

Second Round of Consultation on Requirements for Third-party Service Providers

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This consultation

Why are we consulting

The codes of practice included in this consultation were published under the Radiation Safety Act 2016 (the Act) with requirements for managing entities to use an external service that is either approved by the Director for Radiation Safety or maintains laboratory accreditation under ISO/IEC 17025, or internal capability validated by a qualified expert for individual dosimetry monitoring and leak testing.

After the publication of the non-medical codes of practice (ORS C8, C9, C10, C11 and C12), the Office of Radiation Safety (ORS) received feedback that this approach might not be feasible for some external service providers, and a suggestion that we ask the wider sector for their view on this.

Through the adoption of ISO/IEC17025: General requirements for the competence of testing and calibration laboratories, ORS intended to address feedback received during the initial round of consultation and establish a framework for every person dealing with radiation sources to prevent harmful effects from the use of ionising radiation. However, further feedback received by ORS after the publication of the codes showed that people have different viewpoints of the most appropriate approach to achieve reliability and uniformity of monitoring and testing outcomes. Therefore, ORS invites your feedback on the specified matters in this consultation.

How to provide feedback

You can provide feedback by sending an electronic submission to orsenquiries@health.govt.nz using the Consultation questions section of this consultation document.

The closing date for submissions is 31 October 2020.

Contact

The Director's contact details are:

Office of Radiation Safety

PO Box 5013

Wellington 6140

Email: orsenquiries@health.govt.nz

Fax: 04 496 2340

Introduction

Purpose

The Radiation Safety Act 2016 requires every person dealing with a radiation source to comply with the fundamental requirements set out in the Act including those who carry out any other activity or practice involving the radiation source. To specify operational requirements for those who carry out activities or services as a third-party service provider associated with individual dosimetry monitoring and leak testing, the Director has adopted the ISO/IEC17025: General requirements for the competence of testing and calibration laboratories pursuant to Section 8.7 and 8.71 of the IAEA General Safety Guide No. GSG-7 for Occupational Radiation Protection. This Guide sets out general considerations for a regulatory body when establishing its regulatory framework around management system for service providers.

Scope

The scope of this consultation applies to the clauses that require managing entities to use internal capability validated by a qualified expert or an external service maintains a certain international standard for individual dosimetry monitoring and leak testing.

The affected codes of practice by this consultation are:

- Code of Practice for Diagnostic and Interventional Radiology: ORS C1
- Code of Practice for Nuclear Medicine: ORS C2
- Code of Practice for Radiation Therapy: ORS C3
- Code of Practice for Industrial Radiography: ORS C7
- Code of Practice for Non-medical Irradiators: ORS C8
- Code of Practice for Veterinary Radiation: ORS C9
- Code of Practice for Irradiating Apparatus: ORS C10
- Code of Practice for Unsealed Radioactive Material: ORS C11
- Code of Practice for Sealed Radioactive Material: ORSC12.

Refer to Appendix 1 below for the affected clauses of each code of practice.

Submission form

Your details

This submission was completed by: *(name)* _____

Address: *(street/box number)* _____
(town/city) _____

Email: _____

Organisation *(if applicable)*: _____

Position *(if applicable)*: _____

Additional information

I am, or I represent an organisation that is, based in:

New Zealand Australia Other *(please specify)*: _____

I am, or I represent, a: *(tick all that apply)*

Servicing engineer Organisation that uses/stores material
 Radiation security officer Other *(please specify)*: _____

Privacy

We may publish submissions on the Ministry's website. If you are submitting as an individual, we will automatically remove your personal details and any identifiable information.

If you do not want your submission published on the Ministry's website, please tick this box:

Do not publish this submission.

Your submission will be subject to requests made under the Official Information Act. If you want your personal details removed from your submission, please tick this box:

Remove my personal details from responses to Official Information Act requests.

