Germicidal UV-C Irradiation

SOURCES, PRODUCTS AND APPLICATIONS

September 2020

FOREWORD

About the Global Lighting Association

The Global Lighting Association (GLA) is the voice of the lighting industry on a global basis. GLA shares information on political, scientific, business, social and environmental issues relevant to the lighting industry and advocates the position of the global lighting industry to relevant stakeholders in the international sphere. For more information see www.globallightingassociation.org.

About this document

This is the second in a series of GLA publications on UV-C germicidal irradiation.

The first - *Position Statement on Germicidal UV-C Irradiation: UV-C Safety Guidelines* [1] – is a response to gaps in existing technical safety standards for UV-C devices. It was published in May 2020 as an interim measure pending production of safety standards by standards development organisations such as the International Electrotechnical Commission and Underwriters Laboratory.

This second document considers the disinfection properties of UV-C irradiation, provides a brief overview of safety issues in the abovementioned UV-C Safety Guidelines and discusses UV-C disinfection sources, products and applications, leading to the conclusion: *UV-C can inactivate malignant microorganisms and viruses safely by applying appropriate safety measures.* In this context it should be noted that initial research results demonstrate that UV-C also effectively neutralises SARS-CoV-2.

This publication will be updated as new information comes to hand and may be accessed in the Library section of GLA's website – www.globallightingassociation.org.

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1 WHAT IS UV-C?

Ultraviolet radiation is a range of electromagnetic radiation with a wavelength immediately below the light visible by the human eye and immediately above that of X-rays. The term 'ultraviolet' means 'beyond violet' (from the Latin ultra, 'beyond'), since violet is the colour with the highest frequency in the spectrum visible by humans (therefore, with the shortest wavelength). Ultraviolet radiation makes up around 10% of the light emitted by the Sun; it is also produced by artificial sources.

UV-C is commonly associated with radiation within the 100-280 nm wavelength range. Below a wavelength of 200 nm (commonly referred to as vacuum UV), UV-C is strongly absorbed by atmospheric oxygen and ozone. Lamps and/or systems designed to provide UV-C radiation above 200 nm are utilized for surface, air and water disinfection.

2 DISINFECTION PROPERTIES OF UV-C

2.1 Germicidal UV-C irradiation (also known as UV-C disinfection lighting)

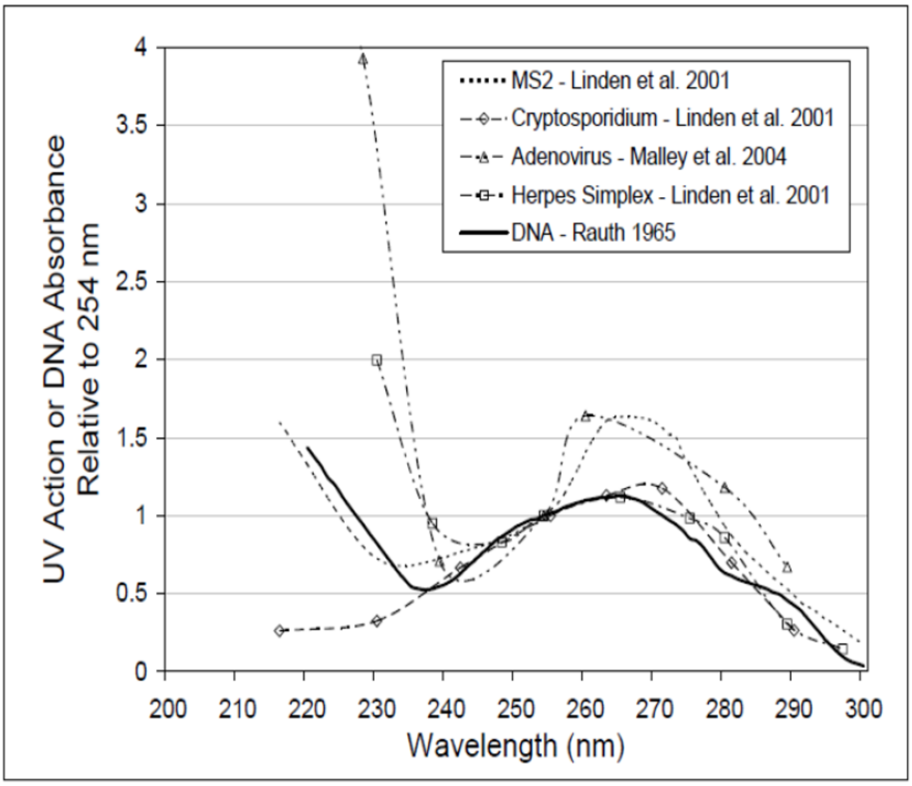
UV-C treatment is an established technology for disinfection and has been applied extensively since 1910 when it was discovered that it can neutralize microorganisms such as bacteria, moulds and yeasts, as well as – and very importantly – viruses.

