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No. S 517

RADIATION PROTECTION ACT (CHAPTER 262)

RADIATION PROTECTION (NON-IONISING RADIATION) (AMENDMENT) REGULATIONS 2019

In exercise of the powers conferred by section 43(1) of the Radiation Protection Act, the National Environment Agency, with the approval of the Minister for the Environment and Water Resources, makes the following Regulations:

Citation and commencement

1. These Regulations are the Radiation Protection (Non-Ionising Radiation) (Amendment) Regulations 2019 and come into operation on 1 August 2019.

- **2.** Regulation 2 of the Radiation Protection (Non-Ionising Radiation) Regulations (Rg 1) (called in these Regulations the principal Regulations) is amended
 - (a) by inserting, immediately after the definition of "AEL", the following definitions:
 - ""ANSI Z136.1 2007" means the American National Standards Institute (ANSI) Z136.1 – 2007 American National Standard for Safe Use of Laser;
 - "ANSI Z136.1 2014" means the American National Standards Institute (ANSI) Z136.1 – 2014 American National Standard for Safe Use of Laser;";

- (b) by deleting the words "Chief Executive" in the definition of "approved" and substituting the word "Director-General";
- (c) by inserting, immediately after the definition of "cavity", the following definition:

""clinical laboratory" —

- (a) means any premises used or intended to be used for any type of examination of the human body or of any matter derived from the human body
 - (i) for the purpose of providing information for the diagnosis, prevention or treatment of any disease;
 - (ii) for the assessment of the health of any person; or
 - (iii) for ascertaining the cause of death or the result of any medical or surgical treatment given to any person; but
- (b) does not include any such premises that are maintained by a registered medical practitioner or registered dentist as part of his medical clinic for the exclusive use of his practice;";
- (d) by inserting, immediately after the definition of "eye examination", the following definitions:

""healthcare establishment" —

- (a) means any premises or conveyance that
 - (i) is used or intended to be used for the provision of any service, or for carrying out any practice

- or procedure, that is related to the diagnosis, treatment or care of persons suffering from any disease, injury or disability; and
- (ii) is declared under paragraph (b) of the definition of "healthcare establishment" in section 2 of the Private Hospitals and Medical Clinics Act (Cap. 248) to be a healthcare establishment for the purposes of that Act; but
- (b) does not include the whole or a part of a private hospital, medical clinic or clinical laboratory;
- "healthcare institution" means any clinical laboratory, healthcare establishment, medical clinic or private hospital that is licensed under the Private Hospitals and Medical Clinics Act;
- "IEC 60825-1:2007" means the International Electrotechnical Commission International Standard IEC 60825-1:2007 Safety of laser products Part I: Equipment classification and requirements;
- "IEC 60825-1:2014" means the International Electrotechnical Commission International Standard IEC 60825-1:2014 Safety of laser products Part I: Equipment classification and requirements;";
- (e) by inserting, immediately after the definition of "licensee", the following definition:
 - ""maternity home" means any premises used or intended to be used for the reception of pregnant women or of women immediately after childbirth;";

- (f) by inserting, immediately after the definition of "maximum timer interval", the following definition:
 - ""medical clinic" means any premises used or intended to be used by a registered medical practitioner, a registered dentist or any other person
 - (a) for the diagnosis or treatment of persons suffering from, or believed to be suffering from, any disease, injury or disability of mind or body; or
 - (b) for curing or alleviating any abnormal condition of the human body by the application of any apparatus, equipment, instrument or device requiring the use of electricity, heat or light;";
- (g) by inserting, immediately after the word "surgical" in the definition of "medical laser", the word ", cosmetic";
- (h) by inserting, immediately after the definition of "minimum interval between consecutive exposures", the following definitions:
 - ""N1 licence" means a licence to manufacture or deal with any of the irradiating apparatus specified in Parts I, II and III of the First Schedule;
 - "N2 licence" means a licence to keep, or possess, for use any of the irradiating apparatus specified in Parts II and III of the First Schedule;
 - "N3 licence" means a licence to use any of the irradiating apparatus specified in Part III of the First Schedule;

