

**Laser Hazard Analysis
for
LUMETRICS™ OptiGauge Measurement
Probe Super LED**

Analysis performed by: Jean M. Hill and Don W. Dawson
Under SATOP RTA #2947

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SYMBOLS

Symbol (unit)	Description
α (mrad)	Apparent angle subtended by a source at the location of the viewer
a_1 (cm).....	Beam Diameter at the beam waist (assume circular Gaussian beam profile) or smallest point, 20 microns at 25 mm
a_2 (cm).....	Beam Diameter at the beam waist (assume circular Gaussian beam profile) or smallest point, 40 microns at 50 mm
C_A	From Table 6: Wavelength Correction Factor
C_c	Table 6 - Wavelength Correction Factor
C_E	Table 6 - Extended-source correction factor for source angles less than 100 mrad
Class IIIb AEL _{es} (W).....	Class 3b - Accessible Emission Limit
D_L (cm).....	Beam Diameter at range r = focal length
$D_m = D_f$ (cm)	Limiting Aperture - Fully lit room having normal 7 mm pupil diameter - no aided viewing (0.7 cm)
E_1 (W/cm ²)	Beam Irradiance - Radiant power incident per unit area upon a surface at 25 mm
E_2 (W/cm ²)	Beam Irradiance - Radiant power incident per unit area upon a surface at 50 mm
E_{retina} (W/cm ²).....	Irradiance on the observer's retina
ϕ (rad).....	Emergent Beam Divergence at 1/e - Since min. beam waist is assumed to be at sample surface, minimum divergence was assumed
Φ_m (W).....	Accessible Emission through the measurement aperture near the beam waist at focal length
Φ_0 (W)	Total Radiant Power of CW beam
λ (nm).....	Wavelength of radiation source
L (W/cm ²)	Radiance of light reflecting from test subject
μ (1/cm)	Atmospheric Attenuation on a very clear day
MPE _{es} (W/cm ²).....	Extended Source Table 5b - Maximum Permissible Exposure (for peak power - single pulse)
MPE _{ss} (W/cm ²).....	Small Source Table 5a - Maximum Permissible Exposure (for peak power - single pulse)
r (cm).....	Distance from sample surface to skin or eye exposure (10 cm)
r_{O1} (cm).....	Length from exit aperture to sample surface, 25 mm +/- 8 mm
r_{O2} (cm).....	Length from exit aperture to sample surface, 50 mm +/- 8 mm
t (sec)	Duration of CW exposure
T_2 (sec).....	Table 6 - Exposure duration beyond which thermal MPE for an extended source is constant in terms of irradiance
τ_λ	Table 9 - Transmission of optics in %
T_{max} (sec)	The CW exposure duration used for classification (Z136.1-2000, Section 8.2.2. - entire work day is 30,000 sec)
Ω_{eye} (sr)	Field of view of observer's eye

Ω_{laser} (sr)..... Solid angle defining the cone of light reflecting from test subject

Extended Source Evaluation:

Class I AEL_{es} (W)..... Class 1 - Accessible Emission Limit - Extended Source using T_{max}

Class IIIa AEL_{es} (W)..... Class 3a - Accessible Emission Limit - Extended Source using T_{max} at 5 times the Class 1 AEL for $\lambda > 700$ nm

Small Source Evaluation:

Class I AEL_{ss} (W)..... Class 1 - Accessible Emission Limit - Small Source using T_{max}

Class IIIa AEL_{ss} (W)..... Class 3a - Accessible Emission Limit - Small Source using T_{max} at 5 times the Class 1 AEL for $\lambda > 700$ nm

Intrabeam Hazard Distance: Unaided Viewing

r_{NOHD1} (cm)..... Nominal Ocular Hazard Distance for f=25 mm

r_{NOHD2} (cm)..... Nominal Ocular Hazard Distance for f=50 mm

Diffuse Reflection Hazard Distance: Unaided Viewing

ρ_{λ} (%)..... Spectral reflectance of a diffuse or specular object at wavelength λ

θ_v (degrees)..... Viewing Angle from the normal to a reflecting surface

r_{NHZ1} (cm)..... Nominal Hazard Zone for f=25 mm

r_{NHZ2} (cm)..... Nominal Hazard Zone for f=50 mm

Specular Reflection Hazard Distance: Unaided Viewing

r_{NHZ3} (cm)..... Nominal Hazard Zone for f=25 mm

r_{NHZ4} (cm)..... Nominal Hazard Zone for f=50 mm

Optical Density: Unaided Viewing

Φ_f (W)..... Effective Power - The amount of power transmitted through an aperture with diameter D_f (assumed to be worst-case)

$D_{\lambda\text{es}}$ Optical Density Required for Unaided Viewing, 20 microns

$D_{\lambda\text{ss}}$ Optical Density Required for Unaided Viewing, 20 microns

1. INTRODUCTION

This report has been produced to give a basic laser classification to the LUMETRICS™ OptiGauge Optical Measurement Probe Super LED based on the ANSI Z136.1-2000, 21 CFR 1040.10, and information provided by LUMETRICS™. The information contained herein does not take into account IEC 60825 or any special measurements of the LED over a range of distances.

“The assessment of the optical hazard associated with beams from sources of light intermediate in quality between a laser and Light Emitting Diodes (LED) has been a challenging problem for the international standards community for a large number of years.” – Hall, S. et al.

The current LED classification requirements “follow IEC 60825 and require a measurement of ‘apparent source size and its location.’ The CIE publication CIE S 009/E: 2002 ‘Photobiological Safety of Lamps and Lamp Systems’ cites apparent source size as part of the methodology to calculate angular subtense and hence, Retinal Hazard. However, a procedure for establishing apparent source size and location is not described.” – Hall, S. et al.

“The apparent source size of an LED is a critical parameter used in the assessment of the ocular viewing hazard of these devices under ISO 60825-1 ‘Safety of Laser Products. Equipment Classification, Requirements and User’s Guide’. Under the committee draft IEC 60825-13 ‘Measurements for the Classification of Laser Products’ a proposed measurement method is described to determine the apparent source size of LEDs. The validity of this method has been questioned at a national and international level and continues to be debated within the various standards bodies, such as IEC, ISO and CIE. Specifically, the applicability of propagation models to low divergence beams from LEDs has been challenged.” – Hall, S. et al.

The LED devices listed in this report have not had their classifications validated through physical measurement. To determine the actual laser classification beyond any reasonable doubt, a suitable measurement facility should be consulted to perform an assessment of the commercial LED sources that LUMETRICS™ is using in the OptiGauge Optical Measurement Probe Super LED. Should one LED be substituted for another and the part numbers and/or vendors differ, a new analysis would be required to accurately characterize the retinal hazard range due to the potential variation in the LEDs.