The effectiveness of UV-C radiation as a disinfectant is determined by:

- action spectrum of the microorganisms and/or viruses
- wavelength of the UV-C radiation (common unit: nm)
- UV-C dose, or fluence, (UV-C energy/unit area, common units: J/m^2 or mJ/cm^2) which is the product of:
    - UV-C irradiance, which is the UV-C power/unit area (common units: W/m^2 or $\mu W/cm^2$); and
    - amount of time the microorganism or virus is exposed to the radiation (common unit: s).
- application characteristics such as:
    - distance of UV-C source to the surface (in the case of surface-disinfection)
    - material surface characteristics (in the case of surface disinfection)
    - air-circulation (in the case of air-disinfection)
    - incident beam-angle of the UV-C source
    - ambient temperature and humidity
    - reflection of ceilings, wall, furniture, etc.

A common graphical method for describing the effects of wavelength as a disinfectant is the germicidal action spectrum. The germicidal action spectrum is standardized in CIE 155 [2] and consists of interpolated values between measured germicidal effectiveness datapoints within the interval 235 nm to 313 nm. The CIE 155 germicidal action spectrum is currently applied in industry for germicidal disinfection purposes. In general, however, the germicidal action spectrum is subject to ongoing research since new developments, such as UV-C-LEDs and Excimer lamps, provide radiation with wavelengths below 235 nm.

Examples of action spectra are given in Figure 1.



Source: Adapted from Rauth (1965), Linden et al. (2001), and Malley et al. (2004)

Fig 1: Action spectra of various microorganisms and viruses as a function of irradiation wavelength

2.2 Disinfection properties of UV-C and COVID-19 virus

The COVID-19 infection is caused by a new coronavirus, named SARS-CoV-2. Coronaviruses (CoVs) comprise four groups of enveloped, single-stranded RNA viruses coated in a lipid bilayer, studded with proteins that protrude like spikes of a crown (hence the name corona). Coronaviruses are a common cause of respiratory infections, including 20% of cases of the common cold. Other coronaviruses include SARS-CoV (2002–04 outbreak) and MERS-CoV (2012–13 outbreak).

SARS-CoV-2 is closely related to SARS-CoV, and thus estimates of UV-C effectiveness against SARS-CoV-2 may be made from SARS-CoV studies[1]. Recent studies performed at Boston University[2] show that with an appropriate UV-C dose, the SARS-CoV-2 virus can be completely inactivated. In a matter

[1] The US Centers for Disease Control and Prevention has identified a fluence of 0.5–1.8 J/cm^2 to effectively inactivate 99.9% of all tested viruses, including influenza A (H1N1), avian influenza A virus (H5N1), low pathogenic influenza A (H7N9), MERS-CoV, SARS-CoV and many others.

[2] Rapid and complete inactivation of SARS-CoV-2 by ultraviolet-C irradiation, Research Square

of seconds, researchers could no longer detect any virus[3]. In addition, studies performed by Bianco et al in Italy confirm that UV-C light is effective at inactivation and inhibition of the SARS-CoV-2 virus[4].

