Assessing the Photobiological Safety of LEDs

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In recent years, there has been a significant increase in the number of products incorporating light-emitting diode (LED) technology. First made commercially available in the late 1960s for use in handheld scientific calculators, LEDs can now be found in a wide range of products, from general and specialty lighting applications and advanced communications technology, to detection systems for security cameras and even consumer entertainment equipment.

Modern LEDs are semiconductor assemblies that emit high-intensity optical radiation across the ultraviolet, visible, and infrared spectrums. In lighting applications, LEDs are more energy efficient and require less maintenance than the incandescent and fluorescent lighting products they replace. However, their increased use has elevated concerns about potentially harmful photobiological effects that can result from even incidental exposure to LED light.

In response to these concerns, today's product safety standards now include specific testing requirements to evaluate and classify the photobiological risks associated with many types of LEDs. This UL white paper presents an overview of the structure and requirements of current photobiological standards for LEDs used in lamps, lamp systems, and other product types, such as information technology equipment.

Beginning with background information on the growth in the use of LEDs, the paper discusses the photobiological hazards associated with exposure to LEDs and other types of lamps. The paper then offers a detailed review of the current photobiological safety standards, IEC 62471 and IEC/TR 62471-2, including summary information on testing, exposure limits, and risk groups. The paper concludes with a look at potential future standards development efforts in this area, and compliance considerations for LED manufacturers.

The Current Market for LEDs

In just a few short years, dramatic improvements in the quality and performance of LEDs has made this technology the lighting option of choice in a wide range of industrial and consumer applications. Today's LEDs provide brightness, color quality and light output equal to or greater than many other commercially available lighting technologies. LEDs also offer longer operating life, reducing or even eliminating the need for replacement, and potentially lowering overall operating costs.

Another positive factor regarding LEDs is their energy efficiency. According to the U.S. Department of Energy, the rapid adoption of LED lighting in the U.S. could result in energy savings of about $265 billion by 2027, and reduce lighting electricity demand by 33%.[1] In portable electronic applications such as mobile phones and tablet computers, the widespread use of LEDs in screen displays reduces power consumption and prolongs battery life.

Improved technology, reduced operating costs and greater energy efficiency help to explain the rapid growth of the LED marketplace. The sale of high-brightness LEDs in 2011 is estimated at $12.5 billion, representing an increase of 8% over 2010 sales of $11.2 billion, and a significant 270% increase over the $4.6 billion in revenue generated in 2007. LED revenue is expected to grow to over $16 billion by 2016, driven largely by an anticipated 33% compound growth in LED lighting and lighting products, and strong demand for LED lighting solutions from the worldwide sign industry.[2]

Countering these growth trends, expanded production to meet the increased demand for products incorporating LED technology has already placed downward pressure on LED unit prices.[3] While such pressure could impact future revenue projections, it is expected that lower unit prices will actually spur even greater demand for LED-based lighting and other products incorporating LEDs.

Photobiological Effects and Potential Hazards Associated with LEDs

As the technology and performance of LEDs have progressed, there are increasing concerns regarding optical radiation produced by LEDs, and the potential exposure risks to humans. Optical radiation includes that portion of the electromagnetic spectrum covering ultraviolet, visible and infrared (IR) radiation (200-3000nm as defined in the photobiological safety standards), and exposure to optical radiation has been linked with a number of reactions that fall within the category of photobiological effects. These effects, which include photochemical and thermal interactions, have been shown to be of risk to living human tissue, specifically to the skin and eye.

Photochemical interactions are usually chemical responses to ultraviolet light in which bonds between electrons in cellular molecules are broken or rearranged. These cellular changes can lead to the deterioration or destruction of cellular functions. Thermal interactions, on the other hand, are most often caused by the absorption of IR radiation which produces an elevated temperature at the site of exposure. Thermal interactions can affect the functional ability of proteins and also lead to cellular damage. It should be noted that photochemical reactions do not solely occur in the ultraviolet region, nor do thermal reactions solely occur in the infrared region.

In humans, exposure to the photobiological effects of light from LEDs primarily affects the skin as well as the front surface of the eye and the retina. As noted in Annex A of IEC 62471, Photobiological Safety of Lamps and Lamp Systems, specific photobiological effects can include the following reactions:

- **Photokeratitis —** Photokeratitis is a photochemical reaction that affects the cornea of the eye and results from exposure to ultraviolet light (usually 200-320 nanometers (nm), 270 nm peak). Symptoms are similar to the irritation resulting from sand or dirt in the eye
- **Ultraviolet erythema —** This photochemical reaction produces a reddening of the skin, similar to a sunburn, and results from exposure to ultraviolet light (200-320 nm, 295 nm peak)
- **Ultraviolet cataract —** As the name implies, an ultraviolet cataract is a photochemical reaction that affects the lens of the eye, and which results from exposure to ultraviolet light (290-325 nm, 305 nm peak). Clouded vision is a typical symptom

