



Approved April 9, 2010
Revised April 12, 2019

AST Guidelines for Best Practices in Laser Safety

Introduction

The following Guidelines for Best Practices were researched and authored by the AST Education and Professional Standards Committee, and are AST approved.

AST developed the guidelines to support health care delivery organization's (HDO) reinforce best practices in laser safety as related to the role and duties of the Certified Surgical Technologist (CST®), the credential conferred by the National Board of Surgical Technology and Surgical Assisting. The purpose of the guidelines is to provide information surgery department supervisors, risk management, and surgical team members can use in the development and implementation of policies and procedures for laser safety in the surgery department. The guidelines are presented with the understanding that it is the responsibility of the HDO to develop, approve, and establish policies and procedures for the surgery department regarding laser safety practices per HDO protocols.

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Rationale

Lasers provide multiple benefits when performing surgery including decrease in postoperative pain, decrease in postoperative surgical site infections, improved wound healing, precise cutting, and reduction in blood loss.¹ However, despite the benefits, risk factors that are identified with the use of lasers include fire, physiologic damage to the eyes, and biological hazards such as laser plume that are addressed by safety standards. Several organizations have been involved in the development of laser standards including the American National Standards Institute (ANSI), American Society for Lasers in Medicine and Surgery (ASLMS), Laser Institute of America (LIA), National Fire Protection Association (NFPA), National Institutes of Health (NIH), National Institute for Occupational Safety and Health (NIOSH), and Occupational Safety and Health Administration (OSHA), as well as the Canadian Centre for Occupational Health and Safety (CCOHS). Surgical personnel should be familiar with the safety standards of these organizations including implementation of safety practices. The following guidelines are broad based and not meant to take the place of the laser standards as established by the above-mentioned organizations; rather these guidelines serve to reinforce the industry established standards and reference those documents that address laser safety in the surgical environment. There are four categories of controls that are applied to the laser environment: administrative, engineering, personal protective equipment, and procedural.² The guidelines in this document focus on administrative, personal

protective equipment, and procedural controls. It is recommended that HDOs have a copy of the following two defining documents for the safe use of lasers available in all areas and departments of the facility where lasers are used: ANSI *American National Standard for Safe Use of Lasers in Health Care Facilities* and OSHA *Guidelines for Laser Safety and Hazard Assessment*. All members of the surgical team should be involved in the process of developing and implementing HDO policies and procedures (P&P) for laser safety.

Evidence-Based Research and Key Terms

The research of articles, letters, nonrandomized trials, and randomized controlled trials is conducted using the Cochrane Database of Systematic Reviews and MEDLINE®, the U.S. National Library of Medicine® database of indexed citations, and abstracts to medical and health care journal articles.

The key terms used for the research of the guidelines include: deputy laser safety officer; Federal Laser Product Performance Standards; health care laser system; laser generated airborne contaminants; laser protective eyewear; laser safety officer; laser safety specialist; laser treatment controlled area; local exhaust ventilation; nominal hazard zone; optical density; personal protective equipment; standard operating procedures. Key terms used in the guidelines are italicized and included in the glossary.

Guideline I

Surgery departments should have established laser safety P&P.

1. The following is a general list of the P&P that the surgery department should ensure are addressed.
 - Laser sanitation.
 - Laser safety audit.
 - Event and near-miss reporting.
 - Proper handling of laser systems.
 - Documentation of laser procedures.
 - Equipment checks before initial laser use.
 - Equipment inspection and preventive maintenance schedules.
 - Maintenance of a list of authorized laser users and team members.
 - Measures for reporting and impounding malfunctioning equipment.
 - Measures to control laser room access, including appropriate signage.
 - Fire safety including fire prevention and response, and airway fire management.
 - Education and training, and competency requirements for laser users and laser team members.
 - Precautions during laser use, for example, covering reflective surfaces, donning proper LPE, laser plume management, and preventing electrical hazards.
2. The following are details of specific items from the previous list that the CST should be particularly familiar. The P&P should be reviewed and as necessary updated every two years by the LSO and laser safety committee (LSC).³
 - A. U.S. regulatory and accrediting agencies have the expectation that an HDO will have an LSO and laser safety program. OSHA uses the ANSI laser standards as its guideline for evaluating a facility's laser safety precautions. Additionally, The Joint Commission (TJC) confirms that an HDO has an established laser safety program that includes a LSO, equipment labeling, routine equipment inspection, and routine

personnel training to determine if the HDO meets TJC's safe-environment-of-care requirements.⁴

- B. The surgery department should designate an individual that has the appropriate level of clinical experience with lasers, completed *laser safety officer* (LSO) training, and achieved certification as a Certified LSO (CLSO) to administer the laser safety P&P.^{1,5}

- (1) The LSO has the authority and responsibility for administering and supervising the laser safety P&P, including the development and revision of the P&P. The duties of the LSO include.⁶⁻¹⁰

- (a) classifying lasers;
- (b) approving procedures;
- (c) complete annual safety audits;
- (d) establish and oversee the laser safety program;
- (e) ensuring that training and medical surveillance are in place;
- (f) establish the *nominal hazard zone* (NHZ) for each type of HCLS (see B, (2) for details);
- (g) evaluating hazards and approving measures to control the hazards (see B, (3) for details);
- (h) supervise the implementation of the HCLS manufacturer's instructions for use (IFU);
- (i) maintain all records regarding the use of the laser (laser log), maintenance, service and repairs (see B, (4) for details);
- (j) coordinate with the risk manager investigating laser adverse events and recommending actions to prevent recurrence;
- (k) supervise and approve the installation of the HCLS, and the services are completed according to the manufacturer's IFU;
- (l) confirm that *personal protective equipment* (PPE) is being used correctly by surgical personnel and the PPE is in proper condition;
- (m) confirm that warning signs that are in compliance with ANSI standards are posted in the correct locations when an HCLS is in use (see B, (2) and B, (5) for details);
- (n) confirm fire extinguishers are in working order, inspected on a periodic basis, and correct extinguishers are available based on the manufacturer's IFU, local fire official's recommendations, and ECRI Institute and American Society of Anesthesiologists recommendation.

- (2) The LSO is responsible for determining the NHZ in the *laser treatment controlled area* (LTCA) and assist in controlling access to the area.

Appendix A provides a sample P&P for controlled access to the laser room.

- (a) The LTCA should only be occupied by surgical personnel who have completed the surgical department laser safety training.
- (b) The NHZ should be communicated to the surgical personnel to avoid unintentional exposure to the laser beam.
- (c) The LTCA should be examined by the LSO and surgery personnel assigned to the laser procedure(s) for the presence of reflective surfaces, such as mirrors and windows.^{1,7,11} Doorways and windows

should be covered with some type of nonreflective barrier, such as curtains or screens, to prevent surgical personnel outside the OR from being exposed to an inadvertent laser beam.¹

- (d) The LSO is responsible for ensuring that surgery personnel working within the NHZ are following safety procedures and practices.
 - (e) The correct warning signs should be displayed in a conspicuous manner on all doors used for entrance to the LTCA to warn that a laser is in use and surgical personnel entering should take the proper safety precautions. OSHA requires placement of warning signs.¹² The surgical team should ensure the door(s) are closed throughout the surgical procedure. When laser surgical procedures are not being performed in the OR, the warning signs should be covered or removed.
- (3) The LSO is responsible for completing a laser hazard evaluation prior to the initial use of a new *health care laser system* (HCLS) that includes verification of the manufacturer's hazard classification label.⁵ The LSO is responsible for being present and supervising the test run of a new laser by laser users and operators.
- (4) The LSO is responsible for keeping the surgery department laser log documenting laser usage up-to-date. The laser log should be consistent with the documentation that is on file for every laser procedure and should be included as a permanent part of the patient's clinical file.⁵ The following are the recommended items that should be documented and included in the patient's clinical record:^{1,5}
- (a) Patient identification.
 - (b) Signature of surgeon.
 - (c) Procedure performed.
 - (d) Surgical teams use of LPE.
 - (e) HCLS setting and parameters.
 - (f) Names and credentials of surgical team.
 - (g) Number of joules, total energy, and watts used.
 - (h) Type of protective eyewear provided for patient.
 - (i) On/off laser activation and deactivation during the procedure.
 - (j) Type of HCLS used during the procedure, including model and serial number.
 - (k) Safety measures that were used during procedure; for example, fire safety equipment, LEV, signs, window barriers.
- (5) The LSO reviews and ensures compliance with all safety measures including functionality of protective equipment, manufacturer's laser controls, and labels and warning signs are in compliance with the *Federal Laser Product Performance Standards* (FLPPS) and ANSI standards.^{5,13}
- (6) The *deputy laser safety officer* (DLSO) and *laser safety specialist* (LSS) are responsible for supervising the safe use of lasers in their respective roles under the supervision of the LSO.