2.3 UV-A and other disinfection sources

The health impacts related to the COVID-19 pandemic may include bacterial, fungal and other infections that are cumulative because of the affected person's compromised immune system and proximity of patients to other infected patients. Depending on occupancy patterns and needs of the space requiring decontamination, it may be appropriate to address this with episodic UV-C disinfection when unoccupied, with continuous disinfection using UV-A [3, 4] or 405 nm visible light [5], [6] while occupied, with spot chemical disinfection, or with a combination of these treatments. In each of these cases, care must be taken to differentiate clinically proven solutions from similar sounding but ineffective products such as black lights and bug lights, as well as unproven chemicals. Note that the efficacy, safety and operational impacts of each lighting solution must be identified and addressed by qualified persons.

3 POTENTIAL UV-C HAZARDS AND SAFETY MEASURES

UV-C devices produce a monochromatic or broadband UV-C irradiance in the 100 nm to 280 nm wavelength range. For effective disinfection purposes, the UV-C irradiance energy of these UV-C devices is much higher than normal sunlight. These high UV-C irradiance energies can present hazards to exposed humans, animals and materials. However proper safety measures can mitigate such effects.

The hazards are twofold - irradiance and ozone (O_3), where:

- The irradiance hazard can damage the human eye and cause a severe sunburn-like reaction to the human skin. The irradiance hazard can also damage materials.
- The ozone (O_3) hazard occurs at wavelengths below 240 nm and can cause a toxic reaction in the human body.

Suitable safety measures vary depending on the UV-C source and application. They may include:

- shielding to prevent direct exposure to people, pets and delicate materials
- fully containing the source in a chamber or enclosure
- access control or presence sensing to prevent operation of the source when a space is occupied
- interlock to prevent operation of the source when its enclosure is opened
- timer or other control to limit operating time per 8-hour period corresponding to maximum irradiance guidelines
- personal protective equipment such as goggles, gloves, mask, shield or dosimeter
- warning labels, installation instructions, operating manual and training.

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[3] Based on the data, it was determined that a dose of 22mJ/cm^2 will result in a 99.9999% (6-log) reduction in 25 seconds.

[4] UV-C doses of just 3.7 mJ/cm^2 were sufficient to achieve a 99.9% (3-log) inactivation, and complete inhibition of all viral concentrations was observed with 16.9 mJ/cm^2.

As with any human-machine interaction, UV-C disinfection sources and products and their application environments must be used correctly to be safe. For more information see the Global Lighting Association's *Position Statement on Germicidal UV-C Irradiation: UV-C Safety Guidelines* [1].

4 UV-C DISINFECTION LIGHT SOURCES

The light source is the core of any UV-C disinfection device. The light source determines the mechanism and effectiveness of microorganism inactivation. UV-C sources include mercury lamps, pulsed xenon lamps, excimer lamps, UV-C LEDs and UV-C lasers. Common light sources are described below and summarised in Appendix A.

4.1 Low pressure mercury lamps

Because of their high efficiency, low cost and technical maturity, low-pressure mercury lamps (LPMs) are widely adopted UV-C sources employed in disinfection and sterilization. LPMs are filled with a rare gas, typically argon at 2-5 Torr (250-700 Pa) pressure, with a few mTorr (0.5-5 Pa) of mercury vapour. At room temperature, mercury has the highest vapour pressure of any of the elements suitable for producing UV-C radiation. The typical spectrum of LPMs consists of two mercury resonance lines in UV, among which the 254 nm radiant efficiency can reach more than 50% for normal power products, while around 30% for high loaded lamps above 300 W. Another strong resonance line at 185 nm, the efficiency of which occurs around one-fifth of 254 nm, can also be applied for disinfection but may cause ozone production due to its high photon energy. Hence there are two types of UV-C LPMs: 254 nm UV-C lamps and 185 nm UV-C lamps which emit both lines. The outline and the geometry of germicidal UV-C LPMs is similar to that of fluorescent lamps commonly used in general lighting.

