Regulatory Guide

How to seek an exemption from a licence

REGULATORY SERVICES

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1. Introduction

Section 30 of the *Australian Radiation Protection and Nuclear Safety Act 1998* prohibits certain activities in relation to controlled facilities. Section 31 of the Act prohibits any dealing with controlled material or controlled apparatus unless the activity or dealing is authorised by a facility or source licence as appropriate, or is prescribed by the Australian Radiation Protection and Nuclear Safety Regulations 2018 (the Regulations) as exempt.

Section 44 of the Regulations describes the dealings that are exempt. Schedule 1 of the Regulations provides exempt activity levels and exempt activity concentration values for specific radionuclides. (Note that the Regulations do not prescribe any controlled facility as exempt).

In addition to the exemptions prescribed in the Regulations the CEO may also on a case by case basis exempt from the need to be licensed those activities in relation to controlled facilities that require a licence under section 30 and those dealings with controlled material or controlled apparatus that require a licence under section 31.

The CEO’s powers to exempt on a case by case basis are at the following parts of the Regulations:

- Subsection 9(2) for apparatus that produces harmful non-ionising radiation when energised prescribed under subsection 9(1)
- Subsection 13(2) for radiation facilities prescribed under subsection 13(1)
- Subsection 43(2) for one or more conducts specified in paragraph 30(1)(a), (b), (c), (d), (e) or (ea) of the Act in respect of a specified controlled person and in relation to a specified controlled facility
- Subsection 44(3) for controlled material or controlled apparatus that produces ionising radiation

The criteria that the CEO will use to determine if an exemption is to be granted on a case by case basis and the matters that he will take into account are explained below.

2. Apparatus that produces harmful non-ionising radiation when energised (subsection 9(2)) and prescribed radiation facilities (subsection 13(2))

Subsection 9(1) prescribes those apparatus that produce harmful non-ionising radiation and which require a licence from ARPANSA under section 31 of the Act. However, under subsection 9(2) the CEO may declare in writing on a case by case basis that a non-ionising radiation apparatus is not a controlled apparatus thereby removing the application of subsection 9(1) on that apparatus.

Subsection 13(1) prescribes those facilities that are for the purposes of the Act ‘prescribed radiation facilities’ (PRFs). These controlled facilities require a licence for any of the conducts specified in paragraph 30(1)(a), (b), (c), (d), (e) or (ea). However under subsection 13(2) the CEO may declare in writing on a case by case basis that a facility is not a PRF thereby removing the application of subsection 13(1) on that facility.

Under subsection 9(3) the CEO must not make a declaration under subsection 9(2) unless the CEO is satisfied that:

(a) the apparatus does not pose an unacceptable hazard to the health and safety of people or to the environment; or
(b) it would be inappropriate for the apparatus to be a controlled apparatus

Under subsection 13(3), the CEO must not make a declaration under subsection 13(2) unless the CEO is satisfied that:

a) the facility does not pose an unacceptable potential hazard to the health and safety of people or to the environment; and

b) it would be inappropriate, in all the circumstances, for the facility to be a prescribed radiation facility.

A controlled person seeking a declaration under subsection 9(2) or 13(2) must therefore provide sufficient evidence for the CEO to conclude that the apparatus or facility meets the respective criteria under paragraphs (a) and (b) above in normal or routine conditions as well as under all reasonably foreseeable abnormal events or conditions.

3. One or more conducts specified in paragraph 30(1)(a), (b), (c), (d) (e) or (ea) of the Act by a specified controlled person in relation to a specified controlled facility (subsection 43(2))

Subsection 43(2) provides the CEO the power to exempt on a case by case basis any of the conducts mentioned in paragraph 30(1)(a), (b), (c), (d) (e) or (ea) of the Act by a specified controlled person in relation to a specified controlled facility (including any future conduct by the controlled person in relation to the controlled facility) provided the conduct does not or will not pose an unacceptable potential hazard to the health and safety of people or to the environment.

A controlled person seeking a declaration under subsection 43(2) must therefore provide sufficient evidence for the CEO to conclude that the conduct for which the exemption is sought will not pose an unacceptable potential hazard to the health and safety of people and the environment in normal or routine conditions as well as under all reasonably foreseeable abnormal events or conditions.

Note that unlike subsection 13(2), which gives the CEO the power to declare that a controlled facility is not a PRF (e.g. a portable neutron generator), subsection 43(2) gives the CEO the power to exempt a controlled person from the need to be licensed to undertake a particular conduct in relation to a controlled facility (e.g. decommission a linear accelerator).

