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Dear Mr. Adams,

This letter reports my safety assessment of the current production model of the Philips goLITE^{TM} BLU that employs an array of blue LEDs. This analysis was based upon characterizing the light source and applying the criteria of appropriate US and international standards for the photobiological safety of lamps and lighting systems.

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Description:

The portable light therapy device is for table-mounted use and consists of an 10-by-6 LED array mounted in an "egg-crate" diffuser such that each LED was highly diffused and sitting within a cubical projection element. Each diffuser cube had approximately 1 by 1 cm internal dimensions, such that the entire array was 11.2 wide by 6.6 cm high. Each LED is mounted approximately 1.1 cm apart in the rectangular grid. The plastic external cover also added some further diffusion over the already diffused, blurred image of each LED, thereby reducing the brightness of each LED. Figure 1 shows the Philips goLITE^{TM} BLU package. The result was a reduced radiance, i.e., a reduced brightness that tends to reduce discomfort glare and provides an additional safety factor for viewers of the product. The typical viewing distance as recommended in the instruction booklet was approximately "20-30 inches" (i.e., 50-75 cm).

The specified ***spectral distribution*** for the LEDs was:

a. Peak wavelength = 467 nm; Figure 2 provides the spectral distribution.
b. Spectral emission consisted of the blue emission. Wavelengths less than ~400 nm were not detectable as shown in the spectral plot.

The rectangular array consisted of 10 vertical columns of 6-row LEDs (i.e., a 60-LED array).

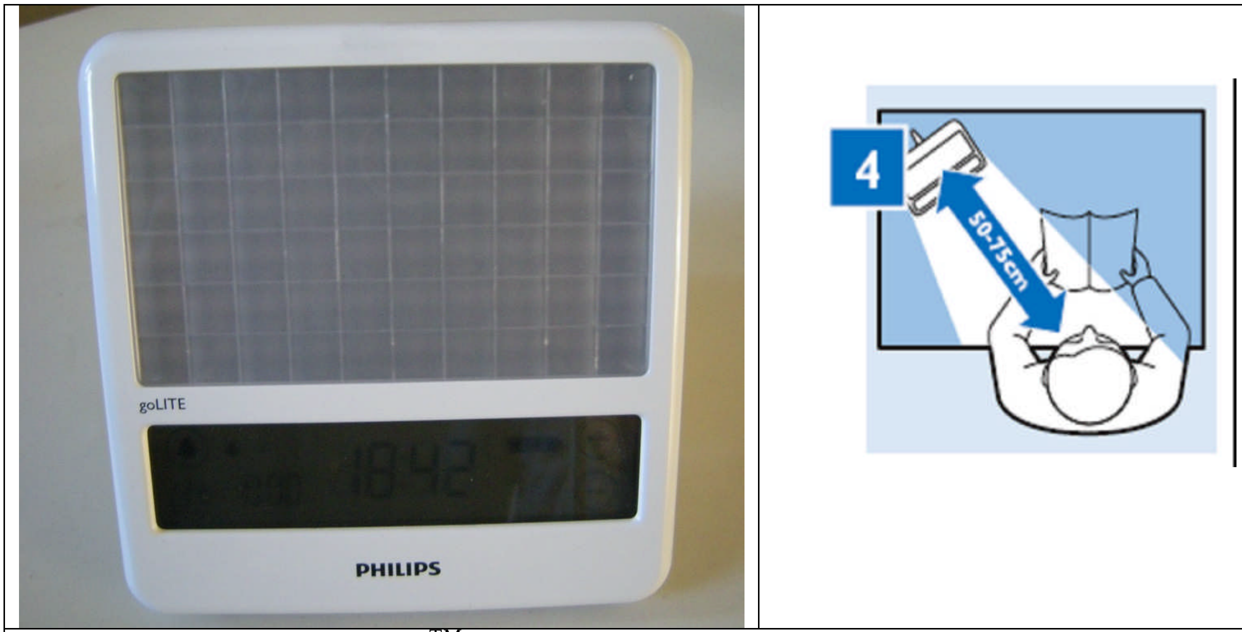

Figure 1. The Philips goLITE$^{\text{TM}}$ BLU is shown in its white 13.5–cm by 14–cm plastic package is shown at left. Recommended positioning of the light during normal use is pictured at right (as shown in the user instructions).