- "N4A licence" means a licence to import any of the irradiating apparatus specified in Parts I, II and III of the First Schedule;
- "N4B licence" means a licence to export any of the irradiating apparatus specified in Parts II and III of the First Schedule;";
- (i) by inserting, immediately after the definition of "non-ionising radiation", the following definition:
 - ""nursing home" means any premises other than a maternity home used or intended to be used for the reception of, and the provision of nursing for, persons suffering or convalescing from any sickness, injury or infirmity;";
- (*j*) by inserting, immediately after the definition of "primary radiation", the following definition:
 - ""private hospital" means any premises used or intended to be used for the reception, lodging and treatment and care of persons who require medical treatment or suffer from any disease, and includes a maternity home and a nursing home;";
- (k) by inserting, immediately after the definition of "radiation worker", the following definition:
 - ""registered dentist" means any person who is registered as a dentist under the Dental Registration Act (Cap. 76), and includes any person deemed to be a registered dentist under section 64(1) of that Act;"; and
- (*l*) by renumbering the regulation as paragraph (1) of that regulation, and by inserting immediately thereafter the following paragraph:
 - "(2) In these Regulations, unless the context otherwise requires, any reference to a numbered Class is a reference to a Class, bearing the

corresponding number, of lasers classified in accordance with the classification set out in the Second Schedule, and includes a reference to an equivalent class of lasers classified in accordance with IEC 60825-1:2007, IEC 60825-1:2014, ANSI Z136.1 – 2007 or ANSI Z136.1 – 2014."

New regulation 2A

3. The principal Regulations are amended by inserting, immediately after regulation 2, the following regulation:

"Laser classification standards

- **2A.** For the purposes of these Regulations
 - (a) the laser classification standards specified in the Seventh Schedule take precedence in the order in which those standards appear in that Schedule; and
 - (b) where a laser has in fact been classified in accordance with 2 or more of those standards, the laser is to be treated as classified in accordance with the standard that takes precedence."

Amendment of regulation 4

- **4.** Regulation 4 of the principal Regulations is amended
 - (a) by deleting the words "Chief Executive" in paragraph (1) and substituting the word "Director-General"; and
 - (b) by deleting paragraph (2) (including the Table) and substituting the following paragraph:
 - "(2) Every application to alter the list of irradiating apparatus in respect of which an N2 licence is granted must be made to the Director-General in such form as the Director-General may require."

Deletion and substitution of regulations 5, 6 and 7

5. Regulations 5, 6 and 7 of the principal Regulations are deleted and the following regulations substituted therefor:

"Fee for licences

- **5.**—(1) The fees specified in the Sixth Schedule are payable in respect of the matters set out in that Schedule.
- (2) The fee for an application for the grant or renewal of a licence must be paid when the application is submitted to the Director-General.
- (3) The fee for an application to alter the list of irradiating apparatus in respect of which an N2 licence is granted must be paid when the application is submitted to the Director-General.
- (4) The annual fee for an N2 licence must be paid on or before each anniversary of
 - (a) the date on which the N2 licence was granted; or
 - (b) such other date as the Director-General may specify in a particular case.
- (5) The Director-General may, in any particular case or class of cases, waive the whole or any part of any fee payable under paragraph (1).

Certain fees cannot be refunded

- **6.** Any fee (specified in the Sixth Schedule) that is payable in respect of a matter
 - (a) cannot be refunded; and
 - (b) cannot be used to offset any fee (specified in that Schedule) that is payable in respect of another matter.

Single N2 licence for all irradiating apparatus under charge of same licensee

7. A single N2 licence may be granted in respect of 2 or more irradiating apparatus under the charge of the same licensee.".

Amendment of regulation 8

- **6.** Regulation 8 of the principal Regulations is amended
 - (a) by deleting the words "a licence to use irradiating apparatus under application reference N3" and substituting the words "an N3 licence"; and
 - (b) by deleting the words "Chief Executive" and substituting the word "Director-General".

