BS ISO 12609-2:2013

BSI Standards Publication

Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications

Part 2: Guidance for use

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National foreword

This British Standard is the UK implementation of ISO 12609-2:2013. It supersedes BS 8497-2:2008 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee PH/2, Eye protection.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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INTERNATIONAL STANDARD

ISO 12609-2

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Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications —

Part 2: Guidance for use

Équipements ophtalmiques de protection contre les sources lumineuses intenses utilisées sur les animaux et les humains pour des applications médicales et cosmétiques —

Partie 2: Directives d'utilisation

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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The committee responsible for this document is ISO/TC 94, *Personal safety – Protective clothing and equipment*, Subcommittee SC 6, *Eye and face protection*.

ISO 12609 consists of the following parts, under the general title *Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications*:

— *Part 1: Specification for products*

— *Part 2: Guidance for use*

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INTERNATIONAL STANDARD ISO 12609-2:2013(E)

Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications —

Part 2: Guidance for use

1 Scope

This International Standard gives guidance and information to users, manufacturers, suppliers, and safety advisors on the selection and use of eye protectors for intense light source (ILS) equipment used on humans and animals for cosmetic and medical applications against excessive exposure to optical radiation in the spectral range 250 nm to 3 000 nm, with the exception of laser radiation.

This International Standard provides guidance on selection of an eye protector expected to cope with the majority of applications and a more rigorous procedure for determining appropriate eye protection against spectral outputs from ILS equipment.

This International Standard is not applicable to eye protectors for use with tanning equipment, ophthalmic instruments, or other medical/cosmetic devices, the safety issues of which are addressed through other European and International Standards.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
attenuation
decrease in the irradiance or radiant exposure as optical radiation passes through an absorbing or scattering medium

2.2
exposure limit values
ELVs
level of exposure to the eye or skin that is not expected to result in adverse biological effects

2.3
intense light source
ILS
device incorporating one or more non-laser sources of optical radiation of the wavelength range 250 nm to 3 000 nm and intended for creating biological effects in humans and animals

Note 1 to entry: It can operate in continuous or pulsed regime.

2.4
ocular hazard distance
OHD
distance at which the beam irradiance, radiance, or radiant exposure equals the appropriate ocular ELVs

2.5
pulse duration
time increment measured between the half peak (50 %) of power points at the leading and trailing edges of a pulse

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2.6
pulse separation
time between the end of one pulse and the onset of the following pulse, measured at the 50 % trailing and leading edges

2.7
skin hazard distance
distance at which the beam irradiance or radiant exposure equals the appropriate skin ELVs

3 Optical radiation hazards

3.1 Risk assessment

3.1.1 The eye is at risk of injury from optical radiation in excess of the exposure limit values (ELVs) (see Annex A). A comparison of the predicted or measured radiation exposure with the applicable ELVs allows an assessment of a personal workplace exposure to optical radiation.

3.1.2 The risk assessment should include the following.

a) Determine the ELVs for exposure duration, type of hazard, and emitting device configuration.

b) Determine the likely exposure level from the ILS taking account of the exposure scenario, e.g. expected use or foreseeable fault conditions.

c) Compare the likely exposure levels with the ELVs.

3.1.3 If other measures are insufficient or inadequate to control the risk of eye exposure in excess of any applicable ELVs, eye protection should be worn. The appropriate F-#, B-#, and/or filter protection factor should be determined at a distance of 200 mm from the ILS. If such eye protection is not available, a calculation using measured spectrally weighted radiance or irradiance has to be carried out in order to verify the suitability of a specific eyewear for a specific ILS source.

NOTE Personnel who might be at risk include the patient/client, ILS equipment operator, assisting staff, and others.

3.1.4 See Annex B for a retinal thermal hazard assessment and Annex C for a worked example calculation.

3.2 Control measures

3.2.1 Any person who is present within the ocular and skin hazard distance should be protected against eye or skin exposure to optical radiation above any applicable ELVs.