4. Controlled material or controlled apparatus that produces ionising radiation (subsection 44(3))

Dealing with a controlled apparatus that can produce ionising radiation that is prescribed in section 44(1) is exempt. However, even if a controlled apparatus or controlled material is not listed in section 44(1), the CEO can, under subsection 44(3), exempt those controlled apparatus or controlled material provided the CEO is satisfied of certain matters prescribed in subsection 44(4) or (5) of the Regulations.

To seek an exemption under subsection 44(4) for a low-dose dealing, an applicant must make a written submission to the CEO and demonstrate that for the particular dealing for which an exemption is sought:

a) the annual effective dose to an individual during normal operations is not likely to exceed 10 μSv; or
b) an accident, misuse or exceptional circumstance affecting the dealing is not likely to produce a dose greater than the effective dose limits. That is, for occupational exposure - not greater than 20 mSv per year averaged over 5 consecutive calendar years and not more than 50 mSv in one year; and for the public not greater than 1 mSv annually.

The use of the word ‘or’ to separate subsection 44(4)(a) and (b) of the Regulations has led to some confusion as to which of these criteria must be satisfied in order for an exemption to be granted. The CEO has determined that the most restrictive of the two tests must be met. In most situations this will be subsection 44(4)(b) but in some cases it may be subsection 44(4)(a).

To seek an exemption in relation to a radiological emergency or its after-effects an applicant must make a written submission to the CEO under subsection 44(5) and include an assessment of the magnitude of individual doses, the number of people exposed and the likelihood that potential exposure will actually occur justifies the dealing being exempt.

To seek an exemption in relation to the after-effects of a previous dealing an applicant must make a written submission to the CEO under subsection 44(5) and include an assessment of the magnitude of individual doses, the number of people exposed and the likelihood that potential exposure will actually occur justifies the dealing being exempt.

To seek an exemption in relation to naturally occurring material or bulk material with a mass more than 1000kg an applicant must make a written submission to the CEO under subsection 44(5) and include an assessment of the magnitude of individual doses, the number of people exposed and the likelihood that potential exposure will actually occur justifies the dealing being exempt.

To avoid delays in assessment, applicants are advised to address both statutory tests in their submission. Any submission for an exemption under subsection 44(4)(a) should address the potential for exposure during maintenance or repair.

Other matters to be addressed include shielding, physical barriers, location, method of operation, frequency of use, etc.

In considering this statutory test in relation to controlled material, the physical and chemical form will be critical and all potential exposure pathways must be considered. Applicants should note that any exemption granted under subsection 44(4) or (5) is made on a case by case basis and relies on the continued presence of the factual circumstances in place at the time the declaration of exemption is made. Should circumstances change then the exemption from the requirement for a source licence may no longer apply.

5. Meaning of ‘case by case basis’

The phrase ‘case by case basis’ refers to specified controlled apparatus, controlled material or controlled facilities owned by or in the possession or control of a specified controlled person. That is, a declaration of exemption will not apply to a whole class of controlled apparatus, controlled material or controlled facilities. Any controlled person who wishes to seek an exemption must apply in writing to the CEO even if an exemption has been granted by the CEO to that controlled person or another controlled person in respect of the same or similar controlled apparatus, material or facility. This is because the CEO will, in applying the relevant statutory criteria, have regard to and take into account all the circumstances in relation to the possession or use of the controlled apparatus, material or facilities. Those circumstances may differ in each case.
6. Notice of intention to declare an exemption

If the CEO proposes to make a declaration of exemption under subsection 43(2) the CEO must publish his intention to do so in a daily national newspaper and on the ARPANSA website as soon as practicable. The notice must include:

(a) either:
   (i) a copy of the proposed declaration or
   (ii) a description of the controlled person, the kind of conduct and the controlled facility that are to be the subject of the declaration and any conditions.

7. Publish declaration of exemption

The CEO must publish a declaration under subsection 9(2), 13(2), 43(2) or 44(2) on ARPANSA’s website as soon as practicable after making it.

8. Revoke a declaration of exemption

The CEO may revoke a declaration made under subsection 9(2), 13(2), 43(2) or 44(2) if the circumstances under which the controlled material, apparatus or facility is owned, possessed or used has changed such that the controlled person can no longer satisfy the statutory tests on which the CEO’s earlier decision was made.

9. Exception to exemption

Under subsection 44(2) the CEO may declare in writing that a particular dealing described in the table in subsection 44(1) has a risk of excessive dose and is therefore not exempted under subsection 44(1). This decision may be taken when:

(a) the annual effective dose to an individual during normal operations is likely to be greater than 10 mSv; or
(b) an accident, misuse or exceptional circumstances affecting the dealing is likely to produce a dose greater than the effective dose limit worked out under sections 77 and 78 of the Regulations.

10. Reviewable decision

A decision to refuse to make a declaration under subsection 9(2), 13(2), 43(2) or 44(2) is reviewable under section 86 of the Regulations.