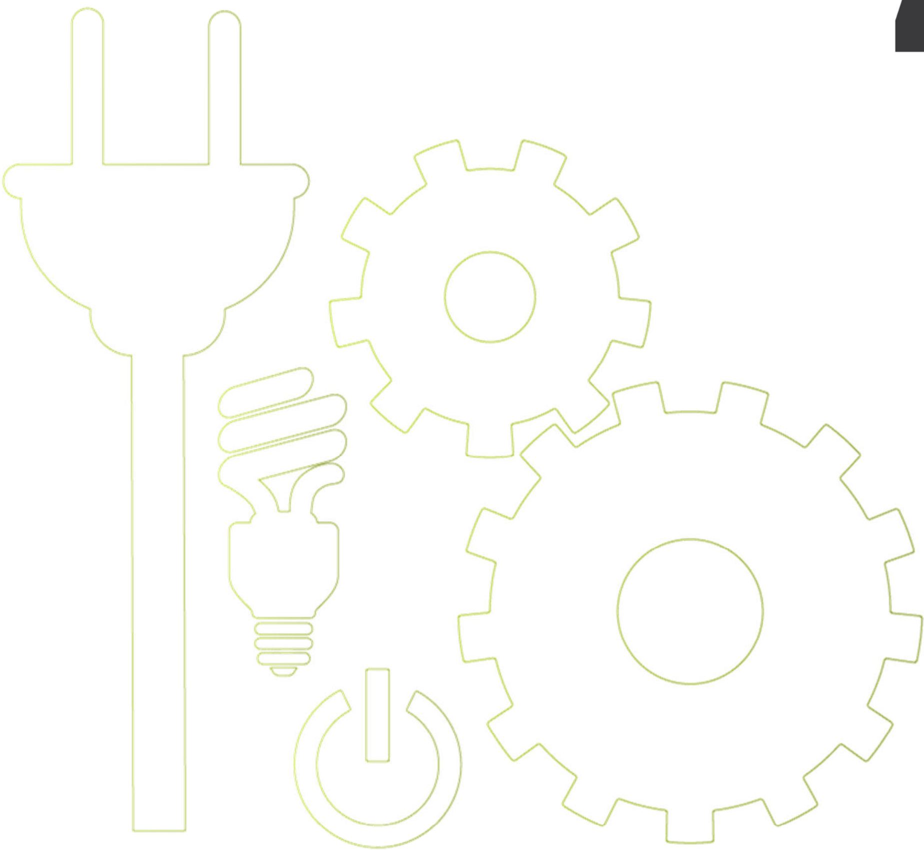
Energy Efficient End-use Equipment
International Energy Agency



Solid State Lighting Annex: Potential Health Issues of SSL

FINAL REPORT

Energy Efficient End-Use Equipment (4E)
International Energy Agency

SSL Annex Task 1

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Solid State Lighting Annex – Potential Health Issues of Solid State Lighting Final Report

This report was prepared by International Energy Agency 4E Solid State Lighting Annex Task 1

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About the IEA 4E Solid State Lighting Annex

The SSL Annex was established in 2010 under the framework of the International Energy Agency's Energy Efficient End-use Equipment (4E) Implementing Agreement to provide advice to its member countries seeking to implement quality assurance programs for SSL lighting. This international collaboration brings together the governments of Australia, Denmark, France, Japan, The Netherlands, Republic of Korea, Sweden, United Kingdom and United States of America. China works as an expert member of the 4E SSL Annex. The SSL Annex closed its first term in June 2014 and started on its second five-year term in July 2014. This report is part of the final reporting from the Annex's first term. Further information on the 4E SSL Annex is available from: http://ssl.iea-4e.org/

About the IEA Implementing Agreement on Energy Efficient End-Use Equipment (4E)

4E is an International Energy Agency (IEA) Implementing Agreement established in 2008 to support governments to formulate effective policies that increase production and trade in efficient electrical end-use equipment. Globally, electrical equipment is one of the largest and most rapidly expanding areas of energy consumption which poses considerable challenges in terms of economic development, environmental protection and energy security. As the international trade in appliances grows, many of the reputable multilateral organisations have highlighted the role of international cooperation and the exchange of information on energy efficiency as crucial in providing cost-effective solutions to climate change. Twelve countries have joined together to form 4E as a forum to cooperate on a mixture of technical and policy issues focused on increasing the efficiency of electrical equipment. But 4E is more than a forum for sharing information – it initiates projects designed to meet the policy needs of participants. Participants find that pooling of resources is not only an efficient use of available funds, but results in outcomes which are far more comprehensive and authoritative. The main collaborative research and development activities under 4E include:

- Electric Motor Systems (EMSA)
- Mapping and Benchmarking
- Solid State Lighting (SSL)
- Electronic Devices and Networks

Current members of 4E are: Australia, Austria, Canada, Denmark, France, Japan, Korea, Netherlands, Switzerland, Sweden, UK and USA. Further information on the 4E Implementing Agreement is available from: www.iea-4e.org

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Acronyms and Abbreviations

4E	Energy Efficient End-use Equipment
ACGIH	American Conference of Governmental Industrial Hygienists
ANSES	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (French Agency for Food, Environmental and Occupational Health & Safety)
ARMD	Age Related Macular Degeneration
CCT	Correlated Color Temperature
CEN	Comité Européen de Normalisation (European Committee for Standardisation)
CENELEC	Comité Européen de Normalisation Électrotechnique (European Committee for Electrotechnical Standardisation)
CFL	Compact Fluorescent Lamps
CIE	Commission Internationale de l´Eclairage (International Commission on Illumination)
CRI	Colour Rendering Index
E_B	Blue light hazard irradiance
EL	Exposure Limits
ELV	Exposure Limit Value
EMF	Electromagnetic Field
EU	European Union
FI	Flicker Index
FOV	Field of View
GR	Glare Index
HF	High Frequency
Hz	Hertz
ICNIRP	International Commission for Non-Ionizing Radiation Protection
IEA	International Energy Agency
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers (North America)
IESNA	Illuminating Engineering Society of North America
ipRGC	Intrinsically photosensitive retinal ganglion cells
IR	Infrared Radiation
L_B	Blue light hazard radiance
LED	Light Emitting Diode
PWM	Pulse Width Modulation
RPE	Retinal Pigment Epithelium
SAD	Seasonal Affective Disorder
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCN	Suprachiasmatic Nucleus
SSL	Solid State Lighting
TI	Threshold Index (disability glare)
UGR	Unified Glare Rating
USA	United States of America
UV	Ultra Violet

Executive Summary

This report addresses the issues of the potential effects of solid-state lighting (SSL) products on human health. This work mainly focuses on glare issues, photobiological effects caused by the optical radiation on the eye and the skin, flickering phenomena and non-visual effects of light, such as the effects on the circadian rhythm and the biological clock. The recommendations of the experts of the 4E-SSL Annex are summarised below.

Electrical risks

The experts consider that the electrical safety of SSL products is appropriately addressed by the compliance with the relevant regional or international electrical safety standards.

Exposure to electromagnetic fields (EMF)

The experts consider that the human exposure to EMFs emitted by SSL products is not a critical issue as their magnitude is generally much smaller than the one corresponding to discharge lamps and a number of household appliances.

Glare

When high luminance LED components are visible by the users, glare can be a critical issue in SSL products. Glare does not constitute a risk in itself but it is a source of discomfort and reversible temporary visual disability that may be indirectly responsible for accidents and injuries. In indoor lighting, glare is assessed by the Unified Glare Rating (UGR) method. However, the UGR method is not applicable to point sources such as visible LEDs incorporated in a luminaire. Lighting manufacturers and designers should not perform UGR calculations on SSL luminaires having visible LED point sources, as this approach can be misleading and yield low UGR values, thereby underestimating the physiological perceived glare. The use of the UGR method should be restricted to SSL products with large diffusers, without any point sources. It is recommended that the maximum luminance of the SSL finished products is specified, whether they incorporate visible LED point sources or not. The luminance ratio between the light source and the background should be computed and adapted to each lighting installation according to visual ergonomics criteria.

Photobiological hazards

A photobiological safety assessment should be carried out for all SSL devices (LEDs, LED modules, LED lamps, LED luminaires, etc.) using the joint CIE S009 / IEC 62471 standard. Following the guidelines of IEC TR 62778, LED manufacturers should report the risk group of their component (RG0, RG1 or RG2).

According to IEC TR 62778, it is sometimes possible to transfer the risk group of an LED to a higher product that incorporates it. In the case of RG2 devices, it is advised that the manufacturer provides the boundary between RG1 and RG2 by reporting the threshold illuminance and the threshold distance, which can be viewed as a reasonable safety distance.

When an RG2 product can be viewed below the threshold distance, it should be labelled according to IEC TR 62471-2, in order to inform the user not to stare at the operating lamp as it may be harmful to the eyes. At the time of this writing, the general public is not aware of potential risks for the eye. It is expected that the application of the labelling system of IEC TR 62471-2 (warning in the case of RG2) will become mandatory in some economies. At the time of preparing this document, no mandatory labelling system was in place for RG2 lighting products.

For SSL products aimed at consumer applications (retrofit LED lamps for instance), the experts recommend the limitation of the risk group to RG1 at 200 mm, which can be considered as the shortest viewing distance encountered at home.

The next revision of IEC 62471 should take into account the sensitivity of certain specific population groups, which can be characterized by an accrued sensitivity to visible light, such as people having pre-existing eye or skin condition, aphakics (people with no crystalline lens), pseudophakics (people with artificial crystalline lenses), children and elderly people as their skin and eyes are more sensitive to optical radiation.

The photobiological standards relative to lighting systems should be extended to cover children less than two years old by taking into account the corresponding aphakic phototoxicity curve published by the International Commission for Non-Ionizing Radiation Protection (ICNIRP) in its guidelines.

Certain categories of workers (lighting engineers, stage artists, etc.) are exposed to high doses of artificial radiation emitted by SSL products during their daily activities. Since the damage mechanisms are not yet fully understood, exposed workers should use appropriate individual means of protection as a precautionary measure (glasses filtering out blue and violet light for instance). The experts recommend the development of personal protective equipment against the blue light hazard resulting from exposure to SSL products and other artificial light sources.

New generations of LEDs emitting white light are currently being developed using violet and UV chips. The photobiological safety of these LEDs and the products using them should be carefully assessed because of potential residual UV and violet radiation in the emission spectrum. The assessment should be conducted for the blue light hazard and UV hazards as well. A careful assessment of the aging of these products should also be conducted as the possible degradation of the luminophores may raise the level of short wavelength radiation, thereby increasing the retinal exposure levels.

Light flicker

Flicker is the modulation of the optical output of a light source. A known effect of flicker is to induce seizures in patients suffering from photosensitive epilepsy. For the general population, flicker may induce a range of symptoms ranging from headaches, migraines and dizziness to impaired visual performances.

SSL products such as LED lamps have a completely arbitrary behaviour in terms of light flicker. Some of them display no flicker while other devices reach the maximum percent flicker value of 100%.

Whether in Europe, the USA or any other country, there is no clear requirement concerning light flicker limitation, which is clearly unacceptable. The experts recommend that mandatory maximum values are set to limit flicker in SSL products.

Non-visual effects of light

All light has a broad range of non-visual effects that should be taken into account for the design and the use of lighting systems. However, it is not clear whether the artificial lighting design should minimize or maximize them. Light can be used to delay or advance the circadian clock, with both beneficial and undesirable effects that need to be taken into account. This is an issue for all artificial lights, not just LED lighting.

The non-visual effects of light depend on the illuminance level, the exposure duration, the timing of the exposure and the light spectrum. The relationships between these quantities and the non-visual effects are not well established. The experts emphasize that the use of a single "melatonin suppressing action spectrum" to compute light quantities is not suited to describing the physiological mechanisms involved in the regulation of the circadian rhythms.

Keeping the retinal irradiance as low as possible is a general rule that can be given to minimize the non-visual effects of light. Although any wavelength in the visible spectrum can activate the non-visual system, the relative sensitivity of non-visual responses is generally reduced in the longer wavelength range. Light richer in yellow, orange and red colours (low colour temperatures such as warm white light) rather than blue and green colours (high colour temperatures such as cold white light), will be less effective to activate non-visual responses such as the melatonin suppression. Inversely, light sources emitting blue and blue-green components and producing high retinal irradiance can be used to trigger - or enhance - the non-visual effects of light.

In comparison with the other lighting technologies, the SSL technology is not expected to have more direct negative impacts on human health with respect to non-visual effects. However, SSL may indirectly be responsible for an overall increase of light exposure. The low cost of LEDs combined with their form factor and their low energy consumption may cause more lighting points to be installed at home, at work or in the streets, thereby increasing the overall exposure to artificial light and the potential risks linked to non-visual effects such as the perturbation of the biological circadian clock. The experts recommend preserving a dark nocturnal environment while maintaining a suitable exposure level during daytime through a combination of daylight and artificial lighting.

1 Introduction

This report presents an overview of the knowledge concerning the safety and the potential health risks of LEDs and products incorporating LEDs such as SSL products. As with any new or emerging technologies, SSL products should be proven to be at least as safe as the products they intend to replace. In new lighting applications where older technologies could not be employed, the safety of SSL products should be assessed considering new or unusual conditions of usage.

In examining possible impacts of SSL to human health, this report addresses the following categories of potential risks:

- Electrical risks
- Potentials risks due to exposure to electromagnetic fields (EMF)
- Potential risks due to exposure to optical radiations. Several phenomena are concerned:
  - the interactions of the optical radiations with the skin and the eye: photobiological risks
  - the undesired effects of optical radiations on the vision system: glare and light flicker
  - the non-visual effects of optical radiations such as the perturbation of circadian rhythms

Many of these risks are not specific to LED lighting and are matters that are taken into consideration when assessing and developing standards for a range of lighting and electronic products.

In addition to these aspects, many health issues can be indirectly associated with lighting, but not specifically with SSL products. Examples are: injuries caused by insufficient lighting in dangerous areas, car accidents along dark roads, ocular fatigue after reading in a dark environment, etc. Such aspects are directly related to lighting installations that do not comply with well-known visual ergonomics requirements. This report will not address these issues, as they are not specifically associated with lighting from SSL products.

2 Electrical Safety

The electrical safety ensures that an electrical product can be used without presenting risks due to excessive heating or electrical shock.

Electrical safety requirements specific to SSL products have been established by international and regional standardization bodies from the time of their introduction to the market. The principal families of SSL products (self-ballasted and non-ballasted LED lamps, LED drivers, LED modules, LED luminaires) are each covered by an IEC electrical safety standard. As it is the case with many types of electrical products, the safety requirements given by the IEC standards (transposed in Europe by the CENELEC standardization body) become mandatory in Europe in the context of the low voltage directive and the CE marking. Other countries may also draw upon IEC electrical safety standards in developing national safety requirements.

2.1 Recommendations

The experts involved in this Annex consider that the electrical safety of SSL products is best ensured by the compliance with the relevant regional or international electrical safety standards.

3 Exposure to Electromagnetic Field Emission

The emission of electromagnetic fields (EMFs) emitted by SSL and other electrical products occurs when they operate. The LED component itself is not likely to emit a significant amount of EMFs due to its very small size compared to the wavelength corresponding to the modulation frequency of the electrical input current. In comparison, discharge lamps all produce a higher level of electric field because their electrodes are connected to high voltage sources. Replacing compact fluorescent lamps and fluorescent tubes with SSL products should therefore lower the electromagnetic exposure of the users. Several measurement campaigns confirmed this fact on a large number of consumer compact fluorescent lamps (CFL) and LED lamps [GAUDAIRE 2010; MONARD 2010].

In SSL products, the most intense source of EMF is certainly the LED driver which is likely to use HF components and solid-state static converters. The levels of EMF should be comparable with those emitted by electronic transformers used in a range of household appliances.

3.1 Recommendations

The experts involved in this annex consider that the human exposure to EMFs emitted by SSL products is not a critical issue as their magnitude is generally much smaller than the one corresponding to discharge lamps and a number of household appliances.

4 Glare

In a typical LED, the chip that emits light is so small that although the total emitted flux may be moderate, the radiance and luminance levels may be extremely high. For example, luminance values greater than 10^7 cd.m^{-2} and radiance values greater than 50 000 Wm^{-2}sr^{-1} are common figures for white LED components used in lighting products [ANSES 2010]. These values are much higher than the values found in the case of common lamps used in general lighting such as fluorescent lamps (1 000 to 10 000 cd.m^{-2}) and halogen lamps (10^5 to 10^6 cd.m^{-2}).Professional high power lamps such as high intensity discharge lamps also have very high luminance levels but are not used by the general public.

