoidable to administer the Act. On this basis, the Government can be assured that the benefits of administering of the Act are being met at minimum cost. Reducing costs to achieve a reduction in proposed fees would breach the obligation to ensure that the purposes of the Act are being met.

³ Ministry of Health, 4 October 2016 (accessed 10 September 2022) (www.health.govt.nz/about-ministry/information-releases/regulatory-impact-statements/radiation-safety-regulations)

The fees calculated in 2016 did not fully take into account the extent of cost increases that have occurred. However, it is reasonable to argue that the people and organisations that pay fees under the Act have enjoyed the exclusive benefit of the undertake in fees.

No submitters identified a social or cultural goal, over and above the administration of the Act, that justifies Crown funding. Crown funding of the memorandum account balance itself, compared to the option of source-licence-holder-funding, was considered to breach the principle of justifiability set out in section 92(3)(c) of the Act.

The annual amount of recovery of the negative memorandum account balance is \$200,000 or a 9.22 percent premium on source licence fees. Recovery over eight years was chosen to reduce the premium percentage compared to recovery over a shorter period of time (for example, six years). This option was deemed to be improving the ease of administration of the recovery, a principle set out in section 92(3)(e) of the Act.

There is a risk that proposed recovery of the negative memorandum account balance over eight years will unfairly (inequitably) capture future new licence applicants who would be required to contribute to an historical under-recovery that they did not participate in. On this basis, the principle of equity set out in section 92(3)(a) of the Act may be breached.

Approximately five percent of source licence applications are anticipated to be new applications (95 percent renewals). Some of the new applications are expected to be from applicants that have lapsed their licence, are former licence holders, or are existing licence holders applying for a new practice or location where a variation is not appropriate. On this basis, it is reasonable to estimate that 2.5 percent of source licence holders in eight years would be new entrants to the market.

Establishing a fee type for new entrants to the market was considered impracticable. The fee type would need to apply to new and renewal applications for eight years and would need to discriminate on the basis that people and organisations had not participated in the past. Given the small size of this group and the relatively low impact of the fee portion on the overall fee, it was deemed that generally, and to the extent practicable, the risk that the recovery of the memorandum account balance was unfair has been minimised.

The overall amount of recovery over eight years (\$1.6 million) was not considered to be a significant amount compared to the overall operating costs of providing safe services that use ionising radiation safety. On this basis, the overall amount of recovery sought is likely to have a low impact and the basis for partial funding from general taxation (to write-off the balance) is correspondingly low.

Cost recovery method

The preferred option (the status quo) of full cost recovery has been chosen.

The alternative option of cross subsidising or partial Crown funding of cost recovery on safety grounds was considered but has not been adopted. The argument that a social or cultural goal should be funded by the Crown, over and above administering the Act, is not sustainable. The argument that the level of the proposed fees could incentivise cost avoidance that might undermine the safety purposes of the Act is worth monitoring, particularly for use licence fees.

However, at the proposed level of fees relative to the operating costs associated with providing services that use ionising radiation, this risk that the fees are too high to be safe has been assessed as being low.

These options meet the full recovery objectives of the 2016 RIS.

Impact

The proposal of full cost recovery in new fees would affect approximately 3,690 current authorisation holders.

For large organisations paying the highest fees the proposed fees increase would not be significant compared to operating costs. Organisations in this category include heavy industry, mining, oil and gas operators, private hospitals and radiology providers, the New Zealand Blood Service, industrial irradiation service providers, testing service providers, some research institutes and universities.

Te Whatu Ora – Health New Zealand is the single largest fee payer. It is estimated that Te Whatu Ora would pay an additional \$93,000 per year as a result of the fees increase (up from \$66,000 to \$159,000).

Sole charge operators and smaller businesses would experience the largest impact because fees (and the risks that need to be managed) do not differentiate on the basis of business size. Organisations in these categories include many private dentists, chiropractors and smaller veterinarian businesses.

A dental practice operating an X-ray unit only would pay an additional \$396 per year. A chiropractor operating an X-ray unit or a veterinarian operating an X-ray unit only would pay an additional \$439 per year. These costs are likely to be passed on quickly to consumers.

Other fee payers include private health services in primary health care, breast screening providers, border and security services (such as baggage screening), some agricultural users, and engineering service providers (such as ground testing).

The majority of fees payers receive at least some Crown funding for their operation.

Proposed changes to fees structure

Different fees for licence renewals

The preferred option to adopt different (lower) fees for licence renewal applications (compared to new applications) has been chosen. The status quo option (and alternative option) was to retain one fee for all licence applications.

Approximately five percent of source applications and approximately 10 percent of use licence applications are for new licences. These applications require additional assessment and technical advice to determine as opposed to renewal applications.

The impact is that application fees would be allocated in better proportion to the costs that they recover.

Refunds

The preferred option to amend source licence refund provisions to support the fees increase and adoption of different fees for renewal applications was chosen.