MEASUREMENTS

Instrumentation

Measurements of the goLITE$^{\text{TM}}$ BLU Model 105704 were performed during August-September 2009 using the following primary instrument:

International Light Model 1400A Radiometer/Photometer, with three detectors:

a. Model SEL240 (#3682) Detector with Input Optic T2ACT3 (#1 8613) that had been calibrated on 11 May 2009 to read directly in terms of the ACGIH/ICNRIP UV-Hazard effective irradiance.

b. Model SEL033 (#3 805) Detector with Input Optic W#6874 and Filter F#14299, which had been calibrated to measure irradiance between 380 and 1000 nm on 11 May 2009. A radiance hood, which limited the field-of-view (FOV) of the detector to 0.45 steradian (sr), was used to directly measure the radiance of the sources.

c. Model SEL033 (#3 805) Detector with Input Optic W#6874 and Filter UVA#28766, which had been calibrated to measure UVA irradiance between 315 and 400nm on 11 May 2009.

d. GenTec Solo2 Laser Power Meter with XLP1 12-1SH2-DO, S/N 174933 thermal detector head. The manufacturer calibrated this unit on February 6, 2008 and remains in calibration.

In addition, for an approximate check, a Minolta Luminance Meter was used to measure the panel luminance as a check of the radiance measurements.

