Zeroth Responders - LSO's Reporting Non-Compliant Lasers – Why, How, and to Whom - A step by step guide.

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Abstract

With the proliferation of inexpensive semi-conductor lasers used in laser pointers and imbedded into commercially available products, an increasing subset of devices reach the marketplace as non-compliant with regulations and standards (e.g.; 21CFR1040.10/.11 and IEC/EN60825). Many such devices are inexpensive enough to be purchased on company purchasing cards bypassing formal oversight by the Laser Safety Officer (LSO) in advance of arrival. Once in place, users have a tendency to use them immediately, especially when they are believed to be Class II/2, Class IIIa/3R or lower.

Further, because of the ease with which users can obtain these and more powerful Class IIIb/3B and Class IV/4 devices, the LSO must become a Zeroth Responder — applying a high level of due diligence to ensure the safety of the user population and general public.

This paper details five real incidents faced by the authors (e.g.; laser pointers, research systems, industrial systems). It goes on to provide action plans to promote the implementation, acquisition, and safety of lasers in the user space. Finally it provides a step-by-step process for LSOs to identify, intervene, and, when necessary, gather evidence to assist regulators and civil authorities when dealing with organizations that manufacture and distribute these devices.

Introduction

Dr. Theodore Maiman claimed to have created one of the first operational pulse lasers in 1960, though this claim was challenged in the early to mid-1980s by Gordon Gould. Dr. Charles Townes of Columbia has been credited with perfecting a continuous wave (CW) version several years later, while others also worked independently to develop gas-based lasers: Javan (HeNe,1960), Bridges (Ar, 1964), and Patel (CO2,1964).

At that time lasers were described by many as a solution looking for a problem to solve. The first lasers were expensive research tools costing $100,000 or more. Even the first industrial lasers were expensive, and were only used in very specialized manufacturing processes like the construction of components for the Saturn V, which eventually took the first men to the moon.

Lesser known at the time of discovery, the semiconductor laser was born in 1962 and did not start finding practical application and use until the late 1970's. This was primarily because of the original semiconductor lasers' lower power and coherence.

Since then, the variety of types of lasers and their applications have grown meteorically. Today, lasers are everywhere and in virtually every type of product, from military weapons, advanced communications, and machine tools, to children's toys. Untrained individuals can even purchase 2W Class IV/4 Laser diode devices for less than $100 through a number of sources.

Semiconductor lasers, numbering in the millions each year, now account for almost half of all lasers produced. According to multiple sources, the laser market is estimated to grow to $14.7 billion in the next few years with $12.9 billion of that figure representing semiconductor-based lasers. The vast majority of questionable laser products are semiconductor based products or use a solid state medium to convert the emissions from a non-coherent light source (LED) into a laser at a new wavelength.

Their small size, ever-shrinking cost and power supply logistics, as well as confusing labeling requirements, create a perfect storm. High power laser diodes are being placed in a wide variety of products with apparent disregard for how they should or will be used, and/or inadequate notification that they are there. A significant percentage of the user population perceive them as innocuous. This is true for individuals in leading-edge research efforts and major universities

(NL is employed at JHU) as well as in industrial settings (SW is employed for a consulting company focusing on these users).

Currently, the FDA/CDRH 21CFR1040.10/.11 is harmonizing with IEC/EN60825. The confusion created for legitimate manufacturers within the industry though potentially hazardous is minor in comparison to the blatant disregard by those who do not want to follow the regulations or standards in order to sell these products.

In commercial (including universities and research) settings, organizations have a fundamental responsibility to ensure that lasers are used safely and properly to prevent injury to employees (users and bystanders), and to the public. For the U.S., this responsibility is codified in the Code of Federal Regulations, FDA/CDRH 21CFR1010 and the general duty clause of OSHA 29CFR1910 series. Implementing the necessary processes, procedures and policies is assigned to the LSO of the organization through the consensus standard Safe Use of Lasers (ANSI Z136.1-2014) and other vertical standards in the series.

With the proliferation of lasers noted above (e.g. number of Class IIIb/3B and Class IV/4 lasers at JHU increased from approximately 50 laser in 2006 to over 250 laser in 2017) the LSO requires tools to assist them in efficiently and effectively evaluating the inherent risks of inadequately engineered and/or documented laser systems, and to provide a path forward for users to be able to safely use these lasers when and where appropriate.