The status quo option was chosen for refunds of use licence and consent fees. This option retains the existing practice of providing a full refund when these types of applications are declined. This change was made to ensure an amount of proportionality could be maintained. The portion of the application fees that would be retained to achieve full cost recovery consisted of almost all the application fee.

The impact of this change ensures that relatively high proportions of the fees paid for declined applications are refunded. This recognises that there is value in receiving and considering applications that may not be able to be granted.

Determining the source licence fee payable (compliance monitoring categories)

The preferred option of re-categorising the practices listed in Schedule 2 of the Regulations was chosen. This option improves the proportionality of the Regulations by ensuring that fees are paid in relation to the costs of inspection.

The status quo option was not considered proportionate, and no alternative options were considered.

The proposals would reduce source licence fees and inspection frequencies for:

- dentists using cone beam computed tomography (approximately 231 licences)
- industrial radiographers using X-ray only (approximately 25 licences)

The proposals set out in appendix 1 would increase source licence fees and inspection frequencies for:

- using fixed nuclear gauges (eg, large scale processing and mining) (approximately 73 licences)
- using irradiating apparatuses for human imaging for non-medical purposes (eg, security inspections) (1 licence)
- using particle accelerators for non-medical purposes (eg, large scale inspections, manufacturing) (approximately 6 licences)
- using pulse generated portable security inspection systems (eg, large scale inspections, manufacturing) (approximately 8 licences).

The impact of these proposals decreases annual inspection-hours by about 795, or the equivalent of 66 average inspections. Inspection-hours are an accurate measure because inspections range in complexity and length.

The inspection-hours that apply to inspectors with industrial expertise would increase slightly, while the reduction in inspection-hours would apply to inspectors with medical expertise. The proposal would allow some reassigning as well as the opportunity to assign more inspection-hours to improve coverage and/or value to the inspection programme.

Determining the source licence fee payable (inspection periods)

The preferred option of removing the term 'inspection period' from regulations 15 and 16 and Schedule 2 of the Regulations has been chosen. This option would ensure that the operational necessities required to support the Act are reflected in the Regulations.

This proposal would ensure that off-site inspection methods as well as on-site inspections are available for the inspection programme. The proposal would also enable flexibility to reschedule inspections if the circumstance require. This would have an overall benefit to quality and flexibility of the inspection programme.

This proposal is supported with an undertaking by the Ministry of Health to publish inspection schedules and annual reports of inspections completed to maintain transparency on inspections.

Proposed new fees

The preferred options for all categories of new fees outlined in the public consultation document have been chosen to ensure full cost recovery. The fees are set in Table 4 of this document. This optional also ensures justifiability in that fees would be better allocated to the costs of the function to which they relate.

Amendments to existing exemptions, prohibitions and restrictions

Exemption for X-ray fluorescence and X-ray diffraction

The preferred option of introducing registration and record-keeping requirements (but not authorisation requirements) has been chosen to improve the certainty and proportionality of the Regulations.

The status quo option is not sufficiently proportionate and alternative option of completely removing the exemption is disproportionate.

This proposal does not affect fees. It does add compliance costs for owners and administration costs for the Ministry of Health.

The impact has been assessed as moderate during the implementation stage (registering) and low in the long term. The known and potential community of users for this equipment (from consultation) is 168 organisations or individuals.

Proposed changes to veterinarian and Medical Imaging Technologists authorisations under Schedule 3 of the Regulations

A modified preferred option has been chosen for the veterinarian authorisation to achieve the same aims set out in the public consultation document. The status quo option has been chosen for Medical Imaging Technologists.

These options would improve the prescription of the operational necessities required to support the Act.

These proposals have no effect on costs or costs recovery.

Other matters that can be dealt with under the Regulations.

A partial exemption for a class of irradiating apparatus referred to as 'Micro-CT' is proposed as a result of submissions. The proposal is in line with that proposed for X-ray fluorescence and X-ray diffraction. The impact of this proposal would relieve a very small number of owners from authorisation fees and provide a small amount of administrative and inspection ease. The impact is estimated as small because these apparatuses may be located at facilities where other radiation sources present ensure that an authorisation is a requirement.

A further exemption was considered as a result of submissions for a portable nuclear gauge (for measuring moisture content in soil for earthworks projects). Technical analysis demonstrated that the equipment cannot meet any of the exemption criteria set out in section 91(1)(a) of the Act. Therefore, this submission was deemed to be out of scope.

Consultation

A six-week public consultation ending on 29 April 2022 was conducted on the proposals following Cabinet approval [CAB-22-MIN-0021].

The consultation used the document *Review of Radiation Regulations 2016 – a consultation document*⁴ to outline the proposals.

The Ministry engaged PricewaterhouseCoopers New Zealand (PwC) to review the method for calculating the fees. PwC's report was considered by Cabinet when the public consultation was approved [CAB-22-MIN-0021] and PwC's report was made available alongside the public consultation document during the consultation.

