



# Assessing the Safety of UV Disinfection Technologies

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The 2020 COVID-19 pandemic has placed unimagined stress on the healthcare industry and on the healthcare professionals who work tirelessly to treat patients and save lives. A critical aspect of delivering effective healthcare is access to adequate supplies of disinfected medical devices and personal protective equipment (PPE). Most conventional methods of disinfection involve the use of chemicals and cleaning agents that are potentially toxic to humans, as well as harmful to the environment. Further, disinfection processes are labor intensive and time-consuming, effectively limiting the amount of space or number of devices that can be quickly disinfected.

Technologies using certain types of ultraviolet (UV) radiation are showing significant promise in the efforts to increase the scale of safe and effective disinfection of essential medical facilities, equipment and supplies, while also contributing to reductions in the number of healthcare associated infections (HAIs). From contained UV disinfection chambers to standalone UV devices and systems installed in operating rooms and patient containment areas, UV disinfection technologies are increasingly providing a safe and environmentally preferred method for achieving and maintaining contaminant-free equipment and supplies.

In this UL white paper, we'll discuss the science behind UV disinfection technologies and the potential benefits in the healthcare industry. We'll also discuss the potential safety risks associated with the use of UV radiation in disinfection processes and the specific aspects of UV technologies subject to testing. Finally, we'll present a case study that showcases how UL is working to help advance the deployment of UV disinfection technologies to address critical healthcare needs.

# What is UV Radiation and How is it Used in the Disinfection Process?

Anyone who has spent time on the beach during the summer season has a basic understanding of the power of UV radiation. UV radiation transmitted from the sun interacts with the skin pigment melanin, which absorbs the radiation and causes the skin to darken as a defense against further damage. The resulting “suntan” may be the goal for many beachgoers, but extended exposure to UV radiation can lead to sunburn and may even prompt the development of certain types of skin cancers. That’s why the application of sunscreen creams and lotions, which effectively block UV radiation, are highly recommended for those spending extended time outdoors.

UV radiation is a form of electromagnetic radiation characterized by wavelengths from 10 to 400 nanometers (nm). As such, it occupies the portion of the electromagnetic spectrum between X-rays and visible light. The sun is a primary source of UV radiation, accounting for about 10% of the sun’s electromagnetic radiation output. But UV radiation can also be produced by various types of specialized lighting systems and devices, including light emitting diodes (LEDs), incandescent and gas discharge lamps, and some types of lasers.

Given the relatively broad portion of the electromagnetic spectrum that it occupies, UV radiation is typically subdivided into one of nine separate categories based on radiation wavelength. The principle categories include: 1) ultraviolet A (UVA), characterized by wavelengths between 315-400 nm; 2) ultraviolet B (UVB), characterized by wavelengths between 280-315 nm; and 3) ultraviolet C (UVC), characterized by wavelengths from 100-280 nm. ISO 21348, Space environment (natural and artificial) – Process for determining solar irradiances, provides further details on each of the UV categories.

The use of UV in healthcare disinfection processes primarily involves systems and devices that generate UVC radiation. UVC radiation generated by the sun is almost completely filtered by the atmosphere’s ozone layer. Exposure to UVC radiation generated by specially designed lighting systems and equipment disrupts the DNA of potentially infectious microorganisms, rendering them incapable of cellular reproduction. Emitted radiation from many types of UVC radiating systems and devices can also be calibrated to target cellular vulnerabilities of specific microorganisms, making it even more effective in disinfection processes.

UVC radiation has been found to provide an effective germicidal solution for the disinfection of operating rooms and other secure environments, as well as critical medical equipment and supplies. According to a recent study conducted by researchers at Columbia University Irving Medical Center and published in 2020, low-dose far-UVC radiation eliminated up to 99.9% of seasonal coronavirus (structurally similar to the current SARS-CoV-2 virus) in a controlled environment.<sup>1</sup> A separate 2019 study found that UVC light-emitting devices were significantly more effective in disinfection procedures in hospitals than standard operating protocols (SOPs).<sup>2</sup>

Equally important, the use of UVC radiation represents a “no contact” approach to disinfection processes that reduces potential infection risks to staff responsible for manual cleaning tasks. UVC-based disinfection also eliminates the use of chemical-based cleaning products that leave residue on cleaned services that can accidentally transfer to healthcare staff and patients.