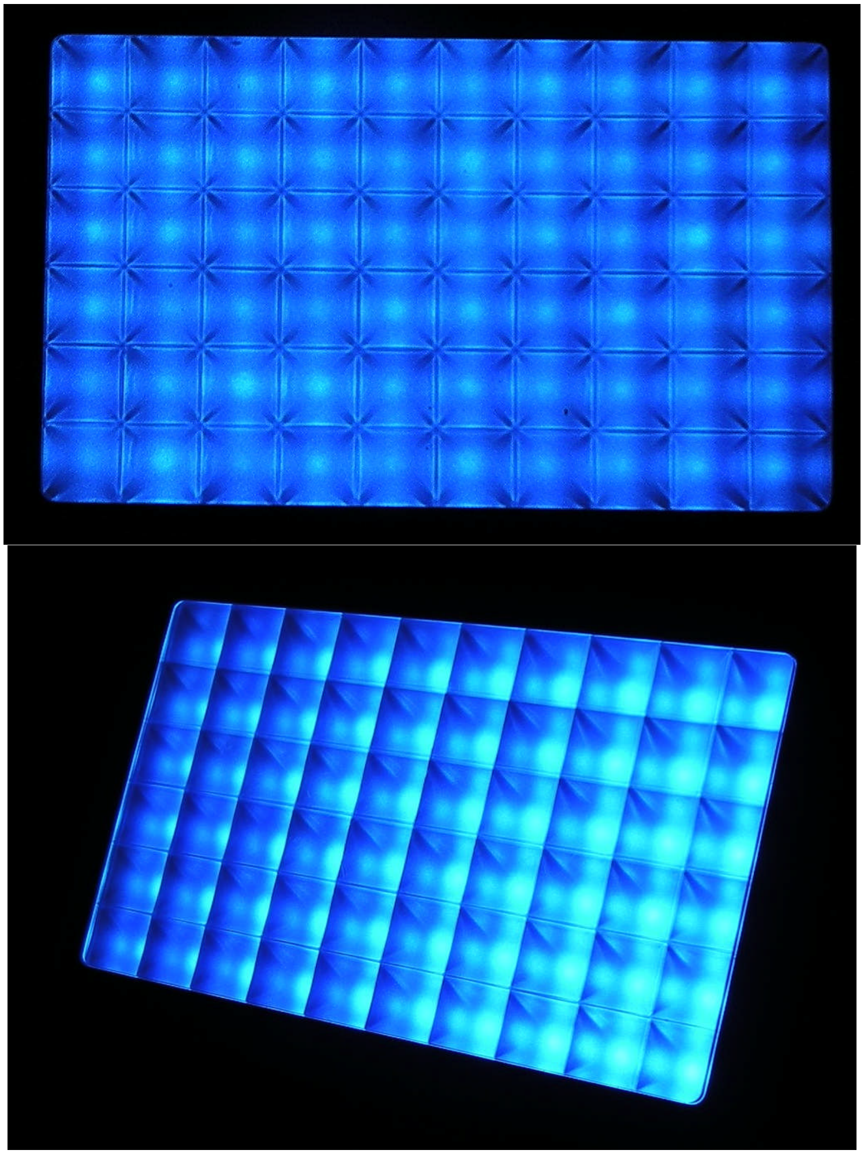

Figure 3. Top: Direct vew image of goLITE showing central 3-mm squares and reflected images above, below and to each side of each diffused element to produce an overall reduced source brightness. Bottom: Oblique view as seen by the user showing reduced luminance.

Measurements

UV Hazard. Measurements of the goLITE^{TM} BLU were first made with an actinic ultraviolet detector head to be certain that no potentially hazardous UV radiation was emitted from the surface of the light panel using the Model SEL240 (#3682) Detector. The UV-Hazard effective irradiance was less than 0.01 $\mu W/cm^2$, which is well below the ACGIH/ICNRIP exposure 8-hour exposure guideline of 0.1 $\mu W/cm^2$. The measurement was actually at the noise level of the instrument. The UVA measurement was also very low: < 0.1 $\mu W^{\bullet} cm^{-2}$ at the surface of the light panel. This is well below the ACGIH 8-hour exposure limit of 1 $mW^{\bullet} cm^{-2}$, and also well below the much more conservative UV-A limit of 33 $\mu W^{\bullet} cm^{-2}$ recommended by ICNIRP.

Photoretinitis Hazard ("Blue-Light Hazard)." Measurements of the light panel were then made with the broad-band visible-near-infrared radiometer detector head, Model SEL033 (#3 805) Detector (with Input Optic W#6874 and Filter F#14299). The unit was always adjusted to maximal output values. Measurements were first made at contact with the surface of the light panels (i.e., the closest points of human access), to search for points of high irradiance and to test for uniformity. The variability was less than approximately 20%. Irradiance measurements were then made along the central axis of highest irradiance out to a distance of 100 cm. Irradiance measurements were made with and without an optical mask that isolated a single diode. The measurements are provided in Table 1. The approximate source size of each individual diffused LED was 3 mm square.

Table '. Radiometric Measurements—Summary of On-Axis Values

Distance (cm)	**Panel Irradiance $\mathrm{mW^{\cdot}cm^{-2}}$**	**Single masked diode irradiance $\mathrm{\mu W^{\cdot}cm^{-2}}$**	**Panel Array Radiance* $\mathrm{mW^{\cdot}cm^{-2\cdot}sr^{-1}}$ ($\gamma = 0.11$ rad)**	**LED Radiance* $\mathrm{mW^{\cdot}cm^{-2\cdot}sr^{-1}}$ ($\gamma = 0.011$ rad)**	**LED Blue Radiance* $\mathrm{mW^{\cdot}cm^{-2\cdot}sr^{-1}}$ ($\gamma = 0.011$ rad)**	**Array Blue Radiance $\mathrm{\mu W^{\cdot}cm^{-2\cdot}sr^{-1}}$ ($\gamma = 0.11$ rad)**
1	8.4	--	--			3.2
10	2.1	84?	5.3	--	--	3.2
20	1.23 (1.3†)	62	5.2*	13	7.9	3.2
30	0.55	29		15	9.1	--
40	0.36	17	--	15	9.1	--
50	0.26	11	--	14	8.5	---
60	0.18	--	--	--	--	---
70	0.13	--	--	--	--	---
80	0.105	--	--	--	--	--
90	0.083	--	--	--	--	--
100	0.067	--	--	--	--	--

*Measurements of array radiance at 20 cm and beyond were not possible because of the field of view of the radiance hood (0.47 sr). However, radiance does not vary with distance for the same source area measured. The average panel radiance corresponds to a luminance of 0.41 $\mathrm{cd^{\cdot}cm^{-2}}$ (i.e., 4,100 $\mathrm{cd^{\bullet}m^{-2}}$). The spot luminance measurements were consistent with the readings obtained with the International Light instrument. Individual LED luminance and calculated radiance obtained using both instruments were averaged over the standardized 11-mrad cone angle ($\Omega = 9.5 \text{ X } 10^{-5}$ sr) for brief viewing periods up to 100 s, and 0.11 radian for long-term viewing. The individual LED radiance values at less than 50 cm were for central LED bright spots.

