

ICNIRP STATEMENT

LIGHT-EMITTING DIODES (LEDS): IMPLICATIONS FOR SAFETY

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LIGHT-EMITTING DIODES (LEDs): IMPLICATIONS FOR SAFETY

International Commission on Non-Ionizing Radiation Protection (ICNIRP)¹

Abstract—Since the original ICNIRP Statement was published in 2000, there have been significant improvements in the efficiency and radiance (i.e., optical radiation emission) of LEDs. The most important improvement is the development of ‘white’ LEDs that can be used as general lighting sources, which are more efficient than traditional lighting sources. LEDs emitting in the ultraviolet wavelength region have also become available and have made their way into consumer products. All these changes have led to a rise in concern for the safety of the optical radiation emissions from LEDs. Several *in vitro* and animal studies have been conducted, which indicate that blue and white LEDs can potentially cause retinal cell damage under high irradiance and lengthy exposure conditions. However, these studies cannot be directly extrapolated to normal exposure conditions for humans, and equivalent effects can also be caused by the optical radiation from other light sources under extreme exposure conditions. Acute damage to the human retina from typical exposure to blue or white LEDs has not been demonstrated. Concern for potential long-term effects, e.g. age-related macular degeneration (AMD), remains based on epidemiological studies indicating a link between high levels of exposure to sunlight and AMD. When evaluating the optical radiation safety of LEDs, it has now been established that published safety standards for lamps, not lasers, should be applied. Thus far, the only clear, acute adverse health effects from LEDs are those due to temporal light modulation (including flicker). Glare can also create visual disturbances when LED light fixtures are not properly designed. Further research is needed on potential health effects from short- and long-term exposure to new and emerging lighting technologies. *Health Phys.* 118(5):549–561; 2020

Key words: International Commission on Non Ionizing Radiation Protection; health effects; safety standards; radiation, non-ionizing

INTRODUCTION

THE ORIGINAL ICNIRP Statement on light-emitting diodes (LEDs) and laser diodes (ICNIRP 2000) focused on distinguishing between these two types of diode sources. It is now well-established that the potential hazards from LEDs are more similar to those from conventional lamps than they are from lasers. Since the publication of the ICNIRP Statement on LEDs and laser diodes in 2000 (ICNIRP 2000), there have been significant changes in LED technology, and their use has become more widespread. In fact, they are expected to be the major domestic and public light source in use by 2030 (<https://www1.eere.energy.gov/buildings/publications/pdfs/ssl/energysavingsforecast14-summ.pdf>). The main driving force behind the rapid growth in the production and sales of “white” LEDs for general lighting is their higher efficiency and longer life compared to traditional light sources; e.g. incandescent and fluorescent lamps. Since 2000, LEDs have become even more efficient and less expensive. In addition, one of the important changes in LED technology since 2000 is the extension of available wavelengths into the ultraviolet (UV) region. LEDs are now available at wavelengths as short as 214 nm. LEDs emitting in the UV-A (315–400 nm) region are sold for fluorescence applications and even appear in some toys. They are also commonly found in UV nail curing devices, sold both for salon and home use. In addition, UV-emitting LEDs are now being used in the forensics, photolithography, curing, disinfection, water purification and medical device industries (including dentistry). LEDs with emission wavelengths from the UV-C to the short wavelength visible region are being used as a non-antibiotic method of germicidal and infection control (Gillespie et al., 2017; Wengraitis et al. 2013). The increased availability of these UV-emitting LEDs has led to concerns about increased exposures of consumers to potentially harmful UV radiation. There are also increasing concerns about visible light emitted from LEDs, as general

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lighting and consumer products containing extremely bright LEDs are becoming more widely available. Visible LEDs are widely used in illumination sources, displays, and in many home entertainment systems, toys, signal lamps, and optical fiber communication. Common examples include cellphone, tablet and laptop screens, TVs, traffic signals, and automotive headlights. Infrared LEDs (also known as “IREDs,” emitting at wavelengths up to 4300 nm, or 4.3 μm) have been used in optical fiber communication and optical surveillance systems and have found application in many new technologies; e.g., face and gesture recognition, eye trackers, diagnoses and identification, proximity sensors, and machine vision.

While the higher power laser diodes have historically been considered to pose “eye hazards,” traditional LEDs were generally regarded as safe, with no need for LED safety standards at the time of the 2000 ICNIRP Statement (ICNIRP 2000; IESNA 1996a and b). ICNIRP’s role is to review scientific knowledge about potential hazards and recommend exposure guidelines. Standardization bodies, such as the International Electrotechnical Commission (IEC) employ ICNIRP exposure guidelines to develop emission limits used in product safety standards. With the development of shorter wavelength and higher power LEDs, there has been an effort to apply lamp safety standards to LED products. LEDs are now, for example, covered by the International Commission on Illumination (CIE) S009/IEC 62471:2006 *Photobiological safety of lamps and lamp systems* standard (IEC 2006), which is currently undergoing revision. That standard provides the methods for the classification of lamps into one of four Risk Groups (RGs), RG0, RG1, RG2, and RG3, which are based on established exposure limits (ELs). If a lamp is classified as RG0, also known as “exempt,” there is considered to be no hazard associated with exposure to this lamp. For exposure at the classification distance, the risk from exposure to lamps in risk groups above RG0 increases gradually up to RG3. If a lamp is classified as RG3, it is considered to potentially pose a high risk, and exposure to this lamp may pose a hazard even for a brief exposure, particularly at close distances. See CIE S009/IEC 62471:2006 *Photobiological safety of lamps and lamp systems* standard (IEC 2006; Sliney et al. 2016) for further information about the different RGs.

