B3.4 Doubled Nd:YAG (KTP), 532 nm, pulsed and CW. The KTP laser is a frequency doubled Nd:YAG laser. The depth of penetration is less than that of the Nd:YAG laser, approximating that of the argon laser of similar wavelength. Typically delivered through an optical fiber, the absorbed laser energy results in precise excision in contact and coagulation in a non-contact mode. Principal applications for the pulsed 532 nm laser are ENT, dermatology, urology and general surgery. The quasi-CW 532 nm laser is used for photocoagulation (superficial) ophthalmology (e.g., retinal and anterior segment).

B3.5 Alexandrite, 755 nm, pulsed. Principal applications are in dermatology and plastic surgery. Used for its melanin absorption in pigmented lesions and hair reduction procedures.

B3.6 HeNe, 633 nm, CW. Principal applications are for aiming HCLSs, low level laser therapy and photodynamic therapy (see B2.3).

B3.7 Ruby, 694 nm, pulsed. Principal applications are in dermatology and plastic surgery where high-energy pulses selectively vaporize tissue.

B3.8 Laser Diodes, 532-980 nm, CW and pulsed. Principal applications are in a broad range of surgical applications including urology, gynecology, gastrointestinal (GI), ENT, ophthalmology, low-level laser therapy and PDT. Fiberoptic delivery systems can be contact or non-contact.

B3.9 Nd:YAG, 1064 nm, 1330 nm, operated in several modes. Principal applications are in photocoagulation, tissue excision and photodisruption. Used in ophthalmology, gastroenterology, urology, and dermatology.

B3.10 Er:Glass, 1540 nm, pulsed. Principal applications are in dermatology and plastic surgery.

B3.11 Ho:YAG, 2100 nm, pulsed. The output of the laser may be delivered either in a contact or non-contact mode through a fiber. Because high pulse energies can be passed through flexible glass fibers, it is useful in laparoscopic and arthroscopic procedures, spinal procedures, and in urology, gastroenterology, and dermatology, as well as other surgical specialties.

B3.12 Er,Cr3+:YSGG, 2780 nm, pulsed. Principal applications are in dental surgery. The Er,Cr3+:YSGG laser operates at about 2780 nm in a pulsed mode. Water absorption is high at this wavelength (shallow penetration), which is effective in the ablation and coagulation of surface tissues.

B3.13 YSGG, 2790 nm, pulsed. Principal applications are in dermatology and plastic procedures. The YSGG laser operates at about 2790 nm in a pulsed mode. Water absorption is high at this wavelength (shallow penetration), which is effective in the ablation, coagulation and collagen stimulation of surface tissues.

B3.14 Erbium:YAG, 2940 nm, pulsed. Principal applications are in otologic surgery, skin resurfacing and ophthalmology. The erbium laser operates at about 2940 nm in a pulsed mode. Water absorption is high at this wavelength (shallow penetration), which is effective in the ablation of surface tissues.

B3.15 CO_2, 10,600 nm, operated in several modes. Principal applications are vaporizing, excision and coagulation through a variety of delivery systems. Used in plastic surgery, dermatology, neurosurgery, gynecology, general surgery, urology, otolaryngology, and podiatry.

B3.16 Picosecond and Femtosecond Lasers. Lasers with extremely short pulses can generate extremely high peak powers even with low energies in each pulse. Because of the short pulsewidth of picosecond and femtosecond lasers (pulsewidths of the order of 10^{-12} s and 10^{-15} s, respectively), microjoule pulses produce megawatt peak power pulses. When focused, such short pulses will create optical breakdown and cause local disruption of tissue. This technology is being applied to create thin corneal sections using the laser beam focused to a given plane within the cornea for refractive surgery, or planes or cylinders within the lens for cataract surgery. Picosecond lasers are also being used for treatment of tattoos and wrinkles.

Table B1. Wavelength Effects for Various Lasers

Laser Type	Wavelength (nm)	Mechanism	Tissue Affected			
			Skin	Cornea	Lens	Retina
ArF (Pulsed)	193	Photodissociative	X	X		
XeCl (Pulsed)	308	Thermal/Photodisruptive	X	X	X	X [a]
He-Cd (CW)	325	Thermal/Photodisruptive	X	X	X	X
XeF (Pulsed)	351	Thermal/Photodisruptive	X	X	X	
Argon (CW)	457.9-528.7	Thermal/Photodisruptive	X			X [b]
Doubled Nd:YAG (KTP) (Pulsed)	532	Thermal/Photodisruptive	X			X
HeNe (CW)	633	Thermal				X
GaAs (Pulsed and CW) (diode)	780-980	Thermal	X			X
Nd:YAG (Pulsed)	1064	Thermal/Photodisruptive	X			X
Nd:YAG (CW)	1064, 1330	Thermal	X	X	X	X
Erbium:YAG (Pulsed)	1540	Thermal	X	X		
Ho:YAG (Pulsed)	2100	Thermal	X	X		
Hydrogen Fluoride (Pulsed)	2730	Thermal	X	X		
Erbium:YAG (Pulsed)	2940	Thermal	X	X		
CO_2 (CW)	10,600	Thermal	X	X		