3.2.2 The extent of the skin and ocular hazard distance might vary according to the type of ILS equipment used and the optical properties of the output optics attachments.

3.2.3 Exposure to optical radiation should be reduced, as far as reasonably practicable, by means of physical safeguards, such as engineering controls. Personal protection should only be used when engineering and administrative controls are impracticable or incomplete, in accordance with Figure 1.

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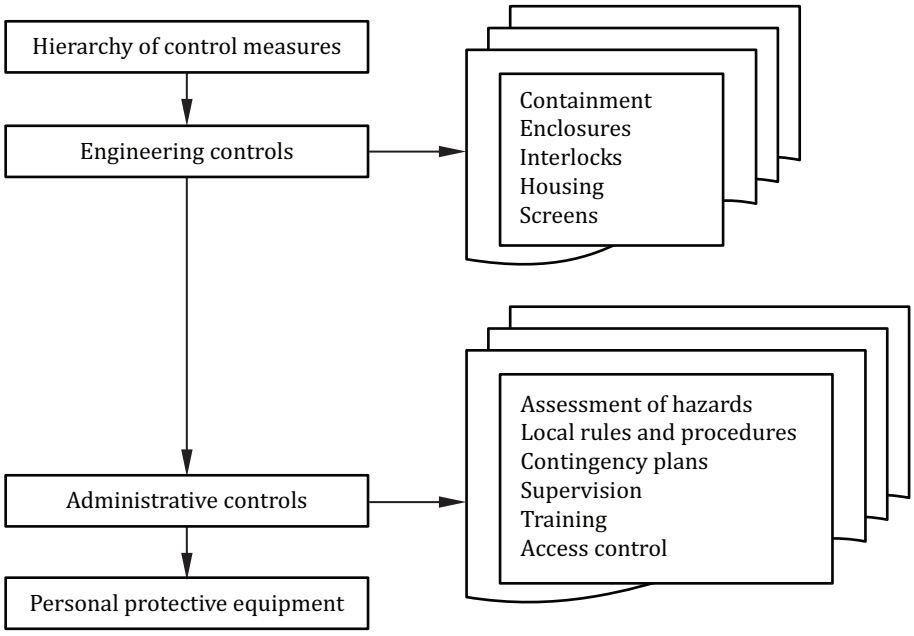

Figure 1 — Hierarchy of control measures

4 Eye protection

4.1 Protective eyewear

4.1.1 Reduction of unintended exposure should be included in the design specifications of the ILS equipment. Exposure to optical radiation should be reduced, as far as reasonably practicable, by means of physical safeguards, such as engineering controls.

4.1.2 When the treatment region is close to the eye, the patient's or client's protective eyewear should be selected carefully, as there will be a significant risk of exposure in excess of the ELVs. Consideration should also be given to the good fit of safety eyewear to prevent penetration of optical radiation from around the frame.

4.1.3 Different types of eye protection might be required for patients/clients, ILS equipment operators, and supporting personnel.

4.1.4 An unambiguous and robust method of marking the ILS protective eyewear should be employed to ensure that there is a clear link to the particular ILS equipment device for which it has been specified, and to facilitate this, a simplified classification scheme has been introduced.

4.1.5 A checklist to help select protective eyewear for the patient/client is given in Annex D.

4.1.6 A checklist to help select protective eyewear for the operator is given in Annex E.

4.2 Filter protection factor (FPF)

4.2.1 ELVs should be used to determine the required attenuation level of ILS protective filters because they refer to effective, i.e. spectrally weighted, values.

4.2.2 Optical density or shade numbers should not be used for the characterization of ILS protective filters as they do not take into account the difference in the effect of different wavelengths on the eye.

4.2.3 FPF is a factor by which the protective filter attenuates the weighted ocular exposure. If the risk assessment demonstrates that ocular exposure limits are exceeded, the FPF of the protective eyewear

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