- C. An LSC should be established to advise on and ensure compliance with laser safety P&P.¹
- (1) The LSC should be a multidisciplinary committee that includes: anesthesia provider(s), CST, chief of surgery, chief operating officer, director of biomedical engineering, director of medical staff continuing education, director of nursing, DLSO, environmental manager, health technology manager, LSO, LSS, risk manager, sterile processing department supervisor, surgeon representing each specialty that uses lasers, surgery department supervisor.¹
 - (2) The LSC duties may include the following:⁵
 - (a) development of P&P for laser use;
 - (b) oversight of the laser safety program;
 - (c) assessing staffing and equipment needs;
 - (d) overseeing laser safety education and competency verification;
 - (e) strategic planning for and acquisition of laser-related technology;
 - (f) conducting periodic reviews of the quality of care provided to patients undergoing laser procedures;
 - (g) appoint an LSO who is given the authority and responsibility of enforcing and monitoring the surgery department laser safety program;^{1,7,8,14,15,16}
 - (h) establishing credentialing requirements and verifying the qualifications of surgeons who operate lasers in the HDO, including reviewing applications and recommendations for delineation of clinical laser privileges
 - (3) The surgery department should have procedures in place for the management and reporting of laser incidents to the LSO and LSC.
 - (a) The LSC is responsible for reviewing the incident, and provide recommendations and/or an action plan to prevent a recurrence of the incident.
 - (b) The surgery department should have P&P that address reporting surgical personnel who violate laser safety P&P, intentionally or unintentionally, to the LSO and the incident reviewed by the LSC to determine recommendations and/or action plan to prevent future safety violations.
- D. Written *standard operating procedures* (SOP) for the beam shape, alignment, and testing of a HCLS that includes safety precautions should be obtained from the manufacturer, approved by the LSO for all Class 3B and Class 4 HCLS, and maintained on file for access by all surgical personnel.² (See Appendix J for additional information on laser classes).
- (1) The CST is responsible for aligning the laser optical system, including beam, beam deflectors, lenses, and mirrors, prior to activation of the HCLS to prevent inadvertent eye exposure of surgical personnel during the procedure. The CST should follow the manufacturer's instructions for laser alignment.
 - (a) Alignment should be completed prior to the patient transported into the OR.

- (b) Proper alignment of the free beam infrared (IR) laser beam should be confirmed with a visible aiming beam prior to activation.^{5,13} A Class 1 or Class 2 low power visible laser should be used for path simulation for alignment of higher power visible or invisible laser beams.⁶ Alignment should be achieved by testing the laser beam alignment and quality using an appropriate testing device according to the laser wavelength, such as a wet tongue depressor, plastics, or laser thermal paper.¹³ When using a wet tongue depressor, the CST should confirm there are no flammable materials behind it and should position a wet towel underneath the tongue depressor.⁵ When performing alignment, the CST should have the delivery device attached and the device positioned such that the aiming beam is perpendicular to the surface of the testing device.⁵
 - (c) The CST may wear alignment eye wear; however, this type of eye wear is used for lower power visible laser beams. Alignment eye wear should not be worn during the operation of a high power HCLS; the LPE with the correct OD should be worn.⁹
- (2) All lasers require confirming the beam shape is correct prior to activation as per manufacturer's specifications.⁵
 - (a) Beam accuracy should be tested by firing the beam through the applicator (fiber optic, micromanipulator, handpiece) according to the written manufacturer's procedures.
 - (3) A surgical laser should not be used if the alignment and/or beam shape are inaccurate. The LSO and surgeon should confirm the alignment with the CST, and review the quality of the beam shape. If necessary, the delivery optics should be cleaned and the laser fiber replaced according to manufacturer's instructions to improve the beam quality.
- E. The LSO and surgical team are responsible for confirming that proper precautions have been taken to protect the patient's eyes from injury by inadvertent laser beam exposure.^{1,7,8,11,14}
 - (1) The LSO is responsible for approving the methods to be used to protect the patient's eyes. Methods include laser corneal shields and eye pads. The correct eye protection should be appropriate for the HCLS that will be used and based upon the laser wavelength.⁵
- F. Laser PPE should be worn by the surgical team who are within the NHZ during laser use.^{1,7,8,11,14,15,17-22}
 - (1) Eye injuries are the greatest risk from lasers.¹ *Laser protective eyewear* (LPE) includes glasses or goggles of proper *optical density* (OD). The lenses should not be glass or plastic.¹ The LPE should withstand direct and diffuse scattered laser beams. Goggles should have side shields to protect against back reflection and side entrance of inadvertent laser beams.^{5,9} Contact lenses are not an acceptable form of LPE; prescription lens wearers should don appropriate LPE.⁵ Appendix B provides a sample P&P for ocular safety.

- (a) Upon selection and purchase of LPE, the following information should be provided by the manufacturer and kept on file for access by surgical personnel:
 - i. Verification the product(s) meet(s) the standards for resistance to flammability.
 - ii. OD that is clearly and permanently marked or labeled on the LPE.^{5,21,22}
 - iii. Manufacturer's recommendations on cleaning methods, shelf life, and storage.
 - (b) Prior to use the CST should confirm the OD and wavelength printed on the LPE, particularly if the surgery department has more than one type of laser. If a surgery department has more than one type of laser, it is recommended that the LPE and laser handpiece are color coded to assist the surgical team in using the correct LPE.²³
 - (c) The CST should complete periodic cleaning and inspection of LPE to ensure the maximum condition of the eyewear. The eyewear lenses should be gently cleaned according to manufacturer's instructions. Prior to every use the CST should inspect the lenses for cracking, discoloration, pitting, and/or scratches including light leaks and coating damage that would allow for eye injury.¹ The CST should also inspect the frame to ensure proper fit and functioning, and straps or other devices used to hold the eyewear in place for excessive wear or damage. If the lenses are damaged, the LPE should be immediately discarded and reported to the LSO.^{1,8}
- (2) PPE includes gloves, masks, surgical gowns, and scrub suits to protect the skin from laser ultraviolet (UV) radiation. The potential for skin damage depends on the type of HCLS, laser beam power, and duration of exposure.⁹ The HCLS manufacturer and/or LSO should specify the appropriate PPE for the protection of the skin.
- (a) A standard surgical glove usually provides adequate protection against UV.⁵
 - (b) The circulator should wear an appropriate scrub suit jacket that is flame resistant and covers the arms.²
 - (c) A surgical gown provides adequate protection for the arms.⁵ However, the use of a fire-resistant surgical gown should be used in the presence of a HCLS.²
 - (d) Specially designed high-filtration laser surgical masks capable of filtering particulate matter as small as 0.1 μm should be worn by surgical personnel during laser surgical procedures. The manufacturer's written instructions for use should be kept on file for access by all surgical personnel. The instructions should include the manufacturer's time limits for effectiveness.⁵ The LSO is responsible for confirming the high filtration mask meets the standards as stated in the OSHA 29CFR 1910.134 Respiratory Protection standard.²³ To be effective, the mask should have a

moldable nosepiece and flexible side panels that is worn in a manner that snugly covers the nose and mouth.²⁴ The mask should be changed after every surgical procedure or if it becomes wet during a procedure.²⁴ Laser masks consist of electrostatically charged synthetic fibers that upon becoming wet, the moisture can eliminate the electrostatic charge and decrease the filtration ability of the mask.²⁴ Routine surgical masks do not work due to filtering capability of only 5 μm or larger.²⁵ Double masking should not be allowed as it does not provide proper protection against particulate matter. The surgical team should be aware that plume evacuation is the primary method for protection against plume hazards, and high filtration masks are a second line of defense.^{5,9}

G. In general surgery, approximately 10% of reported surgical fires involve lasers as the source of ignition.¹ Additionally, ECRI Institute estimates that approximately 75% of surgical fires occur in oxygen-enriched atmospheres.¹ Due to the fire hazards that lasers present, surgical personnel should complete the surgery department's fire safety training. Fire safety training is essential to preparing surgical personnel to be able to work efficiently and quickly as a team in the event of a real fire.^{26,27}

(1) The three goals of a fire safety program are to:¹

- (a) safely manage fuels;
- (b) safely manage ignition sources; and
- (c) minimize or avoid oxidizer-enriched atmospheres near the surgical site.

