

Australian Radiation Protection and Nuclear Safety Amendment (2022 Measures No. 1) Regulations 2022

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated

5 August 2022

David Hurley Governor-General

By His Excellency's Command

Ged Kearney

Assistant Minister for Health and Aged Care

Parliamentary Secretary to the Minister for Health and Aged Care



Contents	S		
	1	Name	1
	2	Commencement	1
	3	Authority	1
	4	Schedules	1
Schedule 1—Amendments			2
Ausi	tralian I	Radiation Protection and Nuclear Safety Regulations 2018	2



1 Name

This instrument is the Australian Radiation Protection and Nuclear Safety Amendment (2022 Measures No. 1) Regulations 2022.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information			
Column 1	Column 2	Column 3	
Provisions	Commencement	Date/Details	
1. The whole of this instrument	The day after this instrument is registered.	10 August 2022	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *Australian Radiation Protection and Nuclear Safety Act 1998*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Australian Radiation Protection and Nuclear Safety Regulations 2018

1 Section 4

Insert:

AS/NZS IEC 62471:2011 means the Australian/New Zealand Standard AS/NZS IEC 62471:2011 *Photobiological safety of lamps and lamp systems*, published jointly by, or on behalf of, Standards Australia and Standards New Zealand, as existing on 8 December 2018.

2 Section 4 (table item 26 in the definition of Group 1)

Repeal the item, substitute:

- Controlled apparatus that produces ionizing radiation and is not mentioned in another item of this table or in the definition of *Group 2* or *Group 3*, dealings with which do not have the potential for accidental exposure likely to exceed the dose limits mentioned in sections 77 and 79
- 27 Controlled apparatus that produces non-ionizing radiation and is not mentioned in another item of this table

3 Section 4

Insert:

GSR Part 3 means Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards—IAEA Safety Standards Series No. GSR Part 3, published by the International Atomic Energy Agency, as existing on 1 March 2022.

Note:

GSR Part 3 could in 2022 be viewed on the International Atomic Energy Agency's website (https://www.iaea.org).

incident means:

- (a) any unintended event, including an operating error, equipment failure, initiating event, accident precursor, near miss or other mishap; or
- (b) any unauthorised act, whether or not malicious;

the consequences or potential consequences of which are not negligible.

4 Section 4 (paragraph (d) of the definition of *non-ionizing radiation* exposure limits)

Omit "the Australian/New Zealand Standard AS/NZS IEC 62471:2011 *Photobiological safety of lamp and lamp systems*, published jointly by, or on behalf of, Standards Australia and Standards New Zealand, as existing on 8 December 2018", substitute "AS/NZS IEC 62471:2011".

5 Section 4

Insert:

notifiable incident means any of the following:

- (a) an incident that exposes a person to a dose of ionizing radiation that exceeds an effective dose limit mentioned in section 77 or an equivalent dose limit mentioned in section 79;
- (b) an incident involving a diagnostic or interventional medical procedure resulting in an observable acute radiation effect;
- (c) an incident involving exposure to non-ionizing radiation from controlled apparatus that:
 - (i) exceeds the non-ionizing radiation exposure limits; or
 - (ii) results in noticeable eye or skin damage;
- (d) a theft or loss of controlled material or controlled apparatus, other than controlled material or controlled apparatus in Group 1;
- (e) an incident involving the release of controlled material if the result of the activity value division steps for the controlled material is greater than 10⁴;
- (f) an incident involving transport of a package of controlled material if:
 - (i) the result of the activity value division steps for the controlled material is greater than 10⁴; and
 - (ii) the package is damaged in such a way that safety provisions are degraded.

solid clearance material: see subsection 65(7).

solid clearance value: see subsection 65(8).

6 At the end of section 5

Add.

(3) Subsections (1) and (2) do not apply for the purposes of subsections 65(7) to (9).

Note: Subsections 65(7) to (9) deal with the activity concentration of progeny nuclides in relation to solid clearance material by reference to GSR Part 3.

7 Subsection 44(1) (paragraphs (a), (g) and (h) of table item 7, column headed "Description of dealing")

Repeal the paragraphs.

8 Subsection 44(1) (paragraph (i) of table item 7, column headed "Description of dealing")

Omit "communications", substitute "detection and ranging".