†An irradiance of 1.30 $\mathrm{mW\bullet cm^{-2}}$ was obtained with the GenTec thermal radiometer which confirms the measured values with the IL1400A radiometer.

Spectroradiometric Measurements

Spectral irradiance measurements were performed by Apollo Light. By employing the spectral distribution, it was possible to calculate the relative effective blue-light hazard and luminous efficacy of radiation. The luminous efficacy was 78 $\mathrm{lm^{\bullet}W^{-1}}$, and the blue-light-hazard fraction was: 0.607 (i.e., 60.7 %).

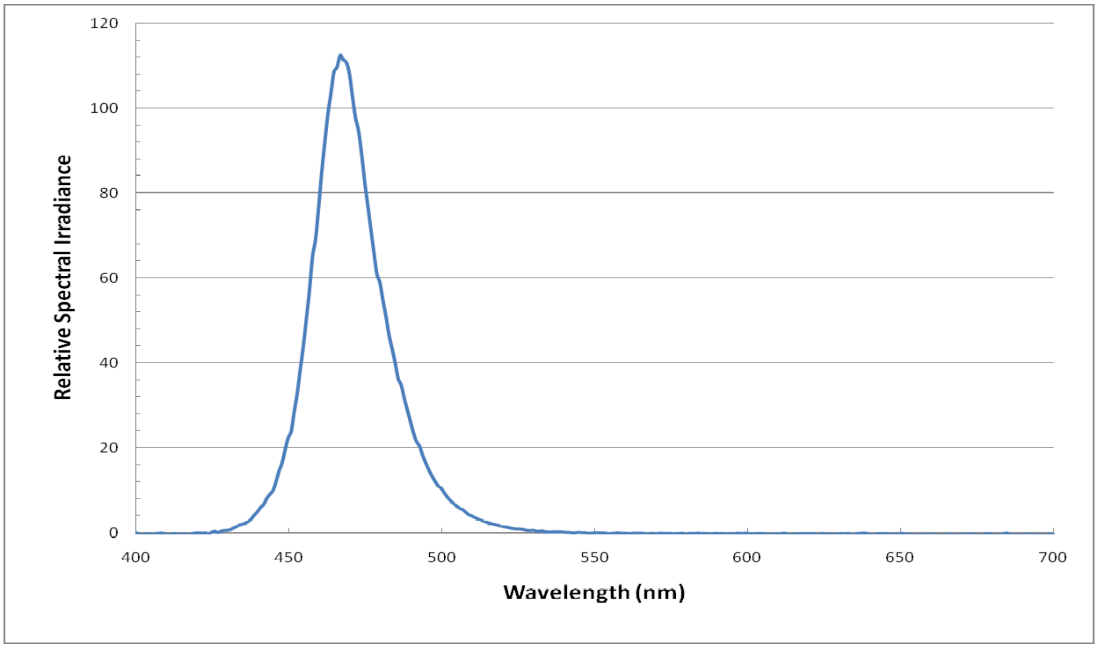

Figure 2. Spectral irradiance distribution from measurements performed by Apollo. Spectral weighting provided a luminous efficacy of radiation of 78 $\mathrm{lm}^{\bullet}\mathrm{W}^{-1}$, a blue-light-hazard fraction of 0.607 (i.e., 60.7 %).

POTENTIAL HAZARDS

The eye is well adapted to protect itself against optical radiation (ultraviolet, visible and infrared radiant energy) from the natural environment and mankind has learned to use protective measures, such as hats and eye-protectors to shield against the harmful effects upon the eye from very intense ultraviolet radiation (UVR) present in sunlight over snow or sand. The eye is also protected against bright light by the natural aversion response to viewing bright light sources. The aversion response normally protects the eye against injury from viewing bright light sources such as the sun, arc lamps and welding arcs, since this aversion limits the duration of exposure to a fraction of a second (about 0.25 s).

