
Proposed Radiation Safety Regulations: Submission form

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)	Ms Marie Warner
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Organisation (if applicable):	Dental Council
Position (if applicable):	Chief Executive

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

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

Introductory comments

Thank you for the opportunity to submit comments on the proposed radiation safety regulations. The Dental Council (the Council) submission will be limited to the aspects relating to the licensing requirements by oral health practitioners (source and use), and obligations associated with safe handling of radiation sources within dental practice.

Under the Health Practitioners Competence Assurance Act 2003 the Council regulates oral health practitioners. This include dentists (includes dental specialists), dental hygienists (includes orthodontic auxiliary as a subset of dental hygiene), dental therapists, clinical dental technicians and dental technicians.

The Council sets standards to ensure oral health practitioners practise competently and safely, with the ultimate aim to protect the safety of the public of New Zealand.

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.

The Council agrees with the Ministry of Health's preferred option that no further information for inclusion in application forms is prescribed in regulations, as long as the criteria and obligations for source and user licences are transparent and clearly articulated within the Radiation Safety Act 2016. Detailed application information is not required within regulations.

Process related information, such as application requirements, can be made available on the website and/or other forms of communication. This has the benefit of timely updates as required, without the necessary legal obligations associated with law and/or regulation amendments, as long as the changes fits within the intent and ambit of the enabling legislation.

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.

Should a need for regulations be identified through this consultation process, then minimum requirements would be most appropriate – with more detail contained on the website and/or application forms. As long as expectations are clear and available at the point of application.

As mentioned in the consultation document, section 29 allows the Director with the ability to request any further information from an applicant – so any regulations and/or application form can only be considered minimum requirements.

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

N/A

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.

The Council sets competencies for its graduates. This defines the benchmark competencies for practitioners entering the profession and for clinical practice.

The Council competencies for all oral health professions contain a similar expectation on radiation capabilities, within the respective scopes of practice, being:

Provide or make provision for oral health care: Radiography

Related to patients needs with relevant structures in view

Adequate film quality correctly mounted

View ideal for diagnosis

Satisfactory radiation safety

Accurate report recorded.

A registered oral health practitioner with a current annual practising certificate would be able to, within the respective scope of practice, competently and safely use a radiation source (X ray machine) for dental diagnostic purposes.

As the Council previously confirmed in a letter to the Office of the Radiation Safety (dated 4 August 2015), the oral health practitioners that can take radiographs/images with a radiation source within their scopes of practice are:

- dentists,
- dental specialists:
 - Endodontics
 - Oral and maxillofacial surgery
 - Oral medicine
 - Oral pathology
 - Oral surgery
 - Orthodontics
 - Paediatric dentistry
 - Periodontics
 - Prosthodontics
 - Public health dentistry (or community dentistry)
 - Restorative dentistry
 - Special needs dentistry
- dental hygienists*
- dental therapists*
- orthodontic auxiliaries*.

However, some practitioners registered within those scopes of practice marked with an asterix, education had not included the taking and interpretation of radiographs – and those practitioners cannot perform radiography activities. Those practitioners are identifiable by exclusions placed on their scopes of practice – as published on the Council’s public register, available at www.dcnz.org.nz

For dental hygienists and orthodontic auxiliaries, one or both of the following exclusions could appear on the practitioner's scope of practice:

- taking extra-oral radiographs
- taking intra-oral radiographs.

For dental therapists, one or both of the following exclusions could appear on the practitioner's scope of practice:

- radiography (scope activity: Taking periapical and bitewing radiographs)
- diagnostic radiography (scope activity: Taking and interpreting periapical and bitewing radiographs).

Examples of how such exclusions would be displayed on the public register are:

- *Dental hygiene:*
Scopes of Practice: Dental Hygiene Practice
(Excludes Extra-oral Radiography **and/or** Intra-oral Radiography)
- *Dental Therapy:*
Scopes of Practice: Dental Therapy Practice
(Excludes Radiography).

The Council is of the view that the following oral health practitioners would be competent to safely use radiation equipment within their respective scopes of practice:

- registered with a current annual practising certificate in the **general dental practice and dental specialist scopes of practice**
- registered with a current annual practising certificate in the **dental hygiene and/or orthodontic auxiliary scopes of practice with no exclusion in taking extra-oral radiography and/or taking intra-oral radiography**. If a dental hygienist has an exclusion in one of the radiograph activities they can still competently and safely use the radiation equipment – but clinically still need to practise within their registered scopes of practice (i.e not take a type of radiograph in which they have an exclusion).
- registered with a current annual practising certificate in the **dental therapy scope of practice with no exclusion in radiography**. It is our view that an exclusion in diagnostic radiography (interpretation of radiographs) falls outside the discussion for the purpose of obtaining a source or use licence.