4.2 Medium-pressure and high-pressure mercury lamps

Medium-pressure and high-pressure mercury lamps, which can emit a continuous spectral base overlapped with many atomic lines of mercury and argon, are generally used in photochemical reactions. The 185 and 254 nm mercury resonance lines are mostly absorbed in the discharge so that the radiative excited transitions occur between higher energy levels. This results in strong lines such as 313, 365, 405, 436, 546 and 578 nm. Because of the high-power density of 0.5-20 kW applied to the 0.2-2 m electrodes gap, the 250-280 nm UV-C radiation in medium-pressure mercury lamps (MPMs) is strong enough for germicidal action. However, their high heat may require additional cooling systems, which increases equipment cost and security risk. For these reasons MPMs have mainly been utilized in large flow water sterilization systems.

4.3 Pulsed-driven xenon lamps

Pulsed-driven xenon lamps, commonly called intensive pulsed light (IPL), are high intensity discharge sources whose transient power can reach more than 50 kW, leading to very high intensity in a single pulse. The full spectrum of xenon lamps covers ultraviolet to near infrared light. Such light has a strong continuous base with atomic lines around 275 nm, which can be applied for germicidal use. IPL has proven effective for disinfection of air, surfaces and food [7-10]. It is believed that both the photothermic and UV photochemical effects results in microorganism inactivation. Advantages include rapid and effective treatment, no chemical residue and no peculiar odour. However, like

MPMs, high energy consumption and critical heat dissipation requirements limit the application of IPL.

4.4 Excimer lamps

Excimer sources are commonly referred to as excimer lamps, exciplex lamps, or more generally excilamps. They can produce a relatively narrow spectrum of ultraviolet and vacuum ultraviolet radiation from excimer molecules. Recently, KrCl excilamps that can provide 222 nm narrow-band radiation have gained attention as a consequence of some COVID-19 reports stating that this far-UV-C radiation can efficiently inactivate microorganisms and viruses without harm to exposed mammalian skin and eyes [11-14]. This suggests potential of excilamps in open fixtures for air and surface disinfection.

With filtered 222 nm KrCl excimer lamps, a monochromatic 222 nm irradiance can be used in occupied space within appropriate design parameters and observing published safety guidelines. Studies utilising exposure levels much higher than current safety guidelines have been published recently [15-17]. More research is in progress to further evaluate the human physiological effects from exposure to 222 nm irradiance.

The inactivation effect of 222 nm KrCl excimer lamps against seasonal corona viruses has been confirmed. The inactivation effect against SARS-CoV-2 specifically is currently under investigation.

The design of the excimer lamp will influence the degree to which ozone is a concern.

4.5 UV-LEDs

As solid-state light sources, UV-LEDs show promise in various UV special applications and have been a research focus in recent years. Major breakthroughs have occurred recently with UV-A LED technology at or below 365 nm, leading to mass production. However, because of the limited germicidal properties of UV-A radiation, they are recommended for UV-A/TiO2 photo-catalysis [15-18] rather than solely employed in most disinfection or sterilization applications [19-21]. Deep UV (DUV) LEDs, including UV-B (280-315 nm) LEDs and UV-C (<280 nm) LEDs, are highly effective on microorganism inactivation [22-31], but there are few practical applications due to the low efficiency, low power and high cost. DUV LEDs are expected to gain prominence because of such advantages as high flexibility associated with geometry, size and selectable combined wavelengths [32-36]. Advanced oxidation technology (AOT) based on UV-LEDs have become another research trend for disinfection and sterilization [37-40]. When technology hurdles are overcome, growth may be expected for deep UV LEDs in germicidal applications.

5 UV-C PRODUCTS AND APPLICATIONS

UV-A, UV-B and UV-C irradiance can inactivate microorganisms such as bacteria, bacterial spores, moulds and yeasts. In addition, UV-C irradiance can also inactivate viruses. Each type of organism and virus requires a specific dose for inactivation.

UV-C products are used for air, water and surface disinfection in industrial, commercial, medical, public and residential environments. Understanding UV-C application use and environment is key to applying appropriate safety precautions and personnel training needed to operate and maintain UV-C equipment (see *Position Statement on Germicidal UV-C Irradiation: UV-C Safety Guidelines*).

5.1 Air disinfection

Trapped or recirculated indoor air contains microorganisms and viruses. These contaminants are spread throughout the building and can infect residents and cause illness.

