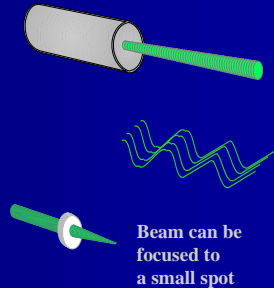


Laser Safety Management

Danny Fok

Properties of Laser light

- Monochromatic (single wavelength)
- Directional (almost parallel low angular divergency)
- Coherent (in phase)
- Pulse or continuous



Types of Lasers

- Gas laser
- Solid state laser
- Dye laser
- Semiconductor / Diode laser



Laser Applications

- Materials processing
- Metrology / Measurement
- Medical / Beauty therapy
- Entertainment
- Communication



Laser Applications

■ Others ---



Related Legislations on Laser Safety

- Occupational Safety & Health Ordinance (Cap 509)
- Consumer Goods (Safety) Ordinance (Cap 456)
- Factories and Industrial Undertakings (Protection of Eyes) Regulations (Cap 59S)
- Places of Public Entertainment Ordinance (Cap 172)
- Regulations of Medical Devices (in draft)
- - - - - -

Regulations of Medical Devices (in draft)



- Medical Device Control Office (MDCO) of the Department of Health established in July 2004
- to set up a risk-based and cost-effective regulation on the supply and use of medical devices with reference to harmonized standards and procedures recommended by the Global Harmonization Task Force

What is a medical device?

A medical device in general refers to any instrument, apparatus, appliance, material or other article, excluding drugs, used for human beings for diagnosis, prevention, treatment, monitoring of diseases or injuries; or for rehabilitation purposes; or for the purposes of investigation, replacement or modification of body structure or function. In addition, it includes devices used for examination of human specimens. International practices classify medical devices into different classes based on their risk to patients, users and other persons.

Class	Risk Level	Examples
I	Low	Surgical drill, saw, tongue depressor, bandage, dressing, walking aid.
II	Medium - Low	Hypodermic needle, suction pump, gastroscope, transdermal stimulator.
III	Medium - High	Lung ventilator, contact lens disinfectant, orthopaedic implant, X-ray machine, <u>laser</u> .
IV	High	Heart valve, implantable cardiac pacemaker, heparin-coated catheter.



Regulations of Medical Devices (in draft)

Scope of Control by the Medical Device Administrative Control System

- **Pre-market Approval** is in the form of voluntary listing of medical devices, importers and local manufacturers complying with specific requirements. They will be listed in one of the following lists -
 - The List of Devices, including Class IV, Class III and Class II
 - The List of Importers
 - The List of Local Manufacturers
- **Post-market Surveillance** is the review of the experience of using those devices that have been placed on the market. The surveillance system would monitor and co-ordinate the management of adverse incidents, safety alerts and recalls related to the use of medical devices.
- **Recognition of Conformity Assessment Bodies** is the acceptance of a list of agencies from which manufacturers could ask them to assess their medical devices for compliance with the requirements related to safety and performance.

Regulations of Medical Devices (in draft)

Scope of Control by the Medical Device Administrative Control System

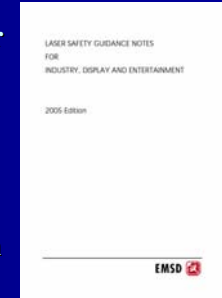
- The system also plans to control the use and operation of medical devices
- For instance, the use of Class3B and 4 lasers and intense pulsed light devices intended for medical therapy and beauty procedure are proposed to be operated by trained personnel only.

Implementation Progress

- The implementation of the first phase of the Medical Device Administrative Control System (MDACS) commenced with the listing of Class IV medical devices on 26 November 2004.
- On 14 November 2005, the second phase of the MDACS was extended to cover Class III and Class II medical devices.
- The Conformity Assessment Body Recognition Scheme was launched on 13 October 2006 as phase III of the MDACS.