- **Photoretinitis —** Also known as "blue light retinal injury," photoretinitis is a photochemical reaction to visible light (usually 400-500 nm, 445 nm peak) that affects the retina. Common symptoms include blind spots, also known as scotoma. Photoretinitis has been linked to macular degeneration
- **Retinal thermal injury —** This thermal reaction (usually 400-1000 nm, 500 nm peak) affects the retina and the choroid of the eye, and results from exposure to visible and infrared light. As with photoretinitis, symptoms include blind spots, or scotoma
- **Infrared cataract —** Infrared cataract is a reaction to infrared light (anywhere from 700-1400 nm, peak likely between 900-1000 nm) and affects the lens of the eye, and results in a clouding of vision. It is presumed to be a thermal photobiological effect, but is also possibly a photochemical reaction

LEDs that result in potential concern for producing photobiological reactions in humans include those used in illumination and lighting applications. LEDs used in devices for the purposes of infrared transmission are also of concern. Not all LEDs, however, produce potentially harmful photobiological reactions. For example, so-called single "indicator" LEDs used to show the status of a device (such as an "on/off" indicator on a monitor) do not typically present a significant level of risk to humans, and are not usually evaluated under the current photobiological safety standards.

The Development of Photobiological Safety Standards and Requirements

Today's photobiological safety standards have their origins in efforts during the 1990s to accommodate LED-related radiation requirements within existing laser safety standards. The rationale for this initial effort was based on a number of technical characteristics shared by lasers and LEDs, as well as some common applications. Toward this end, the principle laser safety standard, IEC 60825, Safety of laser products, was first modified in 1993 to address LED requirements, and again in 1996 and 2001. However, the constraints of addressing the differences in laser and LED emissions within the scope of a single standard made clear that a standard devoted exclusively to photobiological safety of lamps, including LEDs, would eventually be necessary.

In response to these challenges, the Illuminating Engineering Society of North America (IESNA) developed a photobiological safety standard specifically covering lamps and lamp systems, including LEDs. IESNA RP-27, Recommended Practice for Photobiological Safety for Lamps and Lamp Systems: General Requirements, was published in 1996, and was adopted as an American National Standard by the American National Standards Institute (ANSI). The essential requirements of RP-27 were later adopted by the International Commission on Illumination (CIE) in its standard CIE S 009/E: 2002, Photobiological Safety of Lamps and Lamp Systems, published in 2002.

The work of the IESNA and the CIE in the area of photobiological safety requirements specific to LEDs ultimately led to the development of IEC 62471, Photobiological Safety of Lamps and Lamp Systems. First published in 2006, IEC 62471 is mostly based on the photobiological safety requirements found in ANSI/IESNA RP-27, but reflects some changes in the weighting functions for certain wavelengths and the start/stop points for wavelength ranges for certain hazards. The introduction of IEC 62471 led to the removal of LED-specific radiation safety requirements from IEC 60825 in 2007.

The IEC has also issued a technical report intended to provide further guidance on the manufacturing requirements and control measures related to LEDs. First published in 2009, IEC/TR 62471-2, Photobiological Safety of Lamps and Lamp Systems—Part 2: Guidance on manufacturing requirements relating to non-laser optical radiation safety, offers clarification on the application of the photobiological safety requirements of IEC 62471 at the end-product level. IEC/TR 62471-2 also includes information on product labeling, user information statements, viewer related risk, and occupational safety issues.

IEC 62471 is now recognized in many countries as the key standard addressing photobiological safety issues related to lamps, lamp systems and other non-lamp sources of optical radiation. Certain individual product safety standards for products incorporating LEDs, such as those covering information technology equipment and consumer electronic devices, are being revised to reference IEC 62471. However, current versions of many product standards may still reference IEC 60825, and products presently on the market may reflect testing and certification to the earlier radiation requirements found in IEC 60825.

Photobiological Requirements of IEC 62471

IEC 62471 is a testing and classification standard that lays out a process for assessing the relative photobiological safety of lamps, lamp systems, and other non-lamp sources of optical radiation. The process consists of three basic stages as follows: 1) measuring absolute radiance and irradiance levels, 2) comparing effective ("weighted") levels with the exposure limits defined by the standard, and 3) determining a risk group to which a product is assigned based on the level of hazard to the skin and eye. The following sections discuss each of these stages in further detail.

Measurements

IEC 62471 defines two key radiometric parameters to assess the level of harmful radiation produced by a given product, irradiance and radiance. Irradiance measures the total amount of radiation at an illuminated surface from the entire hemisphere above, and evaluates the risk of hazards to the skin and to the front of the eye. Radiance measures the amount of actual light collected by the pupil, and evaluates the risk of hazards to the retina of the eye.