[a] Simultaneous cornea/lens/retinal effects observed in some biological studies.
[b] Photochemical effects dominate for long term exposures (> 10 s) of the retina.

Table B2. Ocular MPEs for Selected Surgical/Medical Lasers

Laser Type	Wavelength (nm)	MPE ($mW \cdot cm^{-2}$)			
		t = 0.25 s [a]	t = 10 s [b]	t = 600 s [c]	t = 30 000 s [d]
ArF	193	-	-	-	0.0001
XeCl	308	-	-	-	0.0013
XeF	351	-	-	-	0.0333
Argon	457.9-528.7	2.5	-	0.14	0.14
Krypton	530	2.5	-	1	1
	568	2.5	-	1	1
	647	2.5	-	1	1
Dye Laser [e]	630	2.5	-	1	1
HeNe	633	2.5	-	1	1
GaAs (CW) (diode)	840	-	1.9	1.9	1.9
Nd:YAG Q-switched [f]	1064	-	0.022	0.022	0.022
Nd:YAG (CW)	1064	-	5.0	5.0	5.0
Nd:YAG (CW)	1330	-	220	220	220
Ho:YAG (Pulsed)[b]	2100	-	100	100	100
CO_2 (CW)	10,600	-	100	100	100

[a] Aversion response time.

[b] Unintentional viewing at wavelengths greater than 700 nm (with no visible component).

[c] Intentional viewing of diffused reflections from small sources (less than α_{min}).

[d] Cumulative exposure, 8 h working day.

[e] Argon or KTP laser pumped tunable dye laser used in PDT therapy.

[f] Repetitively pulsed at 11 Hz, 12 ns pulses.

Table B3. NHZ Distances for Selected Surgical Lasers without Delivery System Constraints

Laser Type	MPE Exposure Time Criteria (s)	NHZ (m)		
		Diffuse [a]	Laser with Lens [b]	Laser without Lens
CW Visible [c] 400 – 700 nm	0.25	NONE	33.6	500
CW Nd:YAG 1064 nm	10	0.47	6.5	800
CW CO_2 10,600 nm	10	0.18	2.38	178
Q-SW Nd:YAG 1064 nm	$1\text{-}20 \cdot 10^{-9}$	NONE	0.73	356

[a] It is assumed that worst case reflection ($\rho = 1$) and worst case viewing angle ($\cos \theta = 1$) prevail; viewing distance > 20 cm.

[b] Distance from focus.

[c] HeNe, Argon, dye, etc. (see Appendix B3).

Table B4. Laser Criteria used for NHZ Distance Calculations

Laser Parameter	CW Visible	CW Nd:YAG	CW CO_2	Q-SW [a] Nd:YAG
Wavelength (nm)	400 – 700	1064	10,600	1064
Beam power (W)	5	100	100	-
Beam energy (mJ)	-	-	-	2
Beam divergence (mrad)	1	2	2	1
Beam size at aperture (mm)	2	2	20	25
Beam size at lens (mm)	3	6.3	30	25
Lens focal length (mm)	200	25.4	200	50
MPE ($\mu W/cm^2$) @ 10 s	-	5.0×10^3	1.0×10^5	-
MPE ($\mu W/cm^2$) @ 0.25 s	2.5×10^3	-	-	-
MPE ($\mu J/cm^2$) @ 1-20 ns	-	-	-	2

[a] Typical for Ophthalmological use.

Appendix C
Safety Controls of Laser Beam and Non-Beam Hazards in Health Care

C1. General

The use of lasers has many technical advantages in a myriad of medical specialties. However, both laser beam and associated non-beam hazards must be understood and controlled. This is accomplished by acquired training during a medical residency program offering medical laser instruction or through postgraduate courses. A proper understanding of intended laser usage, care and handling of equipment and following safety procedures can help HCP avoid these hazards. It is important to appreciate that management of these issues is consistent irrespective of the health care practice setting (e.g., hospital, ASC, clinic, veterinary office, spa and salon).