Guidelines for Laser Safety in Hong Kong

- a voluntary guidance from EMSD – “Laser Safety Guidance Notes for Industrial, Display and Entertainment” (2005)
- other voluntary guidelines for different professional bodies, e.g., “Guidance on Safe Use of Lasers in Medical Practices” issued by the Hong Kong Medical Association (1994)



Laser Safety Standards

The International Standard issued by the International Electrotechnical Commission :

IEC 60825-1: 2001

Safety of Laser Products – Equipment classification, requirements and user's guide

is the standard most commonly adopted by many countries in the world

Laser Classification

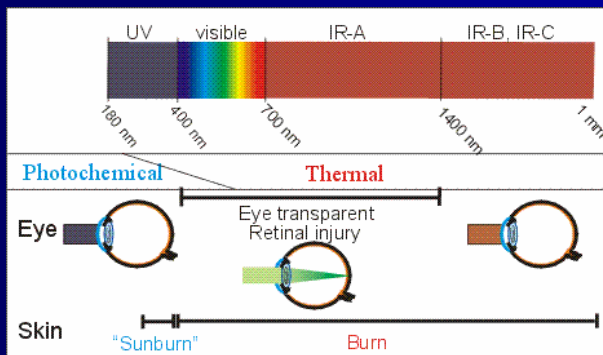
(according to IEC 60825-1)

Class	Properties
1	Inherent safe.
1M	Safe provided optical instruments are not used.
2	Visible lasers. Safe for accidental exposure (< 0.25 s).
2M	Visible lasers. Safe for accidental exposure (< 0.25 s) provided optical instruments are not used.
3R	Not safe. Low risk.
3B	Hazardous. Viewing of diffuse reflection is safe.
4	Hazardous. Viewing of diffuse reflection is also hazardous. Fire risk.

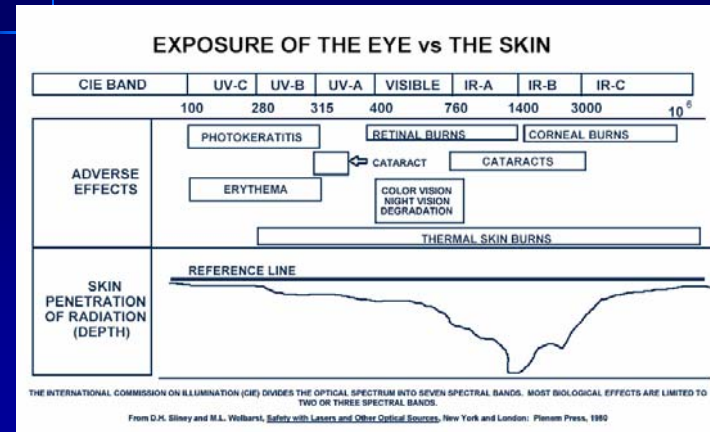
Embedded laser product - a laser product which, because of engineering features limiting the accessible emissions, has been assigned a class number lower than the inherent capability of the laser incorporated.

Beam Hazards

- Hazards associated with the radiation itself
- Cause eye and skin damage



Effects on the Eye & Skin



Maximum Permissible Emission (MPE)

- Maximum level of exposure to laser radiation without adverse biological changes in the eye or skin
- Tables of MPE are compiled for reference according to different standards, e.g. the IEC :

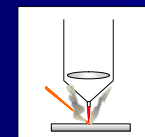
Laser wavelength (nm)	Exposure time (sec)	Ocular MPE (mW/cm ²)	Skin MPE (mW/cm ²)
10600 (CO ₂)	10 (ocular), 10 (skin)	100	100
1064 (Nd:YAG)	10 (ocular), 10 (skin)	5	1000
633 (HeNe)	0.25 (ocular), 10 (skin)	2.5	200
514 (Argon)	0.25 (ocular), 10 (skin)	2.5	200
351 (Excimer) (XeF)	10 (ocular & skin), 3x10 ⁴ (ocular & skin)	100 1	100 1

- The minimum optical density required for the laser eye protectors and the nominal ocular hazard zone are derived from the MPE

Non-beam Hazards

Non-beam hazards are laser associated hazards that cause :

- Electric shock
- Chemical exposure
- laser generated air contaminants
- Fire / Explosion