As a starting point, this paper will provide a set of tools based on the authors' real experiences. Examples include:

- A commercial telecom system being produced and transferred to a new company as part their technology acquisition despite having misleading labeling, documentation, and engineering controls.
- A multiple-unit measuring system that is missing anything identifying compliance to any accepted standard being installed into a linear production line
- A researcher using personally purchased 1w IR (808nm and 930nm) lasers as part of their PhD thesis project.
- Laser pointers improperly labeled as Class 2 when they were really Class 3B
- An Optical Tweezer Experiment purchased as laser lab kit brought in as an educational tool in an undergraduate teaching lab.

DISCUSSION

What is a Zeroth Responder?

A Zeroth Responder is a person, already present when a potentially hazardous system is introduced, and if an event occurs, has the skills necessary to minimize the consequences of an incident to others. Additionally, this person is able to develop and/or implement a plan that will ensure the ongoing safety of all involved.

For lasers this means:

- Reviewing and identifying questionable laser products before they enter the organization.
- Being a subject matter expert of the inherent hazards that exist with using lasers in a variety of situations.
- Taking the time to identify all associated laser hazards and inform stakeholders of their existence.
- Having the tools and skills to mitigate the risks associated with those potential hazards.
- Ensuring that users understand how mitigating the risks will result in improved outcomes.
- Implementing recommended mitigation techiques such that the required utility of the laser is maintained.

For Zeroth Responder LSOs to be successful, organizations must provide them with the resources and the authority to ensure that the recommended safety risk mitigation techniques are implemented. This includes an understanding in the user community that the LSO is there to make their lives better, and that these officers should not be seen as impediments to the work that is being performed, whether it be an industrial/commercial project destined for distribution or cutting-edge research.

The LSO has two functions in this context: Safety and Quality Assurance/Code Compliance. Both function when implemented properly, and will actually improve the quality of the organizations' output while improving efficiency and reducing cost.

Case Studies

The following case studies show how common (from a simple acquisition sense) to complex (part of an integrated product development sense) the issue of non-compliant products can be (and how vigilant an LSO must be).

#1 - Test Sets

Figure 1: Telecom Test Enclosure

- Type - Professional
- Identification Stage – By producer
- Market - Commercial
- Segment – Telecom
- Description of Incident / Event

A global telecommunications equipment manufacturer was in due-diligence for the acquisition of a small business which manufactured laser-based test sets.

- Discovery

  During a physical audit of assets, a business analyst discovered a few "odd" test sets, and questioned the lack of any labeling or documentation.

- Price Proposal

  $600,000 contract value equals $20,000/unit (600,000/30)-NRE amortized over each unit.

- Audit Results
  - The sample unit was found to contain fiber-optically coupled laser diodes with the following characteristics:
    - 850nm @ 1.26W
    - 1310nm @ 0.32W
    - 1550nm @ 0.63W
  - The test sets were determined to be designed to test/"ring" long-haul fiber-optic network nodes under an internal R&D/D contract to support a customer request.
  - The product was most certainly not Class I/1, did not have any labeling, engineering controls, or documentation.
  - Additional units were evaluated and found to have similar features.

- Determination

  The test sets did not comply with FLPPS, ANSI, or IEC/EU standards

- Disposition
  - An "all-hands" search was announced and performed to scour the facility to locate any/all like test sets. Twenty-two (22) operational units were found; eight (8) units were found not working.
  - Customer proceeded forward with the acquisition after subtracting the estimated cost to be compliant with existing regulations and standards.

- Lessons Learned

During M&A activities, ALL risks need to be determined prior to establishing liabilities of sale affecting sale price.

Items which seem a normal part of the technology chain cannot be assumed to be compliant with regulations and standards unless evaluated.

#2 Sensing Gauges

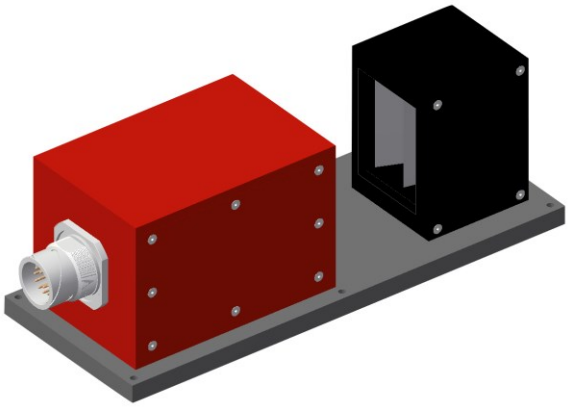

Figure 2: Sensing Gauge Assembly

- Type - Professional
- Identification Stage – By producer
- Market - Commercial
- Segment – Manufacturing
- Description of Incident / Event

  A linear production line required a specific type of laser-based measurement gauges throughout the system. The chosen manufacturer was located in Italy.