(2) Fire safety training should include the following: fire triangle; classes of fires; extinguishing requirements for each class of fire; procedures to be taken for an airway, HCLS, or surgical drape fire, and the responsibilities of each member of the surgical team; location and method to shut off power, gases, and flammable liquids; location of fire alarms; location of fire-fighting equipment and extinguishers; and emergency evacuation procedures and routes.^{26,28,29} The training program should include fire drills that involve fire-fighting personnel, use of the fire extinguisher, and location of the remote shutoff for gases conducted no less than once-per-year.³⁰ See Appendix C for a sample P&P on non-beam hazards. See Guideline VII for fire-prevention measures that should be taken regarding laser fibers.

(a) Surgery personnel should know the location of the medical gas control valves and their location in the surgery department to be able to turn them off. Since the gas is the oxidizer in the fire triangle, turning it off assists with controlling the fire.²⁶

(b) Fire blankets should not be used in the OR for the following reasons: blankets are manufactured from wool and have the potential for catching fire, thus causing the fire to spread; blanket can contribute to surgical site contamination and infection; and the blanket can trap the fire underneath it causing the patient more injury than necessary.³¹

- (c) Evacuation routes should be established in the surgery department. The routes should be established in collaboration with local fire officials and according to NFPA 101.³² The evacuation routes should be clearly marked in the surgery department and throughout the HDO.²⁶ Surgical patient(s) should be evacuated to the closest area where patient care can be safely delivered.²⁶
- (d) NFPA 99 recommends scheduling fire drills that include evacuation procedures annually; however, NFPA 101 recommends fire drills to be held at least quarterly on each shift.^{30,32}
- (3) The surgery department should obtain the written HCLS manufacturers' instructions that include fire safety features and fire hazards that are specific to the HCLS.²⁹ The instructions should provide guidance to the surgical team for managing a laser fire.²⁹
- (4) The surgery department should have a written fire prevention plan that is kept on file and can be accessed by employees. New employees should review the plan prior to working with lasers.²⁹ Additionally, the plan should be periodically reviewed by the LSO and LSC, and if necessary, updated.
- (5) Surgical personnel should complete training when there are changes to the laser equipment, and/or purchase of a new HCLS and equipment.
- (6) Classes 3B and 4 laser beams should always be considered a significant ignition source.²⁹ No materials are considered fire safe when a laser beam is present in an oxygen-enriched atmosphere.²⁹ The surgical team should be aware of the following health care categories of potential fuel sources.²⁹
 - (a) Fabrics: dressing materials; gowns; head covers; masks; patient warming devices; shoe covers; surgical drapes; towels.
 - (b) Laser circuitry: beam hoses/tubes; fiber-optic cables.
 - (c) Ointments: petroleum-based gels.
 - (d) Patients: Hair; gastrointestinal gases (hydrogen, hydrogen sulfide, methane).
 - (e) Plastic/rubber products: anesthetic masks; breathing circuits; endotracheal tubes; gloves; patient warming devices; surgical drapes.
 - (f) Prepping agents: alcohol, benzoin, chlorhexidine gluconate.
- (7) When assisting the surgeon with placing sterile drapes, the CST should ensure the drapes are carefully arranged to minimize oxygen buildup underneath.²⁶
- (8) During a surgical procedure, the HCLS should be in the stand-by position except when the surgeon indicates he/she is ready to use the laser.^{5,9}
- (9) The sterile surgical team members should complete training in the use of the emergency shutoff switch.²⁹ The switch should be available to the surgeon for immediate shutdown of the HCLS.
- (10) The proper fire extinguisher should be immediately available for use in the instance of a laser fire. The HDO should select fire extinguishers according to the NFPA 10 standard.³³

- (a) Surgical personnel should complete training in the use of a fire extinguisher.²⁹
 - (b) Fire extinguishers should not be used for extinguishing a surgical drape fire.
 - (c) The Class C CO₂ fire extinguisher is recommended by the ECRI Institute and American Society of Anesthesiologists for electrical fires, including lasers.¹
 - (d) The fire extinguisher(s) and supplies should be inspected and tested on an annual basis.³³
 - (e) When laser procedures are not being performed, the extinguisher should be stored in a room that meets local, state, and federal regulations as well as National Fire Protection Association's standards.²⁹
- (11) The CST is responsible for having a basin of sterile water available on the sterile field in the event of sponges, surgical drapes, or towels igniting.⁵
- (12) Dry combustible sponges and towels should never be placed on the sterile field during laser procedures. The four non-disposable towels used to square off an incision should be moistened with sterile water prior to placement. Sponges should be moistened in sterile water or saline prior to use. The CST is responsible for monitoring the moisture level of the sponges to prevent drying out.
- (13) The use of foam positioning devices should be avoided; however, if used, the devices should be moistened in water or saline before placement.
- (14) The use of fire-resistant surgical drapes is recommended; however, no matter what level or rating of resistance a manufacturer communicates to the purchasing HDO, fire-resistant drapes are still flammable. The two key factors for the selection of surgical drapes are the flammability rating and the capability for producing LGAC.⁵
- (a) Cloth and paper drapes should not be used due to their high flammability. Based on studies, polypropylene drapes that contain wood pulp are more flammable.^{3,4}
 - (b) The CST should ensure the sterile drape(s) are securely in place to prevent movement during the procedure into the laser beam path. The CST should assist the surgeon confirming the drapes have not moved prior to activating the laser.
- (15) Flammable solutions should not be used or be present on the sterile field.
- (a) Patient skin preparation solutions should not be allowed to pool around and/or under the patient, and should be allowed to dry to prevent the vapors from collecting and being trapped under the surgical drapes.^{9,25,26}
 - (b) Iodine-based solutions should be wiped off if the surgeon is incising the skin with a laser wavelength that can be absorbed by pigmentation.
 - (c) Surgical team members should not use hair spray, styling gels, or mousses that increase the flammability of hair, and the

preoperative instructions provided to the patient should also state not to use the same products the day of surgery.

- (d) The surgical team members should ensure that their hair, including facial hair, is fully covered during the surgical procedure. If the patient's hair is near the laser impact site, it should be covered with wet sponges or towels to prevent ignition.
- (16) If laser surgery is performed near the patient's teeth, such as a microlaryngoscopy, a dental protector that is non-flammable that can withstand laser impact should be used since an inadvertent laser beam can pit a tooth.
- (17) The surgical team should ensure the proper measures are completed to prevent a methane gas explosion when using the laser in the rectal area.³⁴
- (a) A preoperative enema should be performed on the day of surgery.
 - (b) The CST should provide the surgeon with a suction tip and tubing to evacuate residual methane gas from the rectum prior to starting the procedure. The CST should remove and discard the suction tip and tubing from the sterile field after use. It is recommended the surgeon and CST change the outer gloves of the double gloving, and don new sterile gloves, and then the CST can set-up a new sterile suction tip and tubing.
 - (c) According to surgeon's preference, the perianal region should be completely covered with wet sponges to prevent the escape of methane gas.^{1,5}
- (18) During head and neck surgical procedures, CSTs should assist the surgical team in preventing airway fires by providing small pledgets, which are part of the surgical count, that are moistened in sterile saline for placement around the endotracheal (ET) tube to provide additional protection against the laser beam.^{1,35} The CST should periodically moisten the sponges to prevent drying.
- (19) The anesthesia provider will inflate the ET tube cuff with a saline and methylene blue mixture.^{5,15,36} If the cuff ruptures during the procedure, the presence of the blue dye on the pledgets alerts the sterile surgical team. The saline released from the ruptured cuff aids in extinguishing airway fires. If an airway fire is suspected, the surgical team should take immediate action because hot gases can be forced into the patient's lungs causing extensive life-threatening airway and lung tissue injuries.
- (a) The anesthesia provider is responsible for immediately removing the ET tube and turn off the anesthetic gases to the patient.
 - (b) Surgical team should remove all flammable and burning material from the airway. The CST may need to immediately provide to the surgeon some type of clamp such as a Crile or Kelly, or forceps, such as DeBakey forceps, to remove the sponges that were packed around the ET tube.
 - (c) CST should immediately provide water to be poured into the patient's airway.

