

Australian/New Zealand Standard™

**Safe use of lasers and intense light
sources in health care**



AS/NZS 4173:2018

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Australian/New Zealand Standard™

Safe use of lasers and intense light sources in health care

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Sub-Committee HE-003-12, Lasers in Medical Procedures, under the responsibility of Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 4173:2004, *Guide to the safe use of lasers in health care*.

The objective of this Standard is to specify requirements for the safe use of lasers and intense light sources, including intense pulsed light (IPL) for diagnostic, cosmetic and therapeutic uses in health care facilities (including hospitals, private medical facilities and dental practices) and the cosmetic industry. To this end, it identifies engineering and administrative control measures designed to avoid the most significant hazards, and includes in Appendices explanations of basic laser and light physics as they apply to this Standard, and radiation/tissue interactions. Protocols to be observed during certain specialist medical and dental procedures are also included.

This Standard was prepared in the knowledge that separate Standards exist for medical laser and IPL equipment (AS IEC 60601.2.22, *Medical electrical equipment, Part 2.22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*, and AS IEC 60601.2.57, *Medical electrical equipment, Part 2.57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use*, respectively). These Standards incorporate mandatory engineering and installation requirements to be observed by the manufacturers and constructors. Accordingly, this Standard concentrates on identifying those administrative needs and user precautions which are of equal importance. In particular, the importance of staff training is emphasized and this Standard—

- (a) identifies appropriate levels of staff training (i.e. not all staff are required to be trained to the same level); and
- (b) recommends that relevant educational organizations insist on formal medical laser/ILS training and certification of post graduate specialists.

This Standard differs from the second (2004) edition in the following respects:

- (i) Changes to the IEC laser classification scheme.
- (ii) The terminology and language used is intended to make it easier to read, interpret, and implement where applicable, for users and administrators alike.
- (iii) Normative material has been separated from informative material, the latter being in Appendices.
- (iv) Descriptions and definitions have been updated, taking into account the changes in the technology and science of lasers in health care since the second edition.
- (v) Inclusion of consideration of intense light sources, in particular IPLs which, while using incoherent light and thus not lasers, have similar operator and patient safety issues.

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The term ‘informative’ has been used in this Standard to define the application of the appendix to which it applies. An ‘informative’ appendix is only for information and guidance.

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FOREWORD

Laser technology applied to health care offers the potential for practical solutions to clinical procedures in areas hitherto regarded as difficult to manage. These include areas where the tissue is delicate (e.g. the retina), extremely vascular (e.g. the liver and tumours), or where access is difficult (e.g. the central trachea), cosmetic treatments, dentistry and veterinary medicine. Lasers are also increasingly used in non-destructive tissue applications for pain relief and tissue repair (photobiomodulation, sometimes known as low level laser therapy), as well as in diagnostic procedures such as laser Doppler flowmetry, optical coherence tomography, and laser-induced fluorescence.

Complementary to lasers is a new class of devices known as intense light sources, predominantly, but not exclusively, used in cosmetic medicine. The most common device in this class is called intense pulsed light (IPL).

The development of super-powerful, quasi-monochromatic light emitting diodes (LEDs) which can be mounted in planar arrays or articulated arms also provide a further source of high light intensity in clinically useful narrow bandwidths for cutaneous phototherapy. The primary clinical use of LED arrays is in photodynamic therapy (PDT) whereby biological tissue including a photosensitizer may absorb more heat than without a photosensitizer. The risks, including non-linear effects are dealt with in a separate IEC standard in development (IEC 60601-2-75) at the time of publication.

Use of intense light sources, including IPLs and by extension LED arrays, has been included as this is a rapidly growing technology in medical care, and, while they are incoherent (i.e. not laser) sources, the patient and operator safety issues are very similar. Some laser users may also use intense light sources, and some clinical applications can use either technology.

It is not intended that the recommended control measures should restrict or limit the use of laser and intense light source radiation which may be intentionally administered to a patient for diagnostic, cosmetic, therapeutic, surgical or medical research purposes. However, the controls are those considered necessary for the safety of all attending staff, as well as those which should be considered as fundamental to patient safety.

The laser types and applications addressed in this Standard are current at the time of writing. Given the rapid development in the field, efforts will be made to revise the Standard as the technology and its applications change.

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Australian/New Zealand Standard**Safe use of lasers and intense light sources in health care**

SECTION 1 SCOPE AND GENERAL

1.1 SCOPE

This Standard specifies requirements for the safe use of lasers and laser systems as well as intense light sources (ILS) in the treatment of humans for diagnostic, cosmetic, therapeutic, medical and dental uses in health care facilities, including hospitals, private medical facilities and dental practices, and the cosmetic industry.

NOTE: Information on lasers and ILS, and their properties, is provided in Appendix A.

The Standard explains the procedural and administrative controls necessary for the safety of patients, health care staff, maintenance personnel, and others who may be in the vicinity of the treatment room and in need of protection against inadvertent exposure. Engineering controls are an important part of laser safety and form part of the laser equipment or the installation. These are briefly described to provide an understanding of the general principles of protection.

Detailed specification of laser equipment, installation and engineering controls are not included in this Standard, such requirements being separately specified in AS IEC 60601.2.22.

NOTES:

- 1 The principles of laser operation and the nature of the associated hazards are briefly described. Examples of specific guidelines for the safe use of lasers in a variety of clinical applications are given in Appendix B.
- 2 Intense light sources (ILS) including intense pulsed light (IPL) and light-emitting diode (LED) are polychromatic but still may be an optical or thermal hazard. In particular, safety eyewear designed for laser use is not safe for use with ILS and the reverse. IPL equipment requirements are set out in AS IEC 60601.2.57.
- 3 ILS other than IPLs also used in health care are included within the scope of this Standard as they are increasingly being used in photobiomodulation and phototherapy applications. A future edition or addendum to this Standard may be required as international standards relating to LED use in health care are developed.
- 4 Guidance on biological effects is provided in Appendix D.

1.2 APPLICATION

The Standard is intended for application in hospital operating rooms, clinics, dentistry or private practices, where laser or intense light source equipment is used in association with diagnosis, therapy, surgery or cosmetic treatment.

Safety principles incorporated in this Standard may be equally applied to the use of lasers in veterinary practice.

It is intended for use by the governing body of a health care facility (e.g. a hospital), the management, clinicians, nurses, nurse practitioners, engineers, physical scientists, dentists and other personnel concerned with the application or the use of lasers in diagnostic, cosmetic, therapeutic, medical and dental procedures.

While the new class of devices known as intense light sources (ILS) have been included in this edition, the predominant ILS device at the time of publication is the intense pulsed light (IPL) source. As such, much of this Standard is specifically devoted to IPLs. Where general ILS safety principles are covered, these are placed under a general ILS heading.

Unless otherwise stated, only ILS of Risk Group 3 require adherence to the requirements of this Standard.

NOTE: Appendix G provides information on the classification of risk groups.

