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Risks of using far-UVC radiation for disinfection in the presence of people

Recommendation of the
German Commission on Radiological Protection

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**Risiken des Einsatzes von Fern-UVC-Strahlung
zur Desinfektion in Anwesenheit von Menschen
Empfehlung der Strahlenschutzkommission**

This translation is for informational purposes only, and is not a substitute for the official recommendation. The original version of the recommendation, published on www.ssk.de, is the only definitive and official version.

Preface

Ultraviolet (UV) radiation is capable of inactivating or eradicating microorganisms and viruses and has therefore been used for decades to disinfect water, room air or solid surfaces. For disinfection purposes, such radiation is currently applied predominantly in the UVC spectral range and at a wavelength of 254 nm, in particular. Since this radiation can cause both acute and long-term damage to the eyes and skin, human exposure must be avoided. For some time, and particularly since the start of the SARS-CoV-2 pandemic, there have been discussions concerning the use of far-UVC radiation (spectral range of 200 nm to 240 nm), mostly at wavelengths around 222 nm, for disinfection in the presence of people. Due to the very low penetration depth of this shortwave far-UVC radiation into human tissue, it is often argued that no health consequences for humans are to be expected. Against this background, the Commission on Radiological Protection (Strahlenschutzkommission, SSK) was asked to comment on the risks of using far-UVC radiation for disinfection in the presence of people while also considering potentially vulnerable groups such as children, the elderly, and people with skin and eye diseases. The Working Group “Risks of using Far-UVC Radiation for Disinfection in the Presence of People” of the “Non-Ionising Radiation” Committee was appointed to compile an opinion with a scientific background. The group comprises the following members:

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1 Introduction

UVC disinfection is a proven method that has been used for many decades to kill or inactivate pathogenic microorganisms and viruses in indoor air, water, and on solid surfaces. Although the respective UVC-action spectra vary depending on the pathogen, they all have a pronounced maximum of 260 nm in common: UVC radiation of this wavelength is most effective at damaging the deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) of microorganisms and viruses, leading to their eradication or inactivation. Mercury vapour lamps with a maximum emission of 254 nm, coming close to the wavelength of 260 nm mentioned above, are mainly used to produce UVC radiation.

However, the UVC disinfection method also poses risks to humans. These risks include, e.g. acute damage to the eyes, such as inflammation of the cornea (photokeratitis) or conjunctiva (photoconjunctivitis), and skin cancer as a serious long-term consequence. To date, every effort has been made to avoid inadvertently exposing humans to UVC radiation from artificial sources. Where human exposure cannot be ruled out in the workplace, the exposure limits (EL) based on the recommendations of the International Commission on Non-Ionizing Radiation Protection (ICNIRP) must be observed. Over the last three decades, these ELs have been identical to those of the American Conference of Governmental Industrial Hygienists (ACGIH). In the workplace, employees are informed of the risks associated with UVC exposure, and various technical, organisational and personal protective measures are taken to prevent excessive exposure. However, in the case of employees belonging to potentially vulnerable groups because they are especially sensitive to UV radiation, compliance with the ELs does not always suffice. Individually adapted protective measures are therefore provided for these employees.

Research into the use of UVC radiation for disinfection at wavelengths below 254 nm has been ongoing for about ten years. Radiation at a wavelength in the partial interval of the UVC spectral range between 200 nm and 240 nm is referred to as far-UVC radiation. To produce UVC radiation in this wavelength range, e.g. krypton chloride (KrCl) excimer lamps with a maximum emission at 222 nm or light-emitting diodes (LEDs) with a peak at around 233 nm are used. In various studies listed in the following chapters, it is assumed that no relevant DNA damage to the skin could occur as only the uppermost layers of dead skin would be affected due to the low penetration depth of far-UVC radiation. Moreover, as postulated in these publications, the increased absorption of far-UVC radiation in the tear film covering the anterior segment of the eyeball would significantly reduce the risk of photokeratitis or photoconjunctivitis. Hence, no acute or long-term health consequences are to be expected in humans. Due to possible conflicts of interest among the authors of numerous relevant studies, however, there is reason for a certain scepticism concerning the conclusions drawn from the studies. Nevertheless, the exposure limits recommended by the ACGIH for protecting the eyes and skin in the far-UVC spectral range have already been modified and increased significantly (see section 3.5.4).

In addition to the disinfecting action of UVC radiation in general, due to its low penetration depth, far-UVC radiation is a topic of discussion with respect to its use in the presence of people – such as in public spaces through unshielded open sources of radiation. Since the start of the SARS-CoV-2 pandemic in particular, this method is promoted as a simple solution for reducing infections from airborne pathogens indoors (Blatchley et al. 2023). However, the potential use of open sources of radiation in the presence of people in public spaces requires fundamentally new safety considerations as to how and with what exposure duration UVC radiation can be used.

According to the advisory mandate of the then Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) dated 10 June 2021, the German Commission on

Radiological Protection (SSK) was asked to draw up an opinion on the “Risks of using Far-UVC Radiation for Disinfection in the Presence of People”. Potentially vulnerable groups, such as children, the elderly, and individuals with skin and eye diseases, were also to be included in these considerations (see section 3.5.5). The recommendation of the SSK presented here represents the response to this advisory mandate.

To assess the risks of using far-UVC radiation for disinfection indoors in the presence of people, the latest scientific data has been compiled and analysed in this recommendation. The UVC radiation of the sun does not occur in the natural environment of humans, as it is completely absorbed in the stratosphere. Since humans have so far been exposed only occasionally and inadvertently to UVC radiation from artificial sources, no epidemiological data is available with respect to the harmful effects of UVC radiation on human eyes and skin. The current level of knowledge is presented with respect to

- the effect of far-UVC radiation on microorganisms and viruses,
- the effect of far-UVC radiation on the skin (in animal studies, studies on human skin models or human skin),
- the effect of far-UVC radiation on the eye (in animal studies, in studies on the human eye),
- the definition of exposure limits in the UVC spectral range and their applicability to potentially vulnerable groups.

Like the sun, the artificial sources addressed in this recommendation, such as mercury vapour lamps, excimer lamps or LEDs, are sources of incoherent optical radiation. Lasers, which predominantly emit coherent optical radiation, are not considered in this recommendation.

2 SSK recommendation

To avoid any potential harm to public health, the SSK recommends that a legal norm be established to regulate the use of far-UVC radiation through unshielded, open sources of radiation for eradicating or inactivating pathogenic microorganisms and viruses **in the presence of people in public spaces**. At the very least, the SSK recommends that the protection of the population be aimed at the level intended by the exposure limits currently recommended by the ICNIRP, as already implemented in existing occupational health and safety regulations. Furthermore, the SSK deems it necessary to protect in particular potentially vulnerable groups from the use of far-UVC radiation.

The SSK states:

In view of the novelty of the use of far-UVC radiation and its potentially harmful photobiological effects, the SSK believes the current data does not suffice to rule out health risks to the population from its use.

- *Important aspects for assessing the risks of far-UVC radiation were hardly covered by the studies currently available.*

Studies published to date on the risks of far-UVC radiation have only addressed short-term exposure; only a few studies have so far investigated chronic exposure. The effect of far-UVC radiation on the eyes has hardly been studied and thus far has mainly been examined in animal models. Only very few studies directly involve the human eye. No epidemiological data is available concerning the effect of far-UVC radiation on the eyes and skin. Likewise, there are no studies into the effect of far-UVC radiation on injured or damaged skin.

- *The majority of the studies analysed reveal ambiguities with respect to the radiometric measurements.*

In the majority of the studies, the validity of the specified radiant exposure (dose) has not been adequately demonstrated. Information on irradiance levels, irradiation duration and methods of radiometric measurement is often missing. In some cases, the information on the employed measuring devices raises the question whether it was even possible to determine the applied radiant exposure correctly. Future studies should adequately describe the nature and method of the radiometric measurements, demonstrate that the measuring devices have been validated and calibrated and, if necessary, apply standardised measurement conditions.

- *Authors express conflicts of interest in many of the studies analysed.*

Conflicts of interest have been declared in many publications. The principle of the filtered KrCl excimer lamps that are currently used predominantly in the field of far-UVC radiation has been patented by the lead author of some studies. Only one manufacturer licenses out such lamps and made them available for several studies, in part also directly sponsoring the studies in question. The SSK is therefore concerned that the conclusions may be subject to relevant bias.

- *There are no studies into potentially vulnerable groups.*

There are basically no studies that include potentially vulnerable population groups. Given the potentially harmful effects of far-UVC radiation, a risk to these groups from uncontrolled exposure in public spaces cannot be ruled out.

- *The studies analysed relate primarily to cellular DNA damage; hardly any consideration was given to other potential targets of far-UVC radiation.*

The low penetration depth of far-UVC radiation in biological tissue is attributable to the high level of absorption by proteins. Some of the inactivating effect, especially with respect to viruses, is attributed to protein damage. Inhibition of enzymes is a known effect of UVC radiation and is therefore used, e.g. in the food industry. The tear film, with its complex composition and diverse tasks, could be adversely affected by enzyme inhibition. Such inhibition and the underlying photochemical mechanism are not thoroughly understood.

- *The harmful effect of far-UVC radiation on the microbiome of the skin and surface of the eye have not been sufficiently studied.*

If people are exposed to far-UVC radiation in public spaces, due to more effective inactivation potential compared to UVA and UVB radiation, it cannot be ruled out that this leads to an inactivation of the microbiome of the exposed skin and eye surface and consequently to “hyperdisinfection” (as results, e.g. from constantly using antimicrobial washes). Such an effect should be investigated more thoroughly, especially with respect to the latest data on the importance of the microbiome in and on humans.

- *As yet, there is no concept for verifying compliance with exposure limits.*

The use of UVC radiation in the presence of humans necessitates compliance with the exposure limits recommended by the ICNIRP and legally specified for workers. When using far-UVC radiation in the presence of people in public spaces, however, exceedance of the ELs cannot be ruled out because the exposure of individuals cannot be adequately controlled in this case. As the total radiant exposure depends on the irradiation duration, prolonged or repeated periods of exposure can cause the ELs to be exceeded. For anyone who is already exposed to UVC radiation in the workplace, in particular,

exposure to far-UVC radiation in public spaces would imply additional UVC exposure (cumulation).

- *Exposure limits do not account for vulnerable groups.*

The ELs recommended by the ICNIRP apply to risks associated with eight hours of exposure to UVC radiation. The ICNIRP stresses that the recommended ELs are aimed at protecting workers and that, with due caution, they could also be applied to the general population. However, they cannot be used to protect overly photosensitive individuals or individuals exposed to photosensitising substances. No precautionary measures can therefore be defined at present for minimising or preventing harmful effects on the health of potentially vulnerable groups of people (such as children and the elderly).

- *Basic principles of radiation protection are not considered.*

The ICNIRP expressly supports the principle that any decision that changes the exposure situation should bring more benefit than harm (ICNIRP 2020). According to current knowledge, however, it cannot be assumed that the use of far-UVC radiation for disinfection in the presence of people would comply with this principle. Technically and economically equivalent alternatives already exist whereby human exposure to UVC is minimised. E.g. there are systems in which the UVC source is contained in a closed unit or the source is shielded to ensure that anyone present is not exposed to UVC radiation (see section 3.2.2).

- *Monitoring of the technical reliability of the devices employed, e.g. filtering, is not regulated.*

Several studies have demonstrated that optical filtering is mandatory when using KrCl excimer lamps, to minimise the proportion of harmful UVB and UVA radiation. The reliability of the lamps and efficiency of the filtering in the long term have not yet been studied, however. In addition, there are hardly any standards or regulations on certification or type approval and on monitoring the technical reliability of far-UVC systems. Consequently, there is a risk of uncontrolled circulation of unfiltered or technically unreliable devices through online retail, especially in the private sector.

The use of far-UVC radiation **in the medical sector**, e.g. for prophylactic disinfection, is justifiable from the radiation protection point of view, as this involves a controlled, temporary exposure of humans, that should take place after previous indication and weighing up of benefits and risks in accordance with the provisions of the Medical Devices Act. When doing so, however, alternative disinfection methods, such as chemical disinfection, should always be considered in a benefit-risk analysis, especially with respect to potentially vulnerable groups. No such analyses are available for far-UVC radiation, however.

3 Scientific background

3.1 UVC radiation and its physical properties

Ultraviolet radiation (UV radiation) entails optical radiation at wavelengths between 100 nm and 400 nm. UV radiation is further divided into UVA radiation (315 nm to 400 nm), UVB radiation (280 nm to 315 nm) and UVC radiation (100 nm to 280 nm) (CIE 2020). Portions of the particularly energy-rich UVC radiation comprise sufficient energy to damage DNA and RNA. For this reason, UVC radiation can also be used for disinfection purposes; it is important to consider, however, that not only microbial but also human DNA can be damaged at these wavelengths.

In the context of this recommendation, “far-UVC radiation” refers to the spectral range of 200 nm to 240 nm. There is no clear definition internationally, however. Whereas UVC radiation at a wavelength of 254 nm is mainly used at present for disinfection purposes, a wavelength of 222 nm is currently preferred in the far-UVC spectral range.

The UVC radiation to which humans are exposed comes exclusively from artificial sources. UVC radiation from the sun is completely absorbed by ozone and oxygen molecules in the stratosphere and does not reach the Earth’s surface.

Although they do not serve illumination purposes, many artificial sources that also emit UVC radiation are referred to as lamps. Even sources of radiation that emit UV radiation only are referred to exclusively as lamps (e.g. KrCl excimer lamp).

3.1.1 Absorption of UVC radiation

Concerning the scope of this advisory mandate, the absorption of UVC radiation in the air in our environment is especially relevant. It is comprised of approx. 78% nitrogen and 21% oxygen. Noble gases (e.g. argon, helium) and carbon dioxide, methane and hydrogen account for less than 1%. Dust particles and water vapour are also found in the air.

The main portion of UVC radiation absorption occurs in the air and is taken up by oxygen and the ozone layer; this process depends heavily on the wavelength, however. Figure 3.1 provides a calculation of the transmission of UV radiation in a layer of air or oxygen that is one metre thick. The figure shows that air for UVC radiation above 190 nm is almost transparent, whereas at shorter wavelengths there is little transparency. The absorption of UVC radiation at shorter wavelengths leads to the emergence of ozone. Based on the advisory mandate, the question of the adverse health effects of ozone that can be produced by UVC radiation is not addressed in this recommendation.