- (d) When the airway or breathing circuit fire is extinguished, the anesthesia provider is responsible for reestablishing ventilation by mask.
 - (e) The surgeon is responsible for assessing the trachea for injury and examine if any ET fragments are in the airway to be removed.¹ The CST may need to request and set-up for a bronchoscopy.
 - (f) The anesthesia provider and surgeon are responsible for assessing the patient's status to determine if the procedure can continue and establish a plan for ongoing care.
 - (g) The surgical team should bag and label all the involved materials and devices for later examination to assist in determining the cause of the airway fire.
- (20) An important component of the surgery department laser safety P&P is a laser time-out procedure that is in addition to the surgical time out as a measure to prevent fires in the OR. It is recommended that a checklist that is placed in the patient's medical records is completed prior to the laser being activated by the surgeon. The checklist should be repeated when there is a change of surgical team member(s) in the OR, such as anesthesia provider, CST, or circulator, or a long waiting period has occurred between laser standby and next use, such as waiting on results of a frozen section from the pathologist.³⁷ The following is a list of items that should be included in the checklist.³⁷ Appendix C provides a sample comprehensive laser safety checklist.
- (a) Watts.
 - (b) Laser mode.
 - (c) Type of laser.
 - (d) Key removed.
 - (e) Windows covered.
 - (f) Type of laser fiber used.
 - (g) Laser has been test fired.
 - (h) Patient outcomes recorded.
 - (i) Sponges and towels are wet.
 - (j) Integrity of laser fiber verified.
 - (k) Name of surgical procedure(s).
 - (l) Non-flammable ET tube is used.
 - (m) Eye protection is placed on patient.
 - (n) Laser warning signs are on the door(s).
 - (o) Plume evacuator is ready to be used by CST.
 - (p) Eye protection is donned by surgical personnel.
 - (q) Fire extinguisher is in the OR and verified as being full.
 - (r) Sheath length has been measured pre- and post-procedure.
- (21) When a fire in the OR is confirmed, the surgical team should coordinate in accomplishing the following actions:¹
- (a) Announce there is a fire and immediately halt the procedure.
 - (b) Anesthesia provider is responsible for stopping the flow of anesthetic gases to the patient.

- (c) Surgical team rapidly remove burning materials from patient and provide the necessary patient care according to the type of fire.
- (d) CST immediately provides water for dousing the fire.
- (e) Although fire extinguishers should not be the first choice when addressing a surgical fire, they may be needed in the instance a fire is extensive and continues to burn the patient and/or is an acute threat to the surgical team.

H. Surgical personnel should complete training on the HCLS electrical safety requirements.

- (1) The surgery department should follow the OSHA 29CFR 1910.147 Control of Hazardous Energy (Lockout/Tagout) standard.³⁸
- (2) Solution bottles should never be placed on the laser unit to prevent spillage that could cause internal damage to the laser circuitry.
- (3) The surgical team should ensure that the OR floor and equipment that is positioned on the floor, such as the laser foot pedal, are kept dry, particularly during endoscopic procedures that require the use of irrigating solutions throughout the procedure.
- (4) The manufacturer's instructions should be followed for grounding the laser unit. The surgical team should confirm the HCLS is properly grounded prior to each use.
- (5) Electrical cords should be inspected before each use for breaks, cracks, or fraying that could cause an electrical shock or fire.²⁵
- (6) The LSO and surgical team members are responsible for confirming there is no electromagnetic interference that will occur between the HCLS and other electrical equipment.⁹
- (7) Manufacturer's labels or HDO labels should be affixed to the laser unit providing electrical rating, frequency, and watts. The labels should never be removed or covered.
- (8) Surgical team members should complete training to know how to properly check the connections to water-cooled lasers to prevent water overflow onto the OR floor.⁹
- (9) The power output of the laser system should be checked prior to the start of the procedure with a power meter, as well as frequently checked throughout the surgical procedure.⁵
- (10) Only authorized service personnel, for example, biomedical technicians who have completed training, should be allowed to remove the HCLS outside cover to perform maintenance and service work.

I. Laser plume evacuation should be performed during a laser procedure to remove *laser generated airborne contaminants* (LGAC). (See Appendix C)

- (1) Research has consistently confirmed the presence of bio-aerosols, particles, steam, and toxins in laser plume.³⁹ The particles consist of blood, carbonized tissue, and DNA from bacteria and viruses, thus potentially having carcinogenic and mutagenic properties.³⁹⁻⁴¹ Research and the report of two laser surgeons diagnosed with oropharyngeal human papillomavirus (HPV) indicates that HPV may be transmitted through the laser plume.⁴²⁻⁴⁵ Another study reports that researcher's detected 62

organic compounds including carcinogens and toxins during laser hair removal treatment. The plume also contained three chemicals with daily exposures that exceeded OSHA daily permissible limits, and if a LEV had not been used, some of the ultrafine particles would exceed levels considered safe.⁴⁶ Additionally, there is a significantly increased incidence of nasopharyngeal warts in laser surgeons when compared to a control group.⁴⁵ The LGAC can also have an unpleasant odor, and potentially cause ocular and upper respiratory tract irritations.¹ Additionally, when lasers are used during orthopedic procedures, particulates and metal fumes may be generated.⁵ Lastly, lasers can produce toxic chemicals produced by the pyrolysis of human tissue.⁴⁷ Dyshemoglobinemias (carboxyhemoglobin and methemoglobinemia) have been confirmed in research to occur in patients during laser laparoscopic procedures. The concentration of plume and physiologic changes that occur depend on the amount of tissue pyrolyzed, duration of smoke exposure, and effectiveness of plume evacuation.⁴⁷ Refer to the bibliography for a comprehensive listing of journal articles publishing research over the span of several years. See Table 1 for additional details regarding laser plume content.

Table 1. Laser Plume Contents, Sources Potential Health and Safety Hazards, and Control Measures

Laser Plume Content	Source	Potential Health and Safety Hazard	Controls
Dust	Procedures using CO ₂ lasers	Lung damage	- Appropriate masks - Plume scavenging system (PSS)
Toxic chemicals*	Laser beam contact with human or animal tissues, plastics, perfluoro-polyethylene polymer (e.g., Teflon), coated products	- Fire - Irritation - Carcinogenic, mutagenic, and teratogenic potential	- Respiratory protection suitable for plume composition - PSS
Biological Agents	Laser beam contact with tumors, HIV, culture medium, bacteria, warts, treated skin	- Infection	- Respiratory protection suitable for plume composition - Protective clothing and gloves - PSS
Smoke	Laser beam vaporization, incision, CO ₂ laser beam contact with skin	- Respiratory damage - Eye damage - Irritation - Obstruction of workers' field of vision	- Scavenging of smoke near the source - Suitable eye and respiratory protection

* Toxic chemicals can include: benzene, formaldehyde, acrolein, aldehydes, polycyclic aromatic hydrocarbons, cyanides, and methane hydrogen cyanide.

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- (2) NIOSH recommends using a combination of general room and *local exhaust ventilation* (LEV).³⁹ It should be noted that general room ventilation itself is not sufficient to capture the contaminants generated by the laser plume.³⁹ The two types of LEV are portable plume evacuators and room suction systems. The LEV should be appropriate to the amount of plume that may be produced during the surgical procedure. The hazardous area for LGAC exposure can exceed the NHZ.^{5,39}
 - (a) If small amounts of plume are anticipated, such as during a minor procedure, the use of an in-line suction filter may be used that is positioned between the suction canister and ceiling or wall connection.²⁴ The in-line filter should be replaced according to manufacturer's instructions.²⁴
 - (b) A high-efficiency LEV is a more reliable unit that consists of a charcoal filter, vacuum, and high-efficiency particulate air (HEPA) or ultra-low penetration air (ULPA) filter.^{24,39}
- (3) The CST should hold the plume evacuator wand within two inches of the treatment site.^{24,39,48} Evacuation efficiency is reduced when held farther away. However, the CST should be cognizant of the laser beam path to avoid placing the plume evacuator wand within the path causing beam reflection. The vacuum tubing should be changed after each surgical procedure and treated as biohazardous waste.²⁴
 - (a) The CST should be aware if a purge gas flow will be used with a CO₂ laser that causes the plume to spread. The CST is responsible for holding the evacuator wand as close to the tissue target site as possible without obstructing the surgeon's view of the surgical site.
- (4) If a plume evacuation foot pedal is used it should be positioned near and activated by the CST. The foot pedal should be clearly labeled.
- (5) Only trained surgical personnel, such as biomedical technicians, should change the HEPA or ULPA filters.
 - (a) A lingering odor and/or plume in the OR should alert the surgical team that the filter needs to be changed.²⁴ Additionally, the HCLS should have an indicator light to signal to the surgical team the filter needs to be changed.⁴⁰ The HCLS manufacturer should provide in writing its recommendation for how often a filter should be changed including the procedure for changing capture devices, filters, and tubing according to local, state, and federal regulations, and HDO P&P.^{39,40} The absorbers, capture devices, filters, and hoses are considered biohazardous waste and should be handled and disposed of according to manufacturer's written instructions, and local, state, and federal regulations, and HDO P&P.^{39,40}

- (b) New filters and hoses should be installed on the LEV for each procedure.³⁹
- J. Surgical personnel should practice proper body mechanics when moving a HCLS, particularly to prevent injury to the lumbar region. The use of carts with large wheels can make it easier to transport a HCLS. Extreme care should be taken during transportation of the laser unit to an OR to not hit it against a wall or sides of a doorway to avoid damage to the unit and laser arm.

