

RADIATION PROTECTION ACT
([CHAPTER 262, SECTION 28](#))

RADIATION PROTECTION
(NON-IONISING RADIATION) REGULATIONS

Rg 1

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ABBREVIATIONS EMPLOYED IN THESE REGULATIONS

°C	:	degree Celcius
kg	:	kilogram
dB	:	Decibel
T	:	tesla
J	:	joule
μSv	:	microsievert
B ₀	:	static magnetic field strength
dB/dt	:	rate of change of magnetic field strength with time
r.m.s. volts	:	root mean square volts
sr	:	steradian
m	:	meter
cm	:	Centimeter
mm	:	millimeter
μm	:	micrometer
nm	:	nanometer
l	:	litre
ml	:	millilitre
s	:	second
μs	:	microsecond
Hz	:	hertz
kHz	:	kilohertz
MHz	:	megahertz
GHz	:	gigahertz

kW	:	kilowatt
W	:	watt
mW	:	milliwatt
μW	:	microwatt

PART I

PRELIMINARY

Citation

1. [These Regulations](#) may be cited as the Radiation Protection (Non-Ionising Radiation) Regulations.

Definitions

2. In these Regulations, unless the context otherwise requires —

“accessible location” means any point that can be reached by any part of the human body;

“AEL” means accessible emission limits;

“applicator” means the part of the ultrasound device designed to transmit ultrasonic power from the transducer to the patient or materials, and includes the transducer and any associated housing;

“approved” means approved in writing by the Chief Executive;

“beam” means a collection of rays that may be parallel, convergent or divergent;

“cavity” means that portion of the microwave oven in which food or other materials may be heated, cooked or dried;

“collateral radiation” means any electronic product radiation, except laser radiation, emitted by a laser apparatus as a result of the operation of the laser or any component of the laser apparatus that is physically necessary for the operation of the laser;

“continuous wave” —

(a) in relation to ultrasound, means a wave in which the ratio of the temporal maximum pressure amplitude to the root-mean-square pressure amplitude, each spatially averaged over the effective radiating surface, is less than or equal to 1.05; and

(b) in relation to a laser, means an emission of laser radiation for a period of 0.25 second or longer;

“deal” means any activity involving an irradiating apparatus other than use, possess for use and import or export;

“diameter” means the minimum diameter of a circular aperture that, when placed to intercept laser beam with the plane of the circular aperture perpendicular to the

direction of propagation of the beam, will permit 86.5% of the total beam power to be transmitted;

“divergence” means the full angle of spread of a laser beam;

“door”, in relation to microwave oven, means a movable barrier which prevents access to the cavity of the microwave oven during operation and whose function is to prevent emission of microwave energy from the passage or opening which provides access to the cavity;

“exit aperture” means an opening or window in the protective enclosure of a laser system that is designed to allow laser radiation to be transmitted outside;

“exposure position”, in relation to ultraviolet sunlamp, means any location, orientation, place or distance relative to the ultraviolet radiating surfaces of the sunlamp at which it is recommended by the manufacturer that the user of the sunlamp be exposed;

“external surface”, in relation to microwave oven means the outside surface of the cabinet or enclosure provided by the manufacturer as part of the microwave oven, including any door, door handle, latch and control knob;

“eye examination” means the following examinations performed by a registered medical practitioner:

- (a) visual acuity examination;
- (b) manifest refraction examination;
- (c) external ocular examination;
- (d) examination by slit lamp;
- (e) examination of the ocular fundus with an ophthalmoscope; and
- (f) any other necessary examination;

“individual” means any natural person;

“installation” means the area of radiation hazard under the administrative control of the person possessing the irradiating apparatus;

“integrated irradiance” means the radiant energy incident per unit area of surface expressed as J/m^2 ;

“irradiance” means radiant power incident per unit area expressed as W/m^2 ;

“irradiating apparatus” means any apparatus of a type specified in [the First Schedule](#);

“laser” means any device that can be made to produce light primarily by the process of stimulated emission;

“laser radiation” means all electromagnetic radiation generated by a laser that is coherent and propagates collinearly through space;

“lasing medium” means a material that emits laser radiation by virtue of stimulated

- transitions between specific electronic or molecular energy levels;
- “leakage radiation” means all radiation other than the useful beam;
- “licensee” means a person who holds a licence under the [Act](#);
- “maximum exposure time”, in relation to the ultraviolet sunlamp, means the longest time interval for continuous exposure recommended by the manufacturer of a sunlamp;
- “maximum timer interval”, in relation to ultraviolet sunlamp, means the longest time interval setting on the timer of a sunlamp;
- “medical laser” means any laser product manufactured, designed, intended or promoted for purposes of in vivo diagnostic, surgical or therapeutic laser irradiation of any part of the human body;
- “minimum interval between consecutive exposures”, in relation to sunlamp, means the shortest time interval between 2 consecutive exposures recommended by the manufacturer of a sunlamp;
- “non-ionising radiation” means electromagnetic radiations and fields with wavelengths greater than 100 nm or acoustic radiations and fields with frequencies below 16 Hz and above 16 kHz;
- “person”, includes any company or association or body of persons, corporate or unincorporate;
- “primary radiation” means radiation coming directly from any irradiating apparatus;
- “protective enclosure” means a structure that encloses a laser and its accessory components and restricts the emission of laser radiation to one or more than one exit aperture;
- “protective eyewear” means any device designed to be worn by the user to reduce, directly or indirectly, the radiation reaching the eyes;
- “protective housing” means a structure that encloses the components of a laser system and prevents the emission of laser radiation except through an exit aperture;
- “pulse” means an intermittent emission of laser radiation for a duration of less than 0.25 second;
- “pulse duration” means the time interval measured between the half-peak power points on the leading and trailing edges of a pulse;
- “radiation” means non-ionising radiation for the purpose of these Regulations;
- “radiation hazard” means the danger to the health of an individual arising from exposure to radiation emitted from an irradiating apparatus;
- “radiation level” means the corresponding radiation power density expressed in W/m^2 ;
- “radiation work” means work which involves the use, handling or operation of any irradiating apparatus specified in [Parts II](#) and [III](#) of [the First Schedule](#);

- “radiation worker” means any individual who is engaged in or is employed for part or whole of his working time to do radiation work;
- “SAR” means specific absorbed rate;
- “safety interlock” —
- (a) in relation to a microwave oven, means a device or system of devices which is intended to prevent generation of radiation when access to the cavity is possible;
 - (b) in relation to a laser, means a device associated with the protective housing of a laser apparatus to prevent human access to excessive laser radiation;
- “scanned laser radiation” means laser radiation having a time varying direction, origin or pattern of propagation with respect to a stationary frame of reference;
- “scattered radiation” means radiation which, during its passage through a substance, has been deviated in direction or has been modified by an increase in wave length;
- “service” means any adjustment, procedure or servicing method prescribed by the manufacturer of an irradiating apparatus;
- “service controls” means any control provided by the manufacturer for the purpose of adjustment of an irradiating apparatus and that, under normal conditions of use, is not accessible to the user of the apparatus;
- “shutter” means a mechanism that, in its closed position, intercepts the radiation beam and prevents the emission of radiation from the irradiating apparatus;
- “spectral irradiance” means the irradiance resulting from radiation within an infinitesimally small wavelength range expressed as $W/m^2/nm$;
- “spectral transmittance” means the spectral irradiance transmitted through protective eyewear divided by the spectral irradiance incident on the protective eyewear;
- “timer” means any device that is incorporated into an irradiating apparatus and is capable of terminating the emission of radiation from the apparatus at the end of a preset time interval;
- “user controls” means a control provided by the manufacturer for the purpose of operation of an irradiating apparatus that, under normal conditions of use, is accessible to the user of the apparatus.

PART II

CONTROLLED NON-IONISING RADIATION APPARATUS

Controlled apparatus

3. The [Act](#) and these Regulations shall apply to the following irradiating apparatus:

- (a) ultraviolet sunlamps;

- (b) microwave ovens;
- (c) medical and industrial ultrasound apparatus;
- (d) magnetic resonance imaging (MRI) apparatus;
- (e) entertainment lasers; and
- (f) high power lasers.

PART III

LICENCES

Application for licences

4.—(1) Every application for a licence or for renewal thereof shall be made to the Chief Executive in such form as he may require.