If any input parameters have changed from the original input parameters that were provided by LUMETRICS™ (those parameters that are listed in this report), this analysis is no longer valid and a new analysis will need to be performed.

—————
DANGER
—————
NEVER
POINT A LASER
DIRECTLY INTO
THE EYE

2. ASSUMPTIONS

The equations herein have been modified from the “standard configuration” laser equations to compensate for the configuration of the instrument. This analysis assumes worst-case input parameters for classification. The following is a list of the assumptions that were made in order to perform the analysis:

- The total length of time that an operator could be exposed to radiation is equal to eight hours, or in other words, an average work-day.
 - The exposure duration is not limited.
 - The exposure time can vary from seconds to days.
 - The instrument does not have an automatic shut-off switch.
 - This instrument operates with a Continuous Wave (CW).
- The beam waist is considered to be the worst-case beam diameter that results in the greatest direct energy density from the light source.
 - The worst-case viewing distance is assumed to be 10 cm
- 5 x 70 aided viewing optics were not considered in this analysis because the instrument is used strictly indoors in a laboratory or manufacturing setting; thus, the analysis performed will be for unaided viewing only.
- A small source is worse than a large extended source due to the eye focusing the light source onto the fovea and retina.
- The wavelength to be assessed was provided directly by LUMETRICS™ as 1310 nm, which is in the near infrared region of the electromagnetic spectrum. Therefore, this instrument is not a Class 2 laser because Class 2 lasers fall within the visible wavelength range of 400 to 700 nm only. This instrument falls within the 400 to 1400 nm region of the electromagnetic spectrum that can present a Retinal Hazard, Skin Hazard, and a Thermal Hazard. Corneal and Lens Hazards are for ultraviolet and mid to far infrared lasers that fall within the ranges of 200 to 400 nm and 1400 nm to 1 mm, respectively. Be aware that some lasers can also cause photochemical damage.
- Since a specific divergence was not provided, an average value of 0.5 mrad was assumed, 0.02 mrad was used for a focal length of 25 mm and 0.01 was used for a focal length of 50 mm.
 - The subtended angle was assumed to be less than 1.5 mrad
 - α is less than 1.5 mrad; therefore, $T_2 = 10$ sec
- The sample size of the subject being measured is assumed to be from 10 microns to 15 mm.
- The sample can be positioned anywhere in the region that begins 8 mm before the beam waist and ends 8 mm after the beam waist.
- The sample is transparent to translucent.

- The sample can contain a mirror surface or be completely diffuse; thus, both diffuse and specular reflection must be taken into account.

3. INPUT PARAMETERS

The five most important parameters that affect the classification of a laser are the

- Wavelength (nm)
- Minimum Beam Diameter or Beam Waist (cm)
- Minimum Divergence (radians)
- Minimum Pulsewidth (seconds), including Pulse Repetition Frequency (PRF) (Hz)
- Maximum Output Power (W).

These inputs are to be assigned values that represent the worst-case values that the laser could possibly produce. The input parameters used for this analysis are listed in Table 1.

Table 1. LUMETRICS™ Input Parameters

Parameter	Symbol	Value
Wavelength (nm)	λ	1310
Minimum Beam Diameter or Beam Waist (cm)	$a_{1, 25}$	0.00002
	$a_{2, 50}$	0.00004
Minimum Divergence* (radians)	ϕ_1	0.02
	ϕ_2	0.01
Minimum Pulsewidth (seconds), including Pulse Repetition Frequency (PRF) (Hz)	t_1	10
		CW
Maximum Output Power (W)	Φ_o	0.010, 0.015, 0.020, 0.025
Focal Length from exit aperture to sample surface (mm +/- 8 mm)	r_{o1}	2.5
	r_{o2}	5.0

*The Minimum Divergence was derived from SLED information supplied by LUMETRICS™

4. STEPS FOR LASER CLASSIFICATION DETERMINATION

A. Determine T_{\max}

The maximum exposure time is determined from the minimum of the laser design and the values established in ANSI Z136.1, Section 8.2.2. Normally, 10 seconds would be appropriate for evaluating hazards in the non-visible wavelengths of the near infrared (700 to 1400 nm). However, a longer exposure duration will be assumed for this analysis because an operator can be present at the instrument for an eight hour work day. Therefore 30,000 seconds will be used for T_{\max} .

B. Determine the Measurement Aperture, D_m , from Table 9 in ANSI Z136.1

Since this analysis assumes that aided viewing will not be used with this instrument, Table 8 is used instead of Table 9. From Table 8, the Aperture Diameter, D_m , for eye in the spectral region from 400 to 1400 nm and a T_{\max} duration of 30,000 seconds is 7 mm, or 0.7 cm.

C. Compute the Accessible Emission Φ_m (W)

This value is computed near the beam waist if the beam waist is external to the laser, but not necessarily at the beam waist. The accessible emission measurement is recorded at the location where the most hazardous exposure occurs external to the laser system. If a laser has no external beam waist and a large divergence, accessible emission is measured or computed at a range of 10 cm from the output aperture.

$$\Phi_m = \Phi_o \tau_\lambda \left[1 - e^{-\left(\frac{D_m}{D_L}\right)^2} \right] W$$

From Table 9, $\tau_\lambda = 0.7$

The Accessible Emission is assumed to be 0.010, 0.015, 0.020, and 0.025 W for the purpose of this analysis.

D. Determine the Limiting Aperture Diameter, D_f , from Table 9 in ANSI Z136.1

From Table 8, The Aperture Diameter, D_f , for the eye in the spectral region from 400 to 1400 nm and a $t = T_{\max}$ duration of 30,000 seconds is 7 mm, or 0.7 cm.

E. Determine if the laser is a Class I laser by finding the Class I AEL

Using paragraphs 3.3.1.1 and 3.3.1.2 and Tables 5a or 5b and Table 6 in ANSI Z136.1, compute the MPE for an exposure time of T_{\max} .

Since this instrument has a long exposure duration of 30,000 seconds, Table 5b will be used.

For the near infrared in the 1050 to 1400 nm region and an exposure duration of 30,000 seconds, the MPE (W/cm^2) is calculated using the following equation

$$MPE = 9.0 \cdot C_C C_E T_2^{-0.25} \times 10^{-3} W/cm^2$$

From Table 6, $C_C = 8$, $C_E = 1.0$ for $\alpha < \alpha_{\min}$, and $T_2 = 10$ sec; thus, for an extended source $MPE_{es} = 0.0405 \text{ W/cm}^2$, and for a small source $MPE_{ss} = 0.0400 \text{ W/cm}^2$.

