FEATURE

Photonics Compliance Issues

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Many compliance issues face those involved with the integration of Photonics[1] devices and systems into products and the workplace

Introduction

This is the second part of a two part series describing the compliance issues involved with developing, integrating, and using photonic devices (see definition below). Since they are among the only devices in Photonics requiring both safety and compliance issues cognizance, we shall focus on LASERs and related systems throughout the series.

We will examine the compliance of Photonics by focusing on the relevant European standards. Next, the subtleties of design and integration will be discussed. Finally, the article will conclude with case studies of various Photonics compliance-related activities.

Relevant European Standards and Regulations

As with the US Federal code (FDA 1040), compliance issues are tied closely with safety directives. The following lists 2 the more relevant European standards and regulations pertaining to the proper compliance of photonics devices and systems:

89/392/EEC. Council Directive on June 14, 1989 on the Approximation of the Laws of the Member States Relating to Machinery (also known as the Machinery Directive).

89/686/EEC. Council Directive on December 21, 1989 on the Approximation of the Laws of the Member States Relating to Personal Protective Equipment.

89/656/EEC. Council Directive on November 20, 1989 on the Minimum Health and Safety Requirements for the Use by Workers of Personal Protective Equipment at the Workplace.

EN 414:1991. Safety of Machinery; Rules for the Drafting and Presentation of Safety Standards.

EN 292. Safety of Machinery; Basic Concepts, General Principles of Design.

1. Part 1: Basic Terminology and Methodology.

2. Part 2: Technical Principles and Specifications.

IEC Publication 1040. Power and Energy Measuring Detectors, Instruments and Equipment for Laser Radiation, Bureau Central de la Commission Electrotechnique Internationale, Genève (1990).

IEC Publication 601-2-22. Medical Electrical Equipment Part 2. Particular Requirements for the Safety of Diagnostic and Therapeutic Laser Equipment. Bureau Central de la Commission Electrotechnique Internationale, Genève (1992-05).

ISO/DIS 11 252. Lasers and Laser Related Equipment: Minimum Requirements for Documentation, International Organization for Standardization.

ISO/DIS 11 253. Lasers and Laser Related Equipment: Mechanical Interfaces, International Organization for Standardization.

ISO/DIS 11 254. Lasers and Laser Related Equipment: Test Method for Laser Induced Damage Threshold of Optical Components, International Organization for Standardization.-

ISO/CD 11 145. Lasers and Laser Related Equipment: Terminology, Symbols and Units of Measure for the Specification and Testing of Lasers and Laser systems, International Organization for Standardization.

ISO/CD 11 151. Lasers and Laser Related Equipment: Standard Optical Components for Lasers and Laser Equipment, International Organization for Standardization.

prEN 207. Personal Eye-Protection: Filters and Eye-Protectors against Laser Radiation (Laser Safety Eye-Protectors), European Committee for Standardization, Brussels (1988).

prEN 208. Personal Eye-Protection: Eye-Protectors for Adjustment Work on Lasers and Laser Systems (Laser Adjustment Eye-Protectors), European Committee for standardization, Brussels (1985).

DIN E 5335. Abschirmungen an Laser-arbeitsplätzen; Sicherheitstechnische Anforderungen und Prüfung.

DIN VDE 0835. Leistungs-und Energiemegeräte für Laserstrahlung, Beuth-Verlag, Berlin (1981).

DIN VDE 750 Teil 226. Medizinische elektrische Geräte; Diagnostische und therapeutische Lasergeräte; Besondere Festlegungen für die Sicherheit.

DIN V 18 733. Laser und Laseranlagen; Mindestforderungen für Herstell-erangaben.

DIN V 18 739. Laser uno Laser - anlagen; Mechanische Schnittstellen.

DIN V 18 732. Laser und Laseranlagen; Prüfverfahren für optische Komponenten.

1. *Teil 1:* Zerstörschwelle für laser-induzierte Schädigung.
2. *Teil 2:* Absorptionsgrad

DIN V 18 730. Laser und Laseranlagen; Grundbegriffe der Lasertechnik.