There are a variety of LED types ranging from surface emitters to super-luminescent diodes (SLDs). The latter have some characteristics more typical of diode lasers, but as they do not contain a resonant cavity, no optical gain or ‘laser action’ can occur. Questions have therefore arisen as to whether laser or incoherent radiation ELs should be applied to each type of emitter. Since this Statement is intended for the general public, it will not cover SLDs, which are special purpose and generally not purchased or used by the general public. It should be mentioned that, if desired, ICNIRP laser exposure limits (ICNIRP 2013b) could

be used to evaluate potential hazards from SLDs, since they approximate a “point source.” For more information on the different types of LEDs, see the Appendix.

Based upon current exposure limits, most visible LEDs and IREds - particularly surface-emitting LEDs - pose no acute hazard to the eye. However, there are some specialty lighting products, e.g., stage lights, that could potentially fall into RG3, as defined in current lighting safety standards (IEC 2006; CIE 1999; ANSI/IESNA 2015, 2017). However, it should be noted that the emission limits of the current edition of IEC 62471 (IEC 2006) are based on the pre-2013 ICNIRP (ICNIRP 1997) exposure limits for retinal thermal hazards. One should remember that these classifications are based on very conservative assumptions (Sliney et al. 2016; Schulmeister et al. 2019) and that just because a particular lamp may fall into a high risk group (i.e., RG 3), it may not produce an injury in an exposure duration of ≤ 0.25 seconds nor for somewhat longer exposure durations, depending on the particular exposure location, pupil diameter and other factors. However, it would be prudent to follow manufacturer’s instructions and to avoid eye or skin exposure from such light sources within the distances where exposure limits are exceeded.

Light-emitting diodes of low to moderate brightness (also known as “luminance”— see Basic Terminology below) are used in many types of visual displays as indicator lights and many related products. Higher power LEDs and IREds are used as signal lamps and in a wide variety of domestic and industrial products and can compete with laser diodes in limited optical communications systems; i.e., in local-area networks (LANs). LEDs such as these could be considered ‘intense’ light sources. The differences in output characteristics between laser diodes and LEDs define both their uses and their potential hazards.

ADVANCES IN LED TECHNOLOGY

In addition to the expansion of available LED wavelengths into the UV and IR, “white” LEDs are now commonly available and rapidly replacing incandescent and fluorescent lighting for GLS applications. This broadband spectrum is achievable through the combined use of a UV (approximately 390 nm) or blue (approximately 450 nm) LED and a phosphor or through a combination of red, green and blue (RGB) LEDs (Fig. 1). This development has led to the current widespread use of these white LEDs for general illumination due to their lower power consumption/greater efficiency and longer life compared to traditional incandescent and fluorescent lamps. The lifetime of LEDs can be more than 50,000 h of operation – much longer than conventional light sources. Depending on the design of the “white” LED, the correlated color temperature (CCT) can

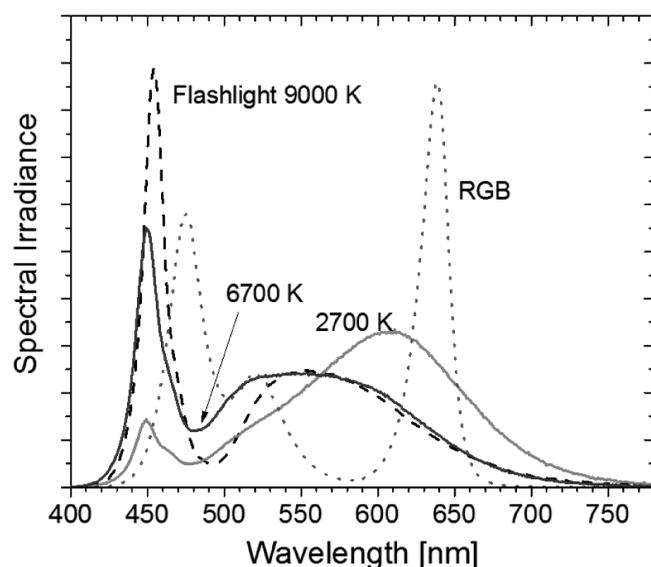


Fig. 1. Relative spectral irradiance of a 9,000 K LED torch/flashlight, a 6,700 K cold “white,” early first-generation “white” LED showing a strong peak in the blue region and a broad peak at longer visible wavelengths through the use of a phosphor, a 2,700 K warm “white” LED, and a RGB-type LED.

be significantly greater; i.e., the output spectrum is more blue than traditional incandescent or even fluorescent lamps. A “white” LED will have no measurable UV emission, making it potentially safer than fluorescent or incandescent lamps. LEDs used for general lighting will also emit significantly less red and near-infrared radiation (600–1400 nm) than traditional light sources, which has raised concern that the lack of exposure to these frequencies could have adverse health consequences (Whitehead and Osborne 2017; Schierz 2019). The efficiencies of LEDs have improved significantly over the past decade, increasing from approximately 50 lumens (lm) per electrical watt (W) in 2005 to approximately 250 lm W⁻¹ today. The CCTs of early LEDs were 6,000 K or higher. However, these were not well-accepted by the public because the bluish-white light was described as harsh, with poor color rendering. Thus, it was recognized that a warmer CCT of approximately 3,000–4,000 K is more acceptable. In fact, in several cities in the US and in Europe, installation of high CCT LEDs in street lighting led to so many complaints from residents about glare and interference with sleep from the spectrum and brightness of the lights that total replacement with lower CCT LEDs was required (AMA 2016). For comparison purposes, the CCT of daylight is in the range of 6,000 to 7,000 K, while on a cloudy day, it is in the range of 4,000–5,000 K (PHE 2016), and incandescent lamps have CCTs in the range of 2,700 K.

There are currently mainly two different approaches employed for “white light” production: phosphor-converted and red, green, blue (RGB) or red, green, blue, and amber color-mixed LEDs.