# Potential Risks Associated with UV Disinfection Technologies



While UV-based technologies used in disinfection practices in healthcare settings offer several clear advantages over manual disinfection methods, they also come with a number of potential risks for healthcare workers and patients alike.

The most critical of these risk stems from the photobiological effects of UV radiation. As noted previously, even limited exposure to UVC radiation can trigger changes at the cellular level, leading to the deterioration or destruction of normal cellular function. In humans, radiation from UVC-based systems used for disinfection can affect the skin as well as the front surface of the eye and the retina. As noted in Annex A of IEC 62471, Photobiological Safety of Lamps and Lamp Systems, specific photobiological effects can include the following reactions:

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

In addition to the potential photobiological effects associated with UV radiation, there are also risks associated with exposure to ozone. Ozone is a common oxidizing agent that is a natural byproduct of the interaction between UV radiation and air. Further, some UVC-based disinfection systems are intentionally designed to produce ozone since it is believed to have a synergistic fungicidal effect on certain organisms when used in conjunction with UV radiation.

But ozone generated in an enclosed space can be hazardous to human health, especially for those suffering from underlying respiratory conditions such as asthma, bronchitis and emphysema. Even for those who are otherwise healthy, breathing in ozone can trigger throat irritation, coughing and airway inflammation, and can damage lung tissue, leading to reduced lung function.

Aside from risks that can directly affect the safety of healthcare workers and patients, prolonged exposure to UV radiation in general can impact the quality and structural integrity of certain components and materials used in the medical equipment and supplies being disinfected. Just as exposure to UV radiation affects the cellular structure and functioning of living organisms, it also can impact the molecular structure of many natural and synthetic polymers, such as rubber, neoprene and polyvinyl chloride (PVC).

Over time, materials and components exposed to UV radiation can become more brittle or less flexible, crack or disintegrate. In the least harmful outcomes, the damaging effect of UV radiation on materials and components can shorten the anticipated useful life of a given piece of equipment, or increase the frequency of equipment maintenance and repair. In worse case scenarios, degraded materials and components can lead to the failure of a medical system or device during use, potentially putting patients and healthcare workers at risk.

# Testing and Labeling of UV Radiation Systems and Equipment Used for Disinfection



In the U.S., the Food and Drug Administration (FDA) is responsible for regulating radiation-emitting electronic products, including UV-based technologies used in disinfection practices in healthcare settings. However, unlike FDA regulations applicable to other radiation emitting devices, the specific requirements for UV radiation disinfection systems and equipment are general in nature. Accordingly, it is up to the manufacturer to demonstrate that their UV-based disinfection product conforms with the essential performance and safety requirements detailed in applicable federal regulations.<sup>3</sup>

## Demonstrating Compliance Using Recognized Consensus Standards

One route to demonstrating conformity with FDA regulations is to test a product in accordance with one or more FDA-recognized consensus standards. The FDA currently recognizes several voluntary standards that are directly applicable to the evaluation of UV radiation disinfection systems and devices. These include:

- IEC/UL 61010-1, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements
- IEC 62471, Photobiological Safety of Lamps and Lamp Systems
- ANSI/IES RP-27.1, Recommended Practice for Photobiological Safety for Lamps and Lamp Systems – General Requirements.

IEC/UL 61010-1 takes a hazard-based approach to the safety assessment of most types of electrical equipment for specified risks. Risks addressed in the standard include electric shock or burn, mechanical hazards, spread of fire, excessive temperature, the effects of fluid and fluid pressure, and the effects of radiation. The scope of the standard applies to the use of laboratory electrical equipment wherever that equipment is intended to be used, so that equipment can be used by both professionals and non professionals.

An informative annex, Annex DVC, is included in UL 61010-1, the North American equivalent to IEC 61010-1, and represents a deviation to the international standard applicable in the United States and Canada. The Annex provides threshold limit values (TLVs) for UV radiation in the spectrum range between 180 and 400 nm, consistent with guidelines issued by the American Conference of Governmental Industrial Hygienists (ACGIH). The inclusion of UV TLVs in the Annex are intended to establish exposure limits for uncontained UV radiation that is not associated with adverse health effects.

