Department of Health and Human services
Population Health

Radiation Protection Act 2005

CERTIFICATE OF COMPLIANCE:

STANDARD FOR RADIATION APPARATUS -

LOW INTENSITY LASER

(CLASS 3B)

SECTION 1: REQUIREMENTS FOR CERTIFICATES OF COMPLIANCE FOR CLASSES OF RADIATION APPARATUS

SECTION 2: PARTS OF STANDARDS AND CODES OF PRACTICE ADOPTED BY THIS STANDARD

This information can also be accessed at
http://www.dhhs.tas.gov.au/peh/radiation_protection

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Section 1 – REQUIREMENTS FOR CERTIFICATES OF COMPLIANCE FOR CLASSES OF RADIATION APPARATUS.

PART – A

Section 2 of this Standard is to be used by an accredited person when assessing Radiation Apparatus, classified by Radiation Protection Act 2005 licences as "Laser Class 3B", used for low intensity laser therapy in areas such as physiotherapy, chiropracty and podiatry, for the purpose of issuing a certificate of compliance in accordance with 17 (1) (b) of the Radiation Protection Act 2005 when these radiation apparatus are to be used for veterinary radiology only.

The Radiation Apparatus must be shown to fully comply with the requirements in Section 2 of this Standard.

† **Where an item was demonstrated to comply at the time of manufacture or supply, ongoing compliance for that item may be stated only if it is reasonable to assume there has been no change, modification, damage or unacceptable wear and tear to that item since the time of manufacture.**

The requirements in Section 2 are taken from the following:

AS/NZS 2211.1-2004 IEC 60825-1:2001,MOD	Safety of laser products Part 1:Equipment classification, requirements and users guide.
AS/NZS 3200.2.22-1997 IEC 601-2-22:1995	Approval and test specification-Medical electrical equipment Part 2.22 Particular requirements for safety – Diagnostic and therapeutic laser Equipment.
AS/NZS 4173:2004	Guide to the safe use of lasers in health care.
RAR	Regulatory Authority Requirement

PART – B

Section 2 of this Standard is to be used by an accredited person when assessing Radiation Apparatus, classified by Radiation Protection Act 2005 licences as "Laser Class 3B", used for low intensity laser therapy in areas such as physiotherapy, chiropracty and podiatry, for the purpose of issuing a certificate of compliance in accordance with 17 (1) (b) of the Radiation Protection Act 2005 when these radiation apparatus are to be used for veterinary radiology only.

The holder of a licence to manufacture or sell such Radiation Apparatus must be able to show that the Radiation Apparatus fully complies with the following Standards*.

AS/NZS 2211.1-2004 IEC 60825-1:2001,MOD	Safety of laser products Part 1:Equipment classification, requirements and users guide.
AS/NZS 3200.2.22-1997 IEC 601-2-22:1995	Approval and test specification-Medical electrical equipment Part 2.22 Particular requirements for safety – Diagnostic and therapeutic laser Equipment.
AS/NZS 4173:2004	Guide to the safe use of lasers in health care.

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* In many cases radiation apparatus will bear the **"CE"** mark, and comply with the requirements of **MDD 93/42/EEC.** As part of the process of obtaining a CE mark the manufacturer makes an application to a "Certifying Body" to have the equipment assessed. Annex III of the MDD directive states that in making an application for **"EC type examination"** the manufacturer would, in their application, state the "Standards" that they wished to be tested against (article 5).

In order for licensed manufacturers or sellers to issue a certificate of compliance under the Radiation Protection Act 2005, they need only demonstrate that they hold, or have access to, the "***EC Declaration of Conformity"*** documents which show that the "make and model" of apparatus they are supplying complies with the Standards listed in Part B above.

Section 2 – PARTS OF STANDARDS AND CODES OF PRACTICE ADOPTED BY THIS STANDARD

ITEM	Requirements
laser product -general engineering specifications	
protective housing†	**AS/NZS 2211.1 4.2.1** each laser product must have a protective housing which, when in place, prevents human access to laser radiation (including errant laser radiation) in excess of class 1, except when human access is necessary for the performance of the function (s) of the product.
removal of parts for service†	**AS/NZS 2211.1 4.2.2.** any parts of the housing or enclosure of a laser product (including embedded laser products) that can be removed or displaced for service and which would allow access to laser radiation in excess of the AEL assigned and are not interlocked must be secured in such a way that removal or displacement of the parts requires the use of tools
safety interlocks†	**AS/NZS 2211.1 4.3.1 a), b)** a safety interlock must be provided for access panels of protective housings when both of the following conditions are met: a) the access panel is intended to be removed or displaced during maintenance or operation. b) the removal of the panel gives access to laser radiation levels designated by X in the table. Removal of the panel must not result in emissions through the opening in excess of Class 1 M or Class 2 M as applicable according to the wavelength. The safety interlock must be of a design which prevents the removal of the panel until the accessible emission levels are below the AEL of the Class assigned and, in any case, below the limits specified in 4.3.1 b). Inadvertent resetting of the interlock must not in itself restore the emission values above the AEL of the class assigned nor above the limits specified in 4.3.1 b).

