

**LEGAL NOTICE NO.....**

**THE NUCLEAR REGULATORY ACT  
(NO 29 OF 2019)**

**IN EXERCISE of the powers conferred in the Nuclear Regulatory Act, the Cabinet Secretary makes the following Regulations-**

**THE NUCLEAR REGULATORY ACT (NON-IONIZING RADIATION) REGULATIONS, 2021**

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<b>PART I: PRELIMINARY</b>	
Citation.	1. These Regulations may be cited as Nuclear Regulatory Act (Non-Ionizing Radiation) Regulations, 2021.
Interpretation.	<p>2. In these Regulations, unless the context otherwise requires-</p> <p>“accessible location” means any point that can be reached by any part of the human body;</p> <p>“accident” means any unintended event, including operating errors, equipment failures and other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection and safety;</p> <p>“act” means the Nuclear Regulatory Act, 2019;</p> <p>“ael” means accessible emission limits;</p> <p>“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;</p> <p>“approved” means approved in writing by the authority;</p> <p>“beam” means a collection of rays that may be parallel, convergent or divergent;</p> <p>“cavity” means that portion of the microwave oven in which food or other materials may be heated, cooked or dried;</p> <p>“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;</p> <p>“continuous wave” —</p> <p>(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</p> <p>(b) in relation to a laser, means an emission of laser radiation for a period of 0.25 second or longer;</p> <p>“deal” means any activity involving an irradiating apparatus other than use, possess for use and import or export;</p> <p>“divergence” means the full angle of spread of a laser beam;</p>

“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;

“EIRP” means the equivalent isotropically radiated power. This is the product of the power supplied to the antenna and the antenna gain in a given direction relative to an isotropic antenna (absolute or isotropic gain);

“EMF” Electromagnetic Field;

“entertainment laser” means any laser designed for use in a laser light show or any laser facility or mobile laser system containing such a laser.

“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;

“healthcare institution” means any clinical laboratory, healthcare establishment, medical clinic or hospital that is licensed under the health act and medical practitioners and dentist act;

“ICNIRP Guidelines” means the Guidelines published by the International Commission on Non-Ionizing Radiation Protection

for limiting exposure to time-varying electric, magnetic and electromagnetic fields (up to 300 GHz).

“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;

“leakage radiation” means all radiation other than the useful beam;

“licensee” for purposes of these regulations means authorized person under the act;

“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.

“maternity home” means any premises used or intended to be used for the reception of pregnant women or of women immediately after childbirth;

“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 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

	<p>electricity, heat or light;</p> <p>“medical laser” means any laser product manufactured, designed, intended or promoted for purposes of in vivo diagnostic, surgical, cosmetic or therapeutic laser irradiation of any part of the human body;</p> <p>“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;</p> <p>“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;</p> <p>“operator” means any person, organization, or government entity authorized by the Authority to engage in an associated activity or undertake the operation of an associated facility. In relation to transport of radioactive material, operators include shippers, carriers and consignees.</p> <p>“person” means any natural or juridical person;</p> <p>“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;</p> <p>“protective eyewear” means any device designed to be worn by the user to reduce, directly or indirectly, the radiation reaching the eyes;</p> <p>“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;</p> <p>“pulse” means an intermittent emission of laser radiation for a duration of less than 0.25 second;</p> <p>“pulse duration” means the time interval measured between the half-peak power points on the leading and trailing edges of a pulse;</p> <p>“radiation” means non-ionizing radiation for the purpose of these regulations;</p> <p>“radiation hazard” means the danger to the health of an person arising from exposure to radiation emitted from an irradiating apparatus;</p> <p>“radiation level” means the corresponding radiation power density expressed in <math>w/m^2</math>;</p> <p>“radiation-related accident” means any accident involving an irradiating apparatus;</p>
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“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 person who is engaged in or is employed for part or whole of his working time to do radiation work;

“registered dentist” means any person who is registered as a dentist under the medical practitioner and dentist act (cap. 252);

“sar” (specific absorbed rate) means the rate at which energy is absorbed per unit mass by a human body when exposed to a radio frequency electromagnetic field;

“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;

“sunlamp” means ultraviolet lamp or apparatus incorporating



	<p>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.</p> <p>“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;</p> <p>“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.</p> <p>“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.</p>
Objective	<p>3 The objective of these regulations is to establish requirements that must be satisfied to ensure safety and to protect people, property and the environment from non-ionizing radiation and fields with wavelengths greater than 100 nm or acoustic radiations and fields with frequencies below 16Hz and above 16kHz.</p>
Scope	<p>4(1) The regulations shall apply to:</p> <ul style="list-style-type: none"> <li>a) manufacture, import, export, possession and use of irradiating apparatus including: <ul style="list-style-type: none"> <li>i. ultraviolet sunlamps;</li> <li>ii. microwaves;</li> <li>iii. medical and industrial ultrasound apparatus;</li> <li>iv. magnetic resonance imaging (MRI) apparatus;</li> <li>v. entertainment lasers; and</li> <li>vi. high power lasers.</li> </ul> </li> </ul> <p>(2) For the purposes of these Regulations —</p> <ul style="list-style-type: none"> <li>(a) the laser classification standards specified in the Seventh Schedule take precedence in the order in which those standards appear in that Schedule; and</li> <li>(b) where a laser has in fact been classified in accordance with two or more of those standards, the laser is to be treated as classified in accordance with the standard that takes precedence.</li> </ul>

	<b>PART II: LICENCES</b>
Application for licenses	<p>5 The applicant shall:</p> <p>(1) apply for a license or for renewal of a license to the Authority in a prescribed form.</p> <p>(2) apply to the Authority in case of the need to alter the list of irradiating apparatus in respect of a license to keep, or possess, for any use of the irradiating apparatus specified in Parts II and III of the First Schedule.</p> <p>(3) In this regulation, for purposes of renewal, GKNIR2 licence shall be exempted.</p>
Fee of licences	<p>6 (1) The fees specified in the Sixth Schedule are payable in respect of the matters set out in that Schedule.</p> <p>(2) The fee for an application for the grant or renewal of a license must be paid when the application is submitted to the Authority.</p> <p>(3) The annual fee for an GKNIR2 licence must be paid on or before—</p> <p>(a) the date on which the GKNIR2 licence was granted; or</p> <p>(b) such other date as the Authority may specify in a particular case.</p> <p>(4) A single GKNIR2 licence may be granted in respect of two or more irradiating apparatus under the charge of the same licensee.</p> <p>(5) The Authority may, in any particular case or class of cases, waive the whole or any part of any fee payable under Rule 7-paragraph (1).</p>
Nonrefundable fees	<p>7 Any fee (specified in the Sixth Schedule) that is payable in respect of a matter —</p> <p>(a) cannot be refunded; and</p> <p>(b) cannot be used to offset any fee (specified in that Schedule) that is payable in respect of another matter.</p>
Medical examination	<p>8 Every person applying for an GKNIR3 licence shall:</p> <p>a) within 12 months prior to his application, undergo a medical examination, which shall include:</p> <p>i. eye examination; and</p>

	<ul style="list-style-type: none"> <li>ii. any other examination as may be required by the Authority,</li> <li>b) be certified fit to be engaged in radiation work by an approved registered medical practitioner.</li> </ul>
Conditions for licences	<p>9(1) An GKNIR1 licence may be granted only to persons who are equipped with test equipment, workshop facilities, and any other requirements as may be required by the Authority for performing the service and repair function on the type of irradiating apparatus that they are dealing with.</p> <p>(2) An GKNIR2 licence may be granted only to persons who, in the opinion of the Authority, will be able to ensure the safe use of the apparatus.</p> <p>(3) An GKNIR3 licence for use of any medical laser that is a Class 3b laser may be granted only to persons whom the Authority thinks fit, subject to provisions in Regulation 16.</p> <p>(4) 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 Authority sees fit to impose and the conditions so imposed by the Authority may at any time be varied, added to or revoked by the Authority.</p> <p>(5) A licence granted under the Act for the use of irradiating apparatus —</p> <ul style="list-style-type: none"> <li>(a) may be restricted to a specified apparatus or to apparatus of a specified kind; or</li> <li>(b) may be restricted to a specified use (or type or nature of use) or to use at a specified place.</li> </ul> <p>(6) No person shall use any irradiating apparatus for any purpose other than that specified in his licence in respect of that apparatus.</p>
Cancellation or suspension of licences	<p>10 (1) The Authority may, in its discretion, cancel or suspend for such period as it deems fit, any licence if the licensee —</p> <ul style="list-style-type: none"> <li>(a) has obtained the licence by means of a fraudulent or incorrect statement;</li> <li>(b) commits an offence under the Act;</li> <li>(c) commits a breach of or fails to comply with or observe any of the conditions of the licence;</li> </ul>

