SLOVENSKI STANDARD
oSIST prEN IEC 62471-6:2021

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Fotobiološka varnost ultravijoličnih sijalk

Photobiological Safety of Ultraviolet Lamp Products

Sécurité photobiologique des appareils à lampes ultraviolettes

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Photobiological Safety of Ultraviolet Lamp Products

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NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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PHOTOBIOLOGICAL SAFETY OF LAMPS AND LAMP SYSTEMS –

Part 6: Ultraviolet lamp products

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This edition includes the following significant technical changes with respect to the previous edition:

a) ...;

b)

50 The text of this International Standard is based on the following documents:

FDIS	Report on voting
XX/XX/FDIS	XX/XX/RVD

51

52 Full information on the voting for its approval can be found in the report on voting indicated in
53 the above table.

54 The language used for the development of this International Standard is English [change
55 language if necessary].

56 This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in
57 accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available
58 at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are
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60 The committee has decided that the contents of this document will remain unchanged until the
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62 specific document. At this date, the document will be

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64 • withdrawn,
65 • replaced by a revised edition, or
66 • amended.

67

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INTRODUCTION

Most lamps and lamp products are safe and do not pose photobiological risks except under unusual exposure conditions; however, one group of products—ultraviolet lamp products—can under some conditions pose optical hazards during use and require risk assessment for direct and indirect exposure of the eyes and skin. Optical radiation hazards from all types of lamps or other broadband light sources are assessed by the application of IEC62471/CIES009 Standard, Edition 1, 2006, *Photobiological Safety of Lamps and Lamp Systems*. IEC 62471 covers LEDs, incandescent, low- and high- pressure gas-discharge, arc and other lamps. It also covers lamps which are designed primarily to emit ultraviolet radiant energy, such as ultraviolet sources intended to excite fluorescence of irradiated materials, for insect light traps, for scientific studies, mineral identification, for non-destructive testing, germicidal irradiation, and other purposes. This vertical standard (IEC 62471-6) provides a risk group (RG) classification system for all ultraviolet lamp products, and the assessment distances and measurement conditions for different products. It includes manufacturing and user safety requirements that may be required as a result of an ultraviolet lamp product being assigned to a particular risk group. The scope is limited to products where the sole intent is to emit ultraviolet radiant energy. The advantage of applying this standard, intended solely for ultraviolet lamp products, instead of the horizontal IEC 62471 standard, is that the risks from visible and infrared optical radiation need not be assessed using this document, as they are assumed to be insignificant for a lamp that emits mainly UV. The assigned risk group of an ultraviolet lamp product using this standard also may be used to assist with any needed risk assessments, e.g. for occupational exposure in workplaces. National requirements may exist for the assessment of products or occupational exposure or for the exclusion of certain RGs for use by the general public.

PHOTOBIOLOGICAL SAFETY OF LAMPS AND LAMP SYSTEMS –

Part 6: Ultraviolet lamp products

1 Scope

This Standard provides the optical radiation safety requirements for ultraviolet lamp products, including UV LED products.

This standard provides requirements for:

- optical radiation safety assessment and ultraviolet-product risk groups;
- user information for safety measures;
- appropriate labelling of ultraviolet lamp products

This standard addresses those lamps and lamp products where the ultraviolet emission serves the primary purpose of the product and where more than half of the optical radiation emitted between 180 nm – 3 000 nm is in the spectral region 180 nm – 400 nm. If more than half of the optical radiation emitted between 180 nm – 3 000 nm is outside of the spectral region 180 nm – 400 nm, then the base standard IEC 62471-1 should be used. This standard covers medical diagnostic devices/products that emit primarily UV radiation.

Because photobiological effects from UV radiation are based on the total accumulated exposure (dose) received, this standard relies on the concept of 'Time-weighted Average' exposures where the assessment distance for determining the RG is chosen based on realistic exposure distances and exposure durations. In other words, it is not expected that people will be exposed at very close distances, e.g. 20 – 30 cm, for extended periods of time. This standard is needed to provide assessment distances and specific guidance that are application-specific and realistic rather than the more general values in IEC 62471 where the specific application is unknown and time-weighted average exposures are not application-specific.

