

SESLHD PROCEDURE COVER SHEET



Health
South Eastern Sydney
Local Health District

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SUMMARY	Procedures to ensure that medical lasers are used safely.

COMPLIANCE WITH THIS DOCUMENT IS MANDATORY

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1. POLICY STATEMENT

The South Eastern Sydney Local Health District (SESLHD or the LHD) is committed, through a risk management approach, to protecting employees, contractors, students, volunteers, patients, members of the public and the environment from unnecessary exposure to laser radiation, arising from the systems and processes which use lasers within its facilities.

This document provides procedures to ensure that lasers are used safely and appropriately in accordance with the requirements of SESLHDPD/337 – Laser Safety.

2. BACKGROUND

2.1 Introduction

The word "LASER" is an acronym for "Light Amplification by Stimulated Emission of Radiation". Laser devices emit an intense, coherent and highly directional beam of light which may or may not be visible, depending on the type of laser.

Laser devices are sources of non-ionising radiation (NIR). This form of radiation is distinguished from ionising radiation by a different mechanism of interaction with matter. Non-ionising radiation is so called because it does not carry enough energy to ionise atoms. Instead, it interacts with matter by, for example, generating heat.

Many different materials may be used as the laser medium and the laser type is commonly known by the particular medium used. Each medium produces light of a particular wavelength, or, in terms of visible light, colour. Table 1 lists some common medical lasers including the region of the electromagnetic spectrum represented by the laser light.

Laser	Wavelength (nm)	Region of EM spectrum
Excimer	< 400	Ultraviolet (UV-A, B & C)
Argon	488 – 515	Blue/green
KTP:YAG	532	Green
Krypton	530 – 680	Yellow/green
Dye (various)	400 – 900	Ultraviolet to Infrared
Diodes (various)	515 – 1700	Visible to Infrared
Neodymium:YAG	1064	Near Infrared (IR-A)
Holmium:YAG	2100	Mid Infrared (IR-B)
Erbium:YAG	2940	Mid Infrared (IR-B)
Carbon Dioxide (CO ₂)	10600	Far Infrared (IR-C)

Table 1 – Some common medical lasers

2.2 Properties of Lasers

Lasers emit electromagnetic radiation (light) which is monochromatic and has low divergence.

Monochromaticity

Monochromaticity refers to one colour or wave length. Each laser produces light in a narrow band of wavelengths, appearing as a single colour. Sunlight, by contrast, is made up of many colours, or a broad spectrum of wavelengths of light.

Low divergence

A laser emits its light in one direction only in a near parallel beam, i.e. it has very low divergence. This means that the beam power can all be concentrated in a tiny area, yielding a very high power density. This gives laser radiation a far greater potential to cause injury than light from any other source.

2.2.1 Modes of Operation

Most lasers used in medicine operate in one of two modes:

Continuous wave

This is where the beam is present continuously while in operation.

Pulsed mode

The laser output is not continuous but is delivered in a series of pulses. High-energy pulsed lasers can produce extremely high peak power output over a very short period, and can cause tissue damage in less than a nanosecond. High energy pulses (super-pulses) are typically used for breaking down stones.

2.2.2 Laser Delivery Systems

All lasers require a means of transmitting the radiation to the treatment site – this is known as a delivery system. The laser wavelength determines the type of delivery system. Four types are in common use:

- Direct delivery
- Articulated arm
- Hollow flexible waveguide
- Optical fibres

In general, ultraviolet, visible and near infrared lasers (up to about 2000 nm) can use optical fibres, while longer wavelengths can only be transmitted by the other methods.

2.3 Tissue Effects of Lasers

The interaction of light with human tissue is complex. The potential for injury depends upon the laser wavelength, the exposure duration, the beam intensity and the site of exposure. Note that exposure of the body to laser radiation at any wavelength can cause injury, often in the form of serious burns, both to the skin and to the eye, where the consequences can be particularly severe.

As the eye focuses visible light, increasing its power density, serious damage to the interior tissues of the eyes (especially the sensitive retinal layer), *including permanent loss of vision*, can result from the viewing of even quite low power lasers within the visible and near-infrared band. This can occur with exposure levels that, at the front of the eyes and

at the skin, are completely harmless.