9 Subsection 44(1) (at the end of the cell at table item 7, column headed "Description of dealing")

Add:

- ; (q) a range finder with power less than 5 milliwatts;
- (r) an optical light source that:
 - (i) emits infra-red or visible light at a level not exceeding the exposure limits mentioned in AS/NZS IEC 62471:2011; and
 - (ii) is not a laser product

10 Subsection 44(1) (at the end of the table)

Add:

- 10 The dealing is with a gaseous tritium light device that:
 - (a) is used solely for safety purposes; and
 - (b) includes not greater than 74 GBq of tritium;

and no other controlled apparatus or controlled material

- 11 The dealing is with an electron capture detector or similar device used in gas chromatography containing:
 - (a) a nickel-63 sealed source with activity not greater than 750 MBq; or
 - (b) a tritium source with activity not greater than 20 GBq;

and no other controlled apparatus or controlled material

12 The dealing is with lighting products that include krypton-85 and no other controlled apparatus or controlled material

11 Subsection 44(2) (heading)

Omit "excessive", substitute "non-trivial".

12 Paragraph 44(2)(a)

Repeal the paragraph, substitute:

(a) under reasonably foreseeable circumstances, the effective dose to an individual is likely to be greater than 10 microsieverts in a year; or

13 Paragraph 44(2)(b)

Omit "a dose greater than the effective dose limit worked out under sections 77 and 78", substitute "an effective dose to an individual greater than 1 mSv in a year".

14 Paragraph 44(4)(a)

Repeal the paragraph, substitute:

(a) under reasonably foreseeable circumstances, the effective dose to an individual is likely to be not greater than 10 microsieverts in a year; or

15 Paragraph 44(4)(b)

Omit "a dose greater than the effective dose limit worked out under sections 77 and 78", substitute "an effective dose to an individual greater than 1 mSv in a year".

16 Section 49 (table item 1, column headed "Fee (\$)")

Omit "10,098", substitute "10,299".

17 Section 49 (table item 2, column headed "Fee (\$)")

Omit "11,220", substitute "11,444".

18 Section 49 (table item 3, column headed "Fee (\$)")

Omit "795", substitute "810".

19 Section 49 (table item 4, column headed "Fee (\$)")

Omit "2,346", substitute "2,392".

20 Section 49 (table item 5, column headed "Fee (\$)")

Omit "8,772", substitute "8,947".

⁴ Australian Radiation Protection and Nuclear Safety Amendment (2022 Measures No. 1) Regulations 2022

21 Paragraph 50(2)(a)

Repeal the paragraph, substitute:

(a) \$171 for each hour, or part of an hour, spent in assessing the application, less \$10,299; and

22 After paragraph 53(e)

Insert:

(ea) whether the applicant has shown that the applicant has considered interactions between technical, human and organisational factors in the management of safety;

23 After paragraph 54(e)

Insert:

(ea) whether the applicant has shown that the applicant has considered interactions between technical, human and organisational factors in the management of safety;

24 After section 57

Insert:

57A Preventing and minimising human error and organisational failures

- (1) The holder of a licence must take all reasonably practicable steps to prevent and minimise human errors and organisational failures involving controlled materials, controlled apparatus or controlled facilities described in the licence.
- (2) In doing so, the holder must take into account human and organisational factors.

25 Section 58 (heading)

Omit "accidents", substitute "incidents".

26 Subsection 58(1) (heading)

Omit "accidents", substitute "incidents".

27 Subsection 58(1)

Omit "prevent accidents", substitute "prevent incidents".

28 Subsection 58(2) (heading)

Omit "an accident", substitute "a notifiable incident".

29 Subsection 58(2)

Omit "If an accident", substitute "If a notifiable incident".

30 Paragraphs 58(3)(a) and (b)

Omit "accident", substitute "notifiable incident".

31 At the end of subsection 58(3)

Add:

; and (c) to manage the notifiable incident in a way that facilitates investigation and learning.

32 Paragraph 58(4)(a)

Omit "accident" (wherever occurring), substitute "notifiable incident".

33 Paragraph 58(4)(b)

Repeal the paragraph, substitute:

- (b) give the CEO a written report about the notifiable incident, including the causes of the notifiable incident, within:
 - (i) 14 days of the notifiable incident happening; or
 - (ii) if the CEO extends the period—the extended period; and

34 Subparagraphs 58(4)(c)(i) and (d)(i)

Omit "accident", substitute "notifiable incident".

35 Subsection 58(5)

Omit "accident" (wherever occurring), substitute "notifiable incident".

36 Subsection 58(6)

After "subparagraphs", insert "(4)(b)(i),".

37 At the end of section 58

Add:

(7) However, subsections (4) and (5) do not apply to the extent that the licence makes other arrangements for a matter mentioned in the subsections.

38 After paragraph 60(1)(a)

Insert:

(aa) ensuring that such plans and arrangements consider human and organisational factors to reduce human error and organisational failures; and

39 At the end of subsection 60(1)

Add.

; and (d) ensuring that such safety analysis reports consider human and organisational factors to reduce human error and organisational failures.