(2) Except as provided in [regulation 5](#), the following fees shall be payable for every issue or renewal of a licence:

<i>Application Reference</i>	<i>Type</i>	<i>Fee</i>
N1	licence to manufacture or deal with any of the irradiating apparatus specified in Parts I, II and III of the First Schedule	\$210 per annum
N2	licence to keep or possess for use any of the irradiating apparatus specified in Parts II and III of the First Schedule	\$155 per annum
N3	licence to use any of the irradiating apparatus specified in Part III of the First Schedule	\$105 per annum
N4	licence to import any of the irradiating apparatus specified in Parts I, II and III of the First Schedule and to export any irradiating apparatus specified in Parts II and III of the First Schedule	\$40 per consignment.

Fee for licences

5. The fee for any of the licences under application references N1, N2 and N3 issued for a period not exceeding 3 calendar months, 6 calendar months, 9 calendar months, 12 calendar months or 24 calendar months shall be one-quarter, one-half, three-quarters, once or twice, respectively, of the amount specified in [regulation 4\(2\)](#).

Non-refundable fee

6. Any fee paid for an application for the issue or renewal of any licence under these Regulations shall not be refundable.

Separate licence required for each apparatus

7. For the purpose of a licence to keep or possess for use of irradiating apparatus under application reference N2, a separate licence will be required for each irradiating apparatus.

Medical examination

8. Every individual applying for a licence to use irradiating apparatus under application reference N3 shall, within 12 months prior to his application, undergo a medical examination, which shall include eye examination and any other examination as may be required by the Chief Executive, and shall be certified fit to be engaged in radiation work by an approved registered medical practitioner.

Conditions for licences

9.—(1) A licence under application reference N1 to manufacture or deal with irradiating apparatus may be granted only to persons who are equipped with test equipment, workshop facilities, and any other requirements as may be required by the Chief Executive for performing the service and repair function on the type of irradiating apparatus that they are dealing with.

(2) A licence under application reference N2 to keep or possess for use of irradiating apparatus may be granted only to persons who, in the opinion of the Chief Executive, will be able to ensure the safe use of the apparatus.

(3) Subject to [regulation 15](#), a licence under application reference N3 for use of class 3b medical lasers may be granted only to individuals whom the Chief Executive thinks fit.

(4) Subject to [regulation 15](#), a licence under application reference N3 for use of class 4 medical lasers may be granted only to registered medical practitioners and registered dentists.

(5) Any licence may be granted subject to such conditions, in addition to any condition that may be prescribed in respect of licences generally, as the Chief Executive sees fit to impose and the conditions so imposed by the Chief Executive may at any time be varied, added to or revoked by the Chief Executive.

(6) Without prejudice to the generality of the powers conferred by [paragraph \(4\)](#), a licence granted under [section 8 of the Act](#) for the use of irradiating apparatus may be restricted to a specified apparatus or to apparatus of a specified kind, or may be restricted to specified use or type or nature or may be restricted to its use at a specified place.

(7) No person shall use any irradiating apparatus for any purpose other than that specified in his licence in respect of that apparatus.

Cancellation or suspension of licences

10.—(1) The Chief Executive may, in his discretion, cancel or suspend for such period as he thinks fit any licence if the licensee —

- (a) has obtained the licence by means of a fraudulent or incorrect statement;
- (b) commits an offence under the [Act](#);

- (c) commits a breach of or fails to comply with or observe any of the conditions of the licence;
- (d) is unable to act owing to illness or otherwise; or
- (e) has for any reason ceased to be entitled to hold the licence.

(2) Subject to [section 17 of the Act](#), every decision of the Chief Executive under this regulation shall be final.

Renewal of licences

11.—(1) On application being made to the Chief Executive in the prescribed manner, the Chief Executive may grant to the applicant a renewal of any licence held by the applicant or may, if the Chief Executive thinks fit, refuse to grant a renewal of the licence.

(2) [Section 9 of the Act](#) and [regulation 9](#) shall apply to every application for the renewal of a licence as if it were an application for a new licence.

(3) In granting any renewal of a licence, the Chief Executive may endorse the existing licence or he may issue a new licence in lieu thereof, but every such new licence shall show on the face thereof that it is a renewal of the licence.

(4) Every application for the renewal of a licence shall be made not later than one month before the date of expiry of the current licence or within such further time as the Chief Executive may allow in any particular case.

(5) The renewal of a licence may be granted in advance and shall, unless previously cancelled, take effect from the expiry date of the licence.

(6) Where application for renewal of a licence is made under this regulation, the licence shall, where the application is not disposed of before the date of expiry of the licence, continue in force until the application is disposed of.

(7) Subject to [section 17 of the Act](#), every decision of the Chief Executive on an application for renewal of a licence under this regulation shall be final.

Notification on change of address

12. Every licensee who at any time changes the address of his authorised premises as appearing in the register of licences shall, within 2 weeks of the change of address, send to the Chief Executive a notice of his new address and the Chief Executive shall thereupon amend the entry in the register relating to that licensee accordingly.

PART IV

GENERAL REQUIREMENTS

Age requirement

13. No individual below the age of 18 years shall be engaged in radiation work.

Conditions for engaging in radiation work

14. No individual shall be engaged in any radiation work with any laser unless he holds a licence authorising him to do so.

Control of use of apparatus

15. No individual shall be granted a licence to do radiation work with a laser unless he, in the opinion of the Chief Executive, has been adequately trained and has special knowledge in the safe use of laser.

PART V

CONTROL OF RADIATION EXPOSURE

Possession of apparatus

16. No person who has in his possession or custody or use any irradiating apparatus shall cause, permit, or suffer any individual, or any part of his body, to receive a radiation level greater than can be justified in the circumstances and in no case, in excess of the appropriate level specified in [the Third Schedule](#).

Use of radiation for medical procedure

17. [Regulation 16](#) shall not be construed so as to limit the intensity of the radiation which may be intentionally applied to an individual as a necessary part of any diagnostic, therapeutic and surgical procedure.

Protection for public

18. Every licensee shall do all that is reasonably practicable to restrict the extent to which the members of the public or other workers under his supervision are exposed to the radiation.

Radiation accident investigation

19. Where any radiation worker has reasonable cause to believe that an occurrence which is liable to result in any person receiving a radiation level in excess of any of the exposure limits specified in [the Third Schedule](#) has taken place, he shall report the circumstances to the licensee who shall forthwith make an investigation or arrange for an investigation to be made.

Reporting radiation accident to Chief Executive

20. Where an investigation made under [regulation 19](#) confirms that there is exposure in excess of the limits permitted under [the Third Schedule](#), the licensee shall —

- (a) forthwith notify the Chief Executive;
- (b) suspend the radiation worker from work in which he will be exposed to radiation;
- (c) arrange for medical examination of such radiation worker which may include eye examination and any other examination as may be required by the Chief Executive;

and

- (d) keep a record of the circumstances in respect of that radiation worker.

PART VI

SUNLAMPS

Definition of sunlamp

21. Sunlamp means ultraviolet lamp or apparatus incorporating one or more ultraviolet lamps intended for irradiation of any part of the living human body, by ultraviolet radiation with wavelengths in the air between 180 nm to 400 nm, to induce skin tanning or other cosmetic effects.

Requirements for sunlamps

22.—(1) Every sunlamp shall be designed and constructed in such a manner that, under the conditions of use specified by the manufacturer —

- (a) the sunlamp functions in accordance with [paragraphs \(10\), \(11\) and \(12\)](#) for as long as the sunlamp has its original components or replacement components recommended by the manufacturer; and
- (b) no individual who uses the sunlamp will be exposed to ultraviolet radiation in excess of the exposure limits specified in Table 3 in [the Third Schedule](#).

(2) Every sunlamp shall be designed and constructed in such a manner that —

- (a) all marks, labels and signs in accordance with [regulation 23](#) are permanently affixed to and clearly visible on the external surface when the sunlamp is assembled for use; and
- (b) all controls, meters, lights or other indicators are readily discernible and clearly labelled to indicate their function.

(3) Every sunlamp shall be designed and constructed to include the following safety features:

- (a) a control by which the sunlamp may be easily turned off by the person being exposed at any time without disconnecting the electrical plug or removing the ultraviolet lamp or lamps; and
- (b) a timer that satisfies [paragraph \(11\)](#).