- Discovery

  During incoming inspection, compliance to IEC/EN60825 was expected, but no labeling was found and entire safety-based sections of the operating manual were non-existent.

- Price Proposal

  $600.00/unit x four (4) units ($2,400 total value) for production line project value of $1.8M

- Audit Results
  - Upon review of a sample unit, it was found to contain a diode laser 650nm @ 50mW
  - The products were determined to not meet the specifications listed. In fact, the emission characteristics listed in datasheets and on the OEM's website, were actually minimum and not maximum. The product was not Class IIIA/3A, as advertised and required, and did not have any labeling, engineering controls, or documentation. Others were evaluated and found to have similar features.

- Determination

  The sensors did not comply with FLPPS, ANSI, or IEC/EU standards.

- Disposition

  The vendor was contacted and products returned. A replacement vendor was sourced in the US.

- Lessons Learned
  - If a laser product is sourced from overseas, insist on seeing a copy of either the Manufacturers Checklist or (preferably), a Test Report. If the manufacturer claims compliance to FLPPS, make sure a valid CDRH Accession Number exists (request and receive CDRH acknowledgement letter/email).
  - Incoming inspection is the best stage to make sure product components are compliant and meet physical and performance specifications.

#3 PhD Thesis Project

Figure 3: 1W IR Laser in Stand to control NHZ

- Type - Professional
- Identification Stage – By end user
- Market - Consumer
- Segment – Research
- Description of Incident / Event

  A Research Professor, contacted the Laboratory Safety Advocate of university indicating that one of their graduate students was performing some experiment that would be utilizing IR lasers emitting approximately 1W each.

- Discovery

  The student had purchased two 1W lasers (808 and 980nm) with personal funds for the purpose of conducting final experiments required to complete their PhD thesis. The student had no prior documented training to use lasers.

- Price Proposal
  - <$300.00 for each of the two lasers
  - <$250.00 for the test stand

- Audit Results
  - Laser 1 – 808nm @ 1.1-1.2W
  - Laser 2 – 980nm @ 0.9-1.1W
  - Neither laser was properly marked. User manual was inadequate. Both had control keys that were removable with the laser in the powered condition.

- Determination

  The lasers did not comply with FLPPS, ANSI, or IEC/EU standards. The student had inadequate training to use laser safety and properly.

- Disposition
  - The first step was to train the student as a laser operator under the university's laser safety program. Once this was accomplished, the student readily understood what needed to be done and actively participated in accomplishing the creation of a safe working environment.
  - The lasers were the property of the student. He had obtained them using his own funds and needed them to complete his PhD thesis research. Working with the student, the LSO developed a detailed SOP along with a test fixture that would allow the student to continue his research in a timely fashion. The apparatus was designed so that it could be treated as an inherently-safer Class I/1 laser system. The system was able to be used in the open lab area without the need for any eye protection by the operator or the other lab users.

- Lessons Learned
  It is important that all laser users are fully cognizant as to the potential risks that exist with lasers. This starts with appropriate education of the user population and a detailed evaluation of the specifics of the system installation.

  When the laser installation is properly implemented, experiments can be done with better quality, in less time, and with fewer hazards to users and other personnel. In this case, the system also provides more repeatability for the experiment with less effort.

#4 Pirated Laser Presenter

- Type - Professional
- Identification Stage – By end user
- Market - Commercial
- Segment – Office Product
- Description of Incident / Event

  LSO received a report from a user that two supposedly identical laser presenters had very different emission profiles. One was much brighter than the other. The users wanted to know if one laser pointer was bad.