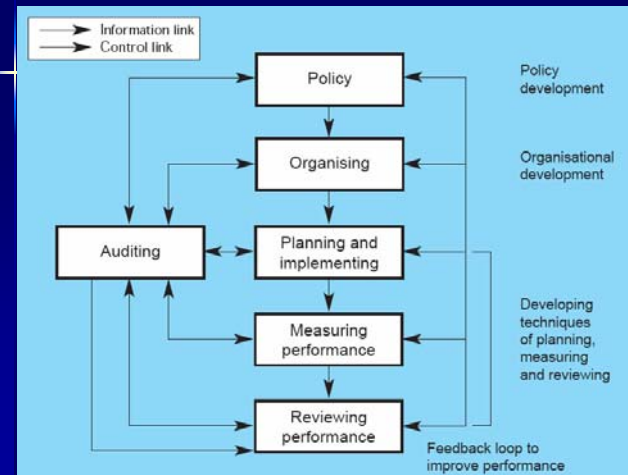
Laser Safety Management in the PolyU

(for Class 3B and 4 lasers)

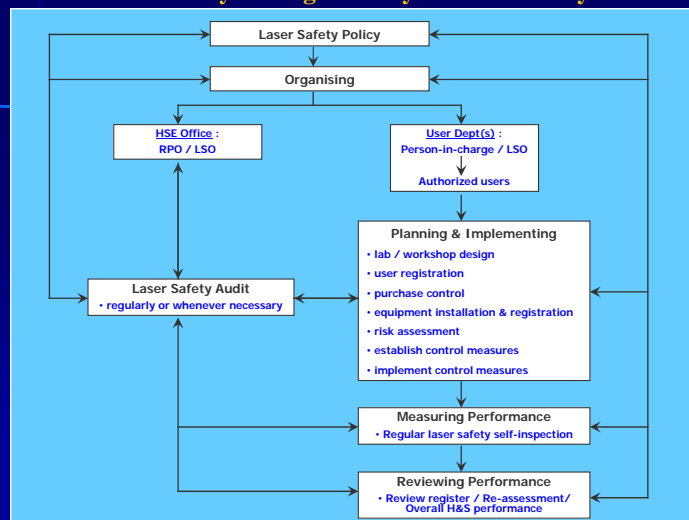


Key Elements of Successful Health & Safety Management

suggested by the Health & Safety Executive, UK (HSG65)



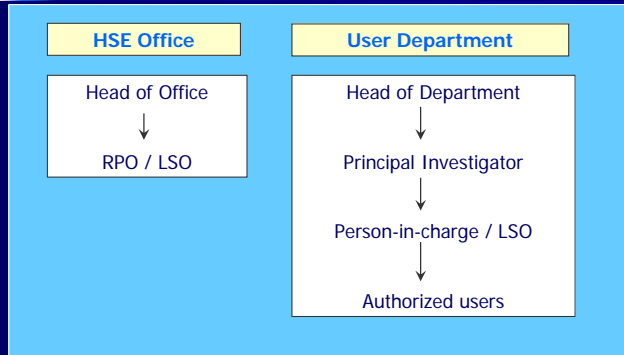
Laser Safety Management System in the PolyU



Laser Safety Policy

- **Code of Practice for Laser Equipment :**
Laser safety policy and requirements are laid down in this document
- **Guidelines for Laser Safety :**
Reference information with technical details on laser safety

Organisation



Responsibilities of the Laser Safety Officer at the HSE Office

The LSO is a qualified staff taking up the following duties :

- formulate laser safety guidelines
- conduct safety and health risk assessments
- conduct laser safety training
- advise on appropriate control measures
- monitor the enforcement of the control measures
- report any accidents to the Government LSO
- conduct accident investigation

Health & Safety Responsibilities of the Person-in-charge at the User Department

This person should be appropriately trained but need not technically involved with the use of laser equipment or develop expertise in laser safety beyond the day-to-day requirements of the department concerned. His/Her duties are to :

- ensure that safety procedures for the laser equipment are established and followed by users
- conduct regular safety inspection on the laser equipment and the working environment
- report any accidents or incidents to the HSE Office



Planning on Laser Safety

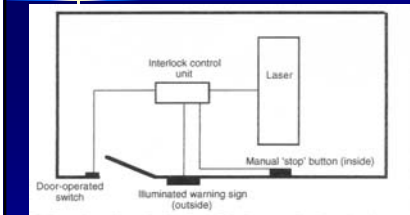
According to the document "Building Requirements for a High Power Laser Laboratory" provided by the HSE Office, the design of a new laboratory or workshop that involves the use of a Class 3B or 4 laser equipment should take the followings into considerations :