(4) Every ultraviolet lamp intended for use in a sunlamp shall be designed and constructed in such a manner that it can only be inserted and operated in a sunlamp apparatus.

(5) Every sunlamp shall be designed and constructed in such a manner that failure or malfunction of any component of the sunlamp does not result in the sunlamp not complying with [paragraphs \(10\), \(11\) and \(12\)](#).

(6) Every sunlamp shall be accompanied by sufficient sets of protective eyewear that meet

the requirements of [paragraph \(12\)](#) to at least equal the maximum number of persons who may, at the same time, be exposed to ultraviolet radiation from the sunlamp, as recommended by the manufacturer of the sunlamp.

(7) Every ultraviolet lamp intended for use in a sunlamp or any packing uniquely associated with an ultraviolet lamp shall have a label that contains —

- (a) the words “DANGER — Ultraviolet radiation. Follow instructions. Use only in fixture equipped with a timer”; and
- (b) the model designation.

(8) [Paragraph \(7\)](#) shall not apply to an ultraviolet lamp that is designed and manufactured for use in a sunlamp that is maintained and serviced by the same manufacturer.

(9) Every sunlamp shall be equipped with —

- (a) instructions for the operation and safe use of the sunlamp that include a statement stating the maximum number of persons who may, at the same time, be exposed to ultraviolet radiation from the sunlamp, as recommended by the manufacturer of the sunlamp;
- (b) instructions for obtaining repairs and recommended replacement components and accessories that are compatible with the sunlamp, including protective eyewear, ultraviolet lamps, timers, reflectors and filters, in order that, if installed or used as directed the sunlamp continues to comply with the provisions of this Part; and
- (c) a warning that the instructions accompanying the sunlamp shall always be followed to avoid or minimise potential injury.

(10) Every ultraviolet lamp intended for use in a sunlamp shall function in such a manner that, at any distance in any direction from the sunlamp, the irradiance within the wavelength range from 200 nm to not more than 260 nm does not exceed 0.3% of the irradiance within the wavelength range from 260 nm to not more than 320 nm.

(11) The timer required by [paragraph \(3\)\(b\)](#) shall be designed so as to —

- (a) be adjustable to preset times and have maximum timer interval not exceeding the maximum exposure time;
- (b) have an error not greater than 10% of the maximum timer interval of the sunlamp;
- (c) not automatically reset and therefore cause radiation emission to resume when the sunlamp emissions have been terminated by the timer; and
- (d) not preclude a user of a sunlamp from resetting the timer before the end of the preset timer interval.

(12) The protective eyewear required by [paragraph \(6\)](#) shall have a spectral transmittance not exceeding a value of 0.1% over the wavelength range from 200 nm to not more than 320 nm and a value of 1% over the wavelength range from 320 nm to not more than 400 nm and shall be sufficient over wavelengths greater than 400 nm to enable the user to see clearly enough to read the labels and reset the timer.

Requirements for labelling of sunlamps

23.—(1) Each sunlamp shall have, on its external surface, the following information and instructions:

- (a) the name and address of the manufacturer and the distributor;
- (b) the model designation, the serial number and the month and year of manufacture;
- (c) the recommended exposure positions and the directions for determining the recommended exposure positions;
- (d) a warning that the use of exposure positions other than the recommended exposure positions may result in overexposure;
- (e) the maximum exposure time in minutes;
- (f) the minimum interval between consecutive exposures; and
- (g) the type and model designation of each ultraviolet lamp intended to be used in the sunlamp unless the sunlamp is manufactured, maintained and serviced by the same manufacturer.

(2) Each sunlamp shall have, on its external surface, a radiation warning sign that —

- (a) is shown in 2 contrasting colours;
- (b) has no outer dimensions less than 2 cm;
- (c) is clearly visible and identifiable from the exposure position;
- (d) bears the words “WARNING — ULTRAVIOLET RADIATION — FOLLOW INSTRUCTIONS — FAILURE TO USE PROTECTIVE EYEWEAR MAY RESULT IN SEVERE BURNS OR OTHER EYE INJURY — IF DISCOMFORT DEVELOPS, DISCONTINUE USE AND CONSULT A PHYSICIAN”; and
- (e) incorporates a statement to indicate that —
 - (i) as with natural sunlight, overexposure can cause eye injury and sunburn;
 - (ii) repeated exposure may cause premature aging of skin and skin cancer;
 - (iii) medications or cosmetics applied to the skin may increase sensitivity to ultraviolet light;
 - (iv) a person who does not tan in the sun most likely will not tan from the use of this apparatus;
 - (v) a person having a history of skin problems or having a specially sensitive skin to sunlight shall consult a physician before use;
 - (vi) overexposure shall be avoided.

PART VII

MICROWAVE OVENS

Definition of microwave oven

24. Microwave oven means a device designed to heat, cook or dry food or material within a cavity through the application of microwave energy with the frequency ranges from 890 MHz to 6 GHz and is used in an industrial establishment, a commercial establishment, a restaurant, a cafeteria, in or with a vending machine, or in the home.

Requirements for microwave ovens

25.—(1) Every microwave oven shall be designed and constructed in such a manner that, under the conditions of use specified by the manufacturer, it functions in accordance with requirements under this regulation for as long as the microwave oven has its original components or replacement components recommended by the manufacturer for at least 100,000 use cycles or openings and closings of the oven door.

(2) Every microwave oven shall be designed and constructed to include the following safety features:

- (a) for each microwave power source, a device or indicator that provides a visible indication of the status of operation of the oven;
- (b) where power can be varied by a user control, an indicator to show the level of microwave power applied to the cavity;
- (c) where a total microwave power generating capacity of 25 kW or more is used, a lock on the control panel requiring the insertion of a key before microwave power can be generated;
- (d) where access to the cavity is not by a conveyor, a door constructed and positioned so as to ensure any leakage radiation does not exceed the limits prescribed under this regulation;
- (e) a covering or baffle arrangement over any viewing screen, vent or access port in the cavity wall, other than any opening through which conveyor borne material enters or leaves the cavity, that prevents the insertion of any object into the cavity while the microwave power source is in operation;
- (f) where the oven is equipped with a door as specified in [sub-paragraph \(d\)](#), at least 2 electrically and mechanically independent interlocks positioned so as to ensure that —
 - (i) the door cannot be opened until the microwave power generating component has been turned off; and
 - (ii) the microwave power generating component cannot be turned on while the door is opened;
- (g) a device to monitor one or more of the interlocks required by [sub-paragraph \(f\)](#) that renders the oven inoperable when a monitored interlock fails or is otherwise rendered inoperable; and
- (h) components and shields constructed and positioned so that adjustments to the service

controls and user controls to yield maximum possible output do not produce leakage radiation in excess of the limits prescribed under this regulation.

(3) Where a microwave oven is equipped with a conveyorised system, a warning sign described in [regulation 26](#) shall be permanently affixed to its external surface adjacent to each entry and exit port.

(4) Where the generation of X-ray within a microwave oven in excess of 25 μSv per hour averaged over 10 cm^2 is possible while the oven is functioning in accordance with [paragraph \(5\)](#), an X-radiation warning sign in the form specified in [the Fifth Schedule](#) is clearly visible while the microwave oven is being serviced, shall be permanently affixed to the microwave oven power generating component.

(5) Every microwave oven shall, when fully assembled and operating with its service controls and user controls adjusted to yield the maximum output, function in such a manner that —

(a) the leakage radiation, measured with the instrument prescribed by paragraph (7)(b), at all points at least 5 cm from the external surface of the oven, does not exceed —

(i) 10 W/m^2 with the test load prescribed by [paragraph \(7\)\(a\)](#) placed —

(A) in the centre of the shelf in the cavity, in the case of an oven that is designed for cooking and that has a total microwave power generating capacity not greater than 1.5 kW;

(B) as specified by the manufacturer, in the case of an oven other than an oven described in [sub-paragraph \(A\)](#);

(ii) 50 W/m^2 without a test load, where the oven is operable in such condition; and

(b) the intensity of X-ray exposure, at 5 cm from the external surface of the oven, does not exceed 5 μSv per hour spread over an area of 10 cm^2 .