2.3.1 *Photothermal Interaction*

The most common result of exposure to laser radiation is the production of heat which, because of the highly intense nature of the laser beam and its ability to be finely focused, can generate very high temperatures, easily sufficient to coagulate or evaporate small volumes of tissue.

2.3.2 *Photochemical Interaction*

Absorbed optical radiation can directly modify the chemical structure of certain tissue components (chromophores). Normally, this photochemical effect is desirable - both vision and the tanning of skin are dependent on it. However, when exposure duration or repetition rate is excessive the normal recovery processes may be inhibited and longer term damage, such as the formation of cataracts, may be initiated. Photochemical effects are most likely to occur at short wavelengths (i.e. towards the ultraviolet end of the spectrum).

2.3.3 *Photoablation*

This involves direct breaking of molecular bonds and subsequent release of biological material. Ultraviolet radiation is very strongly absorbed by biomolecules so penetration depths are small, of the order of a few micrometres.

2.3.4 *Photomechanical Interaction*

Photomechanical effects arise with the use of very short duration, high energy pulses, where there is insufficient time for thermal diffusion to spread the energy around the target tissue. Instead, the tissue expands rapidly, generating an acoustic shockwave that causes mechanical disruption to cellular structures. Laser lithotripsy relies on this effect to disintegrate stones in the renal pelvis and gall bladder.

2.3.5 *Biostimulation*

Low intensity lasers produce a stimulating effect in tissue. Biostimulation lasers, operating in the red or infra-red region, have been reported to produce microcirculatory effects and to stimulate certain cellular processes, and may be used in physiotherapy to promote tissue healing.

2.4 **Hazard Classification of Lasers**

Lasers are grouped into hazard classes under IEC AS/NZS 60825-1 as:

- Class 1 Inherently safe
- Class 1M As Class 1, but beam not safe to view with optical magnifiers
- Class 2 Low hazard – blink response provides sufficient protection
- Class 2M As Class 2, but beam not safe to view with optical magnifiers
- Class 3R Visible radiation, direct viewing hazardous, blink reflex protects
- Class 3B Higher risk than Class 3R – direct viewing hazardous
- Class 4 Direct and indirect viewing hazardous, skin exposure hazardous

EVERY LASER MUST BE CLEARLY MARKED WITH ITS HAZARD CLASS

2.5 Hazards of Lasers

2.5.1 Eye Exposure

The principal hazard is damage to the eye. Laser radiation in the visible and near infrared wavelength regions can penetrate the eye and damage the retina, usually permanently, while ultraviolet laser radiation and far infrared radiation can damage the surface of the eye. Damage from Class 4 lasers can occur in a fraction of a second, far quicker than the eye can blink to interrupt the beam. The hazard can arise from direct exposure to the laser beam or accidental reflections of the beam from shiny objects.

The mechanisms of laser-induced damage are illustrated in Figure 1.