In addition to their higher luminous efficiency and longer life, modern LEDs also have the ability to be easily tuned; i.e., the adjustment of intensity and spectrum of the light emission (usually by mixing high and low CCT LED chips in one luminaire). This has led to an interest in what has been called “human centric lighting” (Houser 2018) where the color and intensity of the LED emission is altered throughout the day, depending on the desired effect on human behavior. Higher CCT (“cool” light) is thought to increase alertness, while lower CCT (“warm” light) is expected to induce relaxation/calmness. However, research in this area is not mature, and much more work is needed to determine the optimum lighting conditions for different tasks and different groups of people (e.g., hospital staff vs. patients).

BASIC TERMINOLOGY

In order to discuss the characteristics and potential hazards of LEDs, some basic terminology is required:

- Blue-light hazard (BLH) - term used to describe the potential for a photochemical injury of the retina (photoc maculopathy); i.e., not a “thermal” injury. The sensitivity function, or action spectrum, $B(\lambda)$, is defined over the wavelength range of 300 - 700 nm, but the peak effectiveness of this injury occurs at approximately 435 - 440 nm, which is in the violet-blue region of the optical spectrum.
- Correlated color temperature (CCT) - parameter used to describe the apparent color temperature of light by relating it to the temperature of a Planckian thermal radiator, in units of Kelvin. There have been reports that CCT is not appropriate for a source like LEDs due to their spectral characteristics. Unfortunately, lighting designers also use a sense of temperature to describe LED and fluorescent hues, such as “cool white” or “warm white,” but in this case “warm” actually refers to a lower CCT.
- Illuminance (at a point of a surface) - quotient of the luminous flux $d\phi_v$ incident on an element within the exposed area, by the area dA of that element, units of $\text{lm m}^{-2} = \text{lux}$.
- Irradiance (at a point of a surface) - the quotient of the radiant flux $d\phi$ incident on an element within the exposed area, by the area dA of that element, units of W m^{-2} .
- Luminance (in a given direction, at a given point of a surface) - the flux of effective photopic radiation emitted per unit solid angle in a given direction, per unit area of a source, units of $\text{lm m}^{-2} \text{sr}^{-1}$. This quantity is used to describe visual “brightness.”
- Photopic sensitivity - relates to the sensitivity of the human eye which peaks at the wavelength of 555 nm; the sensitivity function is defined as $V(\lambda)$. Technically, this typical, or average response is that of the “CIE Standard Photometric Observer” (CIE 2016).

- Radiance (in a given direction, at a given point of a surface) - the flux of radiation emitted per unit solid angle in a given direction, per unit area of a source, units of $\text{W m}^{-2} \text{sr}^{-1}$.
- Retinal thermal hazard (RTH) - term used to describe the potential for a thermal injury to the retina. The sensitivity function, or action spectrum, $R(\lambda)$, is defined over the wavelength range of 380 - 1,400 nm, but the peak effectiveness of this injury occurs at approximately 435–700 nm. The exposure limit (EL) for this hazard is dependent on the angular subtense, α , of the source and the exposure duration, t .
- Steradian (sr) - the SI unit of solid angle subtended by the area on the surface of a unit sphere, with origin at the center of the sphere. It is analogous to the radian, which quantifies planar angles.

POTENTIAL BIOLOGICAL HAZARDS OF INTENSE LIGHT SOURCES

- The potential optical hazards of exposure to the radiation from intense light sources, such as welding arcs, arc lamps, some tungsten-halogen lamps, LEDs, and lasers can be grouped into at least six separate types of hazards to the eye and skin (WHO 1982; Sliney and Wolbarsht 1980; ICNIRP 1998, 2013; CIE 1999; McKinlay et al. 1988).
- The following effects are related to potential tissue injury from optical radiation:
 - a. Ultraviolet (UV) photochemical injury to the cornea (photo-keratitis), conjunctiva (photo-conjunctivitis) and lens (cataract) of the eye and skin (180 to 400 nm) (WHO 1982; Sliney and Wolbarsht 1980; Duchene 1991; ICNIRP 2004);
 - b. Thermal injury to the retina of the eye (380 to 1,400 nm) (WHO 1982; Sliney and Wolbarsht 1980; Duchene 1991; ICNIRP 1996, 2013);
 - c. Blue-light photochemical injury to the retina of the eye (principally 400 to 550 nm; unless the eye lacks a natural crystalline lens, also known as ‘aphakic’; then 300 to 550 nm) (Ham et al. 1976; Ham 1989; Sliney and Wolbarsht 1980; Lund et al. 2006; ICNIRP 2013a). The aphakic weighting function (ICNIRP 2013a) should be used for risk assessment of individuals missing their natural lens or for children under the age of 2 y, whose lens transmits more UV than the adult lens.
 - d. Infrared thermal hazards to the lens; e.g., cataracts (approximately 800 to 3,000 nm) (WHO 1982; Sliney and Wolbarsht 1980; Ham et al. 1976; Lund et al. 1996; Pitts and Cullen 1981);
 - e. Thermal injury (burns) of the cornea of the eye (approximately 1,400 nm to 1 mm) (WHO 1982; Sliney and Wolbarsht 1980); and
 - f. Thermal injury to the cornea or skin (180 nm–1 mm) from high irradiances, lengthy exposures or high temperature of outer lamp casing (WHO 1982; Duchene et al. 1991; Sliney and Wolbarsht 1980; Pfefer et al. 2009).

Retinal hazards

Acute hazards. Retinal hazards are dependent upon the brightness of the source, and the limited brightness (i.e., radiance or luminance) of LEDs have historically placed them in a category of “not-of-concern” in safety circles. The radiance of the brightest surface-emitting LED (SLED) sources was previously comparable to the radiance of a tungsten lamp filament; i.e., about $2.5 \text{ W cm}^{-2} \text{sr}^{-1}$ ($25 \text{ kW m}^{-2} \text{sr}^{-1}$). Currently, as noted below in the section on LED specifications, the state-of-the-art SLEDs can emit as much as $50 \text{ W cm}^{-2} \text{sr}^{-1}$ ($500 \text{ kW m}^{-2} \text{sr}^{-1}$).