This Standard does not provide requirements for:

- lamps which primarily emit visible and/or infrared radiant energy
- lamp products used for general lighting or infrared illumination or heating, which are treated in separate standards.
- fluorescent ultraviolet lamps for tanning (covered by IEC 60335-2-27 and IEC 61228).
- medical treatment devices/products (see IEC 60601-2-57), but covers UV medical diagnostic products.

2 References

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 62471/CIE S009, *Photobiological safety of lamps and lamp systems*

3 Terms and Definitions

To be completed by the project group as needed

3.1
actinic UV
capable of producing a photochemical effect. In the context of this standard, the biological effects have a demonstrated action spectrum, S(λ), and refer most significantly to UV-B and UV-C effects, e.g, UV erythema (skin reddening), UV photokeratitis ('welder's flash' or 'snowblindness'), etc. See Annex B

3.2
assessment distance
distance used to determine the Risk Group Classification of a lamp or lamp product

3.3
blue light hazard
potential for a photochemically induced retinal injury resulting from radiation exposure at wavelengths primarily between 400 nm and 500 nm.

Note 1 to entry: This damage mechanism normally dominates over thermal mechanisms for intense visible light for viewing times exceeding 10 s, but is rarely of concern from UV lamps (unless the basic lamp is an arc lamp).

3.4
competent person
a person who can demonstrate a combination of knowledge and skills to effectively, efficiently, and safely carry out specific activities

3.5
consumer
a person who purchases goods and services for personal use (also termed “ordinary person” in IEC62368). Consumers include not only users of the ultraviolet lamp product, but also all persons who may have access to the lamp product or who may be in the vicinity of the product

3.6
controlled access location
location where an engineering and/or administrative control measure is established to restrict access except to authorised personnel with appropriate safety training

3.7
dose-limited product
a product where the emitted radiant exposure (dose) is limited by time or actual exposure monitoring at the assessment distance to a set level during any day. The emission limit is expressed in J/m^2

3.7.1
emission Limit
a limit defined for each Risk Group, based upon reasonably foreseeable conditions of time-weighted average (TWA) exposure

Note 1 to entry: It incorporates both the concept of exposure duration and exposure distance and is derived from exposure limits, however, the risk group assessment distance incorporates the TWA exposure.

3.8
general lighting source (GLS)
a general term for lamps, nominally of “white” colour, intended for lighting spaces that are typically occupied or viewed by people. See IEC 62471-1/2 (to be updated) for requirements

Note 1 to entry: This standard does *not* cover GLS lamps or lamp products.

3.9
germicidal lamp product
any UV lamp product designed to disinfect by ultraviolet germicidal (UVG) irradiation to inactivate microorganisms so they are no longer capable of replicating and causing adverse health effects

3.10
instructed person
a person who has been instructed and trained by a competent person, or who is supervised by a competent person, to identify ultraviolet sources that may cause pain and to take precautions to avoid unintentional exposure to those sources. [adapted from IEC62368:2018]

3.11
intended use
usage of a product, process or service in accordance with specifications, instructions and information provided by the manufacturer or supplier

3.12
Lamp, UV
electrically powered device emitting optical radiation in the wavelength range between 180 nm and 3000 nm, with the exception of direct, non-diffuse laser radiation

3.13
lamp product, UV
electrically operated product incorporating a lamp or lamps, including fixtures, possible filters or optical elements and incorporated electrical or electronic components, generally as intended by the manufacturer. May include diffusers, enclosures and/or emission-modifying optics

3.14
luminaire, UV
apparatus which distributes, filters or transforms the ultraviolet radiant energy transmitted from at least one source of optical radiation and which includes, except the sources themselves, all the parts necessary for fixing and protecting the sources and, where necessary, circuit auxiliaries together with the means for connecting them to the power supply [modified CIE Definition of luminaire from eILV]

3.15
photocuring lamp product
a lamp product that usually employs UV-A to photopolymerize liquid polymers to a solid state

Note 1 to entry: Examples include photopolymerization of liquid inks in printing or rapid curing of plastic products.

3.16
time-weighted average (TWA) exposure
averaged cumulative exposure dose over a given period (normally daily period) divided by the exposure duration to provide an effective irradiance for both variable distances and durations

Note 1 to entry: The TWA is essential in considering lengthy exposures to ultraviolet hazards, since variable exposure distances at different irradiances and durations determine the reasonably foreseeable worst-case exposures (for photochemical hazards) which correspond therefore to the measured/ calculated irradiance at a specified distance for RG determination (analogous to the 500-lx assessment distance for GLS lamps).