The fact that most LEDs, even low power components, have very high luminance levels has raised concerns about glare, which can be responsible for a discomfort (discomfort glare) or a temporary reduction of visual acuity (disability glare). Disability glare appears with high vertical illuminance levels on the eye (corneal illuminance). Light is scattered in the ocular tissues causing a veiling phenomenon, which can be characterized by a veil luminance. By definition, glare phenomena are temporary and reversible as long as no permanent ocular damage is induced.

Glare is a source of indirect hazards, which are not caused by the light itself. For instance, glare can cause accidents at the work place when machines and tools cannot be safely used. In the everyday life, glare can be the cause of vehicle accidents and falls.

Normalized indices were defined by the Commission Internationale de l'Eclairage (CIE) to characterize the glare of lighting installations. The unified glare rating (UGR) is widely used in indoor lighting as a measure of the discomfort glare. It is related to the luminance ratio of the light source to the luminance of the background. However, the UGR method cannot be applied to very small light sources, whose solid angular subtense is smaller than 0.0003 sr [CIE 1995]. For instance, at a distance of 1 m, the light source must be larger than 1.5 cm x 1.5 cm. Despite this fundamental limitation given by the CIE, lighting manufacturers and designers usually perform UGR calculations on SSL luminaires consisting of multiple small LED sources but incorrectly considering the average luminance over the whole area of the luminaire. This approach is misleading as the resulting UGR is low and does not reflect the physiological perceived glare. Therefore, the use of UGR should be restricted to SSL products with large diffusers, without any visible point sources.

In indoor lighting, luminance classes are often used to define "visually comfortable" luminaires. The luminance classes are not normalized. They correspond to maximal luminance values between 1000 cd.m^{-2} and 5000 cd.m^{-2}, which are relatively low values, only applicable to luminaires fitted with diffusers. It is more accurate to define the visual comfort by using a luminance ratio criterion. For instance, the French standard on visual ergonomics NF X 35-103

[AFNOR 2013] recommends to limit the ratio of the luminaire luminance to the surrounding luminance to a factor between 20 and 80.

Disability glare is often assessed in outdoor lighting, especially for high power installations such as stadium lighting (glare index GR). For street lighting, disability glare is assessed by using the threshold index (TI) which quantifies the reduction of the visual contrast caused by the veil luminance. The disability glare indices GR and TI are applicable to high power luminaires and lighting installations located sufficiently far away from the viewer, whatever the lighting technology.

4.1 Recommendations

Glare can be a critical issue when high luminance LED components are visible by the users. In indoor lighting, glare is assessed by the UGR method. However, the UGR method is not applicable to point sources such as visible LEDs incorporated in a luminaire. Lighting manufacturers and designers should not perform UGR calculations on SSL luminaires having visible LED point sources, as this approach can be misleading and yield low UGR values, thereby underestimating the physiological perceived glare. The use of the UGR method should be restricted to SSL products with large diffusers, without any point sources. It is recommended that the maximum luminance of the SSL finished products is specified, whether they incorporate visible LED point sources or not. The luminance ratio between the light source and the background should be computed and adapted to each lighting installation according to visual ergonomics criteria.

5 Photobiological safety

In addition to the high luminance values, another key feature of LEDs has attracted the attention of lighting specialists and ophthalmologists. The vast majority of commercial LEDs producing white light rely on a chip emitting blue light associated with layers of luminophores to produce light at longer wavelengths by fluorescence. As a consequence, the emission spectrum of a white LED consists of a narrow blue primary peak and a large secondary peak in the yellow-orange-red region. The two peaks are separated by a region of low emission in the blue-green part of the spectrum [BEHAR-COHEN 2011]. In many cases, the blue peak lies in the spectral region corresponding to the highest retinal phototoxicity, as shown in Figure 5—1 and detailed in the following sections.

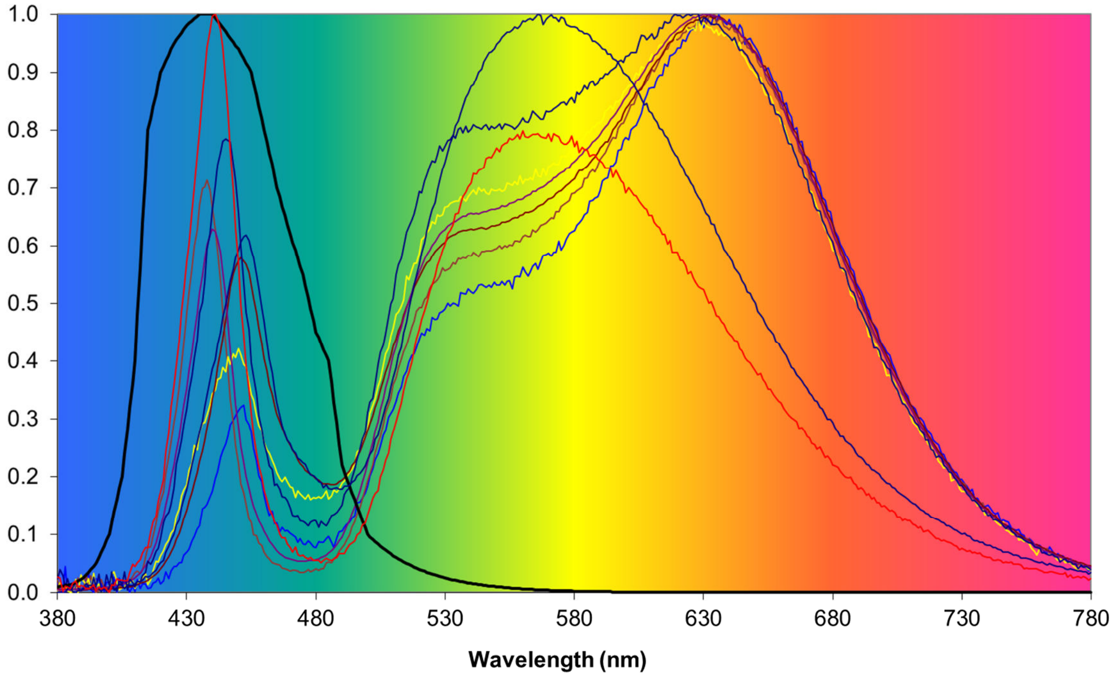


Figure 5—1. Action spectrum B(λ) of the blue light hazard (black curve) and eight examples of LED emission spectra (colored curves), chosen to illustrate the possible coincidence of the short wavelength emission peak with the spectral range of the blue light hazard, maximum at around 437 nm (CSTB data).

Photobiological hazards are related to the effects of optical radiation on the skin and the eye. The international guidelines concerning the human exposure limits to optical radiations are established and regularly updated by ICNIRP (International Commission for Non-Ionizing Radiation Protection). The exposure to incoherent visible and infrared radiation is addressed in [ICNIRP 2013]. The exposure to UV radiation is addressed in [ICNIRP 2004].

In the case of constant light sources (non-pulsed sources), the effects are summarized in the following sub-sections.

5.1 Effects on the skin

The deleterious effects of light to the skin essentially appear in the UV range (for example: erythema, carcinogenesis, aging, melanogenesis, etc.). With visible and infrared radiation, burns can be induced with very high irradiances. LEDs used in SSL are currently far from reaching the high irradiance levels required to burn the skin. Therefore, the general population should not be concerned by potential risks to the skin arising from the use of LEDs in lighting. As it is the case with the very small amount of UV radiation emitted by CFLs, only a small number of people suffering from photosensitive syndromes might see an aggravation of their pre-existing condition triggered by blue light emitted by LEDs. Patients taking photosensitizing drugs should also be aware of a potential risk.

5.2 Effects on the eye

According to the wavelength, optical radiation interacts with different ocular tissues, as Figure 5-2 illustrates.

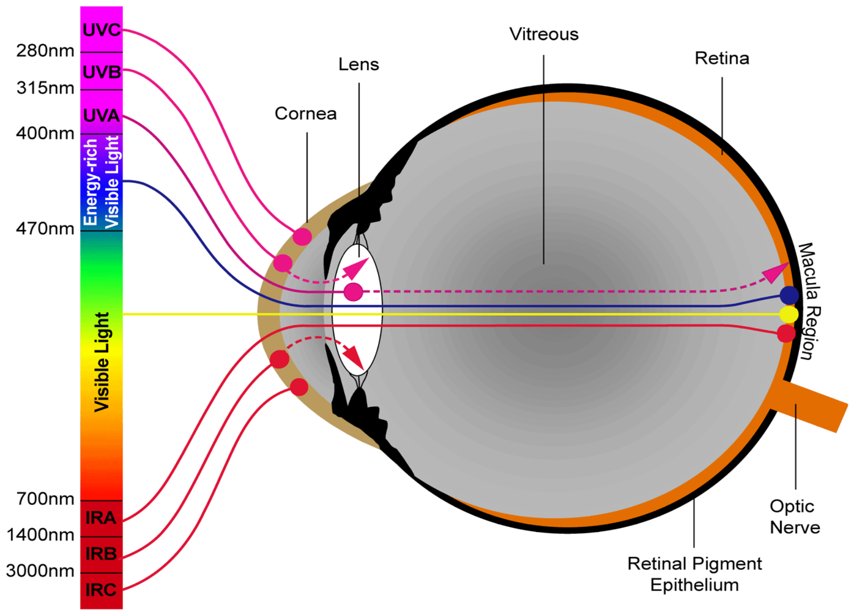


Figure 5—2. Adapted from [BEHAR-COHEN 2011]. Illustration of the different penetration depths of optical radiation in the eye according to the wavelength.

Since UV radiation is mainly absorbed by the cornea and the lens, excessive exposures lead to photokeratitis, photoconjectivitis, and cataracts. Infrared radiation with wavelengths greater than about 1.4 µm are mainly absorbed by the cornea and may induce corneal burns. Emitting negligible amounts of UV and IR radiation, LEDs should not be expected to contribute to the apparition of photokeratitises, photoconjectivitis and cataracts.

Visible light (0.38 µm – 0.78 µm) and near-infrared radiation (0.78 µm – 1.4 µm) are focused on the retina and may induce retinal injuries with excessive exposures, which can be the result of thermal damage or photochemical damage:

- Thermal damage (thermal retinopathy) appears with a short-time exposure to a very high irradiance level inducing a significant temperature change in the retina. The exposure levels needed to produce thermal damage on the retina cannot be met with light emitted by LEDs of current technologies.

- Photochemical damage (photochemical retinopathy) appears either after a short-time intense exposure or after a prolonged exposure to lower light levels in a specific spectral range.

It is important to mention that the retinal exposure to a light source is defined by both the exposure time and the retinal irradiance ($W.m^{-2}$) where the retinal image of the light source is produced by the optical system formed by the cornea and the crystalline lens. The retinal irradiance is proportional to the radiance of the light source ($W.m^{-2}.sr^{-1}$), the transmittance of the ocular media, the pupil diameter and inversely related to the effective focal length of the eye (see Figure 6-3). The exposure dose ($J.m^{-2}$) is the time-integral of the retinal irradiance over the exposure duration [ICNIRP 2013].

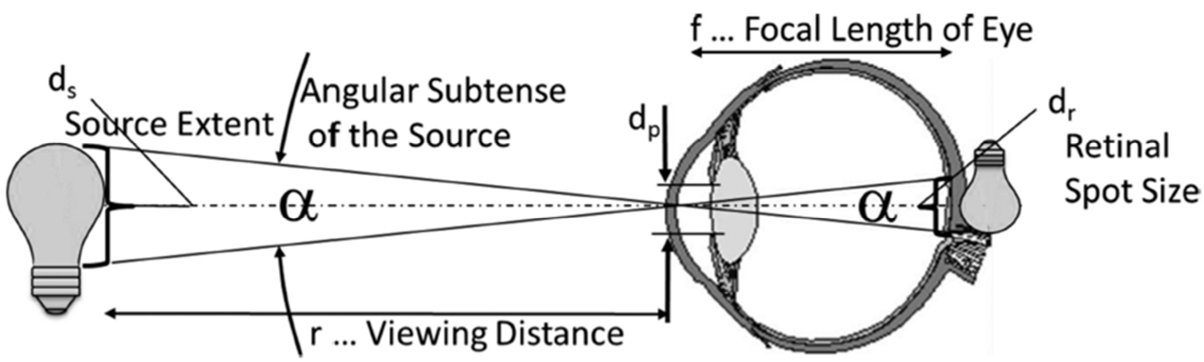


Figure 5—3. Reproduced from [ICNIRP 2013]. Imaging of a light source on the retina showing the retinal image and the angular subtense of the source.

From a photometric point of view, the retinal irradiance and the source radiance do not depend on the viewing distance. The viewing distance only defines the size of the optical retinal image. However, the real "physiological" retinal image is the result of the spreading of the image caused by the eye movements. The influence of the eye movements on the physiological retinal image is more pronounced for small optical images (remote light sources) than for large images (light sources at close range).

5.2.1 Photochemical retinal damage

Visible light falling on the retina interacts with the visual photoreceptors (rods and cones) but also with the retinal pigment epithelium (RPE). The RPE is the outer layer of the retina (Figure 6-4). It plays a crucial role in the phagocytosis of photoreceptor outer segments and the regeneration of visual pigments. RPE cells contain melanin (a photoprotective pigment) and lipofuscin, a substance which accumulates with age and is associated with some retinal disorders such as age-related macular degeneration (ARMD) [BEHAR-COHEN 2011].

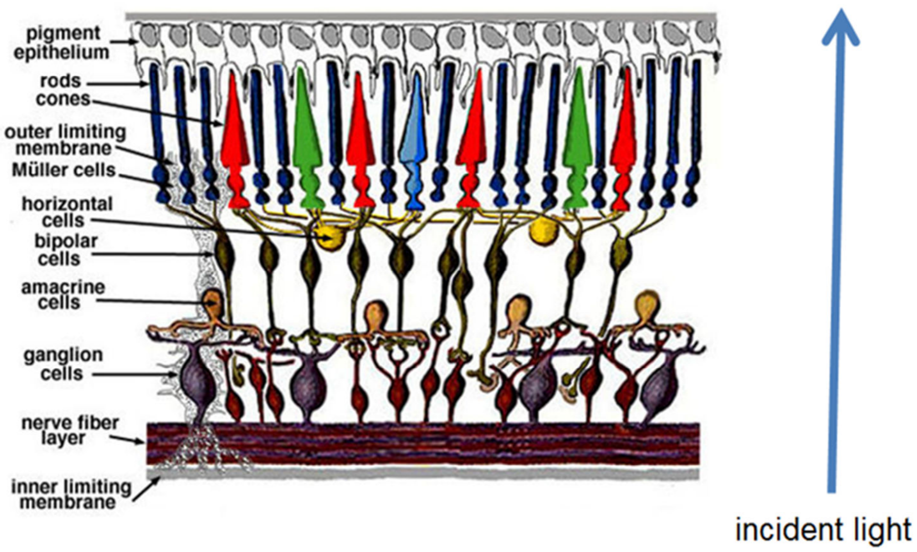


Figure 5—4. Cross-section of the human retina, adapted from [KOLB 2011].

Research in photobiology has been carried out for more than 50 years on mammalian retinas (rats, mice, monkeys) in order to identify the injuries caused by retinal light exposures, that were measured in terms of retinal irradiance dose (in $J.m^{-2}$). This body of research reveals that there could be two types of retinal damage processes induced by visible light [ICNIRP 2013]:

- Type 1 [NOELL 1966]: the damage observed after 12 hours per day (long exposures) is the bleaching of the retinal photopigments, with a possible toxic build-up in the RPE. The action spectrum of the type 1 damage is very similar to the photopic sensitivity of the eye *V(λ)*.

- Type 2 [HAM 1976]: the damage is a photoretinopathy caused by phototoxic reactions in the RPE, following an acute exposure to blue light. Blue light excites lipofuscin by producing reactive oxygen species and free radicals, causing an oxidative stress to the RPE cells.

The existence of type 1 retinal damage was questioned by Van Norren in 2011 [VAN NORREN 2011], following an extensive review of the literature and the lack of reproducible data related to this type of damage. Figure 6-5 is an excerpt from [VAN NORREN 2011]. The graphs summarise the dose obtained for retinal damage as a function of wavelength.

Type 2 damage was first recognised in humans in the 1960’s as the major cause of photoretinitis for arc welders and people who observed a solar eclipse without eye protection [ICNIRP 2013].