The principal retinal hazard resulting from viewing bright light sources is photoretinopathy, e.g., solar retinopathy, with an accompanying scotoma, which can result from staring at the sun (Ham 1989). Solar retinopathy was once referred to as “eclipse blindness” and associated “retinal burn.” However, it should be recognized that the eye is well adapted for protection against the harmful full-spectrum optical radiation from environmental sunlight encountered in all but the most extreme natural environments. Bright light sources such as the sun, arc lamps, and welding arcs produce a natural aversion response by the eye in most cases. This response limits the duration of exposure to a fraction of a second (typically less than 0.25 s) (Sliney and Wolbarsht 1980). Ultraviolet, near-infrared and infrared sources without a significant visible component cannot trigger this natural aversion response, and behavioral viewing patterns, eye fixation, and factors such as eye fatigue must be considered to determine a maximum viewing duration. Prior to conclusive animal experiments, solar retinopathy was thought to occur through a thermal injury mechanism (Ham et al. 1976). However, it has been shown that an intense exposure to short-wavelength light (frequently referred to as “blue light”) can cause a photochemical retinal injury (Ham 1989). The studies of Ham clearly show that violet-blue light (approx. 440 nm) radiation exposure to the retina is 1,000-fold more dangerous than 890-nm radiation (Ham et al. 1984, 1976; Lund 2006). By filtering out short-wavelengths (blue light) from a white-light arc lamp, Ham et al. showed that the risk of photochemical injury to the retina could be significantly reduced (Ham et al. 1976). We are aware of one report of an alleged photochemical retinal injury produced when a teenager stared at a 5 mW, 410 nm LED for 20 s each day for 2 d (Obana et al. 2011). Persistent visual loss with a central scotoma was noted. Injuries of this type appear to be very rare and unlikely to occur unless the subjects purposely

overcome their natural aversion response. However, exposures to LEDs in the UV, violet, and blue wavelength region remain a cause for concern, especially in children who have higher ocular transmittance in this wavelength region than do adults. A recent paper by James et al. (2017) evaluated the potential hazards from LED lamps intended for home use. They found that, if evaluated at an illumination level of 500 lux [as recommended for lamps intended for “general lighting service” (GLS) applications by the American National Standards Institute (ANSI)/Illuminating Engineering Society of North America (IESNA) RP 27.3 guidance (IESNA 2015 and 2017) as well as IEC 62471 (IEC 2006)], all LED lamps fell into the Exempt category. However, if evaluated at a measurement distance of 20 cm, as recommended for non-GLS lamps, one of the LED lamps (a lamp intended for use as a camping lantern) fell into the RG 2 category. It should be noted that this lamp was quite bright and would likely be very uncomfortable to stare at, triggering an aversion response in most individuals. Regarding exposures to young children, Miller et al. (2010) found that the aphakic-weighted emissions from transilluminators (a medical device used to enhance visualization of veins and arteries) employing ‘white’ LEDs could reach the EL for BLH in 1 to 3 min., which would put these products into RG 2. The aphakic weighting function (a biologically-effective weighting for individuals lacking the normal, crystalline lens) was used, because that analysis was focused on risks to neonates who have much higher lens transmittance than do adults.

For the discussion of the risk associated to bright light sources (that are not lasers), photochemical retinal injury is the main concern, because the limited radiance levels should not result in a realistic retinal thermal risk. For the discussion of photochemical retinal injury, it is of vital importance to be aware of the dose nature of injury threshold; i.e., that the injury threshold (for a given spectral distribution) is a constant retinal radiant exposure, at least within a certain exposure duration regime of at least several h. Thus, the photochemical retinal injury threshold can be reached even for relatively low irradiance levels if the exposure duration is long enough.

A study by Krigel et al. (2016) compared the effects from 24 h of continuous exposure to blue, green, and “cold-white” LEDs at 500, 1000, 1500, and 6000 lx (lm m^{-2}) exposure levels in albino and pigmented rats with dilated pupils. At 500 lx, there was a decrease in the number of photoreceptor rows in the superior retina when LED lights were used but not when fluorescent lamps were used. This result held true in both albino and pigmented rats with dilated pupils. The pure blue LED was the most effective in reducing the number of rows in the outer nuclear layer of the retina. Unfortunately, the spectral distribution of the light sources was not measured, so it is unknown if the

fluorescent lamps had similar blue content as the LEDs or not. Another study by Shang et al. (2017) found that blue (460 nm) LEDs produced more functional retinal damage in free-running rats than did green (530 nm) or red (620 nm) LEDs for similar corneal irradiance levels. The animals were exposed to a cyclic schedule of 12 h on/12 h off. This study confirmed results on blue light in vitro (Osborne et al., 2008; Seko et al. 2001; Kuse et al. 2014; Ogawa et al. 2014). However, it should be noted that humans are not likely to be exposed to pure blue LEDs, especially under such lengthy, daily exposure conditions and with dilated pupils. Caution should also be exercised in attempting to extrapolate results in the nocturnal rat to humans, since the ratio of pupil-size to effective focal length in these nocturnal animals is much larger – resulting in much higher retinal irradiance levels compared to that of a human viewing the same source. Studies demonstrating photochemical retinal damage in rhesus monkeys have also been performed for exposure durations of between 4 h and 12 h with dilated pupils, using daylight fluorescent lamps (Sykes et al. 1981) and xenon arc lamps (Lawwill 1977; Kremers 1989). Thus, LEDs are not unique in their ability to produce photochemical damage to the retina under extreme exposure conditions, such as continuous direct exposure for longer than 4 h with dilated pupils. A more recent study with primate eyes (Mukai et al. 2012) has only shown temporary changes in the retina after 8 h of continuous exposure to “white” LEDs, and the Sykes study required pupillary dilation to produce a permanent injury (Sykes et al. 1981).