	<p>(d) is unable to act owing to illness or otherwise; or</p> <p>(e) has for any reason ceased to be entitled to hold the licence.</p> <p>(2) The Authority may, for the purpose of granting a licensee a single GKNIR2 licence in place of every licence under application that was granted to the licensee, cancel each such licence under application reference GKNIR2.</p> <p>(3) Every licence under application reference GKNIR2 continues to be in force, and to have effect, until the earlier of —</p> <p>(a) the date of its expiry; or</p> <p>(b) the date it is cancelled by the Authority. under Regulation 12 (1).</p>
Renewal of licences	<p>11 (1) On application being made to the Authority using GKNIR application forms under Annex 8 the Authority may grant to the applicant a renewal of any licence held by the applicant or may, if the Authority thinks fit, refuse to grant a renewal of the licence.</p> <p>(2) In granting any renewal of a licence, the Authority may endorse the existing licence or 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.</p> <p>(3) 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 Authority may allow in any particular case.</p> <p>(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.</p> <p>(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.</p> <p>(7) In this regulation, for purposes of renewal, GKNIR2 licence shall be exempted.</p>
Notification on change of address	<p>12 Every licensee who at any time changes the address of his authorized premises as appearing in the register of licences shall:</p> <p>a) within two weeks of the change of address, send to the Authority a notice of his new address; and</p>

	b) the Authority may thereupon amend the entry in the register relating to that licensee accordingly.
	<b>PART III: GENERAL REQUIREMENTS</b>
Age requirement	13 No person below the age of 18 years shall be engaged in radiation work.
Conditions for engaging in radiation work	<p>14(1) Subject to paragraphs (2) and (3) below, a person must not engage in any radiation work with any laser unless the person holds a licence authorizing the person to do so.</p> <p>(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:</p> <ul style="list-style-type: none"> <li>(a) the person in charge, or authorized to act on behalf, of healthcare institution;</li> <li>(b) the licensee of the GKNIR2 licence granted in respect of that medical laser.</li> </ul> <p>(3) A person must not engage in any radiation work on a human body with any medical laser that is a Class 4 (four) laser, unless the person is a registered medical practitioner or registered dentist.</p>
Control of use of apparatus	15 No person shall be granted a licence to do radiation work with a laser unless he or she, in the opinion of the Authority, has been adequately trained and has special knowledge in the safe use of laser.
	<b>PART IV: CONTROL OF RADIATION EXPOSURE</b>
Possession of apparatus	<p>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 person, or any part of that person's body, to receive radiation —</p> <ul style="list-style-type: none"> <li>(a) at a level greater than can be justified in the circumstances; or</li> <li>(b) in any case, at a level in excess of any of the following exposure limits: <ul style="list-style-type: none"> <li>(i) the exposure limit specified in Table 3 of the</li> </ul> </li> </ul>

	<p>Third Schedule;</p> <p>(ii) the maximum permissible exposure values specified in Schedule 7.</p> <p>(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 person.</p>
Use of radiation for medical procedure	<p>17 For purposes of medical procedures, this regulation shall not be construed so as to limit the intensity of the radiation which may be intentionally applied to a person as a necessary part of any diagnostic, surgical, cosmetic or therapeutic procedure.</p>
Protection of members of public and workers	<p>18 Licensee shall do all that is reasonably practicable to protect the members of the public or other workers under his supervision from unnecessary exposure to radiation.</p>
Radiation accident investigation	<p>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 —</p> <p>(a) that radiation worker must immediately report the circumstances of that incident to the licensee; and</p> <p>(b) the licensee must immediately make an investigation or arrange for an investigation to be made.</p> <p>(2) For the purposes of paragraph (1), the exposure limits are as follows:</p> <p>(a) the exposure limit specified in Table 3 of Schedule 3;</p> <p>(b) the maximum permissible exposure values specified in Schedule 7.</p>
Reporting radiation accident to the Authority	<p>20 Where an investigation under this regulation 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 —</p> <p>(a) immediately notify the Authority;</p> <p>(b) suspend all work that may expose any radiation worker to radiation;</p>

	<p>(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 Authority; and</p> <p>(d) keep a record of the medical condition of that radiation worker.</p>
Reporting radiation-related accident to the Directorate	<p>21(1) When the Directorate of Occupational Safety and Health Services (DOSHS) is notified of a radiation-related accident, or a report of a radiation-related accident is submitted under the Workplace Safety and Health (Incident Reporting) —</p> <p>(a) the licensee must immediately notify the Directorate of the radiation-related accident; and</p> <p>(b) the licensee, or a radiation safety officer, must submit a written report to the Authority within 10 days after the date of the radiation-related accident.</p> <p>(2) The written report mentioned in Paragraph (1)(b) must contain details of —</p> <p>(a) the time, place and nature of the radiation-related accident;</p> <p>(b) the number of persons affected and the manner in which they were affected;</p> <p>(c) the period during which there was loss of control of non- ionizing radiation or of irradiating apparatus;</p> <p>(d) the actions taken to address the radiation-related accident situation and to minimize the possibility of any future recurrence of such an accident; and</p> <p>(e) any person who may have suffered radiation exposure, and an assessment of the exposure suffered by the person.</p>
	<b>PART V: SUNLAMPS</b>
Requirements for sunlamps	<p>22(1) Every sunlamp shall be designed and constructed in such a manner that, under the conditions of use specified by the manufacturer —</p> <p>(a) the sunlamp functions in accordance with Regulation 23, paragraph (10), (11) and (12) for as long as the sunlamp has its original components or replacement components recommended by the manufacturer; and</p> <p>(b) no person who uses the sunlamp will be exposed to ultraviolet radiation in excess of the exposure limits specified in Table 3 in Schedule 3.</p>

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

(a) all marks, labels and signs in accordance with Regulation 24 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



	<p>by the manufacturer of the sunlamp;</p> <p>(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</p> <p>(c) a warning that the instructions accompanying the sunlamp shall always be followed to avoid or minimize potential injury.</p> <p>(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.</p> <p>(11) The timer required by paragraph (3)(b) shall be designed so as to —</p> <p>(a) be adjustable to preset times and have maximum timer interval not exceeding the maximum exposure time;</p> <p>(b) have an error not greater than 10% of the maximum timer interval of the sunlamp;</p> <p>(c) not automatically reset and therefore cause radiation emission to resume when the sunlamp emissions have been terminated by the timer; and</p> <p>(d) not preclude a user of a sunlamp from resetting the timer before the end of the preset timer interval.</p> <p>(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.</p>
Requirements for labelling sunlamps	<p>23(1) Each sunlamp shall have, on its external surface, the following information and instructions:</p> <p>(a) the name and address of the manufacturer and the distributor;</p> <p>(b) the model designation, the serial number and the month and year of manufacture;</p> <p>(c) the recommended exposure positions and the directions for determining the recommended exposure positions;</p>

	<p>(d) a warning that the use of exposure positions other than the recommended exposure positions may result in overexposure;</p> <p>(e) the maximum exposure time in minutes;</p> <p>(f) the minimum interval between consecutive exposures; and</p> <p>(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.</p> <p>(2) Each sunlamp shall have, on its external surface, a radiation warning sign that —</p> <p>(a) is shown in 2 contrasting colors;</p> <p>(b) has no outer dimensions less than 2 cm;</p> <p>(c) is clearly visible and identifiable from the exposure position;</p> <p>(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</p> <p>(e) incorporates a statement to indicate that —</p> <p>(i) as with natural sunlight, overexposure can cause eye injury and sunburn;</p> <p>(ii) repeated exposure may cause premature aging of skin and skin cancer;</p> <p>(iii) medications or cosmetics applied to the skin may increase sensitivity to ultraviolet light;</p> <p>(iv) a person who does not tan in the sun most likely will not tan from the use of this apparatus;</p> <p>(v) a person having a history of skin problems or having specially sensitive skin to sunlight shall consult a physician before use;</p> <p>(vi) overexposure shall be avoided.</p>
	<p><b>PART VI: ELECTROMAGNETIC FIELDS</b></p>
<p>EMF compliance and</p>	<p>24 (1) These regulations are intended to provide guidance on compliance with the basic restrictions for general public exposure to electromagnetic field (EMF) emissions identified in</p>

enforcement	<p>Tables 3 and 5 of the ICNIRP Guidelines (2020). They apply to:</p> <p>a) Licensees that are subject to an EMF-related condition in their spectrum licence(s); and</p> <p>b) Installers and users of radio equipment that contain an EMF-related condition.</p> <p>(2) These regulations cover the following key areas:</p> <p>a) the measurement and calculation procedures a licensee, installer or user may use to demonstrate compliance as per applicable regulatory guidelines;</p> <p>b) records of processes and other information that a licensee, installer or user should keep in order to demonstrate how it is complying with an EMF-related condition;</p> <p>c) how to ensure compliance when a site is shared with other spectrum users;</p> <p>d) site access requirements; and</p> <p>e) the enforcement options available to KNRA in the event of breach of an EMF-related condition.</p> <p>(3) These regulations concern public exposure to EMF emissions that is exposure to the general public. It does not concern occupational exposure which is governed by pre-existing legislation, namely Occupational Safety and Health ACT.</p> <p><b>A2.4</b> The EMF-related conditions discussed in this regulation concern radio equipment that can operate at powers above 10 Watts EIRP.</p> <p><b>A2.5</b> Throughout this regulation, whenever we refer to the basic restrictions, or to the basic restrictions for general public exposure, we mean the basic restrictions for general public exposure identified in Tables 3 and 5 of the ICNIRP (2020) Guidelines.</p>
Assessing compliance with EMF safety limits	<p>25 (1) Licensees, installers and users should ensure that their use of radio equipment authorized by their license regulations complies with the basic restrictions for general public exposure.</p> <p>(2) It should be noted that the reference levels for general public exposure identified in Table 5 of the ICNIRP Guidelines ‘... are given for the condition of maximum coupling of the field to the exposed individual, thereby providing maximum</p>