1.3 REFERENCED DOCUMENTS

The following documents are referred to in this Standard:

AS

- 1885 Measurement of occupational health and safety performance
- 1885.1 Part 1: Describing and reporting occupational injuries and disease

AS IEC

- 60601 Medical electrical equipment
- 60601.2.22 Part 2.22: Particular requirements for safety—Diagnostic and therapeutic laser equipment
- 60601.2.57 Part 2.57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

AS ISO

- 16571 Systems for evacuation of plume generated by medical devices

AS/NZS

- 1337 Eye and face protection
- 1337.4 Part 4: Filters and eye protectors against laser radiation (laser eye-protectors)
- 1715 Selection, use and maintenance of respiratory protective equipment
- 3200 Medical electrical equipment (series)
- 3551 Management programs for medical equipment
- 4187 Reprocessing of reusable medical devices in health service organizations

AS/NZS IEC

- 60825 Safety of laser products
- 60825.1 Part 1: Equipment classification and requirements
- 60825.14 Part 14: A user's guide
- 62471 Photobiological safety of lamps and lamp systems

IEC/TR

- 62471 Photobiological safety of lamps and lamp systems
- 62471-3 Part 3: Guidelines for the safe use of intense pulsed light source equipment on humans

ISO

- 12609 Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications
- 12609-1 Part 1: Specifications for products
- 14408 Tracheal tubes designed for laser surgery—Requirements for marking and accompanying information

NSW Health

- GL2015 002 Work health and safety—Controlling exposure to surgical plume

1.4 DEFINITIONS

For the purpose of this Standard, the definitions listed in AS/NZS IEC 60825.1, AS IEC 60601.2.22 and AS IEC 60601.2.57 and those below apply. Some definitions apply to lasers only. These are indicated by '(lasers only)' following the term.

1.4.1 Absorption

The process by which laser or ILS energy is taken up by the material that the laser beam illuminates.

1.4.2 Accessible emission limit (AEL) (lasers only)

The maximum accessible emission level permitted for a particular class of laser product.

1.4.3 Accessible radiation

Radiation to which it is possible for the human eye or skin to be exposed in normal usage.

1.4.4 Administrative control

Safety measures of a non-engineering type such as key supervision, safety training of personnel, and warning notices.

1.4.5 Aiming beam (lasers only)

A visible laser beam used to designate the point at which the working beam is anticipated to irradiate the target area.

NOTE: Typically a low power visible laser is used. With visible lasers the working beam may also be attenuated to provide an aiming beam to a level at which it is safe to view specular or diffuse reflections from the target.

1.4.6 Aperture

Any opening through which laser or ILS radiation is emitted, thereby allowing human access to such radiation. In many devices the housing has an aperture to which a fibre optic or other delivery system might be attached. The aperture then becomes the point at which energy leaves the delivery system.

1.4.7 Articulated arm delivery system (lasers only)

A delivery system in which laser energy passes through a hollow rigid arm with mirrors at its flexible joints to allow arm movement and transmission of the laser energy.

1.4.8 Attenuate

Reduce intensity or value.

1.4.9 Average power

The total energy imparted during exposure divided by the exposure duration.

1.4.10 Aversion response

An automatic response of the human body, consisting of closing of the eyelid or movement of the head or the eye itself to minimize retinal exposure to a noxious or bright light stimulant. The response (including the blink reflex) is assumed in this Standard to occur within 0.25 s.

1.4.11 Beam diameter or beam width (lasers only)

The beam diameter, d_u , at a point in space is the diameter of the smallest circle which contains $u\%$ of the total laser power (or energy). For the purpose of this Standard, d_{63} is used. [SI unit: metre].

NOTE: In the case of a Gaussian beam, d_{63} corresponds to the point where the irradiance (radiant exposure) falls to $1/e$ of its central peak value.

1.4.12 Class of laser (lasers only)

See 'laser classification'.

NOTE: Guidance on hazard classes for laser products is provided in Appendix G.

1.4.13 Client

See 'patient'.

1.4.14 Coherent (lasers only)

All the energy in the laser beam is delivered in phase.

1.4.15 Collimated beam (lasers only)

A 'parallel' beam of radiation with very small angular divergence or convergence, i.e. a beam which does not change size with distance.

1.4.16 Competent person

A person who has either formal qualifications in laser and optical safety, or who has a thorough understanding of the safety principles involved, and is familiar with the contents of, and application of, relevant national and International Standards covering laser and optical safety.

NOTES:

- 1 Relevant Standards are those in the AS/NZS IEC 60825 series and AS/NZS IEC 62471 series.
- 2 The competent person may not necessarily be an employee of the facility, but could be an external adviser.

1.4.17 Continuous wave (CW) (lasers only)

Laser operating with a continuous output for a duration greater than 0.25 s.

1.4.18 Convergence (lasers only)

The decrease in the diameter of the laser beam with distance from the exit aperture.

1.4.19 Delivery system

A mechanism or device which facilitates the delivery of laser or ILS energy to the treatment site. See also 'laser delivery system'.

1.4.20 Diffuse reflection

Change of the spatial distribution of a beam of radiation by scattering in many directions by a surface or medium. A perfect diffuser destroys all correlation between the directions of the incident and emergent radiation.

1.4.21 Distal

The termination point of a delivery system, furthest away from its connection to the laser or ILS device (i.e. the end of the fibre which comes into contact with tissue, or the output aperture of the handpiece).

1.4.22 Divergence

The increase in the diameter of the laser or ILS beam with distance from the exit aperture. See AS/NZS IEC 60825.1.

1.4.23 Electromagnetic radiation

Energy that radiates from a source at the speed of light. It includes gamma rays, ultraviolet radiation, visible light, infrared radiation, radio waves and television signals.

NOTE: While the term 'light' strictly applies to visible wavelengths only, it is used interchangeably in this Standard to mean both visible, and invisible ultraviolet and infrared electromagnetic radiation.

1.4.24 Embedded laser product (lasers only)

A laser product which, because of engineering features limiting the accessible emission, is of a class number lower than the inherent capability of the laser incorporated.

NOTE: A laser product which is incorporated in the embedded laser product is called an embedded laser product or an enclosed laser system.

1.4.25 Energy

See 'radiant energy'.

1.4.26 Energy density

See 'radiant exposure'.

1.4.27 Engineering controls

Physical modifications to laser or ILS equipment which reduce hazards to the user and person being treated

NOTE: Examples of engineering controls are interlocks, covered footswitch, warning lights or audible signals

1.4.28 Exposure duration

The duration of a pulse, or series, or train of pulses or of continuous emission of laser or ILS radiation incident upon the human body.

NOTE: For a single pulse, this is the duration between the half-peak power point of the leading edge and the corresponding point on the trailing edge. For a train of pulses, this is the duration between the first half-peak power point of the leading pulse and the last half-peak power point of the trailing pulse.

1.4.29 Eye protection

Any device designed to protect the eyes of all persons within the nominal ocular hazard area (NOHA) during laser procedures, or ocular hazard distance (OHD) for ILS procedures, the device being appropriate for the hazards associated with the laser or ILS and the procedure being undertaken.

1.4.30 Eye safe (lasers only)

The accessible emission is below the AEL of Class 1 or an exposure below the MPE for the eye for the given exposure duration.

NOTE: This term is sometimes incorrectly used for laser emission in the wavelength range above 1400 nm based on higher exposure limits in that wavelength range compared to the retinal hazard region. The term 'eye safe' may only be used to describe Class 1 laser products.

1.4.31 Fibre optic delivery system (lasers only)

A delivery system where laser radiation propagates through an optical fibre to the target site.

1.4.32 Focal length

The distance from the secondary nodal point of a lens to the primary focal point. In a thin lens, the focal length is the distance between the lens and the focal point.

1.4.33 Focal point

The point toward which radiation converges or from which radiation diverges or appears to diverge.

1.4.34 Human access (lasers only)

One of the following:

- (a) Capability for a part of the human body to meet laser radiation either as emitted by the laser product, i.e. radiation that can be intercepted outside of the protective housing.