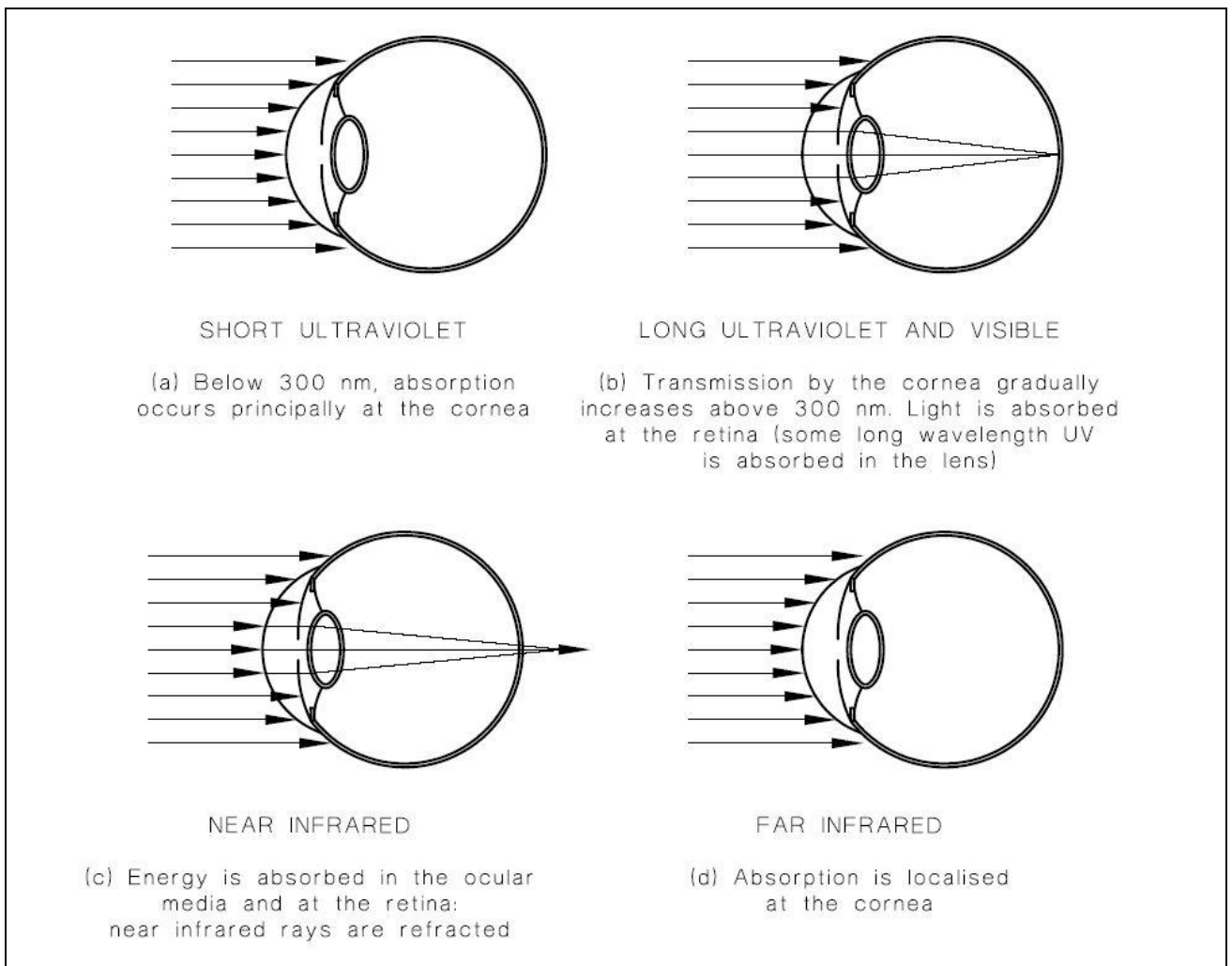


Figure 1. Mechanisms of Laser-induced damage

For staff using lasers it must be stressed that eye damage is most likely immediate and often permanent - thus the local safety rules must be understood and adhered to by all staff involved. The risks of a laser accident occurring may be very small, but the consequences are often serious.

2.5.2 *Skin Exposure*

The penetration of optical radiation into the skin is dependent on its wavelength and is generally greater in the visible and near infra-red regions of the spectrum. As the penetration depth increases, so does the volume of tissue exposed and the amount of radiation required to cause injury is consequently higher. Ultraviolet and mid to far infra-red radiations do not penetrate the skin significantly and thus a very brief exposure can cause serious harm. For most acute laser injuries to the skin a localised laser burn will be the result.

Repeated or extended exposure to low intensity ultraviolet radiation can induce erythema, a photochemical reaction resulting in reddening of the skin, similar to severe sun-burn.

Prolonged exposure over time can initiate long term degenerative processes including premature ageing of the skin and skin cancers.

2.5.3 *Other Hazards*

Other hazards are fire (lasers can ignite flammable materials), skin burns, electrical hazard due to high power and potential hazards from smoke generated by lasers used for tissue ablation (due to the possible presence of live viral material in the smoke plume).

3. PROCEDURES

3.1 Laser Area Qualification

Any area where class 3 or 4 lasers are to be used must first undergo a laser safety assessment. This will be performed by the site Laser Safety Officer, possibly in conjunction with biomedical engineering and/or the designated Laser Safety Supervisor for the Department that controls access to the area.

The Laser Safety Assessment will review:

- Access to the area and whether engineering or administrative controls are sufficient or appropriate;
- Fixed and removable signage available for the area to warn of general or specific laser hazards;
- Light confinement within the area, with consideration of the wavelengths and NOHDs of lasers that might be used in that area;
- Laser hazards within the area, particularly reflective surfaces, flammable materials, conductive materials and laser plume evacuation.