- Separation from other facilities
- Specular reflective surfaces are avoided
- Sufficient lighting
- Local exhaust ventilation if necessary
- Warning light and warning sign at the entrance
- Laser beams are not aimed at the eye level or towards the entrance / walk way
- Door interlock for Class 4 lasers
- Appropriate fire fighting equipment for Class 4 lasers

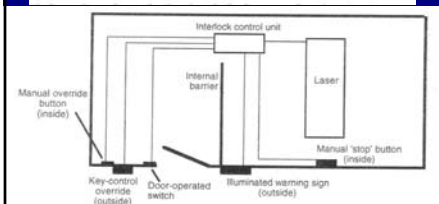


Planning on Laser Safety

--- Laboratory / Workshop Design



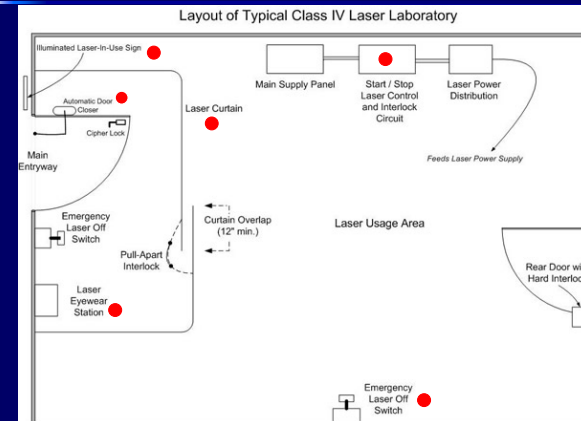
A simple door interlock system



Door interlock + overrides
+ barrier

Planning on Laser Safety

--- Laboratory / Workshop Design



Planning on Laser Safety

--- User Registration

Users are allowed to operate Class 3B or 4 lasers provided that they have been trained in laser safety (either through the e-learning system or the classroom training course) and registered with the HSE Office.



Medical examination (ophthalmic examination) is currently not mandatory for laser users in the PolyU



Planning on Laser Safety

--- Purchase Control

User Departments are required to inform the HSE Office for any purchase of Class 3B or 4 laser equipment either by :

- using the “Tick Box” system in the purchase order, or
- notifying the office directly by phone or email

Planning on Laser Safety

--- Installation & Registration

- Upon installation of a Class 3B or 4 laser equipment, the user department is required to inform the HSE Office for registration of the equipment followed up with a risk assessment.
- A label with the registration no. will also be affixed onto the equipment after registration.



Planning on Laser Safety

--- Risk Assessment

Risk assessment on the laser system is conducted using a set of assessment tools. Four separate elements concerning the laser operation will be considered :

- the equipment
- the process
- the location
- the people



Risk Assessment

--- the Equipment



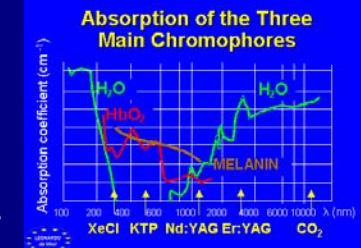
- What is the specification of the laser ? (Class, power, wavelength, etc)
- What is the beam path and how far does the hazard extend ?
- What other hazards are inherent with the laser ?
- What other equipment is the laser being used with ?
- How is the laser being operated ?

Risk Assessment

--- the Process



laser tissue interaction



- What is the laser being used to do ?
- How is the work being carried out ?
- How is the work being controlled ?
- Under what conditions can hazards arise ?

Risk Assessment

--- the Location



- Where is the laser being used ?
- What kind of environment is this ?
- Is the workspace sensibly laid out ?

--- the People



- Who is involved in this activity ?
- How well do they understand the precautions ?
- How aware are they of the hazards ?
- Who else might gain access into the laser area ?

Risk Assessment

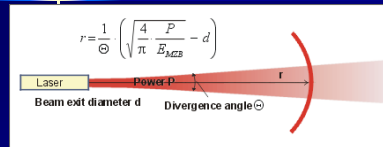
--- the Hazard Area



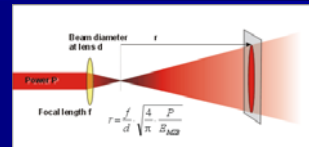
- The laser hazard area or zone can be identified by determining the Nominal Ocular Hazard Distance (NOHD).
- The NOHD is defined as the distance within which the irradiance of a laser beam is greater than the MPE for the eye.
- There is not any eye hazard at a distance greater than the NOHD.

