Characterization of Medical Laser Related Occupational Injuries in the US FDA MAUDE Database

BY

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THESIS

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I want to thank and dedicate this thesis to my awesome God for allowing me to make it this far, and my amazing husband Kevin Smith and family who are my biggest fans and support!
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<td>Full Form</td>
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<td>ACGIH</td>
<td>American Conference of Governmental Industrial Hygienists</td>
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<td>ANSI</td>
<td>American National Standards Institute</td>
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<tr>
<td>BLS</td>
<td>Bureau of Labor Statistics</td>
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<td>CDRH</td>
<td>Center for Devices and Radiological Health</td>
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<td>FEMA</td>
<td>Federal Emergency Management Agency</td>
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<tr>
<td>HCLS</td>
<td>Health Care Laser System</td>
</tr>
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<td>HCW</td>
<td>Health Care Workers</td>
</tr>
<tr>
<td>HFACS</td>
<td>Human Factors Analysis and Classification System</td>
</tr>
<tr>
<td>IR</td>
<td>Infrared</td>
</tr>
<tr>
<td>IWCC</td>
<td>Illinois Workers’ Compensation Commission</td>
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<td>LGAC</td>
<td>Laser Generated Air Contaminants</td>
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<td>MAUDE</td>
<td>Manufacturer and User Device Experience Report</td>
</tr>
<tr>
<td>MPE</td>
<td>Maximum Permissible Exposure</td>
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<tr>
<td>NIOSH</td>
<td>National Institute for Occupational Safety and Health</td>
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<tr>
<td>NHZ</td>
<td>Nominal Hazard Zone</td>
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<tr>
<td>OD</td>
<td>Optical Density</td>
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<tr>
<td>OR</td>
<td>Operating Room</td>
</tr>
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<td>OSHA</td>
<td>Occupational Safety and Health Administration</td>
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<tr>
<td>PPE</td>
<td>Personal Protective Equipment</td>
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<tr>
<td>SCR</td>
<td>Silicone Controlled Rectifier</td>
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<td>SHEL</td>
<td>Software, Hardware, Environment, and Liveware</td>
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<td>TLV</td>
<td>Threshold Limit Values</td>
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LIST OF ABBREVIATIONS (continued)

US FDA      United States Food and Drug Administration
UV          Ultraviolet
SUMMARY

A study of the Manufacturer and User Device Experience Report Database (MAUDE) housed by the United States Food and Drug Administration (US FDA) was conducted to determine if gaps existed in the safety measures present while using medical laser devices. Cases were queried by the Center for Devices and Radiological Health (CDRH) for the time period of 1990 to 2009. Information regarding all injuries and deaths related to the use of medical and/or dental lasers was requested with 1084 cases in total being collected.

After fully analyzing the cases, ten were found to have a completeness of 76%–80% in the categories of the report. They also stated that medical treatment for the employee was performed. Three case studies were developed using the ten cases chosen assessing three categories: beam-thermal burns, beam-eye injuries, and non-beam electrical. Each case study covers the background of the injury issues and provides detail on the recommendations and potential safety gaps missed when performing the procedures identified. Gaps included, but were not limited to, inadequate training, procedural issues, and improper personal protective equipment selection for the task/equipment.

From the ten cases it was found that four contained adequate information to apply to two human factors models that were used to evaluate the root cause of the injuries presented in the descriptions provided. The four cases were found by categorizing each case by occupationally related, percentage of completeness (those 75%–80% complete), documentation and completeness of medical treatment, and device settings that could be identified in the main body of the event description contained within the MAUDE database.

It was found that cases lacked consistency throughout the database and even those that provided adequate information for the human factor models did not allow for a full assessment. The MAUDE database is in need of review and updating.
I. INTRODUCTION

A. Laser Development and Clinical Application

1. Clinical Application of Medical Lasers

In the United States the Food and Drug Administration (US FDA) is responsible for protecting the public against defective products by assuring the safety, efficacy, and security of medical devices, products that emit radiation, and a variety of other goods sold on the market today. The CDRH within the US FDA is responsible for regulating firms who manufacture, repackage, re-label, and/or import medical devices sold in the United States. They also regulate radiation-emitting electronic products such as lasers (1).

The use of lasers in medicine began soon after the first ruby laser was invented in 1960. The variety of applications in biology and medicine has increased over the years and uses continue to grow as technology advances. Early interest centered on the ability of focused laser beams to coagulate blood vessels in the retina and to cut tissue. Lasers permit noncontact interaction with tissue, an important clinical capability (2). According to OSHA, although there are hundreds of different types of lasers, only about a dozen are commonly found in clinical use (101). This includes diagnostic, cosmetic, preventive, and therapeutic applications. Eye correction, skin tattoo removal, hair removal, dermatology treatments, tumor removal, and internal structure corrections are only a few applications for these devices (93, 101, 102).

Three main uses of lasers are photochemical, tissue ablation, and tissue non-ablative procedures. With these procedures one can choose a wavelength that is preferentially absorbed by a particular tissue structure or one can introduce a photosensitizing dye into a tumor or a specific cell type in order to target that tissue for removal with laser energy. The photochemical process is used
largely in tumor identification and removal. During this process a photosensitive dye, which accumulates in specified cells (i.e., cancer cells), is injected into the body. The contrasting wavelength of light is then irradiated on the area and causes photo absorption by the dye, yielding an excited state. The excited state reacts with oxygen generating toxic products such as singlet oxygen. The toxins injure the surrounding cellular environment and kill the cells (i.e., cancer cells) (2).

Tissue ablation involves material removal from evaporative to explosive mechanisms using visible or infrared (IR) lasers that are thermal in nature, which may result in permanently damaged tissue with the misuse of a medical laser device. Non-ablative procedures involve lasers with localized heating without actually removing the tissue. The localized heat is used to coagulate blood and close blood vessels during or after surgery (3).

Table I shows how Ortega-Martinez et al. summarized popularly used instruments and their clinical applications (4):
<table>
<thead>
<tr>
<th>Laser Type</th>
<th>Wavelength</th>
<th>Main Use</th>
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<tr>
<td>Nd: YAG</td>
<td>1064 nm</td>
<td>General surgery (soft tissue applications)</td>
</tr>
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<td></td>
<td></td>
<td>Thoracic Surgery</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Orthopedics</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gynecology</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Urology (prostatectomy, bladder tumors, urethral structures)</td>
</tr>
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<td></td>
<td></td>
<td>Dermatology</td>
</tr>
<tr>
<td>KTP Frequency</td>
<td>532 nm</td>
<td>Plastic surgery (face-lift, brow-lift, rhinoplasty, blepharoplasty)</td>
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<tr>
<td>Doubled Nd:YAG</td>
<td></td>
<td>Urology (prostatectomy, bladder neck contracture, cancers)</td>
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<tr>
<td></td>
<td></td>
<td>Ear/Nose/Throat procedures</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dermatology (tattoo removal)</td>
</tr>
<tr>
<td>Ho:YAG</td>
<td>2.1/µm</td>
<td>Kidney stone fragmentation</td>
</tr>
<tr>
<td></td>
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<td>Treatment of enlarged prostates</td>
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<tr>
<td>Er:YAG</td>
<td>2.94/µm</td>
<td>Skin resurfacing</td>
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<td>Corneal surgery</td>
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<td></td>
<td></td>
<td>Orthopedics</td>
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<tr>
<td></td>
<td></td>
<td>Dentistry</td>
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<tr>
<td>Diode</td>
<td>400–1,000 nm</td>
<td>Photodynamic therapy</td>
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<td>Alexandrite</td>
<td>720–820 nm</td>
<td>Kidney stone fragmentation</td>
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<tr>
<td></td>
<td></td>
<td>Tattoo removal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hair removal</td>
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<tr>
<td>Ti:Sapph</td>
<td>650–1,100 nm</td>
<td>Biochemistry</td>
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<tr>
<td></td>
<td></td>
<td>Photodynamic therapy</td>
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<tr>
<td></td>
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<td>Tomography</td>
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2. **Development of new technologies in medical lasers**

   Lasers have been under refinement since the early 1900s. Max Plank’s publication provided an understanding that light is a form of electromagnetic radiation. This triggered the beginning of further exploration into the laser realm (5). Albert Einstein proposed the theory of stimulated emission in 1917. In stimulated emission, an electron in a higher orbit is brought to a lower orbit by the presence of a photon of exactly the same energy as the energy difference between the two levels. Once this occurs another photon is produced that is identical to the first photon. Photons are also waves and have the same adding ability. With two identical photons emitted they add together to make a highly intensive wave (6). This theory was not utilized until the 1940s when physicists finally found a use for the concept.

   Theodore Maiman, while working at Hughes Research Laboratories in 1960, developed the first operational laser using lasing medium of a ruby that was stimulated with high–energy flashes of intense light (7). Maiman was the first of many who would develop powerful lasers for use in surgery (5). The first use of a laser in surgery was reported in 1965 and the first commercially available medical laser was an argon photocoagulator that came on the market in 1971 (8). In 1978, animal and human cadaver experiments were undertaken that were aimed at vaporizing blood clots with an argon-ion laser delivered via a quartz fiber. The first medical specialties to utilize the laser were dermatology, gynecology and ophthalmology (8).

   Technology continues to evolve and the use of lasers has changed the way surgery is performed, particularly intrauterine and intra-abdominal. The major advantages of the laser are the speed of application, precision, accuracy, hemostatic control, and minimal tissue damage, especially in intra-abdominal surgeries (9). The laser also allows rapid and precise opening depicted by surgeries involving the distal end of the fallopian tube (9).
3. Health care laser systems

The four primary medical/surgical health care laser systems (HCLSs) are Argon, Nd:YAG, Holmium:YAG, and CO₂ lasers. A full system consists of the laser(s), 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 (10). Liquids and gases act as an active medium, also known as an optical amplifier. As a beam of coherent light enters one end of an active medium it is amplified through stimulated emission until a coherent beam of increased intensity leaves the other end of the active medium. Thus, the liquid or gas provides an optical gain in the laser (11).

The Argon laser produces wavelengths of 457.9 nm to 528.7 nm. The primary application is photocoagulation (superficial) and in ophthalmology involving retinal and anterior eye surgery; it is also used in dermatology, urology, and otorhinolaryngology applications (10). Photocoagulation uses the heat from a laser to seal or destroy abnormal leaking blood vessels in the retina (12).

The Nd:YAG laser operates at 1064 nm and can be placed in both pulsed and continuous mode. A pulsed laser supplies energy in short bursts using an excitation mechanism. The gain and output power rise quickly to a high level and drop off, producing a burst of laser light. A continuous-wave laser supplies a constant power to the active medium using an excitation mechanism. The system quickly reaches a “steady-state” condition balancing out loss and gain resulting in a constant output beam (11). An excitation mechanism is a source of energy that excites, or “pumps,” the atoms in the active medium from a lower to a higher energy state in order to create a population inversion. For example, in gas lasers the excitation mechanisms usually consists of an electrical-current flow through the active medium (11). The major applications are in photocoagulation, tissue excision, and photodisruption. Photodisruption involves the delivery of large amounts of energy into very small focal spots in very
brief duration causing instantaneous, highly localized temperature increase (13). The most common applications are in ophthalmology, gastroenterology, urology, and dermatology (10).

Holmium:YAG lasers operate at 2100 nm and are operated by pulse mode. The output of the laser is delivered through a fiber either in a contact or non-contact mode. Contact mode involves a procedure with the fiber tip directly in contact with the tissue or surface being operated on. Non-contact mode is a procedure in which the fiber tip is an assigned distance from the tissue or surface being operated on (14). Because high pulse energies can be passed through flexible glass fibers, it is useful in laparoscopic and arthroscopic procedures, spinal procedures, and in urology, ophthalmology, gastroenterology, dermatology, otorhinolaryngology, and other surgical specialties.

The fourth major HCLS system is the CO₂ laser that operates at 10,600 nm and is operated in several modes. The principle applications are vaporizing, excision, and coagulation, through a variety of delivery systems. This laser is used in plastic surgery, dermatology, neurosurgery, gynecology, general surgery, urology, otorhinolaryngology, and podiatry (10).

B. Health Effects

1. Non-beam hazards

Non-beam exposure concerns include compressed gases, cryogenic material, and carcinogenic materials (15). According to Occupational Safety and Health Administration (OSHA), laser-generated air contaminants (LGAC) from electrosurgical smoke expose an estimated 500,000 health care workers (HCW) each year (16). Improved characterization of these exposures is needed to properly develop appropriate exposure guidance (17).

All HCLSs have the potential to expose HCW to electrical-related hazards that may result from inadequate grounding, maintenance malfunctions, or lack of electrical safety training. These electrical-related hazards include fire and explosion that are caused by the use of flammable liquids, and
oxidizing gases used on and around patients; all are ignition sources (10). Also included in electrical hazards is the potential for electrocution from the medical equipment during use or maintenance. Although little attention is given to the noise parameters of medical laser procedures, potentially damaging peak sound levels (from 90 to 130 dBA) have been reported and control measures should be implemented (18; 19).

It is estimated that approximately 1000 people die of exposure to electricity annually in the United States. In the workplace the most frequent cause of occupational-related death in adults is electrocution (20). Several associated hazards are potentially lethal. These hazards are grouped as shock hazards and fire/explosion hazards (21). Most laser systems involve high potential, high–current electrical supplies. Safe manufacturing practices offer protection from these hazards by the use of insulation, shielding, grounding,; and housing of high–voltage electrical components (21).

In engineering, medical, and research facilities that use lasers, the only fatalities resulting from these devices were from electrocution. Due to the risk of electrocution related to the amount of electrical voltage and current that are required to operate the laser, only experienced technicians should service medical laser equipment (22; 23; 24). During periods of installation, maintenance, repair, calibration, and any other procedures that result in the accessibility to high–voltage components, the risk of electrical shock is always present (25). Medical laser devices pose a high risk for technicians performing maintenance if the equipment is not properly handled and the technicians not properly trained.