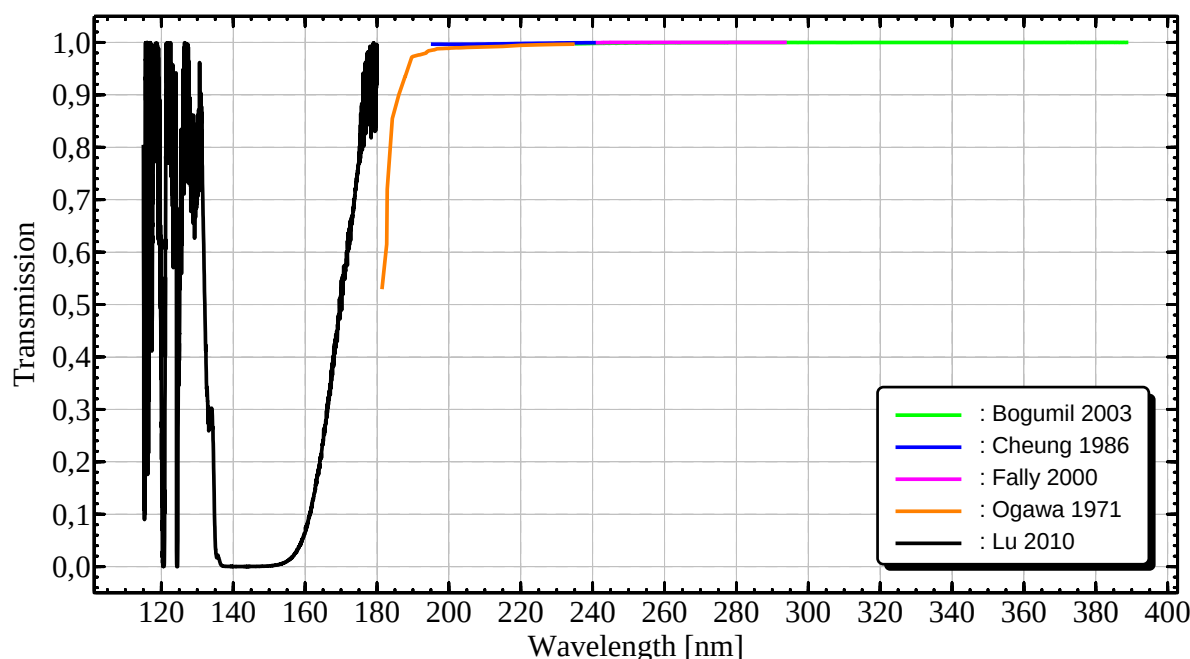


Figure 3.1: Spectral transmission in the UVC spectral range in a one-metre layer of air or oxygen. Transmission was determined using data on absorption cross-sections from Keller-Rudek et al. (2013) according to the literature sources listed in the legend (Bogumil et al. 2003, Cheung et al. 1986, Fally et al. 2000, Ogawa 1971, Lu et al. 2010).

Furthermore, the UVC radiation is also absorbed in water and by organic molecules such as DNA and proteins.

The spectral dependence of the absorption coefficient of purified water with no organic impurities and no oxygen (according to Quickenden and Irvin 1980) is presented in Figure 3.2. As the absorption coefficient changes by two orders of magnitude (1.26 m^{-1} versus 0.01 m^{-1}) between 196 nm and 320 nm, transmission at 196 nm is 28% and thus significantly lower than transmission at 320 nm, which is 99%. However, transmission in purified water of 93% at 222 nm does not differ significantly from the transmission of 97% at 254 nm (absorption coefficients of 0.074 m^{-1} and 0.035 m^{-1} , respectively).

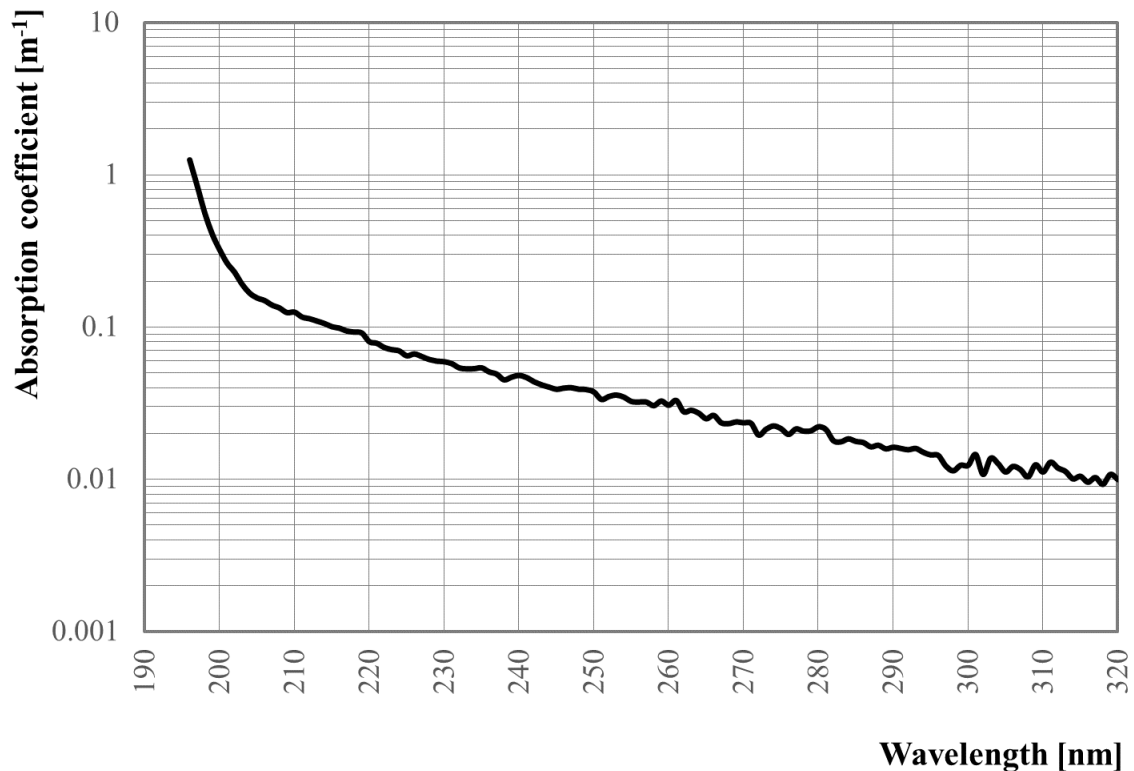


Figure 3.2: Spectral absorption of purified water with no organic impurities and no oxygen (according to Quickenden and Irvin 1980).

The absorption of *Escherichia coli* DNA and the protein trypsin (Voet et al. 1963, Setlow and Doyle 1957), normalised to 254 nm, is shown in Figure 3.3, indicating increased protein absorption of far-UVC radiation.

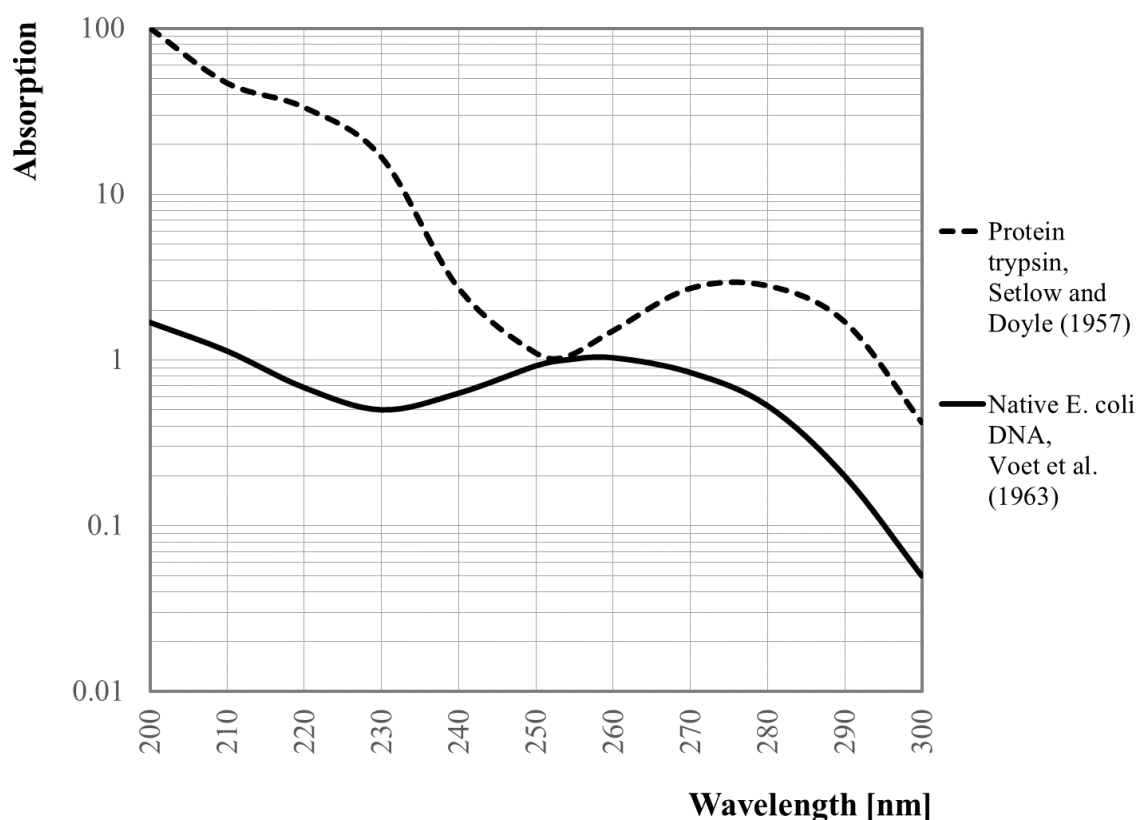


Figure 3.3: Spectral absorption of *Escherichia coli* DNA and the protein trypsin (according to Voet et al. 1963, Setlow and Doyle 1957), normalised to 254 nm.

3.1.2 Physical radiation quantities and units

The effect of UVC radiation on microorganisms, organic and inorganic substances, and especially human organs such as the skin and eyes, depends on the irradiated “dose” which, unlike that of ionising irradiation, is not defined as the amount of energy absorbed per mass. In this context, the term “dose” is used rather for radiant exposure H , i.e. the UVC radiation energy striking a surface, which is measured in joules per square metre (J m^{-2}). The radiant exposure is the product of the irradiation duration t and mean irradiance E , defined as the radiated power per surface area and measured in watts per square metre (W m^{-2}) (see section 3.5.1). Strictly speaking, it would have to be differentiated at which wavelength or in which wavelength range the irradiation occurred, since photobiological action spectra can change considerably according to the wavelength. For this reason, this recommendation specifies the dominant wavelength during irradiation as an index. The ranges used are UVC_{254} for mercury vapour lamps with maximum emission of 254 nm, UVC_{222} for KrCl excimer lamps with maximum emission of 222 nm and UVC_{233} for UVC LEDs with a peak wavelength of around 233 nm.

In the literature, the dose that has been measured is usually expressed in mJ cm^{-2} (mJ/cm^2), whereby 1 mJ cm^{-2} corresponds to 10 J m^{-2} . The inconsistent use of these units can lead to miscalculations of the doses achieved. Therefore, the same unit should always be used when comparing different studies.

3.1.3 Measurement of UV radiation

The irradiated dose H is determined based on the measurements of irradiance E and irradiation duration t . To measure the irradiance, two types of device are mainly used: broadband radiometers and spectroradiometers, which must be calibrated prior to use. Less frequently, film dosimeters are also used.

Broadband radiometers

Broadband radiometers offer spectral responsivity over a specified spectral range. In most cases, they consist of a photodiode and a spectral filter. The combination determines the spectral range in which the devices can take measurements. They are not capable of taking spectrally resolved measurements, however. Their spectral responsivity is not constant, but rather decreases predominantly towards the edges of the usable spectral range. It is therefore necessary to calibrate broadband radiometers directly on the lamp types on which they will subsequently be used. Alternatively, the spectral responsivity of the radiometer can be calibrated to the dominant wavelength of the lamp to be measured (e.g. 222 nm for KrCl excimer lamps). Corresponding correction factors for the broadband radiometer display can then be calculated and the irradiance E obtained. A radiometer calibrated at 172 nm would therefore clearly indicate a false reading.

Since Si photodiodes are mostly used for broadband radiometers which offer high spectral responsivity in the UV to the near-infrared spectral range, it is essential to use an additional filter to effectively delimit the utilisable spectral range when measuring UVC irradiance. It should be noted here that vapour-deposited filters in particular can often have a wider transmission range above approx. 700 nm. An additional false signal and a supposedly too high UV irradiance may therefore be displayed if infrared radiation is present during measurement.

Spectroradiometers

Spectroradiometers can take spectrally resolved measurements of the spectral irradiance $E_{\lambda}(\lambda)$. They can therefore cover a larger spectral range and can be used to measure a wide variety of lamps. The integral of the spectral irradiance measured over the wavelength thereby results in the irradiance E . Two types of device are mainly used. Double monochromator systems can measure spectra with a high resolution and maximum suppression of stray light. The spectrum is thereby scanned and recorded wavelength by wavelength. Such systems are very accurate but take a comparatively long time of several minutes to measure one spectrum; their suitability for determining a dose is therefore limited. Array spectroradiometers can capture an entire spectrum over a short period of time (a few milliseconds to a few seconds), whereby the spectrally dispersed radiation hits an array of photodiodes simultaneously (usually CCD or CMOS cells). These devices are therefore well suited to rapidly determining irradiance. Their compact design, however, makes them highly susceptible to internal stray light. Spectral components from other wavelengths thereby hit sections of the array that are supposed to capture a different, defined spectral range. Depending on the design, this fraction of scattered light is very high, especially in the UV spectral range. In the case of halogen bulbs, which are often used to calibrate array spectroradiometers, infrared scattered light can cause a false radiation fraction of more than 100% of the radiation to be measured, particularly in the range of measurement below 300 nm. Spectral stray light correction of the measurement signal is therefore essential for calibration and application.

Determining the irradiated dose necessitates adaptation of the input optics of the devices, accordingly, which detect the irradiance at the site of irradiation. Hence, the devices usually have a diffuser on the front which serves as an irradiated surface or reference plane. In some cases, the opening of a small integrating sphere also serves as a reference plane and the meter is attached to a further output opening of the sphere. It is also possible for the input optics to be attached to an optical fibre, the other end of which leads to the measuring device. Whatever the design, the devices must always be calibrated with the intended input optics for irradiance measurement. Calibration without a diffuser (e.g. connected directly to a lamp) is not usable. Other input optics with optical lenses or, e.g. the bare end of an optical fibre, cannot be used to measure irradiance as they do not have an irradiated reference plane.

Calibration of the devices, particularly in the far-UVC spectral range, is very complex and may be subject to large measurement uncertainties. It should therefore be carried out by accredited measurement laboratories.

Film dosimeters

Film dosimeters are also used to measure UVC radiation doses. When UVC radiation strikes a film dosimeter, the colour of the film changes depending on the dose. The extent of the colour change in the film can then be used to determine the dose of the UVC radiation to which the film dosimeter was exposed.

One example of a film dosimeter for UVC radiation is the Gafchromic EBT3 film. When this film is exposed to UVC radiation, an irreversible colour change is prompted that can then be quantified with the aid of special scanner software to determine the radiation dose. A further example is the Kodak XV-2 film. Exposing the film to UVC radiation triggers a colour change that is indicated by the disappearance of the blue colour in the film.

In both cases, the colour changes can be used to determine the dose of the UVC radiation. A similar effect is also used on colour cards which indicate a colour change in response to radiation. All film dosimeters demonstrate extremely broad spectral sensitivity and must in each case be calibrated with the aid of other radiometric methods using the radiation sources to be investigated.

In radiotherapy, OrthoCromic OC-1 film is frequently used, e.g. to determine the dose of radiation to be delivered to the patient during treatment. A study by Welch and Brenner (2021) demonstrated that OrthoCromic OC-1 film can also be used for the far-UVC range, provided that calibration is performed accordingly. Since it takes longer for the colour to change, the authors recommend evaluating the change in colour after 48 hours. The authors also point out that the film has a higher level of sensitivity at 254 nm than in the far UVC spectral range and that UVA and UVB radiation can also cause the film to change colour. Care must therefore be taken during application to avoid extraneous radiation and especially solar radiation. Moreover, unfiltered KrCl excimer lamps cause significantly stronger discolouration than filtered lamps.

In general, it should be noted that radiometric measurements in the spectral range below 250 nm are associated with high levels of measurement uncertainty. To correctly measure the exposure to narrow-band radiation, a correspondingly high level of technical effort is required and pertinent experience in the field of UV radiometry is an essential prerequisite. Most of the studies examined in sections 3.3 and 3.4 do not mention the actual effort involved in measurement, the quality of the radiometric measurements is often not assessable and, consequently, a reasonable estimation of the reliability of the given radiometric quantities cannot be made.

3.2 UVC devices/lamps and their application

The use of UVC radiation as a means of eradicating microorganisms and inactivating viruses is now established in many areas. Various sources of radiation are thereby used, the main emissions of which so far lie in the spectral range of 254 nm. The use of far-UVC radiation in the spectral range below 240 nm is a new development of recent years, as is the use of UVC LEDs (see section 3.2.1).

