

Radiation Safety Act 1999

RADIATION SAFETY STANDARD

HR006:2010

Standard for Class 4 lasers used to carry out cosmetic or health related procedures on human beings

Preface

Under section 17 of the *Radiation Safety Act 1999*, a possession licensee who, under a licence, possesses a laser apparatus to carry out a radiation practice, must ensure that the apparatus is not used for this purpose, unless the laser apparatus complies with the relevant standard.

This radiation safety standard HR006:2010 *Standard for Class 4 lasers used to carry out cosmetic or health related procedures on human beings* is made under section 16 of the *Radiation Safety Act 1999*.

This standard sets the minimum safety criteria for laser apparatus used to carry out cosmetic or health related procedures on human beings. Compliance with this standard will assist in ensuring that public and occupational exposure to radiation is minimised.

Queensland Health has prepared this standard based on information derived from reputable sources such as Standards Australia and Standards New Zealand.

The standard will be reviewed periodically to re-evaluate its currency and its appropriateness as the standard for laser apparatus used to carry out a radiation practice.

By ensuring compliance with this radiation safety standard, the standard of laser apparatus in Queensland will be significantly enhanced.

I, Paul Lucas, Deputy Premier and Minister for Health, pursuant to section 16(1) of the *Radiation Safety Act 1999*, make the radiation safety standard HR006:2010 *Standard for Class 4 lasers used to carry out cosmetic or health related procedures on human beings*, for the purposes of the Act.

SIGNED

PAUL LUCAS MP
Deputy Premier
Minister for Health

19 / 08 / 2010

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Standard for Class 4 lasers used to carry out cosmetic or health related procedures on human beings

Section 1 – General

1.1 Scope

This radiation safety standard sets out the minimum requirements for laser apparatus which is used to carry out cosmetic or health related procedures on human beings.

To remove doubt, this standard also applies to laser apparatus that is used to carry out research involving cosmetic or health related procedures on humans.

1.2 Expiry

This radiation safety standard expires on 1 September 2020.

1.3 Documents

Documents which may provide some useful information are listed in Appendix A.

1.4 Definitions

In this standard –

"assessible emission level" means the magnitude of laser radiation of a wavelength and emission duration to which human access is possible.

"Class 1" means a laser which does not permit human access to radiation in excess of the accessible emission limits in Table 1 of the Australian/New Zealand Standard *Laser Safety Part 1: Equipment classification, requirements and user's guide* AS/NZS 2211.1:1997¹ for applicable wavelengths and emission durations.

"Class 2" means a laser which:

- (a) permits human access to radiation in excess of the accessible emission limits of Class 1, but not in excess of the accessible emission limits in Table 2 of the Australian/New Zealand Standard *Laser Safety Part 1: Equipment classification, requirements and user's guide* AS/NZS 2211.1:1997 in the wavelength range from 400 nanometres to 700 nanometres; and
- (b) does not permit human access to laser radiation in excess of the accessible emission limits of Class 1 for any other wavelength.

"Class 3A" means a laser which permits human access to radiation in excess of the accessible emission limits in Class 1 and Class 2 as applicable, but which does not permit human access to radiation in excess of the accessible emission limits in Table 3 of the Australian/New Zealand Standard *Laser Safety Part 1: Equipment classification, requirements and user's guide* AS/NZS 2211.1:1997 for any emission duration and

¹ Copies of the Australian/New Zealand Standard are available from Standards Australia, 232 St Pauls Terrace, Fortitude Valley, Brisbane.

wavelength.

"Class 3B" means a laser which permits human access to radiation in excess of the accessible emission limits in Class 1 and Class 2 as applicable, but which does not permit human access to radiation in excess of the accessible emission limits in Table 4 of the Australian/New Zealand Standard *Laser Safety Part 1: Equipment classification, requirements and user's guide* AS/NZS 2211.1:1997 for any emission duration and wavelength.

"Class 4" means a laser which permits human access to laser radiation in excess of the accessible emission limits in Table 4 of the Australian/New Zealand Standard *Laser Safety Part 1: Equipment classification, requirements and user's guide* AS/NZS 2211.1:1997.

"laser" means any device which can be made to produce or amplify electromagnetic radiation in the wavelength range from 100 nanometres to 1 millimetre primarily by the process of controlled stimulated emission.

"laser apparatus" means a laser which permits human access to laser radiation in excess of the accessible emission limits in Table 4 for Class 3B of the Australian/New Zealand Standard *Laser Safety Part 1: Equipment classification, requirements and user's guide* AS/NZS 2211.1:1997.