DIN V 18 736. Laser und Laseranlagen; Optische Komponenten für den Spektralbereich UV-A bis IR-A.

1. *Teil 1:* Allgemeine Anforderungen
2. *Teil 2:* Symmetrische Bikonvexlinsen
3. *Teil 3:* Plankonvexlinsen
4. *Teil 5:* Fenster
5. *Teil 6:* Hohl - und Planspiegel

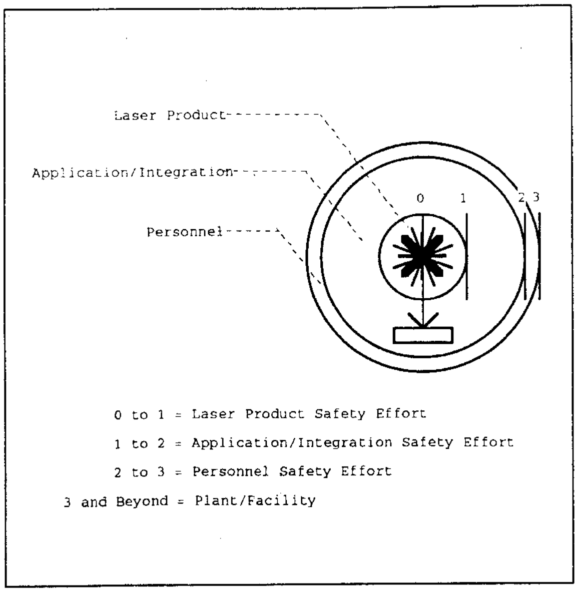

FIGURE 1: Compliance Safety Concerns (Shell Method).

ISO/DIS 11 552. Safety of Machinery: Safety of Machines Using Laser Radiation to Process Material, International Organization for Standardization, Genève (1992)

IEC Publication 825. Radiation Safety of Laser Products, Equipment Classification, Requirements and User's Guide, Bureau Central de la Commission Electrotechnique Internationale, Genève (1984), and Amendment 1 (1991).

Subtleties of Design and Integration

Background

The subtleties of design and integration are based upon complete knowledge of the technology from all aspects. As any new technology is introduced, there is a distinct trend followed.

Introduction Phase. Development of technology and related support systems. Typically, this is where standards and government committees are started and developed to address the regulated and wide-spread use of the technology.

Application Phase.
Development of product or process around new technology. At this phase, the standards and government committees are fully formed, and starting to provide meaningful guidance to the technology and related industry.

Absorption Phase.
Application/integration of new technology into product or process market. At this phase (and at this time period in history), the standards and government committees spend their time internally and externally harmonizing the standards.

The laser has been around since the 60's, and is now considered a "maturing industry." An ever-increasing number of firms are integrating OEM lasers and related systems into their products and processes for use and resale (a true absorption phase industry).

Shell Method

The subtleties of design and integration of photonics devices take on very complicated forms. To simplify the process of integration, the following figure graphically details an easy-to-use concept called the Shell Method see Figure 1).

In its most primary of functions, the Shell Method is a graphical reminder of:

- The layers of adequate protection and related compliance issues associated with the device.
- The relative amount of effort and afforded protection for each layer.

Starting from the center, the first layer, (Product), protects the laser product from the outside world and vice versa in relation to safety and compliance issues.

The second layer, (Application/Integration), allows the laser full access to the application/integration, but protects it from the outside world and vice versa.

The third and final layer, (Personnel), provides protection of the entire system from the outside world and vice versa (mostly through administrative controls). This allows normal interaction with the system by unskilled, untrained operators in any environment.

This unique scheme provides an onion-peel effect for the protection of the laser system from increasing levels of exposure to the outside world and cognizance of related compliance issues. (Please note however, the diagram represents the best case situation and should be used only as a guide as the actual case can vary significantly).