Guideline II

CSTs, as well as other surgical personnel, who use or work in the presence of Class 3B and Class 4 HCLS should complete detailed training in the safe use of lasers to ensure the safety of patients and surgical team during procedures.^{18,29}

1. The laser safety program should reflect the surgery department's P&Ps, as well as ANSI, local, state, and federal regulations and standards. The safety program should be reviewed and updated as necessary every two years by the LSO.³ Components of the safety program include the following:⁵
 - A. Appointment of an LSO who oversees the laser safety program, and responsible for enforcing the laser P&Ps. (See Guideline I for further information).
 - B. Establish a multidisciplinary LSC that develops the safety program P&Ps, and reviews laser incidents. (See Guideline I for further information).
 - C. Establishing usage criteria and authorization procedures for surgical personnel working in the laser NHZ.
 - D. Identifying laser hazards and providing requirements for monitoring compliance with administrative, engineering, and procedural controls.
 - E. Medical examinations that surgical personnel should undergo.
 - F. Establishing educational requirements including credentialing, competency verification, and education and training courses.
 - G. Address equipment and procedural controls, including audits.
 - H. Reporting laser incidents to the LSO and LSC, conducting a cause-effect analysis, and identifying measures to be completed to prevent a recurrent.
2. Initial and annual laser safety training should be required to be completed by the LSO, DLSO, LSS, and laser users (CSTs, RNs, biomedical technicians).⁵
 - A. The laser safety program should provide a thorough understanding of the procedures and safety equipment required to establish and maintain a safe environment in the surgery department.⁵ Overall, the program should address the biological and physical tissue effects caused by lasers, hazards of laser use, how to safely handle and operate the laser equipment and instrumentation, and PPE.^{5,49} Appendices D and E provide the details of a laser safety training course; Appendix F provides an example of a checklist for validating the skills of a laser operator.
 - (1) The laser safety training for CSTs and other surgical personnel should be comparable to the training completed by surgeons to contribute to a surgical team that operates in a coordinated, efficient and safe manner.⁵
 - (2) The program should focus on and be specific to the HCLSs that are in use in the surgery department and the surgical procedures that are being performed. Additionally, the safety training should be distinguished by and

separate from the training that is focused on the methods and techniques for performing surgical laser procedures.⁵

3. The safety training completed by CSTs should be documented and maintained on file by the surgery department, including initial and annual training, as well as additional training, such as when a new HCLS is purchased. The LSO should document the method(s) used for verifying competency and date of when the competency verification was completed.
 - A. CSTs should be required to periodically demonstrate laser competency on all HCLSs that are used in the surgery department.
 - (1) It is recommended the retraining program be provided by an LSO no less than every five years for LSOs, DLSOs, LSS, laser users, and laser operators.⁵
 - B. The surgery department should provide training to CSTs and other surgical personnel when a new HCLS, laser equipment and instrumentation, and/or safety equipment are purchased.
 - (1) CSTs should be required to demonstrate competency when a new HCLS, laser equipment, and/or safety equipment have been purchased by the HDO.⁵

Guideline III

To be appointed/designated as an LSO, the CST should complete an LSO training course.

1. The CST should, at a minimum, have three years of documented comprehensive experience working with lasers in the OR prior to serving in the role of LSO.
2. CSTs who have an interest in serving in the role of LSO should complete a formal medical laser safety course, formal medical LSO course, and achieve certification as a CLSO, and continue by achieving Certified Medical LSO (MSLO).

Guideline IV

Surgery departments should have established laser safety P&P for all borrowed, leased, or owned HCLS.

1. The LSO is responsible for supervising the processes associated with the use of a third-party provider and/or operator of laser equipment. All written records should be filed for access by surgical personnel. (See Appendix G for a sample intake checklist for third party rental of an HCLS.)
 - A. The LSO should confirm the HCLS is in compliance with HDO, local, state, and federal requirements.⁵
 - B. LSO should receive from the third-party provider written records of the HCLS history of calibration, preventative maintenance, and repairs.⁵
 - C. LSO should receive from the third-party provider written records that the HCLS passed required medical equipment management plans (MEMP) for electrical safety testing.⁵
 - D. The LSO should confirm the third-party HCLS technician/laser operator's qualifications meet the requirements of the surgery department including health tests, license, and completion of laser safety training.^{1,5}
 - E. The LSO is responsible for approving the HCLS and its installation according to manufacturer's laser control measures.

Guideline V**The HDO should have established procedural and equipment control policies to avoid potential hazards when Class 3B or 4 HCLS is in use.**

1. Surgical personnel involved in the operation of a HCLS should complete training and demonstrate knowledge of the location and use of operating the emergency control stop for each type of HCLS.
2. Procedural control policy should address communication between surgical team members to confirm that the HCLS ready function is enabled only when the surgeon is ready to treat the target tissue.
 - A. During the surgical procedure, the laser unit should be in the stand-by position at all times except when the handpiece is in the hand of the surgeon and ready to be activated.^{1,5,7,8,11}
3. Procedural control policy should address the control of the laser keys.
 - A. The laser key should only be available to authorized personnel; it should not be given to unauthorized or unqualified surgical personnel.^{1,5,8}
 - B. The laser key should not be left in the laser when it is in storage.^{1,5,8}
 - C. The laser key should not be placed in the laser and the laser operated unless the LSO or DLSO is present.^{1,5,7,8,11}
4. An equipment control policy should address the use of multiple foot pedal switches in the OR.
 - A. The laser foot pedal should be available only to the surgeon who will be operating the HCLS. The surgical team member who is placing the foot pedal on the floor should verbally identify the foot pedal and floor position/placement to the surgeon. A guarded pedal switch or guarded finger-trigger switch should be provided for use by the surgeon.^{1,5,8}
 - B. All other types of foot pedals should be placed away from the laser foot pedal and verbally identified by the surgical team member who is positioning the pedals. If possible, the foot pedals should also be clearly labeled as an extra precaution to prevent inadvertent activation.^{1,5,8}
 - C. The plume evacuation pedal should be positioned for activation by the CST.
 - D. The HCLS should be disabled when other foot-pedal controlled equipment is used to prevent the activation of the HCLS.^{1,5,7,8,11}
 - E. All foot pedal electrical cords should be inspected before each use for breaks, cracks, or fraying that could cause an electrical shock or fire.^{10,25}
5. Accessory attachments, such as endoscopes, handpieces, and remote controls should be compatible with and meet the safety standards for use with the HCLS.
6. An equipment control policy should address communication among the surgical team members confirming laser filters are in place when an operating microscope will be used to protect the eyes of the surgeon and CST.
7. Labels that are affixed to the laser system equipment should be visible at all times and not covered or removed.

8. The surgery department should have P&P for managing and reporting adverse events and near misses related to laser incidents.¹
 - A. If an incident occurs, the surgical team should understand that the laser and any other involved equipment will be held for evaluation, and the laser's control settings should not be touched/left as is when the incident occurred.¹
 - B. It is recommended that the risk manager closely works with the LSO to investigate the incident and identify measures to prevent recurrence.¹
 - C. The risk manager can also ensure that the laser safety program complies with reporting incidents to local, state, and federal authorities, including the FDA that requires reporting device-related injuries and deaths under the Safe Medical Devices Act.⁵⁰ Additionally, incidents should be reported to the FDA's MedWatch and the ECRI Institute's Medical Device Problem Reporting.^{51,52}
9. The LSO should supervise the completion of an annual facility and equipment safety audit to include HCLS, plume removal devices, protective eyewear, surgery department area controls, and warning signs as well as labels on the HCLS.^{1,5,8} The safety audit should include those portions of the HCLS that present a fire hazard.²⁹ The audit should be completed no less than once-per-year.⁵
 - A. The LSO should keep a written log of the audits and HCLS maintenance that includes results and any actions taken to resolve identified discrepancies. The LSO should report the results of the audit and actions to resolve the discrepancies to the LSC.⁵³

Guideline VI

The CST should be responsible for ensuring the correct sterile laser instruments are available for use by the surgeon.