	<p>protection'. Therefore, if the reference levels are met this should ensure compliance with the basic restrictions.</p> <p>(3) Licensees, installers and users should make sure that the EMF levels in the vicinity of their transmitters are no greater than the basic restrictions in any area accessible to the general public. This means that they should not establish, install, modify or use radio equipment on a site unless the total EMF levels from all radio equipment on the site (regardless of who operates that radio equipment) is below the basic restrictions.</p> <p>(4) It is recommended that licensees, installers and users apply methods from KEBS standards and in absence of local standards BS standards such as BS EN 62232:2017, PD IEC TR 62669:2019, BS EN 50385 and BS EN 50401, as they may be amended.</p>
<p>Processes to ensure compliance with EMF safety limits</p>	<p>KNRA may, from time to time, conduct EMF compliance checks and audits. Licensees, installers and users should therefore be in a position to explain the steps they took to ensure compliance with the basic restrictions for general public exposure and provide records demonstrating their compliance. To this end, they should have appropriate processes in place that will enable them to:</p> <ul style="list-style-type: none"> <li>a) Identify the measurements, tests, calculations or other procedures they have carried out.</li> <li>b) Explain why they considered those procedures were appropriate.</li> <li>c) Provide evidence that a site is compliant with the basic restrictions, including by providing, where appropriate, test measurements, calculation results.</li> <li>d) Explain how they ensure they continue to comply with the basic restrictions, including; <ul style="list-style-type: none"> <li>i) When they modify radio equipment on a site;</li> <li>ii) Where for any other reason the power anticipated to be transmitted from the site has increased above that originally assumed; and</li> <li>iii) When they become aware that a site may not be complying with the basic restrictions.</li> </ul> </li> <li>e) Explain what measures are in place to ensure members of the public cannot unknowingly enter areas close to antennas</li> </ul>

	<p>where exposure may exceed the basic restrictions.</p>
<p>Shared and/or Co-located sites</p>	<p>27 (1) When radio equipment is established, installed, modified or used on a shared and / or co-located site, licensees, installers and users should have processes in place to enable them to coordinate amongst themselves for the sole purpose of ensuring the site remains compliant with the basic restrictions and which enables them to:</p> <ul style="list-style-type: none"> <li>a) Explain what processes are in place for ensuring that the total EMF emissions from a shared site comply, and remain compliant, with the basic restrictions.</li> <li>b) Explain what processes are in place for licensees or users that are present on a shared site to be notified if: <ul style="list-style-type: none"> <li>i) Radio equipment is established, installed or modified at shared site; or</li> <li>ii) The anticipated EMF emissions from radio equipment on a shared site increases above that assumed for the purposes of the previous EMF assessment.</li> </ul> </li> <li>c) Explain how they take into account the measurements and/or calculations from the different parties present on the site to ensure the site as a whole is, and remains,</li> <li>d) Explain what processes are in place to address any issues or disputes that arise between licensees, installers or users relating to radio equipment that is established, installed, modified or used on a shared site.</li> </ul> <p>(2) For the avoidance of doubt, it is the party who makes the last change to a site that is responsible for ensuring the total EMF emissions from the site continue to comply with the basic restrictions. If they are unable to demonstrate the continued compliance of the site, they should not make any changes.</p> <ul style="list-style-type: none"> <li>a) Explain what processes are in place for ensuring that the total EMF emissions from a shared site comply, and remain compliant, with the basic restrictions.</li> <li>b) Explain what processes are in place for licensees or users that are present on a shared site to be notified if <ul style="list-style-type: none"> <li>i) Radio equipment is established, installed or modified at shared site; or</li> <li>ii) The anticipated EMF emissions from radio equipment on a shared site increases above that assumed for the purposes of the previous EMF</li> </ul> </li> </ul>

	<p>assessment.</p> <p>c) Explain how they take into account the measurements and/or calculations from the different parties present on the site to ensure the site as a whole is, and remains, compliant.</p> <p>d) Explain what processes are in place to address any issues or disputes that arise between licensees, installers or users relating to radio equipment that is established, installed, modified or used on a shared site.</p> <p>(3) For the avoidance of doubt, it is the party who makes the last change to a site that is responsible for ensuring the total EMF emissions from the site continue to comply with the basic restrictions. If they are unable to demonstrate the continued compliance of the site, they should not make any changes.</p>
Access to sites	<p>28 (1) KNRA may carry out its own EMF emissions measurements from a particular site.</p> <p>(2) Licensees, installers and users should facilitate KNRA being provided with access to a site in order to carry out its own EMF emissions measurements.</p>
Potential enforcement action	<p>29 (1) KNRA will have a range of enforcement options available to it to ensure compliance with the basic restrictions for general public exposure in the ICNIRP Guidelines. These include:</p> <p>Engaging with licensees, installers and users to provide information, advice and/or warnings. Requiring licensed radio equipment to be temporarily or permanently closed down</p> <p>Taking criminal action including;</p> <p>i) Issuing fixed penalty notices; and</p> <p>ii) Instigating criminal proceedings</p> <p><b>NOTE:</b></p> <p>When deciding whether to impose a financial penalty in a specific case and if so, what level of penalty would be appropriate and proportionate.</p> <p>(2) Taking regulatory enforcement action for breach of ICNIRP</p>

	<p>guidelines.</p> <p>(3) KNRA may decide to pursue more than one of these options in the particular circumstances of the case.</p> <p>(4) When deciding whether to take enforcement action and what enforcement action may be the most appropriate, KNRA will consider all relevant factors. These may include the following factors (as appropriate) although other factors may also be relevant:</p> <ul style="list-style-type: none"> <li>i. The available evidence indicating a licensee, installer or user may be in breach of the basic restrictions;</li> <li>ii. The risk of harm to the public including; <ul style="list-style-type: none"> <li>(a) The location of the relevant site and proximity to busy public spaces; and</li> <li>(b) The age and health status of the public at risk; <ul style="list-style-type: none"> <li>i. Whether any breach may be ongoing;</li> <li>ii. The processes a licensee, installer or user has in place to ensure compliance with the basic restrictions and the extent to which they have in place the processes identified in this “Guidance on EMF compliance and enforcement”;</li> <li>iii. The length of time and time of day during which the basic restrictions were exceeded;</li> <li>iv. Whether any breach may be repeated, intentional or particularly flagrant; whether the licensee, installer or user has a history of similar breaches or a poor record of compliance; and</li> <li>v. Whether timely action was taken to bring a site into compliance.</li> </ul> </li> </ul> </li> </ul>
	<p><b>PART VII: ULTRASOUND APPARATUS</b></p>
<p>Requirements for ultrasound apparatus</p>	<p>30(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.</p> <p>(2) Every ultrasound apparatus shall be designed in such a manner that —</p> <ul style="list-style-type: none"> <li>(a) all marks, labels and signs are permanently affixed there on and clearly visible; and</li> <li>(b) all user controls, meters, lights or other indicators are</li> </ul>

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) utilizes 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 Authority, 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 —



	<p>(a) such intensity shall not exceed <math>30 \text{ kW/m}^2</math> for therapeutic ultrasound apparatus, when measured in accordance with paragraph (8); and</p> <p>(b) such intensity shall not exceed <math>1,000 \text{ W/m}^2</math>, for diagnostic ultrasound apparatus, when measured in accordance with paragraph (8).</p> <p>(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.</p> <p>(7) Diagnostic ultrasound apparatus with output level exceeding <math>1,000 \text{ W/m}^2</math> if approved by the Authority shall include instruments for monitoring both exposure level and exposure time.</p> <p>(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 —</p> <p>(a) an ultrasound balance radiometer to measure the ultrasonic power; and</p> <p>(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.</p> <p>(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 <math>\pm 20\%</math> when the output is greater than 10% of the maximum ultrasonic power.</p> <p>(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.</p> <p>(11) The ultrasonic power output shall remain constant within <math>\pm 20\%</math> of its initial value during one hour of continuous operation, at maximum output and at rated supply line voltage, in water at temperature of <math>22^\circ\text{C} \pm 3^\circ\text{C}</math>.</p> <p>(12) The actual ultrasonic frequency of a therapeutic ultrasound apparatus shall not differ more than <math>\pm 5\%</math> from the ultrasonic frequency of the apparatus that is stated on the external surface of the housing of the apparatus.</p> <p>(13) The effective radiating area shall be kept within <math>\pm 20\%</math> of the rated value given by the manufacturer.</p>
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	<p>(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.</p>
<p>Requirements for labelling of ultrasound apparatus</p>	<p>31(1) Every ultrasound apparatus shall, on the external surface of its housing, bear the following information and instructions:</p> <ul style="list-style-type: none"> <li>(a) the name and address of the manufacturer;</li> <li>(b) the name and address of the distributor, if the distributor is not the manufacturer;</li> <li>(c) the type and model designation;</li> <li>(d) the serial number;</li> <li>(e) the month and year of manufacture;</li> <li>(f) the ultrasonic frequencies in kilohertz (kHz) or megahertz (MHz);</li> <li>(g) a statement indicating whether the wave produced by the apparatus is a continuous wave or an amplitude modulated wave;</li> <li>(h) in the case of an apparatus that produces an amplitude modulated wave — <ul style="list-style-type: none"> <li>(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</li> <li>(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</li> </ul> </li> <li>(i) the line voltage used for normal operation.</li> </ul> <p>(2) Every ultrasound apparatus shall, on the external surface of each applicator, bear the following:</p> <ul style="list-style-type: none"> <li>(a) the identification of the type and model of the ultrasound apparatus for which it is designed;</li> <li>(b) where an applicator is a focusing applicator, the focal length and the focal area;</li> <li>(c) a unique serial number or other unique identification;</li> </ul>