Beam Hazards and Compliance Issues

Since our discussion here is centered around lasers as representative photonics devices, the following discusses specifically beam hazards and related compliance issues as broken down into 3 distinctly separate, but yet, always integrated parts:

Product or Process

The product or process to be integrated has a litany of associated potential pitfalls. Although proper packaging may have been performed, and the laser device/system therefore meets or exceeds the necessary UL, FCC, and FDA/CDRH guidelines for performance safety compliance, most laser systems require some modification of the original laser product. This can render some or all certifications invalid. For example, a laser system to be integrated into a product, had to have its' delivery system modified to meet performance requirements of the product. Once the safety aspects of the system were altered (e.g., relocated safety limit switches), the product had to be re-certified with the cognizant agencies.

Personnel

The personnel involved in every phase of the integration, from operations and maintenance, to engineering, safety, and management must be trained in the basics. Some principles of operation are self-evident (i.e., if you use a hammer and place your hand directly on the spot in which you wish to hammer, you could damage your hand), but with laser devices, operations principles are not that straightforward. Therefore, it is most prudent to train all those involved (at all levels) in basic laser science and safety, and the specific operations of integrations themselves. For example, a high-powered excimer laser was used for analytical services in a laboratory. Although the laser itself met the proper performance and safety compliance regulations, its use around personnel was not evaluated. The high energy pulses of the UV beam in air generated ozone.

Environment

The environment where the integrated product or process will be used combines both the factors of the product/process itself and personnel. Solid integrations practice dictates that all relevant factors should be reviewed. It is unfortunate that it is the environment that is typically the last issue to be investigated. From the proper operating environment for a laser device ("dry and cool" is the best rule of thumb), to concerns regarding the materiel and related vapor ejected into the environment by the lasing process itself. For example, a client developed an integrated laser solution which included the surface alloying of a relatively non-corrosive chemical onto the surface of a piece of metal (also non-reactive). No attention was given to the operations environment (very humid and hot). As the laser alloyed the surface, the vapors generated by the process combined with the moist air and damaged the component, the laser/integration, and posed a significant health risk to the personnel.

Non-Beam Hazards[3]

Another aspect to photonics safety and compliance is that of non-beam hazards. These are issues that, along with the associated complications involved with photonics emission, can be very troublesome to protect against. As discussed in Part 1, the majority of serious or fatal photonics accidents, (and source of non-compliance with the code), are non-beam hazards, mainly electrocution. A more complete listing of possible non-beam hazards that have been observed:

Improper electrical design, use of components, grounding, and shielding. As with anything that uses large amounts of voltage and current, often at very high frequencies, Photonics systems do not lend themselves to trivial engineering and design. Proper compliant engineering must make sure there are no spurious emanations coming from the devices through faulty grounding and shielding.

Photonic/laser generated air contaminants. From leaks of constituent lasing and dopant gases, to the freeing of free-radicals in the process itself, Photonics systems emit light as always some part of an electro-chemical process. This process can end up deriving whole new species of gases and air contaminants. Proper compliant engineering dictates the safeguarding of air contamination release and related monitoring.

Excess plasma radiation. As with anything that relies upon a electro-chemical discharge of some fashion (whether the action occurs in the discharge tube itself, or in a set of flashlamps), Photonics systems generate a plasma of sorts near the discharge region. Proper compliant engineering must make sure the levels of x-ray, ultraviolet (UV-A and UV-B), as well as intense visible radiation is contained and not allowed to affect equipment or personnel.

Improper and lack of appropriate robotics control(s). Emerging designs utilize more autonomy, and as such, Photonics systems are the perfect partners to remote location operations. Proper compliant engineering must ensure that there are no violations of electrical, mechanical, and optical regulations anywhere along the route from machine to process.

Excessive noise. As with anything as complex as a high-powered laser system, there are mechanical support systems. Equipment from vacuum pumps to the power supply cycling, can generate a large amount of noise.

Proper compliant engineering must make sure the levels of noise are at or (preferably below) mandated limits.