2. **Beam injuries and health effects**

   Beam hazards describe the direct effect of the laser energy on the skin or eye. The absorption of laser radiation by living tissue can be characterized as producing a thermal, mechanical,
or photochemical effect (18). Transmission and damage mechanisms on the eye and skin depend on the wavelength of the laser.

a. **Eye injuries**

A survey showed that between 1960 and 2002 more than 1,500 injuries were observed, the majority resulting in eye injuries (approximately 70%) (26). The possibility of injury to the eyes is what drives laser safety and controls. This type of trauma can have a tremendous impact on visual function, either by direct damage (retinal holes, scarring, or hemorrhages) to the globe or by inducing long-term changes leading to visual dysfunction (i.e., cataract, choroidal neovascularization) (27; 28). The eye can be damaged by direct or indirect exposure causing temporary to permanent damage.

Exposure to UV radiation (200–400 nm), visible light (400–700 nm), and IR radiation (700–10,000 nm) can damage the eye (29). Light emitted from the visible to near infrared spectrum (400–1400 nm) may cause retinal damage resulting in scotoma (blind spot in the fovea). Ultraviolet (200–300 nm) or far IR (1,400–10,000 nm) spectrum may cause damage to the cornea and/or lens (30).

The injury of the cornea, lens, and vitreous fluid are dependent upon wavelength (31). Corneal tissue absorbs light with wavelengths longer than 1400 nm. Damage to the cornea from these wavelengths results from the absorption of energy by tears and tissue fluids, causing a temperature increase and subsequent denaturation of protein in the corneal surface (27). The cornea surface absorbs all ultraviolet (UV) light ranging from 100 to 315 nm (UV-B/UV-C), producing photokeratitis (welders flash) from a photochemical (chemical reaction induced by light) process that denatures the proteins in the cornea. This is a temporary condition with the corneal tissues regenerating very quickly, less than 24 hours (32). The lens absorbs the largest amount of radiation, wavelengths of 315 to 400 nm (UV-A), causing denaturation of proteins in the lens, resulting in the formation of cataracts (27).
Knowledge of wavelength, intensity, and optical density are required in order to provide adequate engineering and personal protective equipment (PPE) controls which help to mitigate eye tissue damage.

Damage to the retinal tissue occurs when light is absorbed and converted to heat. Heat is created by the melanin granules in the pigmented epithelium through photochemical reaction to the photoreceptor. A photochemical reaction is a chemical reaction set into motion by the absorption of light. In this case the photoreceptor, or cell responsible for detecting light on the interior layer of the eye, is activated. For visible light of 400 to 700 nm (VL), the aversion reflex reduces exposure by causing the individual to turn away from the light. This reflex will not occur if the intensity is great enough to produce damage in less than 0.25 seconds or exposure of 700 to 1400 nm near infrared (NIR) is allowed because the human eye is insensitive to these wavelengths (27).

b. **Skin injuries**

Thermal damage is caused by the conversion of laser energy into heat. The epidermis and dermis, being part of the largest organ with the greatest surface area, are targeted by thermal damage (Table II). Ultraviolet-A (315–400 nm) is the most common kind of sunlight at the earth’s surface, and reaches beyond the top layer of human skin causing hyperpigmentation and erythema. Erythema is an effect caused by increased blood content in the dermis causing redness to the skin. Ultraviolet-A rays can damage connective tissue and increase a person’s risk of skin cancer (33). Ultraviolet-B (280–315 nm) and UV-C (200–280 nm) can cause erythema and blistering, as they are absorbed in the epidermis. Ultraviolet-B is thought to have carcinogenic effects either directly on DNA or from effects on potential intracellular viruses. With the formation of pyrimidine dimers, UV-B has been shown to cause mutagenicity in mammalian cells. Ultraviolet-C rays emitted by the sun could
be very dangerous, but they are absorbed by the ozone layer and most do not reach the ground (27; 33; 34; 35).

Visible light (400–780 nm) penetrates much deeper into the dermis than UV light and can cause erythema as well. Longer wavelengths cause dilatation of the subpapillary plexus vessels causing the skin to look red. There is limited information on the role of visible light in pigmentation. Exposure of normal skin to visible light can result in the induction of immediate pigment darkening, immediate erythema, and delayed tanning (36). Once laser energy is absorbed into the skin, three basic effects are possible—photothermal, photomechanical, or photochemical. Photomechanical reactions cause a change in shape of a material when exposed to light. Photothermal effects occur when water in tissue absorbs the corresponding wavelength of energy and the target tissue is destroyed; this results from the conversion of absorbed energy into heat. The heat will transfer to the tissue target and also the surrounding tissue. The epidermis, which is normally protective, loses its surface due to heat injury causing the collagen to denature and coagulate, forming a dense dark hyalinization zone. This mechanism also causes target tissue to vaporize, shrinking the tissue (37). The main chromophores (part of a molecule responsible for color) that absorb visible light include melanin, oxyhemoglobin, and deoxyhemoglobin.

Infrared radiation consists of wavelengths from 780 nm to 1000 µm, and is subdivided into three regions of increasing wavelength, IR-A (780–1400 nm), IR-B (1400–3000 nm), IR-C (3000 nm–1000µm). Infrared radiation-A can penetrate epidermal and dermal layers and reach subcutaneous tissues without increasing the skin temperature significantly, whereas IR-B and IR-C are absorbed mostly in the epidermal layers and increase skin temperature resulting in thermal sensation ranging from pleasant warmth to thermal burn. Infrared radiation induces molecular vibrations and rotations that cause the temperature increase (38). Infrared radiation can cause skin wrinkling and augment UV-
induced wrinkle formation through induction of matrix metalloproteinases. Matrix metalloproteinases are a member of a group of enzymes that can break down proteins, such as collagen, normally found in the spaces between cells in tissue, and are involved in wound healing, angiogenesis, tumor cell metastasis, (39) and collagen metabolism in skin (40). Exposure of human skin to near-IR induces dermal angiogenesis, or blood vessel formation, and alters the balance between epidermal angiogenic factor and endogenous angiogenic inhibitor (a substance that prevents formation of blood vessels that tumors need to grow). Infrared radiation has also been shown to recruit and activate skin mast cells, a type of white blood cell. If this recruiting increases, a lump may form leading to a mast cell tumor.

C. **Control Strategies**

Protecting personnel from exposure to laser energy begins with the industrial hygiene control hierarchy of substitution, engineering, administrative, and personal protective controls. Multiple engineering controls have been put into place over the years. These include but are not limited to shielding to protect the operator from direct contact with a laser beam; human factor correct monitoring panels that are understandable by working population and that will assist them in avoiding procedural errors; and interlock systems that turn off medical laser equipment if the operator is within range of the beam or another component that would cause serious injury.

Administrative controls include training, thoroughly documented written procedures, and control of resources and equipment. Training is a vital part of control that allows for behavioral change in employees. Written procedures are to be written with the employee in mind. Constructing a safety committee that is made up of employees, managers, and safety personnel will enable all to collaborate and formulate proper procedures that will be executed correctly and follow regulatory guidelines.
Regulating resources and equipment allows for the prevention by management of inappropriate use of PPE and the assurance of maintenance of the medical laser devices.

### TABLE II
SUMMARY OF BASIC BIOLOGICAL EFFECTS OF LASERS ON THE EYE AND SKIN (15; 41)

<table>
<thead>
<tr>
<th>Spectral Region (wavelength)</th>
<th>Eye effects</th>
<th>Skin effects</th>
<th>Type of laser</th>
</tr>
</thead>
<tbody>
<tr>
<td>UV-C (200–280 nm)</td>
<td>Photokeratitis</td>
<td>Erythema (sunburn)</td>
<td></td>
</tr>
<tr>
<td>UV-B (280–315 nm)</td>
<td>Photokeratitis</td>
<td>Accelerated skin aging</td>
<td>Increased pigmentation</td>
</tr>
<tr>
<td>UV-A (315–400 nm)</td>
<td>Photochemical UV cataract</td>
<td>Pigment darkening</td>
<td>Skin burn</td>
</tr>
<tr>
<td>Visible (400–780 nm)</td>
<td>Photochemical and thermal retinal injury</td>
<td>Photosensitive reactions</td>
<td>Skin burn</td>
</tr>
<tr>
<td>IR-A (780–1400 nm)</td>
<td>Cataract Retinal burns</td>
<td>Skin burn</td>
<td>Pulsed Dye Argon Copper Vapor Nd:YAG Ruby Alexandrite Nd:YAG-KTP Alexandrite Diode</td>
</tr>
<tr>
<td>IR-B (1400–3000 nm)</td>
<td>Corneal burn Aqueous flare IR cataract</td>
<td>Skin burn</td>
<td></td>
</tr>
<tr>
<td>IR-C (3000 nm–1000 µm)</td>
<td>Corneal burn only</td>
<td>Skin burn</td>
<td>CO₂</td>
</tr>
</tbody>
</table>
The final control mechanism is that of PPE. In the medical laser realm this includes safety glasses, safety goggles, and personal protective clothing that help to eliminate laser contact with the eyes and skin. A concern when choosing protective clothing is that of flammability. The laser beam and a medium of either gas or liquid (which provide the heat and fuel for ignition), plus clothing and drapery combine to enhance the potential for fire. Using wavelength, optical density and intensity, PPE can be chosen which will properly protect the employee.

Among the key aspects for the prevention of laser injury are exposure guidelines that help facilities to regulate and control hazards. They allow for proper procedures to be put into place to protect health care professionals exposed to laser energy. The guidelines cover engineering, administrative, and personal protective controls that are to be put into place before and during laser operation. Guidance on laser classification is provided.

1. **United States Food and Drug Administration laser classification system**

The US FDA has classified lasers into four distinct classes ranging from Class 1 to Class 4. Each is categorized according to the hazard it may cause to an individual. The laser hazard classification system is based only on the accessible laser radiation. The least hazardous are those in Class 1 which are found in products such as laser printers and CD and DVD players. These pose little to no risk due to the fact that they are incapable of producing damaging laser exposure during operation and this exempts them from any control measures or other form of surveillance (10). Class 1, lasers do not permit human access during their operation due to levels of laser radiation in excess of the accessible emission limit; they are usually enclosed, not granting access to the main laser source (42). Class 2 low-power lasers apply only to visible laser emissions that may be viewed directly for time periods less than or equal to 0.25 seconds (the aversion response of the human eye) (10). Class 3B and 4 are those most commonly used in the clinical setting. The direct beams from Class 3b lasers are immediately
hazardous to the skin, and to the eye when viewed directly. Class 4 lasers are immediately hazardous to the skin and eye from exposure to either the direct or reflected beam, and may also present a fire hazard (1).

Injury severity from a laser depends upon a multitude of parameters once the class is known. These include: “wavelength, energy, aperture size, divergence, continuous or pulsed emission, the absorption characteristics of the tissue exposed, and the circumstances surrounding the exposure (duration, distance, foveal or eccentric viewing)” p.277 (43). Before a new laser product is used the individuals that are to use it should be properly trained and provided with the correct PPE with the assessment of the parameters mentioned above.

2. **American Conference of Governmental Industrial Hygienists**

The ACGIHs produces Threshold Limit Values (TLVs) for laser energy to provide limits that individuals may be exposed to without experiencing adverse effects (44). All of the values given are based on the best available information from experimental studies. The TLVs for direct ocular exposure are based on wavelength and exposure duration. For large or intermediate sources, additional correction factors must be applied in order to calculate the exposure level. The TLVs for skin exposure are also based on wavelength and exposure duration. Correction factors are to be applied to wavelengths between 700nm and 1400 nm; and additional figures are used to aid in the determination of exposure durations requiring calculations of fractional powers (44).

Continuous-wave and repetitively pulsed lasers can both produce repetitively pulsed exposure conditions. Intrabeam viewing holds a TLV that is modified in an instance where the wavelength is between 400 and 1400 nm. The correction factor for this situation is determined by the number of pulses in the exposure. To calculate the number of pulses in an expected exposure situation the pulse repetition frequency (in Hz) is multiplied by the duration of the exposure. Realistic exposures usually
range from 0.25 seconds for a visible source to 10 seconds for an IR source (44). Equation 1 is used to correct TLVs on a per-pulse basis that applies only to thermal-injury conditions (all exposures at wavelengths greater than 700 nm). For wavelengths less than or equal to 700 nm, the correct TLV from Equation 1 applies if the average irradiance does not exceed the TLV for continuous exposure (44).

\[ \text{TLV} = (CP)(\text{TLV for Single-pulse}) \quad \text{Equation 1} \]

3. **American National Standards Institute**

The American National Standards Institute (ANSI) guideline (ANSI Z136.3-2005) Safe Use of Lasers in Health Care Facilities is the main guideline for developing and implementing safe laser use, and has been adopted by The Joint Commission on Accreditation of Healthcare Organizations. This standard provides guidance for the safe use of lasers for diagnostic, cosmetic, preventive, and therapeutic applications in health care facilities. It is intended for use by all personnel associated with the installation, operation, calibration, and maintenance of an HCLS (10). The controls covered in this standard are for equipment that is in its intended operational mode only, not for device maintenance or repair.

The ANSI document contains nine guidelines for HCWs on the safe use of lasers. It begins with a description of the scope, the responsibilities of the laser safety officer, and the general diagnostics of the full HCLS. Hazard evaluation of the laser classification system and the environments they are used in are described along with personnel that may be exposed. Control measures are described, detailing signage and training needed for personnel categories. Medical surveillance of HCWs should be considered for Class 3B and Class 4 laser users. The type of surveillance depends upon the personnel category. Non-beam hazards, the criteria for exposure of the eye and skin, and laser measurements are discussed to be sure that HCWs understand all aspects of the medical laser devices handled (10).
The appendices of the standard provide information that allows clinical staff to abide by the regulatory contingencies set forth by ANSI. Guidance on laser-tissue interaction, lasers and how they are differentiated; tables that summarize the wavelength effects for various lasers; ocular Maximum Permissible Exposure (MPE) limits for selected surgical/medical lasers; Nominal Hazard Zone (NHZ) distances for selected surgical lasers without delivery system constraints; and laser criteria used for NHZ distance calculations are provided (10). The use of medical lasers in surgical and other medical specialties; guidance in equipment set up, maintenance, and related hazards; control measures; fire and explosion hazards; control of smoke and plume; responsibilities and procedures; eye protection; and training are described. Preoperative checklist and laser operator skill verification forms are included. Descriptions of specific specialties, characteristics of the lasers used, and the hazards and precautions to take with each laser delivery system are described. American Society for Laser Medicine and Surgery’s policy on standards of training for physicians on the use of lasers in medicine and surgery is provided in Appendix D of the ANSI standard. It includes credentialing, suggested outlines for laser safety courses to be taught, with Appendix E in the ANSI standard addressing all other personnel that may come in contact or work with the medical laser device. Federal regulatory considerations taken when using and implementing medical devices in a facility are summarized and examples of standard operating procedures are provided (10).