IEC 62471 and ANSI/IES RP-27.1 both address issues related to the photobiological safety of lamps and lamp systems, and are also applicable to UV-based technologies used in disinfection processes. Originally published by the Illuminating Engineering Society in 1996 and subsequently adopted as an American National Standard (ANS) by the American National Standards Institute (ANSI), ANSI/IES RP-27.1 covers the evaluation and control of optical radiation in the wavelength range from 200 to 3,000 nm. The standard includes requirements to mitigate overexposure to UV radiation, as well as guidance, advice and standard methods for evaluating potential optical radiation hazards and for informing the user about such risks.

IEC 62471 is a testing and classification standard that lays out a process for assessing the relative photobiological safety of lamps and other non-lamp sources of optical radiation, including UV radiation. First published in 2006, the requirements of IEC 62471 are principally derived from those found in ANSI/IES RP-27.1, but reflect some modifications in the weighting of certain radiation wavelengths and the start/stop points for wavelength ranges for certain hazards. Today, IEC 62471 is recognized internationally as the key standard for addressing photobiological safety issues.

IEC 62471 maps out a three-stage process for assessing the relative photobiological safety of most forms of optical radiation, including UV radiation. The three stages include:

1. **Measuring absolute radiance and irradiance levels**—Radiance measures the amount of actual light collected by the pupil, and evaluates the risk of hazards to the retina of the eye. Irradiance measures the total amount of radiation at an illuminated surface from the entire hemisphere above and evaluates the risk of hazards to the skin and to the front of the eye.
2. **Comparing effective (“weighted”) levels with the exposure limits defined in the standard**—Measured radiance and irradiance levels are then compared to the limits defined in the standard, which correlate with various exposure times. The limits are based on radiation levels presumed not to create adverse health effects, but they are not intended to strictly define the difference between safe and unsafe levels.
3. **Determining a risk group to which a product is assigned based on the level of hazard to the skin and eyes**—IEC 62471 then applies the following categories to determine a product’s overall level of risk:
  - *Exempt*—Lamp/LED does not pose any photobiological hazard
  - *Group 1 (low risk)*—Lamp/LED does not pose a hazard due to normal behavioral limitations on exposure
  - *Group 2 (moderate risk)*—Lamp/LED does not pose a hazard due to the aversion response or thermal discomfort
  - *Group 3 (high risk)*—Lamp/LED may pose a hazard even for momentary or brief exposure.

IEC 62471 does not directly address manufacturing, labeling, or user safety requirements that may be appropriate for radiation-producing products. IEC/TR 62471-2, Photobiological safety of lamps and lamp systems – Part 2: Guidance on manufacturing requirements relating to non-laser optical radiation safety, provides further guidance related to the installation and use of an end product. The standard specifically addresses hazard distancing, product labeling (including notices, cautions and warnings), user information (including instructions on the safe use of the product), and considerations for personnel responsible for product maintenance.

### Using Other Protocols to Assess Photobiological Risks from UV Radiation

An alternative route to demonstrating compliance with the FDA’s photobiological safety requirements applicable to UV-based disinfection systems and devices is to assess the product in accordance with protocols and guidelines developed by relevant professional associations. One such guidance is the “Threshold Limit Values and Biological Exposure Indices” (TLVs and BEIs), published by the previously mentioned ACGIH.

The ACGIH guidance lays out steps to minimizing human exposure in the workplace to a variety of chemical substances and physical agents, including uncontained UV radiation. The ACGIH document recognizes that human interaction with most equipment can vary considerably and is difficult to address with specific requirements. Therefore, it defines guidelines for three separate exposure parameters, that is: 1) radiation exposure time; 2) radiation magnitude; and 3) distance from the radiation source.

Using the framework detailed in the ACGIH guidance, manufacturers of UV-based disinfection systems and devices may be better positioned to test and measure UV exposure based on the unique design characteristics and intended use parameters of their individual products. In some cases, that assessment may necessitate the application of more stringent exposure radiation limits than those presented in IEC 62471, or changes in how the product is used. But demonstrating compliance with the ACGIH TLV and BEI guidance may also provide a higher level of assurance regarding the safety of a given UV disinfection technology.