These contaminants and the associated airborne infections can be considerably reduced by applying UV-C germicidal irradiation with open fixtures, partially open fixtures or closed fixtures. Products used for air disinfection are typically found in commercial and public environments.

5.1.1 Open fixtures

Air disinfection with open UV-C fixtures is a simple and effective method but occupants of the location must be protected against hazardous irradiance. In commercial and public environments, this method is therefore mostly used in locations where access of occupants is controlled - a so-called *controlled access location*. In professional environments, occupants must use personal protective equipment (PPE).

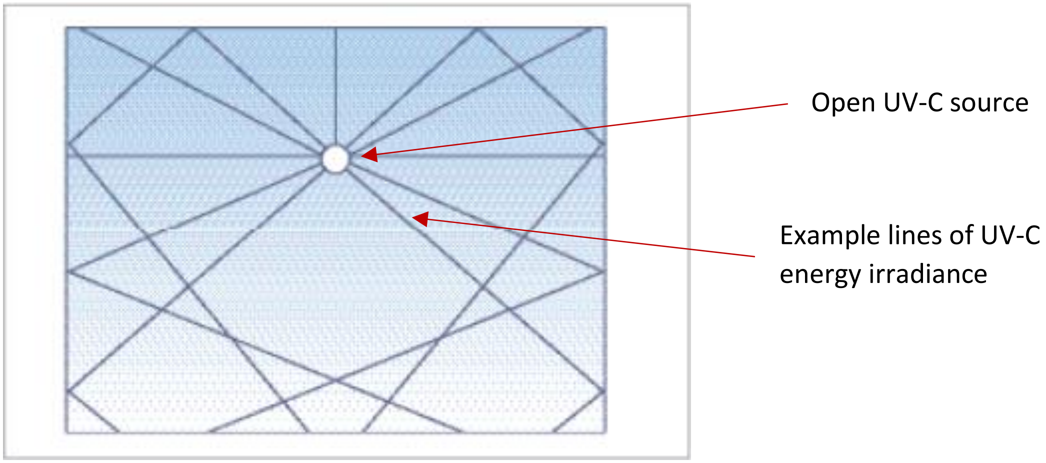

Fig 2. Graphical representation of open UV-C source irradiance in an enclosed, controlled access location

5.1.2 Partially open fixtures

Air disinfection with partially open UV-C fixtures divides the location in an upper area where disinfection occurs and a lower area where occupants can be present without being exposed to hazardous irradiance. A typical example of partially-open fixtures is an upper air device where the UV-C source is directed above a horizontal plane.