Absolute irradiance and radiance levels are measured in nanometer increments, without incorporating any weighting functions of the eye's response to various wavelengths. These absolute levels are then summed according to the equations in the standard over the applicable wavelength range, and weighted where applicable to reflect wavelengths for a particular hazard. The results are the effective, or weighted, irradiance/radiance values.

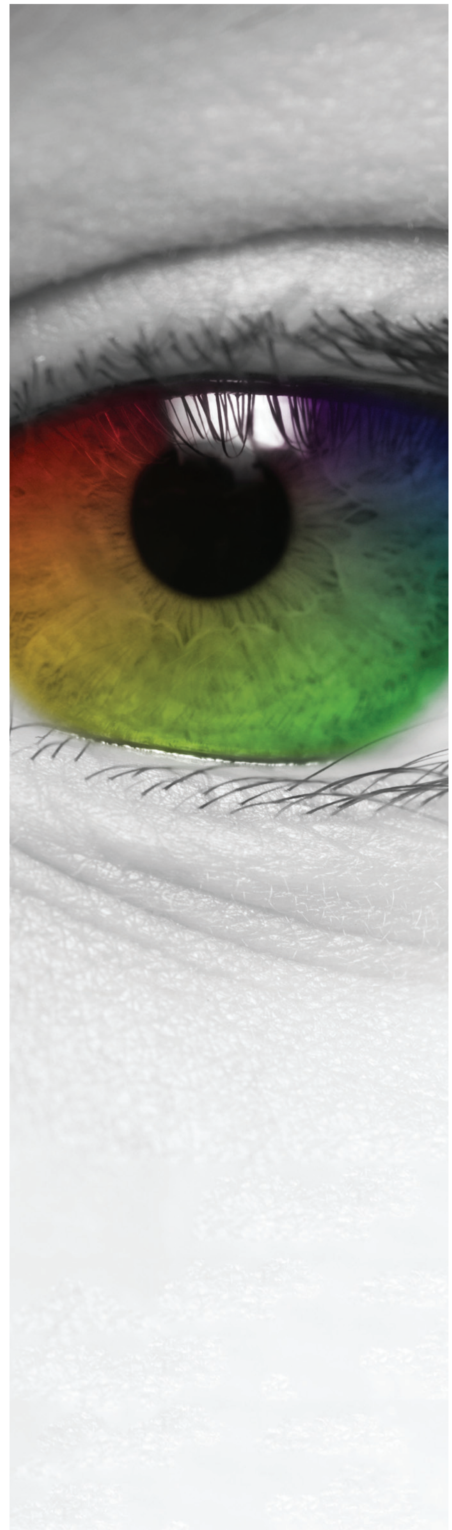
Exposure Limits

Once the effective irradiance and radiance values are determined by laboratory measurement, the results are compared to the limits defined in the standard. The limits are applicable to continuous light sources with minimum exposure time of greater than 0.01 millisecond and a maximum exposure time of not more than eight hours. The limits defined by the standard are based on radiation levels presumed not to create adverse health effects, but they are not intended to strictly define the difference between safe and unsafe levels. Additionally, the defined limits may not accurately define the risk for certain individuals who are more susceptible to adverse health effects from exposure to optical radiation, such as individuals with increased photosensitivity, or those who have lens transplants.

Risk Groups

When a product's effective irradiance and radiance values have been compared against limits defined in the standards, the extent of a product's level of hazard can be established. IEC 62471 uses the following categories to communicate a product's overall level of risk:

- **Exempt —** Lamp/LED does not pose any photobiological hazard



- **Group 1 (low risk) —** Lamp/LED does not pose a hazard due to normal behavioral limitations on exposure
- **Group 2 (moderate risk) —** Lamp/LED does not pose a hazard due to the aversion response or thermal discomfort
- **Group 3 (high risk) —** Lamp/LED may pose a hazard even for momentary or brief exposure

Other Photobiological Safety Requirements

Often, end products incorporate LEDs and other components that produce optical radiation. Because IEC 62471 is a "horizontal" standard, it does not directly address manufacturing, labeling, or user safety requirements that may be appropriate for end products that include components that produce optical radiation.

