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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

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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*

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

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.

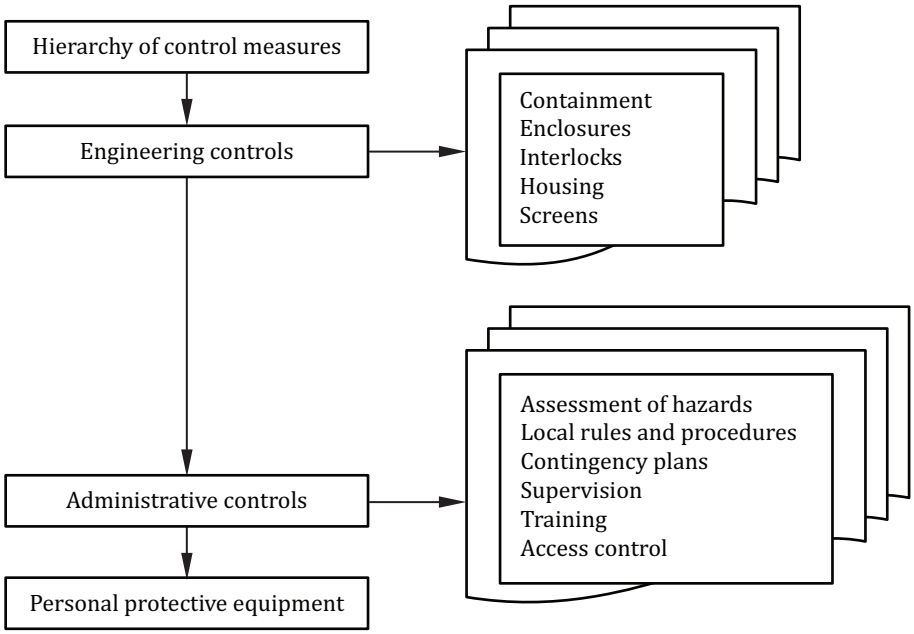

Figure 1 — Hierarchy of control measures

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

should be adequate to ensure the exposure limit is not exceeded (see Annex F). This excess factor is likely to be different for a patient/client and operator; therefore, the FPF of protective eyewear for patient and operator would be different.

4.3 Luminous transmittance and colour perception

4.3.1 The luminous transmittance and the colour of the environment as seen through ILS protective filters (perceived colour) are important characteristics of protective eyewear which enable the operator to perform treatment without compromising non-optical radiation safety (see Annex G and Annex H).

4.3.2 Perceived colour depends on the spectral characteristics of the protective filter and illumination source. Thus, treatment might be performed under general light conditions (white light) or operating procedures might require an operator to observe the patient/client and control the equipment illuminated with radiation from ILS equipment.

In these two cases, the colour of the environment (for example, equipment controls and blood) might appear different when seen through the same protective eyewear.

4.3.3 Colour is described as a (x, y) Commission Internationale de L'Eclairage (CIE) colour coordinate and might be presented in a CIE chromaticity chart (see Annex H). The (x, y) CIE coordinates take into account spectral characteristics of the filter and illumination source.

5 User comfort and secondary safety issues

5.1 Peripheral leakage

Consideration should be given to the good fit of safety eyewear to prevent penetration of optical radiation from around the frame. This should be tested using a bright light prior to each use.

NOTE A patient's aversion response might be altered due to anaesthesia, sedation, or other drugs.

5.2 Secondary reflections from eyewear frame and filters

Secondary reflections from frames or filters of protective eyewear might increase the risk of uncontrolled exposure of the user or others; therefore, mirror-finish or high gloss filters and frames should not be used.

5.3 Quality of filters and clarity of vision

5.3.1 Quality of filters of protective eyewear and clarity of vision should not limit the intended use of the ILS equipment; therefore, these characteristics are essential for an operator and unimportant for a patient/client. Patient/client protective eyewear may be opaque.

5.3.2 Filters of operator's eyewear should be free from any material or surface defects which are likely to impair the intended use, such as bubbles, scratches, inclusions, dull spots, scoring, excessive colouration, or other defects.

5.4 Exposure to bright flashes below ELVs

5.4.1 For lower exposure levels (below ELVs), visual effects due to the temporary visual impairment might pose secondary safety hazards. Transient visual effects include disability (dazzle or veiling) glare, discomfort glare, startle (distraction), and after-images (flash blindness) (see Annex A).