Documentation examples show clinical personnel how to document preoperative laser safety checks, how to determine and validate laser operative skills, and how to create standard operating procedures for safety hazards in the operating rooms (ORs). American national standard institute supplies a full outline and suggestions on how to perform and what to include in a laser safety training program (10).
Administrative controls to avoid injuries include developing and implementing standard operating procedures, training of the authorized personnel laser users, and being diligent on maintenance and servicing of the equipment. American national standard institute recommends a variety of equipment or engineering controls that can be used in addition to those given by the manufacturer such as guarded switches that can be used to prevent inadvertent activation of a device. The facility should be sure that accessory equipment used with the device is compatible with the laser as well. Proper labeling, safety audits, and containment of the laser treatment area are all procedures that should be followed to maintain a working atmosphere with minimalized hazards.

Other beam hazard controls include goggles, face shields, barriers, or windows. Laser windows are made of a variety of materials including tempered glass, laminated glass, and acrylic and are used as additional protection when paired with PPE. Clothing, gloves, and other devices can provide suitable skin protection against laser radiation when worn properly. To identify the correct PPE personnel should consult the operating procedures provided by the manufacturer of the medical laser device and check with the laser safety officer to determine specific needs (45). Laser protective eyewear is selected to reduce the potential ocular exposure below the applicable MPE level. The MPE is the level of laser radiation to which a person may be exposed without hazardous effects or adverse biological changes in the eye or skin. Though MPE values are below known hazardous levels, exposures to the eye or skin at these levels may cause discomfort (10). The MPE is related to the accessible emission limit by the limiting aperture of the eye, which is itself a function of wavelength and exposure time. The accessible emission limit is the maximum total power of radiation that can be emitted from a laser of a particular class (46).

The NHZ is the other major definition for laser safety calculations. This is the distance within which the irradiance of a beam is greater than the MPE. Nominal hazard zone is specific to a given
wavelength and time of exposure as well as for a beam’s path to the eye. A beam path could be direct viewing, specular reflectance, or diffuse reflectance (46). Multiple characteristics are used to determine the MPE: power or energy output, beam diameter, beam divergence, pulse repetition frequency, wavelength, beam path including reflections; beam profile; and maximum anticipated exposure duration. Persons outside of the NHZ boundary would be exposed below the MPE level and are considered to be in a “safe” location. The NHZ evaluation is to define that region where control measures are required (47).

The eyewear must be accompanied by the (a) optical density (OD) at appropriate wavelengths, and (b) the manufacturer’s recommendations on shelf life, storage conditions, and appropriate cleaning methods. It must be specifically selected to withstand either direct or diffusely scattered beams and permanently labeled with the OD and wavelength for which protection is afforded (10). The OD (attenuation) is a logarithmic calculation of the MPE in W/cm² (irradiance units) divided by the maximum safe exposure in W/cm² (48).

\[
OD = \log_{10} \left( \frac{E_0}{MPE} \right)
\]

\(E_0\) is the irradiance incident on the absorber (49).

4. **Illinois Emergency Management Agency**

In Illinois, lasers are also regulated by the Illinois Emergency Management Agency (IEMA) to protect against laser radiation. Any operator of a laser installation must register their laser with the Department of Nuclear Safety before the laser is used in the facility. Control procedures are similar to those placed by ANSI with written operating and safety procedures, training, and a controlled and established area when exposure to laser radiation is above the MPE limit. Protective eyewear, when specified by the laser safety officer, is to be worn when other forms of controls are not applicable and when individuals have access to Class 3B and Class 4 levels of laser radiation. Eyewear
must be in proper condition to ensure the optical filters and holder provide the required OD or greater at the desired wavelengths, and retain all protective properties during use of the device. It also must be suitable for the specific wavelength of the laser and be of OD adequate for the energy of the laser (50).

5. **Occupational Safety and Health Administration**

The Occupational Safety and Health Administration does not have a comprehensive laser standard. The construction industry 29 CFR 1926.54 may be applicable when concerned with PPE (Subpart I). The OSHA regulation 29 CFR 1926.102(b)(2), for eye and face protection, states that “employees whose occupation or assignment requires exposure to laser beams shall be furnished suitable laser safety goggles which will protect for the specific wavelength of the laser and be of optical density adequate for the energy involved.” Citations are usually given by using the general duty clause or, in some cases, Subpart I: when cited employers are required to revise their unsafe work place to comply with industry consensus standards such as the ANSI Z 136.1 Standard (51).

D. **Manufacturer and User Facility Device Experience Database**

The MAUDE database is managed and maintained by the US FDA’s Center for Devices and Radiological Health. Established in 1996, it replaced the previous Medical Device Reporting database (52; 53). The MAUDE report data represents reports of adverse events involving medical devices that may have caused or contributed to a death or serious injury or that may have malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur (54; 55).

Publicly available, MAUDE includes characteristics of the reporter, event (date, location, outcome, description), and manufacturer (name, address, narrative, device information). In 1989, a US
General Accounting Office study found that less than 1% of medical device problems that occurred in hospitals were reported to the US FDA (56). This spurred an expansion of the data collected to consist of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996 (52; 57). Manufacturers, importers, and user facilities are required by federal law to report adverse events as they become aware of them, with submission of reports of device-related deaths, serious injuries, and malfunctions within 30 days (53; 58; 59; 60). The MAUDE database is scheduled to be updated quarterly and the US FDA seeks to include all reports received prior to the update (61; 62; 63). The inclusion of some reports may be delayed by technical or clerical difficulties. With all reporting not being mandatory the database lacks a comprehensive assessment of incidents reported to the US FDA (64).

The MAUDE database may not include reports made according to exemptions, variances, or alternative reporting requirements that are granted under OSHA 21 CFR 803.19 (65). Reporting certain adverse events to the US FDA is mandatory for device manufacturers. However, because not all device manufacturers, users, and distributors adhere to the same threshold or guidelines regarding the disposition of reports, the database is not a reliable source of comprehensive and/or comparative information (66; 67). The quality of information provided in each event report is highly variable and prevents definitive conclusions about causality in many cases, with injury reports providing much more information than death reports (56). The US FDA does not verify the accuracy and completeness of the reports (68). These data are not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices, and should not be used as an information source to substantiate or repudiate the quality of any medical device (69; 70; 71). Adverse events may be overrepresented or underrepresented in literature and in the database due to reporting bias (72).
Currently, 93% of adverse events involving medical devices reported to the US FDA come from industry, 1% from importers, 3% from health care institutions (mandated), and the remaining from voluntary reports (less than 1% from physicians) (56). This database provides a broad cross-section of surgeon experience, skill level, and technique in the United States (61), which usually report “sentinel events”; these are the most serious, life-threatening complications (of the device and related hardware) that generated enough concern and exposure that the physicians or user facilities thought a report was necessary (58). Voluntary reports of adverse events by health care professionals and consumers and of malfunctions by user facilities, such as hospitals and nursing homes, can be reported to the US FDA through the Med-Watch reporting program (73). In fact, with the exponential growth of medical laser procedures, reports pertaining to laser medical devices have increased in the MAUDE database (43). A major weakness is that at this time there is no US FDA-mandated post-marketing complication reporting. Thus, it is thought that the true incidence of complications is greater than what is reported in the MAUDE database (67).

Adverse events occurring outside the United States must also be reported if the device is approved for use in the United States. These events are assigned a unique US FDA event number, and the electronic form contains information such as the date, the device type, a brief narrative describing the nature of the complication, and a description of the treatment plan (52). Laser devices in medical and laboratory settings have the ability to be purchased through foreign vendors. Medical laser devices purchased from foreign vendors that are not registered with or approved by the US FDA come with an increased likelihood of safety hazards. If the devices are not registered then proper controls to protect the worker are not recommended and may surface an unknown risk to the operator.

The MAUDE database is a reporting system that helps to signal safety issues but does not assist in determining or conveying root causes of incidents (65). Causality is rarely determined, as reports do
not all have the same amount of detail. Those reports that do have extensive detail from the reporter and the manufacturer may be useful to identify the human error aspects and develop engineering and administrative controls for prevention in the future.

There are alternative databases that can be used to identify occupationally related medical laser injuries. Databases reviewed were as follows: Bureau of Labor Statistics (BLS), Illinois Hospital Association Hospital Compensation Database, Illinois Workers Compensation First Reports of Injury, OSHA IMIS, and the Illinois Trauma Registry (ITR) database.

The BLS database is the principal “Federal agency responsible for measuring labor market activity, working conditions, and price changes in the economy.” Data are collected and analyzed in order to provide information to the public and private decision-making bodies essential to the economy (74). The BLS database does not allow for laser injuries to be a variable that can be specified within the medical field occupations listed. The nature of injury specified only heat injuries with no detail of causation.

The Illinois Hospital Association compiles and manages the hospital discharge database, which is based on billing records. It includes all patients treated for more than 23 hours in any Illinois hospital (i.e., inpatients only) for any medical reason. The Illinois Hospital Association compiles, maintains, and conducts quality control of the dataset. The ICD9 codes were used to identify causes of injury related to lasers. Exposure to radiation falls under code 926 with laser related injuries corresponding to 926.4.

The Illinois Workers’ Compensation Commission (IWCC) operates the administrative court system for workers’ compensation cases in Illinois. There are approximately 60,000 claims filed with IWCC for financial compensation each year. Unlike single carrier states with a well-organized and centralized reporting system (e.g., Washington State), in Illinois the IWCC only handles claims in which the employee and employer are unable to resolve compensation issues for an injury without
administrative intervention. Any aspect paid for prior to initiating a claim through the IWCC that is not disputed by either party is not litigated through IWCC or reported in the dataset. An arbitrator initially hears a workers’ compensation claim. The arbitrator’s decision can subsequently be appealed before a panel of three commissioners. With the use of a general search of the term “laser” a limited quantity of reports were found within this database.

The OSHA Integrated Management Information System (IMIS) was created to provide an in-house resource to OSHA staff and management, and by state agencies that carry out federally approved OSHA programs. The source of information is dependent upon the local federal or state office in the geographical area where the activity occurred. As events occur information is entered into the system by the local agency. The tool is designed and administered to help OSHA manage and direct its resources. The database was searched using a general search of all reports containing the word laser happening between 1999 and 2009 in the state of Illinois. The search provided 17 cases in which injury could not be identified (75).

The ITR was mandated by the state legislature and is managed by the Illinois Department of Public Health. All of the state’s level 1 and 2 trauma centers (N=62; this number keeps dropping as units close) are required to report all patients (1) sustaining traumatic injuries (ICD-9-CM external injury codes E800-995) and admitted to a trauma center for greater than 12 hours, (2) transferred to a level 1 or 2 center, or (3) are dead-on-arrival or die in the emergency department. The database was reviewed using the ICD9 code of 926.4 with a result of minimal cases being reported into the system relating to occupational injury due to medical lasers.

All databases were reviewed and found to hold only minimal laser device injury records, pointing to a deficiency in laser device injury reporting when it comes to occupational hazards. It appears that occupationally related injury to medical laser devices is poorly defined and is a rare injury.
Databases were selected based on those that were available for review and those available to the public that were known to collect worker injury data.

E. **Human Factors Analysis Models**

Accident investigations are conducted in order to understand root cause contributing factors and to develop a corrective action that will prevent future accidents from occurring. The most common contributing factors that lead to a laser accident are an unanticipated eye exposure during alignment, improper use of eye protection, poor housekeeping, lack of planning, equipment malfunction, and improper use of equipment (26). Two classification systems to elucidate factors are the Human Factors Analysis and Classification System (HFACS) and the Software, Hardware, Environment, and Liveware concept (SHEL).

1. **Human factors analysis and classification system**

In the clinical setting HFACS is used to quantitatively characterize the role of human errors and was historically used mostly to analyze data available from existing accident/incident investigations (76; 77). It was developed as an evaluation framework to analyze and classify operator errors in naval and aviation accidents and mishaps. It identifies the human causes of an accident and provides a tool to not only assist in the investigation process, but to target training and prevention efforts (78). It is a tool for reconstructing human contributions to a variety of accidents. This generic model can be restructured to illustrate the origins of error in health care practices and surgery operations (76). The system describes four levels of failure that may occur: (1) unsafe acts (of the operator), (2) preconditions of unsafe acts, (3) unsafe supervision, and (4) organizational influences (Table III). The theory explains that accidents are caused by active failures and latent failures, which are
a result of deficiencies in the organizational and management levels of a system (76; 79; 80). Refer to Figure 1 for a complete visual representation of the model.