There are at least five separate types of hazards to the eye from optical sources:[1]

(a) Ultraviolet photochemical injury to the cornea (photokeratitis) and lens (cataract) of the eye (1 80 nm to 400 nm).

(b) Thermal injury to the retina of the eye (400 nm to 1400 nm).

(c) Blue-light photochemical injury to the retina of the eye (principally 400 nm to 550 nm; unless aphakic, 310 to 550 nm)[2]

(d) Near-infrared thermal hazards to the lens (approximately 800 nm to 3000 nm).

(e) Thermal injury (burns) of the cornea of the eye (approximately 1400 nm to 1 mm).

For the LED optical sources used in the GoLIGHT, only aspects (a) and (c) are relevant, since thermal injury requires optical powers in the milliwatt-to-watt range. Therefore these *photochemical* effects were evaluated. Although UV emissions were not expected, to remove any uncertainty, aspect (a) was measured and confirmed to be of not consequence.

Dosimetric Concepts in Photobiology

The product of the dose-rate and the exposure duration always must result in the same exposure dose (in joules-per-square centimeter at the retina) to produce a threshold injury. Blue-light retinal injury (photoretinitis) can result from viewing either an extremely bright light for a short time, or a less bright light for longer exposure periods. This characteristic of photochemical injury mechanisms is termed *reciprocity* and helps to distinguish these effects from thermal burns, where heat conduction requires a very intense exposure within seconds to cause a retinal coagulation; otherwise, surrounding tissue conducts the heat away from the retinal image. Injury thresholds for acute injury in experimental animals for both corneal and retinal effects have been corroborated for the human eye from accident data. Occupational safety limits for exposure to UVR and bright light are based upon this knowledge. As with any photochemical injury mechanism, one must consider the *action spectrum,* which describes the relative effectiveness of different wavelengths in causing a photobiological effect. The action spectrum for photochemical retinal injury peaks at approximately 435-440 nm. The relative spectral contribution of the LED emission to the blue-light hazard spectrum is 60.7%.

Retinal Hazards

The principal retinal hazard resulting from viewing bright light sources is photoretinitis, e.g., *solar retinitis* with an accompanying scotoma, which results from staring at the sun. Solar retinitis was once referred to as "eclipse blindness" and associated "retinal burn." Only in recent years has it become clear that photoretinitis results from a photochemical injury mechanism following exposure of the retina to shorter wavelengths in the visible spectrum, i.e., violet and blue light. Prior to conclusive animal experiments at that time (Ham, Mueller and Sliney, 1976), it was thought to be a thermal injury mechanism. However, it has been shown conclusively that an intense exposure to short-wavelength light (hereafter referred to as "blue light") can cause retinal injury.

HUMAN EXPOSURE LIMITS

A number of national and international groups have recommended occupational or public exposure limits (ELs) for optical radiation [i.e., ultraviolet (UV), light and infrared (IR) radiant energy]. Two principal groups have recommended ELs for visible radiation (i.e., light), and these recommendations are essentially the same.[3-5] The groups are well known in the field of occupational health--the American Conference of Governmental Hygienists (ACGIH) and radiation protection--the International Commission on Non-Ionizing Radiation Protection (ICNIRP). The ACGIH refers to its ELs as "Threshold Limit Values," or TLVs and these are issued yearly, so there is an opportunity for a yearly revision[3-4]. The current ACGIH TLV's for light (400 nm to 760 nm) have been largely unchanged for the last two decades. The limits are based in large part on ocular injury data from animal studies and from data from human retinal injuries resulting from viewing the sun and welding arcs. The limits also have an underlying assumption that outdoor environmental exposures to visible radiant energy is normally not hazardous to the eye except in very unusual environments such as snow fields and deserts. The ICNIRP publishes Guidelines on limits of exposure to broad-band incoherent optical radiation (0.38 to 3 µm) were published in 1997, and were based upon the ACGIH recommendations to a large extent. The ICNRIP guidelines are developed through collaboration with the World Health Organization (WHO) by jointly publishing criteria documents that provide the scientific database for the exposure limits[7].