3.17
ultraviolet radiation
for practical purposes, any radiation within the wavelength range from 100 nm to 400 nm. The UV-C extends from 100 nm to 280 nm, UV-B from 280 nm to 315 nm, and UV-A from 315 nm to 400 nm as defined by the Commission Internationale de l'Eclairage (CIE)

Note 1 to entry: Ultraviolet radiation at wavelengths less than 180 nm is considered vacuum ultraviolet radiation for the purpose of this standard and is not included in the scope.

3.18
ultraviolet-fluorescence illuminator
any UV-A lamp designed to illuminate and excite fluorescent materials to permit increased visualization of the material

Note 1 to entry: Examples include "black-light" fluorescent illuminators, security-code reading UV-A lamps used for counterfeit money detection, medical applications, etc.

3.19
view-related risk
risk for intended viewers of a source under application-specific realistic conditions, exceeding 1000s in one day

4 Risk Groups Applied for Ultraviolet Lamp-Product Safety Assessments

4.1 Basis for Optical Radiation Safety Risk Group Determination

IEC 62471/CIES009 provides the fundamental method to determine the risk group of any individual lamp and also the default measurement condition to determine the risk group of any lamp or any product incorporating a lamp, unless a vertical (application-specific) standard exists that includes measurement conditions for its specific application. The risk groups in IEC 62471 indicate the degree of risk from potential optical radiation hazards and minimize the need for further measurements. The risk groups were developed based upon decades of lamp use experience and the analysis of accidental injuries related to optical radiation emission (where injuries were, generally, quite rare except from ultraviolet-emitting lamps or arc lamps). The risk groups are also used in determining appropriate measures for risk management. There are four basic risk groups:

- Exempt Group (abbreviation – RG 0) where no optical hazard is considered reasonably foreseeable, even for continuous, unrestricted use. Typical examples are small UV-A LEDs and UV-A fluorescent lamps used to excite fluorescence or domestic insect light traps;
- Risk Group 1 (RG 1) products are safe for most use applications, except for very prolonged exposures where direct ocular exposures may be expected. An example of a Risk Group 1 lamp product are some battery-operated UV-A torches (flashlights) or large, industrial insect light traps;
- Risk Group 2 (RG 2) products generally do not pose a realistic optical hazard because of either discomfort glare from lens fluorescence or where lengthy exposures are unrealistic; examples include some UV-C germicidal fixtures;
- Risk Group 3 (RG 3) products pose a potential hazard even for very brief exposures at close distance, and product safety requirements are generally essential; examples include sunlamp products (IEC 660335-2-27), Vitamin-D lamp products and unenclosed UV-C germicidal lamp products.

IEC 62471 (IEC 62471-1 when amended) does not provide guidance on manufacturing requirements and control measures. These issues are addressed in application-specific vertical standards such as this standard. Labeling requirements and user information for each UV-lamp-product Risk Group are provided in this standard (see para. 7.2).

Requirements for user information are provided in this standard (see 7.1).

4.2 Assessment Criteria (Background) for UV Lamp Products

The standard measurement conditions consider the emission spectrum and, for ultraviolet radiation, the irradiance to determine risk to the eye and/or the skin. The measurement conditions are intended to optimize the signal of trace amounts of UV-B and UV-C radiation that are emitted from lamp products intended to emit largely in the UV-A spectral region. The risk-group assessment distance is related to potentially hazardous exposure conditions and time-weighted-average (TWA) effective assessment distances based upon reasonably foreseeable worst-case exposure durations. This is built into the emission limits. The concept of a hazard distance normally does not apply to photochemical hazards, since UV hazardous doses accumulate, and the daily exposure determines the potential hazard. For time-varying sources, the accumulated exposure (dose) determining the TWA exposure will be the same as a continuous (CW) exposure for the same total duration. Optical sources are rarely at a fixed distance from the eyes, nor does an individual stare at a UV source for 8 hours a day, or more. The UV (actinic) S(λ) corneal/skin limit applies to chronic exposure, where daily skin exposure will be higher than ocular exposure in almost all applications. The risk-group assessment distances therefore vary for each application and are listed in Table 2a – 2c for various types of lamp products.