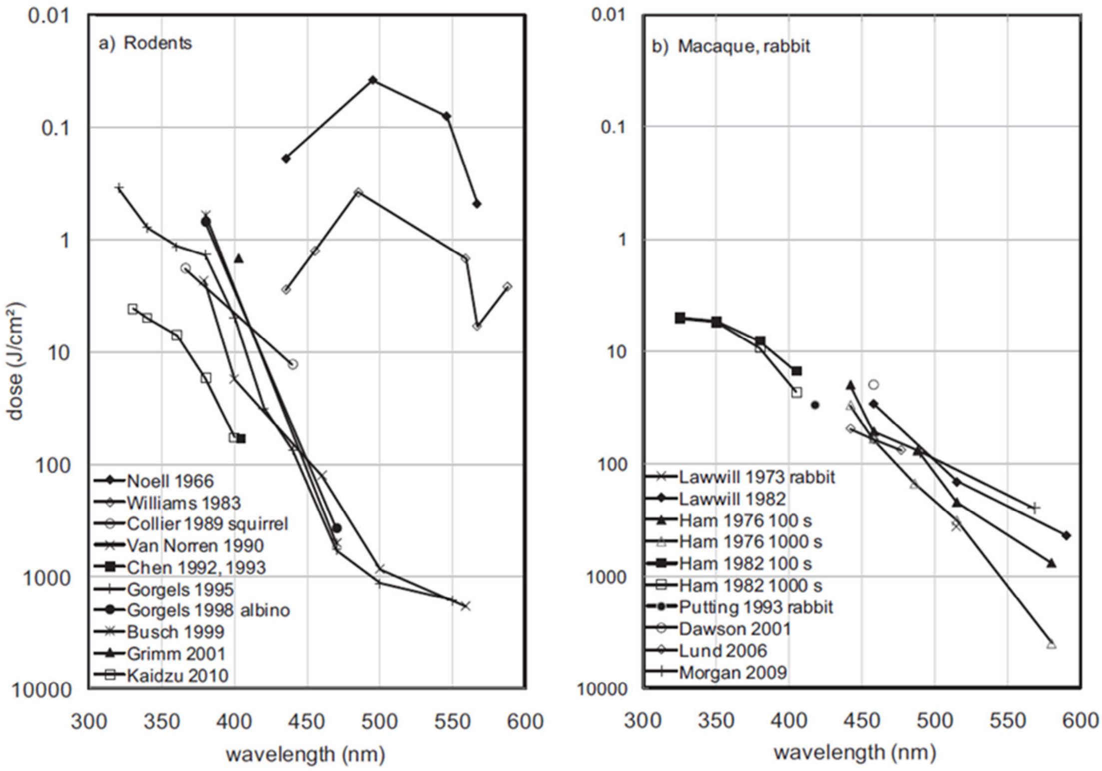


Figure 5—5. Reproduced from [VAN NORREN 2011]. Dose corresponding to observed retinal damage as a function of wavelength. The literature source is indicated by first author and year of publication. (a). Data for rats, except when stated otherwise. (b). Data for macaque, except when stated otherwise.

Research is currently being carried out to investigate the dose and wavelength dependence of light induced retinal damage [SHANG 2014; BOULENGUEZ 2014].

5.2.2 Blue light hazard

Unlike type 1 damage, type 2 damage is rather well established and serves as the basis of the ICNIRP guidelines concerning the blue light hazard. For the general population, the action spectrum of the blue light hazard is $B(\lambda)$, represented in the graph of Figure 6-6. However, people born without crystalline lens (aphakic) or having received intraocular lens implants (pseudophakic) are exposed to a greater amount of retinal blue and UV light compared to phakic subjects exposed to the same light source. In these cases, the action spectrum defined by ICNIRP is *A*(?), also represented in Figure 6-6. ICNIRP also recommends using the A(?) action spectrum when assessing the photobiological safety of infants under the age of two, due to the greater transparency of their crystalline lens [ICNIRP 2013].

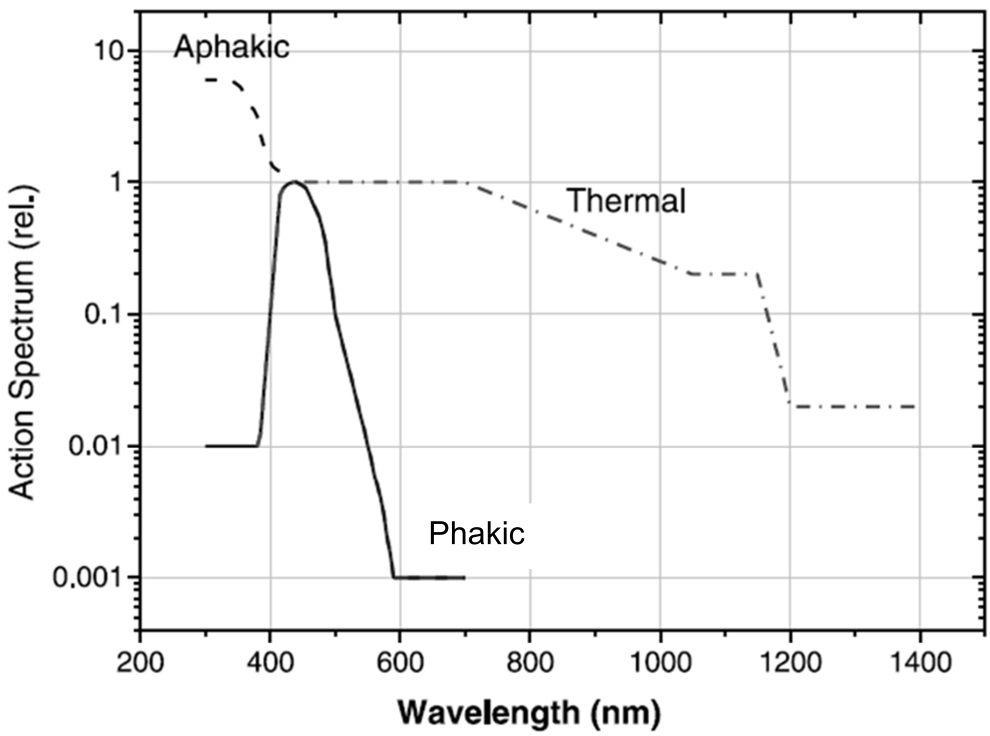


Figure 5—6. Reproduced from [ICNIRP 2013]. Action spectra for blue-light photochemical retinopathy with crystalline lens (phakic) B(λ) and without lens (aphakic) A(λ) and for thermal retinopathy R(λ). The aphakic curve A(λ) aligns with the phakic curve B(λ) at wavelengths greater than 440 nm.

Retinal blue light exposure can be estimated using the ICNIRP guidelines. A quantity called the blue-light weighted radiance L_B can be determined as a function of the spectral radiance L_λ of the light source and the action spectrum $B(\lambda)$, λ being the wavelength:

$$L_B = \sum_{380}^{1400} L_\lambda \times B(\lambda) \times \Delta\lambda \tag{1}$$

L_B is expressed in W.m^{-2}.sr^{-1}. As stated in the previous section, the natural movements of the eye tend to smear the retinal image of source over a wider effective area. The phenomenon is taken into account in the definition of the blue-light radiance L_B. This is the reason why the source radiance should be spatially averaged over an effective field of view (FOV) angle which varies as a function of the exposure duration t. The effective FOV angle is given in Table 5-1. The smallest and largest FOV angles defined in the ICNIRP guidelines are respectively 11 and 110 mrad. These values correspond to a retinal image of 190 µm and 1.9 mm, respectively. Figure 5—7 gives an example of the smallest and largest effective field of view including an LED light source. In the case of the largest field of view, the blue light radiance is less than the true radiance of the light source since the field of view includes non-emitting areas (black zones).

Table 5-1. Effective field of view angle (FOV) angle as a function of the exposure duration [ICNIRP 2013].

Exposure duration (second)	Acceptance averaging angle Υ_{ph} (radian)
$t < 100$ s (about 1.7 min)	0.011
$100 \le t < 10{,}000$ s (about 2.8 h)	$0.0011 \times t^{0.5}$
$t > 10{,}000$ s	0.110
Note: t must be input in seconds to calculate Υ_{ph} in radian	

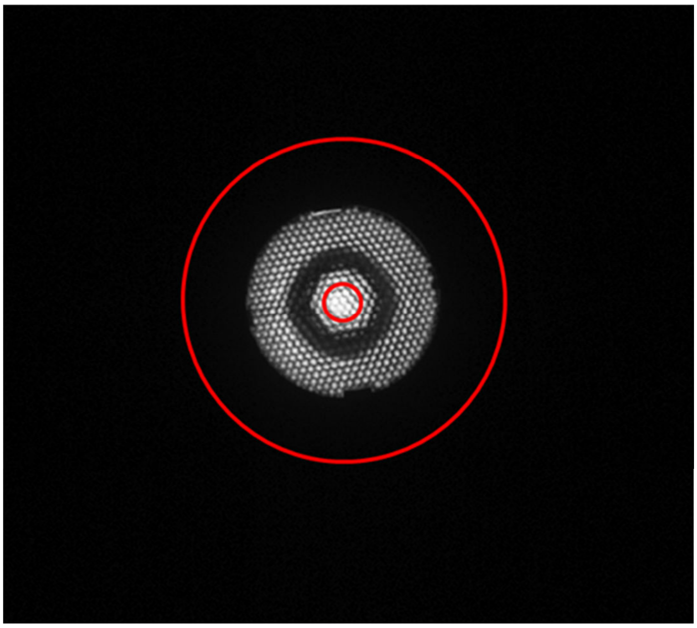


Figure 5—7. Image of an LED source observed at a distance of 200 mm. The largest circle shows a 110 mrad effective field of view corresponding to an exposure longer than 10 000 s. The smallest circle shows an 11 mrad effective field of view corresponding to an exposure of 100 s or less.

ICNIRP defines the blue light effective radiance dose ($J.m^{-2}.sr^{-1}$) as the time-integral of the blue light radiance over the duration of the exposure. For constant light sources, this dose is simply expressed by:

$$D_B = L_B \times t \qquad (2)$$

The exposure limits (EL) set by ICNIRP are the following:

- For an exposure duration t greater than 0.25 s (aversion response) but less than 10 000 s (approximately 2.8 h), the exposure limit is expressed in term of radiance dose :

$$D_B^{EL} = 1 \times 10^6 \, \mathrm{J.m^{-2}.sr^{-1}} \qquad (3)$$

This radiance dose exposure limit is equivalent to a blue light radiance exposure limit:

$$L_B^{EL} = \frac{(1 \times 10^6)}{t} \, \mathrm{W.m^{-2}.sr^{-1}} \qquad (4)$$

- For an exposure duration greater than 10 000 s, the exposure limit is expressed in term of blue light radiance:

$$L_B^{EL} = 100 \, \mathrm{W.m^{-2}.sr^{-1}}$$

(5)

Figure 5—8 shows a graph of the ICNIRP blue light exposure limit expressed in terms of blue light radiance:

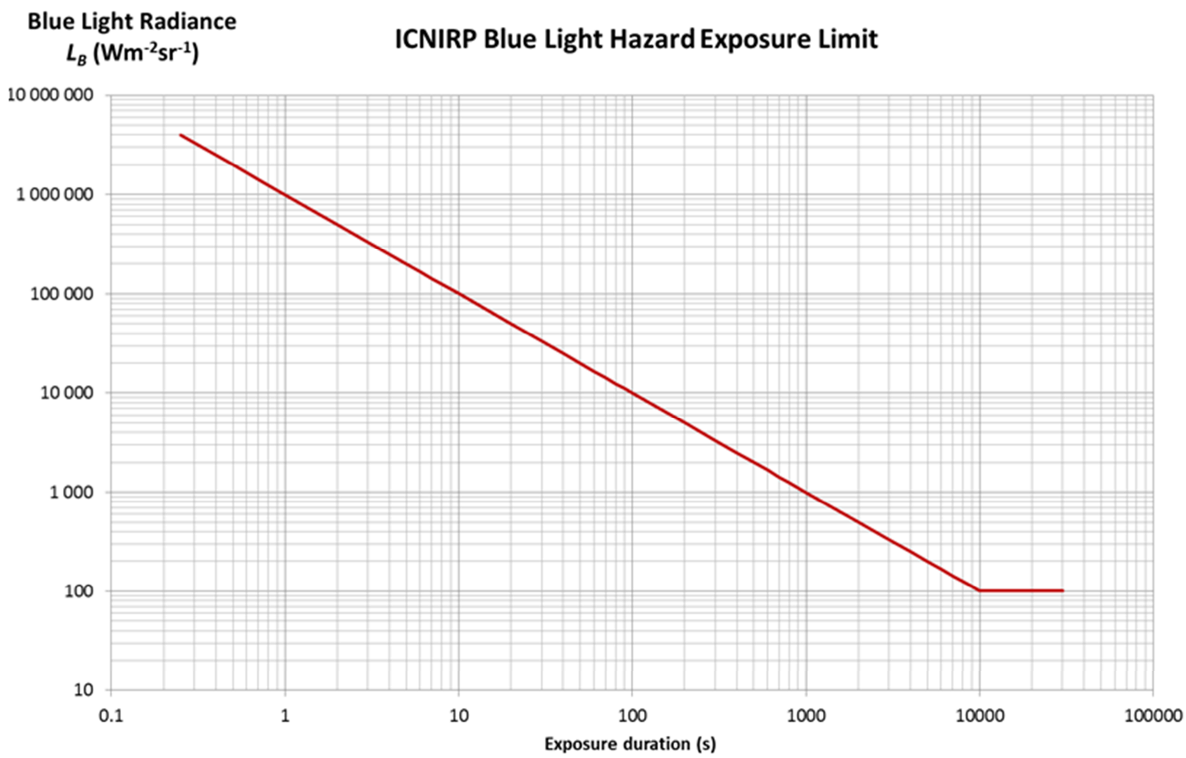


Figure 5—8. Blue light hazard exposure limit defined in [ICNIRP 2013] in terms of blue light weighted radiance

For small sources, corresponding to an angular subtense less than 11 mrad, it is possible to express the exposure limit in terms of blue light hazard irradiance E_B. This case is called the "small source regime". The blue-light weighted irradiance E_B can be determined as a function of the spectral irradiance E_λ of the light source and the action spectrum $B(\lambda)$:

$$E_B = \sum_{380}^{1400} E_\lambda \times B(\lambda) \times \Delta\lambda$$

(6)

Using simple photometric consideration, it can be showed that the small source irradiance is given by the ratio of the radiance to a factor of about 10^4. Because of the eye movements involved in normal visual tasks, the maximum exposure duration that needs to be considered for small sources is 100 s. For this reason, the small source limit is constant for exposure durations longer than 100 s. Therefore, the blue light exposure limit can be expressed in terms of irradiance as follows:

for an exposure duration *t* greater than 0.25 s and less than 100 s:

$$E_B^{EL} = \frac{100}{t}\ \mathrm{Wm^{-2}} \tag{7}$$

- for an exposure duration greater than 100 s and less than 30 000 s:

$$E_B^{EL} = 1\ \mathrm{Wm^{-2}} \tag{8}$$

5.3 Regulations on personal exposure to optical radiations emitted by artificial light sources

The exposure limit values (ELV) given in the ICNIRP guidelines are internationally accepted. In some regions such as the EU and the USA, they are transposed in regional and national regulatory documents. For example, in the USA, the American Conference of Governmental Industrial Hygienists (ACGIH) has set similar ELVs [ACGIH 2001]. In the EU, the Directive 2006/25/EC on artificial optical radiations [EC 2006] requires limiting the personal exposure to artificial optical radiations at the work place. In this regulation, the ELVs set by ICNIRP become mandatory limits that must not be exceeded for the workers. As far as personal exposure to LEDs is concerned, the blue light hazard is included in the scope of the EU Directive. Therefore, employers should assess that workers are not exposed to levels in excess of the exposure limit values. Employers may be able to demonstrate this by using several means: generic assessments, theoretical assessments or measurements. The directive itself does not specify a methodology. However, a number of standards were published to assist with verification of the compliance.

5.4 Assessment of personal exposure to optical radiations emitted by artificial light sources

The personal exposure to artificial optical radiation can be assessed by performing a comparison with the exposure limit values. The general methodology is to perform an assessment of the optical radiation emitted by all the artificial sources that may be incident on the human body in a given occupational scenario. In the EU, the EN 14255-2 standard [CEN 2005] describes the practical methodology used for visible and infrared radiation emitted by artificial sources in the workplace. This standard is applicable to any type of artificial sources. The methodology of EN 14255-2 relies on a work task analysis and the practical measurement of the exposure. This standard methodology is used by European health authorities to control the conformity of work places.