(6) Every microwave oven shall, when the outer enclosure is removed and it is operating with its service controls and user controls adjusted to yield maximum output, function in such a manner that the leakage radiation, measured with the instrument prescribed by paragraph (7)(b) and with the load test prescribed by paragraph (7)(a) in the cavity, at all points at least 5 cm from every mechanical or electronic part of the oven that is accessible to the user of the oven including, but not limited to, the waveguide, cavity, cavity seam, magnetron and magnetron to waveguide connection, does not exceed 50 W/m^2 .

(7) For the purpose of [paragraphs \(5\)](#) and [\(6\)](#) —

(a) the test load shall be —

(i) in the case of an oven that is designed for cooking and that has a total microwave power generating capacity not greater than 1.5 kW — 275 \pm 15 ml of water at an initial temperature of 20 \pm 5°C; and

(ii) in the case of an oven other than an oven described in [sub-paragraph \(i\)](#) —

the substance and amount thereof specified by the manufacturer as the load to be used for testing the oven; and

(b) the instrument used to measure leakage radiation shall —

- (i) be capable of measuring a power density of 10 W/m^2 with an accuracy of ± 2 dB or better; and
- (ii) have an indicator with a response time not greater than 3 seconds.

(8) Failure of any single component of a microwave oven shall not cause the interlock system to be inoperative.

(9) The device required by paragraph (2)(a) shall have a rated lifetime that is not less than 5,000 hours.

(10) Each interlock required by paragraph (2)(f) shall have a rated lifetime of not less than 100,000 on-off cycles.

Requirements for labelling of microwave ovens

26.—(1) Each microwave oven shall have permanently affixed to and clearly visible on its external surface the following information:

- (a) the name of the manufacturer and the model number, serial number and place of manufacture of the oven, and the name and address of the distributor;
- (b) the type of microwave power generating component and the normal operating voltage, operating frequency and normal maximum output power thereof;
- (c) a description of the test load prescribed by [regulation 25\(7\)\(a\)](#); and
- (d) the year and month of manufacture of the oven.

(2) Each microwave oven shall have permanently affixed to and clearly visible on its external surface a warning sign that —

- (a) is shown in 2 contrasting colours;
- (b) has no outer dimensions less than 2 cm;
- (c) is clearly visible and identifiable from 1 m; and
- (d) bears the words “CAUTION — MICROWAVES”.

PART VIII

ULTRASOUND APPARATUS

Definition of ultrasound apparatus

27. Ultrasound apparatus means medical diagnostic apparatus, medical therapeutic apparatus and industrial apparatus designed to generate and emit ultrasonic power at acoustic frequencies above 16 kHz.

Requirements for ultrasound apparatus

28.—(1) Every ultrasound apparatus shall be designed and constructed in such a manner that, under the conditions of use specified by the manufacturer, it functions in accordance with this regulation for as long as the apparatus has its original components or replacement components recommended by the manufacturer.

(2) Every ultrasound apparatus shall be designed in such a manner that —

- (a) all marks, labels and signs are permanently affixed thereon and clearly visible; and
- (b) all user controls, meters, lights or other indicators are clearly visible, readily discernible and clearly labelled to indicate their function.

(3) Every therapeutic ultrasound apparatus shall be designed and constructed to include the following features:

- (a) on the control panel, separate indicator lights or other equivalent indicators that have an expected lifetime of at least 5,000 hours —
 - (i) to show when the line voltage is “ON” or “OFF”; and
 - (ii) to show when the ultrasonic power is being applied to the applicator;
- (b) a power indicator that —
 - (i) in the case of an apparatus that produces a continuous wave, shows by a direct reading the level of the temporal maximum effective ultrasonic intensity; and
 - (ii) in the case of an apparatus that produces an amplitude modulated wave, shows by a direct reading the level of the temporal maximum ultrasonic power and the temporal maximum effective ultrasonic intensity;
- (c) a clear and reliable indicator of the range used, if the power indicator described in [sub-paragraph \(b\)](#) utilises 2 or more different ranges of measurement; and
- (d) a timer that —
 - (i) terminates the generation of ultrasound after a preset time interval and then returns to zero;
 - (ii) does not allow the generation of ultrasound with the timer set at zero; and
 - (iii) is adjustable to settings in increments not greater than one minute.

(4) Where a therapeutic ultrasound apparatus is equipped with an ultrasonic power control, that control shall —

- (a) allow the adjustment of ultrasonic power; and
- (b) have a minimum and maximum adjustment that directly relates to the ultrasonic power level indicator.

(5) Except where an exemption has been granted by the Chief Executive, every ultrasound apparatus shall function in such a manner that when the apparatus is operating with its user

controls adjusted to yield maximum temporal average-spatial average effective ultrasonic intensity —

- (a) such intensity shall not exceed 30 kW/m^2 for therapeutic ultrasound apparatus, when measured in accordance with [paragraph \(8\)](#); and
- (b) such intensity shall not exceed $1,000 \text{ W/m}^2$, for diagnostic ultrasound apparatus, when measured in accordance with [paragraph \(8\)](#).

(6) Diagnostic ultrasound apparatus shall be designed with adjustable controls so that the operator can use the minimum acoustic exposure required to image or obtain other information concerning the organ of interest in each patient.

(7) Diagnostic ultrasound apparatus with output level exceeding $1,000 \text{ W/m}^2$ if approved by the Chief Executive shall include instruments for monitoring both exposure level and exposure time.

(8) The method used to measure the effective ultrasonic intensity for the purposes of [paragraph \(7\)](#) shall produce a result that is at least as accurate as the result that will be produced by using —

- (a) an ultrasound balance radiometer to measure the ultrasonic power; and
- (b) an ultrasound detector of dimensions less than one wavelength in water to measure the pulse repetition rate, the pulse duration and the effective radiating area.

(9) The power indicator referred to in paragraph (3)(b) for every therapeutic ultrasound apparatus shall show on the scale of the ultrasonic power control or on the output power meter the ultrasonic power with an accuracy of $\pm 20\%$ when the output is greater than 10% of the maximum ultrasonic power.

(10) The timer referred to in paragraph (3)(d) for every therapeutic ultrasound apparatus shall be accurate to within 30 seconds for setting less than 5 minutes, to within 10% for settings from 5 to 10 minutes, and to within one minute for setting greater than 10 minutes.

(11) The ultrasonic power output shall remain constant within $\pm 20\%$ of its initial value during one hour of continuous operation, at maximum output and at rated supply line voltage, in water at temperature of $22^\circ\text{C} \pm 3^\circ\text{C}$.

(12) The actual ultrasonic frequency of a therapeutic ultrasound apparatus shall not differ more than $\pm 5\%$ from the ultrasonic frequency of the apparatus that is stated on the external surface of the housing of the apparatus.

(13) The effective radiating area shall be kept within $\pm 20\%$ of the rated value given by the manufacturer.

(14) Quality control procedures and testing programmes for the diagnostic ultrasound apparatus to ensure apparatus performance specifications are met shall be adopted by manufacturers and users.

Requirements for labelling of ultrasound apparatus

29.—(1) Every ultrasound apparatus shall, on the external surface of its housing, bear the following information and instructions:

- (a) the name and address of the manufacturer;
- (b) the name and address of the distributor, if the distributor is not the manufacturer;
- (c) the type and model designation;
- (d) the serial number;
- (e) the month and year of manufacture;
- (f) the ultrasonic frequencies in kilohertz (kHz) or megahertz (MHz);
- (g) a statement indicating whether the wave produced by the apparatus is a continuous wave or an amplitude modulated wave;
- (h) in the case of an apparatus that produces an amplitude modulated wave —
 - (i) the pulse repetition rate, the pulse duration, the ratio of the temporal maximum effective ultrasonic intensity to the temporal average effective ultrasonic intensity, and a description of the wave shape, where these parameters do not vary depending on the power; and
 - (ii) the pulse repetition rate, the pulse duration, the ratio of the temporal maximum effective ultrasonic intensity to the temporal average effective ultrasonic intensity, and a description of the wave shape, all at temporal maximum ultrasonic power where these parameters vary depending on the power; and
- (i) the line voltage used for normal operation.