5.4.2 Exposure to bright flashes cannot be corrected by the passive attenuation filters because passive filters attenuate ambient and flash level simultaneously. To reduce this exposure, auto darkening protective filters should be considered.

5.4.3 Precautions should be taken against secondary safety hazards resulting from a temporary reduction in vision.

5.5 Overheating of eyewear

5.5.1 Excessive heating of eyewear frame and filters by absorbed radiation might cause ocular or cutaneous thermal damage in contact, especially for the patient/client.

5.5.2 The maximum temperature rise should not exceed 5 °C for the duration of treatment.

5.6 Additional considerations for auto darkening filters

Auto darkening filters of protective eyewear exhibit (directly or indirectly, by applied voltage) a change of transmittance in response to exposure to optical radiation. Consideration should be given to the response time of the active filter to ensure that it is appropriate for the ILS in use.

Annex A
(informative)

Ocular exposure to optical radiation

A.1 Exposure limit values (ELVs)

NOTE Attention is drawn to the ICNIRP Guidelines.[11][12]

ELVs represent upper limits on exposure of the eye or skin that is not expected to result in adverse health effects. ELVs are set on the basis of experimental evidence and take into account uncertainties of that evidence. These levels are related to the wavelength of the radiation, the pulse duration or exposure time, the tissue at risk, and, for radiation in the range of 380 nm to 1 400 nm, the size of the retinal image.

The limits for exposure require knowledge of the spectral radiance and/or irradiance of the source, measured at the position of the eye or skin of the exposed person. Because ILS equipment can emit radiation as a series of pulses in a broad spectrum, calculation of the hazards can be complex.

To facilitate this, a simplified classification scheme has been introduced.

The ocular hazard distance (OHD) should be taken into account when specifying the boundaries of the controlled area within which the access to optical radiation and activity of personnel is subject to control and supervision for the purpose of protection from optical radiation.

A.2 Exposures below ELVs

For lower exposure levels (below ELVs), visual effects due to temporary visual impairment might pose secondary safety hazards (see 5.4).

Exposure to near UV/blue wavelength sources at exposure levels below ELVs, according to existing guidance, can induce a fluorescence in the lens of the eye with veiling glare intense enough to degrade visual performance and impair vision at normal indoor lighting levels.

Discomfort glare can develop in working environments where people are exposed to high luminance sources for long periods and might result in loss of visual efficiency. Discomfort glare depends on source brightness and the general field brightness controlling the adaptation level of the observer. CIE 117 recommends the "glare constant" numerical scale as a criterion of discomfort glare, with 150 considered as "just uncomfortable".

To reduce discomfort glare, the use of auto darkening filters should be considered.

The relationship between the lighting of the work area and adjacent areas is also important. Large differences in brightness between the lighting of the work area and adjacent areas might cause visual discomfort or even compromise safety. The maximum recommended ratio of brightness of work area to adjacent areas is 10:1. If this ratio is above 10:1, consideration should be given to additional protective measures.

A.3 Example of an optical radiation hazard

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

Annex B
(informative)

Retinal thermal hazard — Assessment flowchart

The flowchart may be used when the required F-# and/or B-# is not supplied.