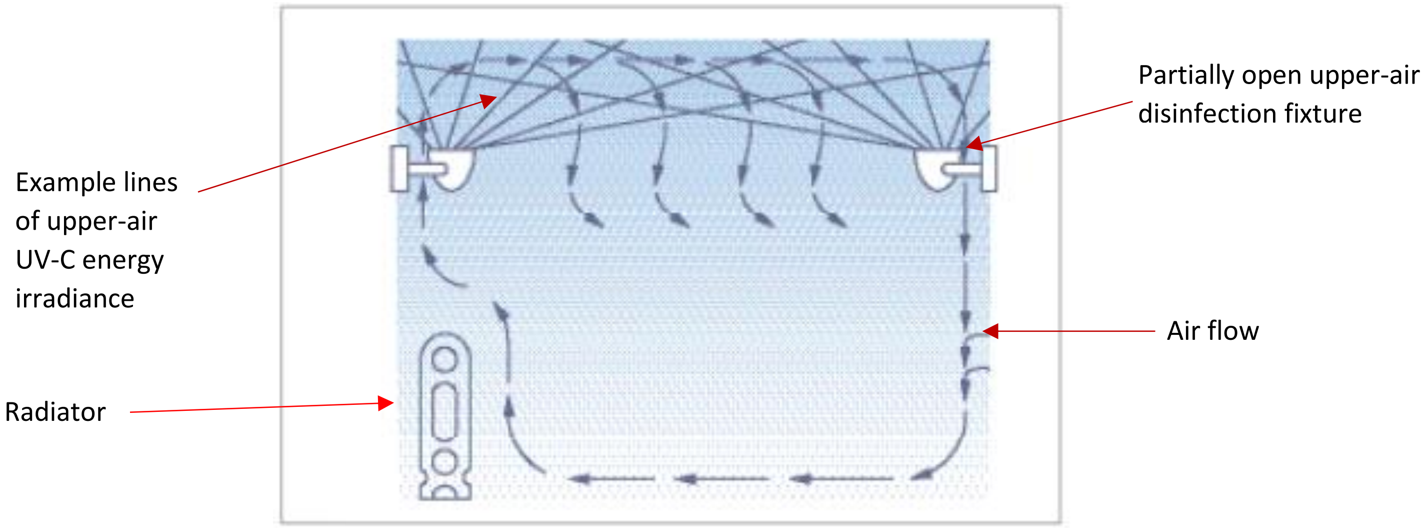

Fig 3. Graphical representation of partially open upper-air disinfection fixture space application

5.1.3 Closed fixtures

Air disinfection with completely closed fixtures has the advantage that occupants are not exposed to hazardous irradiance. Typical examples are closed cabinets and HVAC systems with an integrated UV-C source.

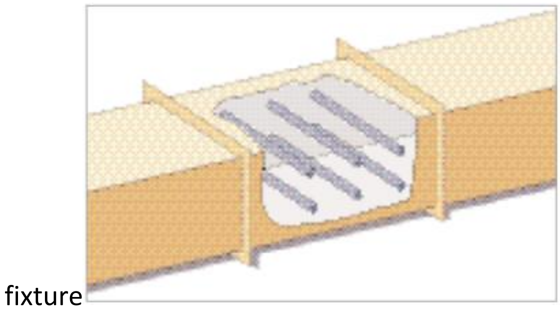

Fig 4. Graphical representation of UV-C sources in a completely closed HVAC system

5.2 Water disinfection

A wide variety of microorganisms in water can cause disease, especially for the very young and elderly, who may have weaker immune systems. UV-C irradiance provides water disinfection without the addition of chemicals that can produce harmful by-products and add unpleasant taste to water. Additional benefits include easy installation, low maintenance and minimal space requirements.

UV-C water disinfection systems are mainly closed systems where direct contact between the UV-C source (lamp) and the water is prevented by a UV-C transparent quartz or polytetrafluoroethylene (PFTE) sleeve.

Typical applications include disinfection of:

- drinking water (including water coolers, dispensers, coffee machines)
- process water
- swimming pools
- fishponds and aquariums

- wastewater

The quality of the water has an important effect on performance of UV-C systems. Common factors that must be considered are iron levels, hardness, total concentration of suspended solids and the UV transmittance. Various organic and inorganic compounds can absorb UV-C, reducing the effectiveness of disinfection.

UV-C water disinfection is mostly found in industrial, public and residential environments.

5.3 Surface disinfection

UV-C surface disinfection applications, like air disinfection applications, can be by applying UV-C germicidal irradiation with open fixtures, partially open fixtures or closed fixtures.

UV-C surface disinfection is only successful if a smooth surface is exposed to direct UV-C irradiance. Microorganisms and viruses in indentations in a rough surface are not likely to be deactivated by indirect UV-C irradiance.

In practice, solid surfaces, granular material and packaging (whether plastic, glass, metal, cardboard, foil etc.) are purified or maintained by means of intensive, direct irradiation.

Rough surfaces, on the other hand, can be better treated with short UV-C wavelengths that produce ozone, since the toxic ozone can penetrate the indentations and tissue of the material and deactivate the microorganisms and viruses. The toxic ozone can only be used in closed cabinets/chambers.

Surface disinfection is used in industrial and public environments. Closed cabinets and chambers may also be used for surface disinfection in residential environments as they are designed with safety interlocks to prevent UV-C exposure.

6 SUMMARY AND CONCLUSIONS

The COVID-19 pandemic has created an urgent need for effective tools to disinfect air, water and surfaces to combat the spread of the SARS-CoV-2 virus. Tools developed to fight the spread of this virus can be used to neutralise viruses and other microorganisms.