F. Determine the Class I Accessible Emission Limit, AEL

Using the MPE and the Limiting Aperture Diameter determine the Class I AEL for the laser.

$$\text{Class I AEL} = MPE \frac{\pi D_f^2}{4} W$$

For a small source, the Class I $AEL_{ss} = 0.0154 \text{ W}$, and for an extended source, the Class I $AEL_{es} = 0.0156 \text{ W}$.

G. Determine if the instrument's Accessible Emission exceeds the Class I AEL

Compare the Class I AEL with the Accessible Emission to determine if the Accessible Emission is less than the Class I AEL. If the Accessible Emission is less than the Class I AEL, the laser is a Class I laser and no further classification is necessary. If the Accessible Emission exceeds the Class I AEL, the laser could be a Class IIIa.

For both small and extended sources, the 10 mW and 15 mW configurations are less than the Class I AEL, giving them a Class I rating.

H. Determine if the laser is a Class IIIa by finding the Class 3a AEL

The Class IIIa AEL = five times the Class I AEL if $\lambda < 400 \text{ nm}$ or $\lambda \geq 700 \text{ nm}$

$$\text{Class IIIa AEL} = 5 \cdot \text{Class I AEL}$$

I. Determine if the instrument's Accessible Emission exceeds the Class IIIa AEL

Compare the Class IIIa AEL with the Accessible Emission to determine if the Accessible Emission is less than the Class IIIa AEL. If the Accessible Emission is less than the Class IIIa AEL, the laser is a Class IIIa laser and no further classification is necessary. If the Accessible Emission exceeds the Class IIIa AEL, the laser could be a Class IIIb.

For both small and extended sources, the 20 mW and 25 mW configurations are less than the Class IIIa AEL, giving them a Class IIIa rating. There is no need to go any further.

J. Determine if the laser is a Class IIIb by finding the Class IIIb AEL

The Class IIIb AEL is any laser that has an average power of less than 500 mW over any 0.25 second interval and is unable to produce more than 30 C_A mJ per pulse, limited to 125 mJ.

From Table 6, $C_A = 5.0$ for λ from 1050 to 1400 nm.

$$\text{Class IIIb AEL} \leq 500 \text{ mW over } 0.25 \text{ seconds and an Energy of less than } 125 \text{ mJ}$$

where $W = J/t$ and $J = W \cdot t$.

K. Determine if the instrument's Accessible Emission exceeds the Class IIIb AEL

Compare the Class IIIb AEL with the Accessible Emission to determine if the Accessible Emission is less than the Class IIIb AEL. If the Accessible Emission is less than the Class IIIb AEL, the laser is a Class IIIb laser and no further classification is necessary. If the Accessible Emission exceeds the Class IIIb AEL, the laser is a Class IV.

5. STEPS FOR DETERMINING HAZARDS

The following is a summary of the general requirements and controls pertaining to laser hazards. For a complete list of hazard requirements and controls, please reference ANSI Z136.1-2000 and 21 CFR 1040.10.

ANSI Z136.1-2000, para. 4.5.1.2:

The general public shall not be exposed nor have access to laser radiation emission at wavelengths outside the visible range (0.4 to 0.7 microns) at levels exceeding the applicable MPE levels under any reasonably foreseeable conditions of operation.

21 CFR 1040.10(f)(5)(i, iii-v), Laser radiation emission indicator:

- (i) Each laser system classified as a Class IIIa laser product shall incorporate an emission indicator that provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I.
- (iii) For laser systems manufactured after August 20, 1986, each separately housed laser and operation control of a laser system that regulates the laser or collateral radiation emitted by a product during operation shall incorporate an emission indicator as required in accordance with paragraph (f)(5) (i) or (ii) of this section, if the laser or operation control can be operated at a separation distance greater than 2 meters from any other separately housed portion of the laser product incorporating an emission indicator.
- (iv) Any visible signal required by paragraph (f)(5) (i) or (ii) of this section shall be clearly visible through protective eyewear designed specifically for the wavelength(s) of the emitted laser radiation.
- (v) Emission indicators required by paragraph (f)(5) (i) or (ii) of this section shall be located so that viewing does not require human exposure to laser or collateral radiation in excess of the accessible emission limits of Class I and table VI.

21 CFR 1040.10(f)(6), Beam attenuator:

- (i) Each laser system classified as a Class II, III, or IV laser product shall be provided with one or more permanently attached means, other than laser energy source switch(es), electrical supply main connectors, or the key-actuated master control, capable of preventing access by any part of the human body to all laser and collateral radiation in excess of the accessible emission limits of Class I and table VI.
- (ii) If the configuration, design, or function of the laser product would make unnecessary compliance with the requirement in paragraph (f)(6)(i) of this section, the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, may, upon written application by the manufacturer, approve alternate means to accomplish the radiation protection provided by the beam attenuator.

21 CFR 1040.10(f)(7), Location of controls:

- (7) Each Class IIa, II, III, or IV laser product shall have operational and adjustment controls located so that human exposure to laser or collateral

radiation in excess of the accessible emission limits of Class I and table VI is unnecessary for operation or adjustment of such controls.

A. Nominal Ocular Hazard Distance

The Nominal Ocular Hazard Distance (NOHD), r_{NOHD} , is the minimum distance from the laser emitter along its optical axis at which no hazard exists to the human eye. An observer at this point or further away would have no adverse eye effects.

$$r_{NOHD} = r_0 + \frac{1}{\phi} \sqrt{\frac{4\Phi_0}{MPE : E_1 \cdot \pi} - a^2} \text{ cm}$$

Intrabeam Hazard Distance: Unaided Viewing		
SLED Source	r_{NOHD1} (f = 25 mm)	r_{NOHD2} (f = 50 mm)
10 mW	30.5 cm	30.7 cm
15 mW	36.8 cm	37.0 cm
20 mW	42.2 cm	42.4 cm
25 mW	46.8 cm	47.1 cm

B. Nominal Hazard Zone for Diffuse and Specular Reflection

$$r_{NHZdiffuse} = \sqrt{\frac{\Phi_0 \rho_\lambda \cos \theta_v}{MPE : E_1 \cdot \pi}} \text{ cm}$$

$$r_{NHZspecular} = \frac{1}{\phi} \sqrt{\frac{1.27 \rho_\lambda \Phi_0}{MPE : E_1}} \text{ cm}$$