In the case of artificial lighting, this standard is applicable to the human exposure to a whole lighting installation, comprising all the lamps and luminaires emitting optical radiation towards the worker.

5.5 Photobiological safety standards for lighting products

The standard assessment of the photobiological safety of a whole installation as described in the previous section is not well adapted to the evaluation of the intrinsic safety of a single lighting product such as a lamp or a luminaire. Following the example of laser safety classes, the lighting industry has helped set up some standards in order to define the potential risks posed by lighting sources. These standards are useful because they provide a classification of a lighting source in different "risk groups". However, it is important to mention that the notion of "risk group" is only applicable to a single product. The exposure to an installation comprising several lighting sources should be assessed using the guidelines of ICNIRP and the general methodology described in the previous section. In particular, the exposure to several lighting sources classified in a low risk group does not guarantee that the total exposure is below the exposure limit. In the case of LEDs, which are concerned with the blue light hazard, there are specific conditions to extend a low risk classification valid for a single LED to typical installation situations. These conditions will be discussed in the following sections.

The photobiological safety of lamps and devices using lamps, such as luminaires and lighting modules, has been internationally addressed by the Commission Internationale de l'Eclairage (CIE), the Illuminating Engineering Society of North America (IESNA) and the International Electrotechnical Committee (IEC) through close collaborations and joint working groups. They led to the following standards describing the photobiological safety of lamps and lamp systems: Joint publication CIE S009 [CIE 2006] and IEC 62471:2006 [IEC 2006], IESNA/ANSI RP-27 series [IESNA 2000, 2005, 2007]. These documents are not identical but similar in content.

5.5.1 The photobiological safety joint standard CIE S009 / IEC 62471:2006

This standard, which concerns the photobiological safety of lamps and devices using lamps, provides a system of classification of the light source in several risk groups. The standard considers all the photobiological hazards listed by the ICNIRP that may affect the skin and the eye (thermal and photochemical hazards) from the ultraviolet to the infrared wavelengths. Guidance is provided to perform the physical measurements (radiance and irradiance) necessary to assess in a laboratory the exposure levels produced by a lighting product.

The standard introduces the notion of risk groups which depend on the duration of the maximum permissible exposure assessed for each type of photobiological hazard: hazards related to actinic UV, hazards related to UV-A, hazards related to blue light (retinal blue light hazard), thermal hazards related to visible and infrared radiations.

Four risk groups are defined:

- Risk Group 0 – Exempt group: no photobiological hazard under foreseeable conditions
- Risk Group 1 – Low risk group: products safe for most use applications, except for very prolonged exposures where direct ocular exposures may be expected
- Risk Group 2 – Moderate risk group: products generally do not pose a realistic optical hazard if the aversion response limits the exposure duration, or when lengthy exposures are unrealistic
- Risk Group 3 – High risk group: products pose a potential hazard even for momentary exposures.

In the case of SSL, which is essentially based on LEDs and OLEDs, the application of the photobiological safety standards CIE S009 and IEC 62471:2009 to current white light sources results in a risk group classification that is only determined by the blue light hazard. In this case, the risk group classification depends on the duration of the maximum permissible exposure of the retina to blue light, as defined by ICNIRP and presented in Figure 5—9:

- Risk Group 0: exposure limit is not exceeded within 10 000 s
- Risk Group 1: exposure limit is not exceeded within 100 s
- Risk Group 2: exposure limit is not exceeded within 0.25 s (aversion time)
- Risk Group 3: exposure limit is exceeded within less than 0.25 s

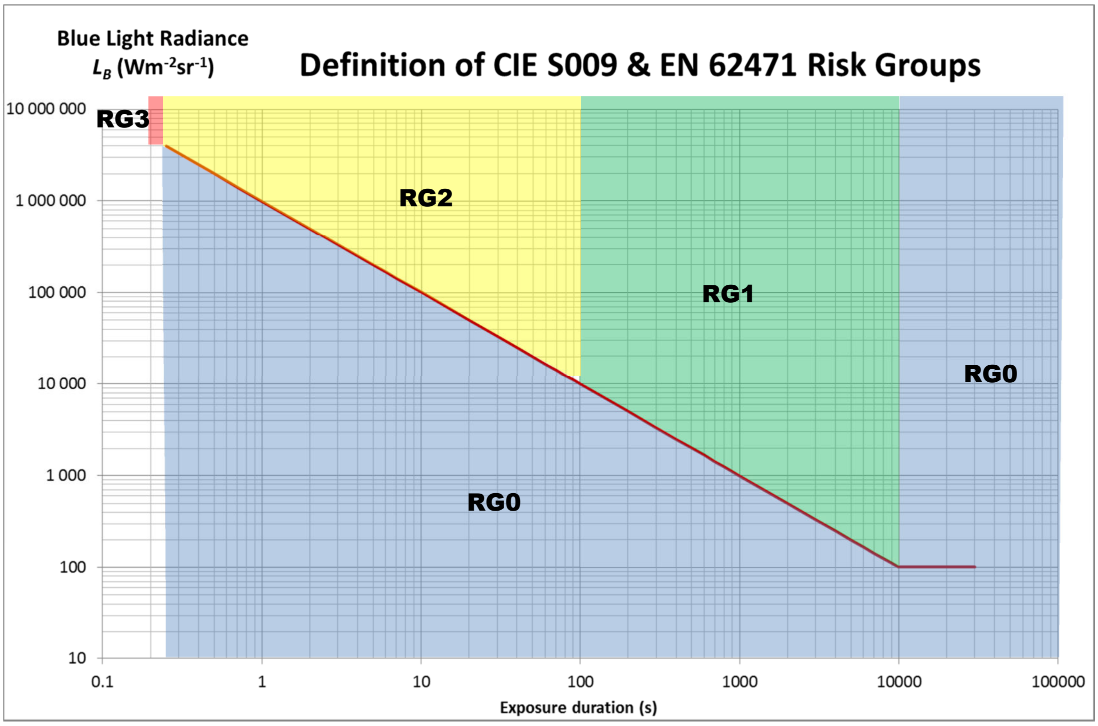


Figure 5—9. Blue light hazard radiance ranges for the defined Risk Groups with reference to the exposure limit defined in [ICNIRP 2013] (red line).

In the case of all types of artificial white light sources, it is highly unlikely that RG3 is reached for blue light hazard. This would occur when the blue light level is a factor of 400 times higher than the RG2 lower limit (i.e. boundary between RG1 and RG2). RG3 for blue light hazard at a colour temperature of 6 000 K is only reached when the luminance is above 4×10^9 cd/m^2 and when the illuminance at the eye is above 400 000 lx (see discussion in Section 5.5.3). It should be noted that RG3 is reached for hazards other than the blue light hazard [IEC 2012] for non-solid state lighting sources.

IEC 62471 defines two different criteria to determine the viewing distance. Light sources used in general lighting should be assessed at the distance corresponding to an illuminance of 500 lx. Other types of light sources should be assessed at a fixed distance of 200 mm.

For LED components, there is no ambiguity in the distance since LED components are not used per se in general lighting. In this case, IEC 62471 requires using the distance of 200 mm.

However, the choice of the viewing distance in IEC 62471 is sometimes ambiguous and not realistic in the context of the real usage conditions. For instance, in stage lighting (theatres, concert halls, etc.), workers are exposed to an illuminance level higher than 500 lx. Sports participants in stadia lit for television coverage are also exposed to levels much greater than 500 lx for extended periods of time. Thus, applying the 500 lx criterion would underestimate the exposure while the 200 mm criterion would greatly overestimate it. In a more common context, directional household lamps are supposed to be assessed using the 500 lx criterion, which corresponds to a typical viewing distance of a few meters. It is however quite common to have shorter viewing distances, as short as 100, 200 or 500 mm at home. Another example is street lighting where the illuminance level is much lower than 500 lx, typically of a few lx. Assessing the exposure to blue light emitted by a street lighting luminaire at the distance giving an illuminance of 500 lx is clearly not appropriate.

Possibly on next review of these standards, rather than a risk group, the notion of “safety distance” or “safety illuminance level” could be considered as being more appropriate to communicate to the installers and to the users, especially the general public. The safety distance of an SSL product would be the minimum distance for which the blue light hazard risk group does not exceed RG1 (products safe for most applications).

IEC issued two technical reports to provide guidance to manufacturers of non-laser light sources when assessing and reporting the photobiological safety of their products. These documents are the IEC TR 62471-2 issued in 2009 [IEC 2009] and IEC TR 62778, issued in 2012 [IEC 2012].

5.5.2 The technical report IEC TR 62471-2

This technical report provides the basis for safety requirements dependent on the risk group classification of IEC 62471. A labelling scheme is provided according to the risk group of the light source, as shown in Table 5-2.

Table 5-2. Reproduced from [IEC 2009]. Hazard-related risk group labeling of lamp systems presented in IEC TR 62471-2.

Hazard	Exempt Risk Group	Risk Group 1	Risk Group 2	Risk Group 3
Ultraviolet hazard 200nm to 400nm	Not required	NOTICE UV emitted from this product	CAUTION UV emitted from this product	WARNING UV emitted from this product
Retinal blue light hazard 300nm to 400nm	Not required	Not required	CAUTION Possibly hazardous optical radiation emitted from this product	WARNING Possibly hazardous optical radiation emitted from this product
Retinal blue light or thermal hazard 400nm to 780nm	Not required	Not required	CAUTION Possibly hazardous optical radiation emitted from this product	WARNING Possibly hazardous optical radiation emitted from this product
Cornea/lens infrared hazard 780nm to 3000nm	Not required	NOTICE IR emitted from this product	CAUTION IR emitted from this product	WARNING IR emitted from this product
Retinal thermal hazard, weak visual stimulus 780nm to 1400nm	Not required	WARNING IR emitted from this product	WARNING IR emitted from this product	WARNING IR emitted from this product

The technical report IEC TR 62471-2 recommends that products should be labelled, exhibiting the risk group of blue light hazard when assessed to be RG2 or RG3. Furthermore, for all products in excess of the exempt group (RG0), the document recommends the manufacturer to provide the following user information:

a) Clear statement that the lamp or lamp system is in excess of the Exempt Group and that the viewer-related risk is dependent upon how the users install and use the product.
b) The most restrictive optical radiation hazard and other optical radiation hazards in excess of Exempt Group (see Table 5-2).
c) Exposure values and the hazard distances with optional graphical presentation of distance-dependent exposure values.
d) Hazard distances for all relevant viewer-related risk groups below the assigned one.

e) Adequate instructions for proper assembly, installation, maintenance and safe use, including clear warnings concerning precautions to avoid possible exposure to hazardous optical radiation.
f) Advice on safe operating procedures and warnings concerning reasonably foreseeable malpractices, malfunctions and hazardous failure modes. Where maintenance procedures are detailed, they should, wherever possible, include explicit instructions on safe procedures to be followed.
g) Reproduction of the required labelling and an explanation of its meaning shown in Table 5-2.
h) Information on what type of user controls may be considered.

Table 5-3 is given in IEC TR 62417-2 to explain the labelling information and to provide guidance on control measure.

Table 5-3. Reproduced from [IEC 2009]. Explanation of labeling information and guidance on control measures.

Hazard	Exempt Risk Group	Risk Group 1	Risk Group 2	Risk Group 3
Ultraviolet hazard 200nm to 400nm	Not required	Minimise exposure to eyes or skin. Use appropriate shielding.	Eye or skin irritation may result from exposure. Use appropriate shielding.	Avoid eye and skin exposure to unshielded product.
Retinal blue light hazard 300nm to 400nm	Not required	Not required	Do not stare at operating lamp. May be harmful to the eyes.	Do not look at operating lamp. Eye injury may result.
Retinal blue light or thermal hazard 400nm to 780nm	Not required	Not required	Do not stare at operating lamp. May be harmful to the eyes.	Do not look at operating lamp. Eye injury may result.
Cornea/lens infrared hazard 780nm to 3000nm	Not required	Use appropriate shielding or eye protection.	Avoid eye exposure. Use appropriate shielding or eye protection.	Avoid eye exposure. Use appropriate shielding or eye protection.
Retinal thermal hazard, weak visual stimulus 780nm to 1400nm	Not required	Do not stare at operating lamp.	Do not stare at operating lamp.	Do not stare at operating lamp.

The technical report also suggests a procedure for the allocation of safety measures. This is done through the assessment of the light source at a distance of 200 mm and the applicable risk group exposure duration.

However, when a lamp is integrated into another product, these assessment conditions may become non-representative. In this case, the product may be assessed at the minimum distance and maximum exposure duration representative of the application-specific conditions of foreseeable access (viewer-related risk).

The applications can be divided into three groups, according to the likelihood of the viewing of the source:

- Unintentional short term : automotive, spot, flash, projection
- Intermittent, occasional (or possible) short-term: many toys, where the normal attention span of a child is short, laboratory equipment, home, signalling
- Intentional (or likely) long-term: displays and general lighting systems

When a product is assessed under application-specific conditions, this viewer-related risk group classification may differ from the risk group of the lamp incorporated into the product. IEC TR 62471-2 provides guidance on the maximum permissible risk group of products accessible under application-specific conditions, as shown in Table 5-4.

Table 5-4. Reproduced from [IEC 2009]. Maximum acceptable risk group of products assessed for viewer-related risk under application specific conditions.

Risk group of the lamp system	**Risk group assessed under application specific conditions – viewer-related risk**		
	Unintentional short term	**Intentional short-term**	**Intentional (or likely) long-term**
Exempt Risk Group	Exempt Risk Group	Exempt Risk Group	Exempt Risk Group
Risk Group 1	Risk Group 1	Risk Group 1	Exempt Risk Group – exposure limited by access distance or by controlled access
Risk Group 2	Risk Group 2	Risk Group 1 – exposure limited by access distance or/and exposure duration or product used in restricted location	Exempt Risk Group – exposure limited by access distance or by controlled access
Risk Group 3	Risk Group 2 – exposure limited by access distance or product used in restricted location	Risk Group 1 – exposure limited by access distance or/and exposure duration or product used in restricted location	Exempt Risk Group – exposure limited by access distance or by controlled access

For instance, if a Risk Group 2 lamp is incorporated into a lighting source (intentional long-term exposure), it is only acceptable if the viewer-related risk group of the lighting source is Exempt (exposure limited by access distance or by controlled access).

If a Risk Group 3 lamp is incorporated into signalling equipment (intentional short-term exposure), it is only acceptable if the viewer-related Risk Group of the signalling equipment is maximum Risk Group 1 – foreseeable exposure is controlled by access distance and/or maximum exposure time.

The lighting industry has experienced some difficulties with the implementation of IEC TR 62471-2 when it is applied to the transfer of LEDs risk group to finished products. The procedure of Table 5-4 is based on worst-case conditions, not reflecting the real use of the LED. This procedure often results in RG2 classification, requiring the use of warning labels. The issue of transferring the risk group of LED components to finished products is more precisely addressed in the technical report IEC TR 62778.

5.5.3 The technical report IEC TR 62778

This technical report was published in order to clarify some ambiguities present in IEC 62471 when assessing the blue light hazard of light sources and luminaires. It provides guidance on how to transfer the photobiological safety information of IEC 62471 from components (for instance LED package, LED module, LED lamp) to a higher level lighting product (luminaire).

The technical report firstly demonstrates quite a strong correlation between the blue hazard efficacy and the correlated colour temperature (CCT) of a white light source. The blue light hazard efficacy $K_{B,v}$ is defined as the ratio between the blue light hazard radiance L_B and the photopic luminance (visual luminance) L, expressed in cd.m^{-2}. The blue light hazard efficacy is expressed in W.lm^{-1}. Figure 5—10 shows a graph representing the blue light hazard efficacy as a function of CCT.

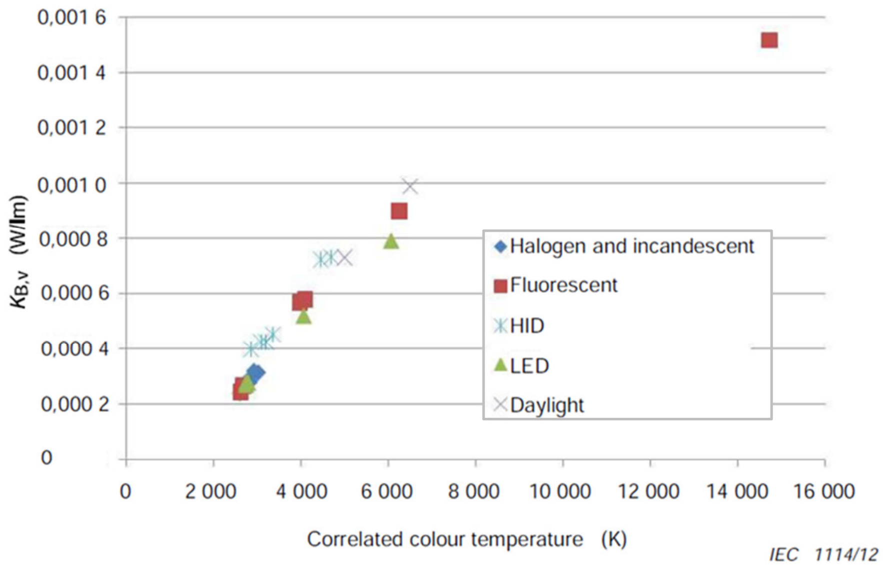


Figure 5—10. Reproduced from [IEC 2012]. Blue light hazard efficacy versus CCT for several white light sources.