Improper and lack of illumination. Probing around confined spaces without adequate lighting can invite personnel to take unnecessary risk while either operating or service/maintaining a laser device. Proper compliant engineering must make sure the levels of lighting are at acceptable limits.

Inadequate ventilation. Photonics systems often use toxic and/or exphixiant gases in their operations. From the gas used in flashlamps and sources, to the effluent gases and vapors generated by the process itself, inadequate ventilation could cause problems from poor quality processes to fatal injuries. Proper compliant engineering must make sure there is always proper ventilation around laser sites.

Inadequately addressed and solved waste disposal concerns. Photonics systems can create waste disposal concerns. From toxic dyes and dirty filters, to the accumulation of excess materials from related application processes. Proper compliant engineering must include the sufficient handling, characterization, and disposal of waste.

Improper and/or lack of appropriate space. Photonics systems can range from devices that can fit onto a fingernail, to massively integrated systems taking up entire buildings-most of which is related to power generation and control. Proper compliant engineering must include appropriate engineering to minimize confined spaces.

Fire hazards. Photonics systems (lasers specifically) by virtue of their operations, are fire hazards. Proper compliant engineering must include appropriate fire engineering to minimize flash points and related material risks.

Improperly handled and labeled compressed gases. Some laser systems (especially those used in processing applications) require compressed gas. These gases can range from inert, yet oxygen-starving types such as Argon (for shielding gas), to highly reactive, highly toxic gases. Proper compliant engineering must include physically safeguarding gases from physical damage as well as monitoring those that are hazardous.

Improper use of laser dyes. Most laser dyes/dye solvents are toxic. From creating the dye stream to leaks in operations, dyes pose a serious threat and should be treated as hazardous material. Proper compliant engineering must include handling controls and barriers to prevent direct exposure to the dye material.

Inadequately addressed and solved worker motion risk concerns. Although evolved, photonics products and processes are not typically designed with proper ergonomics. From reading the controls on a control panel, to the adjustment of optical devices, the typical laser system is not designed for comfort in its operation. Proper compliant engineering must include the application of ergonomics and repetitive motion analysis to ensure a repetitive motion hazard is not created.

Inadequately addressed and solved explosion/implosion concerns. Photonics products and processes contain fragile devices. From the delicate glasswork of a laser resonator, to an all-ceramic pre-ionizer chamber, there is typically an element involved that could explode/implode or cause an explosion/implosion if not operated or handled correctly. Proper compliant engineering must include the design of adequate protective housings around potentially explosive and implosive devices.

Case Studies

Case Study 1: Medical (Surgical Laser Unit)

Background. A start-up medical laser (surgery application) required the compliance engineering and integration of a miniature CO2 laser system into a highly computerized robotic surgical suite.

Specific Problems. The start-up was simply integrating modules already packaged and pre-tested. The problems started when the company had to make sure the system functioned and had to re-file for compliance to the federal standard (21 CFR 1040). Additionally, there were containment and notification aspects to the project that influenced every part of the integration. From the control of the computer interface, to the architecture of the surgical suite (entire room) itself, making sure the laser integration was compliant required a good deal of engineering coordination.

Solution. The approach and related solution was broken down into parts:

1. Teaming - appropriate teaming had to be facilitated with the architects and the related contractors (from HVAC and electrical, to security). Additionally, since SDLI concentrates on only Photonics-related safety and compliance issues, we had to partner with a registered, UL recognized laboratory for the other related compliance issues (such as electrical, EMI/RFI, etc.).
2. Extensive use of the Shell Method- starting with the laser system, we approached the problem by treating each layer of integration and effective compliance as separate. Through the laser systems' integration into the robotic manipulation system, through the robotic systems' integration into the surgical suite, each integration set dove-tailed with each other.

Overall Result. The overall result was a system that was not only safe, but fully compliant at each stage. More importantly, service and maintenance operations (representing the largest risks in terms of compliance and safety violations) are inherently safe and compliant.

Case Study 2: Industrial (Processing Laser Equipment)

Background. A mid-sized industrial machine manufacturer wanted to integrate a high-powered ND:YAG laser into a machining center.