The use of UVC disinfection devices on humans for self-application is generally warned against (BfS 2022). Hence, with many types of devices and applications direct exposure to UVC radiation is largely prohibited (see 3.2.2).

3.2.1 Sources of radiation

To inactivate microorganisms with UVC radiation, gas-discharge lamps are mainly used and increasingly also LED lamps. In the case of discharge lamps, a distinction is made between low-pressure mercury lamps, medium-pressure mercury lamps and excimer lamps. Due to the increasingly restrictive limitation of the use of mercury in electrical and electronic equipment by Directive 2011/65/EU (EU 2011) and accelerated development, more and more products based on UV LEDs are coming onto the market.

3.2.1.1 Low-pressure mercury lamps

Gas-discharge lamps work on the principle of excitation and ionisation of atoms or molecules with electron collisions in an electric field. On recombination from the excited energy states, the atoms or molecules emit a characteristic line spectrum.

In a low-pressure plasma with gas pressures of less than 1 mbar (< 100 Pa), emissions from previously vaporised and excited mercury atoms lie within the UV spectral range, e.g. at wavelengths of 185 nm, 254 nm, 313 nm and 365 nm.

The emission at 185 nm is a strong ozone producer in the surrounding air. Low-pressure lamps with bulbs made of synthetic quartz glass can utilise this spectral range to facilitate the degradation of pollutants, odours and grease through oxidation processes.

To inactivate microorganisms, lamps with coated quartz bulbs are used, in which the transmission of radiation in the far-UVC range is usually completely blocked below 240 nm (ozone-free lamps). Such low-pressure mercury lamps achieve an output efficiency of 33% to 40% of the UV radiated power relative to the electrical power for the main emission line at 254 nm. Lamps are available with an electrical power of up to several hundred watts. Low-pressure lamps, which are filled with amalgam instead of pure mercury, achieve service lives of up to 16,000 hours.

Low-pressure mercury lamps are available in a variety of designs and are used in many technical applications.

3.2.1.2 Medium-pressure mercury lamps

Gas-discharge lamps with a gas pressure between 1,000 mbar and 10 bar (0.1 MPa and 1 MPa) generate a significantly hotter plasma, which delivers a broader spectral band from UVC up to the infrared spectral range. In UVC, a spectrum overlaid with broadened spectral lines is generated from below 200 nm. The lamps achieve significantly higher power densities than low-pressure lamps, but only have a UV efficiency of approx. 10% relative to the electrical power.

Due to the high plasma temperatures, the bulbs achieve temperatures up to 900°C. Lamps with an electrical power consumption of up to 60 kW are used. The output range of the lamps can be dimmed using electrical ballasts so that the radiant power applied can be adapted to changing requirements.

Medium-pressure lamps are used in industrial-scale plants for curing paints and printed products and for disinfecting drinking water supplies. To prevent the generation of chemical by-products by high-energy radiation from the far-UVC spectral range, the bulbs must be coated or special bulb envelopes used to ensure that radiation below 240 nm is completely blocked.

3.2.1.3 Excimer lamps

In a high-energy plasma, short-lived compounds of noble gases or of halogens with noble gases can be produced, which emit optical radiation after a few nanoseconds when they decay. The

excited dimers can only be formed if the noble gas is in an excited state due to a strong plasma discharge. High-frequency, high-voltage power supplies are therefore used to operate excimer lamps. The optical radiation produced when the dimer decays possesses a spectrum with a main emission line that is characteristic of the elements used. The dimers frequently used are Xe₂ with a main emission line of 172 nm, KrCl (222 nm) and XeBr (282 nm).

The KrCl used for applications in the far-UVC range has a main emission of 83% of the radiant power around 222 nm (far-UVC radiation, 200 nm-230 nm), but emits a further 10% in the remaining UVC (230 nm-280 nm), 3% in the UVB and 4% in the UVA range (Hickerson et al. 2021). To restrict the radiation to the far-UVC spectral range and prevent DNA damage from longer-wave UV radiation above 240 nm, appropriate short-pass filters must be used (Narita et al. 2022). The long-term reliability of the lamps and in particular the stability of the filtering over time have not yet been investigated. There is currently no guarantee that systems being brought onto the market are equipped with such a filtering mechanism, which is also usable in the long term. Type approval and certification of lamps in the far-UVC spectral range may be required in the public sector prior to distribution of such systems. In the private sector in particular, there is also a risk of uncontrolled circulation of uncertified, unfiltered or technically unreliable systems through online retail.

KrCl excimer lamps can achieve a UV radiant power of up to 1.5 kW (Skakun et al. 2002). The lamps achieve an efficiency of approx. 18% of the UV radiant power relative to the electrical power.

Excimer lamps are used for ozone generation, photochemical dissociation, surface treatment (UV curing), curing of paints and printed products and, more recently, for eradicating microorganisms and inactivating viruses.

3.2.1.4 LEDs

UVC LEDs are narrow-band semiconductor emitters based on gallium nitride and aluminium nitride alloys whose emission bands can be tuned in the spectral range of 210 nm to 400 nm using different alloy ratios (Kneissl et al. 2019).

LEDs that emit radiation suitable for inactivating microorganisms and viruses are manufactured with peak wavelengths between 265 nm and 280 nm. Individual LEDs achieve a radiant power of up to 100 mW, but only have an efficiency of around 3% to 8% relative to the electrical power. The service life of the emitters extends up to 1,000 hours but decreases significantly for LEDs with high radiant power and shorter peak wavelengths.

LEDs with a peak wavelength of around 230 nm can be used in the far-UVC range. However, individual LEDs of this type currently only achieve a radiant power of about 3 mW and a service life of much less than 100 hours.

The production of UVC LEDs is (still) subject to a tremendous degree of fluctuation in crucial product parameters. E.g. binning¹ ensues with LEDs according to their peak wavelength or the radiant power emitted. This categorisation into graded groups (bins) entails tolerances that permit, e.g. 230 nm ± 5 nm for one bin, meaning that LEDs with peak wavelengths of 225 nm to 235 nm can be used. The spectral curve of UVC LEDs is also generally asymmetrical around the peak wavelength and tapers off further on the longer wavelength side. The actinic effect of

¹ Binning refers to the process by which UV LEDs are sorted into groups or bins during or after manufacture based on their electrical and optical properties, such as power consumption, radiant power and peak wavelength. This ensures that the UV LEDs within a particular group or bin are consistent in terms of their performance and properties.

LEDs in a bin with different peak wavelengths can therefore vary significantly. This should be taken into account when designing and assessing lamps that usually consist of many LEDs from one bin.

The compact design with edges that are just a few millimetres long means that UV LEDs can be combined in large numbers for any technical application. It should be noted, however, that the components require a large amount of cooling given that their efficiency is still low. Due to the high individual costs and the comparatively short service life, large-scale applications of UVC LEDs, e.g. for sterilising drinking water, are still being developed. Some small-scale applications can already be found in the consumer sector, however, such as in water extraction or for the disinfection of smartphones and tablets.

3.2.2 Device types, design and application

Various device types and designs are used depending on the application. In terms of design, a distinction is made between closed systems that almost completely prevent people from coming into contact with the UVC radiation, and semi-open and open systems. The applications for inactivating microorganisms can be differentiated into the categories of disinfection for drinking water, surfaces, indoor air and the medical sector. In addition, there are technical UVC applications where people in a working environment may come into contact with residual radiation.

3.2.2.1 Treatment of drinking water

Closed systems from which no radiation leaks to the outside are used to disinfect drinking water in waterworks. Low-pressure mercury lamps and systems with medium-pressure lamps are employed. Depending on the water throughput, the radiant power can be regulated to ensure that a minimum irradiation dose is always exceeded. Due to the closed design, there is no direct risk to humans. In the case of maintenance and measurement, the ELs can be exceeded in just a few seconds, meaning that strict occupational safety measures are required (DGUV 2016).

Closed devices are used for small consumers, e.g. directly at the tap or for sterilising ponds and swimming pools. Low-pressure lamps and, more recently, UVC LEDs, are mainly used in this case.

3.2.2.2 Treatment of surfaces

All types of design are used for disinfecting surfaces. Low-pressure mercury lamps and, increasingly, UVC LEDs are used.

To disinfect small appliances and utensils, closed systems in the form of boxes and cabinets can be used, in which the objects must be placed and where the radiation can only be activated after the flaps and doors have been closed.

Large flat surfaces can be treated using systems with a semi-open design. In this case, the radiation is only emitted on one side of the system, which is guided over the surface to be disinfected. These systems can be equipped with an automatic emergency switch-off mechanism if they are not in contact with a surface; alternatively, they should only be operated by trained personnel wearing personal protective equipment.

The irradiation of surfaces can also be carried out with open systems, provided there is nobody in the room or anyone in the room is wearing appropriate protective equipment. For this purpose, the systems must be placed in the middle of the room, must be suspended from the ceiling as lamps, or must be motorised and guided through the room. Disinfection robots are also used in such cases, passing through rooms autonomously with nobody present and

irradiating the surfaces and air with UVC radiation. Applications include, e.g. the disinfection of surfaces in hospital rooms, aircraft cabins and in the food industry.

There are attempts to use excimer lamps in the future for such applications while people are present in the room.

3.2.2.3 Treatment of indoor air

All designs are likewise used to inactivate microorganisms in room air; here too, low-pressure mercury lamps are mainly used. The use of UVC LEDs in this area is still under development.

UV radiation chambers can be installed in permanent heating, ventilation and air-conditioning (HVAC) systems and used to sterilise the circulating air before it is released back into the room. The chambers are integrated into the ventilation system and are completely closed so that no further protective measures are required to protect people, apart from an emergency shutdown mechanism in the event that the chambers are opened during operation. There are also components for HVAC systems in which the water used to humidify the room air is sterilised with UVC radiation before being atomised.

Mobile recirculation units have been developed for the subsequent or flexible outfitting of rooms, whereby the room air is sterilised in a radiation chamber and then fed back into the room. Designs range from small table-top units to recirculation cabinets. These closed systems should be designed in such a way that a sufficiently high radiation dose is achieved with a single pass and that no significant levels of radiation leaks from the device.

Semi-open systems are also used in which the radiation is released into an area of the room that people cannot reach. Such systems are usually suspended at a great height (referred to as upper-air systems); on-site measurements must be carried out to ensure that public areas or workplaces are not exposed to significant levels of radiation.

Open systems are designed in a similar way to those for disinfecting surfaces and are generally only used when there is nobody in the room. Systems are also being developed that switch off automatically when somebody approaches (UV curtain). The use of excimer lamps is being pursued in particular with open systems and in future should also be used when people are present in the room.

In all applications for inactivating microorganisms and viruses in room air, it must be physically guaranteed that air contaminated with microorganisms or viruses reaches or enters the systems. In the case of upper-air systems or open systems on the ceiling, this can be achieved by convection or, in the case of HVAC systems or recirculation units, by continuous circulation of the room air. Open systems are particularly relevant in the context of this recommendation.

3.2.2.4 Application in the medical sector

The use of far-UVC radiation is a topic of discussion in the medical sector, in some cases for study purposes. Excimer lamps or UVC LEDs could be used exclusively for the superficial antiseptic treatment of wound margins, skin and mucous membranes, as well as to counteract colonisation with microorganisms, thus offering an alternative to antibiotic or antiseptic ointments, shampoos and rinses. UVC lamps can also be used to prevent and treat postoperative peri-implantitis, an inflammation of soft and hard tissues surrounding implants (Bonneß 2007). Peri-implantitis can occur, particularly in immunocompromised patients, after the insertion of an implant, e.g. a dental prosthesis in the mouth.

With these and similar applications in the medical sector, medical staff and patients may be unintentionally and intentionally exposed to UVC radiation. The potential risks associated with

the use of UVC and especially far-UVC radiation in humans are currently being studied and must also be evaluated more thoroughly in the future.

In medical facilities, UVC radiation is used, e.g. in treatment rooms as an alternative to chemical wipe disinfection. As it cannot be ruled out that UVC disinfection systems are used in rooms where people are present, infrared motion sensors in some systems ensure that the systems switch off immediately. The intention with far-UVC sources is that they can also be used when somebody is present in the room. This document does not address other *medical* applications within the scope of the Medical Device Regulation.

3.2.2.5 Other applications

UVC radiation is now used in many technical applications for surface treatment and in the curing of paints and printing inks with UV radiation. Closed systems (chambers) or semi-open systems (assembly line irradiation) are used here in which occupational safety measures (OStrV 2010) must be heeded and the applicable ELs must be complied with.

3.3 Eradicating microorganisms and inactivating viruses with UVC radiation

The aim of disinfection is to reduce the germ number in relation to microorganisms such as bacteria and fungi, and to reduce the infectivity of viruses. As a measure of the destructive effect, the ability of bacteria and fungi to form colonies (measured in colony forming units (CFU)) under appropriate cultivation conditions is determined from treated versus untreated organisms. Further, as a measure of the infectivity of viruses, the “50 % tissue culture infectious dose” (TCID₅₀), i.e. the dose required to trigger an infection in 50 % of the cell cultures, is presented or the number of areas with cytotoxic effects (“plaque forming units”, PFU) in suitable cell cultures is determined. The values are usually written in logarithmic form. The disinfecting action is then quantified as the log reduction, whereby, e.g. a log 4 reduction corresponds to a reduction of 99.99%. The antimicrobial effect of UVC radiation is well known and is used routinely for disinfecting surfaces in clean rooms or in sterile cabinets and for sterilising medical instruments (see Rudhart et al. 2022). Mercury vapor lamps with a maximum emission in the UVC range at 254 nm (UVC₂₅₄) are usually used here. The destruction of microorganisms with UVC radiation is based mainly on inducing premutagenic damage in the DNA (e.g. cyclobutane pyrimidine dimers (CPD)). As the wavelength decreases, absorption by proteins increases (see Figure 3.3); hence, in the spectral range of far UVC radiation, protein damage also plays a role in eradication (Hessling et al. 2021). Due to the increased protein absorption and scattering with decreasing wavelength, the penetration depth into biological tissue decreases (Zwicker et al. 2022). Due to the strong absorption and scattering, especially of far-UVC radiation in biological material, depending on the test conditions, e.g. by using different culture media or wound secretions, exposure of the microorganisms can be attenuated and thus deviate significantly from the measured radiation dose. The exposure conditions in different studies must therefore be taken into account.

Narita et al. (2020) studied the inactivation of bacteria, bacterial spores, fungi and viruses by means of irradiation with UVC₂₂₂ compared with UVC₂₅₄. In each case, 0.5 ml of suspension (bacteria, bacterial spores and fungi) and 0.2 ml of suspension (viruses) were transferred to a 35 mm culture dish for irradiation. In addition to treatment with UVC radiation, the effect of incubation in ethanol (10 s) was also tested for comparison. Common environmental and hospital microorganisms were studied. The different bacterial strains reacted with different sensitivities, with *Staphylococcus aureus* and *Campylobacter jejuni* being the most sensitive, while *Salmonella enterica* and *Bacillus cereus* were less sensitive. No colony formation could be detected in any of the bacterial strains examined after irradiation with 36 mJ cm⁻² UVC₂₂₂. UVC₂₂₂ and UVC₂₅₄ were similarly effective at inactivating bacteria. The results are listed in

greater detail in Table 3.1. Colony formation could no longer be detected after incubation with ethanol. As expected, endospores were more resistant to radiation. No colony formation could be detected for endospores of *Bacillus cereus* and *Clostridium sporogenes* after irradiation with 96 mJ cm^{-2} UVC₂₂₂. In the case of *Clostridioides difficile*, the same effect was already achieved at a dose of 50 mJ cm^{-2} . All endospores exhibited greater sensitivity to irradiation with UVC₂₅₄ (see Table 3.1). Ethanol had no destructive effect.