This fact was also emphasized in the ANSES report [ANSES 2010]. Figure 5—11 shows the data used in the ANSES report, obtained with a larger set of white LEDs.

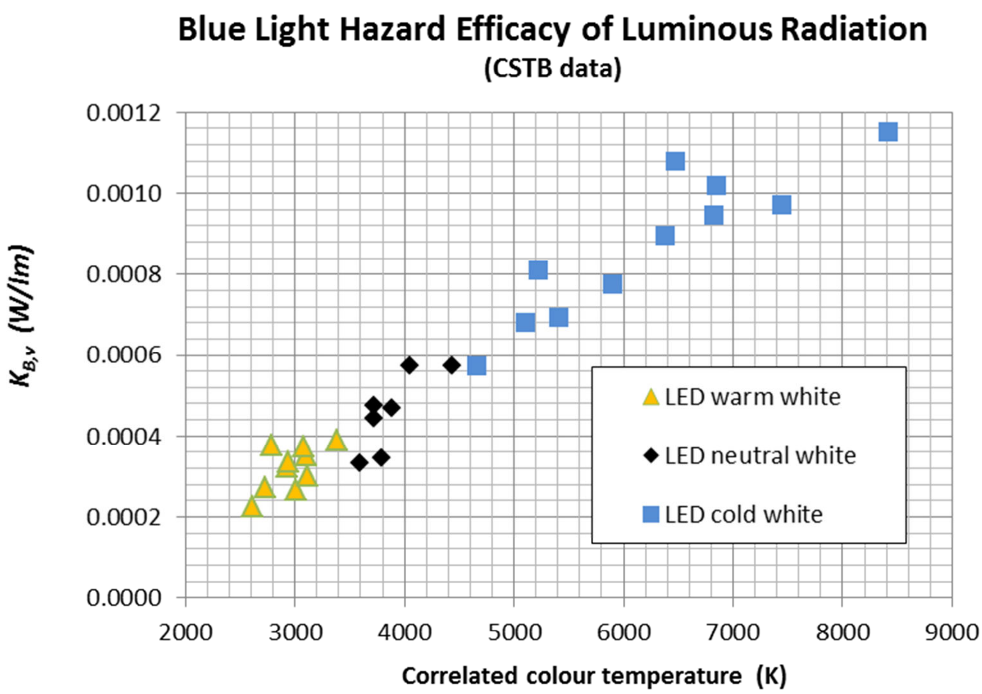


Figure 5—11. Reproduced from [ANSES 2010]. Blue light hazard efficacy versus CCT for a set of white LEDs classified as warm white, neutral white and cold white.

This correlation is used in the IEC TR 62778 document to assess the blue light weighted quantities (blue light weighted radiance in $W.m^{-2}.sr^{-1}$ and irradiance in $W.m^{-2}$) as a function of photometric quantities (visual luminance in $cd.m^{-2}$ and illuminance in lx).

The technical report presents an estimation of the light levels necessary to reach the exposure limits with an exposure of 100 s. The 100 s exposure corresponds to the boundary between RG1 and RG2. According to Eq. (3), the limiting blue light radiance L_B is equal to 10 000 $W.m^{-2}.sr^{-1}$ in this case.

This estimation is performed in terms of luminance levels and illuminance levels in the case of small sources (see Section 5.2.2). The result of this approach is illustrated in Figure 5—12 and Figure 5—13. These graphs show the luminance and illuminance corresponding to the blue light exposure limits at 100 s, the boundary between RG1 and RG2.

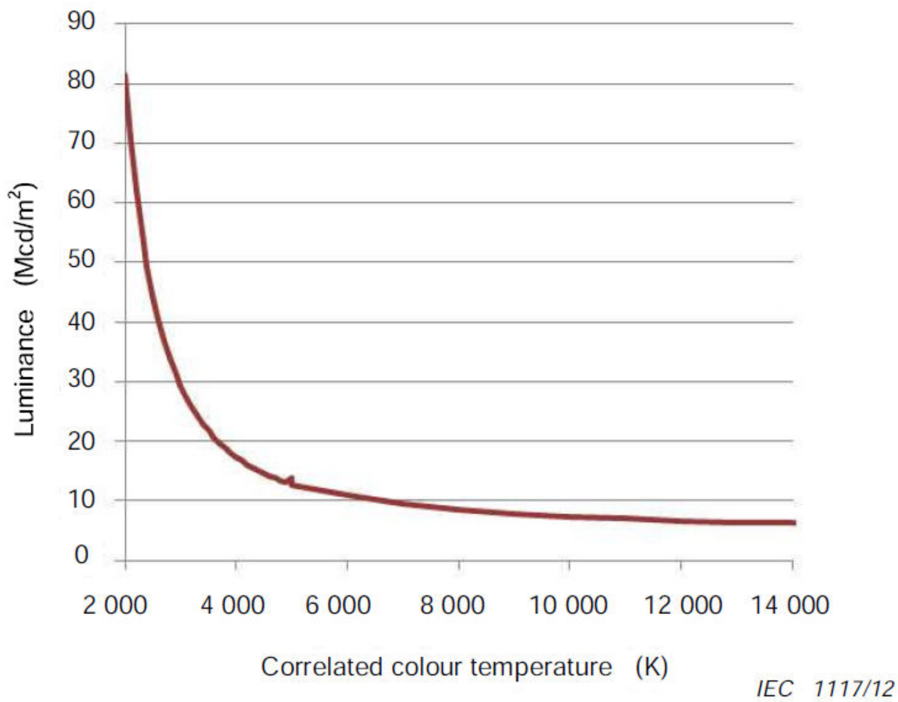


Figure 5—12. Reproduced from IEC TR 62778 [IEC 2012]. Estimate of the luminance level where L_B = 10000 $W.m^{-2}.sr^{-1}$, the boundary between RG1 and RG2, as a function of CCT.

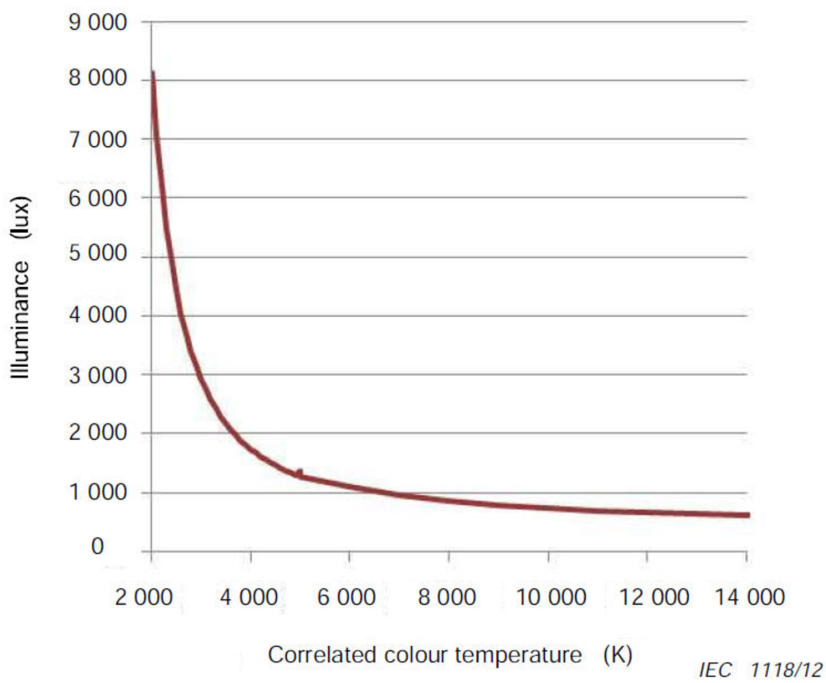


Figure 5—13. Reproduced from IEC TR 62778 [IEC 2012]. Estimate of the illuminance level where E_B = 1 W.m^{-2}, the boundary between RG1 and RG2 for small sources, as a function of CCT.

As explained in the technical report, the small source regime presents a "worst case" in terms of source luminance. Knowing the E_B value at a certain illuminance level essentially gives the maximum exposure duration regardless of the luminance. It means that if the illuminance level at the viewer's eye position is well below the illuminance where E_B = 1 Wm^{-2} (the red line of Figure 5—13), the maximum exposure duration cannot be below 100 s, regardless of the luminance of the light source.

Figure 5—12 also reveals that the 500 lx level is below the red line throughout the CCT range relevant for general lighting. In other words, *the 500 lx criterion can never generate a RG2 classification for white light*.

Another important conclusion drawn in IEC TR 62778 can be inferred from Figure 5—12. The large source regime is valid at short distances, and radiance is a light source property independent of viewing distance. If a light source has a blue light radiance L_B less than 10 000 W.m^{-2}.sr^{-1}, it will have a maximum permissible exposure duration greater than 100 s even with the shortest viewing distances. At longer distances, where it would pass from the large source to the small source regime, the maximum permissible exposure duration can only increase and never decrease. Therefore, if a light source has an L_B less than 10 000 W.m^{-2}.sr^{-1} (i.e. its luminance lies below the red line in Figure 5—12), it cannot be in RG2 no matter at what distance it is evaluated. It follows that whenever either of the two conditions is fulfilled, then a classification greater than RG1 is not possible. In order to give rise to a RG2 situation, both the luminance of the light source and the illuminance at the viewer's eye have to be above a limiting value. In all other situations, the risk group is RG1 maximum, whatever the size and the viewing distance.

Based on Figure 5—12 and Figure 5—13, the technical report IEC TR 62778 proposes some recommendations to assist the consistent application of IEC 62471 for the assessment of blue light hazard of light sources and luminaires. These recommendations are particularly relevant to LEDs and SSL products.

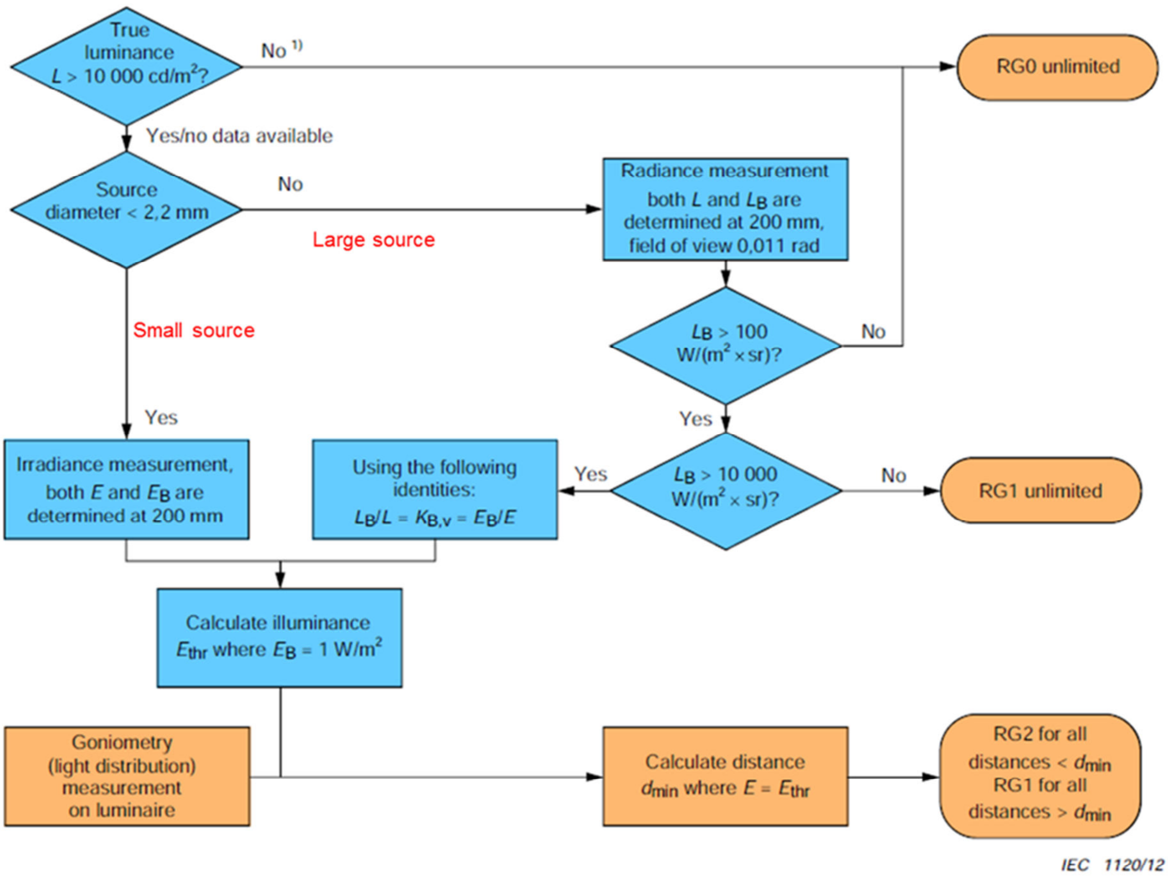
For large sources, having an angular subtense greater than 11 mrad, a measurement of spectral radiance needs to be performed at 200 mm in a FOV of 11 mrad in order to obtain a value of the blue light radiance L_B which will be compared to the RG1 exposure limit of 10 000 $W.m^{-2}.sr^{-1}$. If the result is below this exposure limit, then the classification "RG1 unlimited" can be applied to the light source and higher products incorporating this light source. If the RG1 limit is exceeded, the light source is RG2 and there is a possibility that the final product will also be RG2. IEC TR 62778 then recommends determining the boundary between RG1 and RG2, expressed in terms of a threshold illuminance E_{thr} at which the boundary occurs. The threshold illuminance should be included in the datasheet for transfer to the final product. In the case of a finished product, the threshold illuminance can be converted to a threshold distance d_{thr} corresponding to the boundary between RG1 and RG2. The recommended method to perform this conversion is to use goniophotometric data to identify the maximum luminous intensity. The inverse square law can be used to determine the minimum threshold distance. If goniophotometric data is not available, no guidance is provided but it seems possible to use an illuminance meter to experimentally find E_{thr}.

When the blue light radiance of the large light source is below the RG0 exposure limit of 100 $W.m^{-2}.sr^{-1}$, then the light source is classified "RG0 unlimited". The RG0 can thus be transferred to any type of luminaire using this light source.

For small sources, having an angular subtense less than 11 mrad, the measurement FOV can be reduced so that it underfills the light source. In this case, a blue light radiance value L_B is obtained and the assessment can be performed, yielding RG0, RG1 or RG2 classification.

If the measurement is performed as an irradiance measurement, the resulting blue light irradiance E_B should be compared with the RG1 exposure limit of 1 $W.m^{-2}$. If E_B is above this limit, then the light source is RG2 and the boundary between RG1 and RG2 should be reported in terms of the threshold illuminance E_{thr} and the threshold distance d_{thr}. If E_B is below this limit, then the small light source can be classified RG1 but the risk group cannot be transferred to a finished product (this is due to the treatment of the light source as a point source where the inverse square law dictates that there will be a threshold distance where the exposure limit will be exceeded). In this case, the worst-case is assumed (RG2) and the threshold illuminance should be reported to allow transfer to the final product.

The general methodology described by the IEC TR 62778 to transfer the blue light hazard assessment from the primary light source to the luminaires including this light source is illustrated in Figure 5—14.



[1] The RG0 result following from the ≤ 10 000 cd/m² condition is only valid for white light sources.

Figure 5—14. Reproduced from IEC TR 62778 [IEC 2012]. Flow chart describing the flow of information from the primary light source (in blue) to the luminaire based on this light source (in amber).

Table 5-5 gives luminance values giving risk group not greater than RG0 and RG1, whatever the viewing distance and the source size. If the true luminance of the light source is greater than the values of Table 5-5, but the illuminance at the viewing distance complies with the values of Table 5-6 for the given correlated colour temperatures (CCT), then its classification will not be greater than RG0 or RG1 at the considered viewing distance.