- 7. Regulation 9 of the principal Regulations is amended
 - (a) by deleting the words "A licence under application reference N1 to manufacture or deal with irradiating apparatus" in paragraph (1) and substituting the words "An N1 licence";
 - (b) by deleting the words "Chief Executive" wherever they appear in paragraphs (1), (2), (3) and (5) and substituting in each case the word "Director-General";
 - (c) by deleting the words "A licence under application reference N2 to keep or possess for use of irradiating apparatus" in paragraph (2) and substituting the words "An N2 licence":
 - (d) by deleting the words "a licence under application reference N3 for use of class 3b medical lasers" in paragraph (3) and substituting the words "an N3 licence for use of any medical laser that is a Class 3b laser";
 - (e) by deleting paragraph (4); and
 - (f) by deleting paragraph (6) and substituting the following paragraph:
 - "(6) A licence granted under section 7 of the Act for the use of irradiating apparatus —
 - (a) may be restricted to a specified apparatus or to apparatus of a specified kind; or

(b) may be restricted to a specified use (or type or nature of use) or to use at a specified place.".

- **8.** Regulation 10 of the principal Regulations is amended
 - (a) by deleting the words "Chief Executive" in paragraphs (1) and (2) and substituting in each case the word "Director-General";
 - (b) by inserting, immediately after paragraph (1), the following paragraph:
 - "(1A) The Director-General may, in the Director-General's discretion, cancel or suspend for such period as the Director-General thinks fit any N2 licence, if the licensee fails to pay the annual fee for that licence on or before the last day prescribed in regulation 5(4) for the payment of that fee.";
 - (c) by deleting the words "section 17" in paragraph (2) and substituting the words "section 33"; and
 - (d) by inserting, immediately after paragraph (2), the following paragraphs:
 - "(3) The Director-General may, for the purpose of granting a licensee a single N2 licence in place of every licence under application reference N2 that was granted to the licensee, cancel each such licence under application reference N2.
 - (4) Every licence under application reference N2 that is in force immediately before 1 August 2019 continues to be in force, and to have effect, until the earlier of
 - (a) the date of its expiry; or
 - (b) the date it is cancelled by the Director-General under paragraph (3).

(5) In this regulation, "licence under application reference N2" means a licence granted before 1 August 2019 to keep or possess for use one irradiating apparatus specified in Parts II and III of the First Schedule.".

Amendment of regulation 11

- 9. Regulation 11 of the principal Regulations is amended
 - (a) by deleting the words "Chief Executive" wherever they appear in paragraphs (1), (3), (4) and (7) and substituting in each case the word "Director-General":
 - (b) by deleting the words "Section 9" in paragraph (2) and substituting the words "Section 7";
 - (c) by deleting the words "section 17" in paragraph (7) and substituting the words "section 33"; and
 - (d) by inserting, immediately after paragraph (7), the following paragraph:
 - "(8) In this regulation, "licence" does not include an N2 licence.".

Deletion and substitution of regulation 14

10. Regulation 14 of the principal Regulations is deleted and the following regulation substituted therefor:

"Conditions for engaging in radiation work

- **14.**—(1) Subject to paragraphs (2) and (3), an individual must not engage in any radiation work with any laser unless the individual holds a licence authorising the individual to do so.
- (2) Despite paragraph (1), if a registered medical practitioner or registered dentist has obtained the consent of both of the following persons to use a medical laser at a healthcare institution, the registered medical practitioner or registered dentist does not require a licence to use that medical laser:
 - (a) the individual in charge of that healthcare institution;

- (b) the licensee of the N2 licence granted in respect of that medical laser.
- (3) An individual must not engage in any radiation work on a human body with any medical laser that is a Class 4 laser, unless the individual is a registered medical practitioner or registered dentist.
- (4) In this regulation, "individual in charge", in relation to a healthcare institution, means the chief executive of the healthcare institution or any individual holding an equivalent position in the healthcare institution, and includes any individual authorised to act in that capacity."