	<p>and</p> <p>(d) the effective radiating area in <math>\text{cm}^2</math>.</p> <p>(3) Every ultrasound apparatus shall, on the external surface of its housing, have a radiation warning sign that —</p> <p>(a) is shown in 2 contrasting colors;</p> <p>(b) has no outer dimensions less than 2 cm;</p> <p>(c) is clearly visible and identifiable from 1 m;</p> <p>(d) bears the words “ULTRASOUND”; and</p> <p>(e) contains warning instruction regarding the danger of exposure to liquid-borne ultrasound for operator carrying out operations with ultrasonic cleaning tanks.</p>
	<p><b>PART VIII: MAGNETIC RESONANCE IMAGING APPARATUS</b></p>
<p>Requirements for magnetic imaging apparatus.</p>	<p>32(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.</p> <p>(2) Every magnetic resonance imaging apparatus shall be designed in such a manner that —</p> <p>(a) all marks, labels and signs are permanently affixed there on and clearly visible; and</p> <p>(b) all user controls, meters, lights or other indicators are clearly visible, readily discernible and clearly labelled to indicate their functions.</p> <p>(3) Every magnetic resonance imaging apparatus shall be designed and constructed to include the following features:</p> <p>(a) on the control panel, separate indicator lights or other equivalent indicators —</p> <p>i. to show when the line voltage is “ON” or “OFF”; and</p> <p>ii. to show when the radiofrequency is applied; and</p> <p>(b) a clear and reliable indicator of the strength of the field and the frequency of the radiofrequency used.</p> <p>(4) Except where an exemption has been granted by the Authority, 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 (<math>B_0</math>), and the requirements for the</p>

magnetic resonance imaging installation are to be complied with:

(a) the static magnetic field strength ( $B_0$ ) shall not exceed 3.0 T;

(b) the rate of change of magnetic field strength with time (dB/dt) shall comply with any of the provisions of this subparagraph —

(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 utilize values of dB/dt that may exceed the 6 T/s value under the following conditions:

(A) for axial gradients:

(1) dB/dt < 20 T/s for

$\tau \geq 120 \mu\text{s}$ ;

(2) dB/dt < 2,4000/ $\tau$  T/s for

$12 \mu\text{s} < \tau < 120 \mu\text{s}$  (3) dB/dt < 200 T/s for

$\tau \leq 12 \mu\text{s}$ ,

where the pulse width ( $\tau$ ) 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) SAR  $\leq$  0.4 W/kg for the whole body;

(ii) SAR  $\leq$  8.0 W/kg for spatial peak in any one gram of tissue;

(iii) SAR  $\leq$  3.2 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 localized 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	<p>33(1) Each magnetic resonance imaging apparatus shall bear, on the external surface of its housing, the following information:</p> <ul style="list-style-type: none"> <li>(a) the name and address of the manufacturer;</li> <li>(b) the name and address of the distributor, if the distributor is not the manufacturer;</li> <li>(c) the type and model designation;</li> <li>(d) the serial number;</li> <li>(e) the month and year of manufacture;</li> <li>(f) the static magnetic field strength in Tesla (T); and</li> <li>(g) the line voltage used for normal operation.</li> </ul> <p>(2) Each magnetic resonance imaging apparatus shall display a label which contains, at least, the following information:</p> <ul style="list-style-type: none"> <li>(a) a contraindications section stating that — <ul style="list-style-type: none"> <li>(i) the apparatus is contraindicated for patients who have electrically, magnetically or mechanically activated implants; and</li> <li>(ii) scanning patients with intracranial aneurysm clips is contraindicated unless the physician is certain that the clip is not magnetically active;</li> </ul> </li> <li>(b) a warning statement, warning of — <ul style="list-style-type: none"> <li>(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;</li> <li>(ii) the risk of scanning fetuses and infants;</li> <li>(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;</li> <li>(iv) Radiation Protection (Non-Ionizing Radiation) Regulations</li> <li>(v) the risk to persons with cardiac pacemakers or other implanted devices who enter a zone where the magnetic field exceeds 5 gauss;</li> <li>(vi) the risk to decompensated cardiac patients, febrile</li> </ul> </li> </ul>

	<p>patients and patients with impaired ability to perspire;</p> <p>(vii) the risk of scanning patients with permanent eye-liner tattoo or who are wearing facial make-up which may contain ferromagnetic particles;</p> <p>(viii) the risk of scanning patients suspected of having embedded conductive or magnetically active fragments in or near the eye; and</p> <p>(ix) 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</p> <p>(c) a precaution concerning the scanning of patients —</p> <p>(i) who have a greater than normal potential for cardiac arrest;</p> <p>(ii) who are likely to develop seizures or claustrophobic reactions; or</p> <p>(iii) who are unconscious, heavily sedated or confused and with whom no reliable communication can be maintained.</p> <p>(3) Each magnetic resonance imaging apparatus shall be equipped with an operator's manual which shall, in addition to appropriate directions for use, contain —</p> <p>(a) a description of the recommended training needed by the physician and the operator to operate the apparatus safely and effectively;</p> <p>(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;</p> <p>(c) a description of quality assurance procedures recommended for the user including a detailed specification of all phantoms to be used;</p> <p>(d) recommended maintenance schedules, including designation of whether the user or company service personnel should perform them; and</p> <p>(e) device specifications from the summary specification sheet with ranges where applicable.</p>
	<p><b>PART IX: ENTERTAINMENT LASERS</b></p>
<p>Requirements for entertainm</p>	<p>34(1) Every entertainment laser shall be designed and constructed in such a manner that, under the conditions of</p>

ent laser	<p>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.</p> <p>(2) Every entertainment laser shall be designed in such a way that —</p> <ul style="list-style-type: none"> <li>(a) all marks, labels and signs are permanently affixed and clearly visible; and</li> <li>(b) all controls, meters, light or other indicators are readily discernible and clearly labelled to indicate their function.</li> </ul> <p>(3) Every entertainment laser shall be designed and constructed to include the following safety features:</p> <ul style="list-style-type: none"> <li>(a) a key switch or other control by which the entertainment laser may be turned “ON” and “OFF”;</li> <li>(b) a protective housing;</li> <li>(c) a protective enclosure;</li> <li>(d) a safety interlock or interlocks; and</li> <li>(e) if means are provided to defeat or bypass interlocks for maintenance purposes — <ul style="list-style-type: none"> <li>(i) a visual or aural indication when any interlock is defeated or bypassed; and</li> <li>(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.</li> </ul> </li> </ul> <p>(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.</p> <p>(5) Every entertainment laser shall have the laser labelling and warning signs described in Regulation 33 (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.</p>
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- (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 AEL in accordance with Table 1 of Schedule 2 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 those in Table 1 of Schedule 2.



(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 AEL for 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 Authority, 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 person 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 AEL in accordance with Table 1 of Schedule 2 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 AEL in accordance with Table 2 of Schedule 2, when the radiation is not intended to be viewed by them. Areas where levels of laser radiation in excess of the AEL for 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 paragraphs (8) to (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 unauthorized 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 Authority 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.