1. The CST should provide anodized or ebonized surgical instruments for the surgical procedure to prevent unintended laser beam reflection when the instruments are used near the laser impact site.⁵
 - A. Studies have indicated the optimal surface coating to decrease unintended reflections is a roughened, ebonized coating with a fluoropolymer material.^{8,15,54,55}
 - B. Periodically, the instruments may need recoating due to normal wear.
 - C. The CST should inspect the instruments when setting up the sterile back table and Mayo stand for breaks and scratches in the surface coating. Defective instruments should be immediately removed from the sterile field and transferred to the sterile processing department to be tagged for repair or disposal.
 - D. The instruments should not be etched for identification purposes. Etching disrupts the surface coating allowing for laser reflection.
 - E. The CST should assist the surgeon in monitoring the position of surgical instruments in relation to the laser beam path to avoid reflection.
 - F. If the surgeon requires the use of a non-ebonized instrument, the CST should wrap saline or water soaked radiopaque sponges around the instrument to prevent laser reflection as well as a laser fire.⁸

2. The CST should have sterile quartz and titanium rods available for use as backstops during CO₂ laser surgery.^{1,14} The CO₂ laser beam continues to travel through the tissue after the surgeon has cut or coagulated; therefore, a backstop is necessary to prevent damage to non-targeted tissue.
 - A. Glass rods should not be used due to the possibility of shattering from the absorption of heat from the laser energy.
 - B. Metal rods should not be used due to absorbing the heat generated by the laser energy, and the heated rods can contact and injure adjacent tissue.
 - C. Nonstick rods should not be used due to absorbing the heat generated by the laser energy that can melt the rods that also produces a toxic plume.⁵⁶
3. The CST should have sterile mirrors available that consist of rhodium or stainless steel. Glass-surfaced mirrors should not be used; the glass has the potential for shattering due to heat absorption from the laser energy.⁵⁶
 - A. The CST should inspect the mirrors when setting up the sterile back table and Mayo stand for breaks, cracks, and scratches on the surface that would prevent effective reflection of the laser beam. Defective mirrors should be immediately removed from the sterile field and transferred to the sterile processing department to be tagged for repair or disposal.
 - B. The manufacturer's instructions should be followed for laser wattage limitations to prevent damage to the mirror.⁵⁶

Guideline VII

Specific precautions should be taken by the CST when a fiber is used with the HCLS during an endoscopic procedure. See Appendix I for a sample P&P for handling a laser fiber delivery system.

1. Generally, laser fibers are very small and delicate, and therefore, can be easily broken or damaged by mishandling and overheating. Damaged fibers can lose energy transmission at their tips resulting in ignition of the covering sheath from energy absorbed by the fiber.⁵⁷
 - A. The sterile surgical team should confirm/visualize that the end of the fiber extends past the end of the endoscope by a minimum of one centimeter. Visualization of the fiber tip is important throughout the surgical procedure for fire prevention in instances of tissue debris collecting on the fiber, fiber breakage, or loosening of the connector.⁵
 - B. To decrease the fire hazard presented by a broken fiber, the sterile surgical team should avoid bending, clamping, or leaning against a fiber.⁵
2. The fibers are sharp and can damage an endoscope when inserted through the scope.⁵⁸ The CST can protect the sharp end of the fiber by using a small length of medical-grade catheter sheath with the tip recessed inside the tubing; after the tip is extended past the end of the endoscope, the tubing can be withdrawn and the tip can be visualized.⁹ When setting up the procedure, the CST should compare the manufacturer's laser catheter labeled length to the laser fiber to ensure the fibers will extend beyond the catheter.⁵³ If the length is not sufficient, the CST should remove it from the sterile field and it should be tagged for disposal.⁵³
3. Air or gas should never be used to cool a fiber during an intra-uterine procedure.⁵⁹ Only the coolant that is recommended by the manufacturer should be used. In two cases

investigated by the ECRI Institute at two different HDOs, fatal gas embolism occurred during the use of the Nd:YAG laser. One HDO used CO₂ gas to distend the uterus and the other used air to cool the laser fibers. Surgery personnel should be educated that gas should not be used for uterine distention or to cool laser fibers, and only liquid should be used during hysteroscopic surgery regardless of the laser wavelength.¹ ECRI Institute recommends placing a label with the following wording in a prominent location near the laser aperture: “WARNING: Never use air or gas for fiber cooling or uterine insufflation during hysteroscopic laser surgery or other applications that may present the risk of gas embolism.”¹

4. When not in use and outside of the treatment area, the CST should cover the fiber tip with a wet sponge for protection.⁵ The hot fiber tip should never be placed on the sterile drapes to avoid a fire.
5. When setting up the procedure and at the completion of the procedure, the CST should examine the laser catheter sheath and laser fibers for damage, and if damaged, removed from service and tagged for repairs.^{17,60}
6. During the procedure, each time the catheter sheath and laser fiber are removed from the patient, the CST should examine the sheath and fiber to confirm if they are intact.⁵³ If the sheath and/or fiber are not intact, the CST should immediately report this to the surgical team, pass one or both items off the sterile field, and the surgical team should implement the surgery department’s P&P for retained surgical items.^{53,61}

Guideline VIII

Surgical personnel who work in the area and/or with Classes 3B and 4 HCLS should undergo a health assessment examination with a focus on ocular performance and dermatological risks.

1. The CST should complete a health examination of the eyes prior to working with lasers including color vision, macular function, ocular history, and visual acuity.
 - A. The CST who is involved in a laser incident that may have affected the eyes should complete an ocular examination within 48 hours of the incident.⁵ If the injury to the eye is from a laser operating in the 400 nm to 1400 nm retinal hazard region, the examination should be performed by an ophthalmologist.⁵
2. It is recommended that CSTs who have a history of photosensitivity, dermatological conditions, or working with HCLS that emit UV radiation should undergo a dermatological examination. The CST should disclose their history of medication usage, both over-the-counter and prescription, to identify drugs that are potentially photosensitizing.⁵
3. The health assessment examination records should be maintained according to surgery department policies, and state and federal government regulations.

Guideline IX

The surgery department should review the policies and procedures (P&P) regarding safe use of HCLS on an annual basis.

1. The surgery department should include members of the surgical team and administration when reviewing the P&Ps, including CSTs, surgeons, RNs, risk management, and infection control officer.
 - A. The surgery department should document when the P&Ps were reviewed, revision completed (if necessary), and who participated in the review process.
2. CSTs should be familiar with the P&Ps for the safe use of HCLS. The orientation of new employees should include reviewing the P&Ps.

Guideline X

CSTs should complete continuing education to remain current in their knowledge of the safe use of HCLS.⁶²

1. The continuing education should be based upon the concepts of adult learning, referred to as andragogy. Adults learn best when the information is relevant to their work experience; the information is practical, rather than academic; and the learner is actively involved in the learning process.⁶³
2. It is recommended surgery departments use various methods of instruction to facilitate the learning process of CSTs.
 - A. If the education is primarily lecture, methods to engage learners include presentation of case studies for discussion, and audience discussion providing suggestions for reinforcing safe use of HCLS.
 - B. Other proven educational methods include interactive training videos, and computerized training modules and teleconferences.
 - C. The continuing education should be delivered over short periods of time such as in modules, and not in a one-time lengthy educational session.
3. Continuing education programs should be periodically evaluated for effectiveness including receiving feedback from surgery department personnel.
4. The surgery department should maintain education records for a minimum of three years that include dates of education; names and job titles of employees that completed the continuing education; synopsis of each continuing education session provided; names, credentials, and experience of instructors.

Competency Statements

Competency Statements	Measurable Criteria
<p>1. CSTs are knowledgeable of the risks, patient and surgical personnel hazards, and safety factors associated with the use of HCLS.</p> <p>2. CSTs are qualified to perform the patient care concepts as related to the use of HCLS.</p> <p>3. CSTs are qualified to operate those components of the HCLS in which they have completed training.</p> <p>4. CSTs that complete the education and training, and achieve the relevant certification, can fulfill the role and duties of the LSS, DLSO, or LSO.</p>	<p>1. Educational standards as established by the <i>Core Curriculum for Surgical Technology</i>.⁶⁴</p> <p>2. The didactic subjects of laser equipment and instrumentation, laser safety, and types of HCLS and their applications are included in a CAAHEP accredited surgical technology program.</p> <p>3. Surgical technology students perform the role and duties of the surgical technologist in the use of the HCLS during clinical rotation under the supervision of the program instructor, preceptor, and surgeon.</p> <p>5. As practitioners, CSTs operate the components of the HCLS in which they have completed training.</p> <p>6. CSTs complete continuing education to remain current in their knowledge and skills in the safe use of HCLS, including the annual review of surgery department P&P, and training in the use of HCLS as required by the employer.</p>

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Glossary

deputy laser safety officer (DLSO): Person authorized and responsible for managing the laser safety program in the absence of the LSO.⁶