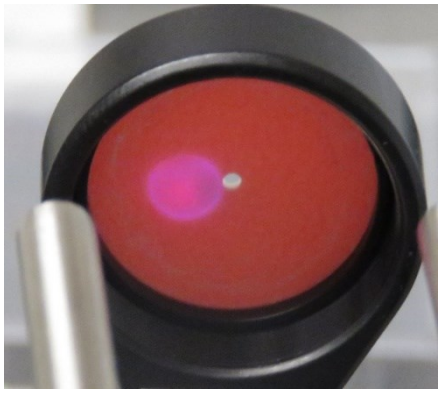

Figure 4: IR Spot produced by Laser Pointer - NOT Class II/2

- Discovery

  Upon analysis of the two laser presenters, it was determined that both were out of specification (see Measurements). Both had emissions in excess of minimum Class IIIb/3B levels. Although both claimed to be Class II/2 lasers, both had significant IR emissions.

  Units were not purchased from a recommended vendor.

- Price Proposal

  The retail price of the laser presenters selected was $70.00 each. They were readily available from a number of vendors, including several which were preferred.

  In order to save $10 per unit the two laser presenters from an online-only vendor, rather than from a university preferred vendor.

- Audit Results

  Presenter 1 –
  - total power @ 532nm – 22-26mW
  - filtered <770nm @ 532nm – 17-19mW
  - filtered >770nm @ 808nm – 6-8mW

  Presenter 2 –
  - total power @ 532nm – 12-14mW
  - filtered <770nm @ 532nm – 6-11mW
  - filtered >770nm @ 808nm – 2.5mW

  Visual inspection indicated these appeared to be properly cleared units, but the output did not agree with the claimed Class II/2 specifications.

- Determination

  Laser were pirated and were not manufactured by the claimed source. They did not comply with FLPPS, ANSI, or IEC/EU standards.

- Disposition

  Laser presenters were pulled from service and replaced with laser presenters from a validated source. Replacement laser pointers where also tested to be in compliance with stated specification and FLPPS.

  The purchased part number for the original laser pointers and the replacements were the same. Without further testing, it would have been difficult to know the issue's real cause.

  Both laser pointers were shipped to CDRH for evaluation. In this case, it was done without contacting vendor.

- Lessons Learned

  Purchase all products from known and vetted vendors.

  The purchased part number for the original laser pointers and the replacements were the same. Without further testing, it would have been difficult to know the issue's real cause.

  When recommending vendors for low cost lasers, be certain to test samples of their products before making any recommendations.

  Finally, especially with 532nm laser pointers, test each unit before releasing them for use. Refer to NIST report.

#5 Optical Tweezers

Figure 5: Safety Warning Sign Demonstrating Local Control Measures

- Type - Professional
- Commercial Stage - Kit
- Market – Education / Training
- Segment – Scientific

- Description of Incident / Event

  New Photonics Lab was being set up as part of expanding the course offering at the university.

- Discovery

  Parts were received as a kit from a known vendor. Reviewing the specifications for the kit made it clear that the lasers in the kit were Class IIIb/3B.

- Price Proposal

  Cost of the individual optical tweezers systems was approximately $8,000 each. This made it a capital item for the university.

  Inclusion of the cover and making this an equivalent Class I/1 system cost the university approximately $150 total for 5 systems.

  Implementing the beam enclosure cover saved the university more than $25,000, which was the estimated cost to:

  - Install black-out curtains for the lab
  - Supply laser safety goggles to all students
  - Provide additionally training to allow students to use of Class IIIb/3B devices in accordance to requirements of ANSI Z136.5-2009.

- Audit Results

  The system as delivered was clearly marketed as a kit containing a Class IIIb/3B laser.

  To be used in the education setting, it needed to be made to be Class I/1.

  Measured power was 658nm @ 32mW

- Determination

  This system was produced and distributed as a kit. The included instructions indicated that the kit was not FLPPS compliant.

  This means that the end user is responsible for ensuring that the final system is appropriate for use in the stated application, and was being sold as OEM.

- Disposition

  A cover was added to the system to enclose the beam allowing the LSO to certify that it was equivalent to a Class I/1 system for internal use only.

- Lessons Learned

  Evaluate all systems before purchase. Ensure that the LSO is involved upfront. By doing this, significant cost savings can be realized.

Step By Step Plan

The authors have devised a process by which LSO or other safety professionals can identify and manage laser products that may or may not be compliant and/or safe.

The Suspicious Laser Product Protocol, or "SLaPP", a three-page document currently hosted by the authors on a public access area of JHU (http://labsafety.jhu.edu/laser-safety/), has been developed with guidance from relevant federal, state, and local agencies to take someone step-by-step through the complexities of determining the compliance and safety status of laser-based products.