Table 5-5. Luminance values giving risk group not greater than RG0 and RG1

Rated CCT	RG1 Luminance limits ($cd\ m^{-2}$)	RG0 Luminance limits ($cd\ m^{-2}$)
CCT ≤ 2350 K	4×10^7	4×10^5
2 350 K < CCT ≤ 2 850 K	1.85×10^7	1.85×10^5
2 850 K < CCT ≤ 3 250 K	1.45×10^7	1.45×10^5
3 250 K < CCT ≤ 3 750 K	1.1×10^7	1.1×10^5
3 750 K < CCT ≤ 4 500 K	8.5×10^6	8.5×10^4
4 500 K < CCT ≤ 5 750 K	6.5×10^6	6.5×10^4
5 750 K < CCT ≤ 8 000 K	5×10^6	5×10^4

Table 5-6. Illuminance values giving risk group not greater than RG0 and RG1

Rated CCT	RG1 Illuminance limits (lx)	RG0 Illuminance limits (lx)
CCT ≤ 2350 K	4 000	40
2 350 K < CCT ≤ 2 850 K	1 850	18.5
2 850 K < CCT ≤ 3 250 K	1 450	14.5
3 250 K < CCT ≤ 3 750 K	1 100	11.0
3 750 K < CCT ≤ 4 500 K	850	8.5
4 500 K < CCT ≤ 5 750 K	650	6.5
5 750 K < CCT ≤ 8 000 K	500	5.0

The methodology of IEC TR 62778 is more accurate than the one presented in IEC TR 62471-2 for the transfer of the risk group of LED components to a higher product which includes them. Table 5-5 and Table 5-6 define situations of RG0 and RG1 classification not requiring radiance or irradiance measurement. This allows a luminaire manufacturer to make sure that a product incorporating such LED components will not be RG2 and therefore will not require the labelling and user information listed in IEC TR 62471-2.

In the case of RG2 LEDs, the specification of the threshold illuminance E_{thr} in the LED datasheet allows the luminaire manufacturer to define use conditions giving a RG0 or RG1 classification for the final product, without having to perform full photobiological testing. The knowledge of the threshold distance is extremely useful for luminaires including RG2 LEDs as it can be compared with the minimum viewing distance that is expected in the use of the luminaire. Protection and control measures can therefore be implemented. This also assists with the determination of the threshold illuminance when multiple luminaires are used (including taking into consideration any variations in color temperatures).

5.6 Limitations of the CIE/IEC blue light hazard assessment

5.6.1 Potential effects of low-level chronic exposures

The maximum exposure limits defined by the ICNIRP and used to define the risk groups in IEC 62471 are not appropriate for repeated exposures to blue light as they were calculated for a maximum exposure of one eight hour day.

The effects of chronic and repeated low-dose exposures to visible light emitted by LEDs are currently being investigated by ophthalmologists, physicians and photobiologists [SHANG 2014 ; BOULENGUEZ 2014]. Researchers are working on identifying the mechanisms of retinal damage caused by chronic exposures of rats to low-intensity LED lighting. The objective is to detect the death of retinal cells well before the retina is bleached, which is the visible signature of retinal damage, observed by fundoscopy.

The first published results show that retinal damage induced by chronic exposure to white LEDs can be detected at much lower levels than the ICNIRP exposure limits.

5.6.2 Potential effects of long-term exposures

The ICNIRP exposure limit values do not take into account the possibility of an exposure over an entire lifetime. Very little is known about the effects of life-long cumulated exposures to blue light emitted by LEDs. According to the Scientific Committee on Emerging and Newly Identified Health risks (SCENIHR) of the European Commission [SCENIHR 2012], no evidence was found indicating that blue light from artificial lighting belonging to Risk Group 0 would have any impact on the retina graver than that of sunlight. The SCENIHR states that IEC 62471 gives limits that are protective against acute effects, while long-term effects are only marginally considered and estimated to be of negligible or small risk.

5.6.3 Sensitive populations

IEC 62471 does not take into account the sensitivity of certain specific population groups, which can be characterized by an accrued sensitivity to visible light:

- People having pre-existing eye or skin condition for which artificial lighting can trigger or aggravate pathological symptoms
- Aphakic and pseudophakic subjects who consequently either cannot or can only insufficiently filter short wavelengths (particularly blue light)
- Children, as their skin and visual system are not mature

- Elderly people as their skin and eyes , particularly the retina, are more sensitive to optical radiation

A general recommendation to these sensitive populations is to use lamps and luminaires emitting a small amount of short wavelength light, which are characterized by a low CCT (warm-white light for instance).

The photobiological standards relative to lighting systems should be extended to cover children - especially infants less than 2 year old - and aphakic or pseudophakic individuals, taking into account the corresponding phototoxicity curve *A(λ)* published by the ICNIRP in its guidelines.

Certain categories of workers are exposed to high doses of artificial light (long exposure time and/or high retinal irradiance levels) during their daily activities (lighting professionals, stage artists, etc.). Since the damage mechanisms are not yet fully understood, exposed workers should use appropriate personal protective equipment as a precautionary measure (glasses filtering out blue light for instance).

5.7 Personal protective equipment against blue light hazard

At the moment, there is no personal protective equipment available against the blue light hazard resulting from exposure to artificial light sources. Some type of laser goggles designed to filter out blue and green laser lines may be used for this purpose, under the prescription of a qualified occupational hygienist. It is worth mentioning that ophthalmic glasses can now be produced with a thin multilayer coating acting as an interferential blue light filter whose rejection band is tuned on the B(λ) spectrum. The current generation of such ophthalmic glasses cannot constitute a personal protective equipment against blue light emitted by artificial light sources. The transmittance is too high to reduce the blue light hazard risk group of a light source. However, they may offer a life-long beneficial protection against the retinal exposure to the combined environmental blue light (daylight, displays, artificial lighting, etc.).

5.8 Blue light hazard exposure data concerning LEDs and SSL products

Since 2009, blue light exposure data concerning LED have been provided by LED manufacturers and professional lighting associations (ELC and CELMA for instance) but also by independent laboratories and governmental agencies (ANSES and SCENHIR for instance). It was found that the blue light weighted radiance L_B produced at a distance of 200 mm from the user by a significant number of blue and cold-white LEDs (bare LEDs and LEDs equipped with a focusing lens) exceed the exposure limits set by ICNIRP for an exposure duration comprised between a few seconds for high power blue LEDs to a few tens of seconds for high power cold-white LEDs, making them classified as RG2.

For example,

Figure 5—15 extracted from [ANSES 2010] shows the variations of the blue light weighted radiance of cold white LEDs as a function of the exposure duration. Table 5-7, also extracted from [ANSES 2010] confirms that cold white LEDs are the most critical white light LED sources for the blue light hazard. These values are consistent with the boundary values of IEC TR 62778 presented in Figure 5—12.

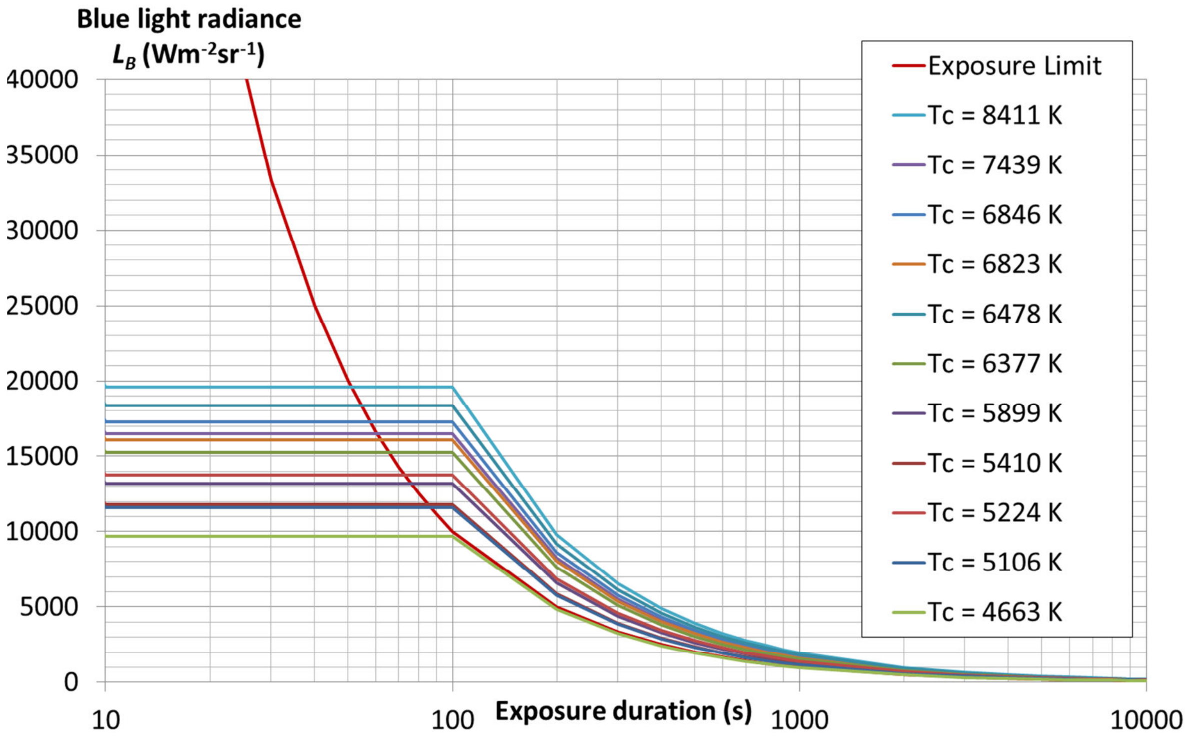


Figure 5—15. Adapted from [ANSES 2010]. Blue light radiance of single chip cold white LEDs emitting a luminous flux of 200 lm, measured at a distance of 200 mm. The exposure limits are exceeded for exposure durations between 50 s and 100 s, corresponding to an RG 2 classification.

Table 5-7. Reproduced from [ANSES 2009]. Results of the IEC 62471 blue light hazard assessment carried out on selected single chip high brightness white LEDs.

	Luminous flux (lm)	Luminance ($cd.m^{-2}$)	Maximum permissible exposure duration	IEC 62471 Risk Group
Cold white	100	1.6×10^7	∞ (exposure limit is never exceeded)	RG0 (no risk)
	200	3.2×10^7	50 s to 100 s (according to correlated color temperature)	RG2 (moderate risk)
Neutral white	100	1.6×10^7	∞ (exposure limit is never exceeded)	RG0 (no risk)
	200	3.2×10^7	100 s to 10 000 s (according to correlated color temperature)	RG1 (low risk)
Warm white	100	1.1×10^7	∞ (exposure limit is never exceeded)	RG0 (no risk)
	200	2.2×10^7		

The potential toxicity of some LED components viewed at short distances cannot be neglected. However, when the viewing distance is increased to one meter, the maximum permissible exposure duration rapidly increases to a few thousands of seconds, up to a few tens of thousands of seconds. These very long exposure durations provide a reasonable safety margin to assert that there is virtually no possible blue light retinal damage from LEDs at longer viewing distances (statement valid for state of the art LEDs at the time of writing this report).

Several classes of products and applications based on RG 2 bare LEDs or LEDs covered by a focusing lens (collimator) can potentially create a high level of retinal blue light exposure when short viewing distances are possible. Examples are (but are not limited to):

- Testing and adjustments of high power blue and cold white LEDs by operators in lighting manufacturing facilities or by lighting installers
- Toys using LEDs (not in the scope of this annex). Children are a sensitive population to blue light retinal exposure. Analysis similar to IEC TR 62778 using the aphakic action spectrum $A(\lambda)$,instead of the phakic action spectrum $B(\lambda)$, should be conducted.
- Automotive LED lights when activated near children and other sensitive people
- LED lamps sold for home applications (consumer market) where situations may potentially occur that lamps are viewed at distances as short as 200 mm.

The conclusion drawn above cannot be extended to all SSL applications because, as explained in the previous sections, the photobiological safety of a final SSL product cannot always be assessed from its LED components. The L_B value of an SSL product can be different from the L_B

value of the LED components that it uses. For instance, a higher L_B can be obtained with a luminaire using an array of low L_B small source LEDs. The case of LED arrays and clusters would necessitate a specific risk assessment method that is not yet included in the current version of IEC TR 62778. Also, a lower L_B can be obtained for a luminaire using a diffuser in front of a high L_B LED.

As explained in the IEC TR 62778 technical report, it is interesting to note that the strict application of IEC 62471 to LED lamps and luminaires used in general lighting (assessment at the distance corresponding to an illuminance level of 500 lx) always leads to an RG 0 or RG 1 classification, similar to traditional indoor light sources (fluorescent lamps, incandescent and halogen lamps).

Nevertheless, when the 200 mm viewing distance was used, several measurement campaigns such as [ANSES 2010] revealed that only a few indoor LED lamps and luminaires belonged to RG2 while traditional indoor light sources (fluorescent and incandescent) were always in RG0 or RG1. This result shows that LED technology potentially raises the blue light risk in home applications where the viewing distance is not limited and light sources are accessible to children and other sensitive people. At the time of this writing, the general public is not aware of potential risks for the eye. It is expected that the application of the labelling system of IEC TR 62471-2 (warning in the case of RG2) will become mandatory in some economies. At the time of preparing this document, no mandatory labelling system was in place for RG2 lighting products.

For SSL products aimed at consumer applications (retrofit LED lamps for instance), the experts recommend the limitation of the blue light hazard risk group to RG1 at 200 mm, which can be considered as the minimum viewing distance encountered at home. The measurement campaigns carried out by several laboratories showed that the vast majority of indoor LED lamps and luminaires already comply with this requirement. This suggests that it is not a critical issue for the SSL industry at large.

It is worth noting that other widely used light sources, particularly high intensity discharge lamps (metal-halide lamps for instance), are also in RG2 and even in RG3 for hazards other than retinal blue light hazard. However, these lamps are intended for clearly identified uses and can only be installed by professionals who should be aware of the safety distance required to limit the exposure.

New generations of LEDs emitting white light are currently being developed using violet and UV chips. This is the case of “GaN on GaN” LEDs which are now incorporated in several commercially available SSL products. Such devices are very interesting from a color rendering point of view as a more continuous and regular spectrum can be achieved with luminophores excited by shorter wavelength radiation than blue light. The photobiological safety of these LEDs and the products using them should be carefully assessed because of potential residual UV and violet radiation in the emission spectrum. The assessment should be conducted for the blue light hazard and UV hazards as well. A careful examination of the aging of these products should also be conducted as the possible degradation of the luminophores may raise the level of short wavelength light emission.

5.9 Recommendations

A photobiological safety assessment must be carried out for all SSL devices (LEDs, LED modules, LED lamps, LED luminaires, etc.). The main tool is the joint CIE S009 / IEC 62471 standard. Following the guidelines of IEC TR 62778, LED manufacturers should report the risk group of their component (RG0, RG1 or RG2).

According to IEC TR 62778, it is sometimes possible to transfer the risk group of an LED to a higher product that incorporates it. In the case of RG2 devices, it is advised that the manufacturer provides the boundary between RG1 and RG2 by reporting the threshold illuminance and the threshold distance, which can be viewed as a reasonable safety distance.

RG2 finished products should be sold with clear information concerning the threshold distance. When there is a possibility of viewing the source below this distance, they should be labelled according to IEC TR 62471-2, in order to inform the user “not to stare” at the operating lamp as it may be harmful to the eyes. At the time of this writing, the general public is not aware of potential risks for the eye. It is expected that the application of the labelling system of IEC TR 62471-2 (warning in the case of RG2) will become mandatory in some economies. At the time of preparing this document, no mandatory labelling system was in place for RG2 lighting products.

For SSL products aimed at consumer applications (retrofit LED lamps for instance), the experts recommend the limitation of the risk group to RG1 when viewed at 200 mm, which can be considered as the shortest viewing distance encountered at home.

The next revision of IEC 62471 should take into account the sensitivity of certain specific population groups, which can be characterized by an accrued sensitivity to visible light, such as people having pre-existing eye or skin condition, aphakics (people with no crystalline lens), pseudophakics (people with artificial crystalline lenses), children and elderly people as their skin and eyes are more sensitive to optical radiation.

The photobiological standards relative to lighting systems should be extended to cover children less than two years old by taking into account the corresponding aphakic phototoxicity curve published by the ICNIRP in its guidelines.

Certain categories of workers (lighting professionals, stage artists, etc.) are exposed to high doses of artificial radiation emitted by SSL products during their daily activities. Since the damage mechanisms are not yet fully understood, exposed workers should use appropriate individual means of protection as a precautionary measure (glasses filtering out blue and violet light for instance). The experts recommend the development of personal protective equipment against the blue light hazard resulting from exposure to artificial light sources.