All current licence holders were directly notified of the consultation. The Ministry also included professional registration bodies and highly affected occupational representative organisations in the consultation.

⁴ Ministry of Health, 16 March 2021 (accessed 10 September 2022) (www.health.govt.nz/publication/review-radiation-safety-regulations-2016-consultation-document)

Twenty submissions were received. The majority of topics raised in the public consultation document received full or majority support in submissions and have proceeded as outlined.

There were two topics in which submissions were split, and these were:

- fees increase
- replacing the term 'inspection period'.

Minor changes have been made to the proposals on exemptions and authorisations as a result of submissions.

Fee increases

Who should pay

Some submitters said that the increased costs outlined in the public consultation document were caused by inefficiency in administering the Act or inaccuracy in calculating the fees. On this basis, some submitters argued that the Crown should fund (or write-off) the negative memorandum account balance.

The Ministry's view is that the cost increases have been necessary and unavoidable to administer the Act. On this basis, the benefits of administering the Act are being met at minimum costs. Reducing costs to achieve a reduction in proposed fees would breach the obligation to ensure that the purposes of the Act are being met.

The Ministry accepts the argument that the fees calculated in 2016 did not fully take into account the extent of cost increases that have occurred. However, it is also reasonable to argue that the people and organisations that pay fees under the Act have enjoyed the exclusive benefit of the undertake in fees. Also, no submitters identified a social or cultural goal, over and above the administration of the Act, that justifies Crown funding.

Submitters supported the method for calculating the proposed fees.

The proposed new fees are identical to the preferred options outlined in the public consultation document.

Refund provisions to support the fee increases

Two submitters raised concerns that introducing the partial retention of fees paid for use licence and consent applications that are declined was inequitable and may disincentivise applications. The portion of the fees proposed to be retained would be close to the full fee. The Ministry accepts this view and these proposals have not been progressed.

This means that a full refund would continue to be paid if a use licence or consent application is declined. The cost of this change would have a negligible effect of cost recovery.

The refund proposals outlined in the public consultation document as the preferred option have been adopted for these proposals.

A submitter pointed out that variations to existing licences cannot be considered to be new-licence applications for the purposes of calculating refunds. The Ministry accepts this view and the proposals in this paper have been adjusted to ensure that variations are treated as renewal applications.

The refund provisions have been adjusted in response to submissions.

Re-categorisation of some practices in Schedule 2 of the Regulations

The preferred option was supported by submitters and these proposals remain unchanged to those outlined in the public consultation document.

Replacing the term inspection periods

Some submitters considered the removal of the term inspection period from the Regulations would also remove transparency of the service provided for the fees that are paid.

The Ministry accepts this view and the proposal has been amended to ensure that a transparent connection between the fee paid and costs of inspection would be retained.

Exemptions and authorisations

Two exemptions were requested as a result of submissions. One was out-of-scope and one has been included in the proposals to amend the Regulations. The impact has been assessed as very small. Technical changes to the authorisation proposals to amend the Regulation have also been made as a result of submissions that will have no effects on costs or fees.

The remainder of proposals are in line with the preferred options outlined in the public consultation document.

Conclusions and recommendations

The Ministry recommends the fees outlined in the public consultation document without adjustments. However, adjustments to the refund proposals have been recommended in response to issues raised in submissions.

Adjustments to the exemptions and authorisation proposals have also been recommended to those outlined in the public consultation document.

All other proposals are recommended in line with the preferred options in the public consultation document.

In the Ministry's view, the public consultation and consideration of submissions satisfies the Minister of Health's requirements to consult on cost recovery under section 92(4) of the Act.

In the Ministry's view, the process for establishing the new fees satisfies the Minister of Health's requirements to have regard, as far as is reasonably practicable, to the principles of equity, efficiency, justifiability, transparency, and ease of administration before recommending the method of cost recovery under section 92(3) of the Act.

The proposed amendments to the Regulations would ensure that the Regulations met the objectives outlined in 2016 RIS.

Implementation plan

All authorisation holders would be advised directly following final Cabinet decisions on these proposals. Professional registration bodies (for example, the Medical Council of New Zealand) and highly affected occupational representative organisations will also be directly advised. Officials will remain available to meet affected parties on request.

The fees increase has signalled in the public consultation document and the likely timeframe to implement the new fees has been signalled, in general terms, on the Ministry's website.

The Ministry has already taken steps to ready its payment and invoicing system for the new fees once Cabinet has taken final decisions.

A new class of irradiating would require registration under the proposals. The Ministry will work with the two known retailers, known owners and known industry sectors. It is expected that full implementation plan will run for some time.

Monitoring and evaluation

The proposals do not create additional work streams and are not expected to be disruptive. The Ministry will continue to monitor and evaluate the performance of the team responsible for administering the Act as has been business as usual.

Review

The Ministry will review the fees in three years to track progress of the memorandum account balance.

A new IT system is expected to be well integrated in three years and an evaluation can also assess the impact of application processing effort.