"laser warning sign" means the non-ionising radiation hazard symbol as described in Figure 2 of the Australian/New Zealand Standard *Laser Safety Part 1: Equipment classification, requirements and user's guide* AS/NZS 2211.1:1997.

Section 2 - Standard – Laser apparatus

Test	Compliance Test	Criteria for Passing the Test
<i>Protective housing</i>		
1	Protective housing	Each laser apparatus must have a protective housing which, when in place, prevents human access to radiation in excess of Class 1, except when human access is necessary for the performance of the functions of the laser.
2	Service	<p>Any parts of the housing or enclosure of a laser apparatus (including embedded lasers):</p> <ul style="list-style-type: none"> (a) that can be removed or displaced for service; and (b) which would allow access to radiation in excess of the accessible emission limit; and (c) are not interlocked; <p>must be secured in such a way that removal or displacement of the parts requires the use of tools.</p>
<i>Access panels and safety interlocks</i>		
3	Safety interlocks	<p>A safety interlock must be provided for access panels of protective housings when both of the following conditions are met:</p> <ul style="list-style-type: none"> (a) the access panel is intended to be removed or displaced during maintenance or operation; and (b) the removal of the panel gives human access to radiation levels in excess of the accessible emission limit to Class 3A. <p>Removal of the access panel must not result in emission through the opening in excess of the accessible emission limit for Class 3A.</p> <p>A safety interlock is not required if the interior accessible radiation is Class 3B, is in the range of 400 nanometres to 700 nanometres, and is less than five times the accessible emission limits of Class 2.</p>

Test	Compliance Test	Criteria for Passing the Test
4	Safety interlock design	<p>The safety interlock must be of a design which prevents the removal of the panel until the accessible emission levels are:</p> <ul style="list-style-type: none"> (a) below the accessible emission limits for a laser apparatus; and (b) below the accessible emission limits for Class 3B, is in the range of 400 nanometres to 700 nanometres, and is less than five times the accessible emission limits of Class 2. <p>Inadvertent resetting of the interlock must not in itself restore emission values above the accessible emission limits of a laser apparatus or above the limits specified above.</p>
5	Override mechanisms	<p>If the safety interlock has a deliberate override mechanism, it must not be possible to leave the override in operation when the access panel is returned to its normal position.</p> <p>The interlock must be clearly associated with a label containing the following information:</p> <ul style="list-style-type: none"> • "Caution – laser radiation when open and interlocks defeated" • "Avoid eye or skin exposure to direct or scattered radiation" <p>If the output of the laser apparatus is:</p> <ul style="list-style-type: none"> (a) outside the wavelength range from 400 nanometres to 700 nanometres, the words "laser radiation" must read "invisible laser radiation"; or (b) at wavelengths both inside and outside this wavelength range, the words "laser radiation" must read "visible and invisible laser radiation"; or (c) is in the wavelength range from 400 nanometres to 700 nanometres, the wording "laser radiation" must read "visible laser radiation". <p>For light emitting diode (LED) radiation, the word "laser" on the label must be replaced by "LED".</p>

Test	Compliance Test	Criteria for Passing the Test
Remote interlock connector		
6	Remote interlock connector	<p>The laser apparatus must have a remote interlock electrical connector. When the terminals of the connector are open-circuited, the accessible radiation must not exceed the accessible emission limit for Class 3A.</p>
Key control		
7	Key control	<p>The laser apparatus must incorporate a key-operated master control. The key must be removable and the radiation must not be accessible when the key is removed.</p> <p>The term "key" includes any of the control devices, such as magnetic cards and cipher combinations.</p>
Laser radiation emission warning		
8	Warning devices	<p>The laser apparatus must give an audible or visible warning when it is switched on or if capacitor banks of a pulsed laser are being charged or have not been positively discharged.</p> <p>The warning device must be fail safe, that is, in failure mode the system is rendered inoperative or non-hazardous.</p> <p>Any visible warning devices must be clearly visible through protective eyewear specifically designed for the wavelength(s) of the emitted radiation.</p> <p>The visible warning device(s) must be located so that viewing does not require exposure to radiation in excess of the accessible emission limit for Class 2.</p>
9	Warning device distances	<p>Each operational control and laser aperture that can be separated by 2 metres or more from a radiation warning device must itself be provided with a radiation warning device.</p> <p>The warning device must be clearly visible or audible to the person in the vicinity of the operational control or laser aperture.</p>
10	Aperture indication	<p>Where the laser emission may be distributed through more than one output aperture, then a visible warning device must clearly visible or audible to the person in the vicinity of the operational control or laser aperture.</p>