If the LSO determines that lasers may be safely used in the area then a qualification report will be issued, detailing the features of the area reviewed and describing any restrictions placed on laser use in the area (e.g. only lasers with NOHD < 2 m).

3.2 Setting up a Laser Theatre

3.2.1 Signage

Warning signs must be placed at all entrances to a room where a laser is in use. These must include an illuminated sign that indicates when the power to the laser is on, and that the laser may be used at any time.

In addition, signs are required on the laser device itself and at all points on the laser where laser radiation is accessible.

The signs must be black on yellow background and the wording must comply with the requirements of AS/NZS 2211.1:2004. The sign must include:

- i. The international symbol for laser radiation
- ii. The laser type
- iii. The laser class
- iv. That eye protection must be worn



Figure 1. A sample laser warning sign including the international symbol for laser radiation

The warning signs must be removed from all doors once the laser is no longer in use, and the key is returned.

A sign must be attached to or around each laser generating device describing what eyewear is necessary. It must use the system specified in AS/NZS 1337.4:2011 so that a user can check their eyewear against it and thus verify they have the proper protection.

3.2.2 Window Coverings

Visible and near visible laser beams (effectively all except CO2 lasers) will pass through window glass, and opaque coverings must be placed on windows when these lasers are used.

Opacity may be wavelength-dependent, so if coverings are used they must be qualified for the purpose by the LSO in consultation with the provider. This may require penetration testing to be performed.

3.2.3 *Eye Protection*

Eye protection appropriate to the laser type in use must be worn in the NOHA. It is important to note that there is no universal protective eyewear, and that staff must check that the correct protection is available (the wavelength for which the eyewear is designed is marked on the frame).

AS/NZS 1337.4:2011 outlines the marking system for protective eyewear. The type, wavelength, scale number, and optionally, the mechanical strength shall be marked on the eyewear.

Type of laser is indicated by:

D – use with a continuous wave laser

I – use with a pulsed laser

R – use with a Q-switched laser

No letter – use with all types

Wavelength of laser - wavelength regions in nanometres will be marked on the eyewear. All wavelengths that the laser produces must fall within the regions marked for the eyewear to be appropriate for use.

The scale number indicates the level of protection the eyewear provides. This ranges from L1 (least protection) to L10 (maximum protection).

An alternative marking scheme is based on Optical Density (OD). An OD of 1 attenuates light by a factor of 10, with each step in OD reducing transmission by an additional factor of 10. Every laser is different, but for most class 4 lasers, an OD of at least 5 will be required.

It is essential to check the operator manual to determine the minimum OD or Scale Number required. If at all unsure, confirm with the Department LSS or site LSO.

The protective eyewear must provide a good fit to the face, with side protection equivalent to the lenses, be resistant to mechanical damage and provide short-term protection against direct laser effects such as melting/burning of the lens.

Water and mild detergents may be used to clean the eyewear. Never use alcohol to clean them.

3.2.4 *Reflective Materials*

Reflections of class 4 lasers are as hazardous as the incident beam. Restrict the use of reflective materials around the operating area, particularly mirrors or mirror-like surfaces. Note that metal surfaces may produce mirror-like reflections in the infra-red region of the spectrum even if they appear dull on inspection.

Class 4 lasers can also produce hazardous reflections from rough surfaces.

3.2.5 *Fire Precautions*

Many lasers have the ability to ignite flammable materials, including alcohol, anaesthetic gas, bowel gas and plastics, so staff must be aware of the location of a nearby fire extinguisher. Note that most fire extinguishers are not appropriate for use on humans, so a supply of sterile water should be made available if there is any possibility of human combustion.

Any materials used in or around the laser target area should be carefully selected, with non-flammable or laser-safe materials used wherever available. Flammable drapes should be kept away from the laser target area or, if considered essential, dampened with sterile water to suppress ignition.

If operating in the endotracheal region it is essential that staff are familiar with the airway fire management protocol.

3.2.6 *Electrical Hazard*

High powered lasers present a significant electrical hazard and conductive fluids (such as water) should be kept away from the laser equipment. Water-based fire extinguishers should be avoided.

3.3 **Controlling Access to the Laser**

The key for each laser shall be kept at in a secure place when not in use, and should only be used to activate the laser under the supervision of a designated Laser Safety Delegate.