- (b) Ability of a human hand or arm to intercept levels of radiation above the AEL of Class 3B.
- (c) For levels of laser radiation within the protective housing that are equivalent to Class 3B or Class 4, the ability of any part of the human body to meet hazardous laser radiation that can be reflected directly by any single introduced flat surface from the interior of the product through any opening in its protective housing.

1.4.35 Intense light source (ILS)

Source of intense broadband non-laser light which emits optical radiation exceeding that of the exempt group (according to AS/NZS IEC 62471), and that is intended to cause a thermal or photo-chemical effect to the target tissue.

NOTE: ILS may incorporate continuously emitting or pulsed flash lamps, incandescent bulbs, LEDs or similar.

1.4.36 Intense pulsed light (IPL)

Equipment, containing a flash lamp, e.g. xenon or krypton, housed in a handheld device, having an emission window with an area of several square centimetres, typically providing a filter which restricts the emission to a band in the visible and infra-red.

[SOURCE: IEC TR 62471-3:2015, 3.3]

1.4.37 Irradiance

A measure of the amount of radiation being delivered to a particular area on a surface. It is the quotient of the radiant flux, d_N , incident on an element of a surface by the area, d_A , of that element.

Also commonly called power density.

$$\text{Symbol } E: E = \frac{d_\phi}{d_A}$$

SI unit: watts per square metre (W/m²)

1.4.38 Laser

Any device which can be made to produce or amplify electromagnetic radiation in the wavelength range from 180 nm to 1 mm primarily by the process of controlled stimulated emission.

1.4.39 Laser accident (lasers only)

A laser incident which results in an adverse outcome.

1.4.40 Laser classification (lasers only)

Refers to the hazard classes into which lasers are grouped based on their accessible levels of laser radiation.

1.4.41 Laser checklist (lasers only)

A list of instructions specifically designed to assist the operator in the safe and optimal use of a laser system.

1.4.42 Laser controlled area (lasers only)

An area where the occupancy and activity of persons within is subjected to control and supervision for the purpose of protection from laser radiation hazards.

NOTE: The LCA may be larger than the NOHA, for example an operating theatre where a Ho:YAG laser is used. It is then usually convenient to regard the whole room as the LCA.

1.4.43 Laser delivery system (lasers only)

A mechanism or device which facilitates the delivery of laser energy to the treatment site.

NOTE: Guidance on laser delivery systems is provided in Appendix C.

1.4.44 Laser emission indicator (lasers only)

Visible or audible signal (or both) which indicates that laser radiation is being emitted through any aperture.

1.4.45 Laser hazard area (lasers only)

Area in which the exposure of the eye and/or the skin exceeds the respective maximum permissible exposure values (MPEs)—see ‘nominal ocular hazard area’.

1.4.46 Laser incident (lasers only)

Any event, associated with a laser procedure, which causes, or has the potential to cause, an adverse outcome to patients, clinical staff or others.

1.4.47 Laser or ILS operator

Any person who operates laser or ILS controls (e.g. parameter settings, actuation switch). The operator may also be the user.

1.4.48 Laser or ILS training

Training specifically prepared to instruct staff associated with the use of a laser or ILS in topics such as principles and safe practices, potential hazards, the appropriate use and operation of a medical laser or ILS.

1.4.49 Laser or ILS user

Any person who controls the delivery of the laser or ILS radiation to the working area.

1.4.50 Laser safety committee (LSC) (lasers only)

A committee specifically established to oversee all safety aspects associated with the use of health care laser(s).

NOTES:

- 1 An alternative approach is to use a safety committee dealing with all forms of light therapy—lasers and ILS.
- 2 See Appendix M for further information on LSCs.

1.4.51 Laser Safety Officer (LSO) (lasers only)

A person who is knowledgeable and competent in the assessment and control of laser hazards and has responsibility and authority for oversight of the control of laser hazards.

1.4.52 Local exhaust ventilator (LEV)

A device which collects the laser or ILS plume and traps, via filtration, hazardous particulates and gases.

NOTE: Also known as a plume evacuator.

1.4.53 Maintenance

Performance of those adjustments or procedures specified in user information supplied by the manufacturer with the laser product, for the purpose of assuring the intended performance of the product. It does not include operation or service.

1.4.54 Maximum permissible exposure (MPE) (lasers only)

The level of laser radiation to which, under normal circumstances, persons may be exposed without suffering adverse effects.

NOTES:

- 1 The MPE levels represent the maximum level to which the eye or skin can be exposed without consequential injury immediately or after a long time and are related to the wavelength of the radiation, the pulse duration or exposure time, the tissue at risk and, for visible and near infra-red radiation in the range 400 nm to 1400 nm, the size of the retinal image.
- 2 For more information on MPE levels and calculation examples, refer to AS/NZS IEC 60825.1.

1.4.55 May

Indicates the existence of an option.

1.4.56 Medical laser product (lasers only)

Any laser product designed, manufactured, intended or promoted for purposes of in vivo diagnostic, surgical, cosmetic or therapeutic laser irradiation of any part of the human body.

1.4.57 Monochromatic

Of one wavelength.

1.4.58 Nominal ocular hazard area (NOHA) (lasers only)

The area within which the beam irradiance or radiant exposure exceeds the appropriate corneal maximum permissible exposure (MPE), including the possibility of accidental misdirection of the laser beam.

NOTES:

- 1 If the NOHA includes the possibility of viewing through optical aids, this is referred to as 'extended NOHA'.
- 2 The NOHA can be highly device-specific and manufacturers may provide NOHA information in equipment manuals.

1.4.59 Nominal ocular hazard distance (NOHD) (lasers only)

The distance at which the beam irradiance or radiant exposure equals the appropriate corneal maximum permissible exposure (MPE).

NOTE: If the NOHD includes the possibility of optically aided viewing, this is termed the 'extended NOHD' (ENOH).

1.4.60 Ocular hazard distance (OHD) (ILS only)

The distance at which the beam irradiance or radiation exposure equals the appropriate exposure limit for the eye.

NOTE: OHD is analogous to NOHD for lasers and has the same meaning and application.

1.4.61 Operation

The performance of the laser or ILS over the full range of its intended functions. It does not include maintenance or service.

1.4.62 Optical density

A number relating to the ability of the lenses of optical filters (i.e. protective eyewear and specialized endoscope filters) to attenuate optical radiation of a particular wavelength or range of wavelengths.

The optical density is the logarithm to base ten of the reciprocal of the transmittance, τ :

$$\text{Symbol: OD} \quad \text{OD} = -\log_{10} \tau$$

1.4.63 Patient

Person receiving the laser or ILS treatment.

NOTE: 'Patient' includes client or customer in aesthetic clinics or beauty salons. The terms 'patient' and 'client' are often used interchangeably. 'Client' normally refers to a person receiving treatment for a non-medically indicated reason.

1.4.64 Peak power

The maximum value of the power delivered in a single pulse.

1.4.65 Photobiomodulation

The use of both coherent and non-coherent light in the visible and non-visible spectrum. Light is absorbed by endogenous chromophores eliciting photochemical or photophysical events (linear and non-linear), triggering non-thermal, non-cytotoxic, biological reactions. These processes result in outcomes including, but not limited to, alleviation of pain or inflammation, promotion of wound healing and tissue regeneration. Often also called Low Level Laser/Light Therapy (LLLT).

1.4.66 Plume

Noxious airborne contaminants generated as by-products, by procedures that rely on the ablation, cauterization or thermal desiccation of tissue by lasers or ILS. Plume may include visible and invisible aerosol particulates, smoke and gases.