Test	Compliance Test	Criteria for Passing the Test
Beam stop or attenuator		
11	Beam stop or attenuator	<p>Each laser apparatus must incorporate one or more permanently attached means of attenuation (beam stop or attenuator, other than a laser energy source switch, mains connector or key control).</p> <p>The beam stop or attenuator must be capable of preventing human access to laser radiation in excess of the accessible emission limits for Class 3A.</p>
Controls		
12	Controls	<p>Each radiation apparatus must have controls located so that adjustment and operation do not require exposure to radiation in excess of the accessible emission limits for Class 2.</p>
Viewing optics		
13	Viewing optics	<p>Any viewing optics, viewport or display screen incorporated in a laser must provide sufficient attenuation to prevent human access to radiation in excess of the accessible emission limits for Class 1, and for any shutter or variable attenuator incorporated in the viewing optics, viewports or display screen, a means must be provided to:</p> <ul style="list-style-type: none"> (a) prevent human access to radiation in excess of the excess of the accessible emission limits for Class 1 when the shutter is opened or the attenuation varied; and (b) prevent opening of the shutter or variation of the attenuator when exposure to laser radiation in excess of the accessible emission limits for Class 1 is possible.
Scanning safeguard		
14	Scanning safeguards	<p>Lasers intended to emit scanned radiation, and classified on this basis, must not, as a result of scan failure or of variation in either scan velocity or amplitude, permit human access to radiation in excess of the accessible emission limit for a laser apparatus.</p>
“Walk-in” access		
15	Access	<p>If a protective housing is equipped with an access panel which provides “walk in” access then:</p> <ul style="list-style-type: none"> (a) means must be provided so that any person entering the housing can prevent unintentional activation of the laser hazard; and (b) an emission warning device must be situated so as to provide adequate warning to any person, who might be within the housing.

Test	Compliance Test	Criteria for Passing the Test
Warning signs		
16	Radiation warning sign	<p>Permanently fixed, legible and clearly visible labels must be so positioned that they can be read without the necessity for human exposure to laser radiation.</p> <p>The label must contain the laser warning sign and the following words:</p> <ul style="list-style-type: none"> • "Laser radiation" • "Avoid eye or skin exposure to direct or scattered radiation" • "Class 4 laser product" <p>Additionally, a label must be affixed close to each aperture which bears the words:</p> <ul style="list-style-type: none"> • "Laser aperture"; or • "Avoid exposure – laser radiation is emitted from this aperture" <p>Lettering and symbols must be black on a yellow background.</p> <p>If the output of the laser is:</p> <p>(a) outside the wavelength range from 400 nanometres to 700 nanometres the words "laser radiation" must read "invisible laser radiation";</p> <p>(b) at wavelengths both inside and outside this wavelength range, the "laser radiation" must read "visible and invisible laser radiation"; and</p> <p>(c) in the visible wavelength range from 400 nanometres to 700 nanometres, the wording "laser radiation" must read "laser light".</p> <p>For light emitting diode (LED) radiation, the word "laser" on the label must be replaced by "LED".</p>

Test	Compliance Test	Criteria for Passing the Test
17	Explanatory label	<p>Each radiation apparatus must be labelled with an explanatory label which contains:</p> <ul style="list-style-type: none"> • the maximum output of the laser radiation • the pulse duration (if appropriate) • the emitted wavelength(s). <p>The identity number and publication date of the Australian Standard, or equivalent, to which the product was classified must also be included on the explanatory label, or in close proximity, on the laser apparatus.</p> <p>This label must be permanently fixed, legible and clearly visible and must be positioned that it can be read without the necessity for human exposure to laser radiation.</p>
18	Labels for access panels	<p>Each connection, each panel of a protective housing and each access panel of a protective enclosure which when removed or displaced permits human access to laser radiation in excess of the accessible emission standards for Class 1 must have affixed a label bearing the words:</p> <ul style="list-style-type: none"> • “Caution – laser radiation when open.” • “Avoid eye or skin exposure to direct or scattered radiation.” <p>If the output is at wavelengths both inside and outside this wavelength range, the “laser radiation” must read “visible and invisible laser radiation”.</p> <p>If the output of the laser is in the visible wavelength range from 400 nanometres to 700 nanometres, the working “laser radiation” must read “laser light”.</p> <p>For light emitting diode (LED) radiation, the word “laser” on the label must be replaced by “LED”.</p>

Appendix A

Documents

Australian/New Zealand Standard. *Laser safety Part 1: Equipment classification, requirements and user's guide*. AS/NZS 2211.1:1997.

Australian/New Zealand Standard. *Guide to the safe use of lasers in health care*. AS/NZS 4173:1994.