(2) Every ultrasound apparatus shall, on the external surface of each applicator, bear the following:

- (a) the identification of the type and model of the ultrasound apparatus for which it is designed;
- (b) where an applicator is a focusing applicator, the focal length and the focal area;
- (c) a unique serial number or other unique identification; and
- (d) the effective radiating area in cm^2 .

(3) Every ultrasound apparatus shall, on the external surface of its housing, have a radiation warning sign that —

- (a) is shown in 2 contrasting colours;
- (b) has no outer dimensions less than 2 cm;
- (c) is clearly visible and identifiable from 1 m;
- (d) bears the words “CAUTION — ULTRASOUND”; and
- (e) contains warning instruction regarding the danger of exposure to liquid-borne

ultrasound for operator carrying out operations with ultrasonic cleaning tanks.

PART IX

MAGNETIC RESONANCE IMAGING APPARATUS

Definition of magnetic resonance imaging apparatus

30. Magnetic resonance imaging apparatus means any medical diagnostic apparatus designed to emit magnetic field and radiofrequency radiations for the purpose of imaging or spectroscopy of the human body or both.

Requirements for magnetic resonance imaging apparatus

31.—(1) Every magnetic resonance imaging apparatus shall be designed and constructed in such a manner that, under the conditions of use specified by the manufacturer, it functions in accordance with [paragraph \(4\)](#) for as long as the apparatus has its original components or replacement components recommended by the manufacturer.

(2) Every magnetic resonance imaging apparatus shall be designed in such a manner that —

- (a) all marks, labels and signs are permanently affixed thereon and clearly visible; and
- (b) all user controls, meters, lights or other indicators are clearly visible, readily discernible and clearly labelled to indicate their functions.

(3) Every magnetic resonance imaging apparatus shall be designed and constructed to include the following features:

- (a) on the control panel, separate indicator lights or other equivalent indicators —
 - (i) to show when the line voltage is “ON” or “OFF”; and
 - (ii) to show when the radiofrequency is applied; and
- (b) a clear and reliable indicator of the strength of the field and the frequency of the radiofrequency used.

(4) Except where an exemption has been granted by the Chief Executive, the manufacturer and the licensee are to ensure the following safety levels for radiofrequency heating (SAR), rate of change of magnetic field strength with time (dB/dt) and static magnetic field strength (B_0), and the requirements for the magnetic resonance imaging installation are to be complied with:

- (a) the static magnetic field strength (B_0) shall not exceed 2.0 T;
- (b) the rate of change of magnetic field strength with time (dB/dt) shall comply with any of the provisions of this sub-paragraph —
 - (i) each magnetic resonance imaging apparatus shall have a maximum dB/dt of not more than 6 T/s;
 - (ii) the licensee is allowed to utilise values of dB/dt that may exceed the 6 T/s

value under the following conditions:

(A) for axial gradients:

$$(1) \text{ dB/dt} < 20 \text{ T/s for} \\ \tau \geq 120 \mu\text{s};$$

$$(2) \text{ dB/dt} < 2,400/\tau \text{ T/s for} \\ 12 \mu\text{s} < \tau < 120 \mu\text{s};$$

$$(3) \text{ dB/dt} < 200 \text{ T/s for} \\ \tau \leq 12 \mu\text{s},$$

where the pulse width (τ) is the width in microseconds of a rectangular pulse or the half period of a sinusoidal dB/dt pulse;

(B) dB/dt for transverse gradients is less than 3 times the limits for axial gradients;

- (c) with respect to radiofrequency heating (SAR), the licensee shall take appropriate measures to ensure the following are complied with:
- (i) $\text{SAR} \leq 0.4 \text{ W/kg}$ for the whole body;
 - (ii) $\text{SAR} \leq 8.0 \text{ W/kg}$ for spatial peak in any one gram of tissue;
 - (iii) $\text{SAR} \leq 3.2 \text{ W/kg}$ averaged over the head; and
 - (iv) exposure to radiofrequency magnetic fields shall not be sufficient to produce a core temperature increase in excess of 1°C and localised heating to greater than 38°C in the head, 39°C in the trunk and 40°C in the extremities;
- (d) the licensee shall establish a warning zone where the magnetic field exceeds 5 gauss to ensure the safety of persons with cardiac pacemakers or other implanted devices; and
- (e) the licensee shall provide a venting system to remove gases resulting from a quench directly to the outside of the building for a superconducting magnet system.

Requirements for labelling of magnetic resonance imaging apparatus

32.—(1) Each magnetic resonance imaging apparatus shall bear, on the external surface of its housing, the following information:

- (a) the name and address of the manufacturer;
- (b) the name and address of the distributor, if the distributor is not the manufacturer;
- (c) the type and model designation;

- (d) the serial number;
- (e) the month and year of manufacture;
- (f) the static magnetic field strength in Tesla (T); and
- (g) the line voltage used for normal operation.

(2) Each magnetic resonance imaging apparatus shall display a label which contains, at least, the following information:

- (a) a contraindications section stating that —
 - (i) the apparatus is contraindicated for patients who have electrically, magnetically or mechanically activated implants; and
 - (ii) scanning patients with intracranial aneurysm clips is contraindicated unless the physician is certain that the clip is not magnetically active;
- (b) a warning statement, warning of —
 - (i) the risk of scanning patients with implanted surgical clips or other ferromagnetic materials or engaged in occupations or activities which may cause ferromagnetic metal implants;
 - (ii) the risk of scanning fetuses and infants;
 - (iii) the risk to patients and other persons that might result from the inadvertent introduction of ferromagnetic materials into proximity with the magnet, along with a recommendation advising the user to establish a security zone to prevent such a risk;
 - (iv) the risk to persons with cardiac pacemakers or other implanted devices who enter a zone where the magnetic field exceeds 5 gauss;
 - (v) the risk to decompensated cardiac patients, febrile patients and patients with impaired ability to perspire;
 - (vi) the risk of scanning patients with permanent eye-liner tattoo or who are wearing facial make-up which may contain ferromagnetic particles;
 - (vii) the risk of scanning patients suspected of having embedded conductive or magnetically active fragments in or near the eye; and
 - (viii) in the case of a superconducting magnet system, the risk of asphyxiation related to quench, along with a recommendation that the magnet room be designed to vent gases directly to the outside; and
- (c) a precaution concerning the scanning of patients —
 - (i) who have a greater than normal potential for cardiac arrest;
 - (ii) who are likely to develop seizures or claustrophobic reactions; or
 - (iii) who are unconscious, heavily sedated or confused and with whom no reliable communication can be maintained.

(3) Each magnetic resonance imaging apparatus shall be equipped with an operator's manual which shall, in addition to appropriate directions for use, contain —

- (a) a description of the recommended training needed by the physician and the operator to operate the apparatus safely and effectively;
- (b) a recommendation to the user to establish an appropriate plan and an emergency procedure for removing and treating any person, who requires emergency assistance, rapidly from the magnet's influence;
- (c) a description of quality assurance procedures recommended for the user including a detailed specification of all phantoms to be used;
- (d) recommended maintenance schedules, including designation of whether the user or company service personnel should perform them; and
- (e) device specifications from the summary specification sheet with ranges where applicable.

PART X

ENTERTAINMENT LASERS

Definition of entertainment laser

33. In this Part, entertainment laser means any laser, laser facility or mobile laser system designed for use in laser light shows. The classes of lasers to which this Part applies are specified in [the Second Schedule](#).

Requirements for entertainment laser

34.—(1) Every entertainment laser shall be designed and constructed in such a manner that, under the conditions of use specified by the manufacturer, it functions in accordance with this regulation so long as its original components or replacement components recommended by the manufacturer are in use.

(2) Every entertainment laser shall be designed in such a way that —

- (a) all marks, labels and signs are permanently affixed and clearly visible; and
- (b) all controls, meters, light or other indicators are readily discernible and clearly labelled to indicate their function.

(3) Every entertainment laser shall be designed and constructed to include the following safety features:

- (a) a key switch or other control by which the entertainment laser may be turned “ON” and “OFF”;
- (b) a protective housing;
- (c) a protective enclosure;

(d) a safety interlock or interlocks; and

(e) if means are provided to defeat or bypass interlocks for maintenance purposes —

- (i) a visual or aural indication when any interlock is defeated or bypassed; and
- (ii) the replacement of any removed or displaced portion of the protective enclosure is not possible when the interlock or interlocks are defeated or bypassed.

