UNDERSTANDING SYMBOLS: LASER LABELING

One of the critical building blocks for your product safety labels is symbols. When it comes to the history and progress of formats and symbols related to labels on laser products, manufacturers face a dilemma in using U.S. regulations versus internationally-accepted standards. This month, we'll explore CDRH-compliant laser labels (for U.S. markets) and IEC-compliant laser labels (for international markets), as well as the future in laser labeling: a new harmonized format.

My long-term involvement on the ANSI Z535 and ISO/TC 145 committees has helped to achieve harmonization in the area of product safety labeling so product manufacturers in a multitude of industries are able to adopt a single safety label system for their products worldwide. For laser safety labeling, this has not happened. Manufacturers of lasers (and products that utilize lasers) face a dilemma; U.S. regulations differ from the internationally-accepted standards which govern laser labeling worldwide. In this article I'll share an overview of both types of laser labeling. I'll then suggest a way forward to harmonize these standards so product engineers will eventually be able to use a single set of laser labels to satisfy both domestic and international market requirements.

CDRH-COMPLIANT LASER SAFETY LABELS

In the U.S., the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) is in charge of laser labeling. As developed by the CDRH, the *Code of Federal Regulations (CFR), Title 21, Subchapter J, Part 1040, Section 1040.10 Laser products* governs the format and content of laser product safety labels. This regulation defines the content and "look" of the safety label based on:

1. The class of laser

2. Whether or not it is invisible, visible, or visible and invisible

3. Whether the laser label is going to be placed on the product, on a non-interlocked protective housing or on a defeatably interlocked protective housing

The label's format and exact word message are defined based on these variables. The laser's class will also determine if your CDRH laser label needs to show the maximum laser radiation output, pulse duration

Figure 1: Examples of CDRH laser class/certification labels

courtesy of **Clarion**®

as seen in **INCOMPLIANCE** Magazine

Geoffrey Peckham is CEO of Clarion Safety Systems and chair of both the ANSI Z535 Committee and the U.S. Technical Advisory Group to ISO Technical Committee 145- Graphical Symbols. Geoffrey can be reached at gmpeckham@clarionsafety.com

(when appropriate), and emitted wavelength(s). See Figure 1. A separate label placed near the laser's aperture may also be required.

Figure 2A: Example of the still permissible older-style IEC laser safety label with separate explanatory information label

The problem with the CDRH laser product regulations is that, even though they were revised in 2014, they use circa-1941 CAUTION and DANGER safety sign formats[1] and a non-ISO-formatted laser symbol. Though the CDRH formats and symbol are obsolete, you have no choice but to use them if compliance with the CDRH standard is your objective.

IEC-COMPLIANT LASER SAFETY LABELS

The International Electrotechnical Commission (IEC) defines the content and "look" of laser safety labeling internationally in the standard *IEC 60825-1 Safety of laser products – Part 1: Equipment classification, requirements and user's guide*. The latest revision to this standard, published in 2014, is very interesting because it offers up two laser label formats to choose from. One of these formats is new to the laser industry. The new format utilizes design principles in line with worldwide best practices for product safety labeling for all industries.

First let's start with the similarities to CFR 1040.10. Like the CDRH labels described above, the content

requirements for IEC laser labels are based on the laser's class, whether it is invisible/visible/invisible and visible, and whether or not the laser label appears on the product, on a readily overridden interlocked panel, or on a non-interlocked panel. Like CFR 1040.10, IEC 60825-1 requires separate aperture labels for some classes of laser products.

The similarities end there. The "look" of IEC laser labels is completely different from CFR 1040.10. The first IEC format is the traditional "symbol + text" format which places the ISO yellow triangle laser warning symbol and text on an overall yellow background (see Figures 2A and 2B). The second, new IEC laser label format combines the ISO yellow triangle laser warning symbol with one or two ISO-formatted prohibition symbols, a DANGER, WARNING or CAUTION risk severity color-coded

Figure 2B: Example of the still permissible older-style IEC laser safety label with explanatory information incorporated into the label