1.4.67 Power (*P*)

The rate at which energy is emitted, transferred or received.

SI unit: watt (W).

1.4.68 Power density

See 'irradiance'.

1.4.69 Proximal

The part of a delivery system near its point of connection to the laser or ILS (i.e. the end of the fibre closest to the laser or ILS and furthest from the end that comes into contact with tissue, or the output aperture of the handpiece).

1.4.70 Pulse mode (lasers only)

A mode of operation for some lasers where the energy is delivered in the form of a single pulse or a train of pulses.

1.4.71 Q-switched laser (lasers only)

A laser that emits short (~ 10 ns–250 ns), high peak-power pulses by means of a Q-switch.

1.4.72 Radiant flux (radiant power)

Power emitted, transferred, or received in the form of radiation.

SI unit: watt (W).

1.4.73 Radiant energy *Q*

Time integral of the radiant flux over a given duration, Δt .

SI unit: joule (J).

1.4.74 Radiant exposure *H*

At a point on a surface, the radiant energy incident on an element of a surface divided by the area of that element.

SI unit: joule per square metre ($\text{J}\cdot\text{m}^{-2}$).

1.4.75 Radiant power

See 'radiant flux'.

1.4.76 Refraction

The change in direction or bending of a light wave when it passes from one medium to another.

1.4.77 Retinal hazard (lasers only)

Potential exposure to laser radiation which could result in damage to the retina, possibly resulting in permanent blindness.

1.4.78 Risk Group (ILS only)

A number from 1 (low risk) to 3 (high risk) derived from an assessment of the photobiological hazards of lamps according to AS/NZS IEC 62471:2011.

1.4.79 Scatter

Change in direction of individual photons within a light beam.

1.4.80 Service

The performance of those procedures or adjustment described in the manufacturer's service instructions, which may affect any aspect of the product's performance. It does not include maintenance or operation.

1.4.81 Shall

Indicates a mandatory requirement.

1.4.82 Should

Indicates a recommendation.

1.4.83 Shutter (lasers only)

A device which opens and closes to allow laser energy to be transmitted out of the laser aperture. In medical lasers, a foot switch typically controls the shutter and thus the delivery of laser radiation to the treatment site.

1.4.84 Specular reflection

A mirror-like reflection.

NOTE: 'Non-specular' is regarded as a diffuse reflection.

1.4.85 Thermal relaxation time

In terms of light bioeffects, generally taken as the time taken for the temperature of a target to reduce to 50% of its peak value. It may range from a few nanoseconds (tattoo particles) to more than one hundred milliseconds (leg venules).

NOTE: An alternative definition as the time taken to dissipate the incident thermal energy by 63% ($1/e$) is sometimes used.

1.4.86 Transmission

Passage of radiation through a medium.

1.4.87 Ultraviolet radiation

Radiation for which the wavelengths of the monochromatic components lie within the range 100 nm to 400 nm, i.e. less than those for visible radiation.

1.4.88 Ultra low penetration air filter (ULPA)

Porous filter normally used for removing particulate matter as small as $0.1 \mu\text{m}$ with a filtration efficiency of not less than 99.999% from the plume.

1.4.89 Visible radiation

Any optical radiation capable of causing a visual sensation.

NOTE: This is taken to mean electromagnetic radiation for which the wavelength of the monochromatic components lie between 400 nm and 700 nm.

1.4.90 Working beam (lasers only)

The beam of laser radiation emitted by the laser equipment for surgical, cosmetic, therapeutic or diagnostic purposes (other than the aiming beam).

SECTION 2 ADMINISTRATION FOR LASERS AND ILS

2.1 LASERS

2.1.1 Safety

Responsibility for the safety of patients and the attending staff during the use of lasers falls equally upon the managers of the health care facility, the administration, the clinicians using the equipment, and all staff concerned with its operation and maintenance.

Building design, equipment design, purchasing specifications, inspection procedures, preventative maintenance schedules, and training programs each contribute to safety. Although a degree of safety can be built into the system and the equipment, the safety of patients and staff also depends on proper maintenance of the installation and ancillary equipment and, most importantly, the competence of staff in the safe use of equipment.

2.1.2 Administration

The safe use of lasers in medical and dental procedures requires consistent application of engineering controls, and conformance with written policies and procedures for best practice. The allocation of staff responsibilities and provision of training are also necessary adjuncts to the safety of both patients and staff.

The following applies:

- (a) A formal policy shall be developed regarding the use of lasers which makes it clear to all staff that active cooperation amongst laser team members, conformance to Standards, and liaison amongst staff, administration and industry are essential for patient, environmental and staff safety. This shall include the appointment of one appropriate person as Laser Safety Officer (LSO) where Class 3B and Class 4 lasers are used. In jurisdictions where laser use is regulated, the LSO (or equivalent under legislation) may be required to have additional qualifications recognized by the relevant authority.

NOTE: See Appendix N for more information on regulatory authorities.

- (b) Criteria and policy for continuing education and training programs for clinicians, nurses and medical laser service personnel shall be established.
- (c) Standard operating procedures (e.g. written hazard-based policies and procedures) shall be developed.
- (d) Consistent methods for documentation of all laser procedures, including appropriate data elements, shall be established.
- (e) Appropriate reporting procedures and action plans following all known or suspected incidents involving lasers shall be developed, e.g. accidental radiation exposures, perforations, broken tips.

NOTE: An example of a procedure for reporting laser incidents is given in this Section and further information is given in AS 1885.1.

In general, a risk management approach should be used.

2.1.3 Training

All clinical theatre and support personnel required to be present on a regular basis during laser operation or maintenance should have a working knowledge of basic light physics, laser safety, laser tissue interactions, applications, and dosimetry affecting the use of clinical lasers. Such staff shall be trained in operating procedures, including handling and care of equipment, set-up, intraoperative monitoring, use of the controls and delivery systems, and use of all accessory equipment.

Personnel requiring laser safety education and training include—

- (a) laser safety personnel;
- (b) laser users, e.g. surgeons, physicians, dentists, nurses and other allied health professionals;
- (c) laser team members, e.g. laser operators, biomedical engineers, technicians, medical physicists;
- (d) laser system service personnel, including either in house or contractor service personnel; and
- (e) incidental personnel, including medical photographers, observers, students, family members and industry representatives.

Each of these groups shall receive training relevant to the specific needs and responsibilities for the type of lasers in use.

All users of Class 3B or 4 laser equipment, and laser team members working within the NOHA, shall provide proof of appropriate education and training in compliance with national, state or local legislation, as appropriate. A local register of such persons may be appropriate.

NOTE: Training is discussed further in Appendix I.

2.1.4 Medical credentialing

Where a facility or practice has a system of credentialing, that system should also be extended to laser users.

NOTE: In jurisdictions having legislation governing laser use or licensing (or both), all required credentials and licenses need to be maintained.

2.1.5 Laser operator certification

Only competent personnel shall be permitted to operate lasers and laser systems. Criteria for certification is to be established by the facility, based on the type of equipment and its applications, practice setting and procedure.

In jurisdictions having legislation governing laser use or licensing (or both), the facility shall be fully satisfied that users obtain and maintain all required credentials and licenses.

2.1.6 Standard operating procedures and checklists

A copy of facility policies and procedures shall be kept in each laser use site. A copy of this Standard or electronic access to it should also be included.

Conformance to policies and procedures, and appropriate standards shall be documented in each laser use site.