UV-C products producing appropriate spectral irradiation can be powerful weapons in combatting microorganisms and viruses that endanger human health. Appropriate UV-C irradiation with sufficient exposure time can produce an effective dose to inactivate viruses and microorganisms. Application specific analysis must be undertaken to ensure the effectiveness of any UV-C product. Additionally, UV-C products can be used in combination with other disinfection tools (UV-A/B, chemicals etc) to produce higher levels of disinfection.

The use of UV-C products requires a high degree of safety diligence. The Global Lighting Association has addressed safety concerns for these products with the publication of its UV-C Safety Guidelines. This was done to provide a roadmap for safety standardization and promote the safe use of UV-C products globally.

Appendix B contains a list of known standards and regulations governing UV-C devices in selected countries and regions. This list is not exhaustive and is intended to provide additional information known at the time of publication. The Global Lighting Association encourages readers to investigate standards and regulations in the country or region of interest.

By their nature, effective UV-C products should generally be specified, installed and operated by trained professionals. The Global Lighting Association does not recommend consumer use without careful consideration and full understanding of safety issues.

It should be noted that regulators are taking a close interest in products claiming to cure or eliminate the SARS-CoV-2 virus. National health regulators have taken action against individuals and companies making such claims where official approval for devices or cures does not exist.[5]

Consumers should be cautioned that disinfection urgency created by the COVID-19 pandemic has seen many UV-C products openly marketed to the public. Many of these products may not provide adequate safeguards from exposure and could be misapplied, particularly in the residential environment. Consumers should be informed of the safety standards, regulations, guidance and precautions when purchasing and using UV-C products.

In conclusion, UV-C can inactivate malignant microorganisms and viruses safely by applying appropriate safety measures. As noted in the Foreword to this document, initial research results demonstrate that UV-C also neutralises the SARS-CoV-2 virus.

The Global Lighting Association's publications on these devices will be updated as new information comes to hand and may be accessed in the Library section of the Association's website – www.globallightingassociation.org.

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APPENDIX A

Typical Performance of Various UV Light Sources

UV light sources	Spectrum	Light source radiant efficiency			Fixture efficiency	Power efficiency	Fixture efficacy			Lamp power
		UV-C	UV-B	UV-A			UV-C	UV-B	UV-A	(W)
LPM	Lines, 254 nm strongest	55.30%	2.80%	1.90%	0.6	0.8	29.90%	1.50%	1.00%	4-800
HPM	Lines with continuous, 365 nm strongest	3.40%	3.20%	5.20%	0.6	0.7	1.70%	1.60%	2.70%	500-20000
PL Xe lamp	Continuous	0.50%	0.50%	1.50%	0.6	0.7	0.20%	0.30%	0.70%	10~50000
KrCl Excilamp	222 nm narrow band, FWHM 2~3 nm	4~10%	-	-	0.6	0.7	1.6~4%	-	-	20~1000
UV-A LED	Band, FWHM ~10 nm	-	-	30~40%	0.9	0.9	-	-	24%~32%	1-36 (chip)
DUV LED	Band, FWHM ~10 nm	<3%	<3%	-	0.9	0.9	<2.4%	<2.4%	-	0.1~3 (chip)

APPENDIX B

Standards and Regulations Governing UV-C Devices in Selected Countries and Regions

The following is not an exhaustive list and is intended as a guide only. Readers should undertake their own investigations to determine a comprehensive list of relevant standards and agencies.

Australia

Standards

AS/NZS 3100

AS/NZS 60335

AS/NZS 2500

Regulatory agency/agencies

Therapeutic Goods Administration

State and Territory electrical safety regulators

Brazil

Standards

ABNT NBR 60335 Segurança de aparelhos eletrodomésticos e similares

ABNT NBR 16248 Proteção ocular pessoal — Filtros para radiação ultravioleta — Requisitos de transmitância e recomendações de uso

ABNT NBR 16695 Vestuário – fator de Proteção ultravioleta – Requisitos e métodos de ensaio

IEC and CIE standards apply when ABNT standards are not available.