Deletion and substitution of regulation 16

11. Regulation 16 of the principal Regulations is deleted and the following regulation substituted therefor:

"Possession of apparatus

- **16.**—(1) Where any person has in that person's possession, custody or use the whole or any part of any irradiating apparatus, that person must not cause, permit or allow any individual, or any part of that individual's body, to receive radiation
 - (a) at a level greater than can be justified in the circumstances; or
 - (b) in any case, at a level in excess of any of the following exposure limits:
 - (i) the exposure limit specified in Table 3 of the Third Schedule;
 - (ii) the maximum permissible exposure values specified in IEC 60825-1:2014.
- (2) Where any person has in that person's possession, custody or use the whole or any part of any irradiating apparatus, that person must do all that is reasonably practicable to prevent harm or injury to any individual.".

Amendment of regulation 17

12. Regulation 17 of the principal Regulations is amended by deleting the words "therapeutic and surgical" and substituting the words "surgical, cosmetic or therapeutic".

Deletion and substitution of regulations 19 and 20 and new regulation 20A

13. Regulations 19 and 20 of the principal Regulations are deleted and the following regulations substituted therefor:

"Radiation accident investigation

- 19.—(1) Where any radiation worker of a licensee has reasonable cause to believe that an incident that is liable to result in any person receiving radiation at a level in excess of any of the exposure limits mentioned in paragraph (2) has taken place
 - (a) that radiation worker must immediately report the circumstances of that incident to the licensee; and
 - (b) the licensee must immediately make an investigation or arrange for an investigation to be made.
- (2) For the purposes of paragraph (1), the exposure limits are as follows:
 - (a) the exposure limit specified in Table 3 of the Third Schedule;
 - (b) the maximum permissible exposure values specified in IEC 60825-1:2014.

Reporting radiation accident to Director-General

- **20.** Where an investigation under regulation 19(1) confirms a report made under that provision, or a licensee has any other reason to believe that there is exposure in excess of any of the exposure limits mentioned in regulation 19(2), the licensee must
 - (a) immediately notify the Director-General;

- (b) suspend all work that may expose any radiation worker to radiation;
- (c) arrange for any radiation worker who may be exposed to radiation to undergo a medical examination, which may include an eye examination and any other examination required by the Director-General; and
- (d) keep a record of the medical condition of that radiation worker.

Reporting radiation-related accident to Director-General

- **20A.**—(1) When the Commissioner for Workplace Safety and Health is notified of a radiation-related accident, or a report of a radiation-related accident is submitted to the Commissioner for Workplace Safety and Health, under the Workplace Safety and Health (Incident Reporting) Regulations (Cap. 354A, Rg 3)
 - (a) the licensee must immediately notify the Director-General of the radiation-related accident;
 and
 - (b) the licensee, or a radiation safety officer appointed by the licensee under regulation 40, must submit a written report to the Director-General within 10 days after the date of the radiation-related accident.
- (2) The written report mentioned in paragraph (1)(b) must contain details of
 - (a) the time, place and nature of the radiation-related accident;
 - (b) the number of individuals affected and the manner in which they were affected;
 - (c) the period during which there was loss of control of non-ionising radiation or of irradiating apparatus;
 - (d) the actions taken to address the radiation-related accident situation and to minimise the possibility of any future recurrence of such an accident; and

- (e) any individual who may have suffered radiation exposure, and an assessment of the exposure suffered by the individual.
- (3) In this regulation
 - "accident" has the meaning given by regulation 3 of the Workplace Safety and Health (Incident Reporting) Regulations;
 - "radiation-related accident" means any accident involving an irradiating apparatus.".

Deletion and substitution of regulation 33

14. Regulation 33 of the principal Regulations is deleted and the following regulation substituted therefor:

"Definition of entertainment laser

- **33.** In this Part, "entertainment laser" means
 - (a) any laser designed for use in a laser light show; or
 - (b) any laser facility or mobile laser system containing such a laser.".