(4) Every entertainment laser shall be designed and constructed in such a way that failure or malfunction of any component of the entertainment laser does not result in leakage of laser radiation in excess of the limits specified in this regulation.

(5) Every entertainment laser shall have the laser labelling and warning signs described in [regulation 35\(1\)\(d\)](#), [\(e\)](#) and [\(f\)](#) permanently affixed to appropriate surfaces inside the laser so as to be clearly visible under conditions of removal or displacement of each removable or displaceable portion of the protective enclosure.

(6) Every entertainment laser shall be equipped with —

(a) an operation manual that contains instructions for —

- (i) the installation;
- (ii) the operation; and
- (iii) the detection of any malfunction of the laser; and

(b) a servicing manual that contains —

- (i) details of the electronic and mechanical control systems;
- (ii) instructions for service adjustments and service procedures including warnings or precautions to be taken to avoid possible exposure to laser radiation or other electromagnetic radiation; and
- (iii) a schedule of maintenance requirements that, if followed, will maintain the safety features indicated in [paragraph \(3\)](#) and keep the scanner functioning in accordance with this regulation during the normal operation and normal lifetime of the scanner.

(7) The laser system, including projector, shall be rigidly mounted to prevent unintended movement or accidental misalignment.

(8) Laser radiation outside the spectral range 400 nm to 700 nm shall be as low as practicable but shall not, in any case, exceed the limits of Class 1 under any possible conditions of operation.

(9) Scanning devices shall incorporate an automatic means to turn off the beam or to prevent laser emission in case the beam stops scanning or slows down significantly. In cases where a mirror ball is used with a scanning beam, the limits of [paragraph \(13\)](#) shall be met with the mirror ball stationary; or the mirror ball shall incorporate an automatic means to turn off the beam or to prevent laser emission if the mirror ball stops rotating or slows down significantly

such that the limits of [paragraph \(13\)](#) or [\(14\)](#) are exceeded. Any such scan failure safeguard system shall have a reaction time fast enough to preclude audience access to levels in excess of Class 1.

(10) Except as stated in [paragraph \(11\)](#), laser light shows shall be under the direct and personal supervision of a licensee and the laser beam to which human access can be gained shall not exceed the limits of Class 2 at any points less than —

- (a) 3.0 m above any surface upon which the audience or general public is permitted to stand; and
- (b) 2.5 m in lateral separation from any position where a person in the audience or general public is permitted during the performance or display, unless physical barriers are present which obstruct access by the audience or general public to such levels.

(11) In cases where the maximum laser output power level is less than 5 mW including all wavelengths and the laser beam path is located at least 6 m above any surface upon which a person in the audience or general public is permitted to stand and at any point less than 2.5 m in lateral separation from any position where a person in the audience or general public is permitted during the performance or display, then a laser operator need not be continuously present if the other provisions of these Regulations are complied with. In other cases, upon application to the Chief Executive, appropriate arrangements may be made for unattended operation.

(12) All laser light shows shall be provided with a key operated “ON-OFF” switch. In the case of the exception under [paragraph \(11\)](#), there shall be a designated individual present who can turn off and secure the laser in case of unsafe operating conditions.

(13) Levels of laser and collateral radiation, measured where the audience is normally located, and laser and collateral radiation measured where the operators, performers and employees are located if the radiation is intended to be viewed by them, shall not exceed the limits of Class 1 during operation. Radiation which shall be measured includes reflections from targets and scattering materials.

(14) Operators, performers and employees shall be able to perform their functions without the need for exposure to laser and collateral radiation in excess of the limits of Class 2 when the radiation is not intended to be viewed by them. Areas where levels of laser radiation in excess of the limits of Class 2 exist shall be clearly identified by posting a sign or by the use of barriers or guards or both to prevent entry of operators or performers into these areas.

(15) Every laser operator shall be situated in a position such that the performers, the audience, beam path and laser display can be viewed by the laser operator at all times during the laser operation.

(16) Where the laser output is limited to less than the maximum power available in order to comply with [paragraphs \(8\)](#) to [\(14\)](#), the laser output power shall be measured, adjusted and recorded before it is operated at each laser light show.

(17) All safety devices necessary to comply with [paragraph \(8\)](#), [\(9\)](#), [\(10\)](#), [\(11\)](#), [\(12\)](#), [\(13\)](#) or [\(14\)](#), such as scanning-beam power interlock, shall be functionally tested and recorded before

each laser light show.

(18) Every laser system shall be secured against unauthorised operation.

(19) The following precautions shall be taken during alignment procedures:

- (a) alignment shall be performed with the laser radiation emission reduced to lowest practicable level;
- (b) only persons who are required to perform alignment shall be in or near the beam path; and
- (c) protective eyewear shall be worn where necessary to prevent hazardous exposure.

(20) Before a laser light show is permitted to operate either at a permanent or temporary job site, the licensee shall provide the Chief Executive with sufficient information, data and measurements to establish that all the relevant requirements of these Regulations shall be complied with during use. This shall include sketches showing the locations of audience or general public, laser, mirror balls and other reflective or diffuse surfaces which may be struck by laser beam, scanning beam patterns, scanning velocity and frequency in occupied areas where beam strikes wall or other structure, and radiometric measurement data including output power and location of all measurements.

(21) In the case of open air shows where a laser beam is projected into the sky, the information submitted shall also include beam spot size, beam divergence and beam power measured at the projector.

(22) Every entertainment laser, when fully assembled and operating with its service controls and user controls adjusted to yield the maximum emission, shall function in such a manner that the intensity of laser radiation at all accessible locations, when measured within a stationary circular area of 0.385 cm^2 and averaged over that area, does not exceed the AEL for Class 1 laser.

Requirements for labelling of entertainment lasers

35.—(1) Every entertainment laser shall have permanently affixed and clearly visible on its external surface the following information:

- (a) the name and address of the manufacturer;
- (b) the name and address of the distributor, if the distributor is other than the manufacturer;
- (c) the model designation, the serial number and the month and year of manufacture;
- (d) the class of laser in accordance to the classification set out in [the Second Schedule](#);
- (e) for pulsed entertainment lasers, the energy per pulse, pulse duration and pulse repetition rate;
- (f) for continuous wave mode entertainment lasers, the output power; and
- (g) the name and address of the manufacturer of the laser or lasers used in the apparatus.

(2) Every entertainment laser shall have permanently affixed and clearly visible on its external surface, a radiation warning sign that —

- (a) is shown in 2 contrasting colours;
- (b) is clearly visible and identifiable from a distance of 1 m;
- (c) has no outer dimension less than 2 cm; and
- (d) is designed in accordance with the appropriate diagram set out in [the Fourth Schedule](#).

(3) In addition, labels bearing the words “CAUTION — HAZARDOUS LASER AND ELECTROMAGNETIC RADIATION WHEN OPEN AND INTERLOCK DEFEATED” shall be affixed to defeatably interlocked protective housings.

PART XI

HIGH POWER LASERS

Definition of high power laser

36. High power laser means any laser apparatus from Class 3b and Class 4 based on the classification set out in [the Second Schedule](#).

Requirements for high power lasers

37.—(1) Every high power laser shall have a protective housing that prevents human access during operation to laser and collateral radiation that exceed the accessible emission limits of Class 1 and the accessible emission limits of collateral radiation specified in Table 5 in [the Second Schedule](#), respectively, wherever and whenever such human access is not necessary for the apparatus to perform its intended function. Wherever and whenever human access to laser radiation levels that exceed the limits of Class 1 is necessary, these levels shall not exceed the limits of the lowest class necessary to perform the intended function of the apparatus.

(2) Every high power laser shall be provided with a safety interlock for each portion of the protective housing which is designed to be removed or displaced during operation or maintenance, if the removal or displacement of such portion of the protective housing permit human access to laser or collateral radiation in excess of the accessible emission limits applicable under [paragraph \(1\)](#). Each required safety interlock, unless defeated, shall —

- (a) prevent such human access to laser and collateral radiation upon removal or displacement of such portion of the protective housing; and
- (b) preclude removal or displacement of such portion of the protective housing upon failure to prevent human access to laser and collateral radiation as required under paragraph (a).