Each of the following sections has much in common with respect to laser beam and non-beam hazards. Therefore, to minimize duplication, the "normal" hazards and associated control measures will be listed here. Where appropriate, sections in the standard will be referenced for further information.

C1.1 Equipment.

C1.1.1 Tests. Test all lasers, delivery systems, and safety equipment prior to the patient's arrival into the LTCA. If HCLS calibration and/or testing are necessary before treatment, these procedures should be completed by an authorized and trained individual in accordance with the manufacturer's directions. Appropriate LPE should be worn during testing and calibration procedures (see 4.2.2, 4.5.1.1 and 4.5.1.2).

C1.1.1.1 Checks. Check the power output of the laser in accordance with the manufacturer's directions. This may be necessary before beginning the procedure. Appropriate LPE should be worn during such checks. To prevent inadvertent exposures, the HCLS should be placed in standby mode when not in use (see 4.2.2 and 4.5.1.1).

C1.1.2 Laser Alignment. The HCLS should not be activated if there is a faulty aiming system, a misaligned beam, or non-functioning aiming beam. Follow the manufacturer's instructions for proper laser alignment prior to clinical use of the laser. Alignment of the beam may be checked by exposure of various test surfaces such as laser specific thermal paper, wood tongue depressors, films and plastics depending on the wavelength. Always follow safe exposure protocol procedures. Testing should be done before the patient is brought into the room (see 9.1).

For example, a focused 0.2 mm beam of a CO_2 laser set at 10 W (CW) for 0.1 s will penetrate a dry tongue depressor leaving a pinhole aperture through which the aiming beam can be seen. More rigorous checks would include testing with each delivery system to be used for the intended procedure (handpiece, microscope) and testing with the intended mode to be used (CW, pulse).

Follow the recommended procedural technique during testing (e.g., setting output power per protocol); delivery device attached; device positioned with aiming beam perpendicular to test target surface. After the beam is fired, the test spot is assessed for both alignment of the aiming

beam and for beam impact quality and shape. A poor quality or shape may affect intended tissue effects.

NOTE—Care should be taken when making test burns on a wooden tongue depressor to ensure that nothing flammable is immediately behind it. Point the beam downward at a perpendicular angle if possible and place a wet towel beneath the tongue depressor.

C1.1.3 Electrical Hazards. Use of any electrical system may give rise to electrical hazards and, consequently, proper grounding and insulation are imperative. For example, the potential electrical hazard is increased during endoscopic urological procedures in which the irrigating solution may wet the floor or equipment. Ensure that operating areas and equipment (e.g., laser footswitch) remain as dry as possible (see 7.2).

C1.1.4 Emergency Shutoff. An emergency shutoff switch must be available to the laser user or operator to allow for rapid shutdown of the HCLS (see 4.2.5).

C1.1.5 Accessory Draping. Appropriate draping techniques should be utilized to minimize the possibility of contamination from equipment as it is brought into the sterile operating field. Care should be taken to ensure that draping materials are not positioned in front of the laser beam. When using a sterile drape to drape a non-sterile laser accessory, it should be made of a fire retardant material when possible and secured in place to prevent slippage that may result in the drape's ignition if it falls into the laser beam pathway. Drapes should be checked prior to use of the laser to ensure that they have not shifted during the procedure (see 7.6).

C1.1.6 Fibers. Examine fibers prior to use. Check all of the fiber's components for breakage or damage including the proximal connector, fiber sheath, bare fiber distal tip and, when using contact tip technology, all contact tips.

C1.1.6.1 Fiber Calibration. If calibration is necessary or recommended, follow the manufacturers' written directions (see 4.2.2).

C1.1.6.2 Fiber Monitoring. Monitor fibers for breakage or damage, distortion of the beam, accumulation of debris on the tip, loosening of the connector, or decreased power delivery.

NOTE—Distortion of the laser beam may mean there is a problem with either the HCLS or the fiber. Disappearance of the beam may mean the aiming and treatment beams are no longer transmitting through the fiber, the aiming beam is no longer functioning, or the fiber is broken or damaged and the HCLS's beam is being emitted somewhere other than the tip.

C1.1.6.3 Fiber Cooling. When coaxial cooling is required or recommended, always use the coolant medium appropriate to the fiber and procedure. Never use air or gas to cool a fiber for intra-uterine procedures.