To facilitate the above principles, the following changes to *Table 2: Proposed groups and their activities that do not require a use licence*, contained within the consultation document, are proposed:

Dental Council	Vocational Scope of practice: general dental practice & dental specialist 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, with no exclusion in radiography	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, with no exclusion in taking extra-oral radiography and/or taking intra-oral radiography	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, with no exclusion in taking extra-oral radiography and/or taking intra-oral radiography	Use of irradiating apparatus for taking of intra-oral and extra-oral radiographs for dental diagnostic purposes
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Please note that the Council is currently consulting on a proposed oral health therapy scope of practice. If this new scope of practice is created then practitioners registered in that scope of practice will also have the capabilities for using X Ray machines embedded within their education and listed within their scope of practice – without any exclusions in relation to radiography. The Council will advise the Office of Radiation Safety of the outcome of the Council's decision in this regard – expected within the next few months.

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.

No specific comment

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

The Council is committed to work with the Office of Radiation Safety on its revised code of practice for dentistry, to ensure ongoing safe and responsible use of radiation within dentistry. The Council can set any additional obligations necessary to assist in achieving this through a practice standard or guideline, if required.

However, the Council believes the knowledge and expertise on the appropriateness of specific radiation sources, safe use of radiation sources, ongoing safety and security, and acceptable radiation levels sit with the Office of Radiation Safety.

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.

Operational discussions on how any change to a practitioner's scope of practice (for example removal of a radiography exclusion or a limitation placed on a particular scope of practice), or practising status could impact on the proposed three year use license, between the regulator and the Office of Radiation Safety should be explored.

Registration and/or practising status changes could happen on a more frequent basis than a 3-year licensing period. For example a practitioner can be removed or suspended from the Register, or not re-apply for a practising certificate if choosing to not practise for a year.

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

Yes

No

Please provide reasons and comments below.

No specific comment

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

N/A

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.

The Council believes the MOH codes of practice focussed on specific areas of radiation source use, such as dentistry, is more user friendly for users. As long as the necessary regulatory standing is maintained for compliance, and more importantly for non-compliance, then the Council sees no reason why not to continue with this approach.

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

N/A

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.

No specific comment

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

No specific comment

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

Yes

No

Please provide reasons and comments below.

No specific comment

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

No specific comment

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

No specific comment

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.

No specific comment

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

No specific comment

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

No specific comment

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.

No specific comment

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

Yes

No

Please provide reasons and comments below.

No specific comment

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.

No specific comment

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

No specific comment

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.

No specific comment

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.

No specific comment

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

No specific comment

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.

No specific comment

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.

No specific comment

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

No specific comment

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.

No specific comment

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?

No specific comment

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

No specific comment

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

No specific comment

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.

No specific comment

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.

No specific comment

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

No specific comment

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.

No specific comment

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.

No specific comment

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.

No specific comment

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

No specific comment

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.

No specific comment

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.

No specific comment

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

No specific comment

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.

No specific comment

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.

No specific comment

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

No specific comment

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.

No specific comment

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

No specific comment

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.

The Council supports the Ministry of Health’s preferred option that codes of practice will set out detailed requirements for responding to incidents and emergencies for each specific area of radiation practice; no additional regulations are required.

Section 18 of the Radiation Safety Act requires source applicants to submit a Radiation safety plan, that identify mechanisms to—

- (i) prevent risks of the kinds described in paragraphs (a) and (b) from arising; and
- (ii) reduce and eliminate those risks if they do arise; and

If required by the Director, set out the steps that the applicant will take to—

- (i) reduce the likelihood of an accident, incident, or emergency that is caused by or involves the radiation source; and
- (ii) mitigate any adverse effects of any such accident, incident, or emergency.

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.

N/A

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

No specific comment

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.

No specific comment

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.

No specific comment

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

No specific comment

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.

Similar to the principle expressed with the application procedure, the Council believes that registration requirements could be published on the website and/or other communication as long as it is clear and transparent, and easily accessible.

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

No specific comment

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.

No specific comment

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

No specific comment

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.

No specific comment

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

No specific comment

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.

The Council agrees with the proposal that the Ministry of Health codes of practice must specify how the fundamental requirements of the Act in relation to record keeping are to be met for each area of radiation practice. The proposal seems appropriate, as requirements can be tailored according to the type, and risk posed by the radiation source.

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.

N/A

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

No specific comment

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.

No specific comment

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

No specific comment

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.

No specific comment

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.

No specific comment

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

No specific comment

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.

No specific comment

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

No specific comment

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.

No specific comment

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

No specific comment

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.

None identified at this point.

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

No specific comment