Regarding effects in humans, a 2016 letter to the editor (Alim-Marvasti et al. 2016) reported on two case studies where individuals experienced several episodes of temporary “blindness” from viewing a smartphone for 10 – 20 min using only one eye, while the other eye was covered by a pillow. The individuals experienced a temporary ‘blindness’ that took several minutes to recover. Alim-Marvasti points out that such experiences of photobleaching are due to normal visual adaptation to light in one eye and darkness in the other eye and should not be reasons for unwarranted concern.

The studies by Ham and colleagues (Ham et al. 1976) of retinal thermal injury thresholds for a filtered xenon-arc source emitting narrow bands of infrared radiation at wavelengths bracketing the 770–950 nm IRED wavelength region showed virtually the same values at 820 ± 5 nm, 860 ± 5 nm, and 910 ± 25 nm. The threshold retinal irradiances for producing just-visible retinal lesions in the rhesus monkey eye were approximately 30 W cm^{-2} for 1 s, 23 W cm^{-2} for 10 s, 20 W cm^{-2} for 100 s, and 19 W cm^{-2} for 1,000 s (all for 500- μm retinal spot diameters and for stationary retinas of anesthetized rhesus monkeys). This is approximately three orders of magnitude higher than the threshold irradiance to achieve photochemically induced

injury of only 0.03 W cm^{-2} for a 1,000-s exposure to 441-nm blue laser light (Ham 1989). Thermal retinal injury has been shown to dominate at wavelengths beyond 550 nm, and the threshold for thermal injury is retinal spot-size dependent because heat flow is more efficient for smaller diameter image sizes. The 500- μm thresholds for thermal injury would be expected to be about twice the value for a 1,000- μm (1-mm) image for this duration (Schulmeister et al. 2011). A retinal thermal injury from viewing a lamp appears to be only possible when viewing a short-arc-lamp under magnification (e.g., a very large-diameter collimated searchlight), such that the retinal image size would be quite large and thermal diffusion less than around a small image typical of a bare arc-lamp or an image projector. Thus, concern for retinal thermal injuries from IRED exposure is less than the concern for photochemical injuries from short wavelength-emitting LEDs.

Photochemically induced blue-light retinal injury thresholds are not spot-size dependent as are retinal thermal injury thresholds. However, because of involuntary eye movements, the blue-light radiance of small sources is spatially-averaged over a circular angle of 11 mrad (corresponding to an irradiance-averaging over about 190 μm at the retina) for viewing durations up to 100 s, according to published methods of hazard analysis (ICNIRP 2013a). The angle of 11 mrad represents a very small assumed range of eye movements, considering they apply to staring durations of up to 100 s. Since task-driven eye movements are larger, ICNIRP provides conservative guidance for averaging radiance over ever increasing angles with increasing duration beyond 100 s (ICNIRP 2013a). It is interesting to compare the blue light-weighted radiance from LED sources to that from traditional incandescent lamps or that of a clear blue sky in summer. Such a comparison was conducted by O'Hagan et al. (2016), who concluded that the blue light-weighted radiance from most commonly used LED products (e.g., smartphones, tablets and computer monitors) was about a factor of 2 to 3 higher than incandescent lamps but a factor of 25 to 200 times lower than that from clear blue summer sky in the UK.

Chronic hazards. Concern has been raised about the increased risk of age-related macular degeneration (AMD) from chronic exposure to bright light (Behar-Cohen et al. 2011; ANSES 2010, 2019; Marshall 2017). Besides the main factor of age, AMD has many potential risk factors, such as smoking, genetic factors, obesity, hypertension, and also exposure to sunlight (Cheung and Eaton 2013; Tomany et al. 2004; Klein 2005; Mitchell 2018). Epidemiological studies on the correlation of sun exposure and risk for AMD are not consistent. Some studies found an increased risk for AMD in populations with higher exposure to sunlight (Taylor et al. 1992; Cruickshanks

2001; Sui et al. 2013; Schick et al. 2016). Some studies associate cataract operation and pseudophakic eyes (eyes that had natural lens removed and replaced with a clear intra-ocular lens) with a higher risk for age-related maculopathy (ARM) (Thapa et al. 2017; Algreve et al. 2006; Klein et al. 1998) or short-wave ("blue") cone dropout (Werner et al. 1989). Other studies did not find a relevant increase of the odds ratio for AMD, particularly after adjustment for multiple comparisons (Khan et al. 2006; Klein et al. 2014; Zhou et al. 2018). Some epidemiological studies even find a "protective" effect, i.e., the group with higher solar exposure had a lower incidence of AMD (Delcourt et al. 2001; Darzins et al. 1997), which illustrates the great challenge of estimating lifetime sunlight exposure in all the epidemiological studies where variable individual pupil-size and recall bias are not accounted for. Nevertheless, the Klein studies (Klein 2006; Klein et al. 2014) revealed signs of accelerated aging of the retina in the most exposed retinal areas when outdoors in sunlight.

Despite conflicting epidemiological data on the relationship between sunlight exposure and AMD, it is believed that high levels of cumulative light exposure may lead to oxidative stress in the retina. This can then lead to the abnormal accumulation of reactive oxygen species in the macula of the eye, which can induce mutagenic mechanisms, leading to degenerative eye diseases, such as AMD (SCHEER 2018). In addition, the long-term changes induced in laboratory animals by exposure to short wavelength visible light have some similarities to those changes seen in patients with AMD (Taylor et al. 1992).

OTHER BIOLOGICAL EFFECTS OF CONCERN

Circadian rhythm disruption

The exposure to intense "cool white"/blue-rich radiation can lead to circadian rhythm disruption since the peak sensitivity of the eye for circadian rhythm regulation is in the blue (i.e., 460–470 nm) wavelength region, where most 'white' LEDs have strong emissions (Brainard et al. 2001; Figueiro et al. 2017; Marshall 2017). It should be noted that exposure to blue-rich radiation disrupts circadian rhythm if the exposure occurs in the evening or nighttime, but not during the day (CIE 2019).