- **15.** Regulation 34 of the principal Regulations is amended
 - (a) by deleting the words "limits of Class 1" in paragraphs (8) and (13) and substituting in each case the words "AEL for Class 1";
 - (b) by deleting the words "Class 1" in paragraph (9) and substituting the words "the AEL for Class 1";
 - (c) by deleting the words "limits of Class 2" wherever they appear in paragraphs (10) and (14) and substituting in each case the words "AEL for Class 2";
 - (d) by deleting the words "Chief Executive" in paragraphs (11) and (20) and substituting in each case the word "Director-General"; and

(e) by deleting the words "AEL for Class 1 laser" in paragraph (22) and substituting the words "AEL for Class 1".

Amendment of regulation 35

- **16.** Regulation 35 of the principal Regulations is amended by inserting, immediately after paragraph (3), the following paragraph:
 - "(4) An entertainment laser is to be treated as complying with this regulation if
 - (a) it is classified in accordance with any standard specified in the Seventh Schedule; and
 - (b) it complies with the requirements for the labelling of entertainment lasers in that standard that correspond to the requirements in this regulation.".

Amendment of regulation 36

17. Regulation 36 of the principal Regulations is amended by deleting the words "laser apparatus from Class 3b and Class 4 based on the classification set out in the Second Schedule" and substituting the words "Class 3b laser apparatus or Class 4 laser apparatus".

- **18.** Regulation 37 of the principal Regulations is amended
 - (a) by deleting the words "accessible emission limits of Class 1" in paragraphs (1), (5), (7), (10), (11), (12), (13) and (14)(b) and substituting in each case the words "AEL for Class 1";
 - (b) by deleting the words "accessible emission limits of collateral radiation" in paragraphs (1), (5), (10), (11), (13) and (14)(a) and (b) and substituting in each case the words "AEL for collateral radiation";
 - (c) by deleting the words "the limits of Class 1" wherever they appear in paragraphs (1) and (19) and substituting in each case the words "the AEL for Class 1";

- (d) by deleting the words "accessible emission limits" in paragraphs (2) and (25)(c) and substituting in each case the word "AEL";
- (e) by deleting the words "accessible emission limits of Class 1" in paragraph (14)(a) and substituting the words "the AEL for Class 1";
- (f) by deleting the words "accessible emission limit" in paragraph (15) and substituting the word "AEL";
- (g) by deleting the words "limits of collateral radiation" wherever they appear in paragraph (19) and substituting in each case the words "AEL for collateral radiation"; and
- (h) by inserting, immediately after paragraph (25), the following paragraph:
 - "(26) A high power laser or high power medical laser is to be treated as complying with all the relevant requirements in this regulation if
 - (a) it is classified in accordance with any standard specified in the Seventh Schedule; and
 - (b) it complies with the requirements for high power lasers or high power medical lasers (as the case may be) in that standard that correspond to the relevant requirements in this regulation.".

- **19.** Regulation 38 of the principal Regulations is amended by inserting, immediately after paragraph (11), the following paragraph:
 - "(12) A laser is to be treated as complying with all the relevant requirements in this regulation if
 - (a) it is classified in accordance with any standard specified in the Seventh Schedule; and

(b) it complies with the requirements for the labelling of lasers in that standard that correspond to the relevant requirements in this regulation.".

Amendment of First Schedule

20. The First Schedule to the principal Regulations is amended —

17

- (a) by deleting "4(2)" in the Schedule reference and substituting "10(5)";
- (b) by deleting "50 W" in Parts I and II and substituting in each case "1200 W"; and
- (c) by deleting Part III and substituting the following Part:

"PART III

- 1. Subject to paragraph 2, an irradiating apparatus is specified in this Part if
 - (a) the apparatus
 - (i) contains a Class 3b laser or Class 4 laser; or
 - (ii) is an entertainment laser containing a Class 3b laser or Class 4 laser:
 - (b) the apparatus produces radiation that could lead to a person being exposed to radiation at levels in excess of the maximum permissible exposure values specified in IEC 60825-1:2014; and
 - (c) persons may be exposed to levels of radiation mentioned in sub-paragraph (b)
 - (i) in the course of the intended operations or procedures of the apparatus;
 - (ii) during a reasonably foreseeable abnormal event involving the apparatus;
 - (iii) during a reasonably foreseeable single fault condition of the apparatus; or
 - (iv) when the protective barriers or access panels of the apparatus (being protective barriers or access panels that may be removed without the use of any specialised equipment) are removed.