The fungal strains examined by Narita et al. (2020) also differed in terms of radiation sensitivity. In tests on the yeast *Candida albicans*, no living cells could be detected after irradiation with a dose of 72 mJ cm^{-2} UVC₂₂₂ or UVC₂₅₄. Much higher doses may be needed to completely eradicate fungal spores. E.g. this effect is only achieved in *Aspergillus niger* spores with a dose of 500 mJ cm^{-2} UVC₂₂₂, while *Trichophyton rubrum* is eradicated at a dose of just 72 mJ cm^{-2} UVC₂₂₂. UVC₂₅₄ was significantly more effective in these experiments than UVC₂₂₂. The authors not only examined fungal spores, but also the growth of fungi based on the formation of hyphae. Again, UVC₂₅₄ proved much more effective than UVC₂₂₂. The growth of hyphae from *Aspergillus niger* was significantly inhibited at a dose of just 250 mJ cm^{-2} with UVC₂₅₄, whereas even at a dose of $1,000 \text{ mJ cm}^{-2}$ UVC₂₂₂ only a minimal influence on hyphae growth was noted. Growth was also severely restricted after irradiation of fungal hyphae of the *Trichophyton rubrum* type with a dose of 72 mJ cm^{-2} UVC₂₅₄, whereas a dose of 250 mJ cm^{-2} UVC₂₂₂ had no effect on growth. After incubation with ethanol, no colonies or fungal hyphae were detected in any of the fungal strains examined.

The sensitivity of the two virus strains investigated likewise differed quite considerably towards both UVC₂₂₂ and UVC₂₅₄ radiation. Whereas *feline calicivirus* (FCV, non-enveloped virus) was inhibited but not completely eradicated by a dose of 36 mJ cm^{-2} UVC, no pathogenic effect was detected after irradiation of *influenza virus A* (enveloped virus) with a dose of just 6 mJ cm^{-2} UVC. In these cases, UVC₂₂₂ and UVC₂₅₄ were equally effective. Incubation with ethanol only achieved inactivation in the case of *influenza virus A*.

In another setting, virus inhibition using UVC₂₂₂ was investigated (Buonanno et al. 2020, Buonanno et al. 2021b). Two human coronavirus species (enveloped viruses), namely *alpha HCoV-229E* and *beta HCoV-OC43*, which trigger sneezing and coughing by infecting the respiratory organs, were irradiated with UVC₂₂₂ as an aerosol. The TCID₅₀ was determined in cell culture as a measure of the infectivity of the specimens. A dose of 1.7 mJ cm^{-2} (*alpha HCoV-229E*) and 1.2 mJ cm^{-2} (*beta HCoV-OC43*) thereby achieved 99.9% virus eradication.

To investigate the bactericidal effect of UVC₂₂₂ in relation to the risk of infection in skin wounds, Narita et al. (Narita et al. 2018a; Narita et al. 2018b) conducted an in vivo study in *BALB/c* mice with methicillin-resistant *Staphylococcus aureus* (MRSA) infection on healthy skin and in wounds. Irradiation of the skin with 75 mJ cm^{-2} UVC₂₂₂ resulted in a reduction of the germ count by approx. two powers of ten ($4.5 \log \text{ CFU}$ to $< 2.8 \log \text{ CFU}$). The non-inactivated germs on the skin are probably attributable to shading in the skin furrows (sulci cutis) or in hair follicles. Irradiation of infected wounds also reduced the germ count. However, with a reduction of $0.9 \log \text{ CFU}$ after irradiation with 75 mJ cm^{-2} UVC₂₂₂, inhibition was lower than in intact skin. Even at a dose of $1,500 \text{ mJ cm}^{-2}$ UVC₂₂₂, a reduction of only $1.6 \log \text{ CFU}$ was achieved. The diminished effect is likely due to the absorbing effect of the wound exudate, which has a high protein content. Above a dose of 150 mJ cm^{-2} , no reduction in the germ count was observed up to 12 days after irradiation, i.e. during wound healing. UVC₂₅₄ was often somewhat more effective than UVC₂₂₂; however, after irradiation with UVC₂₅₄, in addition to a reduced germ count, DNA damage (measured based on CPD formation) was observed in the cells of the wound bed, an effect that was not achieved after irradiation with UVC₂₂₂.

In another setting, Ponnaiya et al. (2018) studied MRSA-infected areas of skin in *SKH1* mice after irradiation with UVC₂₂₂ and UVC₂₅₄. It should be noted, however, that in this case the bacteria were applied to a film, which prevented penetration of the epidermis prior to irradiation. An incision was made in the infected areas and immediately closed with a suture. A significant reduction in germ count was also observed here on day 2 and day 7 after both forms of irradiation.

Fukui et al. (2020) evaluated the bactericidal effect of UVC₂₂₂ in a clinical study involving 20 subjects. An area on the back was irradiated with a dose of 500 mJ cm⁻² UVC₂₂₂. Prior to irradiation and five and 30 minutes after irradiation, the skin was swabbed and colony formation was determined from the eluates. The mean colony count dropped from 7.21±7.48 before irradiation to 0.05±0.23 five minutes after irradiation. A mean value of 0.79±2.53 colonies was found 30 minutes after irradiation. ELISA determination of DNA damage (CPD formation) revealed a low but significantly increased level in irradiated skin biopsies. It should be mentioned in this context that the inactivating effect on the skin microbiome described in this study cannot be ruled out, even when using far-UVC radiation in public spaces. The implications in terms of skin health from potentially inactivating the microbiome through permanent exposure have not yet been adequately examined. The data described above from in vitro and in vivo studies proves the germicidal effect of UVC₂₂₂, which is certainly comparable with that of UVC₂₅₄. This is also confirmed in a review by Hessling et al. (2021), which considers the publications on the use of far-UVC radiation for disinfection from the last 100 years. According to Hessling et al., the publications suggest that a dose of 100 mJ cm⁻² UVC₂₂₂ reduces all pathogens by several orders of magnitude. It should be noted at this point that this dose is roughly four times higher than the EL of 22.7 mJ cm⁻² at 222 nm aimed at protecting the eyes and skin from actinic UV hazards (see section 3.5.1). It is also clear, however, that there are considerable differences in the radiation sensitivity of microorganisms whose inactivation is desired. These differences can depend on the size of the genome but also, e.g. in the case of viruses, on the existence of a viral envelope (enveloped and non-enveloped viruses). The pigmentation of the microorganisms, such as in the *Aspergillus niger* fungus, may also be the reason for reduced sensitivity to UVC radiation. As UVC₂₂₂ is absorbed and dispersed to a considerable extent by proteins and other biological substances, these effects are particularly pronounced when using UVC₂₂₂. The very different doses required to effectively inactivate microorganisms in the described in vitro and in vivo settings probably result for the same reason (Hessling et al. 2021, Hessling et al. 2022). In a study by Zwicker et al. (2022) published recently, these effects were described in great detail. It was shown that sweat, albumin and wound exudate, used as a medium in which to irradiate the microorganisms, greatly reduce the inactivating effect of UVC₂₂₂ compared to UVC₂₅₄. If saline was used as a medium, as usual, UVC₂₅₄ was only slightly more effective. The authors also investigated the effect of UVC₂₃₃, demonstrating that sweat hardly reduced the inactivating effect at all. However, irradiation of skin biopsies with UVC₂₃₃ induced DNA damage in cells in the upper epidermal layers to a greater extent than under UVC₂₂₂. A summary of the aforementioned studies into the effect of UVC radiation on microorganisms is provided in Table 3.1. Conflicts of interest are declared by the authors in all publications listed in this table.

Just like chemical disinfectants that are approved for use in humans (e.g. ethanol, propanol, povidone-iodine, octenidine and chlorhexidine), far-UVC radiation has a non-specific effect on most microorganisms, and not all pathogens are inactivated with the same degree of efficacy. Due to the non-specific effect, however, both methods are suitable for inactivating (multi)resistant microorganisms. This circumstance is important for microorganism reduction as a prophylactic measure and is used to reduce the risk of infection of patients in medical interventions and, in particular, to avoid infection with antibiotic-resistant microorganisms. The

often-highlighted ability of far-UVC radiation to also inactivate antibiotic-resistant microorganisms thus also applies to conventional chemical disinfectants.

Conclusion

In summary, the data shows that the inactivating effect of UVC₂₂₂ is in principle comparable to the effect of UVC₂₅₄. When applied, however, it must be taken into account that UVC₂₂₂ is very strongly absorbed and scattered by proteins and other biological substances. This can severely restrict the inactivating effect and is probably also the reason for a partly very variable radiation sensitivity in the microorganisms that are to be inactivated. In this case, when using far-UVC radiation in public spaces the microbiome of the human skin and the eye surface could also be affected. Data on the use of UVC₂₃₃ demonstrates a better penetration depth due to the lower level of absorption by proteins, which is associated with increased DNA damage in epidermal cells beneath the corneal layer compared to UVC₂₂₂. In principle, a benefit-risk analysis should also be carried prior to the routine use of far-UVC radiation, e.g. for disinfection prior to medical interventions, including potentially vulnerable populations in particular. Also to be considered here, is that chemical disinfectants have a good effect in surface disinfection. The often emphasized property of far-UVC radiation to inactivate even antibiotic-resistant microorganisms also applies to conventional chemical disinfectants.

Table 3.1: Overview of the studies into the effect of UVC radiation on microorganisms. The values specified for radiant exposure H (dose) refer to the conditions described in the references. The irradiation duration and irradiance are not usually stated therein.

Publication	Object of study	Medium in which exposure occurred	UV source/wavelength (filtering, if applicable)	Radiant exposure H (dose)	Effect
Narita et al. 2020 *	Bacterial strains <i>Staphylococcus aureus</i> , <i>Pseudomonas aeruginosa</i> , <i>Echerichia coli</i> , <i>Campylobacter jejuni</i> , <i>Salmonella enterica</i> , <i>Bacillus cereus</i> , <i>Clostridium sporogenes</i>	0.5 ml suspension in a 35 mm culture dish	KrCl excimer lamp/222 nm, filtered	36 mJ cm ⁻²	No colony formation in any of the bacterial strains examined; sensitivity of the bacterial strains very different
			Mercury vapour lamp/254 nm		Equally effective as 222 nm; a few colonies were still detectable for <i>Clostridium sporogenes</i> only
	Endospores of <i>Bacillus cereus</i> and <i>Clostridium sporogenes</i>		KrCl excimer lamp/222 nm, filtered	96 mJ cm ⁻²	No colony formation
			Mercury vapour lamp/254 nm		Living endospores detected
	Endospores of <i>Clostridiodes difficile</i>		KrCl excimer lamp/222 nm, filtered	50 mJ cm ⁻²	No colony formation
			Mercury vapour lamp/254 nm	30 mJ cm ⁻²	Reduction in living endospores reached a plateau
	Yeast <i>Candida albicans</i>		KrCl excimer lamp/222 nm, filtered	72 mJ cm ⁻²	No living cells
			Mercury vapour lamp/254 nm		
	Fungal spores <i>Aspergillus niger</i>		KrCl excimer lamp/222 nm, filtered	500 mJ cm ⁻²	Complete eradication
			Mercury vapour lamp/254 nm	250 mJ cm ⁻²	Complete eradication
	Fungal spores <i>Trichophyton rubrum</i>		KrCl excimer lamp/222 nm, filtered	72 mJ cm ⁻²	Complete eradication
			Mercury vapour lamp/254 nm	36 mJ cm ⁻²	Complete eradication
	Fungal hyphae <i>Aspergillus niger</i>		KrCl excimer lamp/222 nm, filtered	1,000 mJ cm ⁻²	Very small effect on the growth of <i>Aspergillus niger</i>
			Mercury vapour lamp/254 nm	250 mJ cm ⁻²	Growth severely restricted

* The authors declare a conflict of interest.

	Fungal hyphae <i>Trichophyton rubrum</i>	0.2 ml suspension in a 35 mm culture dish	KrCl excimer lamp/222 nm, filtered	250 mJ cm ⁻²	Very small effect on the growth of <i>Trichophyton rubrum</i>
	Mercury vapour lamp/254 nm		72 mJ cm ⁻²	Growth severely restricted	
	Virus strain Feline <i>calicivirus</i> (non-enveloped virus)		KrCl excimer lamp/222 nm, filtered	36 mJ cm ⁻²	Inhibited but not completely eradicated
	Mercury vapour lamp/254 nm		Equally effective as 222 nm		
	Virus strain <i>Influenza virus A</i> (enveloped virus)		KrCl excimer lamp/222 nm, filtered	6 mJ cm ⁻²	No cytopathogenic effect detectable
	Mercury vapour lamp/254 nm		Equally effective as 222 nm		
Buonanno et al. 2020 [*] , Buonanno et al. 2021b	Coronavirus (enveloped) <i>alpha HCoV-229E</i>	Aerosol	KrCl excimer lamp/222 nm, filtered	1.7 mJ cm ⁻² (irradiance 100 μW cm ⁻²)	99.9% virus eradication
	Coronavirus (enveloped) <i>beta HCoV-OC43</i>			1.2 mJ cm ⁻² (irradiance 100 μW cm ⁻²)	99.9% virus eradication
Narita et al. 2018a [*] , Narita et al. 2018b	In vivo study in BALB/c mice with MRSA infection on healthy skin	Mouse skin, in vivo	KrCl excimer lamp/222 nm, filtered	75 mJ cm ⁻²	Germ reduction by 2 log CFU, but 2.5 log CFU remained on the skin
	In vivo study in BALB/c mice with MRSA infection in wounds		KrCl excimer lamp/222 nm, filtered	75 mJ cm ⁻²	Germ reduction by 0.9 log CFU
			KrCl excimer lamp/222 nm, filtered	1,500 mJ cm ⁻²	Germ reduction of 1.6 log CFU
			Mercury vapour lamp/254 nm		Slightly more effective than 222 nm, but also DNA damage in the cells of the wound bed

	MRSA-infected areas of skin in <i>SKH1</i> mice	Mouse skin, in vivo	KrCl excimer lamp/222 nm, filtered	40 mJ cm ⁻² and 300 mJ cm ⁻²	Significant germ count reduction on day 2 and day 7 post irradiation without skin damage
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^{*} The authors declare a conflict of interest.

Ponnaiya et al. 2018 *			Mercury vapour lamp/254 nm		Significant germ reduction on day 2 and day 7 post irradiation
Fukui et al. 2020 *	Study subjects, one area on the back	Human skin, in vivo	KrCl excimer lamp/222 nm, filtered	500 mJ cm ⁻²	The mean colony count dropped from 7.21±7.48 before irradiation to 0.05±0.23 five minutes post irradiation and 0.79±2.53 30 minutes post irradiation. Significantly increased CPD value in irradiated skin biopsies.

* The authors declare a conflict of interest.

