



Date: 27 February 2018
Memo to: Chris Dissinger
From: Ray Lanzafame, SSC-3 Chair
Subject: Clarification of Section 4.6.2.1.3 Eyewear for Endoscopic Procedures

Question

This inquiry was originally submitted to Laser Institute of America (LIA) as secretariat of ASC Z136 and subsequently forwarded to ASC Z136 for response.

I have had difficulty in justifying ANSI Z136.3 section 4.6.2.1.3 "Eyewear for Endoscopic Procedures" which does allow the laser safety officer (LSO) to allow laser safety eyewear to not be worn. Can you clarify for me why this was placed in Z136.3 and what justification a LSO can use amend their policies...

It was determined that the question falls in the category of "clarification" under the guidelines and procedures of ASC Z136. As such the answer has been responded to by the Chair of SSC-3, the subcommittee responsible for the development and maintenance of the ANSI Z136.3 *American National Standard for Safe Use of Lasers in Health Care*. The following is Dr. Lanzafame's response.

ASC Z136 SSC-3 Response

Suffice it to say the questions being raised have been a longstanding source of vigorous debate, discussion and posturing relative to SSC3 and the Z136.3 standards as well as on the part of OSHA and NIOSH, and various facilities, for as long as I have been involved with the process (ca 1982).

Part of the problem is over and/or misinterpretation of the intent of the PPE statements. Specifically, the decision to wear or not wear eye protection (viz. an optically clear protective material) should be driven by the fact that one is in a health care environment where bodily fluids and other materials may contact the face/eyes. This is a separate issue and is independent of whether or not the use of laser protective eyewear is prudent or necessary. The latter must be balanced against the risk of exposure to hazards to patients/personnel vs. the risk of iatrogenic injury if the use of the eyewear substantially interferes with the visual acuity of the surgeon thereby posing a significant risk hazard to the patient and others within the care environment.

The Z136.3 standard has allowed the LSO to make a determination one way or the other, and the current revision, from which I have reproduced some excerpts below, hopefully makes this a bit more clear. Note however, that the excerpts below are still not published but are as the material stands following the EWG review of the approved CDV2.

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3.1 General.

Various aspects of the HCLS influence the total hazard evaluation and thereby affect selection of the control measures to be applied:

- a) The capability of the radiant energy of the HCLS to injure HCP or the patient or target
- b) The environment in which the HCLS is used (e.g., hospitals, ASC's, doctors, dentist, chiropractic and veterinarian offices, salons, spas)
- c) The HCP who may use or be exposed to laser radiation
- d) The delivery system, which is important to defining the extent of the NHZ
- e) The non-beam hazards associated with the HCLS (see Section 7)

Aspects (b), (c), (d) and (e) vary with each laser application and cannot be readily standardized. Normally, laser beam hazards exist only within the NHZ. The total hazard evaluation procedure shall consider all aspects.

4.4.1 NHZ. The NHZ describes the space within which the level of direct, reflected or scattered radiation exceeds the applicable MPE during normal operation. The LSO determines the NHZ from safety information supplied in the manufacturer's labeling, by measurement, by using an appropriate analysis or other equivalent assessment, or by designating the entire room in which the laser is used as the NHZ. The LSO shall ensure that suitable safety practices and procedures are maintained within the NHZ. Under some conditions, the LSO may determine that control measures are required within the entire LTCA defined in 4.4.2. Such situations may arise when movement of people in and out of the NHZ may be anticipated (ANSI Z136.1-2014, Appendix A3). In other conditions, the LSO may determine that control measures are not required within the entire LTCA. Such situations may arise when lasers are used endoscopically as defined in 4.6.2.1.3, or when the lasers in use are outside of the range of retinal hazards.

In establishing the NHZ, the LSO shall ensure that consideration is given to direct, reflected and scattered radiation transmission through open doors or transparent windows, as well as the possibility of equipment malfunction (e.g., fiber breakage) or the intrusion of unauthorized, unprotected people. Viewing the main beam or a specular laser target in the wavelength range of 310 nm to 2800 nm, or even to 4000 nm in rare cases, with an optical instrument or magnification eyewear, endoscope, colposcope or microscope, is potentially hazardous due to the instrument's light-gathering and transmission capability. Use of such

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optical systems without laser-safety filters may therefore effectively increase the NHZ boundaries and shall be considered in the overall hazard analysis.

4.6.1 General. Protective equipment in the form of goggles, spectacles, face shields, barriers, or windows can provide eye protection. Clothing, gowns, gloves and other devices can provide suitable skin protection against laser radiation and biologic hazards. PPE is administratively required and shall be used by all people within the NHZ when a Class 3B or Class 4 laser is operating. PPE is considered the last line of defense against laser and biologic hazards and shall be used when mitigation of laser hazards cannot adequately be performed using engineering or procedural controls

4.6.2.1.2 Eyewear for Fiberoptic Procedures. LPE shall be worn whenever the distal end of the fiber is open and exposed and a potential hazard exists that exceeds the MPE within the NHZ (e.g., dental and dermatologic procedures). In cases where it is reasonably foreseeable that fibers may break or become disconnected during HCLS procedures, thereby resulting in a potential ocular hazard, everyone within the NHZ shall wear LPE.

A distinction should be made between unprotected fibers, such as raw fibers or fiber optic probes, and permanently attached armored fibers used as part of an optical delivery system. In such cases, where the fiber optic component of the delivery system is armored and permanently attached or attached to an interlocked port, it is not necessary to declare the entire room an LTCA and require LPE.

4.6.2.1.3 Eyewear for Endoscopic Procedures. Because of improved fiber design and the reduced frequency of fiber breakage, the LSO may determine that the use of LPE during an endoscopic procedure is not required. If procedural controls are sufficient, as determined by the LSO to limit accidental exposure during endoscopic procedures, the LSO may determine that LPE is not needed.

4.6.2.1.4 Microscopes and Other Optical Viewing Instruments. The laser target site may be viewed by instruments such as operating microscopes, indirect ophthalmoscopes, endoscopes, and slit-lamp microscopes. Appropriate protective filters shall be properly placed to ensure that all potential viewing paths are protected, or LPE shall be worn by persons viewing through accessory viewing ports not protected by filters incorporated into the equipment.

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I also referred the question to David Sliney, PhD, what as you may know is internationally regarded for his expertise relative to eye hazards and assessments, and who is a member of TSC-4, and who also participated as a representative of ASLMS to SSC3 and Z136. His email response and attachment is appended below.

Assessment/Correspondence from David Sliney, PhD (2/3/18):

Ray:

This is tragic misunderstanding. I suspect that the manufacturer's calculations made use of a 10-second or longer direct viewing of the fiber tip; whereas, in a fiber break the ends would move and only momentary accidental exposure might take place, where the NOHD would be much shorter. IEC only requires single-fault conditions be considered in setting up an entire laser system. So, a breakage is a single fault, whereas the break in close proximity of the eye within that 1 meter distance and the person stabilize their position relative to the break to be exposed above the MPE is not reasonably foreseeable. There is probably no risk whatsoever of anyone actually being injured when one considers the safety factors, etc. I think it would be a sad development to remove that sentence. LSOs need to have the latitude to use sound judgement instead of feeling that they have to assume the worst-case of the worst-case of the worst-case....etc.

David S.

At the end of the day, the LSO can make the determination based on the available facts and conditions. We have attempted to provide the LSO with information upon which a cogent decision can be reached.