There have been many studies about the adverse health effects of artificial light exposure, especially at night. Exposure to bright light at night suppresses melatonin and interferes with sleep, which can lead to numerous adverse health effects; e.g., psychological, cardiovascular effects and even cancer (Lunn et al. 2017). The high blue content of "cool white" LEDs causes even more concern because of the peak of sensitivity for regulation of human circadian rhythm at about 470 nm (Marshall 2017). Due to the efforts to develop and utilize more efficient lighting worldwide, artificial light sources such as LEDs have gained widespread use. Although LEDs are significantly more efficient and generate less heat

than traditional incandescent light sources, the early generations of LEDs pose potential new health issues due to their higher color temperature (or higher blue content in their spectrum). Blue light has a higher efficiency to reduce melatonin production at night than do other wavelengths in the visible spectrum (Brainard et al. 2001; Thapan et al. 2001).

Flicker effects

Because LEDs are current-regulated, the only practical way to achieve dimming is to modulate the emission and then reduce the pulse interval. When modulation is present, a flicker can sometimes be perceived (IEEE 2015). Most A/C-driven LEDs are subject to flicker effects, regardless of emission spectrum. Light sources driven directly from the main power supply are likely to have a degree of temporal light modulation. Incandescent lamps tended to produce a sinusoidal output at twice the main frequency. Magnetically ballasted fluorescent lamps also produced temporal light emissions at twice the main supply frequency, and the emissions were linked to adverse health effects in some individuals (Wilkins et al. 1989). The move to electronically ballasted fluorescent lamps, usually operating at several kilohertz, appeared to alleviate these problems. LEDs may be operated at DC or modulated, often at twice the main supply frequency. The light output will track the electrical input to the LED with no significant delay.

Dimming circuits used with LED lighting can introduce temporal light modulation, even for LED lamps operating DC at full output. For some pulsed systems, the mark-space ratio (the ratio of the time duration of the “on” part of the emission to the “off” part) is altered to reduce the average luminance of the source. In others, the electrical drive signal is modulated at various frequencies, or the pulse shape is chopped.

The light from LED lamps operating at twice the main frequency will not produce a visible perception of flicker for most people. However, a proportion of the population may experience headaches, migraine, and a number of other non-specific adverse effects. The mechanism for these effects and determination of the proportion of people affected requires further research. Photo-induced epilepsy is usually associated with flicker rates from 3 Hz to 70 Hz (IEEE 2015) and is only of concern for LED lamps under some failure modes.

There are two other implications of having a light source that is modulated. The first is the phantom array, which is when an observer views a series of images when they move their eyes, or where they are stationary and the light source traverses across the field of view. It is not known whether the adverse health effects reported above are a result of the phantom array.

The other effect is where a moving image appears stationary, the so-called “stroboscopic” effect. This effect has been of concern for decades from the use of fluorescent

lamps in machine shops, where rotating machinery may appear static. This problem was addressed by having different lamps on different phases. With LED lighting, there is a particular concern in domestic environments where rotating devices, such as food mixers, may appear stationary under modulated LED lighting in the kitchen.

Glare

Many early LED lighting products were rushed to market by new start-up companies inexperienced in good lighting design. These early LED fixtures (luminaires) were quite unsuitable for both indoor and outdoor use, as they produced discomfort and disability glare (CIE 2010). Discomfort glare is produced when a light source has a luminance (brightness) vastly greater than surrounding objects (e.g., an auto headlight on a very dark country road as opposed to the same light viewed in daylight). Individuals complain of discomfort under these types of conditions. Disability glare is produced when the luminance of the source is so bright that scattering of light within the human eye obscures surrounding objects. This type of glare becomes more severe in elderly persons because of increasing scatter of the human lens with aging.

For currently available UV or visible LED sources, only aspects (a), (c), or (f) (from “Potential Biological Hazards of Intense Light Sources”) are of potential concern, whereas for IRED sources, only aspects (b), (d), and, for focusing IRED arrays onto the cornea, also (f) are even remotely relevant, since aspects (a) and (c) can only occur from short-wavelength light and UV. For visible LED sources, there are potential concerns for circadian rhythm disruption, flicker, and glare. Thermal injury of the cornea or skin requires concentrated optical powers in the hundreds of milliwatts to watts range. It is important to note that only the relevant potential hazards need to be evaluated when performing a safety evaluation or risk group classification.

Organizations such as the American Medical Association (AMA 2016), the Health Council of the Netherlands (Health Council 2015), the French Agency for Food, Environmental and Occupational Health and Safety (ANSES 2010, 2019), and Public Health England (PHE 2016) have published policy documents expressing concern about the potential adverse health outcomes from the increased use, especially at night, of blue-rich LED lighting. The first generation of “white” LEDs had a higher correlated color temperature (CCT) index, in the range of 6,000 K and higher. Traditional incandescent lamps have a CCT of approximately 2,700 K. There have been recommendations and efforts to lower the CCT of “white” LEDs to below 3,000 K. These efforts should serve to lessen concerns about circadian rhythm disruption from “white” LEDs.