Where $\rho_\lambda = 20\%$ and $\theta_v = 0$ degrees

Diffuse Reflection Hazard Distance: Unaided Viewing		
SLED Source	r_{NHZ1} (f = 25 mm)	r_{NHZ2} (f = 50 mm)
10 mW	0.005 cm	0.005 cm
15 mW	0.006 cm	0.006 cm
20 mW	0.007 cm	0.007 cm
25 mW	0.008 cm	0.008 cm

Specular Reflection Hazard Distance: Unaided Viewing		
SLED Source	r_{NHZ3} (f = 25 mm)	r_{NHZ4} (f = 50 mm)
10 mW	12.5 cm	12.6 cm
15 mW	15.3 cm	15.4 cm
20 mW	17.7 cm	17.8 cm
25 mW	19.8 cm	19.9 cm

C. Optical Density

$$D_{\lambda} = \log_{10} \left(\frac{\Phi_f}{\Phi_{mpe}} \right)$$

Optical Density Required for Unaided Viewing (20 μm)			
SLED Source	D_{λes} (extended source)	D_{λss} (small source)	Recommended OD
10 mW	-0.193	-0.187	N/A
15 mW	-0.017	-0.011	N/A
20 mW	0.108	0.114	1
25 mW	0.205	0.211	1

6. LABELING

21 CFR 1040.10(g), Labeling requirements:

- (g) In addition to the requirements of 1010.2” (certification label) “and 1010.3” (manufacturers’ identification label), “each laser product shall be subject to the applicable labeling requirements of this paragraph.” -

A. General Commercial Labeling

21 CFR 1010.2, Certification:

- (a) Every manufacturer of an electronic product for which an applicable standard is in effect under this subchapter shall furnish to the dealer or distributor, at the time of delivery of such product, the certification that such product conforms to all applicable standards under this subchapter.
- (b) The certification shall be in the form of a label or tag permanently affixed to or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use, unless the applicable standard prescribes some other manner of certification. All such labels or tags shall be in the English language.
- (c) Such certification shall be based upon a test, in accordance with the standard, of the individual article to which it is attached or upon a testing program which is in accordance with good manufacturing practices. The Director, Center for Devices and Radiological Health may disapprove such a testing program on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic products comply with the standards prescribed under this subchapter.
- (d) In the case of products for which it is not feasible to certify in accordance with paragraph (b) of this section, upon application by the manufacturer, the Director, Center for Devices and Radiological Health may approve an alternate means by which such certification may be provided.

21 CFR 1010.3, Identification:

- (a) Every manufacturer of an electronic product to which a standard under this subchapter is applicable shall set forth the information specified in paragraphs (a)(1) and (2) of this section. This information shall be provided in the form of a tag or label permanently affixed or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use or in such other manner as may be prescribed in the applicable standard. Except for foreign equivalent abbreviations as authorized in paragraph (a)(1) of this section all such labels or tags shall be in the English language.
 - (1) The full name and address of the manufacturer of the product; abbreviations such as "Co.," "Inc.," or their foreign equivalents and the first and middle initials of individuals may be used. Where products are sold under a name other than that of the manufacturer of the product, the full name and address of the individual or company under whose name the product was sold may be set forth, provided such individual or company has previously supplied the Director, Center for Devices and Radiological Health with sufficient information to identify the manufacturer of the product.

- (2) The place and month and year of manufacture: (i) The place of manufacture may be expressed in code provided the manufacturer has previously supplied the Director, Center for Devices and Radiological Health with the key to such code. (ii) The month and year of manufacture shall be provided clearly and legibly, without abbreviation, and with the year shown as a four-digit number as follows: Manufactured: (Insert Month and Year of Manufacture.)
- (b) In the case of products for which it is not feasible to affix identification labeling in accordance with paragraph (a) of this section, upon application by the manufacturer, the Director, Center for Devices and Radiological Health may approve an alternate means by which such identification may be provided.
- (c) Every manufacturer of an electronic product to which a standard under this subchapter is applicable shall provide to the Director, Center for Devices and Radiological Health a list identifying each brand name which is applied to the product together with the full name and address of the individual or company for whom each product so branded is manufactured.

21 CFR 1010.4, Variances:

- (a) Criteria for variances.
 - (1) Upon application by a manufacturer (including an assembler), the Director, Center for Devices and Radiological Health, Food and Drug Administration, may grant a variance from one or more provisions of any performance standard under subchapter J of this chapter for an electronic product subject to such standard when the Director determines that granting such a variance is in keeping with the purposes of the Radiation Control for Health and Safety Act of 1968, and: (i) The scope of the requested variance is so limited in its applicability as not to justify an amendment to the standard, or (ii) There is not sufficient time for the promulgation of an amendment to the standard.
 - (2) The issuance of the variance shall be based upon a determination that: (i) The product utilizes an alternate means for providing radiation safety or protection equal to or greater than that provided by products meeting all requirements of the applicable standard, or (ii) The product performs a function or is intended for a purpose which could not be performed or accomplished if required to meet the applicable standards, and suitable means for assuring radiation safety or protection are provided, or (iii) One or more requirements of the applicable standard are not appropriate, and suitable means for assuring radiation safety or protection are provided.
- (b) Applications for variances. If you are submitting an application for variances or for amendments or extensions thereof, you must submit an original and two copies to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
 - (1) The application for variance shall include the following information: (i) A description of the product and its intended use. (ii) An explanation of how compliance with the applicable standard would restrict or be inappropriate for this intended use. (iii) A description of the manner in which it is proposed to deviate from the requirements of the applicable standard. (iv) A description of the advantages to be derived from such deviation. (v) An explanation of how alternate or suitable means of radiation protection will be provided. (vi) The period of time it is desired that the variance be in effect, and, if appropriate, the number of units the applicant wishes to manufacture. (vii) In the case of prototype or experimental equipment, the proposed location of each unit. (viii) Such other information required by regulation or by the Director, Center for

Devices and Radiological Health, to evaluate and act on the application. (ix) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. (x) [Reserved] (xi) If the electronic product is used in a clinical investigation involving human subjects, is subject to the requirements for institutional review set forth in part 56 of this chapter, and is subject to the requirements for informed consent set forth in part 50 of this chapter, the investigation shall be conducted in compliance with such requirements.