C1.1.7 Foot Pedals and Finger-Trigger Devices. All foot-controlled and finger-trigger switches should be guarded. In the case of the footswitch, the pedal should be designed with a hood or cover to prevent accidental activation of the HCLS. The laser user should remove his/her foot from the pedal and the laser should be placed on standby when not in use.

Many surgical procedures employ the use of more than one type of footswitch (pedal) operated device (e.g., drills, electrosurgical units, microscopes, adjustable treatment tables). Care must be taken to ensure that the user is aware of which footswitch operates the laser. Efforts should be taken to obviate the need for the laser user to have access to more than one foot-pedal at any

time. Immediate disabling of the HCLS when other pedal-operated equipment is used will help to minimize the inadvertent activation of the laser. Place footswitch in a location where it will not be accidently activated (stepped on) by patient or ancillary staff.

C1.2 Controlled Area. Authorized people, upon entry to an area where lasers are being used, should be provided with PPE. Such controlled areas should contain the NHZ, the extent of which is clearly delineated and should be posted with appropriate laser area warning signs specific to the wavelength being used (see 4.4.2 and 4.7.1).

C1.2.1 Area Warning Signs. Area warning signs must be in view outside the room where the laser procedure is being performed (see 4.4.2.1).

C1.3 Fire and Explosion Hazards. Fire hazards associated with lasers take many forms. Proper procedures to minimize the hazards should include the following:

a) Use only wet or fire retardant materials in the operative field/treatment site (see 7.6) and protect tissue adjacent to laser impact site with appropriate materials (e.g., wet or fire retardant drapes—see 7.6.1).

b) Water or saline should be readily available during laser procedures where ignition of flammable materials is possible (see 7.6.1).

c) Non-combustible anesthetic agents should be used in surgery (see 7.6.3).

d) Do not use alcohol or other flammable liquids or agents on or near the immediate treatment site while firing the laser. Care should be taken to avoid pooling of prepping solutions on or under the patient, as some agents may present a fire hazard. If alcohol or other flammable liquids or agents are used for the patient skin preparation, the drying time, as recommended by the manufacturer, should be followed (see 7.6.1).

e) Methane or hydrogen gas may be present in the large bowel. The user must be aware of this possibility and take suitable measures to minimize consequences of gas ignition by the laser beam. These may include dietary changes several days prior to laser treatment, the use of antiflatulents or the placement of wet sponges to adequately cover the perianal region (see 7.6.4).

f) Moist towels and biogel wound protective materials will avert the possibility of fire in the immediate proximity of the laser treatment site and may enhance the effectiveness of fire retardant draping materials.

g) Know location and operation of nearest fire extinguisher. A secured portable extinguisher is recommended so that it can be easily transported (see 7.6.1).

h) Combustible or explosive agents should be removed from the LTCA. If they remain in the room, they should be stored in an NFPA-approved metal cabinet or meet the NFPA code.

i) Wall coverings and draperies should be fire retardant.

j) When using an endoscopic delivery system, avoid beam contact with the sheath. A flexible sheath may be flammable while a metal sheath may become heated causing thermal injury to surrounding tissues (see 7.8).

k) When using an ETT, air concentration of 21% oxygen shall be used unless the patient requires otherwise. The balance of the anesthetic gas shall be comprised of an inert gas (e.g., argon or helium and the required anesthetic—see 7.6.2).

l) When using an ETT, a cuffed tube shall be used whenever possible and the cuff shall be inflated with saline solution containing methylene blue. The cuff shall be protected with wet dressings (see 7.6.2).

C1.4 Plume and Plume Control. Lasers capable of vaporization can result in a plume produced at the impact site. Care should be taken to evacuate this plume with the proper device. Evacuation also maintains visibility of the surgical site (see 7.4).

C1.4.1 Personal Equipment. People in the LTCA should wear a high efficiency filtration mask to lessen the potential for inhalation of particulate matter that could be a biohazard to the respiratory tract. However, masks are intended to protect the patient from exposure to the HCP. An appropriate LEV system (e.g., plume evacuators and wall suction system) is considered to be the first line of protection (see 7.4.2.1 and 7.4.2.2).

C1.4.2 Control of LGACs. The ablation of human and animal tissue with lasers may create a visible plume with noxious odors, irritating airborne contaminants, and may disperse infectious material into the air. This process also occurs during electrosurgery. Products used to prepare the treatment site should be allowed to dry to minimize vaporization by-product hazards or reduce possible combustion when exposed to the laser beam. Local exhaust is critical to control the dispersion of these hazardous materials. To be effective, the plume evacuator nozzle should be kept as close as possible to the treatment site. Adequate general room exhaust ventilation is required. In addition, respiratory protection for the HCP may be employed (see 7.4.).