ICNIRP/ACGIH EXPOSURE LIMITS

Blue-Light Photochemical Retinal Hazard

The ACGIH TLV[3] and ICNIRP guidelines are identical for large sources and are designed to protect the human retina against photoretinitis,[8] "the blue-light hazard" is an effective blue-light radiance L_B spectrally weighted against the Blue-Light Hazard action spectrum $B(\lambda)$ and integrated for t s of 100 $J/(cm^2 \cdot sr)$, for $t < 10{,}000$ s, i.e.,

$$L_B \cdot t = \Sigma\, L_\lambda \cdot B(\lambda) \cdot t \cdot \Delta\lambda \;\le\; 100\ \mathrm{J \cdot cm^{-2} \cdot sr^{-1}}\quad \text{effective} \qquad [1]$$

and for t> 10,000 s (2.8 hrs.):

$$L_B = 10\ \mathrm{mW \cdot cm^{-2} \cdot sr^{-1}} \qquad \text{for } t > 10{,}000\ \text{s} \qquad [2]$$

For these very lengthy viewing durations, the radiance is averaged over a 0.11 radian cone angle. To calculate the maximum direct viewing duration when [2] is not satisfied, this maximum "stare time," t-max, is found by inverting Eqn. [1] for a modulated CW source with a weighted radiance of LB:

$$t_{max} = 100\ \mathrm{J \cdot cm^{-2} \cdot sr^{-1}} / L_B \qquad [3]$$

For very small sources that subtend a viewing angle less than α_{MIN}, which is 11 mrad = 0.011 radian, the blue light hazard is evaluated by mathematically weighting the spectral radiance, L_λ, against the blue-light hazard function to obtain LB averaged over the 11 mrad cone (~10^{-4} sr). At the closest intended viewing distance of 30 cm, the individual LEDs are separated by at least 1 cm, i.e., at an angle of 33 mrad apart and are considered independent for the blue-light hazard for brief viewing durations, but totally averaged for lengthy exposure durations. The maximal measured individual LED blue-light effective radiance averaged over the limiting angle of 11 mrad was 9.1 $\mathrm{mW \cdot cm^{-2} \cdot sr^{-1}}$ at 30 cm and 9.1 $\mathrm{mW \cdot cm^{-2} \cdot sr^{-1}}$ at 40 cm. At the 20-cm lamp-safety reference distance, the individual LED blue-light-hazard radiance was 7.9 $\mathrm{mW \cdot cm^{-2} \cdot sr^{-1}}$. These individual radiance values applicable to this small cone angle are all far below the short-term limit of 1000 $\mathrm{mW \cdot cm^{-2} \cdot sr^{-1}}$ by a factor of more than 100-fold. The whole-panel array radiance, which is actually averaged over 0.11 radian (i.e., most of the array at 50 cm) was only 3.2 $\mathrm{mW \cdot cm^{-2} \cdot sr^{-1}}$, which is less than one-third of the long-term viewing limit of 10 $\mathrm{mW \cdot cm^{-2} \cdot sr^{-1}}$, and therefore no limiting viewing durations exist even for direct fixation. Even so, during normal use, an individual would not be expected to stare steadily into the unit—and certainly not at individual diodes, examining the individual bright spots, but perform other tasks. But if they did, a safety factor of at least 100 exists. Because the brightness of the light source, it would be discomforting to stare directly at the light source for any length of time. Furthermore, the user normally would not stare at the LED array on axis, but place the device off-axis, where the brightness is far less. Thus the real safety factors are far greater than for the worst-case, on-axis test conditions described above. The Philips goLITE^{TM} panel is designed to illuminate far greater areas of the retina. For research purposes, if it is desirable to calculate the exact retina irradiance E_r, the method is described in the Annex to this report.