- (2) The application for amendment or extension of a variance shall include the following information: (i) The variance number and expiration date. (ii) The amendment or extension requested and basis for the amendment or extension. (iii) A description of the effect of the amendment or extension on protection from radiation produced by the product. (iv) An explanation of how alternate or suitable means of protection will be provided.
- (c) Ruling on applications.
- (1) The Director, Center for Devices and Radiological Health, may approve or deny, in whole or in part, a requested variance or any amendment or extension thereof, and the director shall inform the applicant in writing of this action on a requested variance or amendment or extension. The written notice will state the manner in which the variance differs from the standard, the effective date and the termination date of the variance, a summary of the requirements and conditions attached to the variance, any other information that may be relevant to the application or variance, and, if appropriate, the number of units or other similar limitations for which the variance is approved. Each variance will be assigned an identifying number.
 - (2) The Director, Center for Devices and Radiological Health, shall amend or withdraw a variance whenever the Director determines that this action is necessary to protect the public health or otherwise is justified by this subchapter. Such action will become effective on the date specified in the written notice of the action sent to the applicant, except that it will become effective immediately upon notification to the applicant when the Director determines that such action is necessary to prevent an imminent health hazard.
 - (3) All applications for variances and for amendments and extensions thereof and all correspondence (including written notices of approval) on these applications will be available for public disclosure in the office of the Division of Dockets Management, except for information regarded as confidential under section 360A(e) of the act.
- (d) Certification of equipment covered by variance. The manufacturer of any product for which a variance is granted shall modify the tag, label, or other certification required by 1010.2 to state:
- (1) That the product is in conformity with the applicable standard, except with respect to those characteristics covered by the variance;
 - (2) That the product is in conformity with the provisions of the variance; and
 - (3) The assigned number and effective date of the variance.

21 CFR 1010.5, Exemptions for products intended for United States Government use:

- (a) Criteria for exemption. Upon application by a manufacturer (including assembler) or by a U.S. department or agency, the Director, Center for Devices and Radiological Health, Food and Drug Administration, may grant an exemption from any performance standard under subchapter J of this chapter for an electronic product, or class of products, otherwise subject to such standard when he determines that such electronic product or class is intended for use by departments or agencies of the United States and meets the criteria set forth in paragraph (a) (1) or (2) of this section. (1) The procuring agency shall prescribe procurement specifications for the product or class of products governing emissions of electronic product radiation, and the product or class shall be of a type used solely or predominantly by a department or agency of the United States. (2) The product or class of products is intended for research, investigations, studies, demonstration, or training, or for reasons of national security.
- (b) Consultation between the procuring agency and the Food and Drug Administration. The United States department or agency that intends to procure or manufacture a product or class of products subject to electronic product radiation safety standards contained in this subchapter should consult with the Center for Devices and Radiological Health, Food and Drug Administration, whenever it is anticipated that the specifications for the product or class must deviate from, or be in conflict with, such applicable standards. Such consultation should occur as early as possible during development of such specifications. The department or agency should include in the specifications all requirements of such standards that are not in conflict with, or are not inappropriate for, the special or unique uses for which the product is intended. The procuring agency should indicate to the Center for Devices and Radiological Health if it desires to be notified of the approval, amendment, or withdrawal of the exemption.
- (c) Application for exemption. If you are submitting an application for exemption, or for amendment or extension thereof, you must submit an original and two copies to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. For an exemption under the criteria prescribed in paragraph (a)(1) of this section, the application shall include the information prescribed in paragraphs (c)(1) through (c)(13) of this section. For an exemption under the criteria prescribed in paragraph (a)(2) of this section, the application shall include the information prescribed in paragraphs (c)(3) through (c)(13) of this section. An application for exemption, or for amendment or extension thereof, and correspondence relating to such application shall be made available for public disclosure in the Division of Dockets Management, except for confidential or proprietary information submitted in accordance with part 20 of this chapter. Information classified for reasons of national security shall not be included in the application. Except as indicated in this paragraph, the application for exemption shall include the following: (1) The procurement specifications for the product or class of products that govern emissions of electronic product radiation. (2) Evidence that the product or class of products is of a type used solely or predominantly by departments or agencies of the United States. (3) Evidence that such product or class of products is intended for use by a department or agency of the United States. (4) A description of the product or class of products and its intended use. (5) An explanation of how compliance with the applicable standard would restrict or be inappropriate for this intended use. (6) A description of the manner in which it is proposed that the product or class of products shall deviate from the requirements of the applicable standard. (7) An explanation of the

advantages to be derived from such deviation. (8) An explanation of how means of radiation protection will be provided where the product or class of products deviates from the requirements of the applicable standard. (9) The period of time it is desired that the exemption be in effect, and, if appropriate, the number of units to be manufactured under the exemption. (10) The name, address, and telephone number of the manufacturer or his agent. (11) The name, address, and telephone number of the appropriate office of the United States department or agency purchasing the product or class of products. (12) Such other information required by regulation or by the Director, Center for Devices and Radiological Health, to evaluate and act on the application. Where such information includes nonclinical laboratory studies, the information shall include, with respect to each nonclinical study, either a statement that each study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations. When such information includes clinical investigations involving human subjects, the information shall include, with respect to each clinical investigation, either a statement that each investigation was conducted in compliance with the requirements set forth in part 56 of this chapter, or a statement that the investigation is not subject to such requirements in accordance with 56.104 or 56.105 and a statement that each investigation was conducted in compliance with the requirements set forth in part 50 of this chapter. (13) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

- (d) Amendment or extension of an exemption. An exemption is granted on the basis of the information contained in the original application. Therefore, if changes are needed in the radiation safety specifications for the product, or its use, or related radiation control procedures such that the information in the original application would no longer be correct with respect to radiation safety, the applicant shall submit in advance of such changes a request for an amendment to the exemption. He also shall submit a request for extension of the exemption, if needed, at least 60 days before the expiration date. The application for amendment or extension of an exemption shall include the following information: (1) The exemption number and expiration date. (2) The amendment or extension requested and basis for the amendment or extension. (3) If the radiation safety specifications for the product or class of products or the product's or class of products' use or related radiation control procedures differ from the description provided in the original application, a description of such changes.
- (e) Ruling on an application. (1) The Director, Center for Devices and Radiological Health, may grant an exemption including in the written notice of exemption such conditions or terms as may be necessary to protect the public health and safety and shall notify the applicant in writing of his action. The conditions or terms of the exemption may include specifications concerning the manufacture, use, control, and disposal of the excess or surplus exempted product or class of products as provided in the Code of Federal Regulations, title 41, subtitle C. Each exemption will be assigned an identifying number. (2) The Director, Center for Devices and Radiological Health, shall amend or withdraw an exemption whenever he determines that such action is necessary to protect the public health or otherwise is justified by provisions of the act or this subchapter. Such action shall become effective on the date specified in the written notice of the action sent to the

applicant, except that it shall become effective immediately when the Director determines that it is necessary to prevent an imminent health hazard.

