**Section 315.APPENDIX A Sample Standard Operating Procedures**

Standard Operating Procedures (SOPs) are governed by institutional policy and are developed, modified and maintained in accordance with the needs of individual facilities. Information relative to safety incorporated into these SOPs is gathered from a wide range of resources, including, but not limited to, the laser system manufacturer or distributor. This Appendix A contains examples of SOPs for issues associated with the use of laser systems. It is recognized that the safety needs of installations with multiple laser systems may be different from those facilities with a single laser system. The samples that follow cannot cover all situations or procedures; they are only intended as models that should be used to accommodate specific requirements. Typically, the Laser Safety Officer shall have the responsibility to see that SOPs are followed.

It is reasonable to expect that the manufacturer of the laser system shall supply safety information that can serve as the cornerstone for the generation of the SOPs. It is incumbent upon the operator to demand the information from the manufacturer. The availability of safety related information is facilitated by the FDA requirement that the manufacturer of laser products provide the user with adequate instructions for the safe operation and maintenance of all laser products.

**SAMPLE 1: Controlled Access to the Laser Room**

**Purpose:** To define the area in which control measures shall be applied and to describe the control measures necessary in order to maintain a safe environment for use of the laser system.

**Policy:** Class 3b and Class 4 lasers shall be operated in areas where traffic flow and compliance with all safety procedures can be monitored.

**Procedure:**

1) Appropriate warning signs shall be posted at eye level on all doors that access a room where a laser is to be operated. These signs shall state all required information and shall be removed when the laser is not in use.

2) Safety goggles labeled with the appropriate wavelength and optical density shall be available at the entry where each door sign is posted.

3) Glass windows shall be covered with shades or filters of appropriate optical density whenever a fiberoptic laser system is operational.

4) All safety procedures shall be followed during service, maintenance and demonstrations.

5) No one shall be allowed into a laser room unless properly authorized and protected.

6) The laser shall not be activated when it is necessary to open the door, if the controlled area extends to the doorway.

7) Laser keys shall be kept in a secured area and signed out only by those authorized to do so.

**SAMPLE 2: Ocular Safety**

**Purpose:** To prevent ocular injuries to personnel working with Class 3b and Class 4 lasers.

**Policy:** Within the controlled area, all personnel shall adhere to appropriate eye protection procedures during all laser applications.

NOTE: Under some conditions, the controlled area may include the entire room in which the laser procedure is performed. Under those conditions, the ocular safety procedures listed in this Sample 2 apply to the entire room. In health care facilities, ocular safety procedures shall also apply to the patient receiving laser treatment.

All personnel involved in maintenance and demonstrations of laser systems shall follow all ocular safety procedures whenever a laser is in operation in the facility.

**Procedure:**

1) Appropriate eyewear shall be worn by everyone in the controlled area while the laser is in operation. Appropriate eyewear consists of glasses or goggles of sufficient optical density to prevent ocular damage at the laser wavelength in use. Exception to this is the operator looking through an attached microscope with a lens that has the appropriate optical density for the laser in use.

2) Prior to use, the operator and ancillary personnel shall be responsible for selecting and examining eyewear for comfort, proper fit, and presence of labels describing both wavelength and proper optical density.

3) If eyewear is damaged, it shall not be worn and a report shall be made to the laser safety officer.

4) Contact lenses are not acceptable as protective eyewear. Prescription lens wearers shall use appropriate laser safety eyewear.

5) All goggles shall have side shields to protect from peripheral injury and impact.

6) Any articulated arm that is not shuttered shall be capped when not connected to the hand piece or the operating microscope.

7) The laser system shall be placed in standby mode when delivery optics are moved away from the target.

8) In health care facilities, patients shall be fitted with appropriately labeled eyewear, or have their eyes covered with wet cloth pads or towels. Metal or dry materials shall be placed on the patient's face or eyes only when indicated.

**SAMPLE 3: Handling of Laser Fiber Delivery Systems in Health Care Facilities**

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

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

**Procedure:**

1) Appropriate eye safety filters shall be used with endo/microscopes.

2) Laser room windows shall be covered completely with appropriate filters, if necessary.

3) Fibers and associated equipment shall be positioned to allow for safe traffic patterns in the room.