### TABLE III
**DESCRIPTION OF HUMAN FACTOR LEVELS IN THE HUMAN FACTORS ANALYSIS AND CLASSIFICATION MODEL (80)**

<table>
<thead>
<tr>
<th>LEVEL</th>
<th>HUMAN FACTOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organizational Influences</td>
<td>Climate: Vision within the organization including aspects of policy, command structure, and culture</td>
</tr>
<tr>
<td></td>
<td>Process: Means by which the vision of an organization is carried out including operations, procedures, and oversight</td>
</tr>
<tr>
<td></td>
<td>Resource management: How human, monetary, and resources necessary to carry out the organizational vision are managed</td>
</tr>
<tr>
<td>Unsafe Supervision</td>
<td>Inadequate supervision: Oversight, management of personnel, and resources, including training, guidance, and leadership</td>
</tr>
<tr>
<td></td>
<td>Problem Correction: Instances when deficiencies among individuals, equipment, training, or other safety areas are “known” to the supervisor, yet allowed to continue</td>
</tr>
<tr>
<td></td>
<td>Inappropriate operations: Management of work, including aspects of risk management, crew pairing, and operational tempo</td>
</tr>
<tr>
<td>Preconditions to Unsafe Acts</td>
<td>Environmental Factors</td>
</tr>
<tr>
<td></td>
<td>Technological environment: Design of equipment and controls, display-interface characteristics, checklist layouts, task factors, and automation.</td>
</tr>
<tr>
<td></td>
<td>Physical Environment: The operational setting and the ambient environment, such as heat and lighting.</td>
</tr>
<tr>
<td></td>
<td>Adverse mental states: Psychological and (or) mental conditions, such as fatigue, pernicious attitudes, and misplaced motivation, that negatively affect performance</td>
</tr>
<tr>
<td>LEVEL</td>
<td>HUMAN FACTOR</td>
</tr>
<tr>
<td>--------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Physical/mental limitations: Physical/mental disabilities, such as poor vision, lack of skill, aptitude, knowledge, and other mental illnesses, that adversely impact performance</td>
</tr>
<tr>
<td></td>
<td>Teamwork: Communication, coordination, and other teamwork issues that impact performance.</td>
</tr>
<tr>
<td></td>
<td>Personal readiness: Off-duty activities, such as adhering to rest requirements, alcohol restrictions, and other mandates, required to perform optimally on the job</td>
</tr>
<tr>
<td>Unsafe Acts</td>
<td>Decision errors: “Thinking” errors represent intended behavior that proceeds as designed, yet the plan proves inadequate for the situation. Errors manifest as poorly executed procedures, improper choices, or simply the misinterpretation of relevant information</td>
</tr>
<tr>
<td></td>
<td>Skill-based errors: Highly practiced behavior that occurs with little thought. These errors frequently appear as breakdown in visual patterns, forgotten intentions, and omitted items during procedures. The technique with which one performs a task is included</td>
</tr>
<tr>
<td></td>
<td>Perceptual errors: Errors arise when sensory input is degraded. Faced with acting on imperfect or incomplete information, operating room staff run the risk of misjudging procedures as well as responding incorrectly to a variety of visual-vestibular illusions</td>
</tr>
<tr>
<td></td>
<td>Routine violations: “Bending the rules.” This type of violation is habitual by nature and often enabled by management that tolerates departures from the rules</td>
</tr>
<tr>
<td></td>
<td>Exceptional violations: Departures from authority, neither typical of the individual nor condoned by management</td>
</tr>
</tbody>
</table>
The fundamentals of this model fall in the theory of the “Swiss Cheese Model,” originally developed by Reason (76). Latent failures influence system error and may result in adverse events if many deficiencies are present within the levels of an organization (80). The HFACS model has been utilized in a number of studies involving medical error. El Bardissi et al. used a modified model for specific issues that are relevant to cardiac surgery. Questions for each category were based on published sentinel event analyses and focus group studies in which specific causes of medical and surgical errors were described (80). The principle finding of their study showed that HFACS can be applied to the cardiovascular surgery operation room (OR) in a comprehensive and global way, aimed at understanding the interplay of human factors in the immediate OR environment and the organizational structure (80). In Celik and Cebi’s study on shipping accidents they proposed an analytical HFACS mechanism for identifying latent human errors. The ability to quantify contributing factors was added to the model to prioritize them in the accidents, which satisfies the need to redesign safety guidelines in different industries (76). The model was developed in response to a trend that showed some form of human error, at various levels, as a primary causal factor in 80% of all flight accidents in the Navy and Marine Corps.

Using HFACS to analyze hundreds of aviation-mishap reports, the Naval Safety Center has identified four aspects of human error as leading contributors which are used in this study: Unsafe Acts of Operators; Preconditions for Unsafe Acts; Unsafe Supervision; and Organizational Influences (78). Each aspect was further broken down into specific definitions. Unsafe Acts of Operators is disseminated into either Skill-based error or Decision errors. A skill-based error requires little if no thought on the part of the operator and is often susceptible to attention failures (78). Decision errors are mistakes that are a result of actions or inactions based on the operator’s lack of knowledge or poor choices. Preconditions for Unsafe Acts include mental conditions and attitudes that affect performance
and poor communication skills or coordination among personnel involved in the event or operation. Unsafe Supervision covers current supervision that has been inappropriate or absent resulting in a failure to provide guidance, training, or to track performance (78). Organizational Influences are a result of inadequate or misinterpreted corporate decisions that govern everyday activities (78). The HFACS model provides the first step in risk management by identifying human-factor problems.

Forty-one accident investigation reports related to machinery space fires and explosions were reviewed in Schroder-Hinrichs et al., 2011 (81). Using an adapted version of the HFACS with modifications made for the machinery space features it was shown that organizational factors were not identified by maritime accident investigators to the extent expected had the International Maritime Organizations guidelines been observed. They were able to select accident investigation reports within a time period of 1990 to 2006 and all consisted of an introduction, narrative, analysis, conclusions, and recommendations. The accident investigation reports varied in detail and length, but were all reviewed and the modified HFACS model was applied (81). Recommendations were not given as they were already provided in the initial investigation reports.

A study by the US Bureau of Mines, spearheading a study into the impact of human error on mining accidents, found that nearly 85% of all mining accidents identified human error as a causal factor (82). Reports between January 2004 and June 2008 provided a total of 508 cases from the Department of Mines and Energy in Queensland, Australia. The completed forms were standard for all mines across the time period examined. A modified version of the HFACS was used to analyze the incident and accident cases. The large limitation of this study was that ad hoc data was used, making it impossible to speak with the people involved in each incident or accident. Only information in the presented reports was able to be used for identification of causal factors (82). To minimize unsafe acts of the operator it was recommended that the reliance on visual detection be minimized and to focus
on an effort to augment vigilance during times when fatigue and boredom affect performance. Another recommendation was given for the act of parking vehicles. By installing an auditory or visual warning system to remind the operator of the proper steps that need to be completed when parking a vehicle the probability of leaving a cab without shutting off the vehicle, applying the parking brake, and turning the wheels in the right direction would decline. The final analysis of this research revealed that skill-based errors were the most common unsafe act and showed no significant differences across mine types. By identifying human causal factors in a systematic fashion, this study had provided mine safety professionals the information necessary to reduce mine incidents/accidents further using the recommendations provided (82).

Due to the fact that HFACS has successfully been modified and utilized in a medical setting it was chosen to also be modified for this study and create a model that would properly assess medical laser injuries. The HFACS model (Figure 1) was applied to multiple cases with only ad-hoc data available from the event and manufacturer descriptions.

2. **Software, hardware, environment, and liveware**

   The SHEL (Hardware, Environment, Liveware, Liveware-Liveware) model was first developed by Edwards (1972) to examine the ergonomic issues in relation to system resources, and later modified by Hawkins (1984) to highlight the nature of the interaction within the Liveware-to-Liveware relationship (83). The organizational component was added to the SHEL model in Chang and Yeh’s 2009 study. This extension enables the role played by the organization of the health care team system to be examined (83).

   The SHEL model is often shown in diagrammatic format and is the conceptual model of ergonomics (See Figure 2) (83). With the use of this model the psychological and behavioral elements
of the individual and the interactions between the individual and other components of the work system can be identified and examined.

The center of the model is the Liveware, or the human operator. The first component matched with the human operator is the Hardware, or equipment design. Ergonomics is an important component for this area where equipment development and design is assessed. The Software consists of the procedures, manuals, checklists, symbology, and computer programs used in the work place.
Figure 1. HFACS Model.
Usually the problems that arise in this area are more difficult to resolve than those in the Hardware section due to the fact that they stem from more behavioral/cognitive issues than mechanical. The Environment can add a variety of stressors to an accident. For example noise, overcrowding, and frequency of disturbance may all contribute to an accident and are characteristics of common attributes in a clinical setting. The SHEL model is also a good source to use when gathering and sorting descriptive data (84; 85).

Ship operation has used the model to analyze human factors that contribute to marine accidents and incidents. Using a questionnaire survey the ship navigation domain was reviewed by operators’ in two types of critical circumstances (collision and grounding avoidance and in-depth exploration of collision factors) (86).

In a study of ground damage incidents from one major airline, 130 reports were reviewed to determine active and latent failure patterns (87). Nine major latent failures were identified and classified using the SHEL model. The nine identified were all separated out into the four major categories of the SHEL model. Poor equipment was identified under Hardware, inadequate space and problems with painted guidelines were found to fall under the Environmental aspect. Lack of awareness of risks/hazards was a latent failure found under Liveware. The Liveware-Liveware interaction showed that poor communication, personnel unaware of concurrent work, correct number of people not used, pressures to maintain on-time departures, and pushback policies not enforced were contributing latent failures (88). This showed that few causes contribute to most ground damage incidents and it’s suggested that by introducing a small number of interventions, a large number of ground damage incidents can be prevented (88).

A study was conducted to review the extent and nature of medical error with a discussion on human factors engineering tools that have potential applicability.
Figure 2. SHEL Model.
The tools discussed included taxonomies of human and system error and error data collection and analysis methods. Medical error was discussed giving historical events that have taken place throughout time (87). For example, in 1930 the Lubeck disaster occurred where 250 infants were given a virulent version of the human tubercle bacilli and not the preventative vaccine, killing 72 patients. Cited causes of medical error include, but are not limited to, errors in medical administration, poor legibility or unavailable charts, lack of allergy status documentation, and fatigue or stress on the operator (87). Human factors engineering approaches were discussed and their use in medicine assessed. The SHEL model was used in previous studies to determine the relationships between the active failure patterns and latent failures. It was found that aviation maintenance parallels medicine in that it is a “highly regulated domain in which large teams of individuals are tasked with maintaining and remediating a highly complex system over many years (p.63),” giving the evidence that the SHEL model is applicable in the medical field (87).

Helmreich and Davies’s study (89) drew on research in aviation to define the human factors issues present in the OR. It also discussed a new approach to human factors training for medical personnel. Training in the aviation field initially focused on an individualistic approach and now has refocused on team issues to include topics of communication, team coordination, and leadership. The success of crew resource management in the aviation field and the conceptual similarities between team activities in the OR and the cockpit has sparked the interest in adapting this approach in medicine.

The SHEL model is a static model that defines the components of performance without defining the processes that these components carry out or influence (89). A survey instrument was created known as the OR Management Attitudes Questionnaire. This has been used to collect data in teaching hospitals in three countries to date. Both survey and observational data indicated that the problems of
the OR parallel those of the cockpit in terms of communications breakdown and inadequate group process (89). The medical field adapted simulator technology in the late 1960s from the aviation field. Surgical simulators were initially employed as part-task trainers to teach technical procedures such as laparoscopic surgery and anesthetic operations. This part-task training approach did not allow for the full team to be involved in the surgical procedures, which is needed to optimize performance (89). Team-oriented medical simulators are in a continual development stage to provide medical personnel with a simulated experience focusing on human factors training. It was found that the majority of accidents and critical incidents involve failures in team performance and tend to involve interpersonal issues, such as: communications, leadership, conflict, flawed decision-making. (89).

F. **Study Objectives**

Upon identifying occupationally related injuries in the MAUDE database, those cases with sufficient information were used to document case studies reviewing the exposure, injury, and root cause. Human factor models were then applied to evaluate these incidents in order to make recommendations to improve the medical instruments and procedures used during the medical laser applications.

Specific objectives were to describe the 54 cases identified as occupationally related and further categorize the data to specify the benefits of the database. Three case studies were composed by categorizing ten selected cases and four of those ten were then chosen to further assess using human factors models. The four cases provided enough information to garner aspects of injury incidents that may be useful for preventative measures. Root cause analysis was performed using both the HFACS and SHEL models and human factors that may have contributed to the accidents were
documented. The MAUDE database was compared to other databases to determine if it is beneficial and to identify areas of the system that can be improved and/or modified.
II. METHODS

At the request of the researchers the MAUDE database was queried by the US FDA’s CDRH on November 2, 2010 for all injuries and deaths related to the use of medical and/or dental lasers, for the time period of 1990 to 2009 (90). A Freedom of Information Act request was made because at the time, in 2009, the MAUDE database online was not searchable or updated frequently (See Appendix A). The data were collected using 224 generic device names and put into PDF format for review. All reports pertaining to laser devices were collected and analyzed (See Appendix B).

A detailed summary report including both in-house and freedom of information format was generated from the information obtained on the MedWatch forms (90). Information from the MedWatch forms 3500A (used for mandatory reporting for regulated industry and user facilities) and 3500 (used for voluntary reporting for consumers and healthcare professionals), which do not contain information protected by Health Insurance Portability and Accountability Act, was pulled and used to create the MAUDE database (91). Events occurring between January 1, 1990 and December 3, 2009 (total of 19 years) were collected by searching for incidents that were the result of a medical laser device, yielding 1084 cases. Upon receiving query results, all cases were reviewed to identify injuries that were occupationally related. Those that clearly specified the individual who was injured were broken down into occupational and nonoccupational related injuries. Those reports that did not contain a verified injured party were immediately eliminated.

After review, 54 cases were identified as containing occupationally related injuries, which were then analyzed for completeness. Categories presented in the reports from the US FDA database were entered into a spreadsheet. Cases were then assessed for completeness in each by counting the
number of categories in which columns were filled and dividing by the total number of categories/columns provided.

Number of cases in the identified percent complete range and the overall percentage that each case fell in regarding the total 54 cases were assessed (See Table IV). It was found that 54% of the total number of occupationally related cases were between 70%–80% complete. The highest percentage of completion was shown to be 80% with the lowest at 44%.