STANDARDS AND REGULATIONS

While safety standards and regulations for lasers have been in place since the 1970s, due to the fact that relatively low risk safety standards for lamps were only developed at the end of the 20th century (IESNA 1996a and b). CIE adopted the scheme developed by IESNA and in 2002 published CIE S009 (CIE 2002), which was later published as IEC 62471 (IEC 2006). The motivation for the development of these lamp safety standards was not a potential risk from LEDs but mainly to assign risk groups based on UV emission from fluorescent lamps and other discharge lamps (Sloney et al. 2016). These general lamp safety standards also apply to LEDs. The IEC has also published a technical report IEC TR 62778 (IEC 2014) to aid the application of the blue light hazard limits of all lighting products (lamps and luminaires), which have the main emission in the visible spectrum. The concept is that product safety standards (that have as a main scope electrical and mechanical safety) for high-intensity discharge lamps or LEDs make reference to this technical report. The product safety standard for LED modules IEC 62031 (IEC 2018) for photobiological safety aspects refers to IEC 62471 (IEC 2006). The safety standard IEC 60335-2-113 for light-emitting devices used for cosmetic purposes (IEC 2016) was mainly developed to apply to intense-pulsed light sources (flash-lamps) used for hair removal but also applies to devices employing LEDs when used for cosmetic purposes. There are also occupational health exposure limits and guidelines used worldwide for evaluating the exposure to incoherent optical radiation, including from LEDs in the workplace and for public exposure (IEC 2006; IESNA 2015, 2017; ICNIRP 2013a; ACGIH 2019).

SAFETY CONSIDERATIONS

LED specifications applicable to safety

For UV-emitting LEDs, irradiance is important for assessing the potential hazards to the cornea, conjunctiva, lens, or skin. ICNIRP (ICNIRP 2004) provides guidelines for the assessment of potential risks from ultraviolet radiation.

Radiance is important for assessing the potential retinal hazards of any bright optical source that can be imaged on the retina. Radiance is generally expressed in optics with units of $\text{W m}^{-2} \text{sr}^{-1}$, and, most importantly, radiance (or “brightness”) is conserved and cannot be increased by any optical lensing. When examining a manufacturer’s specification sheet for an LED, the “brightness” (expressed as either radiance or luminance) is usually not given. Instead, the radiant intensity (W sr^{-1}) or luminous intensity, expressed in candela (cd ; $\text{cd} = \text{lm sr}^{-1}$), is almost always specified. If one knows what the apparent source size is, then one can calculate the radiance or luminance emitted

by the LED. The actual source size is applicable if no lens is incorporated on the LED, but if a lens is used to encapsulate the chip, the actual source size is magnified, and that apparent source size must be used in any hazard evaluation. Because of their limited radiance (compared to lasers, for example), currently available LEDs are not likely to pose a retinal thermal hazard.

The highest radiance of any state-of-the-art SLEDs is on the order of $50 \text{ W cm}^2 \text{sr}^{-1}$ and is limited for fundamental reasons related to phosphor efficiency and thermal properties described earlier. Another factor that limits LED efficiency is called “efficiency droop.” This occurs when excited electrons become too excited to be trapped by the quantum wells in the semiconductor, where they would normally combine with holes. These overly energetic electrons then leak out of the LED device without emitting any light. Thus, overdriving the current through an LED can lead to a reduction in light intensity once it has reached peak efficiency.

Applicable exposure guidelines for eye safety

Because the spectral bandwidth of LEDs is much greater than that of lasers, and because they are not “point sources,” all current occupational and public health exposure limits and guidelines state that LEDs should be treated as incoherent optical sources. Guidelines for incoherent optical radiation and for laser radiation differ for two reasons. For broadband incoherent sources, there is a need to assess several different hazards over a range of wavelengths so that limits for the different hazards (which feature different action spectra and exposure limits) apply in parallel. Secondly, because incoherent sources that are capable of posing a retinal hazard are extended sources (and not point sources as for lasers), exposure limits are best expressed in terms of radiance. In general, the ICNIRP guidelines for incoherent optical radiation are the most appropriate to apply to LEDs (ICNIRP 2013a, 2004). It should be noted that if LEDs are employed in an ophthalmic instrument or a device fixed to the head for intentional lengthy exposures, these limits may not apply, and the exposure assessment approaches in the 2005 ICNIRP guideline for ocular instruments (ICNIRP 2005) should be considered for use in this scenario. This is because the general ICNIRP guidelines for exposure (ICNIRP 2013a, 2004) make assumptions about eye and head movements that serve to ‘relax’ the exposure limits.

Viewing conditions

There are no universally agreed upon limits to the wavelength range of the “visible” spectrum, since the ability to cause a visible sensation is dependent on the intensity of visible radiation reaching the retina (Sloney 2016). The lower limit is generally assumed to be between 360 and 400 nm, and the upper limit between 760 and 830 nm. However, shorter wavelengths may be visible under some circumstances, as wavelengths as short as 310 nm have been

reported to be visible to the human eye (Sloney 2016). LEDs with a peak wavelength shorter than 310 nm will not be visible to the human eye, so these types of LEDs should be supplied with appropriate warnings/user instructions. Most IREDs are not visible under normal usage conditions. Although the CIE definition of the visible spectrum extends only to 780 nm, the visual response continues (at very poor sensitivity) to longer wavelengths. Therefore, high-radiance sources emitting wavelengths longer than 780 nm may be weakly visible. Although most IREDs emit almost all of their energy within the wavelength range from about 800 to 980 nm in the near-infrared spectral region, many IREDs are just barely visible to most individuals viewing them in the dark. For most traditional applications, exposure times would probably be limited to 5–10 s at close range of 20 to 50 cm, although somewhat longer viewing distances and exposures for longer periods might be expected, especially for new technologies like facial recognition or head-mounted displays. All of these exposure conditions must be borne in mind when comparing the output characteristics of LEDs with current guidelines and standards. Since a light source with a radiance equivalent to the EL for incoherent visible radiation is uncomfortably bright, lengthy viewing of visual displays of “white light” LEDs approaching the ELs is not a reasonably foreseeable viewing condition.