2. The Director-General may declare, in any particular case, that an irradiating apparatus described in paragraph 1 is not an irradiating apparatus specified in this Part.".

Amendment of Second Schedule

21. The Second Schedule to the principal Regulations is amended by deleting the Schedule reference and substituting the following Schedule reference:

"Regulations 2(2), 35(1) and 37(1), (5), (10), (11), (13), (14) and (19)".

Amendment of Third Schedule

- **22.** The Third Schedule to the principal Regulations is amended
 - (a) by deleting the Schedule reference and substituting the following Schedule reference:

"Regulations 16(1), 19(2) and 22(1)"; and

(b) by deleting Tables 1 and 2 and the Notes to those Tables.

New Sixth and Seventh Schedules

23. The principal Regulations are amended by inserting, immediately after the Fifth Schedule, the following Schedules:

"SIXTH SCHEDULE

Regulations 5(1) and 6

FEES

 Application for or renewal of an N1 licence for —

(a) a period not exceeding 3 months(b) a period exceeding 3 months but\$105

not exceeding 6 months

(c) a period exceeding 6 months but s157.50 not exceeding 9 months

(d) a period exceeding 9 months but not exceeding 12 months \$210

(e) a period exceeding 12 months but not exceeding 24 months

2.	Application for an N2 licence	\$155 per irradiating apparatus in respect of which the licence is to be granted
3.	Application to alter the list of irradiating apparatus in respect of which an N2 licence is granted	\$155 per irradiating apparatus added to the list
4.	Annual fee for an N2 licence	\$65 per irradiating apparatus in respect of which the licence is granted
5.	Application for or renewal of an N3 licence for —	
	(a) a period not exceeding 3 months	\$26.25
	(b) a period exceeding 3 months but not exceeding 6 months	\$52.50
	(c) a period exceeding 6 months but not exceeding 9 months	\$78.75
	(d) a period exceeding 9 months but not exceeding 12 months	\$105
	(e) a period exceeding 12 months but not exceeding 24 months	\$210
6.	Application for or renewal of an N4A licence	\$40 per consignment of irradiating apparatus imported under the licence
7.	Application for or renewal of an N4B licence	\$40 per consignment of irradiating apparatus exported under the licence

SEVENTH SCHEDULE

Regulations 2A, 35(4), 37(26) and 38(12)

LIST OF STANDARDS

1. IEC 60825-1:2014

- 2. ANSI Z136.1 2014
- 3. IEC 60825-1:2007
- 4. ANSI Z136.1 2007".

Miscellaneous amendments

24.—(1) The principal Regulations are amended by deleting the words "Chief Executive" wherever they appear in the following provisions and substituting in each case the word "Director-General":

Regulations 12, 15, 28(5) and (7), 31(4), 40, 41 and 42.

- (2) The "ABBREVIATIONS EMPLOYED IN THESE REGULATIONS" to the principal Regulations is amended
 - (a) by deleting the word "Celcius" and substituting the word "Celsius":
 - (b) by deleting the word "meter" and substituting the word "metre";
 - (c) by deleting the word "centimeter" and substituting the word "centimetre";
 - (d) by deleting the word "millimeter" and substituting the word "millimetre":
 - (e) by deleting the word "micrometer" and substituting the word "micrometre"; and
 - (f) by deleting the word "nanometer" and substituting the word "nanometre".

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Made on 29 July 2019.

LEE CHUAN SENG
Chairman,
National Environment Agency,
Singapore.

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