Specific Problems. The company wanted to radically change the laser (specifically the laser head) so they can save space within the machine structure. The problems started when the company had to make sure the system functioned and had to re-file for compliance to the federal standard (21 CFR 1040).

Solution. The approach and related solution was relatively straightforward:

1. Review of desired integration vs. current configuration of both machining center and laser system.

2. Comparison and selected of suggested approaches.

3. Application of compliance language to selected approach.

4. Engineering/integration of laser device.

5. Filing of application.

Overall Result. The overall result was a laser system that became totally integrated into the machining center, with the overall resulting system being certified as the safest class (Class I) of laser products by the FDA/CDRH.

Case Study 3: Industrial (Gauging Laser Installation)

Background. A major crystal growth company required the constant surveillance of one of its process to ensure consistent yield.

Specific Problems. The specific crystal grown was very sensitive to mechanical motion in every axis (3 linear and 3 rotational). Additionally, since the temperatures near the oven reached over 1000C, open beam paths had to be used and no conductive materials can emanate from oven (due to the high-power RF used to generate the heat).

Solution. The solution was to use two interferometric sensor suites compared at each optical node. Laser diodes were used for both the sensing and communications (via fiber-optics) back to the processing instrumentation.

Overall Result. The overall result was a completely compliant integrated sensor system that provided resulting data without creating EMI/RFI.

Case Study 4: Commercial (Laser Card-Burn Integration)

Background. A consumer electronics firm desired to develop a new laser that provided a special permanent mark on I.D. cards.

Specific Problems. The company wanted to use a relatively high-powered diode laser to produce the desired effect, but had related problems with air contaminants and toxin generation.

Solution. The approach and related solution included development of a labyrinth access port where an I.D. card could be inserted, but at no time could the laser radiation escape. Additionally, a small, well shielded ionizer was integrated to charge the particles as they were created by the burning process. The particles were picked up by a filter-trap for proper disposal after a period of time.

Overall Result. The overall result was a fairly unique laser application with various hazards and sticky compliance issues (air contamination, RFI/EMI, and static issues), being solved. The overall resulting system being certified as the safest class (Class I) of laser products by the FDA/CDRH.

Case Study 5: Scientific (Laser Purification Experiment)

Background. A major gas producing company was facing the EPA phasing-out a large portion of its gas products (due to ozone depleting aspects). They required a way to purify or "scrub" the ozone depleting elements from the gas product.

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Specific Problems. The specific problems associated with purifying a gas by selective laser ionization starts with a highly intense UV laser (ozone generation, ionization creation of EMI, and RFI created by the power supply). Next comes the coupling of the laser light to the gas stream and the resulting non-precise generation of toxic species.

Solution. The approach and related solution included the dual shielding of both the laser head/system, and the entire purification process. Because of the various RF energies present in the system, a single-point grounding scheme was used with a sensor circuit to ensure the integrity of the grounding.

Overall Result. The overall result was a system that was not only safe, but fully compliant at each stage. More importantly, service and maintenance operations (representing the largest risks in terms of compliance and safety violations) are inherently safe and compliant.

Conclusion

Photonics devices are the future. However, along with the quantum leap they provide in performance/cost characteristics, they also provide a quantum leap in potential hazards-safety and compliance issues. The best way to reduce the risk is through identification then making sure the device is both safe and compliant.

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1. Photonics is the study of the Photon (much like the way Electronics is the study of the electron), from emission through transmission, to detection. Technologies within Photonics include: LASERs, electro-optics, acousto-optics, magneto-optics, and fiber-optics.
2. Re-compiled via: Sutter, Ernst; Standardization in the Field of Lasers in Europe-Towards Common International Standards; Journal of Laser Applications, Vol. 6 (1), pp. 42-48 (1994)
3. Table and subject encapsulated with the help of C. Eugene Moss, Health Physicist, The National Institute of Occupational Safety and Health (NIOSH)