For end product manufacturers, IEC/TR 62471-2 provides further guidance on the appropriate application of the safety requirements of IEC 62471, especially regarding issues related to the installation and use of an end product. IEC/TR 62471-2 specifically addresses the following issues:

- **Hazard distance —** IEC/TR 62471-2 defines hazard distance as the distance where the anticipated exposure level equals the maximum effective radiation values that are not harmful to end users
- **Labeling —** IEC/TR 62471-2 recommends specific types of product labeling, including notices, cautions and warnings, based on the component's IEC 62471-defined risk group and the wavelength of the optical radiation
- **User information —** IEC/TR 62471-2 recommends the inclusion of IEC 62471-defined risk group information, including hazard distances, exposure hazard values, and instructions on the safe use of the end-product
- **Viewer-related risk —** IEC/TR 62471-2 categorizes viewer-related risk as "unintentional short term," "intermittent, occasional short term," and "intentional long term." Viewer-related risk associated with an end product may differ from the IEC 62471defined risk group assigned to a component
- **Maintenance personnel considerations —** IEC/TR 62471-2 recommends that the overall photobiological risk of an end product be based on the IEC 62471defined risk group of the component producing optical radiation

Anticipated Standards Development Activities

As LED technology continues to evolve and applications multiply, standards development efforts on the photobiological safety of lamps and lamp systems (including LEDs) will not remain static. As previously noted, current versions of many product standards still reference IEC 60825 to assess the potential LED radiation hazards. However, a number of these standards are being amended to reflect the photobiological requirements of IEC 62471, including IEC 60950, Information Technology Equipment. Other new standards recently published such as IEC 62368, Audio/Video, Information Technology and Communications Equipment, reference IEC 62471 in their first edition.

Another potentially significant development in this area is the current effort to update UL 8750, Light Emitting Diode (LED) Equipment for Use in Lighting Products. A new edition of UL 8750 is expected to incorporate photobiological safety requirements and safeguards. Consideration may also be given in some cases to modify or waive the requirement for photobiological assessments, for example, where spectral filters have been incorporated to reduce optical radiation levels. Further developments on this front are anticipated sometime in 2012.

Discussions are also reportedly underway regarding the revision of IEC 62471, which may include changes or adjustments in certain exposure limits. No publication date has been set for the release of this update. The IEC is also in the process of developing two additional parts for the IEC 62471 series, including a Part 4, which would provide guidance on measurement methods.[4]

Considerations for Manufacturers

To date, the European Union (EU) is the only jurisdiction that specifically mandates protection against optical radiation under the essential health and safety requirements of its Low Voltage Directive (LVD). As of September 2011, IEC 60825 can no longer be used to evaluate the radiation safety of LEDs under the LVD. However, the EU's version of IEC 62471, EN 62471: 2008, has been harmonized with the requirements of the LVD, so testing to its requirements now provides evidence of compliance with the LVD's requirements in this area. LED manufacturers should strongly consider testing their products in accordance with IEC 62471 to provide continued access to this important market.

Compliance with photobiological safety requirements in the U.S. and throughout the rest of the world is still voluntary. However, evidence of testing to the requirements of IEC 62471 can be used for product certification under the IECEE CB scheme, which supports the mutual acceptance by more than 50 member countries of test reports and certificates dealing with the safety of electrical and electronic products and components. Therefore, compliance with the requirements IEC 62471 can ease the path toward worldwide market access.

Finally, even in the absence of mandatory requirements, voluntary compliance with important product safety standards often influences purchasing decisions. Depending on the safety standards required by a product's intended use, LEDs and other components emitting optical radiation that have not been evaluated according to the requirements of IEC 62471 may be eliminated from consideration. In such cases, LED manufacturers whose products have been evaluated against IEC 62471 have a potentially significant competitive advantage, demonstrating their commitment to producing quality products that meet the most rigorous product safety requirements.

Summary and Conclusion

Technological advances have led to the use of LEDs in a widening array of applications. However, the proliferation of high-intensity LEDs has also increased concerns regarding the potentially hazardous photobiological effects from exposure to LEDs and other emitters of optical radiation. To address these concerns, product safety standards have been developed that detail specific testing methods to assess a product's potential risk.

At present, photobiological testing and certification of LEDs and other optical radiation emitters is mandatory only in the EU. But voluntary testing to the requirements of IEC 62471 clarifies the level of risk associated with these products, and can ease access to markets even where testing is not required. IEC 62471compliant LEDs also enable buyers to make informed decisions regarding the relative safety of comparable products.

For further information about the photobiological safety requirements of LEDs, and UL's work on photobiological safety standards, contact Winn Henderson, staff engineer at Winn.Henderson@ul.com

[1] "Learn About LEDs," Energy Star, U.S. Environmental Protection Agency. Web. 12 Apr. 2012. http://www.energystar.gov/index.cfm?c=lighting.pr_what_are#all_equal

[2] "High-Brightness LED Market Review and Forecast—2011," Strategies Unlimited, Sept. 2011. Web. 12 Apr. 2012. http://www.strategies-u.com/articles/reports/high-brightness-leds/high-brightness-led-market-review-and-forecast---2011.html

[3] For example, see "LED Streetlight's Price Cut in Half," Wall Street Journal, 10 Apr. 2012

[4] "LED-base products must meet photobiological safety standards: part 3," LEDs Magazine, Feb. 2012. Web. 15 Apr. 2012. http://www.ledsmagazine.com/features/9/2/9