A laser key log book shall also be kept by the Laser Safety Supervisor to record when the key was taken and returned and by whom. Laser procedure logs created by the Laser Safety Delegate will be reconciled against the laser key log book monthly. The key log book will be audited quarterly by the LSO.

3.4 **Maintenance**

Maintenance shall only be performed on the laser by appropriately authorised and trained persons, and these persons shall ensure that the laser is left in a safe condition following maintenance.

3.5 **Records**

A record of each procedure (the 'Laser Log Sheet') must be completed before and after operation of the laser. The log will be kept with the machine and be available for audit. In addition, the following records are to be maintained by the Laser Safety Supervisor:

- Inventory and location of laser equipment
- Safety devices, personal protective eyewear inventory
- Quality assurance, preventative maintenance and equipment repair reports
- Laser safety audit reports
- Laser training records
- Laser incident / accident reports

3.6 Procurement

The LSO and Biomedical engineering will be consulted prior to the procurement (purchase or loan) and use of any Laser at SESLHD facilities to ensure appropriate environment hazard management.

3.6.1 Lasers Brought into the Hospital for Trial Purposes

This practice has a particular hazard, in that staff may not be aware of any special precautions of the type of laser being trialled, nor of any special protective eyewear required. The following guidelines must be followed:

The Laser Safety Officer must be informed of any laser being brought in on trial before the laser is delivered.

Biomedical Engineering must be similarly informed so that any necessary electrical safety testing can be performed.

- Staff who will be working with the trial laser must be informed as to the features, hazards and protection required for the laser.
- Medical staff who are to use a trial laser for a new application must be trained in its use, or a trained person must supervise the procedure.

3.7 Training

SESLHD is responsible for providing training and induction of all employees who may be exposed to laser radiation in the work place. Training and induction programs must be documented. Employees and or students receiving such training and induction must have these attendances recorded. The level of training required is dependent on the role to be fulfilled.

All new staff and trainees should be made fully acquainted with the laser apparatus and ancillary devices before use. Only persons who have received training to an appropriate level should be permitted to work with or control Class 3 or Class 4 lasers.

Role	Training Elements
<p><u>General staff</u> General staff are those who may be indirectly involved in a laser procedure or who may work in the vicinity of a laser hazard area. It is essential that they have an understanding of the hazards associated with laser exposure and have sufficient knowledge to protect themselves and avoid creating a danger for others in the area.</p>	<ul style="list-style-type: none"> • Characteristics of laser beams • Laser eye and skin hazards • Laser classification scheme • Properties of different lasers • Beam reflection hazards • Selecting protective eyewear • Controls & controlled areas
<p><u>Support staff</u> Support staff are those working in the</p>	<p>As for General Staff, plus:</p> <ul style="list-style-type: none"> • Delivery systems and applicators

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<p>Laser area whilst the laser is active. The major emphasis for these staff is safety during a procedure and an overall understanding of the various potential hazards associated with laser use. It is essential that they have a basic knowledge of laser science, particularly terminology, tissue interactions and biological effects, as this will help in identification of potential hazards that might arise.</p>	<ul style="list-style-type: none"> • Beam delivery system hazards • Fire hazards • Electrical hazards • Laser plume hazards • Hazards related to anaesthesia & management of the shared airway
<p><u>Laser Safety Delegates (LSD)</u> A LSD must be designated for each laser procedure and is expected to be present throughout. The LSD has primary responsibility for laser safety of staff associated with that procedure.</p>	<p>As for Support Staff, plus:</p> <ul style="list-style-type: none"> • Laser hazard assessment; • Laser access control; • Pre- & post- procedure checklists; • Laser procedure logging.
<p><u>Laser Safety Supervisor (LSS)</u> Each Laser-using Department designates a LSS who has delegated operational responsibility for laser safety within that Department.</p>	<p>As for Laser Safety Delegates, plus:</p> <ul style="list-style-type: none"> • Awareness of standards, regulations and guidelines; • Incident investigation, management and reporting.
<p><u>Laser Operators</u> Laser operators are responsible for controlling the laser device during a procedure, in conjunction with a Laser practitioner.</p>	<p>As for Laser Safety Delegates, plus:</p> <ul style="list-style-type: none"> • Familiarisation with system-specific operating procedures; • Laser system quality assurance; • Laser-Tissue interactions.
<p><u>Laser Practitioners</u> Laser practitioners direct the laser beam during a procedure. They have primary responsibility for the safety of their patient throughout.</p>	<p>As for Laser Operators, plus:</p> <ul style="list-style-type: none"> • Facility credentials for the Laser procedure being performed.
<p><u>Laser Safety Officer (LSO)</u> The LSO is responsible for managing the Laser safety program and ensuring that it conforms with relevant standards, regulations and guidelines.</p>	<p>As for Laser Safety Supervisors, plus:</p> <ul style="list-style-type: none"> • Familiarity with Laser safety and related standards, regulations and guidelines; • Laser area qualification; • Laser classification.