Calculations of the NOHD

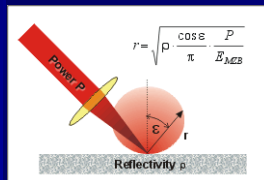
Intra-beam



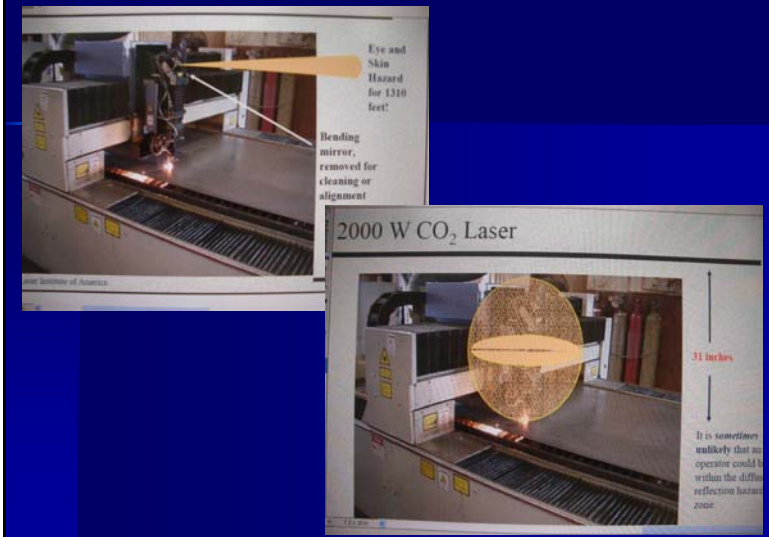
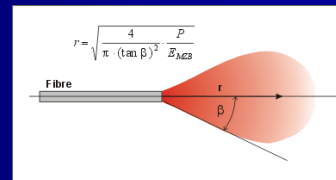
Lens-on-laser



Diffuse reflection



Optical fiber



Risk Assessment

--- Example : a laser welding machine



Establish & Implement Control Measures

- Engineering Controls
- Administrative Controls
- Personal Protective Equipment

Engineering Controls

- Stable mounting (beam not at eye level)
- Protective housings, enclosures
- Interlocks on housings, lasers, doors, etc.
- Control of the beam path (beam tubes, beam stops, etc.)
- Key switches
- Remote firing
- Emergency buttons
- Fume extraction system
- Warning lights
- Filters
- Switch guards, covers
- Alignment aids

Protective Housing / Enclosure

Interlocked housing may convert a high power laser to a Class 1 laser



Door Interlock

Door at the entrance interlocked with the Class 4 laser



microswitches
on the door



reset button

Warning Lights

- should be installed at the entrance
- preferably interlocked with the Class 3B or 4 laser



Key Switch

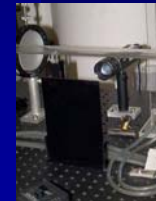
- for Class 3B and 4 lasers
- kept by responsible person



Control of Beam Path

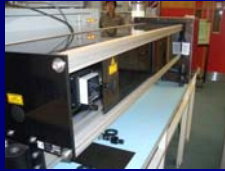
--- Beam Shutter / Stops

- stopping the path of a laser beam
- should be made of proper absorbing material



Control of Beam Path

--- Beam tubes / enclosures



Control of Beam Path

--- partitions, curtains, blinds



Control of Beam Path

--- filtered windows, endoscopes, etc.

