



Date: 1 November 2016
Memo to: Alex Fraser, Ph.D.
From: Tom Lieb, SSC-9 Chair
Subject: ANSI Z136.9-2013, clause 4.4.2.1.2

Question

This inquiry was submitted 12 August 2016 and subsequently deemed an explanation:

Does this area warning system only need to interlock with the laser power supply or beam shutter upon entry in the zone or does it also need to prevent the laser to be restarted if someone is still present in the zone (by another person outside the zone for example).

Answer

The latter. The purpose of these interlock systems is to prevent access to the laser hazard (above Class 1) during operation. By definition, then, the prevention must be continuous during all the time a person is within the potentially hazardous zone, and include the prohibition of re-starts by the person inside or others (there can be exceptions for service personnel performing tests).

Explanation

The clause addresses engineering control measures for a Class 1 system that has an embedded Class 3B or Class 4 laser within. These engineering measures *"shall be designed to interlock with the laser power supply or laser beam shutter so as to prevent access to laser radiation above the applicable MPE"*.

Additionally, it is important to remember that as a Class 1 laser system, human access to exposure above the applicable MPE (AEL in 21 CFR 1040.10 Laser Policy Notice #37) for a walk-in enclosure must be prevented by engineering control measures. To satisfy the safe use requirements of a Class 1 laser system, the safety sensors and interlock are to remain active (preventing emission) while the enclosure is opened and/or while a person is present within the applicable NHZ.

ANSI Z136 standards are USER SAETY documents and do not set the requirements for equipment. Nevertheless, as described in Clause 4.4.1, a laser system that has been built to comply with applicable **product and equipment safety regulations** (e.g. U.S. 21CFR1040.10, IEC 60825-1) and standards (e.g. CSA E60825-1:15) will facilitate their safe use in manufacturing environments. For your reference, attached is a copy of the FDA/CDRH Laser Policy Notice 37, which is interpretive of the 21 CFR 1040.10 mandatory Federal Laser Performance requirements, and discusses the principles and objectives for designing safeguards for walk-in laser enclosures.

Additional Note: ANSI Z136.9-2013 is a consensus standard for laser safe use in manufacturing environments, its mandate is not to prescribe laser equipment build safety performance measures. Informative Appendix D provides guidance regarding this. Ref. D2. *"LSOs, and especially LSOs of facilities that incorporate lasers or laser systems into apparatus for use in the facilities, are strongly recommended to obtain copies of the applicable **laser product standards**. Furthermore, the listing of control measures in this appendix is only a listing and should not be a substitute for the more detailed requirements stated in the standards."*



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