**TABLE IV**
PERCENTAGE OF FIELDS COMPLETED IN THE MAUDE DATABASE OCCUPATIONALLY RELATED REPORTS

<table>
<thead>
<tr>
<th>PERCENT OF COMPLETE FIELDS (%)</th>
<th>NUMBER OF CASES</th>
<th>PERCENT OF CASES (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>40–45</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>46–50</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>51–55</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>56–60</td>
<td>8</td>
<td>15</td>
</tr>
<tr>
<td>61–65</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>66–70</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>71–75</td>
<td>8</td>
<td>15</td>
</tr>
<tr>
<td>76–80</td>
<td>21</td>
<td>39</td>
</tr>
<tr>
<td>Sum</td>
<td>54</td>
<td>100</td>
</tr>
</tbody>
</table>

Those cases that were 76%–80% (21 of the 54 cases) complete were further examined for the documentation and completion of medical treatment for the identified injured employee. After applying a filtering for those who received medical treatment, ten cases remained. The ten cases were then grouped according to the hazard category (beam verse non-beam): beam-thermal skin, beam-thermal eye, and non-beam electrical. These classifications are depicted in the ANSI Z136.3-2005 Safe
After reading through the event and manufacturer descriptions, statements presenting the category and sub-category were used to define each case.

Four cases were found to have the criteria necessary to apply to the human factors models. Criteria includes: (1) Occupationally-related, (2) 75%–80% level of completion, (3) identification of medical treatment being performed on the injured employee, and (4) device settings identified in the report. Human factors models used were: the HFACS and the SHEL models. The models were applied to the four selected cases to identify the interactions between the injured employee and other components of the system.

The human factor levels described by El Bardissi et al. (80) were used to review each case using the HFACS model. Cases were reviewed and each question provided in the article was modified and applied to the medical laser device application to determine root cause. The HFACS’s visual model was adapted from the US Department of Defense Human Factors Analysis and Classification System report (92).

The SHEL model was used to analyze each case by reviewing the performance factors and questionnaire created by Chang and Yeh (2010). Chang and Yeh conducted a survey with air traffic control tasks, but as proven previously, medical settings contain a number of similarities to airline studies, making the SHEL model relevant for use. All questions and factors were modified to fit the clinical laser environment before applying to the cases found in the MAUDE database. (83).

The questions used to measure the six construct areas of the research model were “obtained from existing literature including ICAO (1998), EATCHIP Human Resource Team (1999), and Isaac and Ruitenberg (1999)” (83, p.125). Each item was adjusted to the context of the clinical medical laser environment (Table VI). Items were grouped in different characteristic or interactive dimensions for easy reference. Table V shows the dimensions of the items for measuring each construct, together with
their corresponding statement number. This table was only used as a reference in order to utilize the facts found within the event descriptions. It had no direct effect on Table VI. In the Chang and Yeh (2010) study each question was answered on a five-point Likert scale, ranging from (1) “strongly disagree” to (5) “strongly agree”. With the inability to contact the employee to perform this survey, the model’s questionnaire was applied and modified to the known information documented in the MAUDE report provided. The Likert scale was not applied to this study.
### TABLE V
ITEMS RETAINED FOR THE MEASUREMENT MODEL (ADAPTED TO CMLE) (83)

<table>
<thead>
<tr>
<th>ITEM NUMBER</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>L4</td>
<td>Employees were aware of safety risk with medical laser devices&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>L5</td>
<td>Responsibility of the medical personnel as well as other technicians in the surgery room were understood&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>L6</td>
<td>Language skills were sufficient to perform my job&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>L7</td>
<td>Current experience and skills of the medical personnel were sufficient&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>L8</td>
<td>Medical personnel had complete knowledge of medical laser devices</td>
</tr>
<tr>
<td>L9</td>
<td>Medical personnel could easily make decisions in their job</td>
</tr>
<tr>
<td>L10</td>
<td>Medical personnel decision skill for critical tasks was as good as for routine tasks&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>LL6</td>
<td>Attention to team member's work was given</td>
</tr>
<tr>
<td>LL7</td>
<td>Responsibilities were shared with team members during peak periods&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>LL15</td>
<td>Coordination with other medical team members was done well</td>
</tr>
<tr>
<td>LL16</td>
<td>Members of the medical team worked well together</td>
</tr>
<tr>
<td>LS1</td>
<td>The design of current work checklist was appropriate</td>
</tr>
<tr>
<td>LS2</td>
<td>The current work checklist process is reasonable&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>LS3</td>
<td>The design of current operation procedures is appropriate&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>LS4</td>
<td>The current operation procedure is reasonable&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>LH1</td>
<td>The current medical laser equipment is sufficient</td>
</tr>
<tr>
<td>LH2</td>
<td>The layout of the medical laser equipment is reasonable</td>
</tr>
<tr>
<td>LH3</td>
<td>The supply of supporting facilities (i.e., manufacturer and internal technicians) is sufficient</td>
</tr>
<tr>
<td>LH6</td>
<td>The automation system on the medical laser device is effective</td>
</tr>
<tr>
<td>LH7</td>
<td>The design of the automation system is appropriate</td>
</tr>
<tr>
<td>LH10</td>
<td>The maintenance and backup system is effective</td>
</tr>
<tr>
<td>LH11</td>
<td>The maintenance and backup system is easy to operate</td>
</tr>
<tr>
<td>LE4</td>
<td>The temperature of the operating/maintenance room is good</td>
</tr>
<tr>
<td>LE5</td>
<td>The air quality of the operating/maintenance room is appropriate</td>
</tr>
<tr>
<td>LE6</td>
<td>The operating/maintenance room is a safe workplace</td>
</tr>
<tr>
<td>LE7</td>
<td>The layout of the operating/maintenance room is appropriate</td>
</tr>
<tr>
<td>LO2</td>
<td>The current work schedule is reasonable</td>
</tr>
<tr>
<td>LO8</td>
<td>My supervisor takes into account my suggestions&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>LO9</td>
<td>My supervisor frequently keeps me informed of work conditions&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>LO12</td>
<td>My organization has a good safety culture&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>LO13</td>
<td>My organization encourages me to express safety concerns&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>LO16</td>
<td>Training for performing various medical laser device tasks is sufficient</td>
</tr>
<tr>
<td>LO17</td>
<td>Training for handling abnormal operational conditions is sufficient</td>
</tr>
</tbody>
</table>

<sup>a</sup>Questions unable to apply to study due to lack of information from MAUDE descriptions.

Note: Questions were applied on a subjective basis. Assumptions made based on data provided in MAUDE descriptions.
<table>
<thead>
<tr>
<th>CONSTRUCT</th>
<th>DIMENSION</th>
<th>ITEM NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liveware (L)</td>
<td>Attitude</td>
<td>L1, L2, L3</td>
</tr>
<tr>
<td></td>
<td>Situation Awareness</td>
<td>L4, L5</td>
</tr>
<tr>
<td></td>
<td>Knowledge and Experience</td>
<td>L6, L7, L8</td>
</tr>
<tr>
<td></td>
<td>Decision Making Skills</td>
<td>L9, L10</td>
</tr>
<tr>
<td></td>
<td>Health</td>
<td>L11, L12</td>
</tr>
<tr>
<td>Liveware-Liveware (L-L)</td>
<td>Peer Communication</td>
<td>LL1, LL2, LL3, LL4, LL5</td>
</tr>
<tr>
<td></td>
<td>Teamwork</td>
<td>LL6, LL7, LL8</td>
</tr>
<tr>
<td></td>
<td>Personality Interaction</td>
<td>LL9, LL10</td>
</tr>
<tr>
<td></td>
<td>Leadership</td>
<td>LL11, LL12</td>
</tr>
<tr>
<td></td>
<td>Inter-team Coordination</td>
<td>LL13, LL14, LL15, LL16</td>
</tr>
<tr>
<td>Liveware-Software (L-S)</td>
<td>Checklists</td>
<td>LS1, LS2</td>
</tr>
<tr>
<td></td>
<td>Procedures</td>
<td>LS3, LS4, LS8</td>
</tr>
<tr>
<td></td>
<td>Software and Documentation</td>
<td>LS5, LS6</td>
</tr>
<tr>
<td></td>
<td>Rules</td>
<td>LS7</td>
</tr>
<tr>
<td>Liveware-Hardware (L-H)</td>
<td>Equipment</td>
<td>LH1, LH2, LH3, LH4, LH5</td>
</tr>
<tr>
<td></td>
<td>Automation</td>
<td>LH6, LH7, LH8, LH9</td>
</tr>
<tr>
<td></td>
<td>Maintenance</td>
<td>LH10, LH11, LH12</td>
</tr>
<tr>
<td></td>
<td>Visual Resources</td>
<td>LH13, LH14</td>
</tr>
<tr>
<td>Liveware-Environment (L-E)</td>
<td>Workplace Design</td>
<td>LE1, LE2</td>
</tr>
<tr>
<td></td>
<td>Workplace Quality</td>
<td>LE3, LE4, LE5, LE6, LE7</td>
</tr>
<tr>
<td></td>
<td>Relaxation Setting in Relation to Fatigue and Pressure</td>
<td>LE8, LE9, LE10, LE11, LE12, LE13</td>
</tr>
<tr>
<td>Liveware-Operation (L-O)</td>
<td>Workload</td>
<td>LO1, LO2, LO3</td>
</tr>
<tr>
<td></td>
<td>Policies and Rules</td>
<td>LO4, LO5, LO6, LO7</td>
</tr>
<tr>
<td></td>
<td>Communication</td>
<td>LO8, LO9</td>
</tr>
<tr>
<td></td>
<td>Organizational Structure</td>
<td>LO10, LO11</td>
</tr>
<tr>
<td></td>
<td>Safety Culture</td>
<td>LO12, LO13, LO14</td>
</tr>
<tr>
<td></td>
<td>Training</td>
<td>LO15, LO16, LO17</td>
</tr>
</tbody>
</table>
III. RESULTS

A. Description of 54 Occupational Injury Cases

The database provided by the US FDA’s CDRH, generated from the information obtained on the MedWatch forms from the US FDA website, contained 1084 cases between January 1, 1990 and December 3, 2009.

After reviewing each case it was found that 54 were specific to work-related injuries. Out of the 54 cases presented, 56 actual injuries were found. Within two cases it was found that two employees were injured during the same incident. Events reported were due to malfunction of device (44%; 24/54), injury of device operator (26%, 14/54), or some other occurrence (26%, 14/54), with two reports not containing this information.

Where the event occurred was recorded with a low response rate showing hospitals (39%, 21/54) to be the primary location and ambulatory surgical facilities (2%, 1/54) secondary. Personnel injured varied from physicians to service engineers working in the health care facility. Tables VII and VIII demonstrate the personnel injured and the body injury location.

When the MAUDE database was reviewed, we learned multiple titles were given for similar professions, so we grouped similar personnel titles. Upon completing this characterization, it was found that 61% of the 56 work related injuries were surgeons. Surgical and laser technicians comprised 13% of the 56 work related injuries. The remaining medical professionals injured represented nurses, surgical assistants, and service technicians who performed maintenance on the laser-device equipment. A second column was also added to depict the ten final cases chosen comparatively to the initial 54 cases.
Table VIII shows that the most common injury of these 54 cases was caused by a beam to the skin resulting in burn damage (70%). Burns were in a variety of areas on the body including the hand, arm, leg, and waist. The second most common injury was caused by eye beam exposure (26%). This caused blurred vision, visual spotting, bilateral corneal abrasions, and loss of depth perception. The final category was electrical injury. An injury resulting in a loss of feeling in one employee’s finger to elbow was a result of a shock by a laser device.

### TABLE VII
PERSONNEL INJURED IN THE OCCUPATIONALLY RELATED CASES FOUND IN THE MAUDE DATABASE

<table>
<thead>
<tr>
<th>GROUP TITLE</th>
<th>JOB TITLE GIVEN</th>
<th>NUMBER INJURED (n=56(^a))</th>
<th>FINAL SELECTED (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon</td>
<td></td>
<td>34 (61%)</td>
<td>3 (30%)</td>
</tr>
<tr>
<td>Doctor</td>
<td></td>
<td>11</td>
<td>1</td>
</tr>
<tr>
<td>Physician</td>
<td></td>
<td>13</td>
<td>2</td>
</tr>
<tr>
<td>Surgeon</td>
<td></td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Urologist</td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Technician</td>
<td></td>
<td>7 (13%)</td>
<td></td>
</tr>
<tr>
<td>Scrub Technician</td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Surgical Technician</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Laser Technician</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>OR Technician</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Technician</td>
<td></td>
<td>2</td>
<td>1 (10%)</td>
</tr>
<tr>
<td>Nurse</td>
<td></td>
<td>5 (9%)</td>
<td>1 (10%)</td>
</tr>
<tr>
<td>Surgical Assistant</td>
<td></td>
<td>1 (2%)</td>
<td>1 (10%)</td>
</tr>
<tr>
<td>Facility Employee</td>
<td></td>
<td>1 (2%)</td>
<td>1 (10%)</td>
</tr>
<tr>
<td>Anesthesia Resident</td>
<td></td>
<td>1 (2%)</td>
<td></td>
</tr>
<tr>
<td>Health Professional</td>
<td></td>
<td>1 (2%)</td>
<td></td>
</tr>
<tr>
<td>User Facility Personnel</td>
<td></td>
<td>1 (2%)</td>
<td></td>
</tr>
<tr>
<td>Service Engineer</td>
<td></td>
<td>1 (2%)</td>
<td>1 (10%)</td>
</tr>
<tr>
<td>Service Technician</td>
<td></td>
<td>1 (2%)</td>
<td>1 (10%)</td>
</tr>
<tr>
<td>Operator</td>
<td></td>
<td>3 (5%)</td>
<td>1 (10%)</td>
</tr>
</tbody>
</table>

\(^a\)Two cases contained two employees who were injured.
### TABLE VIII
**INJURY LOCATION IN THE OCCUPATIONALLY RELATED CASES FOUND IN THE MAUDE DATABASE**

<table>
<thead>
<tr>
<th>INJURY</th>
<th>SPECIFIC LOCATION</th>
<th>NUMBER INJURED (N=54)</th>
<th>FINAL SELECTED (N=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure to Beam Burn</td>
<td>Eye</td>
<td>14 (26%)</td>
<td>3 (30%)</td>
</tr>
<tr>
<td></td>
<td>General</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hand</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Finger</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Arm</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Leg</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Waist</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Lost Feeling Finger to Elbow</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Shocked</td>
<td>Ears, Nose, Mouth</td>
<td>2 (4%)</td>
<td>2 (20%)</td>
</tr>
</tbody>
</table>

B. **Case Study Series by Identified Hazard**

The ten cases selected below have been categorized into three series. Each series presents the incident as recorded in the MAUDE database and provides an analysis of the data given in the description. Recommendations follow providing information and resources on precautionary details that could have been taken in order to prevent the injury.