SLaPP PROCESS

In order to accurately assess a potentially non-compliant and/or unsafe laser-based product, the authors offer a straightforward process that is both logical and easy to use.

Limiting risk by capturing and isolating a potentially volatile product is at the heart of LSO's responsibilities.

1) Physically remove the suspicious product from its power source to render it incapable of operation until such time as a determination can be made as to whether these devices can be used safely. The LSO should take secure control of the product until a final safety audit is determination completed.
2) Collect contact and product data. Specifically:
   a) Find out who is collecting the data.
   b) Get a description of the product
   c) Identify the manufacturer
   d) Identify the distribution company or vendor
3) Conduct a safety audit on the questionable device. The audit should include:
   a) Detailed measurements of the emissions of the device. Measuring the emissions should be done in a Class IV/4 LCA. A minimum of five discrete measurements is recommended.
   b) Review of all supplied documentation compare them against FLPPS requirements.
   c) Photo document the device and the tests. Once the laser product is located in the LCA, take a complete set of photos with a scaling element in each frame in order to determine relative size.
4) Based on the testing and review from step 3, make a determination as to compliance.
   a) Does the product emit what was claimed?
   b) Are the proper engineering controls for the class stated in place and operable?
   c) Is the labeling correct and in the proper location(s)?

   If everything appears correct, introduce into organization. If not:
5) Contact the assembler, distributor, and/or vendor to notify the responsible party, according to your evaluation:
   a) The product does not appear to be compliant and will not be introduced into your ecosystem.
   b) In order for you to release the product for use, vendor shall prove compliance of the system or actively correct the non-compliance.

   Note: There are situations when laser products are received that are noted as being OEM parts or are part of a kit (refer to case 5 above). If it is being supplied as a kit, your organization should to take the necessary actions to ensure that the requirements of your internal system can be met before introducing them into your ecosystem. When this is done, it must be recognized that they cannot be reintroduced into commerce without meeting the necessary FDA documentation and labeling requirements.
6) If the assembler, distributor, and/or vendor refuses to or cannot prove compliance to a standard system, and refuses to correct the non-compliance, the LSO must alert the appropriate agencies, starting with the FDA/CDRH. The SLaPP form can assist you in getting all the necessary information to the appropriate agencies.
   a) The FDA /CDRH is the federal gatekeeper for these types of complaints. Filing a complaint with that agency will alert other appropriate agencies as needed. If more information is required, the CDRH will contact you.
   b) Some states (e.g. Texas, New York) and localities, may have additional reporting requirements. Use this form as the basis for those reports.

7) Based upon agency response and collected evidence, discuss with all stakeholders what to do with the product, whether you should accept its use under strict management, or not. .

8) Note decision, execute disposition, and sign-off of SLaPP document.

Conclusions

The confluence of smaller, more powerful, less costly lasers, increasingly limited gatekeeper/stakeholder resources, and complex standards and regulations is creating an increasing number of opportunities for hazardous laser products to be introduced.

We must develop procedures to ensure laser-based products are compliant and safe PRIOR to their introduction in order to prevent injuries to users.

The process proposed here is the start of one such process. LSO are encouraged to utilize this process and to report their results to the laser safety community at large.

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Meet the Authors

Niel Leon is currently the Laser Safety Advocate for the Johns Hopkins University, Homewood Campus. He has been instrumental in upgrading the laser safety program to facilitates the research objectives of JHU principal investigators by maximizing experimental controls and understanding while implement a culture of safety within the university's education pedagogy. He has 38 years of experience in mechanical systems design includes product development, commercialization and field support in both commercial and governmental sectors. Niel Leon's teaching experience ranges from development of corporate training programs to lecturing on Small Business Innovation and Research Grant applications to developing needle-free injections systems.

Scott Wohlstein is the President of The Photonics Group. He is a noted researcher and patent holder and is widely sought after for the design, development, and production of safe, US and EU compliant Photonics-based products and processes. He has 36 years' experience enabling him to assist from 1 person commercial start-ups to various branches of the US and foreign governments in areas such as R&D/D management, safety/risk, and troubleshooting. He has served on the editorial advisory board for Lasers & Optronics, editor for Measurements and Controls and serves on several ANSI Z136 committee.

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