PRODUCT SAFETY STANDARDS

There are both national and international lamp safety standards that address the photobiological safety of lamps and lamp products, which include LEDs.[8-11] In the United States, the Illuminating Engineering Society of North America (IESNA) has issued a series of American National Standards Institute (ANSI) lamp safety standards.[8-10] These employ the ACGIH/ICNIRP exposure limits as emission limits based upon certain times of anticipated exposure. Lamps and lamp products are placed into four risk groups: Exempt (no hazard), Risk Group 1 (RG-1), Risk Group 2 (RG-2) and Risk Group 3 (RG-3) based upon all of the ultraviolet, visible and infrared exposure limits as a function of exposure duration. On the international scene, the CIE (Commission International de l'Eclairage, the International Commission on Illumination) issued CIE Standard S-009E-2002, *Photobiological Safety of Lamps and Lamp Systems*, in 2002 and this was later adopted as a dual-logo standard in 2006 by the International Electrotechnical Commission (IEC) as: IEC 62471:2006. All of these standards follow the same emission limits and risk-group classification. The Philips goLITE^{TM} meets all of the requirements for an Exempt product (without photobiological risk), since it also did not exceed the ACGIH/ICNIRP limits at a reference test distance of 20 cm.

SAFETY ANALYSIS

Since the averaged radiance of the array is below the 10-mW·cm^{-2}·sr^{-1} limit for continuous viewing and thereby meets the requirements for an Exempt product, a warning statement to limit the viewing duration under normal use conditions is not necessary. However, the current cautionary wordings contained in the regular goLITE^{TM} User's Guide could be retained, since the caution advises the user not to stare continuously at the panel, since, as with any bright light source, needless staring should be avoided. Afterimages and discomfort glare might also result from staring. Discomfort glare is strongest when the central retina, the macula, is illuminated; hence, a normal user would find it uncomfortable to stare directly into the source and would naturally follow the arrangement where the source illuminates the peripheral retina.

The Philips goLITE^{TM} meets all of the requirements for an Exempt product (without photobiological risk), since it did not exceed the emission limits provided in both national and international standards for photobiological safety of lamps at the reference test distance of 20 cm. Lamp safety standards of the Illuminating Engineering Society of North America (IESNA)[8-10] and the International Commission on Illumination (the CIE) with the International Electrotechnical Commission (IEC)[11] all place this product in a non-risk, "Exempt" category because the blue-light radiance is to be averaged over an angle greater than 11 mrad for durations greater than 100 s (i.e., collecting field of view $\gamma = 0.0011 \cdot \sqrt{t}$ radian), thus recognizing eye movements increasing in magnitude with time t. The criterion for Exempt status is that the source radiance averaged over $\gamma = 0.11$ radian does not exceed $L_B = 10$ mW·cm^{-2}·sr^{-1}, which it does not; it is less than 1/3rd of this blue-light radiance limit.

CONCLUSION

The Philips BLU goLITE^{TM} as tested operated at emission levels that are below limits recognized as maximal safe exposure values for the times of intended use with the panel not directly viewed and the individual performing other tasks. Indeed, to put this light in perspective, the retinal irradiance for visible wavelengths is comparable to viewing bright sunlight reflected from snow, which people naturally avoid staring directly at for lengthy periods.[12]

David H. Sliney

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Annex: CALCULATING RETINAL EXPOSURE

From knowledge of the optical parameters of the human eye and from radiometric parameters of a light source, it is possible to calculate irradiances (dose rates) at the retina. Exposure of the anterior structures of the human eye to ultraviolet radiation (UVR) may also be of interest; and the relative position of an external light source and the degree of lid closure can greatly affect the proper calculation of this ultraviolet exposure dose in an awake, task-oriented viewing condition.

For lamps and even small LED sources, the closest distance at which any human eye can sharply focus upon a small object is about 10 cm. The value of 10 cm is an exceptionally small value for the near-point of accommodation for the adult human eye. At shorter distances the image of a light source would be out of focus and blurred. In the case of the Apollo light panels there would be no reason for a person to approach that closely. In any case, to calculate the exact retina irradiance E_r, the following formulation applies:

$$E_r = 0.27\ L \cdot \tau \cdot d_e^{2} \qquad [4]$$

where τ is the transmittance of the ocular media (with a maximum of about 0.9 in the visible spectrum).