override mechanism and a label on the interlock	**AS/NZS 2211.1 4.3.2** If a deliberate override mechanism is provided, the manufacturer must also provide adequate instruction about safe methods of working. † It must not be possible to leave the override in operation when the access panel is returned to its normal position. † The interlock must be clearly associated with a label conforming to 5.9.2 "caution - laser radiation when opened and interlocks defeated". † Use of the override must give rise to a distinct visible or audible warning whenever the laser is energised or capacitor banks are not fully discharged, whether or not the access panel is removed or displaced. A visible warning must be clearly visible through protective eyewear appropriate for use with the particular laser.
remote interlock connector	**AS/NZS 2211.1 4.4** each class 3B and 4 laser system must have a remote interlock connector. When the terminals of the connector are open – circuited, the accessible radiation must not exceed class 1 M or Class 2 M as applicable.
key control	**AS/NZS 2211.1 4.5** each class 3B and Class 4 laser system must incorporate a key operated master control. The key must be removable and the laser radiation must not be accessible when the key is removed. In this part the term "key" includes any control devices, such as magnetic cards, cipher combinations, etc.
laser radiation emission warning	**AS/NZS 2211.1 4.6.1** Each Class 3B and Class 4 laser system 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. The warning device must be fail - safe or redundant. Any visible warning must be clearly visible through protective eyewear appropriate for use with the particular laser. The visible warning must be located so that viewing does not require exposure to laser radiation in excess of the AEL for Class 1 M and Class 2 M
warning device distances	**AS/NZS 2211.1 4.6.2** 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. The warning device must be clearly visible or audible to the person in the vicinity of the operational control or laser aperture.
aperture indication	**AS/NZS 2211.1 4.6.3** where the laser emission may be distributed through more than one aperture, then a visible warning device must clearly indicate the output aperture or apertures through which laser emission can occur.

beam stop or attenuator	**AS/NZS 2211.1 4.7** each Class 3B and Class 4 laser system 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). The beam stop or attenuator must be capable of preventing human access to laser radiation in excess of Class 1M or Class 2 M as appropriate,
scanning safeguard†	**AS/NZS 2211.1 4.10** laser products 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 laser radiation in excess of the AEL for the assigned class.
labelling labels for access panels†	**AS/NZS 2211.1 5.2,5.3,5.4,5.5, 5.6 and 5.7** each laser product must carry labels in accordance with of **AS/NZS 2211.1 5.9.1, 5.9.2.** 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 AEL for Class 1 must have labelling as per
laser product -information provided by the manufacturer to the user	**AS/NZS 2211.1 6.1 a), b), c), d), e), f)** The appropriate documentation containing the following information must be available (manufacturers of laser products must provide (or see to the provision of) the following information) a) adequate instructions for proper assembly, maintenance and safe use including clear warnings concerning precautions to avoid possible exposure to hazardous laser radiation and other hazards associated with the equipment. b) A statement in appropriate units of beam divergence for collimated beams, pulse duration and maximum output, with the magnitudes of the cumulative measurement uncertainty and any expected increase in the measured quantities at any time after the manufacture added to the values measured at the time of manufacture (duration of pulses resulting from unintentional mode-locking need not be specified); however those conditions associated with the product known to result in unintentional mode locking must be specified). Additionally for embedded laser products and other incorporated laser products, similar information must be provided to describe the incorporated laser. The information must also include appropriate safety instructions to the user to avoid inadvertent exposure to hazardous laser radiation.
	c) legible reproductions of all required labels and hazard warnings to be affixed to the laser product or provided with the laser product. The corresponding positions of each label affixed to the product must be indicated or, if provided with the product, a statement that such labels could not be affixed to the product but were supplied with the product and a statement of the form and manner in which they were supplied must be provided.

	d) a clear indication in the manual of all locations of laser apertures. e) a listing of controls, adjustments and procedures for operation and maintenance, including the warning "Caution-Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure".
	f) in the case of laser products that do not incorporate the laser energy source necessary for laser emission a statement of the compatibility requirements for a laser energy source to ensure safety.
equipment requirements - for particular uses	
compliance with electrical safety and power calibration	each medical laser product must comply with all of the applicable requirements for laser products of its class. In addition the following apply: **AS/NZS 4173 8.3.6** Distal beam power (or pulse energy) or, alternatively, distal power (or energy) as a percentage of cavity output (which is measured in many lasers) must be regularly determined. Evidence of that this has been done regularly (or in accordance with the manufacturer's requirements) must be available. ***RAR***

Basic User QA tests TABLE 8.1 AS/NZS 4173	**Clause No**	**Equipment Part Recommended Frequency of Test**
		The laser must be subject to regular quality assurance (QA) testing by the user or other appropriate person. A QA checklist comprising the following items is the minimum requirement for QA checking**. NOTE: QA checking is not a substitute for maintenance and servicing of the laser as recommended by the laser manufacturer or agent.** ***RAR***
	8.3.2	Power and footswitch cables. Prior to each use or daily, whichever is least frequent
	8.3.3	Emergency laser stop switches - Monthly
	8.3.4	User-accessible interlocks - Monthly
	8.3.5	Laser emission indicator(s) Prior to each use or daily, whichever is least frequent
	8.3.6	Beam power/pulse energy At the time of preventive maintenance
	8.3.7	Articulated arm movement and physical checks
	8.3.8	Convergence of aiming and main beam Daily, and after repositioning or change of delivery
	8.3.9	Fibre (physical check) Each change of fibre
	8.3.10	Aiming beam quality Prior to each procedure or change of fibre delivery system accessory
	8.3.11	Specialized accessories Prior to each use
	8.3.12	Protective eyewear Prior to each use