1. **Eye injury cases**

   a. **Case 1**

      A field service engineer was servicing a Versapulse laser when a reflected beam hit his eye. No evaluation of the laser was considered to be necessary. The engineer’s face had sweat on it while performing the maintenance procedure and as a result the safety goggles slipped down and his retina was hit by the reflected beam at 532 mm. A beam of 532 mm causes the aversion process to
be activated. In this case the engineer’s right eye was hit by a reflected beam initiating bleeding confirming a high-intensity beam. He went to the hospital and received medication in the form of eye drops and drugs. There was no permanent damage at the time of this report. He was wearing the proper eye wear during the incident and went back to work with a confirmation from the doctor that everything was going well with his eye. The company conducted additional laser safety training for all field service engineers using their product and the incident was also reported to the German authorities.

b. **Case 2**

A supporting physician reported that the operating physician of a Gemini laser had sudden bilateral eye pain and swelling. The operating physician was seen by emergency room personnel and was told he had bilateral corneal abrasions, akin to "welder's eyes", and that he required time off.

The manufacturer, Laserscope, requested the operating physician be seen by an ophthalmologist and to be forwarded the results of the examination. Laserscope also requested the eyewear that was used be sent back for evaluation. The eyewear was dual safety "flip-up glasses". As of 2005 the eyewear was not returned. Follow-up contact with the operating physician was initiated but there was no response by the time this report was placed in the MAUDE database system. The supporting physician also reported that the operating physician had not used the laser without eye protection and that the maximum time in one day did not exceed three or four hours. Laserscope also sent new eyewear to the facility that did not contain the "flip-up" option.

c. **Case 3**

A medical facility reported an eye safety filter on a model 704 laser device failed to activate. The physician received a burn to the left macula with swelling, blurred vision, and loss of
depth perception. The physician was treated by an ophthalmologist following the injury. The manufacturer, Laserscope, was unable to get further information as to the physician’s condition.

Laserscope’s customer service engineer visited the site and could not reproduce the condition the facility stated had happened without overriding the eye safety filter. The tests did show there may have been a problem with the eye safety filters as the eye safety filter mechanism did not recognize the laser device; however, the physician would have had to override the system in order to use the laser. The laser performed properly and according to specification. Laserscope replaced the eye safety filter and the laser was working properly upon completion of the maintenance. The eye safety filter was returned and tested in-house at Laserscope’s facility. This test produced an error that indicated the device was not attached and therefore had a possible electrical problem.

Investigation found that the physician was not wearing laser protective eyewear. Laserscope did not have a service contract with this facility since May 2002. A third-party service company was handling any repairs and service to Laserscope’s equipment.

The model 700 series operator's manual states the following: "Each wavelength of light requires protection matched to that wavelength. Since the laser emits light at 532 nm or with optional Nd: Yag module, 1064 nm, only Laserscope approved eyewear should be worn."

2. **Analysis of cases**

Three cases demonstrated a beam injury to the eye resultant from multiple contributing factors. Cases were assessed for the environment, PPE used or not used, and also the condition of the equipment.

a. **Analysis case 1**

During maintenance the service engineer was in a work environment that induced sweating. This could be a combination of the environment and also the health of the
employee. The goggles provided were inadequate for medium to heavy work that would cause an individual to perspire. Proper training is needed with safety equipment and employers are to ensure that their employees are provided with the correct gear that would withstand the work being performed.

b. **Analysis case 2**

The corneal surface absorbs all UV light ranging from 100 to 315 nm (UV-B/UV-C), producing photokeratitis (welder’s flash) from a photochemical process that denatures the proteins in the cornea. This is a temporary condition because the corneal tissues regenerate very quickly, less than 24 hours (32). It can be concluded that the employee was exposed to UV in this range due to the similarities with welder’s flash/eye. The safety equipment provided had a flip-up option allowing the employee to have the flap down for protection from the laser and then the flap up for a clear non-protective lens while not using the medical laser device. Potential for inadequate use of this type of equipment must be taken into consideration due to the fact that proper use is dependent upon adequate training and supply of PPE within the medical facility. A non “flip-up” device would ensure protection at all times when the safety equipment is worn.

Additional information is needed to identify the environment and equipment malfunctions, if any that contributed to this incident.

c. **Analysis case 3**

The Laserscope device malfunctioned from a possible electrical problem causing the eye safety filter mechanism to not recognize the laser device. Only with the additional action of the operator would the laser actually function. The employee was also found to be without adequate laser protective eyewear during operation of the medical laser device. The operator’s manual quoted gave direction that PPE adequate for the wavelengths being used is needed while using the laser.
Beam injuries to the eye vary depending on the employee and the task being performed. Each of these three cases has environmental and procedural differences. This demonstrates a need for proper inspection and maintenance of PPE and medical laser equipment.

Human behavior is relied upon for protection against laser hazards in the lab and training is a core responsibility to continuously review and improve as well as the evaluation and availability of the correct PPE.

Medical laser devices emit beam and non-beam hazards that primarily affect the eye and skin. Eye injuries initiated the development of laser control mechanisms that would eliminate exposure. The primary control involved in incidents is PPE. The three cases presented showed that improper use or lack of wearing the correct PPE, specifically laser protective eyewear, plays a large role in eye injuries caused by laser beams. Two cases analyzed showed that the equipment was provided yet the employees did not understand the proper use, had inadequate training, or ignored the precautions needed to be taken, continuing with the scheduled procedures. Unsafe conditions and controls currently in place were ignored or unknown.

3. **Skin injury cases**

Skin is the largest organ on the human body and the most exposed. Thermal injuries to the skin were found within the MAUDE database with five cases holding the criteria discussed in this paper.

a. **Case 4**

Sometime during a knee arthroscopy procedure, while lasing the posterior horn section of the knee, the physician noted that the laser fiber (tip) burned through the metal, causing the metal shaft to break approximately one-half inch from the white sticker (lot number/model label located on the proximal end of the device) and burning the physician’s as well as the surgical site on
the patient. The procedure was immediately paused to replace the broken fiber with another of the same model. The procedure continued using the second tip when the physician noted a burn mark on the metal shaft approximately one inch from the distal end of the device. At the same time the physician also noted (on video monitor) minimal charred tissue. The physician proceeded to resect the charred tissue from the patient being operated upon with a shaver. No further incidents occurred during the procedure.

Follow-up with physician's associate regarding the physician's hand indicated that a topical cream was used to treat the burn. No serious injury was associated with this event. It was also noted by the report to the manufacturer that excessive stress may have been applied on the device during the lasing procedure.

b. **Case 5**

It was reported that during set-up to test a fire device, the device was attached to a laser and the power was turned on. A broken fiber close to the tip caused a “pop” to be heard by the surgical team and burned a hole in the scrubs of the surgical assistant, resulting in a burn on the assistant’s right flank at waist level. The burn was minor and treated with an application of topical ointment. No serious injuries were reported.

The manufacturer completed all of the information on this form. Attempts at acquiring the product for evaluation are on-going.

c. **Case 6**

A doctor was lasing a patient’s shoulder with a 30-degree tip when the scrub nurse pulled on the fiber, breaking it and resulting in a burn through the nurse’s glove and a second-degree burn to the skin of the hand. The laser was immediately placed on standby while the scrub
nurse was sent to the emergency room. At the time of the incident, 1713 joules were going through the fiber. No injuries were sustained by the patient.

d. **Case 7**

It was reported that a "technician got burned when the laser was being used." The physician was performing a knee arthroscopy procedure when a "flashing popping noise" was heard under the technician’s arm. The technician noticed a small pinhole burn through the arm of his gown and an “immediate burning sensation” under his left forearm. At that point the technician noted a small pinhole burn through his gown and into his arm. The technician was treated for a third degree/full thickness burn of less than 0.5 cm (approximately 2 x 4 mm) and had full release from treatment as of 2008.

According to the hospital's occupational health director, the technician stated that the device was not tested according to the labeled instructions for use, and he did not recall whether the device passed the laser output test prior to use or whether any change in lasing output occurred during the procedure. This information is documented as reported to Trimedyne, the manufacturer.

e. **Case 8**

It was reported that during a HoLAP procedure the physician sustained a third-degree burn to his hand as a result of a fiber break. Silvadene, a topical ointment, was used to treat the area with no further complications reported.

The subject device was received from the user facility and after investigation by the manufacturer, Lumenis, it was determined that the root cause for the reported event was due to excessive bending forces applied under power in contradiction to device labeling.
4. **Analysis of cases**

a. **Analysis case 4**

During the procedure additional stress may have been applied to the metal shaft used to hold the laser fiber in place. It is assumed that improper usage and handling of equipment was a causal factor for this incident. Factors contributing to the equipment handling may be related to improper training, a rush for surgery to be completed, additional force breaking the fiber, and concentrating the heat. The device was not emitting energy to the fiber tip but was burning the metal shaft taking away the radiated energy from the patient’s procedure. This is noted by the description of minimal charred tissue during the procedure.

It was recommended that current procedures be reviewed to determine if the device is appropriate for the surgeries being performed with it. The first step should be evaluating the equipment to be sure that it is adequate for the procedures being performed in order to minimize possible hazards to the operating physician.

b. **Analysis case 5**

When the alignment device was tested, no one was aware that a laser device was attached to it and powered on. It is vital that during any sort of equipment testing the proper LOTO procedures are used to ensure elimination of “hot” electrical equipment. With the laser equipment being powered on this caused an unknown source to release unexpected energy and injured an employee.

c. **Analysis case 6**

During the procedure the scrub nurse physically pulled on the fiber, which broke the apparatus. This resulted in the nurse being exposed to the heat of the laser working in full capacity.
An unexpected event during surgery could be an explanation for why the nurse pulled on the fiber. It is recommended that the surgical procedure be reviewed for potential gaps and to enforce a pre-task plan before each surgery so that the surgical staff is aware of potential failures and will be prepared to respond properly.

d. **Analysis case 7**

The surgical staff began the procedure without properly evaluating the instrumentation to be used. The device was not tested as required by the manufacturer’s guidelines on the labeled instructions of the equipment. It is recommended that the procedures used to prepare surgical equipment be enforced in the medical facility. Communication amongst the surgical team would have allowed for transparency on the status of the equipment and the point at which the team should be involved in the procedure.

e. **Analysis case 8**

During the surgical procedure additional pressure and stress was placed on the lasing device being used. This was determined to be an additive factor to the breaking of the fiber. It is recommended to have additional training with physicians and technicians on the proper handling of the surgical device.

Beam injury to the skin varies depending on the employee and the task being performed. Each of the five cases reviewed showed a procedural and/or behavioral concern. This demonstrates a need for proper review and enforcement of written procedures and evaluation of the medical laser equipment for adequate usage for a task. The MAUDE database highlights the fact that human behavior is a key component in protection against laser hazards. Continuous review of training, and evaluation and availability of the correct PPE, are a necessary responsibility to improve the safe operation of laser devices, whether in the lab or the OR.
5. **Electrocution injury cases**

a. **Case 9**

A service technician was working on a Medlite C6 laser in an office. The laser was reporting Error 22, which means "no end of charge". Error 22 is shown when the Hv Capacitor is not receiving a full charge and the flashlamp is not flashing. The technician evaluated the system and found the simmer supply was working; the lamp was simmering, but the lamps were not flashing. It was decided that the Hv power supply was in need of replacing. The technician turned off and unplugged the system, and proceeded to lie down on the floor in order to remove the power supply.

The technician disconnected the Hv cable from the power supply that goes to the Hv capacitor, and then disconnected the AC input cable from the supply. The last thing the technician remembered before receiving the shock was removing the control cable from the power supply. The office staff heard a loud bang from the room, found the technician bleeding from the ears, nose, and mouth, and called the building manager who tried to resuscitate the technician. The emergency response team resuscitated the technician, who was taken to the hospital for treatment. The hospital submitted a report to the manufacturer on the site-evaluation of the system and interviews with the office personnel.

The high-voltage power supply silicone controlled rectifier (SCR) board and the charge capacitor were returned from the system for further evaluation: the SCR board was intact, the high-voltage discharge relay and discharge resistors were intact, and the resistance that was connected to the capacitor to discharge it measured 33 kilo ohms. This is consistent with the design, which has 3,100 kilo ohm resistors in parallel.

The high-voltage power supply was opened and the manufacturer found that the bridge rectifier on the input AC was burned and all diodes were shorted, which would not allow the power
supply to develop a high-voltage output. This is consistent with the report indicating that when they the system was turned on, it reported an Error 22 and there was no voltage developed on the charge capacitor. In the report given to the manufacturer, the service technician indicated that he also noticed a burning smell when the system would not flash and was reporting an Error 22. This is consistent with the burned input bridge rectifier in the power supply.

The capacitor was received in good condition, although there was some evidence that the threads on one of the posts were damaged. The posts had some rough spots on the threads, but were not cross threaded. This is consistent with the observation in the report that the nut on the wire going from the charge capacitor to the SCR board was slightly loose. This is the path to rapidly discharge the capacitor. It was observed that the wire on the post could be moved, that it was not tight, but it also was not very loose. The diameter of the ring lug on the wire that goes on that post was very close to the diameter of the post, posing little chance that the loose wire could have been disabled from discharging the capacitor.

The backup discharge resistor on the capacitor measures 2.2 Mega-Ohms, which is consistent with the design. None of the evidence identifies defective components, parts, or design that would cause the accident to happen.