Regulatory agency/agencies

Products related to people's health must follow National Health Surveillance Agency rules.

China

Standards

GB/T 32092-2015

GB/T 19258-2012

Regulatory agency/agencies

National Health Commission

European Union

Standards

EN 62471:2008 Photobiological safety of lamps and lamp systems

EN 60598-1:2015/A1:2018 Luminaires - Part 1: General requirements and tests (EN 60598 series may be used as the basis for risk assessment considering mechanical, electrical and thermal safety)

EN 14255-1:2005 Measurement and assessment of personal exposures to incoherent optical radiation - Part 1: Ultraviolet radiation emitted by artificial sources in the workplace

EN 14255-4:2006 - Measurement and assessment of personal exposures to incoherent optical radiation - Part 4: Terminology and quantities used in UV-, visible and IR-exposure measurements

ISO 12609-2 - Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications - Part 2: Guidance for use

ISO 15858:2016 UV-C Devices — Safety information — Permissible human exposure

Legislation

DIRECTIVE 2006/25/EC (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006L0025&from=EN)

India

Standards

IS 16108 Photobiological Safety of Lamp and Lamp Systems

Japan

Standards

JIS C 7605: 2011 Germicidal lamps

JIS C 9335-2-27: 2020 Household and similar electrical appliance -Safety
Part 2-27: Particular requirements for appliances for skin exposure to optical radiation (equivalent to IEC60335-2-27)

JIS Z 8811: 1968 Measuring Methods of Ultra-Violet Rays for Sterilisation

JIS Z 8812: 1987 Measuring Methods of Eye-hazardous Ultraviolet Radiation

Regulatory agency/agencies

The National Institute for Environmental Studies conducts research into the health effects of ultraviolet rays.

Some manufacturers of UV-C products observe CDC (Centers for Disease Control and Prevention) and WHO guidelines.

New Zealand

Standards

AS/NZS 3100

AS/NZS 60335

AS/NZS 2500

Regulatory agency/agencies

UV-C device safety - Ministry of Business Innovation and Employment - Worksafe NZ

UV-C radiation use for non-medical purposes - No regulator or regulation

Taiwan

Standards

CNS 15592 C4529: Photobiological safety of lamps and lamp systems (equivalent to IEC62471)

CNS 2657 C4063: Low-Voltage Mercury Discharge Tube (for Germ Killing)

Regulatory agency/agencies

No regulatory agency for UV germicide irradiation. Some safety guidelines for germicidal lamps for medical use are the responsibility of Taiwan Center for Disease Control.

United Kingdom

Standards

BS EN 60598EN 62471:2008 Photobiological safety of lamps and lamp systems

EN 60598-1:2015/A1:2018 Luminaires - Part 1: General requirements and tests

EN 14255-1:2005 Measurement and assessment of personal exposures to incoherent optical

radiation - Part 1: Ultraviolet radiation emitted by artificial sources in the workplace

EN 14255-4:2006 - Measurement and assessment of personal exposures to incoherent optical

radiation - Part 4: Terminology and quantities used in UV-, visible and IR-exposure measurements

ISO 12609-2 - Eyewear for protection against intense light sources used on humans and animals for

cosmetic and medical applications - Part 2: Guidance for use

Regulatory agency/agencies

Department for Business, Energy and Industrial Strategy

Office for Product Safety and Standards

United States

Standards

IEC 62471:2006 (https://webstore.iec.ch/publication/7076)

ICNIRP (https://www.icnirp.org/cms/upload/publications/ICNIRPUV2004.pdf)

ACGIH (https://www.acgih.org/forms/store/ProductFormPublic/ultraviolet-radiation-tlv-r-physical-agents-7th-edition-documentation)

IES RP-27

21 CFR 1002.20 - Reporting of Accidental Radiation Occurrences
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1002.20

21 Part 1003 Notification of Defects or Failure to Comply
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1003

21 Part 1004 Repurchase, Repairs, or Replacement of Electronic Products
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1004

Regulatory agency/agencies

Food and Drug Administration

Environmental Protection Agency