3.4 Potential effects of far-UVC radiation on the eyes and skin

3.4.1 Penetration depth and absorption of UV radiation

The depth of penetration into the skin and eye is of particular importance in terms of the health-relevant effects of UV radiation (see Figure 3.4 and Figure 3.5). The penetration depth is the distance after which the optical radiation energy is attenuated to 37% (1/e) when penetrating a specific medium. It depends on the wavelength and the medium. The skin is the largest organ of the human body and due to its structure (see Figure 3.4) acts as a physical barrier, protecting the body against environmental noxes. However, the skin itself (as an organ) can also be affected by these harmful influences (e.g. UV radiation). The thickness of the skin and its individual layers varies considerably and depends, among other factors, on the localisation of the areas of the skin in question. The epidermis (50 μm -150 μm), as the uppermost layer of the skin, is a multilayered squamous epithelium consisting primarily of keratinocytes. Starting from the basal cell layer, keratinocytes differentiate to form the prickly cell layer (stratum spinosum), the granular layer (stratum granulosum) and, as non-nucleated cells, the corneal layer (stratum corneum, 8 μm -20 μm), being ultimately shed as scaly skin. In this way, the epidermis is renewed approximately every four weeks. It is assumed that the original cells for skin cancer are localised in the basal cell layer and in the hair follicles (Blanpain 2013, Gaggioli and Sahai 2007, Garcia et al. 2011). UV radiation of longer wavelengths, such as UVB and UVA radiation, penetrates the skin more deeply (37% of UV radiation at 300 nm and 340 nm reaches a depth of 15 μm and 54 μm , respectively) than UVC radiation (Finlayson et al. 2022). Measurements have shown that 82% of the energy of UVC₂₅₄ radiation is absorbed by 20 μm of the corneal layer (Bruls et al. 1984); however, DNA damage occurs in epidermal cells at this wavelength (Starzonek et al. 2019). In the far-UVC spectral range, the corneal layer is hardly penetrated at all because the radiation energy is heavily absorbed by proteins, especially peptide bonds (Preiss and Setlow 1956).

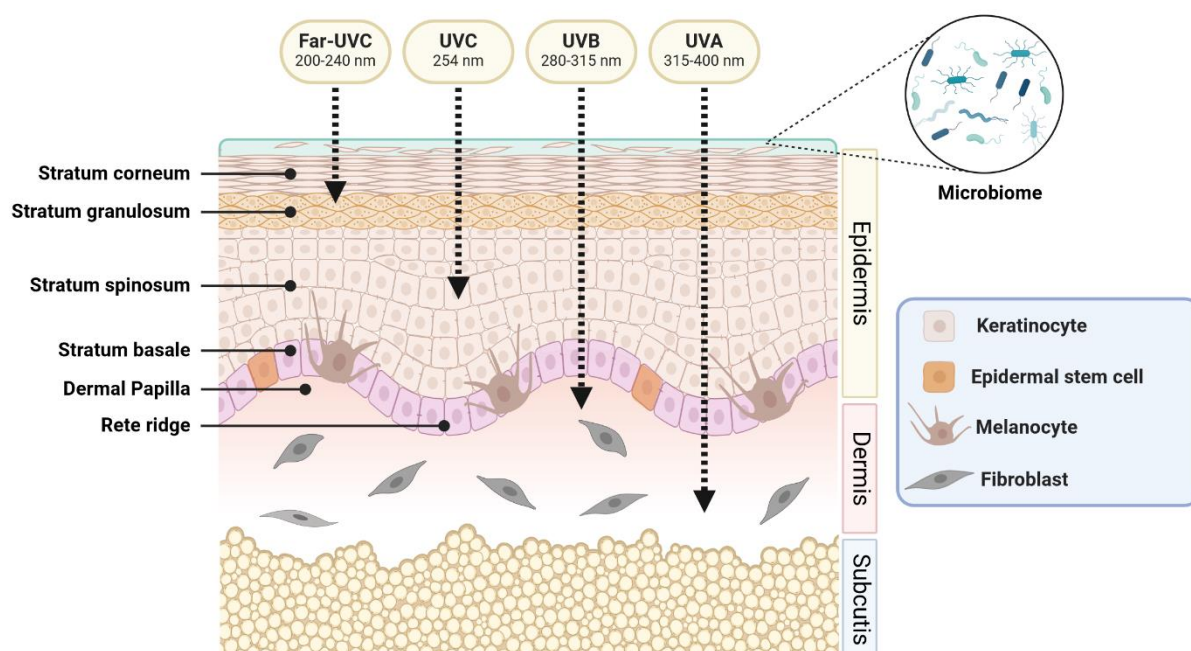


Figure 3.4: Diagram of the penetration depths of optical radiation in the human skin at different UV wavelengths (created with BioRender).

In the eye, the tear fluid forms the outer barrier on the epithelium of the cornea, protecting the eye from harmful environmental influences (Masoudi 2022, Peter et al. 2023, Robciuc et al.

2014). The precorneal tear film is a complex mixture of specific resident microorganisms, proteins, lipids, metabolites and electrolytes. It is roughly divided into three layers: the outer lipid, middle aqueous, and inner mucin layer. The proteins in the middle aqueous layer are responsible for immune and inflammatory reactions and wound healing. Far-UVC radiation to the eye is only absorbed to a small extent in the tear fluid. It should be noted in this context that under certain circumstances about 80% of far-UVC radiation can penetrate the tear fluid, although the underlying literature does not provide any insights into the thickness of the tear film that was examined (Michalos et al. 1994).

Like the stratum corneum of the skin, the superficial wing cells act as a protective shield for the underlying corneal epithelium. The corneal tissue with the highest absorption for UV radiation is the Bowman membrane, followed by the endothelium and, due to its layer thickness, the stroma (Peris-Martinez et al. 2021; cf. Figure 3.5). Across the entire thickness of the corneal stroma, 70% to 75% of UV radiation is absorbed at wavelengths < 310 nm (Kolozsvari et al. 2002). The stem cells of the corneal epithelium that are susceptible to cancer can be found in the basal cell layer of the corneal limbus and are shielded by at least three cell layers (Lavker et al. 2004). Almost all UVC radiation is absorbed in the corneal epithelium. The absorption rates are attributed to high levels of tryptophan residues in the proteins of the stroma (Mitchell and Cenedella 1995) and to high levels of ascorbic acid in the epithelium (Ringvold 1997, Ringvold 1998, Brubaker et al. 2000).

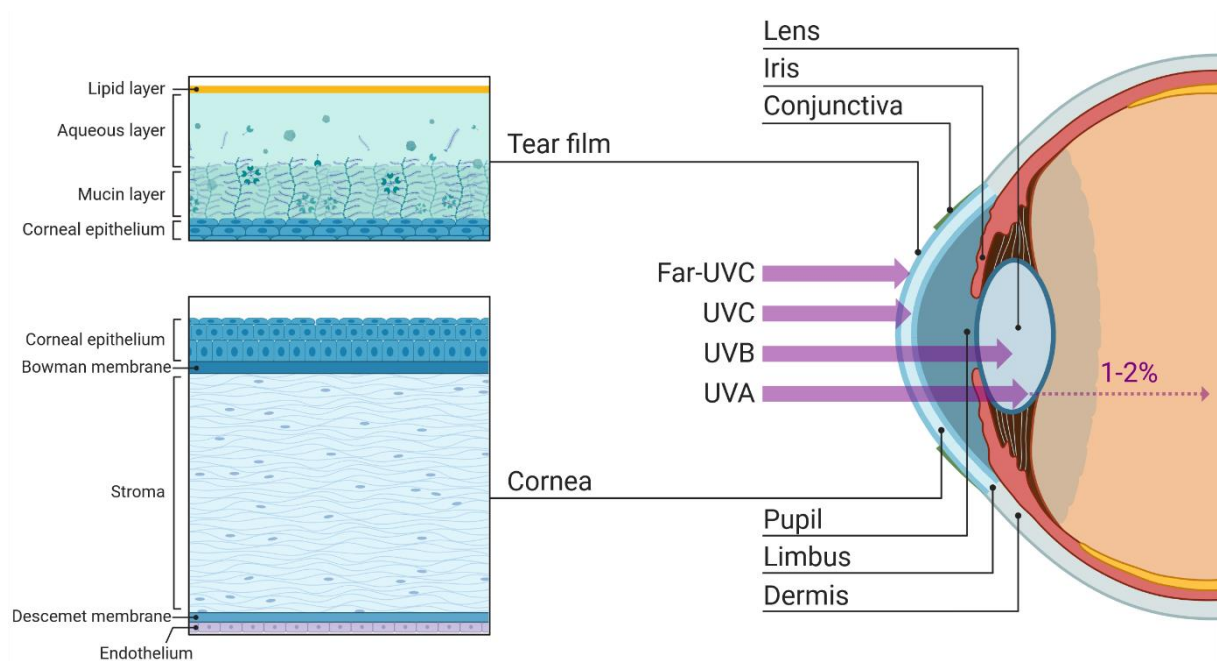


Figure 3.5: Diagram of the penetration depths of optical radiation in the human eye at different UV wavelengths (created with BioRender).

Whereas both the UVB radiation and the UVA radiation are completely absorbed by the lens of the eye at wavelengths below 365 nm, 1% to 2% of the UVA radiation above 365 nm does reach the retina (Glickman 2011, Krutmann et al. 2014, Mainster and Turner 2010).

The outermost protective barrier of the skin and eye surface is formed by their microbiota, which are composed of specific resident microorganisms that appear in a microbiome (Masoudi 2022, Wang et al. 2022, Azzimonti et al. 2023). The protective barriers provide protection against various environmental noxes and are exposed directly, on the other hand, e.g. to UV radiation. In response to such exposure the microbiota can change (Burns et al. 2019, Patra et al. 2019).

3.4.2 Effects of UVC radiation

The crucial aspect in terms of the harmful effects of UVC radiation is whether and to what extent natural protective barriers are compromised or overcome by the shortwave, high-energy radiation. Section 3.3 described how microorganisms on the skin can be inactivated by the use of far-UVC radiation. Damage to the microbiome of the human skin and eye surface from exposure to the use of far-UVC radiation in public spaces – also due to its more effective inactivation potential, e.g. compared to UVA and UVB radiation – cannot be ruled out. A disturbed microbiome, referred to as dysbiosis, is also associated with oxidative stress, and both are involved in the pathogenesis of various conditions, including malignant skin diseases (Peter et al. 2023, Azzimonti et al. 2023).

However, there are good reasons to assume, that human cells in the skin and in the eye are damaged at sensitive endpoints such as DNA. Shortwave high-energy UVC radiation has a lower penetration depth than UVB radiation but greater potential to encourage the formation of premutagenic lesions such as cyclobutane pyrimidine dimers (CPD) and pyrimidine-pyrimidone (6-4) photoproducts (6-4PP). The spectrum of activity of the DNA photoproduct CPD is similar to the UV spectrum that triggers erythema and the spectrum that leads to melanogenesis in human skin and thus to natural UV protection through pigmentation (Young et al. 1998, Parrish et al. 1982). In DNA, the maximum energy absorption (100%) is within the UVC spectral range at 260 nm, whereas in the UVB spectral range 20% of the radiation energy is absorbed at 290 nm and only 3% at 300 nm (Cadet and Douki 2018).

At the cellular level, far-UVC radiation is significantly attenuated by absorption in the cytoplasm before it reaches the cell nucleus (Green et al. 1987). In a study by Ong et al. (2022), monolayer cell cultures (keratinocytes and retinal cells) were exposed to UVC radiation of different wavelengths (277 nm, 254 nm and 222 nm) and identical irradiance. After 60 minutes of irradiation with UVC₂₅₄ and UVC₂₇₇, no cell growth was noted and apoptosis markers as well as the induction of CPD were detected. Cellular effects were also observed after irradiation with UVC₂₂₂: Cell growth was still significant but decreased compared to the non-irradiated control. No apoptosis markers and no CPD were detected, however, despite the number of γ H2AX-positive² cells suggesting DNA damage. The data shows rather convincingly that UVC₂₂₂ can also penetrate cells and trigger a cellular radiation response if, as is the case here, there is no protective effect from a corneal layer (skin).

It is known that, depending on the dose, UV radiation leads to the formation of reactive oxygen species (ROS) in cells which, for their part, can cause oxidative damage to proteins, DNA and

² H2A is a histone molecule that builds the chromatin framework of the DNA together with the H1, H2A, H2B, H3 and H4 histones. The phosphorylation of H2A to γ H2AX is part of the cellular DNA damage response (DDR). While γ H2AX foci in the nucleus are a marker for double-strand breaks, pan-nuclear induction of γ H2AX is an indication of genotoxic stress in the cell (de Feraudy et al. 2010, Stope 2021).

lipids (Bose et al. 2020, de Jager et al. 2017, Volatier et al. 2022). Using a 3D skin model, Tavares et al. (2023) demonstrated that far-UVC radiation also results in the dose-dependent formation of ROS.

3.4.3 Studies into the effect of far-UVC radiation on the skin

Epidemiological studies into skin cancer clearly show that solar UV radiation (UVB and UVA radiation) is regarded worldwide as a risk factor for the development of skin cancer (Moan et al. 2015, Lucas et al. 2019). In 2017, 22,900 people in Germany contracted a malignant skin melanoma for the first time (RKI and GEKID 2021). In 2016, 230,000 new cases of non-melanocytic skin cancer were registered in Germany (RKI and GEKID 2019). In situ carcinomas (malignant tumours confined to the epidermis) are not included in these figures. While approx. 3,000 deaths every year were attributed to melanoma, approx. 1,000 people died from non-melanocytic skin cancer (Destatis 2020). Malignant melanoma accounts for approx. 10% of all skin cancers and is responsible for three quarters of deaths. Although the causal factor of ambient radiation is primarily the UVB component (de Gruijl and Forbes 1995), UVA radiation alone can also be carcinogenic (Wischermann et al. 2008, Jin et al. 2022). It is assumed that oxidative stress is a contributor in this. The oxidative modification of DNA is an important mechanism of UVA-induced skin damage and cancer. Although skin carcinogenesis is generally attributed primarily to UV-induced DNA damage, ROS-induced inflammation is increasingly regarded as playing an important part in UV-induced carcinogenesis. Chronic inflammatory processes in the skin, which themselves may be UV-induced, can thus promote UV-induced skin tumours. Squamous cell carcinoma in particular and basal cell carcinoma exhibit important inflammatory components (Landsberg et al. 2012, Neagu et al. 2019). The extent to which far-UVC-triggered ROS induction causes inflammatory reactions and can contribute to cancer requires further investigation.

Far-UVC radiation is weakened in the stratum corneum to a greater extent than the longer UVC wavelengths or UVB radiation. Only very small portions of the far-UVC radiation penetrate the superficial layers of the epidermis; the deeper epidermal layers as far as the basal cell layer are hardly reached. Hence, some authors assume that far-UVC radiation does not pose a relevant cancer risk in healthy skin. E.g. the risk of photocarcinogenesis is estimated by Nishigori et al. (2023) to be approximately seven orders of magnitude lower from chronic exposure to 222 nm than from exposure to 300 nm or 254 nm. This assessment is based on measurements of UV transmission of the skin at wavelengths above 235 nm (Yamano et al. 2021), however, whereby the transmission for wavelengths below 235 nm was outside the measurement range and therefore could only be estimated.

A number of experimental in vitro and in vivo studies have been conducted into the effect of far-UVC radiation on human skin (e.g. Buonanno et al. 2017, Hickerson et al. 2021, Fukui et al. 2020, Buonanno et al. 2021a, Zwicker et al. 2022, Tavares et al. 2023) and the skin of hairless mice (e.g. Buonanno et al. 2016, Yamano et al. 2020, Forbes et al. 2021). Although much higher doses were used here than would be permissible for human exposure, the vast majority of the studies revealed no measurable negative effects and no evidence of the induction of skin cancer (Welch et al. 2023, Blatchley et al. 2023).