	<p>(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<sup>2</sup> and averaged over that area, does not exceed the AEL in accordance with table 1 of schedule 2.</p>
<p>Requirements for labelling of entertainment lasers</p>	<p>35(1) Every entertainment laser shall have permanently affixed and clearly visible on its external surface the following information:</p> <ul style="list-style-type: none"> <li>(a) the name and address of the manufacturer;</li> <li>(b) the name and address of the distributor, if the distributor is other than the manufacturer;</li> <li>(c) the model designation, the serial number and the month and year of manufacture;</li> <li>(d) the class of laser in accordance with the classification set out in Schedule 2;</li> <li>(e) for pulsed entertainment lasers, the energy per pulse, pulse duration and pulse repetition rate;</li> <li>(f) for continuous wave mode entertainment lasers, the output power; and</li> <li>(g) the name and address of the manufacturer of the laser or lasers used in the apparatus.</li> </ul> <p>(2) Every entertainment laser shall have permanently affixed and clearly visible on its external surface, a radiation warning sign that —</p> <ul style="list-style-type: none"> <li>(a) is shown in 2 contrasting colors;</li> <li>(b) is clearly visible and identifiable from a distance of 1 m;</li> <li>(c) has no outer dimension less than 2 cm; and</li> <li>(d) is designed in accordance with the appropriate diagram set out in Schedule 4.</li> </ul> <p>(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.</p> <p>(4) An entertainment laser is to be treated as complying with this regulation if —</p> <ul style="list-style-type: none"> <li>(a) it is classified in accordance with any standard specified in Schedule 7; and</li> </ul>

	(b) it complies with the requirements for the labelling of entertainment lasers in that standard that correspond to the requirements in this regulation.
	<b>PART X: HIGH POWER LASERS</b>
Requirements for high power lasers	<p>36 (1) Every high-power laser shall have a protective housing that prevents human access during operation to laser and collateral radiation that exceed the AEL in accordance with table I of Schedule 2 and the AEL for collateral radiation specified in Table 5 in Schedule 2, 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 AEL in accordance with table I of Schedule 2 is necessary, these levels shall not exceed the limits of the lowest class necessary to perform the intended function of the apparatus.</p> <p>(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 AEL applicable under paragraph (1). Each required safety interlock, unless defeated, shall —</p> <ul style="list-style-type: none"> <li>(a) prevent such human access to laser and collateral radiation upon removal or displacement of such portion of the protective housing; and</li> <li>(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).</li> </ul> <p>(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 energized, with the protective housing removed or displaced.</p> <p>(4) Replacement of a removed or displaced portion of the protective housing shall not be possible while required safety interlocks are defeated.</p> <p>(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</p>

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 Table 1 of Schedule 2 and the AEL for collateral radiation specified in Table 5 in Schedule 2 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 Table 1 of Schedule 2, 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 ones described in Table 1 of Schedule 2 and the AEL for collateral radiation specified in Table 5 in Schedule 2.

(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 what is described in Table 1 of Schedule 2 and the AEL for collateral radiation specified in Table 5 Schedule 2

(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 limits described in Table 1 of Schedule 2 as unnecessary for the operation or adjustment of such controls.

(13) All viewing optics, view ports 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 limits in Table 1 of Schedule 2 and the AEL for collateral radiation specified in Table 5 in Schedule 2.

(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 the Table 1 of Schedule 2 and the AEL for 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 limits in Table 1 of Schedule 2 and the AEL for 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 AEL 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 in Table 1 of Schedule 2 and the AEL for collateral radiation specified in Table 5 in Schedule 2 when the radiation is not intended to be viewed by them. Any area where levels of laser radiation in excess of the limits in Table 1 of Schedule 2 and the AEL for collateral radiation specified in Table 5 in Schedule 2 exist shall be clearly identified by posting a sign or by the use of barriers or guards or both to prevent unauthorized 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 unauthorized 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  $0.385 \text{ cm}^2$  and averaged over that area does not exceed the following limits:

- (a) during any time interval of less than  $1.8 \times 10^{-5}$  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  $1.8 \times 10^{-5}$  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  $0.01 \text{ J/cm}^2$ ; and
- (d) during any time interval of greater than 10,000 seconds, an irradiance of  $1 \text{ } \mu\text{W/cm}^2$ .

(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

	<p>to each aperture through which is emitted accessible laser radiation in excess of the AEL of the accessible bearing, the words: “Laser Aperture”; and</p> <p>(d) provide a target-indicating device.</p> <p>(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 —</p> <p>(a) it is classified in accordance with any standard specified in the Seventh Schedule; and</p> <p>(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.</p>
<p>Requirements for labelling of lasers</p>	<p>37(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 limits in Table 1 of Schedule 2. If the size or design of the apparatus makes labelling impractical, the label should be included in the user information or on the package.</p> <p>(2) Every Class 1 laser shall have affixed an explanatory label bearing the following words:</p> <p style="text-align: center;">“CLASS 1 LASER PRODUCT”.</p> <p>(3) Every Class 2 laser shall have affixed a warning label as set out in Schedule 4.</p> <p>(4) Every Class 3a laser shall have affixed a warning label as set out in Schedule 4.</p> <p>(5) Every Class 3b laser shall have affixed a warning label as set out in Schedule 4.</p> <p>(6) Every Class 4 laser shall have affixed a warning label as set out in Schedule 4.</p> <p>(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 limits described in Table 1 of Schedule 2 or Class 2 is emitted. The label shall bear the following words:</p> <p style="text-align: center;">“LASER APERTURE or AVOID EXPOSURE — LASER RADIATION IS EMITTED FROM THIS APERTURE”.</p> <p>(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</p>



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 limits in Table 1 of Schedule 2 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)

“AVOID 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 limits in Table 1 of Schedule 2. 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”.

(12) A laser is to be treated as complying with all the relevant

	<p>requirements in this regulation if —</p> <p>(a) it is classified in accordance with any standard specified in Schedule 7; and</p> <p>(b) it complies with the requirements for the labelling of lasers in that standard that correspond to the relevant requirements in this regulation.</p>
	<b>PART XI: MISCELLANEOUS</b>
Responsibility of licensee	38 The licensee shall ensure that the safety of the facility or of the waste shall not be jeopardized by any provision made for the purpose of complying with national or international requirements concerning safeguards of the material.
Appointment of radiation safety officer	39 Every licensee may, subject to the approval of the Authority, appoint a person, 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	40 The Authority 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 person of an excessive radiation unnecessarily.
Prohibition of use of irradiating apparatus	41 The Authority may prohibit the use of any irradiating apparatus if, in his opinion, the use of such irradiating apparatus is likely to result in any person receiving an excessive radiation unnecessarily.
Penalty	42 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 KES. 20,000 or to imprisonment for a term not exceeding 6 months or to both.

## **FIRST SCHEDULE**

### **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 1200 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 1200 W or more, and magnetic resonance imaging apparatus.

### **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 (is applicable to safety of laser products emitting laser radiation in the wavelength range 180 nm to 1 mm); and

(c) persons may be exposed to levels of radiation mentioned in subparagraph (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 specialized equipment) are removed.

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

## **SECOND SCHEDULE**

### **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 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 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 lasers are those that emitting visible and/or invisible laser radiation with the maximum accessible emission levels as specified in Table 3.

Class 3b lasers are those emitting visible and/or invisible laser radiation with maximum accessible emission levels as specified in Table 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.



**Annex 1- Categorization of Nuclear Material**

**SECOND SCHEDULE — continued**

**TABLE 1**

**ACCESSIBLE EMISSION LIMITS FOR CLASS 1 LASER APPARATUS**

	$10^{-8}$ to $10^{-7}$	$10^{-7}$ to $10^{-6}$	$10^{-6}$ to $1.8 \times 10^{-5}$	$1.8 \times 10^{-5}$ to $5 \times 10^{-5}$	$5 \times 10^{-5}$ to 10	10 to $10^3$	$10^3$ to $10^6$	$10^6$ to $3 \times 10^6$
	$2.4 \times 10^{-5} \text{ J}$							
$J^4 \text{ W}$	$7.9 \times 10^{-7} C_1 J(t < T_1)$			$7.9 \times 10^{-7} C_2 J(t > T_1)$		$7.9 \times 10^{-7} C_2 J$		
	$7.9 \times 10^{-7} C_1 J$				$7.9 \times 10^{-3} \text{ J}$	$7.9 \times 10^{-6} \text{ W}$		
$I$	$2 \times 10^{-7} \text{ J}$		$7 \times 10^{-4} t^{0.75} \text{ J}$		$3.9 \times 10^{-3} \text{ J}$		$3.9 \times 10^{-7} \text{ W}$	
	$10^5 t^{0.33} \text{ J.m}^{-2}\text{sr}^{-1}$			$2.1 \times 10^5 \text{ J.m}^{-2}\text{sr}^{-1}$		$21 \text{ W.m}^{-2}\text{sr}^{-1}$		
$I$	$2 \times 10^{-7} \text{ J}$		$7 \times 10^{-4} t^{0.75} J(t < T_2)$			$3.9 \times 10^{-3} C_3 J(t > T_2)$		$3.9 \times 10^{-7} C_3 \text{ W}$
	$10^5 t^{0.33} \text{ J.m}^{-2}\text{sr}^{-1}$			$(t < T_2)$ $3.9 \times 10^4 t^{0.75} \text{ J.m}^{-2}\text{sr}^{-1}$		$2.1 \times 10^3 C_3 \text{ J.m}^{-2}\text{sr}^{-1}$ $(t > T_2)$		$21 C_3 \text{ W.m}^{-2}\text{sr}^{-1}$

**SECOND SCHEDULE — continued****TABLE 2****ACCESSIBLE EMISSION LIMITS FOR CLASS 2 LASER APPARATUS**

Wavelength $\lambda$ (nm)	Emission duration t (s)	Class 2 AEL
400 to 700	$t < 0.25$	Same as Class 1 AEL
	$t \geq 0.25$	$10^{-3}$ W