The only explanation that is possible is that the power supply was able to deposit a charge on the capacitor as it was failing. In addition, the loose nut on the capacitor broke the connection to the fast discharge resistors on the SCR board; consequently the backup bleed resistor was discharging the partially charged capacitor when the service technician contacted a high-voltage point by removing the low-voltage cables from the power supply. Conclusion: If the technician had discharged the high-voltage capacitor as recently instructed to do, this accident would not have happened even if one of the system safety discharge circuits was inoperative.
Due to the serious nature of the incident, the medical facility took additional preventative action steps to impress upon the service personnel the importance of following a specific safety regimen when working in and around high voltage. The service bulletin was incorporated into the service manual in addition to being sent to the service personnel.

As a preventative action, a service bulletin was generated and emailed to all the service engineers and distributors worldwide. This bulletin specifically addressed the safety precautions that must be observed when working in and around high-voltage components. It also stated the minimum wait time that should be observed before attempting to discharge the high-voltage capacitor to allow the backup bleed resistor to discharge the capacitor to minimize the risk if the capacitor is not fully discharged. This service bulletin was also sent via UPS with a return receipt tracking requested to verify that all personnel and distributors received the information. The manufacturing and engineering personnel were trained in these safety procedures.

b. **Case 10**

An employee from a medical facility reported being burned by the plug while unplugging a GreenLight HPS console, and switching the circuit breaker off. The employee was evaluated in the emergency room at the medical facility. It was reported that there were black marks on his fingers and that he had lost feeling from his fingers to his elbow.

Follow-up with the risk manager at the facility revealed that the employee had been admitted to the hospital. No further information was given to the manufacturer, AMS, as to the employee's condition except that he had been released from the hospital a few days later. The risk manager stated that the medical facility had filed a MedWatch report. It was also reported to AMS that the receptacle in the operating room was tested and found working properly. The facility requested a third-party test
of laser, which was performed in 2008. The manufacturer requested that their customer service engineer be on site at the time of the testing and the request was denied.

The third-party report was given to AMS. The report stated that a continuity test was performed on the power cord wires and they checked out fine. The medical facility requested that the laser remain on site since there was no problem found with it by the third party.

Further investigation revealed that the medical facility did not have the correct receptacle. The facility did not want to change the receptacle because they had not yet decided whether to purchase the laser device, which was a demo unit. The bio-med staff used a plug that they owned. The plug was an eagle brand Nemha 10-50p. System tests were performed at the time of install and the laser was within spec. Installation occurred in 2008. The bio-med and AMS customer service engineer tested the system and it was found to be grounded properly.

The AMS visited the site in 2008; the plug had been removed from the laser, and their customer service engineer requested to see it. Initial inspection of the plug revealed no flaws, cracks, or burn marks on the external covering or blades of the plug. The customer service engineer installed the plug and started the laser with no problem. The laser was run through test operations that revealed the system was used three times before the incident. There were no problems from the electrical plug during the process of testing the laser.

Inspection on the inside of the plug revealed both blades had large braze marks. The bio-med engineer indicated that the plug had loose wires; however, the wires were intact with no signs of arcing–and if the wires had caused any arcing there would have been melting on the wires on the cable side, and there were none according to the customer service engineer. The customer service engineer did not have access to the particular operating room where the incident occurred as it was not known by the bio-med which operating room was used.
Pictures were taken of the laser and plug that were used. Pictures were taken of a receptacle that was representative of the one used. The laser was packed and sent to AMS for further evaluation. The manufacturer provided another laser to the facility, which was installed the same day. A follow-up MedWatch report was sent after the evaluation was completed at AMS.

Labeling: AMS GreenLight HPS is in accordance with (b) (4). The GreenLight HPS operator's manual, paragraph (b) (4), under safety states: "electrical : recommended practice vii: all people working in the laser treatment area should be protected from electrical hazards associated with laser use. Electrical hazards with the laser are the same as with any electrical device. Care should be taken when plugging into the wall outlet. The area must be free of water and your hands must be dry. Always disconnect the laser by grasping the plug and not the power cord."

The GreenLight HPS technical service manual, (b) (4), states: "a250 vac, 30 amp, 2 pole, 3 wire plug that is acceptable for portable medical equipment of this current rating is recommended. However, any plug can be used as long as it meets the system's electrical requirements; meets facility, city, county, state, and country ordinances; and complies with (b) (4). Recommended receptacle and plug: receptacle: nema configuration: l6-30r. The plug sent with the machine is the hubbell twist lock plug: (b) (4)."

6. **Analysis of cases**
   
a. **Analysis case 9**

   After receiving an error message on the Medlite C6 laser, the service technician diagnosed that the laser medical equipment needed the HV power supply replaced. It was reported that the system was fully turned off and unplugged giving confirmation to the technician that the equipment was properly locked out and tagged out for maintenance. Unfortunately, during the lock-out tag-out procedure he didn’t ensure that the machine was fully drained of any power within it.
before performing the preventative maintenance. The service technician was shocked and found bleeding from the ears, nose, and mouth. After a thorough manufacturer review none of the evidence identified defective components, parts, or design that would cause the accident to occur. The root cause of the incident turned to human error. If the service technician had fully discharged the high-voltage capacitor as instructed recently in employee training, the accident would not have happened even if the system safety discharge circuits were inoperative. In this case preventative action was taken with the dispersal of a service bulletin providing all safety information that pertains to medical devices that contain high voltage in the medical facility.

The preventative action taken relies solely on human behavior, which is an aspect of safety that is hard to change and regulate. Buying a product with a better interlock system and initiating and maintaining an aggressive maintenance program would allow for engineering controls and accountability within the service department.

b. **Analysis case 10**

While unplugging a GreenLight HPS console an employee was burned and lost feeling from his finger to his elbow, a side effect of electrocution. After sustaining the injury the employee was escorted to the emergency room and admitted to the hospital for his injuries.

A third party was hired to test the equipment causing the injury and no device failure points were found during the diagnostic testing. It was found that the medical facility did not have the correct electrical infrastructure to support the device. The receptacle used was incompatible and it was known that an upgrade was needed but it was not obtained due to the fact that the facility was unsure if they were going to keep the laser demonstration unit.

The facility knowingly used the incorrect receptacle, placing the employee at risk. This could have been prevented by a thorough pre-task plan review covering the components of the system and
the support needed of the facility to run the device. Upon installation the device was found to work properly and within specification, but by the event description the area in which the device failed was not permitted to be viewed by the manufacturer technician, leaving an unknown in the compatibility of the receptacle used during the incident. The plug in which the device was tested could have been the proper receptacle but upon moving the equipment into a different OR the receptacle in the new room was shown to not meet the company’s specifications prescribed in the technical service manual.

Electrocution injury to an employee varies depending on the voltage and current present in the device at the time of injury. Each of the cases reviewed showed a procedural concern. This demonstrates a need for proper review and enforcement of written procedures and evaluation of the medical laser equipment for adequate usage for a task and the information needed for the facility technicians maintaining the equipment. The MAUDE database highlights the fact that human behavior is a key component in protection against laser hazards. Continuous review of training, evaluation and availability of the correct PPE, and evaluation of the facility infrastructure supporting the equipment are a necessary responsibility to improve the safe operation of laser devices in medical facilities.

C. **Application of Human Factor Models**

Four cases were found to have the criteria of completion and information needed for the human factors models discussed in chapter II. The HFACS model was applied by adapting the model created by the Department of Defense (92). Using the definitions provided within the Department of Defense data, analysis tool cases were thoroughly examined by applying each definition to the incident descriptions provided in the MAUDE database. Information that was able to be applied to the models was then pulled out and documented.
The SHEL model was applied by using definitions and tailored questions provided by Chang and Yeh’s (2010) paper. Each case was read through applying each definition and documenting information that applied to the examples and questions given in their research. The Likert scale used within their study was not applied to this study as interaction with employees or the medical facilities was not possible.

Both models provided a similar level of completeness. Overall, with the information provided in the MAUDE database the HFACS model showed a completeness percentage average of 41% (Range: 25%–60%), and the SHEL model with an average of 43% completeness (Range: 7%–60%). Given facts extracted from the MAUDE database case reports were used in the models. Proposed questions and circumstances are identified by starred (*) notation and were not taken into consideration when determining the level of completeness of the models. For the HFACS and SHEL models the sub-categories were used to calculate these percentages of completion.

Using documented MAUDE database reported cases it was found that the most effective human factors model was the SHEL model. This model presented material that was able to be used to obtain a higher percentage of completeness than the HFACS model. When the outlier is eliminated (SHEL Case 1 with 7% completeness), the average percentage is raised from 43% to 56%. In research studies with previously reported cases and limited information the SHEL is shown in this case to categorize the data more effectively.
### TABLE IX
PERCENTAGE OF COMPLETENESS OF THE HUMAN FACTOR MODELS

<table>
<thead>
<tr>
<th>MODEL</th>
<th>CASE</th>
<th># OF POTENTIAL CATEGORIES</th>
<th>#'S FILLED</th>
<th>% COMPLETED</th>
</tr>
</thead>
<tbody>
<tr>
<td>HFACS</td>
<td>1</td>
<td>20</td>
<td>12</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td>3</td>
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<td>9</td>
<td>20</td>
<td>9</td>
<td>45</td>
</tr>
<tr>
<td></td>
<td>TOTAL</td>
<td>80</td>
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</tr>
<tr>
<td>SHEL</td>
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</tr>
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<td>60</td>
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</tr>
<tr>
<td></td>
<td>9</td>
<td>15</td>
<td>7</td>
<td>47</td>
</tr>
<tr>
<td></td>
<td>TOTAL</td>
<td>60</td>
<td>26</td>
<td>43</td>
</tr>
</tbody>
</table>

The description of the cases used in the following models can be found in the previous case study evaluation. Figure 1 and 2 represents Case 6 in the beam-thermal skin injury reports. Figure’s 3 and 4, and 7 and 8 were used to analyze Case 1 and 3 of the beam-thermal eye injury reports. The last case reviewed by Figure 5 and 6 characterizes Case 9 in the electrocution case study series.

The root causes for all four cases have been summarized below by using the HFACS and SHEL Human Factors models, which were adapted to the use of medical laser devices.
Figure 3. HFACS Model Case 1.

Facility Technician was completing a maintenance procedure when the conditions caused sweating that in turn caused the goggles to slip out of protective position. The employee’s eye was injured by the laser beam.

\[ ^a \text{Facility Technician was completing a maintenance procedure when the conditions caused sweating that in turn caused the goggles to slip out of protective position. The employee’s eye was injured by the laser beam.} \]
Facility Technician was completing a maintenance procedure when the conditions caused sweating that in turn caused the goggles to slip out of protective position. The employee’s eye was injured by the laser beam.
During a surgical procedure the surgeon overrode the eye safety filter on the laser to continue the procedure. The surgeon also failed to wear the PPE required to operate the device. Both were causal factors in this incident contributing to injury to the surgeon’s eye by the laser beam.
During a surgical procedure the surgeon overrode the eye safety filter on the laser to continue the procedure. The surgeon also failed to wear the PPE required to operate the device. Both were causal factors in this incident contributing to injury to the surgeon’s eye by the laser beam.
Figure 7. HFACS Model Case 6.

*During a surgical procedure the scrub nurse pulled on the laser fiber and sustained a burn to the hand.
During a surgical procedure the scrub nurse pulled on the laser fiber and sustained a burn to the hand.

Figure 8. SHEL Model Case 6.

aDuring a surgical procedure the scrub nurse pulled on the laser fiber and sustained a burn to the hand.
Figure 9. HFACS Model Case 9.

*Electrocution injury to facility technician.
Figure 10. HFACS Model Case 9.

*Electrocution injury to facility technician.*
Medical laser devices are growing in popularity in the surgical realm. They allow for low-invasive and low-cost surgeries that result in a minimal recovery time for patients. Patient and occupational-related injuries from medical laser devices have been reported since 1968 when the US FDA’s Radiation Incidents Registry was produced due to the Radiation Control Act of 1968 (43). This act required manufacturers of laser equipment to report possible, suspected, and known radiation exposures to the database. In 1982 the US FDA created a new organization called the CDRH to assure the safety and effectiveness of medical devices and to eliminate unnecessary human exposure to radiation. As a result the MAUDE database was created (43). After receiving a list of all medical laser devices reported to the US FDA between 1990 and 2009, a review was completed to find all occupationally related cases. Out of 1084 cases provided, only 54 were found to relate to an occupational injury.

The majority of occupationally related injuries reported in the MAUDE database center around physician’s errors due to machinery malfunction. Burns to the skin represent more than half of the type of injury reported to the database. After reviewing the ten cases that contained the highest percentage of completion in the database, as well as fit the criteria discussed in chapter II, it was clear the error was not only due to the fault of the equipment being used. Incidents showed that with lack of both training and knowledge of the hazards associated with medical laser devices, accidents occur on a regular basis.

Medical laser device injury reporting has been around since the 60s but is misrepresented in all databases. In the BLS database there is no particular factor that separates out injuries specific to lasers. Most other databases just report on patient safety aspects without acknowledging the occupational

IV. DISCUSSION
risk. It is clear that there is a need for a robust reporting system to which employers are held accountable. A system which is enforced by a regulatory agency, such as the US FDA, will allow for greater reliability in the data and beneficial analysis.

Each section of the MAUDE database form has a clear selection criterion that is able to be analyzed quantitatively. The event and manufacturer description are excluded from this due to the fact that there is ambiguity on what is expected in length and depth of description. It should also be noted that a facility’s legal counsel may cause these descriptions to be heavily biased, possibly being a reason for limited information in this area for many cases received. Observation of the database shows a wide variety of description lengths ranging from one sentence to multiple paragraphs. One limitation is the fact that it is difficult to fully analyze a case if adequate data are not available (i.e., metrics of device, individual injured, body part injured, medical treatment). Additional categories within the reports that give defined choices would help to minimize this problem.

The analysis was not fully inclusive in that the research did not question actual medical personnel nor include hands-on evaluations of the cases. Having no direct contact with the injured personnel and only the documentation presented thereafter, not all questions were able to be answered pertaining to the human factors models and case study series. The MAUDE database is also an unreliable source for comprehensive and/or comparative information (66; 67). The accuracy and completeness of the reports is not verified by the US FDA (68) and no denominator can be determined making quantitative comparisons difficult.