Federal Laser Product Performance Standard (FLPPS): Center for Devices and Radiological Health (CDRH) is a regulatory bureau within the FDA of the Department of Health and Human Services. CDRH was chartered by the U.S. Congress to standardize the performance safety of manufactured laser products; these regulations are the FLPPS.⁶

health care laser system (HCLS): Laser system used in health care applications. The HCLS includes the laser or lasers, a delivery system to direct the output of the laser, a power supply with control and calibration functions, mechanical housing with interlocks, and associated liquids and gases required for the operation of the laser.⁶

laser generated airborne contaminants (LGAC): Airborne contaminants generated when a laser beam interacts with target materials. The materials may include, but are not limited to, ceramics, glasses, metals, plastics, tissue, and wood. LGAC may be in the form of aerosols, gases, organic or inorganic particulates, or vapors, and often are a complex mixture of substances in all three states.⁶

laser protective eyewear (LPE): PPE that includes glasses and goggles with side shields, used to protect the eyes from harmful exposure to laser radiation.

laser safety officer (LSO): The LSO is the person authorized by the administration to be responsible for the laser safety program including oversight and control of laser hazards.⁶

laser safety specialist (LSS): In diverse practice areas, such as large facilities or corporations, an LSS is employed under the supervision of the LSO. The LSS is responsible for all aspects of laser safety at each site where lasers are used.⁶

laser treatment controlled area (LTCA): The room within which the HCLS is used, and the occupancy and activity of those within this area are subject to supervision for the purpose of protection against all hazards associated with the use of the HCLS. In a large room, a limited LTCA can be designated if clearly marked and controlled.⁶

local exhaust ventilation (LEV): A system used to remove laser plume during a surgical procedure. There are two types of systems: portable plume evacuator and room suction systems.

nominal hazard zone (NHZ): The space within which the level of the direct, reflected, or scattered radiation during normal operation exceeds the applicable maximum permissible exposure (MPE). Exposure levels beyond the boundary of the NHZ are below the applicable MPE.⁶

optical density (OD): A value that defines the attenuation property of a filter.⁶

personal protective equipment (PPE): Safety protective devices used to mitigate hazards associated with laser use that include gloves, LPE, masks, scrub suits, scrub suit jackets, and surgical gowns.

standard operating procedures (SOP): established methods to be followed routinely for the performance of designated operations.

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Appendix A

Form J1. Controlled Access to the Laser Room

Sample P&P

Purpose: To define the area in which control measures must be applied, and to describe the control measures necessary in order to maintain a safe environment for patients, and for health care personnel (HCP).

Policy: Class 3B and Class 4 lasers will be operated only in areas where traffic flow and compliance with all safety procedures can be monitored.

Procedure:

- a) Laser signs will be posted at eye level on all doors that access a room where a laser will be operated. These signs will state all required information as described in the ANSI Z136.3 standard, and will be removed when the laser is not in use.
- b) Safety goggles labeled with appropriate wavelength and optical density will be available at the entry where each door sign is posted.
- c) Glass windows will be covered with shades or filters of appropriate optical density whenever a fiberoptic laser system is operational.
- d) All safety procedures will be followed during service and demonstrations.
- e) No one will be allowed into a laser room unless properly authorized and protected.
- f) The laser should not be activated when it is necessary to open the door if the NHZ extends to the doorway.
- g) Laser keys will be kept in a secure area and signed out only by those authorized to do so.

APPROVED: _____

DATE: _____

DATE REVIEWED: _____

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Appendix B

Form J2: Ocular Safety

Sample P&P

Purpose: To prevent ocular injuries to patients receiving laser treatment, or to health care personnel (HCP) working with Class 3B and Class 4lasers.

Policy: Within the nominal hazard zone (NHZ), personnel will adhere to appropriate eye protection procedures during all laser applications.

NOTE– Under some conditions, the NHZ may occupy the entire room in which the laser procedure is performed. Under those conditions, the ocular safety procedures listed below apply to the entire room.

Service personnel, biomedical technicians, and those involved in demonstrations of equipment, will follow all ocular safety procedures whenever a laser is in operation.

Procedures:

- a) Appropriate laser protective eyewear (LPE) will be worn by everyone in the NHZ while the laser is in operation. Appropriate LPE consists of glasses or goggles of sufficient optical density (OD) to prevent ocular injury at the laser wavelength in use. Exceptions to this is the operator looking through an attached microscope with a lens that has the appropriate OD for the laser in use.
- b) Prior to use, the user and ancillary personnel will be responsible for selecting and examining eyewear for comfort, proper fit, and presence of labels describing both wavelength and proper optical density.
- c) If damage to the eyewear is observed, or suspected, consult with the LSO about using the eyewear.
- d) Contact lenses are not acceptable LPE. Prescription lens wearers must use appropriate LPE.
- e) All goggles must have side shield to protect from peripheral injury and impact.
- f) Any delivery system that is not shuttered must be capped, or the system turned off, when not connected to the hand piece or the operating microscope.
- g) The laser system must be placed in standby mode when delivery optics are moved away from the target.
- h) Metal or dry materials will be placed on the patient's face or eyes only when indicated.

APPROVED: _____

DATE: _____ **DATE REVIEWED:** _____

Appendix C

Form J4. Non-Beam Hazards

Sample P&P

Purpose: To recognize and effectively deal with a variety of potential non-beam hazards which may be present during laser procedures.

Policy: Non-beam hazards are the purview of safety and industrial hygiene personnel, who will effect the appropriate hazard evaluation and control.

Procedure:

- I. Fire
 - a) Never use alcohol in the area where a laser is to be used. Fibers may be rinsed in hydrogen peroxide or saline intraoperatively.
 - b) Never place a hot fiber directly on paper drapes. Wait until tip is cool before contact is made with flammable material.
 - c) Use fire-retardant drapes, damp packs, or pads. Fill pelvic cavity with Ringer's saline or other appropriate solution during surgery.
 - d) Put laser system in standby mode when procedure is interrupted or terminated.
 - e) Avoid the use of oxygen in the area of laser treatment.
 - f) Avoid laser beam exposure of the sheaths of flexible fiber endoscopes, since many of the sheaths are flammable.
- II. Plume Management
 - a) Remove laser generated airborne contaminants from the energy impact site to reduce the transmission of potentially hazardous particulates.
 - b) Position plume evacuator in the laser treatment room whenever plume is anticipated.
 - c) Check operation of the plume management system prior to the beginning of the case.
 - d) Check the plume filter monitor, and if needed, install a clean filter. Dispose of used filter according to biohazardous procedures.
 - e) In-line filters will be placed between wall suction and the fluid cannister and will be changed as directed by the manufacturer and used filter disposed of according to biohazardous procedures.
 - f) Verify that plume evacuator is properly connected and is independent from surgical suction.
 - g) Use plume evacuation even in cases producing minimal plume.
 - h) Stop procedures if failure of evacuator occurs before or during operation.
 - i) Distal collection port must be no more than 2 cm from impact site, when practical.
 - j) All tubing, connectors, adaptors, and wands will be changed per case, and disposed of according to biohazard procedures.
- III. Electrical Shock
 - a) Install HCLS lasers according to National Electrical Codes.

NOTE—During service or maintenance, precautions must be taken against electrical shock, which may be fatal.

APPROVED: _____

DATE: _____ **DATE REVIEWED:** _____

Appendix D

Form C1. Example Perioperative Laser Safety Checklist

Date _____ Procedure _____

Surgeon _____ Anesthesia _____

Laser Operator _____

Scrub Person _____ Circulator _____

Equipment

Laser _____ Plume Evacuator _____

Delivery System: Handpiece _____ Waveguide _____

Fiber _____ Microscope Lens _____

Pre-Operative

Door Signs/Goggle Posted _____ Fire Extinguisher Checked _____

Windows Covered _____ Keys Obtained _____

Water Basin Opened _____ Eyewear in Room _____

Laser Tested Calibrated by _____ Time _____ OK _____

Plume Evacuator Tested _____ Filter Changed _____

Intraoperative

Laser Eye Protection Needed _____ Yes _____ No _____

All persons in Room Wearing Laser Protective Eyewear _____ Yes _____ No _____

If no, explain _____

Patient's Eyes Protected: Goggles _____ Wet Pads _____ Other _____

Wet Rectal Pack _____ Yes _____ No _____

If no, explain _____

Non-Reflective Instruments _____ Yes _____ No

If no, explain _____

Laser Masks _____ ET Tube used _____

Plume Evacuator Used During Procedure _____

Dosimetry

Laser Time On _____ Time Off _____ Total Time _____

Watts _____ CW _____ Superpulse _____

Joules _____ Number of Pulses _____

Post-Operative

Laser Documentation Completed _____ Keys Returned _____

Laser and Accessories Cleaned and Stored Properly _____

Plume Evacuator Cleaned and Stored Properly _____

Patient Discharge Instructions: Verbal _____ Written _____

Laser Malfunction: _____

Reported to _____ Action taken _____

Laser on Standby Only _____

Additional Comments _____

Laser Operator

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Appendix E

Table G1. Laser Safety Education Program

1. The Laser
 - a. Physics and biological effects
 - b. Dosimetry and beam parameters
 - c. Components of the laser system, delivery devices, and instrumentation
 - d. Overview of clinical applications