**SECOND SCHEDULE — continued****TABLE 3****ACCESSIBLE EMISSION LIMITS FOR CLASS 3A LASER APPARATUS**

Emission Duration (s)	< 10 <sup>9</sup>	10 <sup>9</sup> to 10 <sup>7</sup>	10 <sup>7</sup> to 10 <sup>6</sup>	10 <sup>6</sup> to 1.8x10 <sup>5</sup>	1.8x10 <sup>5</sup> to 5x10 <sup>5</sup>	5x10 <sup>5</sup> to 0.25	0.25 to 10	10 to 10 <sup>9</sup>	10 <sup>9</sup> to 3x10 <sup>9</sup>
0 to 302.5	3x10 <sup>10</sup> W.m <sup>-2</sup>	30 J.m <sup>-2</sup>							
2.5 to 315	1.2x10 <sup>5</sup> W and	4x10 <sup>6</sup> C <sub>1</sub> J and C <sub>1</sub> J.m <sup>-2</sup> ( $t < T_1$ )			(t > T <sub>1</sub> ) 4x10 <sup>6</sup> C <sub>1</sub> J and C <sub>1</sub> J.m <sup>-2</sup>			4x10 <sup>6</sup> C <sub>1</sub> J and C <sub>1</sub> J.m <sup>-2</sup>	
5 to 400	3x10 <sup>10</sup> W.m <sup>-2</sup>	4x10 <sup>6</sup> C <sub>1</sub> J and C <sub>1</sub> J.m <sup>-2</sup>						4x10 <sup>5</sup> J and 10 <sup>6</sup> J.m <sup>-2</sup>	4x10 <sup>5</sup> W and 10 W.m <sup>-2</sup>
0 to 700	1000 W and 5x10 <sup>6</sup> W.m <sup>-2</sup>	10 <sup>6</sup> J and 5x10 <sup>3</sup> J.m <sup>-2</sup>		3.5x10 <sup>-3</sup> t <sup>0.75</sup> J and 18t <sup>0.75</sup> J.m <sup>-2</sup>		5x10 <sup>-3</sup> W and 25 W.m <sup>-2</sup> (Aversion responses protect for emission > 0.25 s)			
0 to 1050	1000WxC <sub>4</sub> W and 5xC <sub>4</sub> x10 <sup>6</sup> W.m <sup>-2</sup>	10 <sup>6</sup> x <sub>4</sub> C <sub>4</sub> J and 5xC <sub>4</sub> x10 <sup>3</sup> J.m <sup>-2</sup>		3.5x10 <sup>-3</sup> t <sup>0.75</sup> C <sub>4</sub> J and 18xC <sub>4</sub> t <sup>0.75</sup> J.m <sup>-2</sup>				6x10 <sup>-4</sup> x <sub>4</sub> C <sub>4</sub> W and 3.2xC <sub>4</sub> W.m <sup>-2</sup>	
0 to 1400	10 <sup>4</sup> W and 5x10 <sup>7</sup> W.m <sup>-2</sup>	10 <sup>4</sup> J and 5x10 <sup>3</sup> J.m <sup>-2</sup>			1.8x10 <sup>-2</sup> t <sup>0.75</sup> J and 90t <sup>0.75</sup> J.m <sup>-2</sup>			3x10 <sup>-3</sup> W and 16 W.m <sup>-2</sup>	
0 to 1530	4x10 <sup>5</sup> W	4x10 <sup>4</sup> J and 100 J.m <sup>-2</sup>	2.2x10 <sup>-4</sup> t <sup>0.25</sup> J and 5600xt <sup>0.25</sup> J.m <sup>-2</sup>					4x10 <sup>-3</sup> W	
0 to 1550	and	10000 J.m <sup>-2</sup>	2.2x10 <sup>-4</sup> t <sup>0.25</sup> J and 5600xt <sup>0.25</sup> J.m <sup>-2</sup>					and	
0 to 4000	10 <sup>11</sup> W.m <sup>-2</sup>	4x10 <sup>4</sup> J and 100 J.m <sup>-2</sup>	2.2x10 <sup>-4</sup> t <sup>0.25</sup> J and 5600xt <sup>0.25</sup> J.m <sup>-2</sup>					1000 W.m <sup>-2</sup>	
0 to 10 <sup>6</sup>	10 <sup>11</sup> W.m <sup>-2</sup>	100 J.m <sup>-2</sup>	5600xt <sup>0.25</sup> J.m <sup>-2</sup>					1000 W.m <sup>-2</sup>	



**SECOND SCHEDULE — continued****TABLE 4****ACCESSIBLE EMISSION LIMITS FOR CLASS 3B LASER APPARATUS**

Wave-length $\lambda$ (nm)	Emission Duration t(s)	$<10^{-9}$	$10^{-9}$ to 0.25	0.25 to $3 \times 10^4$
180 to 302.5		$3.8 \times 10^5$ W	$3.8 \times 10^{-4}$ J	$1.5 \times 10^{-3}$ W
302.5 to 315		$1.25 \times 10^4 C_2$ W	$1.25 \times 10^{-5} C_2$ J	$5 \times 10^{-5} C_2$ W
315 to 400		$1.25 \times 10^8$ W	0.125J	0.5 W
400 to 700		$3.14 \times 10^{11}$ W.m <sup>-2</sup>	$3.14 \times 10^5 t^{0.33}$ J.m <sup>-2</sup> and $<10^5$ J.m <sup>-2</sup>	0.5 W
700 to 1050		$3.14 \times 10^{11} C_4$ W.m <sup>-2</sup>	$3.14 \times 10^5 C_4 t^{0.33}$ J.m <sup>-2</sup> and $<10^5$ J.m <sup>-2</sup>	0.5 W
1050 to 1400		$1.57 \times 10^{12}$ W.m <sup>-2</sup>	$1.57 \times 10^6 t^{0.33}$ J.m <sup>-2</sup> and $<10^5$ J.m <sup>-2</sup>	0.5 W
1400 to $10^6$		$10^{14}$ W.m <sup>-2</sup>	$10^5$ J.m <sup>-2</sup>	0.5 W

*Notes to Tables 1 to 4*

1. There is only limited evidence about effects for exposure of less than  $10^{-9}$ s. The AEL's for these exposure times have been derived by maintaining the irradiance, radiance or radiant exposure applying at  $10^{-9}$ s.
2. Correction factors  $C_1$  to  $C_4$  and breakpoint  $T_1$  and  $T_2$  used in Tables 1 to 4 are defined in the following expressions:

<i>Parameter</i>	<i>Spectral region</i>
$C_1 = 5.6 \times 10^3 t^{0.25}$	302.5 to 400 nm
$T_1 = 10^{0.8(\lambda-295)} \times 10^{-15}$ s	302.5 to 315 nm
$C_2 = 10^{0.2(\lambda-295)}$	302.5 to 315 nm
$T_2 = 10 \times 10^{0.02(\lambda-550)}$ s	550 to 700 nm
$C_3 = 10^{0.015(\lambda-550)}$	550 to 700 nm
$C_4 = 10^{(\lambda-700)/500}$	700 to 1050 nm

3. The wavelength range  $\lambda_1$  to  $\lambda_2$  means  $\lambda_1 \leq \lambda < \lambda_2$

**SECOND SCHEDULE — continued****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  $1.0 \times 10^6$  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  $1 \times 10^3$  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  $10 \text{ cm}^2$  with no dimension greater than 5 cm.

**THIRD SCHEDULE: TABLE 3****EXPOSURE LIMITS FOR ULTRAVIOLET RADIATION**

<b>Wavelength (nm)</b>	<b>Exposure Limits (J/m<sup>2</sup>)</b>
180	2500
190	1600
200	1000
205	590
210	400
215	320
220	250
225	200
230	160
235	130
240	100
245	83
250	70
254	60
255	58
260	46
265	37
270	30
275	31
280	34
285	39
290	47
295	56
297	65
300	100
303	250
305	500
308	1200
310	2000
313	5000
315	1.0 x 10 <sup>4</sup>
316	1.3 x 10 <sup>4</sup>
317	1.5 x 10 <sup>4</sup>
318	1.9 x 10 <sup>4</sup>
319	2.5 x 10 <sup>4</sup>
320	2.9 x 10 <sup>4</sup>
322	4.5 x 10 <sup>4</sup>
323	5.6 x 10 <sup>4</sup>
325	6.0 x 10 <sup>4</sup>
328	6.8 x 10 <sup>4</sup>
330	7.3 x 10 <sup>4</sup>
333	8.1 x 10 <sup>4</sup>

335	$8.8 \times 10^4$
340	$1.1 \times 10^5$
345	$1.3 \times 10^5$
350	$1.5 \times 10^5$
355	$1.9 \times 10^5$
360	$2.3 \times 10^5$
365	$2.7 \times 10^5$
370	$3.2 \times 10^5$
375	$3.9 \times 10^5$
380	$4.7 \times 10^5$
385	$5.7 \times 10^5$
390	$6.8 \times 10^5$
395	$8.3 \times 10^5$
400	$1.0 \times 10^6$