NOTE: Examples of typical policies, forms and checklists are given in Appendix H.

2.1.7 Laser incidents

All laser incidents shall be reported as soon as possible to the LSO or his/her deputy. The following actions shall be taken once the patient is stabilized and safe:

- (a) The procedure shall be discontinued, and the laser equipment isolated in a safe condition, with any key removed and given to the LSO.
- (b) All persons in the room shall be evaluated for injury or for potential unintended laser exposure, and referred for appropriate medical management.
- (c) No equipment shall be removed from the area unless such removal has been authorized by the LSO or his/her deputy.

- (d) The incident shall be documented (with time- and date-stamped photographs, if possible), including details of all persons and equipment in the room, along with their locations at the time of the incident.
- (e) Write a description of what happened in the room, including condition of the patient, instruments and devices in use, level of anaesthesia, and part of the body being treated, before assuming any other duties in the surgical suite, and submit the reports to the LSO.

2.1.8 Incident reporting

2.1.8.1 Incident report

A written report shall be prepared of any laser incident. The report shall contain the following:

- (a) A summary of the circumstances of the incident, which shall specify—
 - (i) the date, location and time of the incident;
 - (ii) the names and designation of all personnel present;
 - (iii) apparent contributing factors to the incident;
 - (iv) recommendations to prevent a recurrence; and
 - (v) the obvious or suspected nature of any injury sustained by any person.
- (b) Full written statements from all persons present at the time of the incident.
- (c) Medical reports on any injured person.
- (d) Listing of equipment in use during the procedure and its condition prior to the incident, with appropriate identification information.
- (e) Full details of the type of laser product noting, in particular, the condition of the equipment immediately after the incident.
- (f) Details of the laser operating parameters leading up to the incident.
- (g) The identified cause of the incident (a root cause analysis may be appropriate).
- (h) Recommended changes to minimize or eliminate the risk of it happening again.

The incident report should be sent to the facility management similarly to any other workplace incident report, and to the relevant regulatory authority where required under legislation. The LSO should also be aware of and follow any medico-legal processes in their facility.

NOTE: Appendix N provides information on advisory and regulatory authorities.

2.1.8.2 Equipment malfunction and personnel injury

Where component malfunction is likely or suspected to have caused an incident, the following applies:

- (a) In Australia

The equipment should be isolated immediately and a report made to the Therapeutic Goods Administration (see Appendix N) pending further actions.
- (b) In New Zealand

The equipment should be isolated and, in the case of non-injurious accidents, a report forwarded to the Ministry of Health. For incidents involving injury an additional report is to be sent to the Accident Compensation Commission.

2.1.9 Ophthalmic examinations

The following recommendations apply:

- (a) A medical examination by a qualified specialist should be carried out immediately (i.e. within 24 h) after an apparent or suspected injurious ocular exposure. Such an examination should be supplemented with a full biophysical investigation of the circumstances under which the accident occurred.
- (b) Specialists performing ophthalmic examinations should be aware that many retinal lesions can be incorrectly attributed to laser damage.
- (c) Routine or pre-employment ophthalmic eye examinations of employees working with health care lasers have no particular medical or safety value. They are sometimes used for medico-legal reasons but have limited value, see 2.1.9(b) and form no part of a laser safety program. Indeed it is possible that some investigations involved may themselves be hazardous. Such investigations should therefore only be carried out when medically advisable (e.g. 2.1.9(a)), and are not to be used otherwise without good justification and informed consent. Eye examinations should in any case be confined to persons working with Class 3B or 4 lasers, these being the classes likely to cause eye damage.

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2.1.10 Skin examinations

Skin examinations should be carried out after any laser accident where there is a possibility of skin damage.

2.1.11 Laser safety audits

Routine and periodic laser safety audits shall be performed in order to ensure conformance to facility policy and standards, accuracy of documentation, and equipment safety. A written audit should include a checklist that identifies nonconformances, follow-up actions determined, who will be responsible, and the timeline for remedies to be completed, and shall be provided to the facility's management.

NOTE: For more information, see Appendix M3.

2.2 ILS

2.2.1 General

Use of ILS in Risk Group 3 (which includes most IPL devices) carries similar risks to staff and patients as lasers, with the possible exception that, due to the source dimensions and the divergent nature of the beam, ocular hazards are less severe.

The safety principles outlined for lasers under Clause 2.1 should be applied to ILS use, with a risk management approach, i.e. according to the ILS application and potential risks involved.

Specific differences between ILS and lasers are as follows:

- (a) ILS equipment shall comply with AS IEC 60601.2.57.
- (b) Eye examinations are not required for ILS use unless medically indicated.

2.2.2 Guidelines

The following are simple guidelines for the drafting of local rules or radiation protection/management plans:

- (a) Local rules should reflect safe working practices and relate to the day-to-day safety management of ILS equipment.
- (b) The local rules should be specific to each ILS system and to the mode of application. Consideration should be given in the local rules for lasers and ILS systems that are co-located.
- (c) The local rules should be amended when conditions change.
- (d) The purpose of local rules is to ensure that all employees are working in a safe environment and that all clients are treated safely.
- (e) All staff personnel who are involved with the use of ILS equipment should be made familiar with the contents of the local rules. Their consent should be declared and the declaration recorded.
- (f) The local rules should be made readily available to staff in the treatment area.
- (g) The local rules should address the following:
 - (i) A register of authorized users.
 - (ii) Arrangements for safe keeping and issue of ILS keys or PIN codes.
 - (iii) Defined region and limits of the controlled area.
 - (iv) Nature of hazards to personnel and clients.
 - (v) Training requirements for persons assisting in or undertaking ILS use.
 - (vi) ILS user's procedures and responsibilities.
 - (vii) Definition of simple pre-use safety checks and instructions.
 - (viii) Personal protective equipment, especially protective eyewear.
 - (ix) Adverse event and equipment fault procedures and logs.

NOTE: Clause 2.2.2 is based on guidance for intense pulsed light (IPL) equipment contained in IEC TR 62471-3:2013 (ED.1.0). This information is reproduced with permission from the International Electrotechnical Commission Copyright© 2015 IEC Geneva, Switzerland. www.iec.ch

2.2.3 Equipment malfunction and personnel injury

Clause 2.1.8.2 applies.

SECTION 3 INSPECTION, TESTING AND PREVENTIVE MAINTENANCE

3.1 GENERAL

Although the user may not be able to undertake the complete testing and maintenance of a laser or ILS device and its accessories, there are some important items that should be checked prior to commissioning and during its service life. The design and applicability of individual tests will depend on the type of laser or ILS.

The provisions of this Section should not be considered as exhaustive or universally applicable. They outline general inspection and testing procedures.

3.2 ACCEPTANCE INSPECTION AND TESTING

Only laser equipment that is in accordance with safety and performance Standards shall be placed into service. Examples of such Standards include AS/NZS IEC 60825.1, AS IEC 60601.2.22, AS/NZS 3551 and the AS/NZS 3200 series. This applies to demonstration or rental equipment as well as to new equipment. Acceptance inspection and testing ensures that conformance with published specifications is achieved and also detects any errors in assembly, damage in transit or other faults.

NOTE: The AS/NZS 3200 series on medical electrical equipment is being progressively superseded by the AS/(NZS) IEC 60601 series.

In particular, the marking of classifications and any other safety markings or instructions shall be verified for conformance with the requirements of AS IEC 60601.2.22. Copies, in English, of all instruction and service manuals, necessary for safe day-to-day operations, shall be provided at the time of purchase. These manuals shall be kept by the health care facility for the operational life of the laser.