New generations of LEDs emitting white light are currently being developed using violet and UV chips. The photobiological safety of these LEDs and the products using them should be carefully assessed because of potential residual UV and violet radiation in the emission spectrum. The assessment should be conducted for the blue light hazard and UV hazards as well. A careful assessment of the aging of these products should also be conducted as the possible degradation of the luminophores may raise the level of short wavelength radiation, thereby increasing the retinal exposure levels.

6 Light flicker hazards

Flicker is the modulation of the light output that can be induced by fluctuations of the mains voltage supply, residual ripples in the DC current powering, or deliberate modulations of the LED input current such as the pulse-width modulation (PWM) used for dimming applications.

It is known that exposure to light flicker (in particular at frequencies between 3 Hz and 65 Hz) can cause photosensitive epileptic seizures in various forms, depending on the individuals and their visual pathology.

According to a document issued by the IEEE [IEEE 2010], about 1 in 4000 individuals is recognized as having photosensitive epilepsy. Repetitive flashing lights and static but spatially repetitive geometric patterns may induce seizures in these individuals. The seizures reflect the transient abnormal synchronized activity of brain cells, affecting consciousness, body movements and/or sensation. The onset of photosensitive epilepsy occurs typically at around the time of puberty. In the age group 7 to 20 years, the condition is five times as common as in the general population. Three quarters of patients remain photosensitive for life. Many factors affect the likelihood of seizures including [IEEE 2010]:

- How quickly the light is flashing (flash frequency). Any repetitive change in a visual stimulus within the frequency range 3 Hz to 65 Hz is potentially a risk with the greatest sensitivities in the range 15 Hz to 20 Hz.
- Brightness: stimulation in the scotopic or low mesopic range (below about 1 $cd.m^{-2}$) has a low risk but the risk increases monotonically with the logarithm of the luminance in the high mesopic and photopic range.
- Contrast with background lighting. Contrasts above 10% are potentially a risk.
- Distance between the viewer and the light source, which changes the size of the image on the retina.
- The location of stimulation within the visual field is important: stimuli presented in central vision pose more of a risk than those that are viewed in the periphery, even though flicker in the periphery may be more noticeable.
- Wavelength of the light. Deep red flicker and alternating red and blue flashes may be particularly hazardous.
- Whether a person’s eyes are open or closed. Bright flicker can be more hazardous when the eyes are closed, partly because the entire retina is then stimulated as the eyelid becomes the light source (due to diffuse transmission of the light).

According to the literature, light flicker is not usually perceptible at frequencies higher than 70 Hz, but it can still have non-visual effects on people. For example, people suffering from migraines are more likely to be sensitive to flicker at high frequencies [IEEE 2010]. Measurements of electroretinograms have indicated that modulation of light in the frequency range 100-160Hz [BURNS 1992] and even up to 19 kHz [BERMAN 1991] is detected by the human retina even though the flicker is too rapid to be visible.

Light flicker combined to rotating motion or spatial patterns may be responsible for stroboscopic effects which may, in turn, induce accidents to workers in proximity to rotating machines and tools which can appear to be rotating significantly more slowly or even be stationary.

Alternatively, pulsed lights may also have some positive effects: it has been reported that the pulsed operation of lamps could offer opportunities for energy savings according to the Broca-Sulzer effect due to enhanced perceived brightness, although these results are still debated in the scientific community. Thus, it is sometimes argued that energy savings can be achieved by using pulsed LEDs at very high frequency. In that case, it is absolutely necessary to understand the sensitivities to flicker of humans in order to avoid any deleterious effects appearing with products using that type of pulsed light.

Laboratory measurement campaigns [KITSINELIS 2013; ZISSIS 2013] demonstrated that some readily available consumer SSL products have very high flicker behaviour. Commercially available LED lamps are especially concerned. Light flickering behaviour was often observed at twice the mains frequency (in Europe mains frequency is 50 Hz thus the observed flicker frequency is equal to 100 Hz). This light flicker is mainly due to the residual voltage fluctuation after the AC/DC rectifier in the lamp power supply.

6.1 Definition and Experimental evaluation of flickering

There are two widely accepted metrics for measuring lamp flicker. Figure 6—1 is used to illustrate these two metrics. The first, called the percent flicker, τ_L, uses the maximum and minimum points *A* and *B* of the fluctuation levels through the following equation:

$$\tau_L(\%) = 100\frac{B-A}{B+A} \tag{9}$$

The second metric is the flicker index *FI* and requires the calculation of the areas above and below the average level of the signal [IESNA 2010].

$$FI = \frac{Area\ 1}{(Area\ 1) + (Area\ 2)} \tag{10}$$

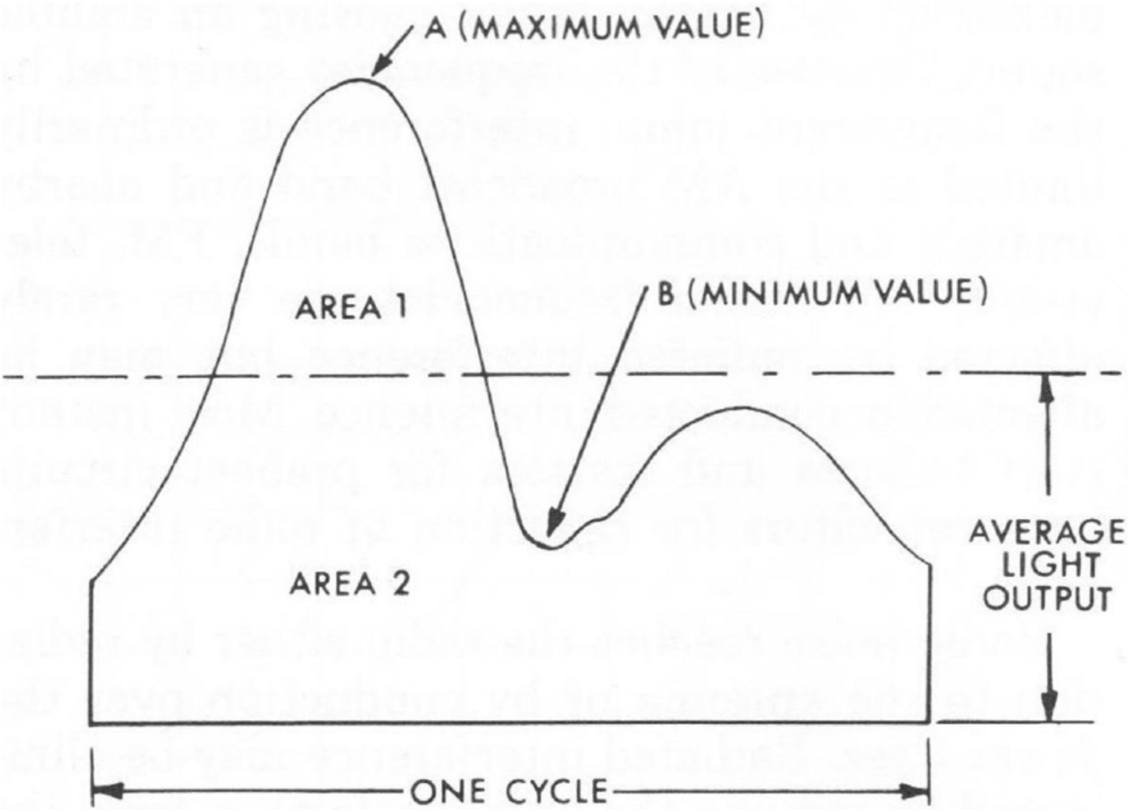


Figure 6—1. Reproduced from [IESNA 2010]. Definition of light flickering metrics

As shown in Figure 6—*2*, it has been demonstrated experimentally in [ZISSIS 2013] that there was an almost linear correlation between percent flicker and flicker index in a sample of commercially available LED lamps (mains voltage lamp incorporating an integrated driver).

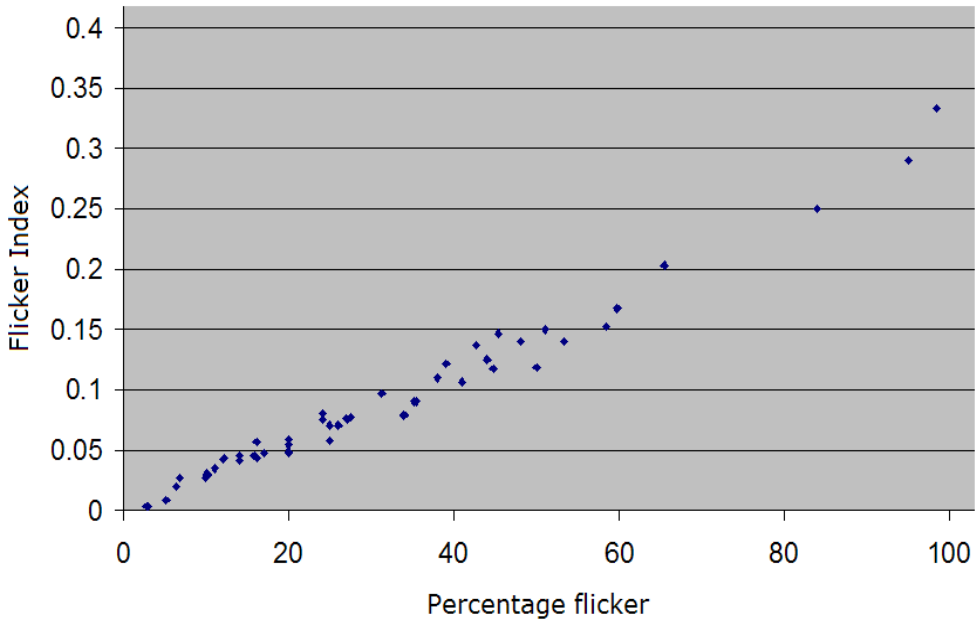


Figure 6—2. Correlation between percent flicker and flicker index as measured in [ZISSIS 2013]

There are other commercially available SSL products that do not follow this behaviour, notably when pulse-width modulation (PWM) techniques are used. In this case, the percent flicker is always 100% while the flicker index may range from 0 to 1.

6.2 Experimental value of light flicker of LED lamps

Figure 6—*3* shows the experimental percent flicker values measured with commercially available LED lamps, CFL and incandescent lamps. It should be noted that a 100 W incandescent lamp has a percent flicker of about 10% due to the filament temperature variation that follows the power waveform. Good quality CFLs may reach a percent flicker of 20%. The highest flicker index value for tested CFL lamps was found to be 0.14.

The situation is completely different for LED lamps. As can be seen in Figure 6—*3*, LED lamps had completely arbitrary behaviours. Some of them featured high quality power supplies that include reliable AC/DC rectifiers and filters. They displayed very low flicker, close to zero. Other devices had percent flicker values up to 100%. In this particular case, the light output turns ON and OFF every 10 ms. Only eight LED lamps were found to have a flicker index less than 0.1, which was the value once quoted in a draft of the Energy Star requirements.

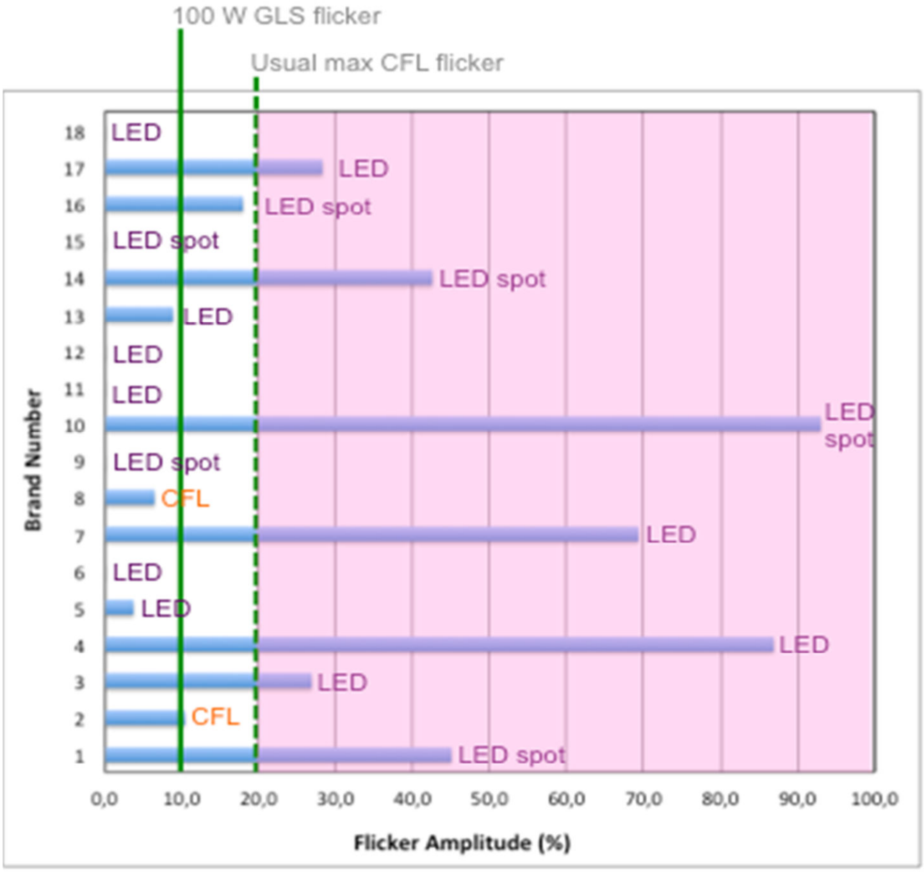


Figure 6—3. Some experimental percent flicker values of various lamp technologies as published in [ZISSIS 2013]

6.3 Flicker requirements

At the present time, no regulation of light flicker is implemented in the EU, the USA or any other countries. This is clearly unacceptable based on the potential health effects and the levels of flicker found in current products.

It is worth mentioning that the current Energy Star requirements consist in reporting the flicker frequency, the highest values of the percent flicker and the flicker index. However, no limits are set in these requirements.

6.4 The case of large outdoor LED displays

An emerging problem in major built up cities is the multiplicity of large outdoor LED displays and billboards. The combination of large and adjacent panels using different supply frequencies may lead to visible stroboscopic effects in the field of view.

6.5 Recommendations

Based on the potential health effects and the levels of flicker found in current SSL products, the experts recommend that limits should be set on flicker values.

7 Non visual effects and possible perturbations of circadian rhythms

Light has a strong influence on the regulation of circadian rhythms. This influence has been observed by chronobiologists in human subjects (including some blind subjects) and many other animal species since the 1980s. Light happens to be the most powerful agent to perform the daily synchronization of the biological circadian clock, whose period intrinsically deviates from 24 hours by a short delay or a short advance of a few minutes, up to a few tens of minutes. In the absence of light stimuli, the circadian clock would drift and become desynchronized with the daily schedule. The most striking feature of this synchronization mechanism is that it only happens through the eye.

The discovery of a new type of photoreceptive cells in the retina in the 1990s provided the physiological basis to explain this phenomenon [BERSON 2002]. Although the mammalian retina consists of a vast majority of photoreceptors that contribute to vision (rods and cones, see Figure 5—4), a small number of ganglion cells were found to have a photoreception capacity that does not contribute to vision. These are the intrinsically photoreceptive retinal ganglion cells (ipRGCs). These cells are directly connected to the suprachiasmatic nucleus (SCN), a tiny region of the brain located in the hypothalamus. The SCN is responsible for controlling circadian rhythms. It has been demonstrated that the excitation of ipRGCs with light is responsible for suppressing the production of melatonin (a “sleep” hormone) by the pineal gland. It is also responsible for many other non-visual effects (pupil constriction, increase of the heart rate and body temperature, stimulation of cortisol production (a “wake up” hormone), etc.

The ipRGCs contain melanopsin, a photopigment that allows them to detect and respond to light inputs. Therefore, it is now well established that the human retina contains five different photoreceptors (rod, L-cone, M-cone, S-cone, ipRGC), each being associated with a specific spectral sensitivity.

The spectral sensitivity of melanopsin was found to be maximal at a wavelength of about 480 nm in several published articles, including [PANDA 2005]. This wavelength corresponds to a blue-green colour. The estimation of the resulting spectral sensitivity of the ipRGCs is very difficult to achieve because, like the other retinal ganglion cells, ipRGCs are connected to the outer segments of the rods and cones (Figure 5—4). This is the reason why the signals generated by ipRGCs are influenced by both the melanopsin photoreception and the signals produced by the rods and cones. This means that the behaviour of the ipRGCs is influenced by all the other photoreceptors. The combination of the various channels into a non-visual ipRGC signal is an active area of research [LUCAS 2014].