40 After paragraph 60(2)(a)

Insert:

(aa) ensuring that such plans and arrangements consider human and organisational factors to reduce human error and organisational failures; and

41 Section 61 (note)

Omit "an accident for the purposes of preventing a reoccurrence of the accident", substitute "a notifiable incident for the purposes of preventing a reoccurrence of the notifiable incident".

6

Australian Radiation Protection and Nuclear Safety Amendment (2022 Measures No. 1) Regulations 2022

42 Subsection 65(5)

Repeal the subsection, substitute:

Exceptions

- (5) Subsections (1), (2), (3) and (4) do not apply to the extent that the licence makes other arrangements for a matter mentioned in the subsections.
- (6) Subsections (1), (2) and (3) do not apply in relation to controlled material that is solid clearance material.

Solid clearance material

- (7) Controlled material is *solid clearance material* if:
 - (a) the material is in solid form; and
 - (b) the total of the results of dividing the activity concentration of each nuclide of artificial origin in the material by the solid clearance value for the nuclide is not greater than one; and
 - (c) the activity concentration of each nuclide of natural origin in the material is not greater than the level for the nuclide set out in in Table I.3 in Schedule I to GSR Part 3.
- (8) The *solid clearance value*, for a nuclide in controlled material, is:
 - (a) if the weight of the controlled material exceeds 1 tonne and Table I.2 in Schedule I to GSR Part 3 sets out an activity concentration level for the nuclide—that activity concentration level; or
 - (b) otherwise—the activity concentration level for the nuclide set out in Table I.1 in Schedule I to GSR Part 3.
- (9) For the purposes of dividing the activity concentration of a nuclide by the solid clearance value for the nuclide in accordance with paragraph (7)(b), the activity concentration of the nuclide is taken to be nil if:
 - (a) all of the following apply:
 - (i) the solid clearance value is an activity concentration level set out in Table I.2 in Schedule I to GSR Part 3:
 - (ii) the nuclide is a progeny nuclide mentioned in note a to that table;
 - (iii) the nuclide is included in secular equilibrium with the corresponding parent nuclide mentioned in that note; or
 - (b) all of the following apply:
 - (i) the solid clearance value is an activity concentration level set out in Table I.1 in Schedule I to GSR Part 3;
 - (ii) the nuclide is a progeny nuclide mentioned in note b to that table;
 - (iii) the nuclide is included in secular equilibrium with the corresponding parent nuclide mentioned in that note.

43 In the appropriate position in Part 8

Insert:

Division 4—Australian Radiation Protection and Nuclear Safety Amendment (2022 Measures No. 1) Regulations 2022

92 Definitions

In this Division:

amending instrument means the Australian Radiation Protection and Nuclear Safety Amendment (2022 Measures No. 1) Regulations 2022.

commencement time means the commencement of the amending instrument.

93 Exempt dealings with controlled material or controlled apparatus

- (1) A declaration that was in force under subsection 44(2) immediately before the commencement time has effect, after the commencement time, as if it had been made under subsection 44(2) as amended by the amending instrument.
- (2) A declaration that was in force under subsection 44(4) immediately before the commencement time has effect, after the commencement time, as if it had been made under subsection 44(4) as amended by the amending instrument.

94 Fees

- (1) The amendments of section 49 made by the amending instrument apply in relation to applications made after the commencement time.
- (2) Section 50, as amended by the amending instrument, applies in relation to applications made after the commencement time.
- (3) Despite the amendments of section 50 by the amending instrument, that section continues to apply, in relation to applications made before the commencement time, as if:
 - (a) those amendments had not been made; and
 - (b) the fee for each hour, or part of an hour, spent after the commencement time in assessing the application were \$171.

95 Licence applications

The amendments of sections 53 and 54 made by the amending instrument apply in relation to applications for licences made after the commencement time.

96 Licence conditions

Preventing and minimising human error and organisational failures

(1) Section 57A, as inserted by the amending instrument, applies in relation to licences issued before, at or after the commencement time.

Preventing, controlling and minimising incidents

- (2) The amendments of section 58 made by the amending instrument apply in relation to:
 - (a) licences issued before, at or after the commencement time; and

(b) incidents and notifiable incidents that happen after the commencement time.

Managing safety

- (3) Paragraphs 60(1)(aa) and (d) and (2)(aa), as inserted by the amending instrument, apply in relation to licences granted after the commencement time.
- (4) In relation to licences granted before the commencement time, those paragraphs apply from the first time after the commencement time that the holder of the licence is required under section 61 to review and update the plans and arrangements, and safety analysis reports, mentioned in section 60 in relation to the licence.

Review and disposal requirements

(5) The amendments of section 65 made by the amending instrument apply in relation to licences issued before, at or after the commencement time.