ILS equipment shall comply with AS IEC 60601.2.57.

At this time, arrangements shall be made to establish and maintain the following documentation:

- (a) Relevant equipment safety standards.
- (b) An equipment service history.
- (c) Schedule for recommended testing and maintenance.

3.3 QUALITY ASSURANCE (QA) TESTING OF EQUIPMENT PARTS

3.3.1 General

Regular testing of the equipment parts covered by this Clause 3.3 shall be performed at the frequency given in Table 3.1, and documented. Care is needed in performing some of these tests to avoid exposing the tester to hazard. This may include having a safety plan, performing the tests in an area away from other persons, or performing testing under LSO supervision.

3.3.2 Cables

Power and footswitch cables shall be checked for damage, particularly where they join to a plug or socket, before the laser is connected to the power.

3.3.3 Emergency stop switches

The function of the emergency stop switch shall be tested, and if it locks in the 'off' position, both the lock and the unlock functions, shall be tested.

3.3.4 Interlocks

Any interlocks (e.g. water flow, presence of fibre) shall be checked for their correct function.

3.3.5 Emission indicators

Visible and audible emission indicators shall be checked for correct function.

3.3.6 Beam power calibration

There are two main causes of loss of power or energy at the distal end of a transmission system, viz. optical misalignment at any stage, or contamination of, or damage to, any of the mirrors, lenses or fibres which may form the transmission system. As a result, distal beam power (or pulse energy) or, alternatively, distal power (or energy) as a percentage of cavity output (which is measured in many lasers) should be regularly determined if possible. Inbuilt calibration systems shall be used where fitted. Even small amounts of contamination on any of the optical components will cause not only loss of power/energy but also absorption of energy, with potential thermal damage to that component. This applies to both pulsed lasers and continuous wave lasers.

Some IPL systems also offer an inbuilt calibration facility, and where fitted, it shall be used before treatment. External measurement of IPL output is technically difficult and should not be attempted by the user.

3.3.7 Articulated arm (lasers only)

Before use, any laser using an articulated arm or micromanipulator shall be checked for physical damage and for each movement over its full range.

3.3.8 Beam coincidence (lasers only)

For lasers using an articulated arm, the coincidence of aiming and working beams shall be tested in accordance with Table 3.1, with the intended delivery system in place. This can easily be performed with a marked wooden tongue depressor as a target. The aiming beam is used to align the working laser to the marked target. Firing the working beam should eliminate the mark. After firing, the burn should be checked for beam mode (uniform circular shape). This, however, needs a defocussed beam which is not always possible to achieve. This test should be performed before a patient has been induced under anaesthesia, whenever the laser delivery system is changed, and whenever the laser has been moved to another room. The rationale for the testing is that the laser, and in particular an articulated arm, can potentially be damaged in transit. Results of testing shall be recorded on the laser log or nursing operative documents. If the test is failed or inconclusive, the laser shall be retested and it shall be verified that it is in its operating condition.

Lenses and mirrors should not be touched as grease from the hands may result in damage. The manufacturer's cleaning and sterilization instructions should be adhered to.

3.3.9 Optical fibres (lasers only)

Optical fibres used with lasers shall be checked for contamination at both ends and for damage along the entire fibre length prior to connection. A magnifying glass of 10×–14× magnification and good illumination may be used for this examination and is sometimes supplied by the laser manufacturer.

WARNING: DO NOT PERFORM THIS TEST IF THE FIBRE IS CONNECTED TO THE LASER.

Both ends of the fibre shall be clean and free of chips and other damage. Coaxial fibres (those in which a fluid or gas is carried in the fibre) shall be checked to ensure that the exit holes are open, and that the coolant flows freely. There should be no residuals or fluids trapped in the coaxial fibre. Special accessories such as sapphire tips and other diffusing devices shall be also checked for cleanliness.

3.3.10 Aiming beam (lasers only)

The quality of the aiming beam at the distal end of the delivery system shall be examined prior to use, and occasionally during use to maintain efficient beam delivery. The beam should be directed at a clean, uniformly light-coloured surface from a distance of some 5 cm to 10 cm. The image shall be uniform and circular. Although a small amount of mottling is acceptable, there should be no smears, blotches, scattered light or dark shadows. The presence of these indicates damage or contamination of the delivery system. For optical fibres, if the aiming beam is clearly defined and of normal brightness, then the fibre is probably in good condition.

3.3.11 Specialized accessories (lasers only)

Any accessories designed for laser use (such as sapphire contact tips, laser instruments and plume evacuators) shall be examined and assessed for damage and correct function, in accordance with the manufacturer's instructions, or for any requirements set by the LSO.

3.3.12 Protective eyewear

Protective eyewear, such as goggles or glasses, as well as any special filters used in endoscopes and other devices, shall be determined as appropriate for the particular laser in use by a competent person, and comply with relevant Standards. (See Appendix K.) Protective eyewear shall be regularly checked and cleaned according to the manufacturer's instructions. Scratches, cracks, colour changes to the lens coatings and damage to frames may reduce the protective efficiency. The required labelling shall also be legible.

NOTE: For more information on eyewear labelling, see Appendix K.

3.3.13 IPL filters (IPL only)

Filters supplied to modify the wavelength distribution shall be checked for damage before use, and wavelength marking shall be clearly visible.

TABLE 3.1
FREQUENCY OF TESTING

Clause No.	Equipment part	Frequency of test
3.3.2	Power and footswitch cables	Prior to each use or daily, whichever is least frequent
3.3.3	Emergency stop switches	6 monthly (unless prohibited by the manufacturer)
3.3.4	User-accessible interlocks	12 monthly
3.3.5	Emission indicator(s)	Prior to each use or daily, whichever is least frequent
3.3.6	Beam power/pulse energy	At the time of preventive maintenance—tested by the supplier's technician
3.3.7	Articulated arm movement and physical checks (lasers only)	Commencement of each procedure
3.3.8	Convergence of aiming and main beam (lasers only)	Daily, and after repositioning or change of delivery system
3.3.9	Fibre (physical check) (lasers only)	Each change of fibre
3.3.10	Aiming beam quality (lasers only)	Prior to each procedure or change of fibre delivery system accessory
3.3.11	Specialized accessories (lasers only)	Prior to each use
3.3.12	Protective eyewear	Prior to each use—each individual to check their own eyewear
3.3.13	IPL filters (IPL only)	Prior to each use—check for damage and visibility of wavelength markings

3.4 PREVENTIVE MAINTENANCE

3.4.1 General

All laser/ILS equipment used in health care shall be maintained by a technically competent person only.

Maintenance comprises—

- (a) preventive maintenance of the device and accessories;
- (b) calibration of the output power, energy and temporal characteristics; and
- (c) user tasks associated with clinical use.

Activities involving a laser shall be carried out in a laser controlled area only.

3.4.2 Cleaning and disinfection

Prior to any maintenance, the equipment and accessories shall be cleaned and disinfected to protect the person carrying out the maintenance. Care shall be taken to ensure that the cleaning materials and disinfectants do not cause damage to the equipment and accessories. The choice of disinfecting agents shall be in accordance with the local infection control policy and procedures.

3.4.3 Preventive maintenance check list

The following checks shall be performed by a competent person:

- (a) Inspect and clean optical components.
- (b) Check and replace or replenish consumables, such as dyes, coolants and filters.
- (c) Verify the output, and correcting, if necessary.