(3) Every high power laser which incorporates safety interlocks designed to allow safety interlock defeat shall incorporate a means of visual or aural indication of interlock defeat. During interlock defeat, such indication shall be visible or audible whenever the laser product is

energised, with the protective housing removed or displaced.

(4) Replacement of a removed or displaced portion of the protective housing shall not be possible while required safety interlocks are defeated.

(5) Every high power laser shall incorporate a readily available remote control connector having an electrical potential difference of no greater than 250 r.m.s. volts between the terminals of the remote control connector. When the terminals of the connector are not electrically joined, human exposure to all laser and collateral radiation from the laser emitting apparatus in excess of the accessible emission limits of Class 1 and the accessible emission limits of collateral radiation specified in Table 5 in [the Second Schedule](#) shall not be allowed.

(6) Every high power laser shall incorporate a key-actuated master control. The key shall be removable and the laser shall not be operable when the key is removed.

(7) Every high power laser shall incorporate an emission indicator which provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class 1, and such emission indicator, shall, prior to emission of such radiation, allow appropriate action to be taken to avoid exposure to the laser radiation.

(8) If the laser and laser energy source are housed separately and can be operated at a separation distance of greater than 2 m, both laser and laser energy source shall incorporate an emission indicator as required in accordance with [paragraph \(7\)](#).

(9) Any visible signal required by [paragraph \(7\)](#) shall be clearly visible through protective eyewear designed specifically for the wavelength of the emitted laser radiation.

(10) Any emission indicator referred to in [paragraph \(7\)](#) shall be located so that viewing does not require human exposure to laser or collateral radiation in excess of the accessible emission limits of Class 1 and the accessible emission limits of collateral radiation specified in Table 5 in [the Second Schedule](#).

(11) Every high power laser shall be provided with one or more permanently attached means, other than laser energy source switches, electrical supply main connectors, or key-actuated master control, capable of preventing access by any part of the human body to all laser and collateral radiation in excess of the accessible emission limits of Class 1 and the accessible emission limits of collateral radiation specified in Table 5 in [the Second Schedule](#).

(12) Every high power laser shall have operational and adjustment controls located so that human exposure to laser or collateral radiation in excess of the accessible emission limits of Class 1 is unnecessary for the operation or adjustment of such controls.

(13) All viewing optics, viewports and display screens incorporated into a high power laser shall at all times limit the levels of laser and collateral radiation accessible to the human eye by means of such viewing optics, viewports or display screens to less than the accessible emission limits of Class 1 and the accessible emission limits of collateral radiation specified in Table 5 in [the Second Schedule](#).

(14) For any shutter or variable attenuator incorporated into such viewing optics, viewports or display screens, a means shall be provided —

(a) to prevent access by the human eye to laser and collateral radiation in excess of

accessible emission limits of Class 1 and the accessible emission limits of collateral radiation specified in Table 5 in [the Second Schedule](#) whenever the shutter is opened or the attenuator varied; and

- (b) to preclude, upon failure of such means as required in [sub-paragraph \(a\)](#), opening the shutter or varying the attenuator when access by the human eye is possible to laser or collateral radiation in excess of the accessible emission limits of Class 1 and the accessible emission limits of collateral radiation specified in Table 5 in [the Second Schedule](#).

(15) Every high power laser which emits accessible scanned laser radiation shall not, as a result of scan failure or other failure causing a change in either scan velocity or amplitude, permit human access to laser radiation in excess of the accessible emission limit permitted for that class of laser.

(16) Every high power laser shall be provided with a manual reset to enable resumption of laser radiation emission terminated by the use of a remote interlock or after an interruption of emission in excess of 5 seconds duration due to the unexpected loss of main electrical power.

(17) Every high power laser shall be under the direct and personal supervision of a licensed laser operator.

(18) Every high power laser shall be provided with a key operated “ON-OFF” switch.

(19) Any licensee using a high power laser apparatus shall be able to perform any of its functions without the need for exposure to laser and collateral radiation in excess of the limits of Class 1 and the limits of collateral radiation specified in Table 5 in [the Second Schedule](#) when the radiation is not intended to be viewed by them. Any area where levels of laser radiation in excess of the limits of Class 1 and the limits of collateral radiation specified in Table 5 in [the Second Schedule](#) exist shall be clearly identified by posting a sign or by the use of barriers or guards or both to prevent unauthorised entry into these areas.

(20) Whenever laser output must be limited to less than the maximum power available, the laser output power shall be measured, adjusted and recorded before it is used.

(21) Every safety device, such as interlock, shall be functionally tested and recorded before it is used.

(22) Every high power laser shall be secured against any unauthorised operation.

(23) The following precautions shall be taken during any alignment procedure:

- (a) the alignment shall be performed with the laser radiation emission reduced to the lowest practicable level;
- (b) only persons required to perform alignment shall be in or near the beam path; and
- (c) protective eyewear shall be worn where necessary to prevent hazardous exposure.

(24) Every high power laser when fully assembled and operating with its service controls and user controls adjusted to yield the maximum emission, shall function in such a manner that the intensity of laser radiation at all accessible locations, when measured within a stationary

circular area of 0.385 cm^2 and averaged over that area does not exceed the following limits:

- (a) during any time interval of less than 1.8×10^{-5} seconds, an integrated irradiance of $5.0 \times 10^{-7} \text{ J/cm}^2$;
- (b) during any time interval, t seconds, that is greater than 1.8×10^{-5} seconds but less than or equal to 10 seconds, an integrated irradiance of $1.8 \times 10^{-3} \times t^{0.75} \text{ J/cm}^2$;
- (c) during any time interval of greater than 10 seconds but less than or equal to 10,000 seconds, an integrated irradiance of 0.01 J/cm^2 ; and
- (d) during any time interval of greater than 10,000 seconds, an irradiance of $1 \mu \text{ W/cm}^2$.

(25) Every high power medical laser shall comply with all the relevant requirements set out in [paragraphs \(1\) to \(23\)](#). In addition, the manufacturer of the laser shall —

- (a) incorporate in each high power medical laser a means for the measurement of the level of that laser radiation intended for irradiation of the human body with an error in measurement of no more than $\pm 20\%$ when calibrated in accordance with [sub-paragraph \(b\)](#). Indication of the measurement shall be in International System Units;
- (b) supply with each high power medical laser instructions specifying a procedure and schedule for calibration of the measurement system required by [sub-paragraph \(a\)](#);
- (c) affix to each high power medical laser, in close proximity to each aperture through which is emitted accessible laser radiation in excess of the accessible emission limits of the accessible bearing, the words: “Laser Aperture”; and
- (d) provide a target-indicating device.

Requirements for labelling of lasers

38.—(1) Every laser shall carry a label or labels in accordance with the requirements of this paragraph. The labels shall be permanently fixed, legible and clearly visible during operation, maintenance or service, according to their purpose. They shall be so positioned that they can be read without the necessity for human exposure to laser radiation in excess of the AEL for Class 1. If the size or design of the apparatus makes labelling impractical, the label should be included in the user information or on the package.

- (2) Every Class 1 laser shall have affixed an explanatory label bearing the following words:

CLASS 1 LASER PRODUCT

- (3) Every Class 2 laser shall have affixed a warning label as set out in [the Fourth Schedule](#).
- (4) Every Class 3a laser shall have affixed a warning label as set out in [the Fourth Schedule](#).
- (5) Every Class 3b laser shall have affixed a warning label as set out in [the Fourth Schedule](#).
- (6) Every Class 4 laser shall have affixed a warning label as set out in [the Fourth Schedule](#).
- (7) Every Class 3b and Class 4 laser shall have affixed a label close to each aperture through

which laser radiation in excess of the AEL for Class 1 or Class 2 is emitted. The label shall bear the following words:

LASER APERTURE OR
AVOID EXPOSURE — LASER RADIATION
IS EMITTED FROM THIS APERTURE

(8) Every connection product, except a product specified in Class 1, shall be described on the explanatory label as shown in [the Fourth Schedule](#) by statements of the maximum output of laser radiation, the pulse duration (if appropriate) and the emitted wavelength or wavelengths.