**FOURTH SCHEDULE**

**LABELLING FOR LASER APPARATUS**

**LABELLING FOR LASER APPARATUS**

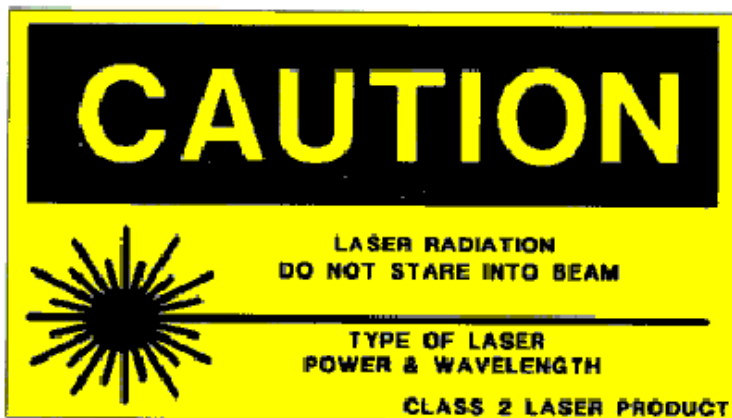
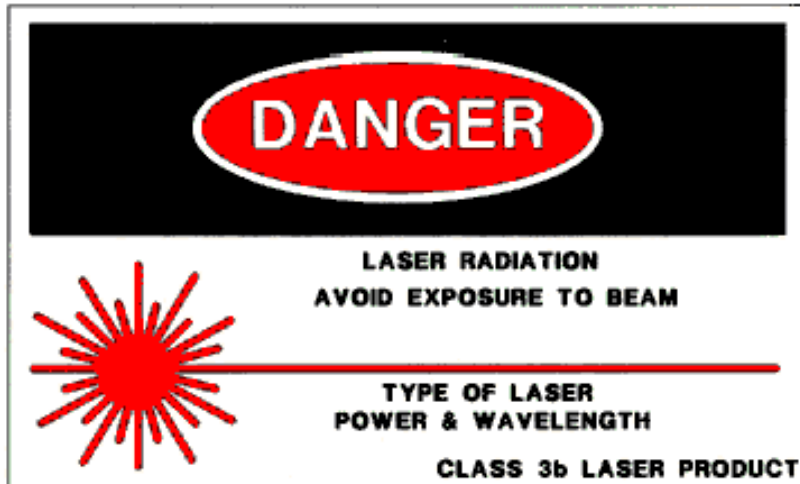
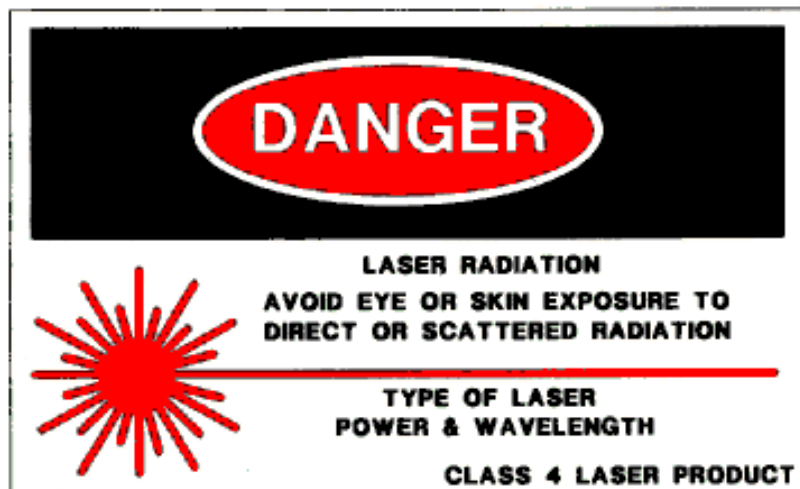


FIGURE 1 *Warning Label for Class 2 Laser Product*



FIGURE 2 *Warning Label for Class 3a Laser Product*

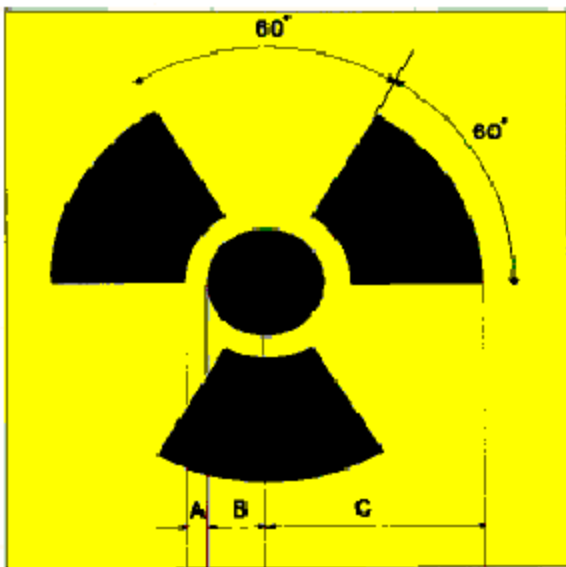
## FOURTH SCHEDULE — continued

FIGURE 3 *Warning Label for Class 3b Laser Product*FIGURE 4 *Warning Label for Class 4 Laser Product*

**FIFTH SCHEDULE****STANDARD SYMBOL FOR DESIGNATING ANY IONISING RADIATION HAZARD**

FIFTH SCHEDULE — continued

Trefoil symbol shall be magenta, purple or black in colour and background shall be yellow.



**Trefoil symbol shall be magenta, purple or black in colour and background shall be yellow.**

**SIXTH SCHEDULE****FEES**

<b>Licence Type</b>	<b>Description</b>	<b>Fees (KSh.)</b>	
<b>GKNIR1</b>	1. Application (registration) for new licence 2. Application for renewal licence (annually) 3. Addition 0.5%CIF of manufactured apparatus	<b>20,000</b> <b>15,000</b>	<b>Manufacture</b>
<b>GKNIR2</b>	4. Application (registration) for new licence 5. Application for renewal licence (annually)	<b>10,000</b> <b>5,000</b>	<b>Possess and use</b>
<b>GKNIR3</b>	6. Application (registration) for new licence 7. Application for renewal licence (annually)	<b>5,000</b> <b>2,000</b>	<b>Keep or use</b>
<b>GKNIR4</b>	8. Application (registration) for new licence 9. Application for renewal licence (annually) 10. Addition 0.5%CIF of manufactured apparatus	<b>5,000</b> <b>2,000</b>	<b>Import</b>
<b>GKNIR5</b>	11. Application (registration) for new licence 12. Application for renewal licence (annually) 13. Addition 0.5%CIF of manufactured apparatus	<b>5,000</b> <b>2,000</b>	<b>Export</b>

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**SEVENTH SCHEDULE**

**LIST OF STANDARDS**

1. IEC 60825-1:2014 - (Australian standards) Safety of laser products - Part 1: Equipment classification and requirements. To buy from Standards Store.

**8TH SCHEDULE**

**GKNIR APPLICATION FORMS**

**GKNIR 1- Manufacture Application Form**



**For Official Use only**

Ref: .....

Reg. No .....

License No. ....

Receipt No.....

APPLICATION FOR REGISTRATION AND  
 LICENSE TO MANUFACTURE OR DEAL IN  
 NON-IONIZING RADIATION DEVICE OR  
 MATERIAL

*Complete this notification form and return to the Authority.  
 Where space is insufficient for any item, attach additional signed  
 sheets.*

1. Name and address of the responsible officer (i.e. legal person) making the notification: .....

Postal Address: .....

Tel: .....

Fax: .....

E-mail Address: .....

2. Business Registration No, .....

3. Is this a New/Renewal application? .....

If Renewal, provide Radiation Protection Board Registration No.....

4. (i) Brief description of irradiating device(s) or radioactive material(s)\*.

.....  
.....  
.....

(ii) Cost of the device or material KSh\* .....

(In words .....  
)

5. Do you have manufacturer's certification?

Yes\*.....No.....

6. Origin/destination of the non-ionizing radiation device or non-ionizing radiation material

(i) Point of origin and address.....

(ii) Destination and address.....

(iii) No. of packages.....  
.....

(iv) Source strength ratings (nm/Hz)  
.....

(v) Mode of transportation and storage conditions.....

(vi) Precautionary measures during transportation  
.....  
.....

7. Describe the purpose for which the non-ionizing radiation device(s) or non-ionizing radiation material(s) will be used (e.g. medical, scientific, industrial, e.t.c)



***Official Stamp:***

**Notes:**

1. The dealer shall notify the Kenya Nuclear Regulatory Authority of every sale of non-ionizing radiation device(s) or non-ionizing radiation material(s).
2. No sale of non-ionizing radiation device or non-ionizing radiation material is permitted unless the purchaser is duly registered by the Kenya Nuclear Regulatory Authority.
3. Disposal of non-ionizing radiation device or non-ionizing radiation material must be certified by the Kenya Nuclear Regulatory Authority

\* Attach certificate from the manufacturer, technical specifications of irradiating device(s) or radioactive material(s) proof of cost, architectural drawings of the storage facility, Business Registration Certificate or delete as necessary

**GKNIR 2- Possess and Use**



\_\_\_\_\_

\_\_\_\_\_

**For Official Use only**

Ref: .....

Reg. No .....

License No. ....

Receipt No.....

APPLICATION FOR REGISTRATION AND  
 LICENSE TO POSSESS AND USE NON-IONIZING  
 RADIATION DEVICE OR MATERIAL

*Complete this notification form and return to the Authority.  
 Where space is insufficient for any item, attach additional signed sheets.*

1. Name and address of the responsible officer (i.e., legal person)..... making the notification:

Postal Address: .....