As a consequence of this type of retinal signal processing, it seems questionable to normalize an action spectrum of the human non-visual photoreception system, as it was done for instance in [DIN 2009]. The effective spectral sensitivity fundamentally depends on the context (current and past states of the visual and non-visual photoreceptors). Similarly, the efforts that are currently made to quantify the light quantities by using a "melatonin suppressing action spectrum" as a weighting function of the spectral quantities may be misleading as the resulting quantities cannot reflect the physiological mechanisms involved in the regulation of the circadian rhythms. It is not yet possible to predict the non-visual effects of light exposure based on the spectral composition and the irradiance level.

In specific and well-defined environments, experimental work allowed researchers to draw important conclusions. For instance, in the case of a prolonged exposure to diffuse white light emitted by a large source, Gronfier et al. [GRONFIER 2004] concluded that the non-visual effects of light depend on the intensity of light and the exposure duration. For instance, a nocturnal exposure at an illuminance level of 10 000 lx lasting 6.5 h led to a delay of more than 2 h in the production of melatonin. A light exposure given at the same time with the same duration but with an illuminance level of 100 lx produced a delay of 1 h. The relationship between the illuminance level and the non-visual effects seems to be non-linear. In addition, the non-visual effects of light depend on the time at which the exposure is done. A phase response curve was published in [KHALSA 2003] showing that exposure to light during the evening has the effect of delaying the circadian clock whereas the exposure during the morning has the opposite effect of advancing the circadian clock.

The authors of [LUCAS 2014], who include some of the most prominent researchers in the field on the non-visual effects of light, recognize that light has a broad range of non-visual effects that should be taken into account for the design and the use of lighting systems. However, the authors cannot take a firm position to whether the lighting design should minimize or maximize the non-visual effects of lights. Knowing these effects, light can be used to delay or advance the circadian rhythm, with both beneficial and undesirable effects. For instance, the performances of night-shift workers in a bright environment illuminated with blue-enriched light sources will be enhanced but their circadian rhythm will be shifted, resulting in sleep disorders and other deleterious effects. Conversely, a dimmer lighting will minimize the perturbation of the circadian rhythm but it will affect the visual ergonomics and the work performances.

Very general rules are given in [LUCAS 2014] to minimize the activation of the ipRGCs and the non-visual effects of light:

- Keep the retinal irradiance as low as possible. There is no established threshold below which the non-visual system is inactive. Total darkness during sleep may be ideal.
- With respect to the visible light spectrum, any wavelength can activate the non-visual system.

However, the relative sensitivity of non-visual responses is generally reduced in the longer wavelength range. Light richer in yellow, orange and red colours rather than blue and green colours, will be less effective to activate non-visual response such as the melatonin suppression.

Inversely, light sources containing blue and blue-green components producing high retinal irradiance should be used to promote the activation of ipRGCs and the non-visual effects of lights.

LEDs and SSL devices are very flexible in terms of emission spectrum. Coloured and white LEDs can be combined to produce a large variety of spectra, ranging from quasi monochromatic (coloured light) to quasi continuous (white light). This degree of variety in the choice of the emission spectrum is unique among the light source currently used in lighting. As a consequence, LED devices are now used by physicians to treat certain conditions by controlling the non-visual effects of light (phototherapy). For example, the seasonal affective disorder (SAD) can be efficiently treated using controlled light exposures. In the future, the better understanding of the non-visual effects of light, combined with the availability of spectrally tuneable LED devices, is expected to develop the applications of phototherapy for the treatment of disorders caused by a dysfunctional biological clock.

7.1 Recommendations

All light has a broad range of non-visual effects that should be taken into account for the design and the use of lighting systems. However, it is not clear whether the artificial lighting design should minimize or maximize the non-visual effects of lights. Light can be used to delay or advance the circadian clock, with both beneficial and undesirable effects that need to be taken into account. This is an issue for all artificial light, not just LED lighting.

The non-visual effects of light depend on the illuminance level, the exposure duration, the timing of the exposure and the light spectrum. The relationships between these quantities and the non-visual effects are not well established. The experts emphasize that the use of a single "melatonin suppressing action spectrum" to compute light quantities is not suited to describing the physiological mechanisms involved in the regulation of the circadian rhythms.

Keeping the retinal irradiance as low as possible is a general rule that can be given to minimize the non-visual effects of light. Although any wavelength in the visible spectrum can activate the non-visual system, the relative sensitivity of non-visual responses is generally reduced in the longer wavelength range. Light richer in yellow, orange and red colours (low colour temperatures such as warm white light) rather than blue and green colours (high colour temperatures such as cold white light), will be less effective to activate non-visual responses such as the melatonin suppression. Inversely, light sources emitting blue and blue-green components and producing high retinal irradiance can be used to trigger - or enhance - the non-visual effects of light.

In comparison with the other lighting technologies, the SSL technology is not expected to have more direct negative impacts on human health with respect to non-visual effects. However, SSL may indirectly be responsible for an overall increase of light exposure. The low cost of LEDs combined with their form factor and their low energy consumption may cause more lighting points to be installed at home, at work or in the streets, thereby increasing the overall exposure to artificial light and the potential risks linked to non-visual effects such as the perturbation of the biological circadian clock. The experts recommend preserving a dark nocturnal environment while maintaining a suitable exposure level during daytime through a combination of daylight and artificial lighting.

8 Conclusions

In this report, the potential health effects of SSL and LED light sources have been described in the context of the known effects of artificial optical radiation on human health. The effects on the eye and the skin have been presented and analysed. Glare and flickering phenomena have been detailed. Non-visual effects of light, such as the effects on the circadian rhythm and the biological clock have also been studied. The conclusions reached for each type of potential effect are summarized below.

8.1 Conclusions related to glare

In a typical LED, the radiance and luminance levels may be extremely high, much higher than the values found in the case of common lamps used in general lighting, making them more susceptible to producing glare. Glare does not constitute a risk in itself but it is a source of discomfort and temporary visual disability. It can be the indirect cause of accidents.

In indoor lighting, glare is assessed with the index UGR, defined by the CIE. The UGR is not applicable to point sources such as visible LEDs incorporated in a luminaire. However, lighting manufacturers and designers usually perform UGR calculations on SSL luminaires having visible LED point sources but incorrectly considering the average luminance over the whole area of the luminaire. This approach is misleading as the resulting UGR is low and does not reflect the physiological perceived glare. Therefore, the use of UGR should be restricted to SSL products with large diffusers, without any point sources. In all cases, it is recommended that the maximum luminance of the SSL finished products is specified, whether they incorporate visible LED point sources or not. The luminance ratio between the light source and the background should be computed and adapted to each lighting installation according to visual ergonomics criteria.

In outdoor lighting, the disability glare indices GR and TI, defined by the CIE, are applicable to high power luminaires and lighting installations located sufficiently far away from the viewer, whatever the lighting technology.

8.2 Conclusions related to the blue light hazard

The blue light hazard is the only photobiological hazard currently required to be considered in the present SSL technologies, at the exception of LEDs using a UV emitting semiconducting structure. The blue light hazard is related to the photochemical damage caused by blue and violet light on the retina. Two key features of LEDs have attracted the attention of lighting specialists, ophthalmologists and photobiologists:

- Most LED components are very bright small sources of visible light (high luminance and radiance values)

- The vast majority of commercial white light LEDs have an emission spectrum which exhibits a blue peak.

The blue light hazard is associated with blue light retinal irradiance. Due to the high radiance of LEDs, the retinal irradiance levels are potentially high and must be carefully considered. In general, the photochemical damage of the retina depends on the accumulated dose to which the person has been exposed, which can be the result of a high intensity short exposure but can also appear after low intensity exposures repeated over long periods. Blue light is recognized as being harmful to the retina, as a result of cellular oxidative stress. Blue light is also suspected to be a risk factor in the age-related macular degeneration.

Retinal blue light exposure can be estimated using the ICNIRP guidelines. The retinal blue light exposure levels produced at a distance of 200 mm by blue and cold-white LEDs often exceed the exposure limits after an exposure between a few seconds (blue LEDs) to a few tens of seconds (cold-white LEDs). As a consequence, the short-distance potential toxicity of these LED components cannot be neglected.

However, when the viewing distance is increased beyond one meter, the maximum exposure duration rapidly increases to a few thousands of seconds, even up to a few tens of thousands of seconds. These very long exposure durations provide a reasonable safety margin to assert than there is virtually no possible blue light retinal damage from LEDs at longer viewing distances (statement valid for state of the art LEDs at the time of writing).

Several usages and applications based on bare LEDs or LEDs associated with a focusing lens (collimator) are directly concerned by a potentially high level of retinal blue light exposure. Examples are (but are not limited to):

- Testing and adjustments of high power blue and cold white LEDs by operators in lighting manufacturing facilities and by lighting installers
- Toys using LEDs (not in the scope of this annex). Children are a sensitive population to blue light retinal exposure.
- Automotive LED lights when activated near children and other sensitive people (not in the scope of this annex).
- LED lamps sold for home applications (consumer market) in which case lamps can be viewed at distances as short as 200 mm.

For all SSL devices (LEDs, LED modules, LED lamps, LED luminaires, etc.) products, the blue light hazard risk assessment must be carried out. The main tool is the IEC 62471 standard. It provides a system of classification of light sources in several risk groups, according to the maximum permissible exposure duration assessed at a given viewing distance: Risk Group 0 or Exempt group (no risk), Risk Group 1 (low risk), Risk Group 2 (moderate risk), Risk Group 3 (high risk).

IEC 62471 defines two different criteria to determine the viewing distance. Light sources used in general lighting should be assessed at the distance corresponding to an illuminance of 500 lx. Other types of light sources should be assessed at a fixed distance of 200 mm.

For LED components which will be integrated in a higher product, IEC 62471 requires using the distance of 200 mm. The application of the IEC 62471 measurement technique at 200 mm often lead to RG2 classification (moderate risk) for blue and cold white LEDs.

The choice of the viewing distance in IEC 62471 is sometimes ambiguous and not realistic in the context of real usage conditions. The technical report IEC TR 62778 was published in 2012 to clarify and resolve this ambiguity of IEC 62471 when it is applied to the blue light hazard assessment of LEDs and SSL devices.

Following the guidelines of IEC TR 62778, LED manufacturers should report the risk group of their component (RG0, RG1 or RG2). According to IEC TR 62778, it is sometimes possible to transfer the risk group of an LED to a higher product that incorporates it. In the case of RG2 devices, it is advised that the manufacturer provides the boundary between RG1 and RG2 with the threshold illuminance and the threshold distance, which can be viewed as a reasonable safety distance. RG2 products should be sold with clear information concerning the threshold distance. Otherwise, RG2 products should be labelled according to IEC TR 62471-2, in order to inform the user “not to stare” at the operating lamp as it may be harmful to the eyes. At the time of this writing, the general public is not aware of potential risks for the eye. It is expected that the application of the labelling system of IEC TR 62471-2 (warning in the case of RG2) will become mandatory in some economies. At the time of preparing this document, no mandatory labelling system was in place for RG2 lighting products.

For SSL products aimed at consumer applications (retrofit LED lamps for instance), the experts recommend the limitation of the risk group to RG1 at 200 mm, which can be considered as the shortest viewing distance encountered at home.

IEC 62471 does not take into account the sensitivity of certain specific population groups, which can be characterized by an accrued sensitivity to visible light:

- People having pre-existing eye or skin condition for which artificial lighting can trigger or aggravate pathological symptoms
- Aphakics (people with no crystalline lens) and pseudophakics (people with artificial crystalline lenses) who consequently either cannot or can only insufficiently filter short wavelengths (particularly blue light)
- Children, as their skin and visual system is not mature
- Elderly people as their skin and eyes are more sensitive to optical radiation

The photobiological standards relative to lighting systems should be extended to cover children and aphakic or pseudophakic individuals, taking into account the corresponding phototoxicity curve published by the ICNIRP in its guidelines.

Certain categories of workers are exposed to high doses of artificial light (long exposure times and/or high retinal irradiance levels) during their daily activities (examples: lighting professionals, stage artists, etc.). Since the damage mechanisms are not yet fully understood, exposed workers should use appropriate individual means of protection as a precautionary measure (glasses filtering out blue light for instance). At the moment, there is no personal protective equipment available against the blue light hazard resulting from exposure to artificial light sources. Some type of laser goggles designed to filter out blue and green laser lines may be used for this purpose, under the prescription of a qualified occupational hygienist.

New generations of LEDs emitting white light are currently being developed using violet and UV chips. The photobiological safety of these LEDs and the products using them should be carefully assessed because of potential residual UV and violet radiation in the emission spectrum. The assessment should be conducted for the blue light hazard and UV hazards as well. A careful assessment of the aging of these products should also be conducted as the possible degradation of the luminophores may raise the level of short wavelength radiation, thereby increasing the retinal exposure levels.

8.3 Conclusion about light flicker

Flicker is the modulation of the optical output of a light source. A known effect of flicker is to induce seizures in patients suffering from photosensitive epilepsy. For the general population, flicker may induce a range of symptoms ranging from headaches, migraines and dizziness to impaired visual performances.

SSL products such as LED lamps have a completely arbitrary behaviour in terms of light flicker. Some of them display no flicker while other devices reach the maximum percent flicker value of 100%.

Whether in Europe, the USA or any other country, there is no clear requirement concerning light flicker limitation, which is clearly unacceptable. The experts recommend that mandatory maximum values are set to limit flicker in SSL products.

8.4 Conclusions about non-visual effects and possible perturbation of the circadian rhythm

Light has a strong influence on the regulation of circadian rhythms. The discovery of a new type of retinal photoreceptive cells, the ipRGCs, provided the physiological basis to explain this phenomenon. It has been demonstrated that the excitation of ipRGCs with light is responsible for suppressing the production of melatonin. It is also responsible for many other non-visual effects.

The ipRGCs contain melanopsin, a photopigment that allows them to detect and respond to light inputs.

The signals generated by ipRGCs are influenced by both the melanopsin photoreception and the signals produced by the rods and cones. As a consequence, it seems questionable to normalize an action spectrum of the human non-visual photoreception system. The effective spectral sensitivity fundamentally depends on the context (current and past states of the visual and non-visual photoreceptors). Similarly, the efforts that are currently made to quantify the light quantities by using a "melatonin suppressing action spectrum" may be misleading as the resulting quantities cannot reflect the physiological mechanisms involved in the regulation of the circadian rhythms. It is not yet possible to predict the non-visual effects of light exposure based on the spectral composition and the irradiance level.

Nevertheless, in specific and well-defined environments, experimental work concluded that the non-visual effects of light depend on the illuminance level and the exposure duration, though the relationship between the illuminance level and the non-visual effects is not well established and seems to be non-linear. In addition, the non-visual effects of light depend on the time at which the exposure is received.

All light has a broad range of non-visual effects that should be taken into account for the design and the use of artificial lighting systems. However, it is not clear whether the lighting design should minimize or maximize the non-visual effects of lights. Light can be used to delay or advance the circadian clock, with both beneficial and undesirable effects that need to be taken into account. This is an issue for all artificial light, not just LED lighting.

Keeping the retinal irradiance as low as possible is a general rule that can be given to minimize the activation of the ipRGCs and the non-visual effects of light. Although any wavelength in the visible spectrum can activate the non-visual system, the relative sensitivity of non-visual responses is generally reduced in the longer wavelength range. Light richer in yellow, orange and red colours rather than blue and green colours, will be less effective to activate non-visual response such as the melatonin suppression. Inversely, light sources containing blue and blue-green components producing high retinal irradiance can be used to promote the activation of ipRGCs and the non-visual effects of lights.

LEDs and SSL devices are very flexible in terms of emission spectrum. LEDs can be combined to produce a large variety of spectra, ranging from coloured light to white light. This degree of variety in the choice of the emission spectrum is unique among the light source currently used in lighting. As a consequence, LED devices are now used by physicians to treat certain conditions by controlling the non-visual effects of light (phototherapy). In the future, the better understanding of the non-visual effects of light, combined with the availability of spectrally tunable LED devices, is expected to develop the applications of phototherapy for the treatment of disorders caused by a dysfunctional biological clock.

In comparison with the other lighting technologies, the SSL technology is not expected to have more direct negative impacts on human health with respect to non-visual effects. However, SSL may indirectly be responsible for an overall increase of light exposure. The low cost of LEDs combined with their form factor and their low energy consumption may cause more lighting points to be installed at home, at work or in the streets, thereby increasing the overall exposure to artificial light and the potential risks linked to non-visual effects such as the perturbation of the biological circadian clock.

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