In a study from 2015 (Woods et al. 2015), signs of skin redness and CPD were found in two of four healthy subjects with skin phototypes I and II. An unfiltered UVC lamp with a peak wavelength of 222 nm was used here in the dose range below the threshold for the bacteriostatic effect. The UV emission portion in the wavelength range > 250 nm was 3%. Any damage to the cells in the basal cell layer is attributed by the authors to this exposure to the elements of

longwave UVC emission when basal cells lying above the tips of the dermal papillae³ (see Figure 3.4) were not shielded sufficiently by the tissue above. This study was repeated with similar and higher doses by Fukui et al. (2020) using optically filtered radiation from excimer lamps with no UVC emissions above 230 nm (UVC₂₂₂). No signs of erythema could be observed here. However, a small but significant increase in CPD was found, compared to non-irradiated skin. Eadie et al. (2021) also found no cutaneous effect from exposing human skin type II on the forearm to a cumulative dose of UVC₂₂₂ radiation of 1,500 mJ cm⁻². Only an irradiation dose of 6,000 mJ cm⁻² resulted in a weak and transient yellowish discolouration of the exposed top layer of the epidermis. In this case, no erythema was noted at exposures up to 18,000 mJ cm⁻². CPD were not investigated. Using an in vivo skin model (EpiDerm), Buonanno et al. (2021a) found no significant increase in premutagens (CPD) or other DNA lesions after applying 125 mJ cm⁻² of filtered far-UVC radiation; only at an exposure of 500 mJ cm⁻² was a slight increase observed. Yamano et al. (2020) applied a far-UVC radiation dose (UVC₂₂₂ radiation) of 500 mJ cm⁻² to two genotypes of hairless mice that are highly susceptible to carcinogenesis. Weak evidence of increased premutagenic lesions was found in these mice, but only in the uppermost cells of the epidermis. This result has been verified by in vivo studies in human skin (Hickerson et al. 2021). Zwicker et al. (2022) demonstrated that irradiation of excised human skin with 40 mJ cm⁻² in the UVC₂₃₃ range resulted in CPD formation directly beneath the stratum corneum and that no CPD could be detected after 24 h. Attention was drawn to the fact that acute damage to the superficial layers of the epidermis plays no role in the delayed effects, as these cells die within a few days. In a recent study by Tavares et al. (2023), examination of reconstructed human skin (RHS) after a single radiation dose of 500 mJ cm⁻² and 1,500 mJ cm⁻² UVC₂₂₂ revealed no significant induction of CPD or 6-4PP photoproducts. However, thickening of the epidermis was observed 48 hours after irradiation with the highest dose. When examining the proteome, a pathway analysis showed no changes for most pathways compared to the untreated control. Only for regeneration processes of the skin were there indications of potential inhibition after irradiation with UVC₂₂₂. However, in the RHS specimens irradiated with UVC₂₂₂, increased expression of matrix metalloproteinases MMP-1 and MMP-9, which are associated with UV-induced skin ageing, was noted. In parallel, expression of the inhibitor of these metalloproteinases (TIMP-1) was found to be increased. Together with induction of ROS, which was also detected, radiation effects induced by UVC₂₂₂ were then observed in RHS. In mice subjected to chronic irradiation, there were again no radiation-induced structural, histological changes after 40 days of daily exposure to eight-hours of radiation (25 mJ cm⁻² UVC₂₂₂). In the study of matrix metalloproteinases, only the expression of MMP-9 was found to be slightly increased. Neither acute nor chronic irradiation with UVC₂₂₂ resulted in DNA damage.

The results of the first study for estimating the risk of skin cancer and non-cancerous skin lesions from long-term exposure (15.2 months) to UVC₂₂₂ revealed no signs of an increased risk of skin cancer in hairless mice (Welch et al. 2023). The 96 animals kept in groups were exposed to eight hours of inhomogeneous irradiances daily, five days per week (doses of 55 mJ cm⁻² to 400 mJ cm⁻²), for 66 weeks. A film dosimeter (OrthoChromic Film OC-1) was used in the study to measure the doses. The authors also found no evidence of an increase in non-cancerous skin lesions from far-UVC radiation.

³ The epidermis and dermis are interlinked. The protrusions of the epidermis into the dermis are referred to as rete ridges. The protrusions of the dermis into the epidermis are called dermal papillae. The uppermost tips of the dermal papillae protrude far into the epidermis so that the basal cells above can come very close to the surface of the skin (cf. Figure 3.4).

Since effects in the skin associated with exposure to far-UVC radiation are largely dependent on the stratum corneum thickness (SCT), consideration must be given to the fact that the SCT does not differ significantly between individuals with normal and sensitive skin (Richters et al. 2017) and is generally not dependent on sex, lineage/ancestry and age, whereby the skin of elderly subjects (average age 50 years) was compared in this case with skin of younger subjects (average age 29 years) (Tagami 2017). There are no statistically significant differences in SCT between individuals with skin cancer and people who are healthy (Lock-Andersen et al. 1997). In infants, however, the stratum corneum is 30% thinner and the epidermis 20% thinner than in adults. The corneocytes are 20% and the cells of the granular layer 10% smaller than those in adults, suggesting faster cell turnover in infants. The density and size distribution of the papillae in the skin also vary. A pronounced direct structural relationship between the morphology of the stratum corneum and the dermal papillae was observed only in the skin of infants (Stamatas et al. 2010).

So far, no robust data is available concerning the effects of regular or prolonged exposure to far-UVC radiation, e.g. of injured or damaged skin or in vulnerable populations such as children (BfS 2022).

3.4.4 Studies into the effect of far-UVC radiation on the eyes

Exposure of the human eye to UVB and UVA radiation has been thoroughly investigated in laboratory and epidemiological studies and an association with age-related diseases of the anterior segment of the eye such as pterygium (Threlfall and English 1999), droplet keratopathies (Gray et al. 1992) and cortical cataracts (Threlfall and English 1999) established. There is also evidence of a relationship between UVC and UVB radiation and corneal inflammation (photokeratitis) as well as conjunctivitis (photoconjunctivitis) from acute exposure, and skin tumours in the eyelids (basal cell carcinoma and squamous cell carcinoma) and malignant melanomas of the eyelids and conjunctiva from long-term exposure (Hampel et al. 2022). Intense exposure to UV radiation causes 80% of basal cell carcinomas in the head and neck area, of which approximately one fifth are found in the eyelids (Shi et al. 2017). The most common form of malignant eyelid tumour is basal cell carcinoma, accounting for around 90% of cases. The proportion of eye tumours with metastatic potential, is 5%-10% for squamous cell carcinoma of the eyelids, 1%-5.5% for sebaceous gland carcinoma, < 1% for melanoma and approx. 0.5% for Merkel cell carcinoma (Gniesmer et al. 2023).

The effects of exposing the eye to radiation at wavelengths below 254 nm have been examined in only few studies to date (Sliney et al. 1991, Kaidzu et al. 2019, Pitts 1974, Pitts and Tredici 1971, Sugihara et al. 2023). The threshold for photokeratitis in the rabbit cornea was determined by Sliney et al. (1991) at a wavelength of 193 nm using an excimer laser. The authors conclude that the penetration depth of the applied shortwave radiation in the epithelial cell layer is limited and an intact tear film can help protect the cornea against the weak scattered laser radiation. Pitts and Tredici (1971) found that the cornea is most sensitive to UV radiation of 270 nm and reacts with symptoms of photokeratitis. With the aid of slit-lamp biomicroscopy, staining and surface mapping, Kaidzu et al. (Kaidzu et al. 2019, Kaidzu et al. 2021) determined thresholds for photokeratitis on a rat eye model 24 hours after exposure to four UVC wavelengths (207 nm, 222 nm, 235 nm and 254 nm) and one wavelength in the UVB spectral range (311 nm). An effect on the cornea was detected here for 207 nm and 222 nm above the threshold values of 15,000 mJ cm⁻² and 5,000 mJ cm⁻² respectively. Such exposures far exceed the exposure limits that are currently applicable (about 300 and 220 times higher, respectively). Kaidzu et al. (Kaidzu et al. 2019, Kaidzu et al. 2021) also performed a histological assessment of the cornea using CPD as a marker for DNA damage. The depth of the observed CPD varied with the wavelength; at 207 nm and 222 nm, the CPD marker was only found in the upper superficial cells, which are shed within a few days during the normal life cycle of the corneal epithelium.

In the eye, the cells of the cornea that are susceptible to cancer are found in the limbus, i.e. the transition zone between the cornea and the dermis (sclera). UV radiation reaches the corneal endothelium at a wavelength of 311 nm and 254 nm, the middle section of the corneal stroma at 235 nm, and the outer portion of the corneal epithelium at 222 nm and 207 nm (Kaidzu et al. 2019, Kaidzu et al. 2021). Even in the cornea of pigs, which is similar in size and structure to that of the human eye, UVC radiation at a wavelength of 222 nm only reached the superficial layer of the limbal epithelium; consequently, it is also assumed here that there are no harmful effects on stem cells in the basal portion of the corneal limbus (Kaidzu et al. 2023). The thresholds for corneal injuries from far-UVC radiation reported by Kaidzu et al. (Kaidzu et al. 2019, Kaidzu et al. 2021) are significantly higher than those reported by Pitts, who compared exposure data from 39 human eyes against data from rabbits and primates (Pitts 1974).

In a study with six subjects exposed to UVC₂₂₂ radiation for about 6.7 hours per week for 12 months, Sugihara et al. (2023) observed no acute or chronic eye damage. The applied dose of about 2.8 mJ cm⁻² per day did not exceed the EL of 22.7 mJ cm⁻² at 222 nm for protecting the eyes against actinic UV hazards (see section 3.5.1). Since effects on the cornea in conjunction with exposure to far-UVC radiation also depend on tear film thickness, it is important to note that no significant interindividual difference was found in the thickness of the mucoaqueous tear film or the lipid tear film between healthy subjects and patients with dry eye in a study of tear film thickness involving 49 subjects (Segev et al. 2020). According to Masoudi (2022), further investigation of the “normal” tear profile and the functionality of the tear film that depends on this profile would require the participation of a broad spectrum of sample populations, whereby age, ethnicity, sex, geographical and environmental parameters would need to be considered.

Conclusion drawn from the skin and eye studies

In healthy human skin, far-UVC radiation only reaches as far as the outermost layer, which consists of dead cells (corneal layer, stratum corneum). The prerequisite is that longer-wave radiation is reliably filtered out. With filtered UVC₂₂₂ radiation, premutagenic lesions were only detected in the uppermost cells of the epidermis, which in any case are shed within a few days. A prerequisite for the protective effect is a well-established, intact corneal layer, the thickness of which can also vary depending on age and is still very thin in infants. Studies to date have shown that the suprabasal cells and cells of the basal layer of the human epidermis are not damaged. Concerning the thickness of the corneal layer, the available data does not produce any evidence of the existence of significant subgroups of people who are systematically more susceptible to UVC exposure than the average population according to age, sex, health status and genetics. In accordance with mouse studies, it is therefore assumed that the risk of skin cancer from far-UVC radiation is not increased. However, no epidemiological studies into skin carcinogenesis from UVC radiation are available to date.

Concerning the effect of far-UVC radiation on the eye, only few studies are available. Unlike the skin, the outermost layer of the cornea also contains intact epithelial cells. The tear film above the corneal epithelium absorbs only a minimal amount of far-UVC radiation; hence, an intact tear film offers only very limited protection. So far, animal studies have not demonstrated that far-UVC radiation damages the deeper cells.

When assessing the effects of far-UVC radiation on the skin and eyes and thus its use in the presence of humans, the lack of robust data on the effects of regular or prolonged exposure to far-UVC radiation, e.g. on injured or damaged skin or in vulnerable populations such as children, must be taken into account. Nevertheless, due to the intense absorption of far-UVC radiation by proteins and possibly by ROS formation, harmful effects cannot be ruled out. This activity could affect the proteins of the tear fluid in the eye in particular and thus have health

consequences, e.g. in terms of immunological protection against pathogens (Masoudi 2022). There has been little study so far into the damage caused to proteins by far-UVC radiation and the resultant, potential inhibiting effect on enzymatic processes. Research is needed to this end (see Chapter 4). In addition to the potential harmful effects on cells, the influence of far-UVC radiation on the microbiome of the skin and eyes must also be investigated.

It should be stressed that conflicts of interest were declared in many publications which address the effect of far-UVC radiation on the skin (5 out of 11 studies) and eyes (all studies) (see Table 3.2 and Table 3.3). The SSK is therefore concerned that the conclusions drawn are subject to bias.

Table 3.2: Studies into the effect of UVC radiation on the skin.

Publication	Object of study	UV source/wavelength	Radiant exposure H (dose)	Effect		
				DNA damage		Other endpoints
				CPD	6-4PP	
Fukui et al. 2020 *	Test subjects, one area on the back	KrCl excimer lamp/222 nm, filtered	500 mJ cm ⁻²	Small but significant increase in CPD		No signs of erythema
Eadie et al. 2021	In vivo, skin type II on the Fitzpatrick scale, inner forearms of one subject (self-tests)	KrCl excimer lamp/222 nm, filtered	1,500 mJ cm ⁻² (irradiance 6.1 mW cm ⁻²)			No skin change visible
			6,000 mJ cm ⁻² (irradiance 6.1 mW cm ⁻²)			Yellowing of the skin, reversed within 24 h
			Up to 18,000 mJ cm ⁻² (irradiance 6.1 mW cm ⁻²)			No erythema
Buonanno et al. 2021a *	In vitro 3D model of human skin, EpiDerm-FT	KrCl excimer lamp/222 nm, filtered	23 mJ cm ⁻² to 150 mJ cm ⁻² (irradiance 0.59 mW cm ⁻²)	No significant increase in CPD	No significant increase in 6-4PP	
			500 mJ cm ⁻² (irradiance 0.59 mW cm ⁻²)	Small but statistically significant increase in CPD in the uppermost epidermal layer	No significant increase in 6-4PP	
		KrCl excimer lamp/222 nm, unfiltered	23 mJ cm ⁻² to 500 mJ cm ⁻² (irradiance 0.85 mW cm ⁻²)	CPD formation	Formation of 6-4PP	

* The authors declare a conflict of interest.

Yamano et al. 2020 *	Two genotypes of hairless albino mice (wild type and photosensitive <i>Xpa</i> knockout type)	KrCl excimer lamp/222 nm, filtered	Wild type: 500 mJ cm ⁻² , radiation 3 times a week; <i>Xpa</i> knockout type: 50 mJ cm ⁻² and 100 mJ cm ⁻² , radiation twice a week (duration 10 weeks, irradiance 1 mW cm ⁻²)			No skin tumours or corneal damage after 15 weeks of observation
			Both genotypes 500 mJ cm ⁻²	CPD formation in the outermost layer of the epidermis		No erythema or ear swelling
Hickerson et al. 2021	Full ex vivo human skin model	KrCl excimer lamp/222 nm, filtered	6,100 mJ cm ⁻² (radiation duration 1,000 s)	Minimal CPD formation, limited to the upper layer of the epidermis		
		Narrowband UVB lamp/maximum emission at 311 nm	515 mJ cm ⁻² (radiation duration 188 s)	CPD formation throughout the epidermis		
	In vivo, forearms of two subjects (study authors)	KrCl excimer lamp/222 nm, filtered	6,100 mJ cm ⁻²	Minimal CPD formation, limited to the upper layer of the epidermis and few CPD-positive cells in the subjects with thicker stratum corneum		
Zwicker et al. 2022	Excised human skin/reconstructed equivalents of human skin	KrCl excimer lamp/222 nm, filtered above 230 nm	40 mJ cm ⁻² (irradiance 3.34 mW cm ⁻²)	(0.5±0.5)% CPD-positive keratinocytes		
		KrCl excimer lamp/222 nm, filtered above 230 nm	80 mJ cm ⁻² (irradiance 3.34 mW cm ⁻²)	Not observed	Not observed	
		LED array/233 nm, FWHM 12 nm filtered above 240 nm	20 mJ cm ⁻² to 60 mJ cm ⁻² (irradiance 0.041 mW cm ⁻²)	Negligible (on the surface directly beneath the stratum corneum)		

* The authors declare a conflict of interest.