- (f) Identification of equipment covered by exemption. The manufacturer of any product for which an exemption is granted shall provide the following identification in the form of a tag or label permanently affixed or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use or in such other manner as may be prescribed in the exemption:

CAUTION

This electronic product has been exempted from Food and Drug Administration radiation safety performance standards prescribed in the Code of Federal Regulations, title 21, chapter I, subchapter J, pursuant to Exemption No. ____, granted on _____."

B. Class I Labeling

21 CFR 1040.10(d)(4), Class I dual limits:

- (4) Laser or collateral radiation in the wavelength range of greater than 400 nm but less than or equal to 1.400 nm exceeds the accessible emission limits of Class I if it exceeds both:
- (i) The Class I accessible emission limits for radiant energy within any range of emission duration specified in table I of this paragraph, and
 - (ii) The Class I accessible emission limits for integrated radiance within any range of emission duration specified in table I of this paragraph.

21 CFR 1040.10(e)(1), Tests for determination of compliance:

- (1) Tests for certification. Tests on which certification under 1010.2 is based shall account for all errors and statistical uncertainties in the measurement process. Because compliance with the standard is required for the useful life of a product, such tests shall also account for increases in emission and degradation in radiation safety with age.

ANSI Z136.1-2000 para. 3.3.1.1 outlines the requirements for labeling Class I lasers. The only required label is the manufacturer's identification label combined with certification label that it meets the 21 CFR 1040.10. Since LUMETRICS™ is manufacturing multiple lasers that can have differing power outputs, but look identical due to the housing used, it is recommended as a best engineering practice that a laser classification label be placed on a Class I laser identifying it specifically as a Class I laser to prevent manufacturing personnel from potentially confusing it with another laser that is not a Class I laser during the manufacturing process.

C. Class IIIa Labeling

21 CFR 1040.10(g)(8)(i), Warning for visible and/or invisible radiation:

- (8) On the labels specified in this paragraph, if the laser or collateral radiation referred to is:
- (i) For invisible radiation, the word "invisible" shall appropriately precede the word "radiation."

21 CFR 1040.10(g)(2)(i), Class IIIa and IIIb designations and warnings

- (i) Each Class IIIa laser product with an irradiance less than or equal to $2.5 \times 10^{-3} \text{ W/cm}^2$ shall have affixed a label bearing the warning logotype A (Figure "1" of paragraph (g)(1)(ii) of this section) and including the following wording:

[Position 1 on the logotype]	"INVISIBLE LASER RADIATION--DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS"
[Position 2 on the logotype]	"25 mW, CW, 1310 nm SLED"
[Position 3 on the logotype]	"CLASS IIIa LASER PRODUCT"

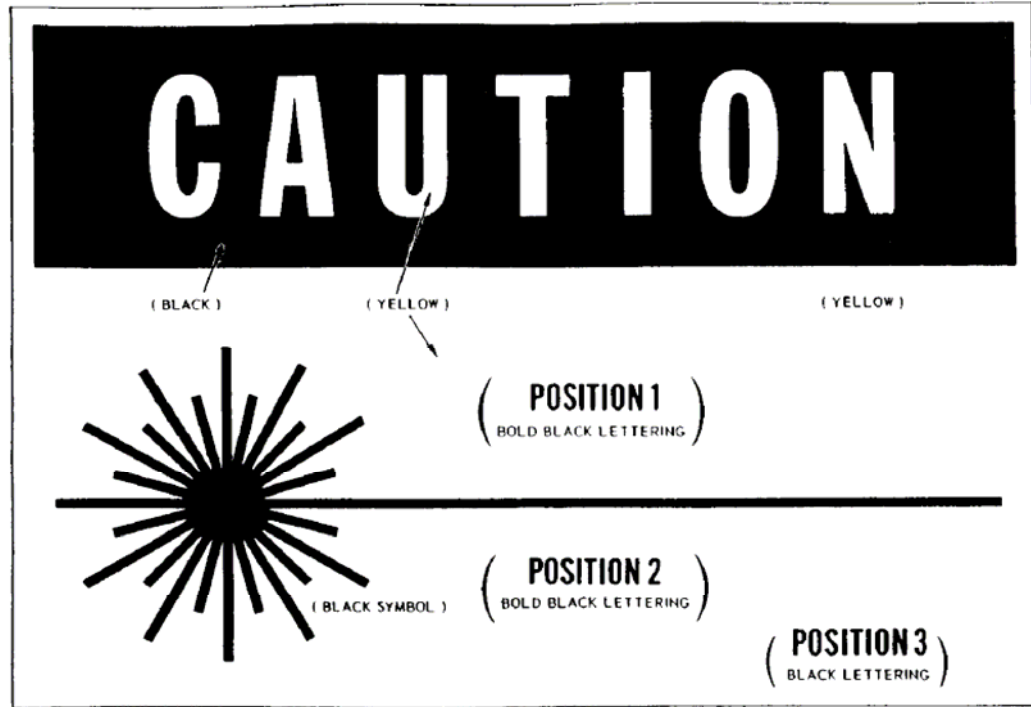


Figure 1. Logotype A

D. Determine the Irradiance

21 CFR 1040.10(e)(3)(ii):

- (ii) The irradiance (W/cm^2) or radiant exposure (J/cm^2 equivalent to the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and, for irradiance, within a circular solid angle of acceptance of 1×10^{-3} steradian with collimating optics of 5 diopters or less, divided by the area of the aperture stop (cm^2).

$$E = \frac{1.27 \Phi_0 e^{-\mu r}}{D_L^2} \text{ W/cm}^2$$

Where $\mu = 10^{-7} \text{ cm}^{-1}$, atmospheric attenuation on a very clear day and $r = 10 \text{ cm}$, or the distance from sample surface to skin or eye exposure.