2. Administrative and Procedural Controls
 - a. Laser committee
 - b. Role of the LSO, DLSO (if assigned), LSSC/LSS (if assigned)
 - c. Development of policies and procedures
 - d. Documentation methods
 - e. Regulations, standards and recommended professional practices
 - f. Certification criteria and skills validation

3. Perioperative Equipment
 - a. Controlled access
 - b. Eye protection
 - c. Reflection hazards
 - d. Flammability hazards and draping
 - e. Electrical safety
 - f. Management of plume
 - g. Management of anesthesia in airway surgery
 - h. Equipment testing, aligning and troubleshooting

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Appendix F

Table G2. Laser Safety Education Program

		MD	RN	Tech (CST)	Service	LSO
1)	Laser Physics/Biological Effects	X	X	X	X	X
2)	System Components/Delivery Devices/Instrumentation	X	X	X	X	X
3)	Federal, State, Local Regulations	X	X	X	X	X
4)	ANSI Z136.1, Z136.3 Standards	X	X	X	X	X
5)	Institutional Policy and Procedures	X	X	X	X	X
6)	Hazard Classification	X			X	X
7)	Access to Laser Key/Authorized Personnel		X			X
8)	Documentation/Incident Reporting	X	X		X	X
9)	Anesthesia Hazards/Controls	X	X	X		X
10)	Personal Protective Equipment	X	X	X	X	X
11)	Patient Protection	X	X	X		X
12)	Operational Skills Workshops	X	X	X	X	X
13)	Procedure for Safety Audits					X
X denotes content area for education						

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Appendix G

Form C2. Example Laser Operator Skills Validation

The Applicant (Name) _____

1. Has read policies and procedures. _____
2. Submitted a certificate of attendance at an approved course of not less than _____ CEUs. _____
3. Attended equipment in-service training by LSO or designee. _____
4. Knows security procedure for obtaining keys. _____
5. Follows safety precautions while setting up the room and assembling equipment. _____
6. Knows how to assemble laser delivery systems and accessory equipment. _____
7. Can perform daily maintenance procedures. _____
8. Operates control panel properly:
 - power settings _____
 - time exposure _____
 - standby/ready _____
 - emergency off _____
 - shutter _____
9. Test fires/calibrates laser output. _____
10. Assembles, checks, operates plume evacuator system. _____
11. Positions laser, footpedal, and delivery systems. _____
12. Completes all documentation. _____
13. Knows proper methods for cleaning and storing. _____
14. Demonstrates ability to monitor laser safe room. _____

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Appendix H

**Table G3. Example Intake Checklist for Third Party Rental
of Health Care Laser System (HCLS)**

Date		BMET Approved
Facility Medical Equipment Management Program (MEMP)	(name)	
3 rd Party/Rental HCLS Company name, phone number, website, etc.	(name)	
3 rd Party/Rental Company current proof of compliance with State regulations and registrations		
3 rd Party/Rental HCLS Technician/Laser Operator – meets facility requirements for vendor qualifications (health tests, OR orientation, license, etc.)	(identify)	
Make, model, and serial number of HCLS	(identify)	
HCLS Preventative Maintenance (PM), calibration and maintenance records current, available and on file		
HCLS passed required MEMP electrical safety testing (e.g., NFPA 99-2015 Health Care Facility Code)		
HCLS entered into MEMP inventory control system for specific date(s) of use	(dates)	
Electronic accessories entered into MEMP inventory control system		

Health Care Facility (HCF) Laser Safety Officer (LSO) or Designee		LSO Approved
HCLS scheduled for approved procedure by credentialed physician	(name) (physician/procedure)	
HCLS and accessories cleaned/decontaminated per HCF policies and procedures		
HCLS has a complete inventory of all equipment, accessories, and other supplies (i.e., treatment fibers, drapes, ET tubes, etc.) brought into the facility, validation of sterility, and FDA approval for use.		
If 3 rd party brings in reusable devices, the LSO must verify that the device is FDA approved and packaged as a sterile device		
If reprocessed devices are used (e.g., fibers, filters, tubing) 3 rd party company must supply official documents from their company detailing their procedures for cleaning and sterilizing the devices, testing for accuracy and safety after reprocessing, and criteria for discontinuing the use of the devices during or after rental use.	(identify)	
Documentation of ANSI compliant laser safety training completed by 3 rd party/rental HCLS technicians in the HCF	(identify)	
3 rd party/rental HCLS technician/laser operator is fully aware of HCF laser P&Ps		
Z136 standard compliant LPE, window barriers, area warning signs available and properly used per HCF policies and procedures		
HCLS is fully tested/aligned/calibrated by the 3 rd Party/Rental HCLS Technician/ Laser Operator prior to patient receiving anesthesia, and/or brought into the treatment or operating room		

Health Care Facility (HCF) Laser Safety Officer (LSO) or Designee	(name)	LSO Approved
3 rd Party/Rental HCLS Technician/ Laser Operator is present and fully attendant to the HCLS during use		
LSO verifies that staff is expected to be in the room with the 3 rd party vendor, can operate the HCLS and monitor the safety of the room during its use, should the technician become unable to perform these duties		
3 rd party/rental HCLS technician/ laser operator completes any/all documentation and removes all accessories/supplies upon completion of procedure		
Facility personnel has documented the case according to policy, does not sign vendor log sheets, and obtains a copy of all forms and documentation the 3 rd party intends to remove from the facility		

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Appendix I

Form J3. Handling of Laser Fiber Delivery Systems

Sample P&P

Purpose: To promote safe and proper handling of laser fiber delivery systems and to limit the potential for the fiber breakage, damage, and reduced efficiency during clinical laser procedures.

Policy: Personnel handling laser fibers will ensure compliance with all safety procedures and will consider the fiber an extension of the laser system, governed by applicable standards, and regulations.

Procedure:

- a) Appropriate eye safety filters will be used with endo/microscopes.
- b) Laser room windows will be covered completely with appropriate filters, if necessary.
- c) Fibers and associated equipment will be positioned to allow for safe traffic patterns in the room.
- d) The fiber will be examined for breaks or damage of the distal tip, proximal connector, and catheter sheath. If deficiencies or damage are noted, another fiber must be obtained. Fiber will be calibrated in accordance with manufacturer's directions.
- e) Do not use clamps or other instruments to secure fiber in the operative site.
- f) Always use coaxial cooling that is appropriate to the procedure.
- g) Never use gas to purge a fiber in the intrauterine cavity.
- h) Never operate the laser unless you see the aiming beam, if used, and the tip of the fiber beyond the end of the endoscope.
- i) Monitor the fiber for distortion of the beam, decreased power transmission, and accumulation of debris on the tip.
- j) Never reuse a disposable fiber without manufacturer's directions.
- k) Always put the laser in standby mode when not aimed at a target.

APPROVED: _____

DATE: _____ **DATE REVIEWED:** _____

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Appendix J

Descriptions of Each Class of Lasers^{2,65}

Laser Class	Hazard(s) Description	Examples
1	<ul style="list-style-type: none"> • Do not pose a hazard. 	CD players, laser printers, bar code scanners
1M	<ul style="list-style-type: none"> • Do not normally pose hazards for unaided viewing unless beam is viewed with collecting optics such as a microscope. 	Distance-measuring instruments, IR telecom
2	<ul style="list-style-type: none"> • Lower power visible lasers. • Do not normally present a hazard due to normal human bright-light aversion response, for example, blinking. • Potential for hazard if viewed directly for extended time periods. 	Same as Class 1.
2M	<ul style="list-style-type: none"> • Does not normally present a hazard for unaided viewing. • Potentially hazardous if laser beam is viewed with collecting optics. 	Same as Class 1M.
3R ¹	<ul style="list-style-type: none"> • Lasers that have a lower risk of producing eye injury as compared to other Class 3 lasers. • Have fewer requirements as compared to lasers that have higher levels of risk. 	Laser pointers, laboratory lasers
3B	<ul style="list-style-type: none"> • Lasers that can produce a hazard if viewed directly, including intrabeam viewing of specular reflections. • Generally, not capable of producing hazardous diffuse reflection. • Generally, not a fire hazard. 	Laboratory lasers, medical lasers
4	<ul style="list-style-type: none"> • Lasers that produce a hazard from direct, specular, or diffuse reflections. • Potential significant skin hazards. • Potential significant fire hazards. 	Commercial light shows, industrial lasers, surgical lasers

1. Lasers can be classified as Classes 1M and 2M even if their output exceeds the Class 3R level as long as the output does not exceed the Class 3B level.