4) The fiber shall be examined for breaks or damage of the distal tip, the proximal connector and the catheter sheath. Fiber shall be calibrated in accordance with manufacturer's directions. If deficiencies or damage are noted, another fiber shall be obtained.

5) Do not use clamps or other instruments to secure fiber in the operative site.

6) Always use coaxial cooling that is appropriate to the procedure. Never use gas to purge a fiber in the intrauterine cavity.

7) Never operate the laser unless the aiming beam (if used) and the tip of the fiber beyond the end of the endoscope are both visible.

8) Monitor the fiber for distortion of the beam, decreased power transmission and accumulation of debris on the tip.

9) Never reuse a disposable fiber without manufacturer's directions.

10) Always put the laser in standby when not aimed at a target.

**SAMPLE 4: Non-Beam Hazards in Health Care Facilities**

**Purpose:** To recognize and effectively deal with a variety of potential non-beam hazards that 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

1) Never use alcohol in the operative field. Fibers may be rinsed in hydrogen peroxide or saline intraoperatively.

2) Never place a hot fiber directly on paper drapes. Wait until tip is cool before contact is made with flammable material.

3) Use fire-retardant drapes, damp packs or pads. Fill pelvic cavity with Ringer's, saline or other appropriate solution during surgery.

4) Put laser system in standby mode when procedure is interrupted or terminated.

5) Avoid high levels of oxygen in the operative field.

6) Avoid laser beam exposure of the sheaths of flexible fiber endoscopes, since many of the sheaths are flammable.

II. Plume Management

1) Remove laser generated airborne contaminants from the laser target area to reduce the transmission of potentially hazardous particles.

2) Position smoke evacuator in the operating room whenever a plume is anticipated.

3) Check operation of the plume management system prior to the beginning of a procedure.

4) Check the plume filter monitor and, if needed, install a clean filter.

5) In-line filters with minimum 0.3 μm filtration shall be placed between wall suction and the fluid canister for:

a) Suction line not connected to evacuator

b) Procedures producing minimal plume

c) Failure of evacuator before or during operation

6) Distal collection port shall be no more than 2 cm from impact site when practical.

7) All tubing, connectors, adaptors and wands will be changed between patients and disposed of according to biohazard procedures.

III. Electrical Shock

1) During service or maintenance, precautions shall be taken against electrical shock that may be fatal.

2) Medical lasers shall be installed and operated in conformity with the National Electrical Code.

**SAMPLE 5: Work Practices for Optical Fiber Communications Systems (OFCS)**

**Purpose:** To recognize and effectively deal with a variety of potential hazards that may be present when working on an OFCS.

**Policy:** Engineering controls shall not take the place of good work practices. Good work practices are essential to operating, servicing and maintaining OFCS, especially with higher power systems that utilize Class 3b and Class 4 lasers.

**Procedure:** The following presents some basic guidelines when working on any OFCS.

1) Trained Personnel. Only authorized, trained personnel shall be permitted to install or perform service on OFCS containing Class 3b or Class 4 lasers.

2) Unterminated Fibers

a) Do not view the end of a fiber with unprotected eye. Fiber should only be viewed with an indirect image converter or with a filtered optical instrument or optical density (OD) sufficient to reduce the exposure to levels below the appropriate MPE.

b) Always cover the ends of unterminated fibers with a splice protector, tape or end caps.

3) Splicing. Splicing on ribbon cables, fixed array cables or OFCS containing Class 3b or Class 4 lasers shall be de-energized or viewing systems incorporating personal protection shall be employed.

4) Installation and Testing. The laser source shall be first to be disconnected and last to be connected when installing and/or testing an OFCS.

5) Modifications. No modifications shall be made to the OFCS or associated equipment without management or supervision authorizations. Such modifications may alter the service group classification of the OFCS.

6) Labels. Any damaged or missing optical safety labels shall be reported immediately to the supervisor.

7) Other Hazards

a) Use of protective guards or shields shall be used during splicing and cleaving operation to prevent direct injury from small lengths or particles of fiber. Proper disposal of fiber pieces avoids subsequent embedding in clothing or skin.

b) Optical photocuring may present a UV or light source hazard. Protective filter lenses of the appropriate optical density shall be worn if viewing of the light source is probable.

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