CONCLUSION AND RECOMMENDATIONS

It has now been established that safety evaluations and related measurement procedures for LEDs should follow the general guidelines for incoherent sources (ICNIRP 2013a, 2004; IEC 2006). The clear conclusion is that LEDs, whether visible or IR, are more like lamps in terms of spectral bandwidth emission profile and radiance and are not like lasers; they are safe under reasonably foreseeable usage conditions when compared to ELs for acute exposure. This conclusion applies equally well to visible and IR LEDs stared at for 100 s or less. The same cannot be said for UV and violet-emitting LEDs.

It is recognized that the determination of appropriate viewing durations and distances under different conditions of use is needed for any optical radiation hazard assessment. The future development of additional application-specific safety standards, which may be applied to realistic exposure and viewing conditions, will also contribute to reducing unnecessary concerns regarding LED/IRED safety. Data from animal studies raises concerns for potential retinal damage from extended exposure to blue-rich LEDs. However, the conditions under which the animals were exposed, such as dilated pupils and direct viewing of a bright light source for at least 4 h are considered extreme and not typical for humans. The extrapolation of these results to humans is also not straightforward, especially because the experimental

animals in these studies were nocturnal animals and experienced much higher retinal irradiance values than would humans viewing the same source, due to differences in their eye geometry. Although white LEDs are expected to become a ubiquitous artificial light source in the near future, it is not expected that they will cause acute retinal damage under reasonably foreseeable viewing conditions. The long-term risks of exposures to high luminance, high color temperature (i.e., blue-rich) white LEDs or other high color temperature sources, are currently unknown, but they are not expected to pose a retinal hazard for healthy individuals. However, some segments of the population, e.g., newborns (Point 2018), young children and the elderly (SCHEER 2018), may be more susceptible to some biological effects from blue-rich LEDs. UV, IR, and high brightness pure blue LEDs must be used with more caution as they will stimulate no or a reduced aversion response. Current higher-brightness computer and cellphone displays expose the retina to higher short-wave-light radiances than previously in most traditional office settings but, if comfortable to view, these levels should not be considered harmful (nor sleep-disruptive if viewed during daytime).

Lastly, the growing use of tunable LEDs to influence human behavior and wellness could lead to greater exposure to blue/short wavelength light than is currently achievable with traditional light sources. This trend needs to be monitored, since the widespread use of blue-rich LEDs in schools, offices, or medical facilities could significantly increase the amount of blue/short wavelength light received at the retina over an individual’s lifetime. Fortunately, the use of high CCT LEDs is not increasing because the public found this blue-rich light harsh and uncomfortable. Lower CCT LEDs are expected to become the light source of choice for general lighting in the near future. These “warmer” light sources in well-designed fixtures that are designed to minimize glare and are installed in accordance with good lighting design principles should pose no more of a hazard than traditional lighting sources of similar color temperature. In fact, since white LEDs do not emit UV as did most fluorescent lamps and some incandescent lamps, they might be a safer choice from that aspect. The only demonstrated adverse health effects from LEDs thus far are those associated with temporal light modulation, which includes flicker, stroboscopic risks, and those effects possibly arising from inappropriately installed lighting systems that cause glare. Further research is needed on trends in artificial lighting, such as laser-pumped non-coherent sources and potential health effects of exposure to optical radiation spectra and intensities to which humans have not been traditionally exposed.

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APPENDIX: LED TECHNOLOGY

What are the key differences between the different types of LEDs?

The early generations of surface-emitting LEDs had a radiance of the same order of magnitude as traditional tungsten filament lamps, but newer technology has enabled LEDs to exceed the radiance of traditional incandescent light sources. The emission surface of an LED chip is normally on the order of a square mm and, when magnified, appears as a large disc or square area of high brightness. In addition to being sold as single chip designs, LEDs are now commonly packaged in arrays, allowing even more light to be produced. The LED chips employed in conventional lighting (also known as “General Lighting Service,” or “GLS”), flashlights or “electric torches,” indicator lamps and displays are surface emitters. Edge emitters may be used in technical applications like optical fiber communications.

The radiance of a surface-emitting LED is limited both by semiconductor physics and device structure. State-of-the-art LEDs have a quantum efficiency of 25 to 50%; i.e., 25 to 50% of the electrons flowing through the semiconductor junction are converted into photons. As more current flows through the semiconductor junction, nonradiative mechanisms heat the semiconductor and reduce the efficiency, resulting in a self-limiting radiance. For visible radiation-emitting LEDs, light is typically emitted only from the front facet of the device, often collected by an integral molded plastic lens. UV-emitting LEDs use special UV-transmitting lenses. IREDS often have substrates transparent to the generated photons, resulting in a greater external efficiency—more photons escape the device before being absorbed.

Device types and comparisons

Common device types are as follows:

1. Surface-emitting (large area) LED (SLED);
2. Edge-emitting LED; and
3. Organic LEDs (OLED) mainly used in displays, i.e., televisions.

Each of these devices will be described in the following.

SLEDs are the conventional LEDs that have existed for decades. They consist of a chip of semiconducting material doped with impurities to create a p-n junction. Common semiconductors used in the construction of LEDs include gallium, silicon, indium, nitride, and synthetic sapphire.

Edge-emitting LEDs have a device structure different from that of the surface-emitting LED. The beam spread is generally smaller for an edge-emitting LED than for a surface-emitting LED. In addition, the spectral bandwidth of edge-emitting LEDs is slightly narrower than for a surface-emitting LED. Typical dimensions of the emitting stripe are $3 \mu\text{m} \times 100 \mu\text{m}$, with an active region several hundred microns long. Because of the energy density in the long active region, high radiances are achieved at the emitting facet, making it easier to launch the light into an optical fiber. The radiance of edge-emitting LEDs is orders of magnitude higher than surface-emitting LEDs.

OLEDs are made by placing a series of organic thin films between two conductors. OLEDs have the advantage of being able to be manufactured on flexible plastic substrates and do not require a backlight, making them thinner and more efficient than liquid crystal displays (which do require a backlight). They are often used in mobile phone displays, television screens/monitors, and in the automotive industry.