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1. These formats were eliminated from the nation's primary product safety label standard, ANSI Z535.4, in 2002, and as of 2013, OSHA changed their regulations to include the newer ANSI workplace safety sign formats, signaling a movement towards the new warnings technology nationwide.
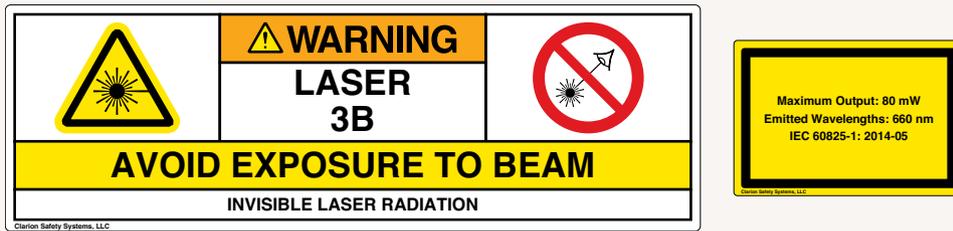
Figure 2C: Example of the new IEC laser safety label with separate explanatory information label

signal word panel, and brief text message panels (see Figures 2C and 2D). The IEC standard allows specific radiation output information to be either placed on separate "explanatory" labels (Figure 2A and 2C) or incorporated into the laser safety label (Figure 2B and 2D). According to IEC, the name and publication date of the standard which the product was classified to must be included on the explanatory label (as shown in Figure 2A and 2C) or on another label within close proximity.

Figure 2D: Example of the new IEC laser safety label with explanatory information incorporated into the label

TOWARDS A SINGLE FORMAT FOR LASER LABELING

The interesting thing about the 2014 edition of IEC 60825-1 is that it presents engineers with a new format choice that is symbol-based (so more information can be conveyed across language barriers) and uses color-coded severity level panels to appropriately denote the level of risk. The new IEC format is derived from the world's principle standard for product safety labels, *ISO 3864–2 Graphical symbols – Safety colours and safety signs – Part 2: Design principles for product safety labels*.[2] What's more, this new label format is contained in the U.S. *ANSI Z535.4 Standard for Product Safety Signs and Labels*, the nation's principle standard for safety labels for <u>all</u> industries.

The differences between CFR 1040.10 laser labels and the newer-style IEC 60825-1 labels could not be clearer. CFR defines the old; the newer IEC format defines the new. Make no mistake about it;

the new IEC label format is part of the growing trend industries are shifting to: a greater reliance on symbols to communicate and draw attention to safety messages, precise use of severity level panels to define risk, and clear, concise text. My advice to the FDA committee in charge of the CDRH standard's next revision is to abandon the 1941-era safety label formats and replace them with the newer ISO 3864-2 harmonized safety label formats depicted in the 2014 version of IEC 60825-1. This committee should also sort out differences in laser classification schemes. When this is done, manufacturers will have a single scheme of laser labeling that will meet the needs of both U.S. and international markets.

A LASER LABEL RESOURCE

Finding the laser label that meets your specific requirements is easy with the Clarion website's updated laser safety label section [1]. You can filter results according to your variables to find the exact CDRH, IEC old-style or IEC harmonized laser product safety label needed.

Stay tuned for the next article in this year's *On Your Mark* series which will explore the history and progress in standardized symbols related to emergency stop buttons. Ⓝ

REFERENCE

[1] http://www.clarionsafety.com/Laser-Hazard-Labels

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2. As chair of the U.S. TAG to ISO/TC 145, the ISO committee in charge of writing the ISO 3864 family of standards, and as principle author of ISO 3864-2, I can definitively tell you that the new IEC format is based on ISO 3864-2, which, in turn, is based on ANSI Z535.4. Thus, use of the new IEC format will also m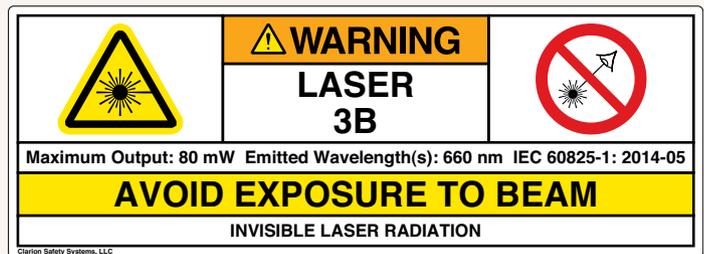ean compliance with both ISO 3864-2 and ANSI Z535.4.