### When UV-Based Disinfection Systems and Equipment Are Deemed a Medical Device

Finally, it is important to note that, depending on the specific nature of their intended use, UV disinfection systems and devices used in healthcare settings may also be classified by the FDA as a “medical device.” If that is the case, the disinfection system or device would be subject to the FDA’s regulations and review process applicable to products intended for use in medical applications. Requirements applicable under these regulations are in addition to FDA regulations intended to address UV radiation aspects of a given system or device, and are beyond the scope of this paper.

# UL's Approach to the Testing and Listing/Recognition of UV Disinfection Systems

UL has long been recognized as trusted source for the testing and certification of UV-based technologies used in consumer, commercial and healthcare applications. UL UVC safety certification includes testing in accordance with recognized standards and protocols applicable to the product's intended use and use environment, and products that demonstrate compliance are authorized to bear the UL Mark. UL can also conduct performance testing of UV-based technologies, with or without safety certification.

For most UV-based technologies intended for disinfection processes in healthcare environments, UL conducts safety testing and certification in accordance with the requirements IEC/UL 61010-1 and IEC/UL61010-2-040, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials. UL also applies the requirements of IEC 62471 to assess personal injury risks related to UVC exposure (Annex DVC of IEC/UL 61010-1 should be considered, since it directly relates to the ACGIH Guidelines). Depending on the preferred regulatory approval outcomes identified by the manufacturer, we may assess UV-based disinfection systems and devices for compliance with the photobiological safety requirements of ANSI/IEC RP 27.1 in place of those in IEC 62471.

Testing protocols may also be customized to incorporate specific provisions of the ACGIH TLV and BEI guidance in cases where a given product includes unique design features or characteristics for which safety cannot be sufficiently assessed using established standards.

During the COVID-19 pandemic, UL's testing and certification of certain types of UV disinfection systems has been instrumental in helping companies introduce new and innovative UV-based technologies in crucial care areas in hospitals. To cite just one example, UL recently worked with a healthcare technology company in New York to test and certify the company's UVC sterilization system, designed for large-scale mobile UV disinfection of operating rooms, intensive care units (ICUs) and hospital emergency departments. We were able to complete a thorough evaluation of the system for compliance with FDA radiation-related regulations in advance of bringing the system to market, including electrical and UV radiation emissions testing. As a result, the system received UL certification for compliance with the FDA's safety and photobiological requirements.





## Conclusion

UV technologies used for disinfection processes in healthcare settings hold great promise in efforts to stop the spread of highly infectious diseases. But providing for the safety of healthcare workers and patients is of paramount importance, making the safety of UV technologies critical for their widespread deployment and use. UV-based disinfection systems and devices that have been tested and found compliant with the relevant standards and protocols for electrical and photobiological safety are essential tools in making the disinfection processes safer for everyone involved.

**For more information about UL's UV radiation testing and certification services for disinfection technologies, and how UL can assist your company's efforts to bring innovative UV-technologies to market, visit our website at <https://www.UL.com/offerings/ultraviolet-uv-c-light-testing-and-certification>. Or contact us at [medical.inquiry@ul.com](mailto:medical.inquiry@ul.com).**

## Endnotes

1. “Far-UVC light (222 nm) efficiently and safely inactivates airborne human coronaviruses,” published in Scientific Reports and posted to the website of Nature Research, 2020. Web. 3 July 2020. <https://www.nature.com/articles/s41598-020-67211-2>. Also see “Far-UVC Light Safely Kills Airborne Coronavirus,” article posted to the website of Columbia University Irving Medical Center, June 24, 2020. Web. 3 July 2020. <https://www.cuimc.columbia.edu/news/far-uvc-light-safely-kills-airborne-coronaviruses>.
2. “Evaluation of an Ultraviolet C (UVC) Light-Emitting Device for Disinfection of High Touch Surfaces in Hospital Critical Areas,” study published in the International Journal of Environmental Research and Public Health, 16 October 2019. Web. 3 July 2020. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6801766/>.
3. See 21 U.S.C., Title 21, Chapter 9, Subchapter V – “Drugs and Devices,” Part C – “Electronic Product Radiation Control,” Sec. 360kk – “Performance standards for electronic products,” Web. 3 July 2020. <https://www.govinfo.gov/content/pkg/USCODE-2010-title21/html/USCODE-2010-title21-chap9-subchapV-partC-sec360kk.htm>.



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