3.8 Credentialling

Each Laser-using Department must establish and document a credentialling procedure for Laser practitioners. This must be done by the Head of Department in consultation with the facility Director of Medical Services and with the approval of the site LSO.

When credentials are granted, copies of all supporting documents must be provided to the LSO for record keeping purposes.

Unless specifically authorised by the DMS, only senior Medical Officers may obtain Laser credentials. Junior Medical Officers, including Registrars, may only perform Laser procedures under the supervision of a credentialled Medical Officer.

3.9 Laser Incidents and Accidents

A laser incident is an incident adversely affecting, or likely to adversely affect, the health or safety of any person because of exposure to laser radiation.

The following procedures must be followed in the event of actual or suspected malfunction of a laser or the exposure of a person to the laser radiation.

- The user is to switch off the equipment at the main supply.
- The user is to remove the key and place a DO NOT OPERATE label on the equipment.
- The equipment must not be used until the unit is repaired
- The Laser Safety Supervisor is to document the incident (with photographs if possible), including details of all persons and equipment in the room.
- If exposure to the eye(s) is known or suspected an ophthalmic examination should be undertaken as soon as possible.
- An incident report must be submitted to IIMS by the Laser Safety Supervisor or by the staff member involved. A full investigation of the cause of the incident must be undertaken. This may require an investigation team to be established including the Laser Safety Officer. The incident report should include:
 - A full description of the incident including details of the laser involved, the procedure being performed and staff present at the time of the incident;
 - Circumstances of any injury, including presence/absence of eye protection, laser wavelength and pulse duration and the distance of the victim from the laser source at the time of injury;
 - Action taken to re-establish a safe working environment;
 - Proposals to prevent a recurrence.

If any actual or potential injury is involved, the standard Workplace Health and Safety incident management and reporting procedures must be followed.

4. DOCUMENTATION

- Register of approved Laser safety supervisors, nurses and operators
- Register of credentialed Laser practitioners
- Laser theatre qualification reports
- Laser Key Control Log Sheets
- Laser Procedure Log Sheets

5. AUDIT

The following documentation must be maintained and audited on at least an annual basis:

- Training records of all staff who may use or be present during the use of the laser, including safety and operational training
- Clinical credentials of all staff who will use the laser – registrars/fellows **MUST** be supervised by a credentialed surgeon
- Laser procedure and laser key log sheets
- Maintenance records of the equipment.

6. REFERENCES

- SESLHDPD/337- Laser Safety
- AS/NZS 4173:2018 *Safe use of lasers and intense light sources in health care.*
- IEC AS/NZS 60825-1 2014 *Safety of Laser Products.*
- AS/NZS 1336 2014 *Eye and face protection—Guidelines.*
- AS/NZS ISO 19818.1 2023 *Eye and face protection—Protection against LASER radiation.*
- ACORN Standard 2023, *Laser Safety*

7. VERSION AND APPROVAL HISTORY

Date	Version	Version and approval notes
Sept 2011	Draft	Richard Smart, Radiation Safety Officer in conjunction with the Laser Safety Officers
Apr 2012	0	Approved by SESLHD Clinical and Quality Council
Dec 2017	1	
30 October 2024	2.0	Major review. Brought into compliance with updated referenced documents. Change of coding for eye protection. Paragraph 3.2.3 Major change in the way internal credentialing occurs. Previous version relied on Hospital Credentialing committee, but not all hospitals in the District have credentialing committees. Paragraph 3.8. Approved by SESLHD Patient Safety and Quality Committee.