Please return this form:

By email to: orsenquiries@health.govt.nz

Consultation questions

The Office of Radiation Safety is seeking comments on the following:

Purpose

1. Do you agree that the Director's intention to achieve an acceptable standard for monitoring or testing outcomes provided either by validated internal capability or external services that maintain a certain international certification or accreditation is appropriate?

Yes

No

If no, please provide alternative suggestions for the scope of this code.

Proposed wording for the affected codes of practice in Appendix 1

2. Do you think that the proposed wording in bold in Appendix 1 below aligns with the Director's intention and the IAEA's recommendations for third party service providers?

Yes

No

If no, please provide details of parties that should/should not be included and any changes that should be made to the descriptions.

Appendix 1

Affected codes and clauses	Published requirements	Proposed wording in this consultation
Monitoring and measurement section		
<p>ORS C1 Code of Practice for Diagnostic and Interventional Radiology, Clause 13(b)</p> <p>ORS C2 Code of Practice for Nuclear Medicine, Clause 11(b)</p> <p>ORS C3 Code of Practice for Radiation Therapy, Clause 13(b)</p> <p>ORS C7 Code of Practice for Industrial Radiography, Clause 10(b)</p>	<p>In order to satisfy the monitoring and measurement requirements, the managing entity must: b) for continuous individual monitoring, use an external service or internal capability only if that service or capability:</p> <ul style="list-style-type: none"> i) is approved by the Director ii) returns results within 20 working days of receiving all necessary raw information. 	<p>In order to satisfy the monitoring and measurement requirements, the managing entity must: b) for continuous individual monitoring,</p> <ul style="list-style-type: none"> i) use internal capability validated by a qualified expert; or ii) use an external service that maintains either laboratory accreditation under ISO/IEC 17025 for an appropriate scope or accuracy and uniformity of results by participating in ongoing intercomparison exercises if using other suitable international standards
<p>ORS C8 Code of Practice for Non-medical Irradiators, Clause 7(b)</p> <p>ORS C9 Code of Practice for Veterinary Radiation, Clause 11(b)</p> <p>ORS C10 Code of Practice for Irradiating Apparatus, Clause 10(b)</p> <p>ORS C11 Code of Practice for Unsealed Radioactive Material, Clause 10(b)</p> <p>ORSC12 Code of Practice for Sealed Radioactive Material, Clause 10(b)</p>	<p>To satisfy the monitoring and measurement requirements, the managing entity must: (a) use appropriate monitoring equipment (b) for continuous individual monitoring, use an external service that:</p> <ul style="list-style-type: none"> i) maintains laboratory accreditation under ISO/IEC 17025 for ionising radiation dosimetry; and ii) returns results to the managing entity within 20 working days of receiving all necessary raw information. 	<ul style="list-style-type: none"> iii) use an external service or internal capability that returns results to the managing entity within 20 working days of receiving all necessary raw information.

Affected codes and clauses	Published requirements	Proposed wording in this consultation
Sources or equipment section		
<p>ORS C8 Code of Practice for Non-medical Irradiators, Clause 3(i)(iv)</p> <p>ORS C11 Code of Practice for Unsealed Radioactive Material, Clause 4(c)(iv)</p> <p>ORSC12 Code of Practice for Sealed Radioactive Material, Clause 4(c)(iv)</p>	<p>The managing entity must: conduct leak tests of sealed sources to confirm that there is no leakage of radioactive material:</p> <ul style="list-style-type: none"> i) using an external service that maintains laboratory accreditation under ISO/IEC 17025 for ionising radiation dosimetry, or internal capability validated by a qualified expert 	<p>The managing entity must: conduct leak tests of sealed sources to confirm that there is no leakage of radioactive material:</p> <ul style="list-style-type: none"> i) using internal capability by a qualified expert; or ii) using an external service that maintains either laboratory accreditation under ISO/IEC 17025 for an appropriate scope or accuracy and uniformity of results by participating in ongoing intercomparison exercises if using other suitable international standards