- (d) Verify correct operation of shutters(s), interlocks, emergency switches and footswitch.
- (e) Verify that all modes of operation are within the manufacturer's specification.
- (f) Ensure all optical beam delivery systems are functioning correctly.
- (g) Check aiming beam/working beam alignment.
- (h) Verify that the equipment is electrically safe.

NOTE: The above checks will normally be carried out by the manufacturer's agent or a suitably qualified person.

The output power or energy indicators incorporated in Class 3B and Class 4 lasers, and IPLs, shall be calibrated when and as required, according to the manufacturer's instructions and the health care facility's biomedical procedures.

SECTION 4 SAFE PRACTICES

4.1 GENERAL

The safe use of health care lasers, regardless of the practice setting, requires responsible commitment to compliance with Standards and policies by all personnel. In particular, vigilance is required to ensure that—

- (a) policies and safety procedures are implemented;
- (b) appropriate equipment is used for the intended purpose;
- (c) equipment used complies with safety and performance requirements, e.g. Standards and regulations;
- (d) risk assessment has been performed;
- (e) known hazards are appropriately controlled; and
- (f) persons carrying out procedures have appropriate education and training.

4.2 ESSENTIAL SAFETY REQUIREMENTS

The following requirements and recommendations apply to lasers and ILS:

- (a) Users and operators shall be familiar with exposure hazards and appropriate methods to control these hazards.
NOTE: See Appendices E and F for guidance on ILS and laser hazards respectively.
- (b) Users and operators shall have training and knowledge of safety characteristics and operational details of the particular laser/ILS in use, and its associated equipment.
NOTE: See Appendices E and F for guidance on ILS and laser hazards.
- (c) An LSO shall be appointed who is fully trained in laser operation, use and safety, where Class 3B and Class 4 lasers are used.
- (d) Where practicable, a deputy LSO (DLSO) should be appointed to fulfil the duties of the LSO in his/her absence.
- (e) A laser safety committee (LSC) should be established at the workplace if appropriate.
NOTE: See information on LSCs in Appendix M.
- (f) Only competent persons shall be permitted to use lasers/ILSs.
- (g) Only competent persons shall service laser/ILS systems.
- (h) Equipment shall be correctly classified according to AS/NZS IEC 60825.1 (lasers) or AS/NZS IEC 62471 (IPLs), and be electrically and mechanically safe, i.e. in conformance with appropriate Australian/New Zealand Standards, or, where there are none, International Standards (IEC and ISO).
- (i) Eye protection, appropriate for the particular laser/ILS and its application, shall be made available, and use by all personnel shall be enforced within the NOHA.
- (j) The safety rules and equipment instructions shall be made available at the site of use. Such rules and instructions shall be written in English, and in terms understandable to all personnel in the laser controlled area.
- (k) Appropriate warning signs and compatible laser protective eyewear shall be posted at all entrances to the controlled area. All personnel shall be aware of the rules for establishing and maintaining a controlled area, including the meaning of posted signs, use of protective eyewear, and controlled entry into the NOHA.
- (l) Safety performance of laser equipment is assured by the LSO, through effective, regular servicing based on the manufacturer's instructions, timely repair, staff education and training in proper care and handling, and periodic audit. Inspection and maintenance schedules are required to be developed, upheld and reported to the LSO. Similarly, there should be a parallel process for ILS equipment.

- (m) The controls of the laser/ILS shall be monitored whenever it is activated and at all times during testing and use.

The following requirements apply to lasers only:

- (i) A NOHA or NOHD shall be specified for areas of laser use by a competent person (in accordance with AS/NZS IEC 60825.14).
- (ii) Fire safety training shall be provided to all personnel.
- (iii) Fire extinguishers, and when necessary, fire blankets, shall be positioned immediately outside every laser controlled area, or inside, subject to a risk assessment.

NOTE: For information on risk assessments, see Appendix L.

Table 4.1 summarizes health care laser hazard classification and safety requirements, and Table 4.2 for ILS.

NOTE: For more information see Appendix G.

TABLE 4.1
LASER EQUIPMENT CLASSIFICATION AND
SAFETY REQUIREMENTS IN A HEALTH CARE ENVIRONMENT

Laser classification	Potential hazard	Installation (laser controlled area)	Personnel safety	Training requirements
Class not identified	Do not use laser. Potential hazard level unknown. Laser unclassified. Contact supplier/manufacture for classification and label. Laser does not comply with Australian/New Zealand or International Standards.			
Class 1	Safe	Unrestricted	Nil	Operation only
Class 1M	Safe, unless viewed with telescopic optics such as binoculars. Restricted to 302.5 nm to 4000 nm	Unrestricted	Do not view with telescopic optical instruments	Operation only
Class 1C	Safe for operator/user. Skin hazard to patient potentially high as embedded laser may be up to Class 4	Unrestricted. NOTE: Area warning signs are recommended.	Nil (external accessible emission limited to Class 1 by definition)	Operation only
Class 2	Low	Unrestricted	Do not stare into beam due to potential short term effects	Operation only
Class 2M	Low, unless viewed with telescopic optics such as binoculars	NOTE: Area warning signs are recommended if collimated beams used.	Do not view with telescopic optical instruments	Operation only
Class 3R	Low level eye hazard	Unrestricted i.e. safety depends on responsible use	Do not view beam directly	Operation only. Basic laser safety training recommended

(continued)

TABLE 4.1 (continued)

Laser classification	Potential hazard	Installation (laser controlled area)	Personnel safety	Training requirements
Class 3B	Eye hazard, and potential skin hazard at upper levels of class	Controlled area warning signs. Controlled access. Key/PIN equipment controls	Exposure to beam hazardous. Controls for prevention of ocular exposure essential. PPE required in NOHA.	Operator and user laser safety training
Class 4	Eye and skin hazard. Possible fire and fume hazards	Controlled area warning signs. Controlled access. Key/PIN equipment controls.	Eye or skin exposure to direct or scattered radiation dangerous .Controls for prevention of ocular exposure essential. Controls for prevention of skin exposure may be required. PPE required in NOHA.	Operator and user laser safety training.

TABLE 4.2

**ILS EQUIPMENT CLASSIFICATION AND SAFETY REQUIREMENTS IN A
HEALTH CARE ENVIRONMENT**

ILS risk group*	Potential HAZARD	Installation (controlled area)	Personnel safety	Training requirements
Exempt group	Safe under reasonably foreseeable conditions	Unrestricted	Nil	Nil
1	Low risk – does not pose a hazard due to normal behavioural limitations on exposure	Unrestricted	Nil	Operation only
2	Moderate risk – does not pose a hazard due to aversion response to very bright light sources or due to thermal discomfort	Unrestricted	Nil	Operation only
3	High risk – may pose a hazard even for momentary or brief exposure	Controlled area warning signs. Controlled access. Key/PIN equipment control.	Eye exposure to direct or scattered radiation may be hazardous. Contact skin exposure to direct radiation may be hazardous. Controls for prevention of ocular exposure essential. Controls for prevention of skin exposure may be required. PPE required in OHA.	Operator/user safety training

* See Appendix G for an explanation of risk groups.