Using all ten cases for application of the human factors model did not prove practical due to the lack of specified information within the reports. This became the final filter for the human factor models breaking the ten cases down to four. Further breakdown to choose cases quantifiably became difficult due to minimal categorical data within the event and manufacturer descriptions provided.
After full review it can be concluded that the MAUDE database does not provide enough information to be applied to human factors models. Although some cases offer enough information to identify a root cause, out of the 54 occupationally related cases provided, only four provided the information needed to apply the models. With the limited data provided it can be determined that human factors models will not be effective in analyzing data from the MAUDE database.

The models that were applied to the selected four cases revealed that lack of PPE, poor procedure follow-through, and lack of understanding of the inherent hazards were the top three root causes found. Various improvements of the MAUDE database will prove to be beneficial if an understanding of the state of medical laser injuries is to be obtained. Mandating within the reporting form that the majority of categories are required to be filled in would allow for a larger source of data to be compared. Also, specifying clear direction and expectations for the event and manufacturer descriptions would drive consistency of information from those involved. The US FDA should consider restructuring their reporting format to provide manageable data. Due to the fact that they currently do not check the reliability or validity of currently entered reports, mandating categories and providing drop-down menu selections would help to field poor reporting documentation.
REFERENCES


44. ACGIH. "2009 Threshold Limit Values and Biological Exposure Indices." *ACGIH* (2009).


APPENDIX A

Food and Drug Administration
Division of Freedom of Information (HFI-35)
Office of Shared Services
Office of Public Information and Library Services
5600 Fishers Lane
Rockville, MD 20857

Jennifer Pierce
1111 S. Wabash Ave. #1701
Chicago, IL 60605

Subject: Freedom of Information Act Request

My name is Jennifer Pierce, and I am a researcher at the University of Illinois at Chicago. I am writing to request de-identified information regarding all injuries and deaths related to the use of medical and/or dental lasers, particularly for the time period of 1990 to the present. The list of products within the MAUDE database that I am interested in obtaining information for includes, but is not limited to:

- Laser for gastro-urology use
- Laser therapy product
- Laser benign prostatic hyperplasia
- Laser dental
- Laser dental soft tissue
- Laser ENT microsurgical carbon dioxide
- Laser microsurgical argon for use in otology
- Laser microsurgical argon for use other than in otology
- Laser neodymium YAG for gynecologic use
- Laser neodymium YAG ophthalmic for posterior capsulotomy
- Laser neodymium YAG ophthalmic for uses other than posterior capsulotomy
- Laser neodymium YAG pulmonary surgery
- Laser neurosurgical
- Laser neurosurgical argon
- Laser ophthalmic
- Laser surgical gynecologic
- Laser/fluorescence caries detection
- Laser system phacoysis

The ideal format for the data would be an excel spreadsheet, with headings that include:

- Model Number
- Event Date
- Event Type
- Patient Outcome
- Event Description
- Device Event Key
- MDR Report Key
- Event Key
- Report Number
- Device Sequence Number
- Product Code
- Report Source
FOI RELEASABLE OUTPUT

User Name: 136576
Report Date: 11/02/2010
Notes: 2009-9701
Application: MAUDE QUERY (GUI)
Report Name: EVENT REPORT DETAIL LISTING
Report Description: DETAIL SUMMARY REPORT, BOTH IN-HOUSE & FOI FORMAT, WILL BE GENERATED FROM THE INFORMATION OBTAINED ON THE MEDWATCH FORMS.

Search Criteria: Date of The Event
BETWEEN 01-JAN-1990 AND 03-DEC-2009
Generic Name (D2 Device Type):
- LASER VISION CORRECTION SURGERY MACHINE
- LASER VISION CORRECTION
- LASER VEIN TREATMENT
- LASER VARICOSITY REMOVAL SYSTEM
- LASER USED FOR PERMANENT HAIR REMOVAL
- LASER USED FOR LASIK
- LASER UNIT
- LASER TUBE
- LASER TREATMENT, SURGICAL, POWERED
- LASER RESISTANT ENDO TRACHEAL TUBE, CUFFED, 5.5MM
- LASER REFRACTIVE EYE SURGERY SYSTEM
- LASER PRODUCT
- LASER PROBE, OPHTHALMIC
- LASER PROBE, OPHTHALMIC
- LASER PROBE SMTR 1.5
Generic Name (D2 Device Type)

LASER PROBE
LASER POWERED SURGICAL INSTRUMENT (GEX)
LASER POWERED SURGICAL INSTRUMENT
LASER PHOTODISRUPTOR
LASER PHOTODISRUPTER
LASER PHOTOCOAGULATOR
LASER PHOTOCOAGULTOR
LASER PERFORATOR
LASER MACHINE
LASER LITHOTRIPTER
LASER LIGHTGUIDE
LASER LASIK
LASER KEROTOME
LASER KERATOME
LASER-FLEX TRACHEAL TUBE 6.0MM
LASER-FLEX TRACHEAL TUBE 5.0MM
LASER KARATOME
LASER INTRUMENT, SURGICAL, POWERED
LASER INSTRUMENT, SURGICAL, POWERED.
LASER INSTRUMENT, SURGICAL, POWERED
LASER INSTRUMENT, SURGICAL POWERED
LASER INSTRUMENT SURGICAL, POWERED
LASER INSTRUMENT FIBER AND PROCEDURE KIT
LASER INSTRUMENT FIBER AND KIT
LASER INSTRUMENT FIBER & PROCEDURE KIT
LASER INSTRUMENT FIBER
LASER INSTRUMENT
LASER INDIRECT OPHTHALMOSCOPE
LASER HOLMIUM FIBER
LASER HEADPIECE USED IN RETINAL SURGERY
LASER HANDPIECE
LASER HAIR THERAPY
LASER HAIR REMOVAL SYSTEM
LASER HAIR REMOVAL DEVICE
LASER HAIR REMOVAL
LASER GENERATOR
LASER FOR TREATMENT OF SECONDARY MEMBRANE FOLLOWING CATARACT
APPENDIX B (continued)

Generic Name (D2 Device Type)

- LASER FOR SKIN RESURFACING
- LASER FOR PROSTATE ABLATION
- LASER FOR LASIK EYE SURGERY
- LASER FOR HAIR REMOVAL
- LASER FOR EYE SURGERY FOR VISION CORRECTION
- LASER FOR EYE CORRECTION
- LASER FOR CORRECTIVE EYE SURGERY
- LASER FLEX
- LASER FIBOR WITH RIGID HANDPIECE
- LASERTUBUS 6MM
- LASERTUBUS 4MM
- LASERTUBUS
- LASERTRIPTER
- LASERTRACHEAL TUBE
- LASERSCOPE GREEN LIGHT PV-ADDSTAT FIBERS
- LASERSCOPE FIBER
- LASERSCOPE 20 DEGREE TIP
- LASERSCOPE
- LASERS FOR HAIR REMOVAL
- LASERS
- LASERBLADE FIBER
- LASERBALDE FIBER
- LASER/LIGHT DEVICE
- LASER-SURGERY DEVICES-REUSABLE
- LASER-SURGERY DEVICES - REUSABLE
- LASER-SURGERY DEVICES
- LASER-SURGERY DEVICE
- LASER-SHIELD 11 TUBE
- LASER-POWERED SURGICAL INSTRUMENT
- LASER-GENTLELASER/COOLGLIDE/GENTLE YAG
- LASER-FLEX TRACHEAL TUBE WITH CUFF 6.0MM
- LASER-FLEX TRACHEAL TUBE CUFFED 5.5MM
- LASER-FLEX TRACHEAL TUBE CUFFED 5.0
- LASER-FLEX TRACHEAL TUBE 6.0MM
- LASER DELIVERY AND ELECTROCAUTERY HANDPIECE
- LASER SLIT LAMP USED IN OPHTHALMOLOGY
- LASER SLIT LAMP PROTECTION DEVICE (ARGON)
- LASER SLIT LAMP ATTACHMENT
APPENDIX B (continued)

Generic Name (D2 Device Type)
- LASER SKIN RESURFACER
- LASER SHIELD ENDOTRACHEAL TUBE
- LASER SHEATH FOR CHRONIC LEAD REMOVAL
- LASER SHEATH
- LASER SCALPEL
- LASER RESISTANT ENDOTRACHEAL TUBE, CUFFED, 6.0
- LASER FIBER FOR LASERSCOPE KTP/YAG LASER
- LASER FIBER DELIVERY DEVICE
- LASER FIBER DEFLECTOR
- LASER FIBER AND PROCEDURE KITS
- LASER FIBER AND PROCEDURE KIT
- LASER FIBER AND KIT
- LASER FIBER 7FR FLEX WRETOSCOPE
- LASER FIBER - LIGHTGUIDE
- LASER FIBER - FIBER OPTIC LASER DELIVERY SYSTEM
- LASER FIBER (REUSABLE)
- LASER FIBER (LIGHT GUARD)
- LASER FIBER (200)
- LASER FIBER
- LASER EYE SURGERY
- LASER EXCIM
- LASER ET TUBE
- LASER ENERGY DELIVERY PROBE
- LASER ENDO PROBE
- LASER DOPPLER BLOOD FLOW MONITOR
- LASER DISCECTOMY ENDOSCOPE KIT
- LASER DISCECTOMY DEVICE
- LASER DISC DECOMPRESSION PROBE
- LASER DIODE HAIR REMOVER SYSTEM
- LASER DELIVERY SYSTEM
- LASER DELIVERY FIBER, FIBER OPTIC
- LASER DELIVERY DEVICE
- LASER CORD
- LASER CONSOLE
- LASER CATHETER
- LASER CARDIAC LEAD REMOVAL DEVICE
- LASER BEAM MACHINE
- LASER BASKET, 4 WIRE
APPENDIX B (continued)

Generic Name (D2 Device Type)
- LASER BASKET
- LASER AHERECTOMY CATHETER
- LASER ASSISTED ENDOSCOPIC SPINAL DISECTOMY
- LASER FIBER, REUSEABLE
- LASER FIBER, KTP
- LASER FIBER, HOLMIUM, SINGLE-USE
- LASER FIBER, HOLMIUM, SINGLE USE
- LASER FIBER, HOLMIUM
- LASER FIBER, FLAT TIP, HOLMIUM
- LASER FIBER, 600 MICRON
- LASER FIBER, 1000 MICRON
- LASER FIBER WIRES
- LASER FIBER SMA 400 UM BASE FIBER ASSY
- LASER FIBER QUARTZ CONTACT DELIVERY SYSTEM
- LASER FIBER OPTIC CABLE ASSY
- LASER, INSTRUMENT, SURGICAL POWERED
- LASER, YAG
- LASER, SURGICAL, YAG
- LASER FIBER, SINGLE USE
- LASER, SURGICAL, HOLMIUM
- LASER FIBER OPTIC
- LASER FIBER FOR PROSTATE RESECTION
- LASER SMOKE EVACUATOR
- LASER - OMNIPULSE
- LASER ASSISED SPINAL DISECTOMY
- LASER AND FIBER OPTIC LASER DELIVERY SYSTEM
- LASER ADVERTISED FOR HAIR REMOVAL
- LASER ACCESSORIES
- LASER ABLATION
- LASER 1055
- LASER SURGICAL EQUIPMENT
- LASER SURGICAL DEVICE
- LASER SURGERY DEVICE
- LASER SURGERY
- LASER, GREEN
- LASER, GENERATOR
- LASER, FIBROPTICS
- LASER-FLEX TACHEAL TUBE 5.5MM
Generic Name (D2 Device Type)

LASER-FLEX ENDOTRACHEAL TUBE
LASER, FIBER
LASER, ENDOVENOUS DEVICE
LASER, DERMATOLOGIC
LASER, CUTERA INC
LASER, COSMETIC
LASER, CO2
LASER, CARDIAC LEAD REMOVAL SYSTEM
LASER YAG ADD
LASER YAG
LASER WAVEGUIDE FIBER
LASER, SURGICAL, FOR USE IN DERMATOLOGY
LASER, SURGICAL, CO2
LASER, SURGICAL, CARBON-DIOXIDE
LASER, SURGICAL
LASER, Q-SWIITCHED ND: YAG
LASER, PVP
LASER, PROSTATE
LASER, OPHTHALMOLOGY
LASER, OPHTHALMIC
LASER, OPHTHALMIC, DIODE
LASER, OPHTHALMIC
LASER, ND:YAG (KTP)
LASER, ND: YAG
LASER, KTP, UROLOGIC
LASER, KTP
LASER, INSTRUMENT, SURGICAL, POWERED
LASER, INSTRUMENT, SURGICAL POWERED
LASER - GEN 4 OR
LASER - FLEX TRACHEAL TUBE 6.0MM
LASER
LASER (LASER TRIPTER)
LASER & FIBER
LASER TREATMENT CARD
LASER TIP (CONE)
LASER TIP
LASER TATTOO REMOVAL
LASER TATTOO REMOVAL SYSTEM
APPENDIX B (continued)

Generic Name (D2 Device Type)

- LASER SYSTEM, EYE TRACKING DEVICE
- LASER SYSTEM, ENDOVENOUS, PROCEDURE KIT
- LASER SYSTEM
- LASER SWITCHABLE TIP 90 DEGREE
- LASER SURGICAL INSTRUMENT
- LASER SURGICAL EXCIMER
- LASER, INSTRUMENT SURGICAL, POWERED
- LASER, HOLMIUM, UROLOGICAL
- LASER, HOLMIUM
- LASER, HO:YAG, GENERAL PURPOSE
- LASER, HANDPIECE
- LASER, GREENLIGHT PVP
- LASER, GREENLIGHT
- LASER, FIBERTONE
- LASER FIBERT
- LASER FIBER; IMPLANT WIRE
- LASER FIBER
- LASER FIBER-600 MICRON-CONTACT SCAPEL
- LASER FIBER, SURGICAL, REUSEABLE
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