Tel: .....

Fax: .....

E-mail Address: .....

2. Business Registration No,.....

3. Type of Radiation facility under application .....  
 (See Third Schedule under Radiation Protection regulations)

4. Is this a New/Renewal application?.....

If Renewal, provide Kenya Nuclear Regulatory Authority No. ....

(

5. Describe the purpose for which the non-ionizing radiation device or non-ionizing radiation material will be used (e.g., medical, scientific, industrial, etc.)

.....

6. (i) Brief description of the non-ionizing radiation device or non-ionizing radiation material \*.

.....  
.....

(ii) Name and contact of supplier.....

(iii) Cost of the non-ionizing radiation device or non-ionizing radiation material KSh\*.....

(In words  
.....  
.....)

(iv) Name and contact of service engineer.....

.....  
.....

7. Brief description of the non-ionizing radiation premises (e.g., open, enclosed, building material used, location of the non-ionizing radiation device or non-ionizing radiation material in the building, e.t.c)  
\*

.....

.....  
.....





***Official Stamp:***

**Notes:**

1. Radiation Safety Inspections shall be carried out only by Kenya Nuclear Regulatory Authority certified service provider for purposes of licensing.
2. Disposal of irradiating device or radioactive material must be certified by the by Kenya Nuclear Regulatory Authority

\* Attach technical specifications of device or material, proof of cost, architectural drawings of the irradiation premises and Business Registration Certificate, as applicable.

GKNIR 3- KEEP OR USE



**For Official Use only**

Ref: .....

Reg. No .....

License No. ....

Receipt No.....

APPLICATION FOR REGISTRATION AND  
 LICENSE TO KEEP OR POSSESS AND USE  
 NON-IONIZING RADIATION DEVICE OR  
 MATERIAL

*Complete this notification form and return to the Authority.  
 Where space is insufficient for any item, attach additional signed sheets.*

1. Name of the applicant.....
- Postal Address: .....
- Tel: .....
- Fax: .....
- E-mail Address: .....
2. Business Registration No,.....
3. Type of Radiation facility under application.....  
 (See Third Schedule under Radiation Protection regulations)
4. Is this a New/Renewal application?.....
- If Renewal, provide Kenya Nuclear Regulatory Authority No. ....

(

5. Describe the purpose for which the non-ionizing radiation device or non-ionizing radiation material will be used (e.g. medical, scientific, industrial, e.t.c)

.....

6. (i) Brief description of the non-ionizing radiation device or non-ionizing radiation material \*.

.....  
.....

(ii) Name and contact of supplier.....

(iii) Cost of the non-ionizing radiation device or non-ionizing radiation material KSh\*.....

(In words  
.....  
.....)

(iv) Name and contact of service engineer.....

.....  
.....

7. Brief description of the non-ionizing radiation premises (e.g., open, enclosed, building material used, location of the non-ionizing radiation device or non-ionizing radiation material in the building, etc.) \*

.....  
.....  
.....

8. Radiation Safety Officer in case of non-ionizing radiation material or installation engineer in-charge in case of non-ionizing radiation device.



**Notes:**

1. Radiation Safety Inspections shall be carried out only by Kenya Nuclear Regulatory Authority certified service provider for purposes of licensing.
2. Disposal of irradiating device or radioactive material must be certified by the by Kenya Nuclear Regulatory Authority

\* Attach technical specifications of device or material, proof of cost, architectural drawings of the irradiation premises and Business Registration Certificate, as applicable.

GKNIR 4 - IMPORT



**For Official Use only**

Ref: .....

Reg. No .....

License No. ....

Receipt No.....

**APPLICATION FOR REGISTRATION AND  
LICENSE TO IMPORT NON-IONIZING RADIATION DEVICE OR MATERIAL**

*Complete this notification form and return to the Authority.  
Where space is insufficient for any item, attach additional signed sheets.*

1. Name and address of the responsible officer (i.e. legal person) making the notification: .....

Postal Address: .....

Tel: .....

Fax: .....

E-mail Address: .....

2. Business Registration No, .....

3. Is this a New/Renewal application? .....

If Renewal, provide Radiation Protection Board Registration No .....

4. (i) Brief description of irradiating device(s) or radioactive material(s)\*.

.....

(ii) Cost of the device or material KSh\* .....

(In words .....)

5. Do you have manufacturer's certification?  
Yes\* .....No.....

6. Origin/destination of the non-ionizing radiation device or non-ionizing radiation material

(vii) Point of origin and address.....

(viii) Destination and address.....

(ix) No. of packages.....

(x) Source strength ratings (KV/mA/MeV/Bq/Ci, etc.)  
.....

(xi) Mode of transportation and storage conditions.....

(xii) Precautionary measures during transportation  
.....

7. Describe the purpose for which the non-ionizing radiation device(s) or non-ionizing radiation material(s) will be used (e.g. medical, scientific, industrial, etc.)

8.  
.....

9. Radiation Safety Officer in case of radioactive material or installation engineer in-charge in case of irradiating device.

Name.....

Radiation Protection Board Registration No.....

Radiation Protection Board Licence No.....

Designation.....

Alternative contact address.....

10. List of other Radiation Safety Officers/Engineers (use separate sheet if necessary)

Name	Registration No.	Licence No.
.....	.....	.....
.....	.....	.....

**Declaration by Applicant:**

I ..... hereby declare and certify that the information given in this application including attachments thereto is true and correct to the best of my knowledge and belief.

**Date:** ..... **Signature:** .....

**Designation**.....

**Official Stamp:**

**Notes:**

1. The dealer shall notify the Kenya Nuclear Regulatory Authority of every sale of non-ionizing radiation device(s) or non-ionizing radiation material(s).
2. No sale of non-ionizing radiation device or non-ionizing radiation material is permitted unless the purchaser is duly registered by the Kenya Nuclear Regulatory Authority.
3. Disposal of non-ionizing radiation device or non-ionizing radiation material must be certified by the Kenya Nuclear Regulatory Authority

\* Attach certificate from the manufacturer, technical specifications of irradiating device(s) or radioactive material(s) proof of cost, architectural drawings of the storage facility, Business Registration Certificate or delete as necessary



GKNIR 5- EXPORT



**For Official Use only**

Ref: .....

Reg. No .....

License No. ....

Receipt No.....

APPLICATION FOR REGISTRATION AND  
 LICENSE TO EXPORT NON-IONIZING  
 RADIATION DEVICE OR MATERIAL

*Complete this notification form and return to the Authority.  
 Where space is insufficient for any item, attach additional signed sheets.*

1. Name and address of the .....  
 responsible officer (i.e. legal .....  
 person) making the notification:  
  
 Postal Address:  
  
 Tel: .....  
  
 Fax: .....  
  
 E-mail Address: .....
2. Business Registration No, .....
3. Is this a New/Renewal application? .....
- If Renewal, provide Radiation Protection Board Registration No .....
4. (i) Brief description of irradiating device(s) or radioactive material(s)\*.

.....  
.....  
.....  
.....

(ii) Cost of the device or material Ksh\* .....

(In words .....  
)

5. Do you have manufacturer's certification?  
Yes\*.....No.....

6. Origin/destination of the non-ionizing radiation device or non-ionizing radiation material

(xiii) Point of origin and address.....  
.....

(xiv) Destination and address.....

(xv) No. of packages.....  
.....

(xvi) Source strength ratings (KV/mA/MeV/Bq/Ci, etc.)  
.....

(xvii) Mode of transportation and storage conditions.....

(xviii)Precautionary measures during transportation  
.....  
.....

7. Describe the purpose for which the non-ionizing radiation device(s) or non-ionizing radiation material(s) will be used (e.g. medical, scientific, industrial, etc.)

8.  
.....  
.....

9. Radiation Safety Officer in case of radioactive material or installation engineer in-charge in case of irradiating device.

Name.....  
.....

Radiation Protection Board Registration  
No.....

Radiation Protection Board Licence  
No.....

Designation.....  
.....

Alternative contact  
address.....  
...

10. List of other Radiation Safety Officers/Engineers (use separate sheet if necessary)

Name	Registration No.
Licence No.	
.....	.....
.....	.....
.....	.....
.....	.....

**Declaration by Applicant:**

I ..... hereby declare and certify that the information given in this application including attachments thereto is true and correct to the best of my knowledge and belief.

**Date:** ..... **Signature:**  
.....

**Designation**.....  
.....

***Official Stamp:***

**Notes:**

1. The dealer shall notify the Kenya Nuclear Regulatory Authority of every sale of non-ionizing radiation device(s) or non-ionizing radiation material(s).
2. No sale of non-ionizing radiation device or non-ionizing radiation material is permitted unless the purchaser is duly registered by the Kenya Nuclear Regulatory Authority.
3. Disposal of non-ionizing radiation device or non-ionizing radiation material must be certified by the Kenya Nuclear Regulatory Authority

\* Attach certificate from the manufacturer, technical specifications of irradiating device(s) or radioactive material(s) proof of cost, architectural drawings of the storage facility, Business Registration Certificate or delete as necessary