May 2019
JEH/HHU

ZVEI Information and Action Recommendation for Manufacturers and Users of Laser Products

Handling of the discrepancy between the limit values of the laser safety standard EN 60825-1:2014 and the occupational health and safety Directive 2006/25/EC "Artificial optical radiation".

Introduction

Electrical and electronic products with laser functions (hereinafter referred to as "laser products") must comply with the relevant European product safety Directives when they are placed on the market. For a large number of products, this is the Low Voltage Directive 2014/35/EU. If these products are work equipment, they may only be used if they pose no risk to the worker at the workplace. For laser products, the employer must therefore carry out a risk assessment in accordance with Directive 2006/25/EC and, if necessary, take appropriate protective measures.

In the past, EN 60825-1:2007 could be used for the classification of laser products both by the manufacturer and by the employer, because this standard was based on the same set of limit values as used in Directive 2006/25/EC. EN 60825-1:2014 is also giving the presumption of conformity under the Low Voltage Directive and is therefore generally used by manufacturers for their product development.

Discrepancy in limit values between new standard EN 60825-1:2014 and Directive 2006/25/EC

Until 2014, EN 60825-1:2007 and 2006/25/EC were based on identical calculations and limit values of the *ICNIRP guidelines* of 2000. ICNIRP, the *International Commission on Non-Ionizing Radiation Protection,* is a group of independent scientists recognised by the WHO and the *International Labour Organisation (ILO).*

In 2013 ICNIRP published new limit value recommendations, which were incorporated in EN 60825-1:2014. The standard is listed in the Official Journal of the EU under the Low Voltage Directive 2014/35/EU and leads to a presumption of conformity. On the other hand, there is no longer any presumption of conformity for the superseded standard. However, the basic principles of occupational health and safety apply unchanged according to the status of 2000, so that the employer cannot use the manufacturer's classification according to EN 60825-1:2014 for risk assessment at the workplace.

It should be noted that a large number of other product standards (e.g. from the EN 62368 or EN 60947 series) also refer to the new EN 60825-1:2014 for the aspect of

ZVEI - German Electrical and Electronic Manufacturers' Association - Lyoner Straße 9 - 60528 Frankfurt/Main, Germany
innovation policy
Phone: +49 69 6302-393 - Fax: +49 69 6302-234 - E-mail: huhle@zvei.org

President: Michael Ziesemer - Chairman of the Management Board: Dr. Klaus Mittelbach

laser safety or will do so in the near future. This means that also for products under these standards the employer cannot use the indicated laser classification for his risk assessment according to the occupational health and safety Directive.

Evaluation

An adaptation of the European OH&S Directive 2006/25/EC to the new state of the art would be urgent and desirable, but cannot be foreseen at present. The limit values of EN 60825-1:2014 are based on the current ICNIRP recommendations and thus correspond to the state of the art of science and technology. Laser products of Class 1 and Class 2 according to EN 60825-1:2014 are therefore considered safe products in the sense of the European product safety Directives, regardless of whether they are used as consumer products or as work equipment. An obvious and practicable approach for the risk assessment of laser products at the workplace would be to use the product classification according to EN 60825-1:2014, as this corresponds to the state of the art of science and technology and the worker is not at risk for laser products of Class 1 and Class 2, even if the exposure limit values of Directive 2006/25/EC are exceeded. From a legal point of view, however, the obsolete exposure limit values of Directive 2006/25/EC represent the official basis for the risk assessment, which makes this approach inadmissible and results in the recommended action described below.

Recommendation for action to manufacturers and employers

According to the Low Voltage Directive 2014/35/EU, the manufacturer is obliged to carry out a conformity assessment before placing a product on the market. For the manufacturer, the indication of the laser class results from the application of standard EN 60825-1:2014. Employers, on the other hand, are dependent on the classification according to the older standard EN 60825-1:2007 for occupational health and safety measures due to the EC Directive on artificial optical radiation at the workplace 2006/25/EC.

If, in the case of a laser product for professional use, the manufacturer's classification according to EN 60825-1:2014 differs from that which an employer must use according to EN 60825-1:2007 for the risk assessment at the workplace, the manufacturer should draw attention to this fact. This can be done in the operating instructions, for example, with the following wording:

Note for employers:

This laser product has laser Class X according to the manufacturer assessment based on the Low Voltage Directive 2014/35/EU in conjunction with the currently valid standard EN 60825-1:2014, which is applicable to manufacturers when placing the product on the market. Due to deviating legal requirements in occupational health and safety according to Directive 2006/25/EC, this product must be evaluated according to the older standard EN 60825-1:2007. Employers must therefore instead use laser Class Y as basis for occupational health and safety measures.