Beam Irradiance		
SLED Source	E ₁ (f = 25 mm)	E ₂ (f = 50 mm)
10 mW	5.64 x 10 ⁻⁵ W/cm ²	5.08 x 10 ⁻⁴ W/cm ²
15 mW	8.47 x 10 ⁻⁵ W/cm ²	7.62 x 10 ⁻⁴ W/cm ²
20 mW	1.13 x 10 ⁻⁴ W/cm ²	1.02 x 10 ⁻³ W/cm ²
25 mW	1.41 x 10 ⁻⁴ W/cm ²	1.27 x 10 ⁻³ W/cm ²

An alternate means of deriving the irradiance is to analyze the geometry of the device in use. The light incident on the test subject reflects in a cone defined by the divergence angle, ϕ . The solid angle (measured in steradians) subtended by this cone is defined as

$$\Omega_{laser} = \phi \cdot 4 \frac{sr}{rad}$$

The power density per solid angle represented by the emittance divided by the reflected cone's dimension is known as the radiance, L.

$$L = \frac{MPE}{\Omega_{laser}} W/cm^2 sr$$

The solid angle (measured in steradians) describing the view by an observer's eye of the reflection is defined as the area of the pupil divided by the square of the distance from the eye to the target, or Ω_{eye} .

$$\Omega_{eye} = \frac{1/4 \pi D_m^2}{r^2}$$

The irradiance on the retina, then, is the product of the solid angle subtended and the radiance, or

$$E_{retina} = L \Omega_{eye} W/cm^2$$

21 CFR 1040.10(g)(2)(ii), Class IIIa designations and warnings:

- (ii) Each Class IIIa laser product with an irradiance greater than 2.5×10^{-3} W/cm² shall have affixed a label bearing the warning logotype B (Figure "2" in this paragraph) and including the following wording:

[Position 1 on the logotype]	"INVISIBLE LASER RADIATION--AVOID DIRECT EYE EXPOSURE"
[Position 2 on the logotype]	"25 mW, CW, 1310 nm SLED"
[Position 3 on the logotype]	"CLASS IIIa LASER PRODUCT"

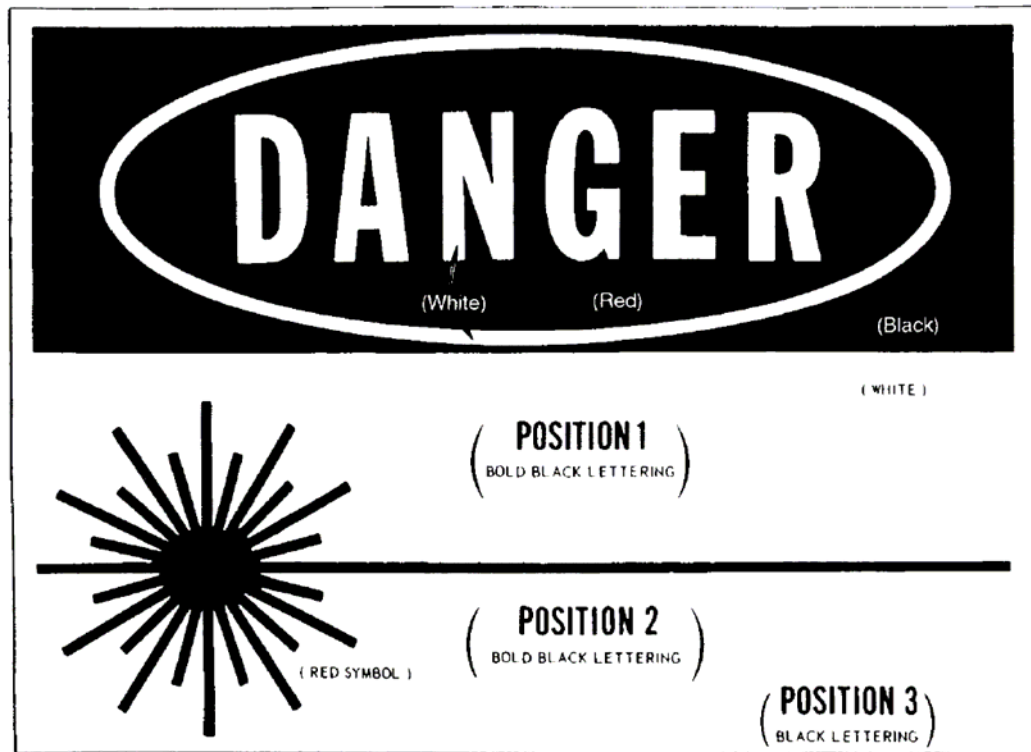


Figure 2. Logotype B

21 CFR 1040.10(g)(4), Radiation output information on warning logotype:

- (4) Each Class II, III, and IV laser product shall state in appropriate units, at position 2 on the required warning logotype, the maximum output of laser radiation, the pulse duration when appropriate, and the laser medium or emitted wavelength(s).

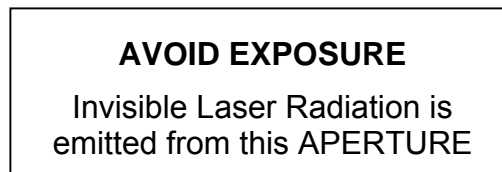


Figure 3. Aperture Label

21 CFR 1040.10(g)(5) Aperture label:

- (5) Each laser product, except medical laser products and Class IIa laser products, shall have affixed, in close proximity to each aperture through which is emitted accessible laser or collateral radiation in excess of the accessible emission limits of Class I and table VI of paragraph (d) of this section, a label(s) "(Figure 3)" bearing the following wording as applicable. "AVOID EXPOSURE--Laser radiation is emitted from this aperture," if the radiation emitted through such aperture is laser radiation.

21 CFR 1040.10(g)(9), Positioning of labels:

- (9) All labels affixed to a laser product shall be positioned so as to make unnecessary, during reading, human exposure to laser radiation in excess of

the accessible emission limits of Class I radiation or the limits of collateral radiation established to table VI of paragraph (d) of this section.

21 CFR 1040.10(g)(10), Label specifications:

- (10) Labels required by this section and 1040.11 shall be permanently affixed to, or inscribed on, the laser product, legible, and clearly visible during operation, maintenance, or service, as appropriate. If the size, configuration, design, or function of the laser product would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, on the Director's own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s) or alternate wording for such label(s) as applicable.