Should match with the wavelength of the laser in use



Emergency Buttons

Should be accessible in the vicinity



Fume Extraction System

Local exhaust system with opening close to the fume origin



Exhaust system for material processing



Smoke evacuator for laser plume extraction in laser surgery

Switch Guards, Covers

- Guarded operating switch
- Avoid firing of laser accidentally
- Avoid confusion with other switches (if there are many)



Administrative Controls

- Laser Safety Office or person-in-charge
- Registration of laser equipment and users
- Designated laser controlled areas
- Buddy system
- Warning signs
- Demarcation
- Standard operating procedures
- Emergency and accident reporting procedures

Warning Signs and Labels

(Class 2, 3 & 4 lasers)

ANSI



IEC or BSEN



Demarcation of Hazard Areas

Increased awareness to laser beam or other hazards such as mechanical hazard



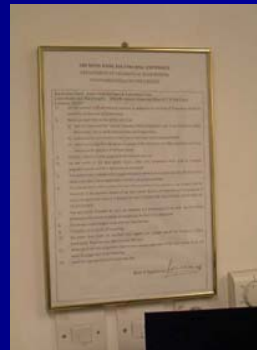
Designated Laser Control Area

Designated laser control area is accessible to registered laser users only



Standard Operating Procedures

- written procedures for operating, maintaining or servicing Class 3B or 4 laser
- should be prepared after a risk assessment
- should be made known to all personnel involved



Outlines for Standard Operating Procedures

- **Basic information** - location, description of laser (lasing medium, power, wavelength, classification, etc.)
- **Hazards** – eye and skin hazards, electrical, chemicals, and other recognized associated hazards
- **Controls** – PPE (eyewear) required, training required, laser control area, entryway control, buddy system, etc.
- **Operating procedures** - including safety measures, normal operation, start up and shut down procedures, special procedures such as emergency, alignment, etc.

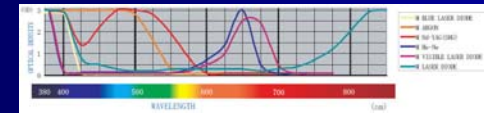
Personal Protective Equipment

- PPE as a last resort
- appropriate laser protective eyewear to protect the eyes
- suitable clothing to protect the skin



Selection of Laser Protective Eyewear

- wavelength of the laser being used



- optical density (OD), damage threshold and visible light transmission
- goggles or spectacles



Selection of Laser Protective Eyewear

- lens : glass or plastic



- mechanism : absorption or reflection
- comfort and fitness
- compliance with standards (e.g., EN207 or EN208)

Maintenance of Laser Protective Eyewear

- should be kept in an appropriate receptacle providing clear type identification and protection from dusts and scratching
- located near the entrance of the laser control area
- if to be worn by more than one person, antiseptic spray, lens cleaner, etc. should be provided in the vicinity
- should be inspected regularly for signs of any damage or degradation
- any defects should be repaired or the eyewear replaced
- eyewear that has or may have exposed to the direct beam of a laser should be discarded immediately

Measuring Performance

- **Person-in-charge or LSO of the user department is required to conduct self-inspection safety check on Class 3B and 4 laser facilities bi-monthly using a checklist**
- **The completed checklist should be documented for further audit by the HSE Office**



APPENDIX

LAW SAFETY CHECKLIST

Date _____

Lawyer Name _____ Operator _____

Pre-Treatment

- _____ Obtain local, state, and federal regulations, permit laws.
- _____ Obtain state accreditation when applicable or in non-permit states.
- _____ Obtain necessary permits if applicable.
- _____ Obtain copy of local policies on treatment costs.
- _____ Check treatment costs.
- _____ Check budget for cleanup location.
- _____ Verify education levels and certifications are valid.
- _____ Obtain all necessary permits in treatment area.
- _____ Check mapping for if required.
- _____ Review permit for treatment types.

Initial Treatment

- _____ Personnel and public have appropriate risk protection.
- _____ Personnel wear proper PPE.
- _____ Verify that all workers are appropriately in full PPE.
- _____ Verify if materials needed under current local treatment.
- _____ Verify if safety considerations are being followed.

Post-Treatment

- _____ Take notes and remove any.
- _____ Address safety issues and other safety requirements.
- _____ Address equipment and materials to dispose.
- _____ Document treatment and volume.

Excerpt from the Safety Plan & Spill/Release Report, Page 4 of 10
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Reviewing Performance

- The user department is required to review the risk registers (including Class 3B and 4 lasers) annually
- Re-assessment of the potential hazards is required in case of any modification or relocation of the lasers
- Overall performance in health and safety (including laser safety) is reviewed regularly by the HSE Office or external consultant

Laser Safety Audit

- The HSE Office conduct laser safety audit at user departments with Class 3B or 4 lasers every 6 months
- Such audit includes document checks, interviewing with users and physical inspection



The End

Thank you