C1.4.3 Plume Evacuators. Plume evacuators must be maintained in accordance with the manufacturer's instructions. Of particular importance is the necessity to follow the manufacturer's instructions for inspection and replacement of the unit's filters. Failure to follow these instructions may result in poor product performance or product failure. Plume evacuator filters and associated accessories contaminated with patient by-products or pathogens should be handled and disposed of utilizing standard precautions (see 7.4.1 and 7.4.2.1).

C1.5 Responsibilities and Procedures.

C1.5.1 General. A laser trained staff member should be present during all laser procedures. The laser staff member may be the LSO or a designee of the LSO. This individual's responsibilities are to monitor the safety of the patient, the environment, the staff, and the equipment during laser procedures. If this individual is not the LSO, he/she should be empowered with the authority to enforce compliance with safety P&Ps (see 1.3.1, 4.2.3 and 4.2.5).

C1.5.2 P&Ps. Written P&Ps should cover laser beam and non-beam hazards. They should be included in laser educational programs and should be available within the practice setting. They should be reviewed annually and revised as warranted (see 4.2 and 4.2.1).

C1.5.3 Storage. The HCLS key should be stored in a secure area to prevent misuse by unauthorized people (see 4.2.5).

C1.5.4 Qualified Personnel. Only qualified and authorized individuals should operate the laser or be responsible for the care and management of the optical delivery system (see 4.2.5 and 4.4.2.2).

C1.5.5 Delivery Control. Control of the delivery systems should be maintained at all times. If the system is not actively being used, the HCLS should be disabled by placing it in the standby mode. When a fiber delivery system is used, avoid laying a hot fiber or fiber tip on the drapes. Clamps on fiber optic materials may crush or break the material and should not be used. The use of clamps on fiber optics is a fairly common reason for fiber optic breakage. Adequate warning should be given by the laser user before commencement of lasing (see 4.2.5 and 7.6.1).

C1.5.6 Laser Log. A laser log should be used to document laser usage for compliance with safety P&Ps. The contents and data content of the laser log is determined by the facility's policy (see 1.3.2.5 and 4.2).

C1.5.7 Incidents. Any incident, including fire or inadvertent harm to the patient or HCP by the laser, with tissue damage beyond that expected from therapeutic laser use, must be reported to the proper authorities. These include the LSO and the Laser Safety Committee. They may also include the FDA in accordance with Medical Device Reporting (MDR) Regulations 21CFR803 for reporting adverse events, OSHA and state agencies as required. It may be of value to conduct a "root cause analysis" and evaluation of the adverse event in order to make procedural or protocol adjustments, and to educate the user and HCP in an effort to ensure such an event is not repeated. Incidents should be noted of people not following safety procedures (e.g., not applying plume evacuators properly, refusing to wear or use LPE of the proper OD for the wavelength being used—see 5.1).

C1.5.8 Collateral Damage. Laser treatment should be designed to minimize collateral damage in adjacent tissue. The means will vary. Some techniques may employ covering nearby tissues with a protective material (e.g., wet towel or sponge), while other techniques may result in adjustment of the laser beam delivery modalities (e.g., using a high-powered short pulsewidth delivery rather than a low powered CW mode may result in a more efficient tissue effect without creating unnecessary thermal injury to surrounding tissues). It should be the responsibility of the user to be familiar with the particular laser system being used and the means by which to achieve the expected tissue effects (see Appendix E).

C1.6 Eye Protection. One of the greatest single risks for people using lasers is eye injury to the cornea or retina from direct or reflected laser beams. The user, the laser operator and all individuals in the laser treatment room that are within the NHZ should avoid looking directly into the path of the laser beam and wear LPE. The patient should be provided appropriate eye protection as determined by the LSO (see 4.4.4, 4.6.1, 4.6.2.1, and 7.4.1). Caution: LPE is not designed for looking directly at a laser beam.

OSHA and state regulations concerning eye protection during procedures should be strictly observed because of the potential risk of contamination by blood borne pathogens; splash guards and face shields may be used in conjunction with proper LPE when protection is needed.

C1.6.1 Laser Protective Eyewear (LPE). LPE must be clearly labeled with its OD at the particular wavelength being used. It should be emphasized that using endoscopes, microscopes or video monitors does not preclude the laser beam being emitted from a break in an optical