7. DOCUMENTATION REQUIRED FOR SALE OF LASERS

21 CFR 1040.10(h), Informational requirements:

- (1) User information. Manufacturers of laser products shall provide as an integral part of any user instruction or operation manual which is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each laser product:
 - (i) Adequate instructions for assembly, operation, and maintenance, including clear warnings concerning precautions to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and 1040.11.
 - (ii) A statement of the magnitude, in appropriate units, of the pulse durations(s), maximum radiant power and, where applicable, the maximum radiant energy per pulse of the accessible laser radiation detectable in each direction in excess of the accessible emission limits in table I of paragraph (d) of this section determined under paragraph (e) of this section.
 - (iii) Legible reproductions (color optional) of all labels and hazard warnings required by paragraph (g) of this section and 1040.11 to be affixed to the laser product or provided with the laser product, including the information required for positions 1, 2, and 3 of the applicable logotype (figure 1 of paragraph (g)(1)(ii) or figure 2 or paragraph (g)(2)(ii) of this section). The corresponding position of each label affixed to the product shall be indicated or, if provided with the product, a statement that such labels could not be affixed to the product but were supplied with the product and a statement of the form and manner in which they were supplied shall be provided.
 - (iv) A listing of all controls, adjustments, and procedures for operation and maintenance, including the warning "Caution--use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure."
 - (v) In the case of laser products other than laser systems, a statement of the compatibility requirements for a laser energy source that will assure compliance of the laser product with this section and 1040.11.
 - (vi) In the case of laser products classified with a 7 millimeter diameter aperture stop as provided in paragraph (e)(3)(i) of this section, if the use of a 50 millimeter diameter aperture stop would result in a higher classification of the product, the following warning shall be included in the user information: "CAUTION--The use of optical instruments with this product will increase eye hazard."
- (2) Purchasing and servicing information. Manufacturers of laser products shall provide or cause to be provided:
 - (i) In all catalogs, specification sheets, and descriptive brochures pertaining to each laser product, a legible reproduction (color optional) of the class designation and warning required by paragraph (g) of this section to be affixed to that product, including the information required for positions 1,

2, and 3 of the applicable logotype (figure 1 of paragraph (g)(1)(ii) or figure 2 of paragraph (g)(2)(ii) of this section).

- (ii) To servicing dealers and distributors and to others upon request at a cost not to exceed the cost of preparation and distribution, adequate instructions for service adjustments and service procedures for each laser product model, including clear warnings and precautions to be taken to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and 1040.11; and in all such service instructions, a listing of those controls and procedures that could be utilized by persons other than the manufacturers or the manufacturer's agents to increase accessible emission levels of radiation and a clear description of the location of displaceable portions of the protective housing that could allow human access to laser or collateral radiation in excess of the accessible emission limits in tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section. The instructions shall include protective procedures for service personnel to avoid exposure to levels of laser and collateral radiation known to be hazardous for each procedure or sequence of procedures to be accomplished, and legible reproductions (color optional) of required labels and hazard warnings.

21 CFR 1040.10(j), Modification of a certified product:

- (i) The modification of a laser product, previously certified under 1010.2, by any person engaged in the business of manufacturing, assembling, or modifying laser products shall be construed as manufacturing under the act if the modification affects any aspect of the product's performance or intended function(s) for which this section and 1040.11 have an applicable requirement. The manufacturer who performs such modification shall recertify and re-identify the product in accordance with the provisions of 1010.2. and 1010.3.

8. CONCLUSIONS

Laser class analysis based upon the ANSI Z136.1-2000, 21 CFR 1040.10, and information provided by LUMETRICS™ of the LUMETRICS™ OptiGauge Optical Measurement Probe Super LED leads to the following conclusions:

Laser Class		
SLED Source	f = 25 mm	f = 50 mm
10 mW	Class I	Class I
15 mW	Class I	Class I
20 mW	Class IIIa	Class IIIa
25 mW	Class IIIa	Class IIIa

Appropriate labeling of the laser device per the criteria in Section 6 of this report is required if the product is intended to be sold to other companies to be used in their manufacturing process, used inside another manufacturer's external housing, the general public, or to the military.

- Class I (ANSI Z136.1-2000, para. 3.3.1.1)
 - Manufacturer's Identification label
 - Certification label
 - Classification label (recommended but not required)
 - Exemption label (military contracts only)
- Class IIIa
 - Manufacturer's Identification label
 - Certification label
 - Logotype label
 - Aperture label
 - Exemption label (military contracts only)

DANGER

NEVER

LOOK DIRECTLY INTO

A LASER BEAM

In addition, to maximize eye safety during the Class IIIa device's operation, LUMETRICS™ should ensure that users are instructed to keep the probe tip aimed away from their faces and at least **48 cm (19 inches)** away from their unprotected eyes.

Failure to observe this protocol could result in ocular damage due to intentional long-term (> 0.25 seconds) direct viewing. – ANSI Z136.1-2000, para. 4.6.2.1.

Additionally, the Class IIIa lasers should not be kept at eye-level for an operator in a standing or sitting position due to the potential for ocular damage from the invisible laser beam over intentional long-term use.

Users should wear Optical Density glasses designed to prevent penetration of the Class 3a probe's invisible light output into their eyes and onto their retinas when within the 48 cm (19 inch) NOHD. An **OD 1.0 at 1310 nm** is a suitably conservative prescription for viewing within the NOHD. Reference ANSI Z136.1-2000, Section 4.6.2.4 for guidance on selecting the appropriate OD eyewear suitable to the tasks being performed.

It would be advisable for LUMETRICS™ to send a designated primary and back-up for official Laser Safety Officer (LSO) training in order to establish the proper labeling and controls of the hazards associated with their laser manufacturing facility and for the protection of manufacturing personnel and visitors to the facility or laboratory as well as to calculate all future Laser Hazard Analyses. – ANSI Z136.1-2000, para. 5. and subs.

The LED devices listed in this report have not had their classifications validated through physical measurement. To determine the actual laser classification beyond any reasonable doubt, a suitable measurement facility should be consulted to perform an assessment of the commercial LED sources that LUMETRICS™ is using in the OptiGauge Optical Measurement Probe Super LED. Should one LED be substituted for another and the part numbers and/or vendors differ, a new analysis would be required to accurately characterize the retinal hazard range due to the potential variation in the LEDs.

If any input parameters have changed from the original input parameters that were provided by LUMETRICS™ (those parameters that are listed in this report), this analysis is no longer valid and a new analysis will need to be performed.

9. BIBLIOGRAPHY

American National Standard for Safe Use of Lasers, ANSI Z136.1-2000, Laser Institute of America, 2000.

Code of Federal Regulations, 21 CFR 1010: Performance Standards for Electronic Products: General: April 1, 2006:

- 1010.2 - Certification
- 1010.3 - Identification.
- 1010.4 - Variances.
- 1010.5 - Exemptions for products intended for United States Government use.

Code of Federal Regulations, 21 CFR 1040.10: Performance Standards for Light-Emitting Products, Laser Products, April 1, 2006.

Hall, S. et al.: *Investigation of a measurement technique to determine the apparent source size for light emitting diodes.* Research Report 345, National Physical Laboratory and Europtics, Ltd. Middlesex, United Kingdom: HSE Books, 2005.