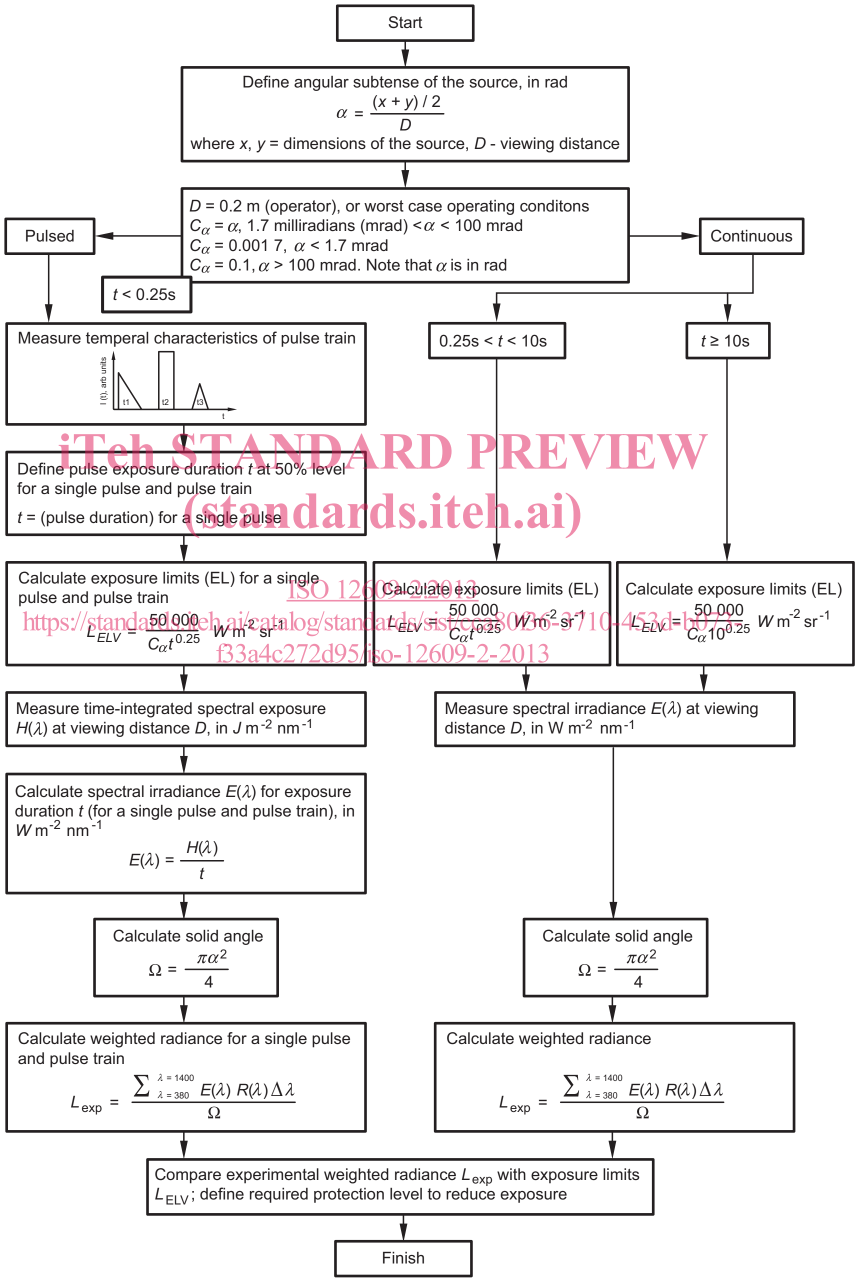
Start
Define angular subtense of the source, in rad
α = (x + y) / 2 / D
where x, y = dimensions of the source, D - viewing distance
D = 0.2 m (operator), or worst case operating conditons
Cα = α, 1.7 milliradians (mrad) < α < 100 mrad
Cα = 0.001 7, α < 1.7 mrad
Cα = 0.1, α > 100 mrad. Note that α is in rad
Pulsed
Continuous
t < 0.25s
Measure temperal characteristics of pulse train
0.25s < t < 10s
t ≥ 10s
Define pulse exposure duration t at 50% level for a single pulse and pulse train
t = (pulse duration) for a single pulse
Calculate exposure limits (EL) for a single pulse and pulse train
L_ELV = 50 000 / Cα t^0.25 W m^-2 sr^-1
Calculate exposure limits (EL)
L_ELV = 50 000 / Cα t^0.25 W m^-2 sr^-1
Calculate exposure limits (EL)
L_ELV = 50 000 / Cα 10^0.25 W m^-2 sr^-1
Measure time-integrated spectral exposure H(λ) at viewing distance D, in J m^-2 nm^-1
Measure spectral irradiance E(λ) at viewing distance D, in W m^-2 nm^-1
Calculate spectral irradiance E(λ) for exposure duration t (for a single pulse and pulse train), in W m^-2 nm^-1
E(λ) = H(λ) / t
Calculate solid angle
Ω = πα² / 4
Calculate solid angle
Ω = πα² / 4
Calculate weighted radiance for a single pulse and pulse train
L_exp = Σ_{λ=380}^{λ=1400} E(λ) R(λ) Δλ / Ω
Calculate weighted radiance
L_exp = Σ_{λ=380}^{λ=1400} E(λ) R(λ) Δλ / Ω
Compare experimental weighted radiance L_exp with exposure limits L_ELV; define required protection level to reduce exposure
Finish

Figure B.1 — Flowchart for the assessment of retinal thermal hazard