(9) Every connection, panel of a protective housing and every access panel of a protective enclosure which when removed or displaced permits human access to laser radiation in excess of the AEL for Class 1 shall have affixed a label bearing the following words:

CAUTION — LASER RADIATION WHEN OPEN

In addition, such label shall bear the following words:

(a) DO NOT STARE INTO BEAM

if the accessible radiation does not exceed the AEL for Class 2.

(b) DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS

if the accessible radiation does not exceed the AEL for Class 3a.

(c) EXPOSURE TO BEAM

if the accessible radiation does not exceed the AEL for Class 3b.

(d) AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION

if the accessible radiation exceeds the AEL for Class 3b at any wavelength.

(10) Appropriate labels shall be clearly associated with each safety interlock panel which may readily be defeated and which will then permit human access to laser radiation in excess of the AEL of Class 1. Such labels shall be visible prior to and during interlock override and be in close proximity to the opening created by the removal of the protective housing and shall bear the following words:

CAUTION — LASER RADIATION WHEN OPEN
AND INTERLOCKS DEFEATED

(11) If the output of the laser is outside the wavelength range 400 nm to 700 nm, the explanatory label shall be modified to read “Invisible laser radiation”, or if the output is at wavelengths both inside and outside this wavelength range, to read “Visible and invisible laser radiation”.

MISCELLANEOUS

Responsibilities of licensee

39. Every licensee shall ensure that the user of every irradiating apparatus is trained and has sufficient knowledge in using the irradiating apparatus under his charge.

Appointment of radiation safety officer

40. Every licensee may, subject to the approval of the Chief Executive, appoint an individual, who has satisfactorily undertaken a course of study in the use of radiation monitoring equipment and the principles of radiation safety or equivalent experience as a radiation safety officer for the purposes of supervising the use or custody of any irradiating apparatus for any work he is licensed to do.

Prohibition of use of premises

41. The Chief Executive may prohibit the use of any premises or part thereof for any purpose if, in his opinion, the use of such premises or part thereof is likely to result in the receiving by any individual of an excessive radiation unnecessarily.

Prohibition of use of irradiating apparatus

42. The Chief Executive may prohibit the use of any irradiating apparatus if, in his opinion, the use of such irradiating apparatus is likely to result in any individual receiving an excessive radiation unnecessarily.

Penalty

43. Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$2,000 or to imprisonment for a term not exceeding 6 months or to both.

FIRST SCHEDULE

Regulations 2 and [4\(2\)](#)

CLASSIFICATION OF — IRRADIATING APPARATUS

PART I

The apparatus under this Part are ultraviolet sunlamps, microwave ovens, fetal heart monitoring doppler non-imaging ultrasound apparatus and any other industrial ultrasound apparatus with power output of not more than 50 W, and any apparatus with any or combination of the above as part of the apparatus.

PART II

The apparatus under this Part are medical diagnostic imaging ultrasound and therapeutic ultrasound, industrial ultrasound apparatus with power output of 50 W or more, and magnetic resonance imaging apparatus.

PART III

The apparatus under this Part are entertainment lasers and Class 3b and Class 4 lasers.

SECOND SCHEDULE

Regulations 33, [35\(1\)](#), [36](#) and [37\(1\)](#), [\(5\)](#), [\(10\)](#), [\(11\)](#), [\(13\)](#), (14) and (19)

CLASSIFICATION OF LASERS

The hazard classification specified for lasers are defined by the output parameters and accessible emission levels (AELs) of radiation. The classes are as follows:

- Class 1: Class 1 lasers are those that are inherently safe so that the maximum accessible emission level as specified in Table 1 cannot be exceeded under any condition, or the lasers are safe by virtue of their engineering design.
- Class 2: Class 2 lasers are those emitting visible laser radiation in the wavelength range from 400 nm to 700 nm. The maximum accessible emission levels are as specified in Table 2.
- Class 3a: Class 3a lasers are those that emitting visible and/or invisible laser radiation with the maximum accessible emission levels as specified in Table 3.
- Class 3b: Class 3b lasers are those emitting visible and/or invisible laser radiation with maximum accessible emission levels as specified in Table 4.
- Class 4: Class 4 lasers are those emitting visible and/or invisible laser radiation at levels exceeding the accessible emission limits for Class 3b as specified in Table 4.

Accessible Emission Limits for Class 1 Laser Apparatus

Class 2 Laser Apparatus

ACCESSIBLE EMISSION LIMITS FOR CLASS 3a LASER APPARATUS

Accessible Emission Limits for CLASS 3b LASER APPARATUS

TABLE 5
ACCESSIBLE EMISSION LIMITS FOR
COLLATERAL RADIATION FROM LASER PRODUCTS

1. Accessible emission limits for collateral radiation having wavelengths greater than 180 nm but less than or equal to 1.0×10^6 nm are identical to the accessible emission limits of Class 1 laser radiation —
 - (i) in the wavelength range of less than or equal to 400 nm, for all emission durations;
 - (ii) in the wavelength range of greater than 400 nm, for all emission durations less than or equal to 1×10^3 seconds.
2. Accessible emission limit for collateral radiation within the X-ray range of wavelength is 5 $\mu\text{Sv/hr}$, averaged over a cross-section parallel to the external surface of the apparatus, having an area of 10 cm^2 with no dimension greater than 5 cm.

THIRD SCHEDULE

Regulations 16, 19, 20 and [22\(1\)](#)

TABLE 1

EXPOSURE LIMITS FOR SKIN EXPOSURE FROM A LASER BEAM

<i>Wavelength, (nm)</i>	<i>Exposure Duration, (sec)</i>	<i>Exposure Limits, (EL)</i>
200 to 400	10^{-3} to 3×10^4	same as TABLE 2
400 to 1400	10^{-9} to 10^{-7}	$0.2 M_A \text{ kJ/m}^2$
400 to 1400	10^{-7} to 10	$11 M_A t^{1/4} \text{ kJ/m}^2$
400 to 1400	10 to 3×10^4	$2 M_A \text{ kW/m}^2$
1400 to 10^6	10^{-9} to 3×10^4	same as TABLE 2

TABLE 2

EXPOSURE LIMITS FOR DIRECT OCULAR EXPOSURES FROM A LASER BEAM (INTRABEAM VIEWING)

<i>Wavelength (nm)</i>	<i>Exposure Duration (s)</i>	<i>Exposure Limits</i>
180 to 302	10^{-9} to 3×10^4	0.03 kJ/m^2
303	10^{-9} to 3×10^4	0.04 kJ/m^2
304	10^{-9} to 3×10^4	0.06 kJ/m^2
305	10^{-9} to 3×10^4	0.10 kJ/m^2
306	10^{-9} to 3×10^4	0.16 kJ/m^2
307	10^{-9} to 3×10^4	0.25 kJ/m^2

308	10^{-9} to 3×10^4	0.40 kJ/m^2
309	10^{-9} to 3×10^4	0.63 kJ/m^2
310	10^{-9} to 3×10^4	1.00 kJ/m^2
311	10^{-9} to 3×10^4	1.60 kJ/m^2
312	10^{-9} to 3×10^4	2.50 kJ/m^2
313	10^{-9} to 3×10^4	4.00 kJ/m^2
314	10^{-9} to 3×10^4	6.30 kJ/m^2
315 to 400	10^{-9} to 10	$5.6 \text{ t}^{1/4} \text{ kJ/m}^2$
315 to 400	10 to 10^3	10.0 kJ/m^2
315 to 400	10^3 to 3×10^4	0.01 kJ/m^2
400 to 700	10^9 to 1.8×10^{-5}	0.005 J/m^2
400 to 700	1.8×10^{-5} to 10	$18 \text{ t}^{3/4} \text{ J/m}^2$
400 to 550	10 to 10^4	100 J/m^2
550 to 700	10 to T_1	$18 \text{ t}^{3/4} \text{ J/m}^2$
550 to 700	T_1 to 10^4	$100 \text{ M}_B \text{ J/m}^2$
400 to 700	10^4 to 3×10^4	$0.01 \text{ M}_B \text{ W/m}^2$
700 to 1050	10^{-9} to 1.8×10^{-5}	$0.005 \text{ M}_A \text{ J/m}^2$
700 to 1050	1.8×10^{-5} to 10^3	$18 \text{ M}_A \text{ t}^{3/4} \text{ J/m}^2$
1050 to 1400		