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4.3 OPERATIONAL PRACTICES

The following common safety measures apply to lasers and ILS:

- (a) Policies and procedures and safety check lists shall be made available prior to laser use.
- (b) A laser/ILS shall never be fired unless it is aimed at the chosen target site.
- (c) Adequate eye protection shall be worn by all persons who may enter the NOHA (see Clauses 4.8 and 4.9).
- (d) The patient's eyes shall be protected when not the intended target for the beam. Protection may take the form of impenetrable barrier eye shields, safety eyewear, or other LSO-approved safety devices, appropriate for the laser or ILS in use.
- (e) It shall be confirmed that the calibration and maintenance of the laser or ILS equipment has been performed according to the health care facility's schedule.
- (f) Entry into the NOHA by observers and other non-staff personnel should be limited to those having prior approval and documented knowledge of safety policies.
- (g) The laser or ILS, when not in use, shall be stored or disabled (e.g. by removal of the control key) so as to prevent unauthorized use. If the laser is fitted with a PIN control instead of a key, the PIN shall be changed from the factory default to a local value at installation. The PIN code shall be kept in a safe place, or the equipment manual.
NOTE: The primary purpose of a key or PIN is to prevent unauthorized access and thus unsafe use.
- (h) The laser or ILS system shall be placed on stand-by whenever it is not being actively fired at the target, to prevent accidental activation and firing.

The following applies to lasers only:

- (i) Both user and operator shall be aware of the active status of a laser at all times during testing and use. When operator and user are separate, verbal communication between user and operator helps prevent accidental activation of the laser and unintended firing.
- (ii) When a Class 4 laser is used, measures shall be taken to prevent the possibility of ignition of materials in oxygen-enriched atmospheres. Safety procedures, appropriate for the laser in use, shall be determined.
- (iii) When lasers are fitted with an aiming device, the laser shall not be used if the aiming device is malfunctioning or not visible.
- (iv) Where an articulated arm delivery system is used, the alignment between the working laser beam and the aiming system shall be checked daily or before each use.
- (v) Measures shall be taken to prevent the unintentional reflection of the laser beam from an instrument or other specular material/objects. The following requirements and recommendations apply to such measures:
 - (A) All specular material in or near the beam path shall be removed.
 - (B) The use of polished instruments should be avoided.
 - (C) The operator and user should be aware that a surface which is not specular to visible light may be specular or near specular to far infra-red laser radiation.
 - (D) Consideration shall be given to the selection and use of instruments used in association with the laser device, in particular, the use of blackened surgical instruments as efficient energy absorption may result in excess heating and cause unintended patient burns.

- (E) The surface characteristics of instruments used in laser surgery of the upper aero-digestive tract should have low specular or direct reflectance.

NOTE: Choice of instruments with appropriate surface characteristics will help to minimize tissue injury.

- (vi) All windows, doorways and open portals allowing viewing into the NOHA shall be protected or screened in such a manner as to reduce the transmitted laser radiation to levels below the MPE. Protection or screening shall be fitted to the interior surface of the window, and shall meet any other local requirements such as infection control.
- (vii) When performing an endoscopic procedure, the laser transmission fibre shall be inserted into the endoscope and visualized beyond the end of the endoscope, before activating or firing (or both) the laser. This is for both personnel and equipment safety.

4.4 REMOVAL OF AIRBORNE CONTAMINANTS

4.4.1 General

In cases where heat is used to vaporize tissue or hair, air-borne contaminants are present, and such contaminants shall be evacuated appropriately from the field.

NOTE: See Appendices E and F for a description of the hazards.

Airborne contaminants shall be captured, as near as practicable, to the point of evolution, and removed by an active or passive plume evacuation system, with the capture device positioned not more than 2 cm from the target site. This plume evacuation system shall be designed so as to ensure that infective agents are not inhaled or passed downstream in the air handling/exhaust system. For example, this may be accomplished with a plume evacuation system (LEV) containing charcoal for adsorption of gases, and an ULPA filter.

Wall suction shall not be used without a 0.1 µm in-line filter placed between the wall outlet and the floor canister as venturi wall return units may become blocked with plume particles and/or can contaminate plant systems, if not filtered properly. These filters are time limited by the manufacturer, and should be selected based on the amount of time for use that is anticipated. In-line filters shall be disposed of according to standard infection control procedures for handling items contaminated with blood borne pathogens.

Plume evacuator filters shall be monitored and replaced on a regular basis, following the manufacturer's instructions. In cosmetic practice, specifically hair removal, the presence of a strong odour, indicates airborne concentration of numerous hazardous gases. Filters differ from the ULPA filters used for thermal plume, and may for example contain a large matrix of carbon designed to adsorb the gases and prevent inhalation hazard to staff.

Laparoscopic procedures may result in accumulation of plume in the intra-abdominal cavity, and this can be a patient safety hazard. Plume shall be removed by closed evacuation systems and shall not be vented unfiltered into the room by releasing the valve on the scope.

All materials used to collect airborne contaminants (e.g. filters, masks and tubing) are considered a bio-hazard and shall be handled and disposed of, using standard precautions (see AS/NZS 4187) for blood-borne pathogens.

Where ILS are used, especially for hair removal, similar airborne contaminants are likely to be present and may have similar risks as for laser plume. Use of a risk management approach to the hazard is strongly recommended.

4.4.2 Operator and patient protection

During surgery in or near patient respiratory passages, adequate ventilation is necessary for patient protection. Where air-borne contaminants are present, masks or other respiratory protectors complying with AS/NZS 1715 should be worn by all staff in the treatment room during all procedures. Such masks may become less efficient as they become saturated with moisture, and are not recommended as a first line of protection against air-borne contaminants. Where used, respirator masks shall be fit-tested to assure proper fit for all personnel. The use of masks shall be monitored.

4.5 REDUCTION OF EXPLOSIVE HAZARD

This Clause (4.5) applies to lasers only and is not applicable to ILS use.

To reduce the risk of fire/explosion, it is recommended that the lowest possible safe concentration of oxygen (normally <30%) shall be used in laryngotracheal procedures. Additional adequate preparation should be provided for colonic procedures, e.g. purging the bowel of methane. The use of intravenous anaesthetic techniques, rather than inhalation techniques, is recommended to prevent laser pyrolysis of anaesthetic agents.

4.6 PLUME AND OTHER NOXIOUS MATERIALS

4.6.1 General

Measures shall be taken to ensure adequate removal of plume generated by the procedure. The details of plume removal are not the subject of this Standard. Refer to AS ISO 16571 for further information. See also NSW Health document GL2015 002.

4.6.2 Dye lasers

Dyes and the solvents used with dye lasers are often toxic. The manufacturer's handling instructions shall be rigorously observed when draining and filling dye lasers. Skin contact with the fluid used and inhalation of its vapour shall be avoided. Refer to local regulations on the disposal of waste materials.

4.7 USER PRACTICES DURING SPECIALIST CLINICAL APPLICATIONS

NOTE: Additional safe practices to be observed during specific uses of lasers are listed in Appendix B.

4.8 EYE PROTECTION—LASERS

4.8.1 General

Eye protection devices, specifically designed for the wavelength and classification of the laser in use, shall be worn within the laser controlled area, in addition to other controls that may be in place to ensure that personnel will not be exposed in excess of the ocular MPE. Such personnel include the patient, laser operator, laser user, anaesthetists, assisting staff and observers.

The extent of the NOHA will vary according to the type of laser used and the delivery system. It can also vary during use due to factors such as the fibre used (beam size and divergence) and changes in operating factors such as power/energy. Unless the size of the NOHA is well known, it is advisable to designate the entire room in which the laser is used as the laser controlled area.

For some open laser operations, floor- or ceiling-mounted laser barriers are used to enclose the laser controlled area. However, the boundary of such barriers is based on knowledge of the NOHA.