		LED array/ 233 nm, FWHM 12 nm filtered above 240 nm	80 mJ cm ⁻² (irradiance 0.041 mW cm ⁻²)	(18.3±3.0)% CPD- positive keratinocytes (on the surface directly beneath the stratum corneum)		
		Mercury vapour lamp/ 254 nm	40 mJ cm ⁻² (irradiance 0.54 mW cm ⁻²)	(44.2±3.7)% CPD- positive keratinocytes (as far as the basal cells)	(21.5±1.9)%	
		UVB lamp with a small UVA component/280 nm- 400 nm	3 mJ cm ⁻² (irradiance 0.041 mW cm ⁻²)	94% CPD-positive keratinocytes (as far as the basal cells)		
Tavares et al. 2023	Reconstructed human skin (RHS) in vitro	KrCl excimer lamp/222 nm, filtered	1,500 mJ cm ⁻²	No significant induction of CPD	No significant induction of 6-4PP	Detachment of stratum corneum and thickening of epidermis 48 hours post irradiation Induction of ROS Possible inhibition of skin regeneration processes Increased expression of matrix metalloproteinases MMP-1 and MMP-9 Intensified expression of the inhibitor of these metalloproteinases (TIMP-1)
		Mercury vapour lamp/ 254 nm				Detachment of stratum corneum and granular layer 48 hours post irradiation Increased expression of matrix metalloproteinases MMP-1 and MMP-9 Strong induction of ROS

	In vivo HRS/J mouse model	KrCl excimer lamp/222 nm, filtered	1,500 mJ cm ⁻²	No significant induction of CPD	No significant induction of 6-4PP	Mild skin damage No histological changes Slightly increased expression of MMP-9
		Mercury vapour lamp/254 nm		Induction of CPD	Induction of 6-4PP	
		KrCl excimer lamp/222 nm, filtered	25 mJ cm ⁻² per day, duration 40 days			No sunburn or desquamation of the skin on the back Expression of MMP-9, though less effective than at 254 nm Strong induction of ROS
		Mercury vapour lamp/254 nm	6 mJ cm ⁻² per day, duration 40 days			No sunburn or desquamation of the skin on the back Increased expression of MMP-9 Induction of ROS
Welch et al. 2023	Hairless SKH-1 albino mice	KrCl excimer lamp/222 nm, filtered	Mean doses of 55 mJ cm ⁻² to 130 mJ cm ⁻² and 400 mJ cm ⁻² (inhomogeneous) 8 hours daily, 5 days per week for 66 weeks (15.2 months)			No skin cancer and no non-carcinogenic skin lesions
Buonanno et al. 2016 *	Hairless mice	KrBr eximer lamp/207 nm, filtered	157 mJ cm ⁻² (irradiation duration 7 h)	CPD not significantly increased	6-4PP dimers not significantly increased	Epidermal thickness – no difference compared to the skin of unexposed mice Skin tissue differentiation – no statistical difference compared to unexposed skin

* The authors declare a conflict of interest.

		Mercury vapour lamp/ 254 nm		35-fold increase in CPD	26-fold increase in 6-4PP dimers	2.8-fold increase in average epidermal thickness Differentiation of keratinocytes – 3-fold increase in K6A synthesis
Buonanno et al. 2017 *	Hairless mice	KrCl excimer lamp/222 nm, filtered	157 mJ cm ⁻² (irradiation duration 7 h)	CPD not significantly increased	6-4PP dimers not significantly increased	Epidermal thickness – no statistical difference compared to unexposed mice Differentiation of keratinocytes – no statistical difference compared to unexposed skin
		Mercury lamp/ 254 nm	157 mJ cm ⁻² (irradiation duration 7 h)	CPD increased	6-4PP dimers increased	Average epidermal thickness increased Differentiation of keratinocytes – 3-fold increase in K6A synthesis
	In vitro 3D model of human skin, EpiDerm-FT	KrCl excimer lamp/222 nm, filtered	Up to 150 mJ cm ⁻²	CPD not significantly increased	6-4PP dimers not significantly increased	
		Mercury lamp/ 254 nm		CPD increased	6-4PP dimers increased	
Ong et al. 2022	Human cell cultures (HEK-A keratinocytes and ARPE-19 retinal cells)	KrCl excimer lamp/222 nm, filtered	60 min (irradiance 73 µW cm ⁻²)	None		Cells retained their ability to grow without activating apoptosis. However, a dose- dependent reduction in cell viability was noted. Tumour suppression was down-regulated one to three days after exposure.
		Mercury vapour lamp/ 254 nm		CPD formation		Cell death induced by apoptosis
		LED/ 277 nm, 5x5 array		CPD formation		Cell death induced by apoptosis

* The authors declare a conflict of interest.

Table 3.3: Studies into the effect of UVC radiation on the eye.

Publication	Object of study	UV source/wavelength	Radiant exposure H (dose)	Effect	
				Eye damage	CPD
Kaidzu et al. 2019 *	Albino rats	KrCl excimer lamp/222 nm, filtered	30 mJ cm ⁻² 150 mJ cm ⁻² 600 mJ cm ⁻² (irradiance 5.7 mW cm ⁻²)	No corneal damage	
		Mercury vapour lamp/ 254 nm	30 mJ cm ⁻² (irradiance 1.1 mW cm ⁻²)	No corneal damage	
			150 mJ cm ⁻² (irradiance 1.1 mW cm ⁻²)	Keratitis	
			600 mJ cm ⁻² (irradiance 1.1 mW cm ⁻²)	Corneal erosion	
Kaidzu et al. 2021 *	Albino rats	KrBr eximer lamp/207 nm, filtered	30 mJ cm ⁻² to 15,000 mJ cm ⁻² (irradiance 0.83 mW cm ⁻²)	Corneal damage above 15,000 mJ cm ⁻²	Only in the uppermost layer of the cornea
		KrCl excimer lamp/222 nm, filtered	30 mJ cm ⁻² to 5,000 mJ cm ⁻² (irradiance 4.2 mW cm ⁻²)	Corneal damage above 5,000 mJ cm ⁻²	Only in the uppermost layer of the cornea
		Xenon lamp/ 235 nm, filtered	10 mJ cm ⁻² to 300 mJ cm ⁻² (irradiance 0.077 mW cm ⁻²)	Corneal damage above 300 mJ cm ⁻²	In the cells of the middle layers of the corneal epithelium
		Mercury vapour lamp/ 254 nm	10 mJ cm ⁻² to 300 mJ cm ⁻² (irradiance 1.3 mW cm ⁻²)	Corneal damage above 20 mJ cm ⁻²	In all cells of the cornea
		Narrowband UVB lamp/311 nm	30 mJ cm ⁻² to 600 mJ cm ⁻² (irradiance 2.3 mW cm ⁻²)	Corneal damage above 600 mJ cm ⁻²	In all cells of the cornea

* The authors declare a conflict of interest.

Kaidzu et al. 2023 *	Albino rats **	KrBr excimer lamp/207 nm, filtered	1,500 mJ cm ⁻² (irradiance 0.18 mW cm ⁻² – 0.25 mW cm ⁻²)		No CPD-positive cells in the basal cells of the limbus
			2,500 mJ cm ⁻² (irradiance 0.25 mW cm ⁻²)		Weakly CPD-positive cells in the limbus
			10,000 mJ cm ⁻² (irradiance 0.86 mW cm ⁻² – 0.91 mW cm ⁻²)		Strong CPD-positive cells throughout the limbus, including the basal cells
		KrCl excimer lamp/222 nm, filtered	1,500 mJ cm ⁻² (irradiance 4.2 mW cm ⁻² – 5.0 mW cm ⁻²)		Slightly stronger CPD-positive cells in the upper layer
			2,500 mJ cm ⁻² (irradiance 4.2 mW cm ⁻²)		Moderately CPD-positive cells throughout the limbus
			5,000 mJ cm ⁻² (irradiance 4.2 mW cm ⁻²)		Strong CPD-positive cells throughout the limbus, including the basal cells
		Xenon lamp/ 235 nm, filtered	30 mJ cm ⁻² (irradiance 0.079 mW cm ⁻² – 0.16 mW cm ⁻²)		Weak CPD-positive cells as far as the middle layer
			300 mJ cm ⁻² (irradiance 0.11 mW cm ⁻² – 0.17 mW cm ⁻²)		Cells in the upper layer with even stronger CPD positivity
			600 mJ cm ⁻² (irradiance 0.082 mW cm ⁻²)		Cells in the middle layer with strong CPD positivity and cells in the basal layer with weak CPD positivity
		Mercury vapour lamp/ 254 nm	20 mJ cm ⁻² (irradiance 1.1 mW cm ⁻²)		Cells in the middle layer with strong CPD positivity, basal cells with weak CPD positivity

* The authors declare a conflict of interest.

** CPD in upper limbus 24 hours post irradiation

			100 mJ cm ⁻² (irradiance 1.1 mW cm ⁻²)		All cells in the limbus CPD-positive, also the basal cells
			300 mJ cm ⁻² (irradiance 1.1 mW cm ⁻²)		Cells with even stronger CPD positivity
		Narrowband UVB lamp/ 311 nm	30 mJ cm ⁻² (irradiance 2.0 mW cm ⁻² – 2.3 mW cm ⁻²)		No CPD-positive cells
			150 mJ cm ⁻² (irradiance 2.0 mW cm ⁻² – 2.3 mW cm ⁻²)		CPD-positive cells in the middle layer and in the basal cell layer
			600 mJ cm ⁻² (irradiance 2.0 mW cm ⁻² – 2.3 mW cm ⁻²)		CPD-positive cells throughout the limbus
	Pigs' eyes ***	KrCl excimer lamp/222 nm, filtered	600 mJ cm ⁻² (radiation duration 120 s)		CPD-positive cells in the uppermost layer
		Mercury vapour lamp/ 254 nm	600 mJ cm ⁻² (radiation duration 546 s)		CPD-positive cells in the upper layer and 50 µm-100 µm deep, but not in the basal layer
Sugihara et al. 2023 *	Human (6 subjects, 5 of whom wore glasses)	KrCl excimer lamp/222 nm, filtered	The lamps were alternately on for 200 s and off for 1,600 s. Maximum irradiance on the subjects' eyes 0.002 mW cm ⁻² 12 months, mean length of stay 6.7 h per week (approx. 1 h per day, irradiation 2.8 mJ cm ⁻² per day)	No acute or chronic effects	

* The authors declare a conflict of interest.

*** CPD in limbus immediately after irradiation

3.5 Protection against the risks of UV radiation from artificial sources

3.5.1 Exposure limits recommended by the ICNIRP for protecting the eyes and skin against actinic UV hazard

The ICNIRP analyses and evaluates the scientific data available on the health effects of non-ionising radiation – both optical radiation and electromagnetic fields. When drawing up recommendations, the Committee respects the principles upon which protective measures should be based while leaving the responsibility for issuing appropriate regulations and specifications for use to the various international and national authorities and institutions. The exposure limits recommended in the ICNIRP Guidelines form the foundation for various European directives, such as EU Directive 2006/25/EC on the protection of workers against the risks arising from artificial optical radiation (EG 2006).

In its 2004 guidelines, the ICNIRP (ICNIRP 2004) published recommendations for ELs to protect the eyes and skin from the harmful effects of incoherent UV radiation from artificial and natural sources. The recommendations were limited to wavelengths above 180 nm – UV radiation at wavelengths below 180 nm was considered to be of only little practical biological relevance, as it is already absorbed in the air (see section 3.1.1).

The recommended ELs apply to the risks from eight hours of exposure to UV radiation. The ICNIRP stresses that the recommended ELs are intended to protect workers and that, with due caution, they could be applied to the general population. However, they cannot be used to protect overly photosensitive individuals or individuals exposed to photosensitising substances. Furthermore, the ELs apply to continuous and pulsed incoherent UV radiation if the duration of exposure is not less than 1 µs.

The action spectrum specified by the ICNIRP for the wavelength range of 180 nm to 400 nm ($S(\lambda)$) with a view to actinic UV hazard to the eyes and skin (Figure 3.6) defines the effective irradiance E_{eff} that can be used to assess a risk to the eyes and skin and is given by the following formula:

$$E_{\text{eff}} = \sum_{\lambda=180 \text{ nm}}^{\lambda=400 \text{ nm}} E_{\lambda}(\lambda) \cdot S(\lambda) \cdot \Delta\lambda, \quad (1)$$

Whereby

$E_{\lambda}(\lambda)$ is the measured spectral irradiance,
 $S(\lambda)$ the action spectrum for actinic UV hazard, and
 $\Delta\lambda$ the increment of the measurement.

If the irradiance remains constant during the period in question t , the effective radiant exposure H_{eff} can be calculated:

$$H_{\text{eff}} = E_{\text{eff}} \cdot t \quad (2)$$

To protect the eyes and the skin from actinic UV hazard, an EL for effective radiant exposure H_{eff} of

$$H_{\text{eff}} = 30 \text{ J m}^{-2} \quad (3)$$

is recommended at wavelengths between 180 nm and 400 nm. This EL applies to single or repeat exposures during an eight-hour period (30,000 s). The permissible exposure duration

$t_{\max}$ depending on E_{eff} for periods of less than 30,000 s can be calculated using the following formula:

$$t_{\max} = \frac{30 \text{ J m}^{-2}}{E_{\text{eff}}} \quad (4)$$

Table 3.4 provides a list of the ELs of effective radiant exposure H_{eff} for various wavelengths of monochromatic radiation sources and the action spectrum $S(\lambda)$ in the wavelength range between 180 nm and 280 nm. Figure 3.7 shows the ELs from the ICNIRP Guidelines for protecting the eyes and skin from the actinic UV hazard for monochromatic radiation sources.

Table 3.4: *Excerpt of the action spectrum for actinic UV hazard $S(\lambda)$ in the wavelength range of 180 nm to 280 nm (according to ICNIRP 2004, supplemented by the wavelengths 207 nm, 222 nm and 233 nm according to DIN 5031-10:2018-03) as well as examples of ELs of effective radiant exposure H_{eff} for monochromatic radiation sources (in mJ cm^{-2})*

$\lambda [\text{nm}]$	$S(\lambda)$	E [mJ cm^{-2}]
180	0.012	250
190	0.019	160
200	0.030	100
207	0.0606	49.5
210	0.075	40
220	0.120	25
222	0.132	22.7
230	0.190	16
233	0.220	13.6
240	0.300	10
250	0.430	7
254	0.500	6
260	0.650	4.6
270	1.000	3.0
280	0.880	3.4

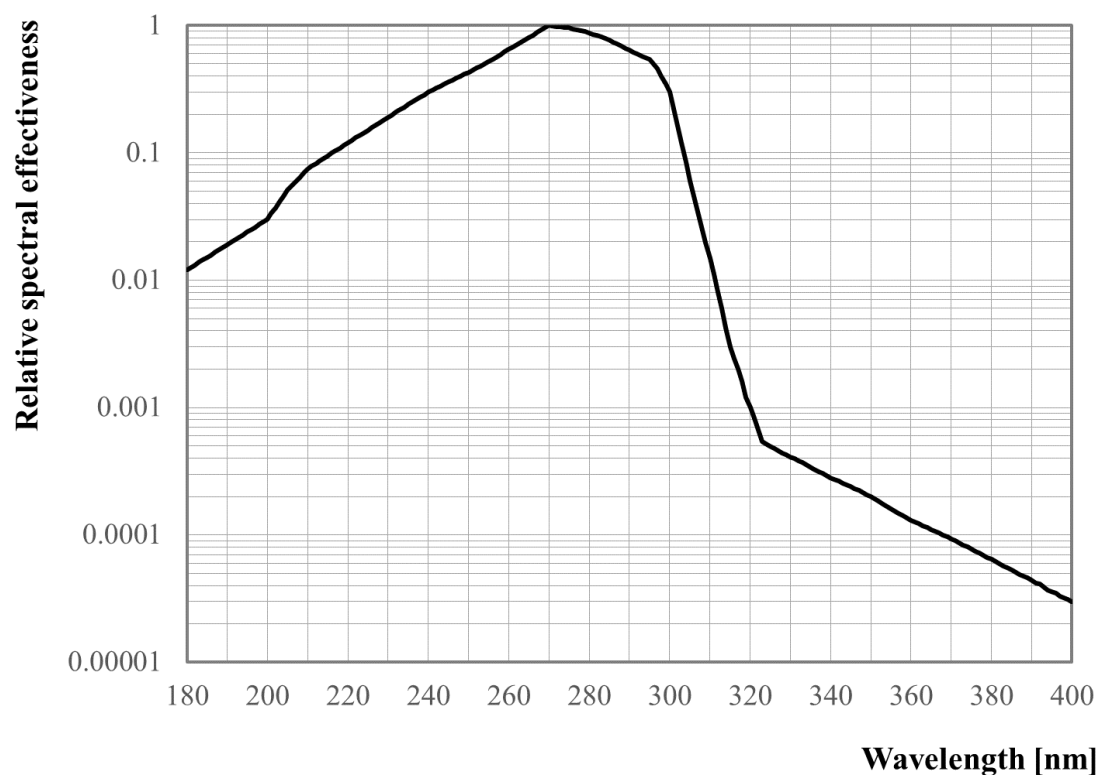


Figure 3.6: Relative action spectrum $S(\lambda)$ for the risks to the eyes and skin from UV radiation according to ICNIRP 2004. The maximum of the action spectrum is at 270 nm and is normalised to 1.

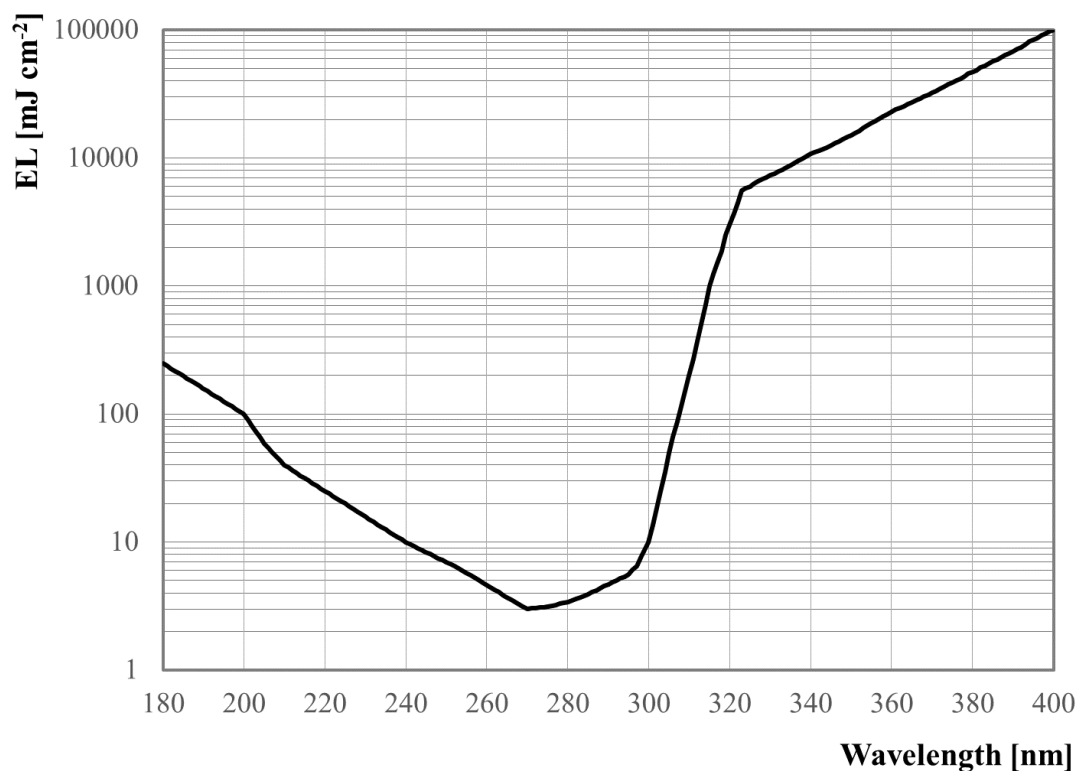


Figure 3.7: ELs of the ICNIRP Guidelines for monochromatic radiation sources (ICNIRP 2004, refer to Table 1 therein) to protect the eyes and skin against the actinic UV hazard.

3.5.2 Legal regulations concerning incoherent UV radiation from artificial sources

With the passing of European Directive 2006/25/EC (EG 2006), the minimum requirements were established in the EU Member States for protecting workers against the risks of exposure to artificial optical radiation at work. The Directive contains the ELs for exposure to incoherent optical radiation and laser radiation. The ELs are defined as the maximum permissible values for exposure of the eyes or the skin to artificial optical radiation and are based on the guidelines published by the ICNIRP, in the case of incoherent UV radiation on the 2004 ICNIRP Guidelines (ICNIRP 2004). The ELs for incoherent optical radiation are listed in Annex I of EU Directive 2006/25/EC (EG 2006). While the Directive lays down the minimum requirements for protecting workers, when implementing them nationally the EU Member States may also retain or pass more stringent requirements, especially lower ELs.

EU Directive 2006/25/EC (EG 2006) has been transposed into German law in the form of the Occupational Safety and Health Ordinance on Artificial Optical Radiation (OStrV) (OStrV 2010). The provisions of the OStrV apply not only to workers but also to pupils, students and other individuals working in educational institutes who are exposed to artificial optical radiation while pursuing their activities. A general regulation to protect the general population does not exist, however.

The OStrV (OStrV 2010) makes reference to the ELs for incoherent UV radiation that are contained in the annexes to EU Directive 2006/25/EC (EG 2006). The national transposition of the EU Directive in the form of the OStrV means that the ELs specified in the directive are also legally binding in Germany.

The OStrV (OStrV 2010) contains the essential requirements for the protection of workers against risks from artificial optical radiation but is not sufficiently specific to enable a risk assessment to be conducted in operational practice and establish appropriate protective measures.

Technical Rules on the Occupational Safety and Health Ordinance on Artificial Optical Radiation (TROS) have therefore been developed to specify the requirements of the OStrV, e.g. for incoherent optical radiation (TROS IOS 2013). Application of TROS IOS provides the employer with legal certainty, as it triggers what is referred to as the presumption of conformity: On applying TROS IOS, it can be assumed that, in terms of incoherent optical radiation, the provisions of the OStrV and the specified ELs are met.

If workers are exposed to UV radiation from artificial sources in the workplace, the employer must assess all the risks relating to the employee health and safety. The employer must determine and evaluate the exposure from artificial optical radiation. There is a potential risk to workers if the ELs could be exceeded. Manufacturer data can be used in the risk assessment, e.g. by categorising risk groups in accordance with standard DIN EN 62471 “Photobiological safety of lamps and lamp systems” (DIN EN 62471:2009) (see section 3.5.3).

Appropriate protective measures should be established in the event that ELs are exceeded. Replacement with less hazardous procedures or equipment is most important in this case, followed by technical protective measures which are to be prioritised over organisational measures. Personal protective equipment must only be used if technical and organisational measures are insufficient or cannot be implemented. The employer must identify the areas of work in which the ELs may be exceeded. If workers are at risk, the employer must ensure that the workers in question receive instruction based on the outcome of the risk assessment. Such instruction must be provided prior to commencing the activity and at regular intervals thereafter, but once a year as a minimum.

3.5.3 Risk groups according to DIN EN 62471 lamp safety standard

The internationally valid standard IEC 62471:2006 “Photobiological safety of lamps and lamp systems” (IEC 62471:2006), which has been adopted unchanged in the national German standard DIN EN 62471 (DIN EN 62471:2009), describes how to assess the photobiological safety of artificial sources of incoherent optical radiation.

In Germany, product safety is regulated by the Act on Making Products Available on the Market (Product Safety Act - ProdSG 2021). European Directive 2001/95/EC on General Product Safety (EG 2001) was transposed into national law with this act. The ProdSG is of great importance both to protecting consumers and to occupational safety and covers a wide range of products, including lamps and lamp systems. According to the ProdSG, manufacturers, importers and distributors may only place products on the market which are so designed that their intended or foreseeable use cannot endanger personal safety and health. Various European directives have been transposed into German law in the ProdSG, including the Low Voltage Directive 2014/35/EU (EU 2014).

The manufacturer of a product designated for the internal European market must conduct a conformity assessment in accordance with Directive 2001/95/EC (EG 2001) to confirm the safety of the product. In the conformity assessment, the safety requirements of the EU directives must be adhered to. As these directives are mostly worded in general terms, specific technical requirements must be derived from regulations that reflect the generally recognized rules of technology. Presumption of conformity exists in particular if harmonised standards have been applied by the manufacturer. These are European standards compiled by European standardization organisations on behalf of the European Commission. The harmonisation of standards is announced in the Official Journal of the European Union. All harmonised European standards must be implemented as national standards. The harmonised product standards are listed under the EU directives. E.g. lamp safety standard DIN EN 62471 (DIN EN 62471:2009) is a harmonised product safety standard listed under the Low Voltage Directive 2014/35/EU (EU 2014).

Since the manufacturer does not know the future exposure conditions (distance from source, exposure duration), the assessment is based on the emission of a lamp. According to the standard DIN EN 62471 (DIN EN 62471:2009), these are subject to emission limits (maximum permissible effective irradiance at a certain distance), which relate to specified exposure duration.

Lamps are classified into different risk groups according to their risk potential. Each risk group is assigned maximum foreseeable exposure durations at a reference distance, which differ depending on the nature of the photobiological risk. The higher the risk group, the shorter the permitted exposure duration. The emission limits derived from the maximum permissible irradiation duration of the risk groups (effective irradiances) have been determined using the equation 4 (see section 3.5.1) based on the ICNIRP recommendations published in the relevant standardisation body. The emission limits for continuous-wave lamps in accordance with DIN EN 62471 (DIN EN 62471:2009) for protecting the eyes and skin from actinic UV hazard and the corresponding exposure durations for the risk groups are shown in Table 3.5. The reference distance for UVC sources is 20 cm.

Table 3.5: *Maximum exposure durations and resulting emission limits for continuous-wave lamps to protect against actinic UV hazard for risk groups according to DIN EN 62471 (DIN EN 62471:2009). If the emission limit for risk group 2 is exceeded, the UV source is assigned to risk group 3.*

Photobiological hazard	Emission limit/ exposure duration	Risk group 0 (free group)	Risk group 1	Risk group 2
Actinic UV hazard	Effective irradiance [mW cm^{-2}]	0.0001	0.0003	0.003
	Exposure duration [s]	30,000 (8 h)	10,000 (2.78 h)	1,000 (0.28 h)

3.5.4 New exposure limits of the ACGIH

In their 2021 publication, Sliney and Stuck (2021) argue that a very conservative safety factor was used in determining the ELs in the UVC spectral range. They discuss the need to revise the ELs in the UVC spectral range, as several new studies would indicate that the thresholds for the skin and the eyes in this wavelength range are significantly higher (Sliney et al. 1991; Buonanno et al. 2017; Narita et al. 2018c, Yamano et al. 2020; Fukui et al. 2020; Kaidzu et al. 2019; Kaidzu et al. 2021; Eadie et al. 2021) than the thresholds in the study by Pitts (1974). As an arc-lamp monochromator with a large spectral bandwidth was used in this study, it is assumed that the derived action spectrum was strongly flattened. Based on the new studies listed above (where in some cases self-experiments by the authors took place), the authors proposed different action spectra for the skin and the eyes at wavelengths below 300 nm, which imply in part a significant increase in the ELs for both skin and eyes. The action spectrum for the skin applies if the eyes are not exposed.

At the end of 2021 (ACGIH 2022), the ACGIH adopted the two new action spectra and changed its ELs. They therefore deviate significantly from the ELs and action spectrum $S(\lambda)$ of the ICNIRP Guidelines (ICNIRP 2004) for UVB and UVC radiation. Figure 3.8 compares the new relative action spectra of the ACGIH (ACGIH 2022) for the skin and the eyes with the action spectrum for the actinic UV exposure hazard $S(\lambda)$ of ICNIRP 2004. In Figure 3.9a and Figure 3.9b, the new ELs for monochromatic radiation of ACGIH 2022 for the skin and the eyes are compared against the corresponding ELs of ICNIRP 2004. In addition, measurements from various studies are presented that, according to Sliney and Stuck (2021), underpin the course of the new ELs. In Table 3.6, the ELs of ICNIRP 2004 are compared with the new ELs of ACGIH 2022 for monochromatic radiation at selected wavelengths.

The ACGIH states clearly that the curves do not represent a legal norm, nor are they supported by the ACGIH for such use. The ACGIH also points out that all the limits given are designed as guidelines or recommendations for protecting workers in the workplace and serve no other purpose. Nevertheless, they are frequently already considered to be new, valid limits by some manufacturers and new products are thus promoted as compliant with the ELs of ACGIH 2022.

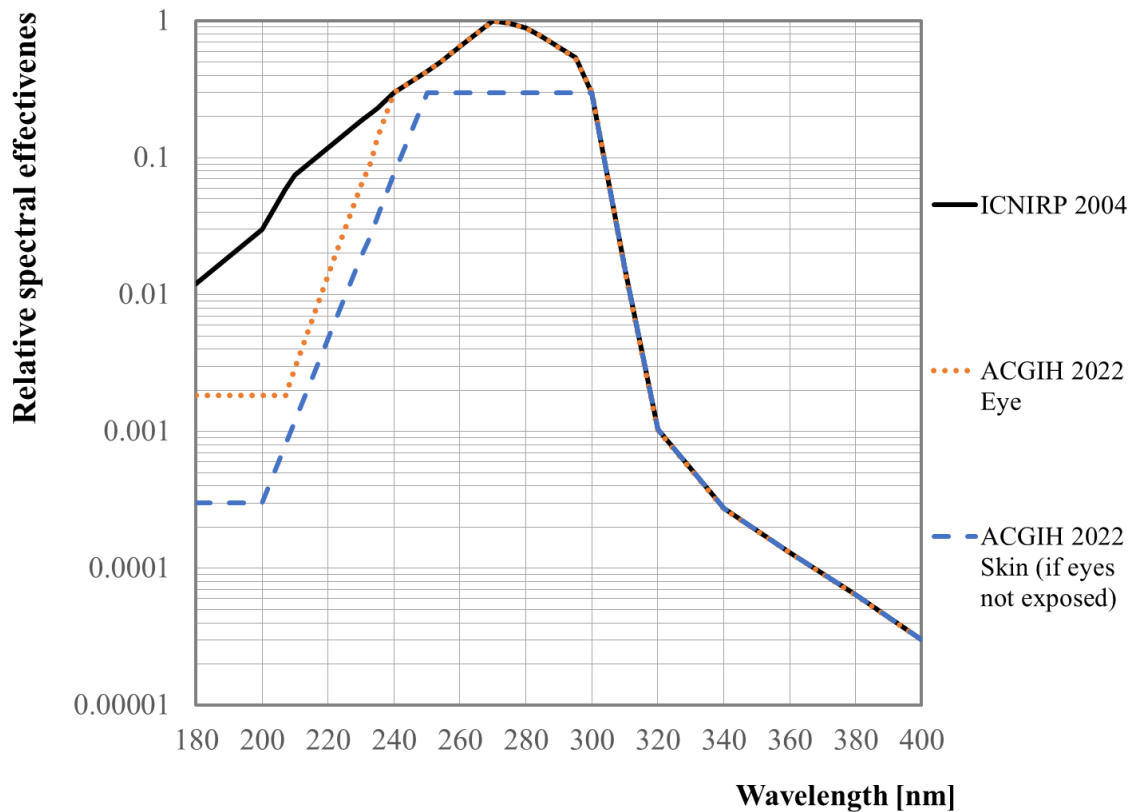
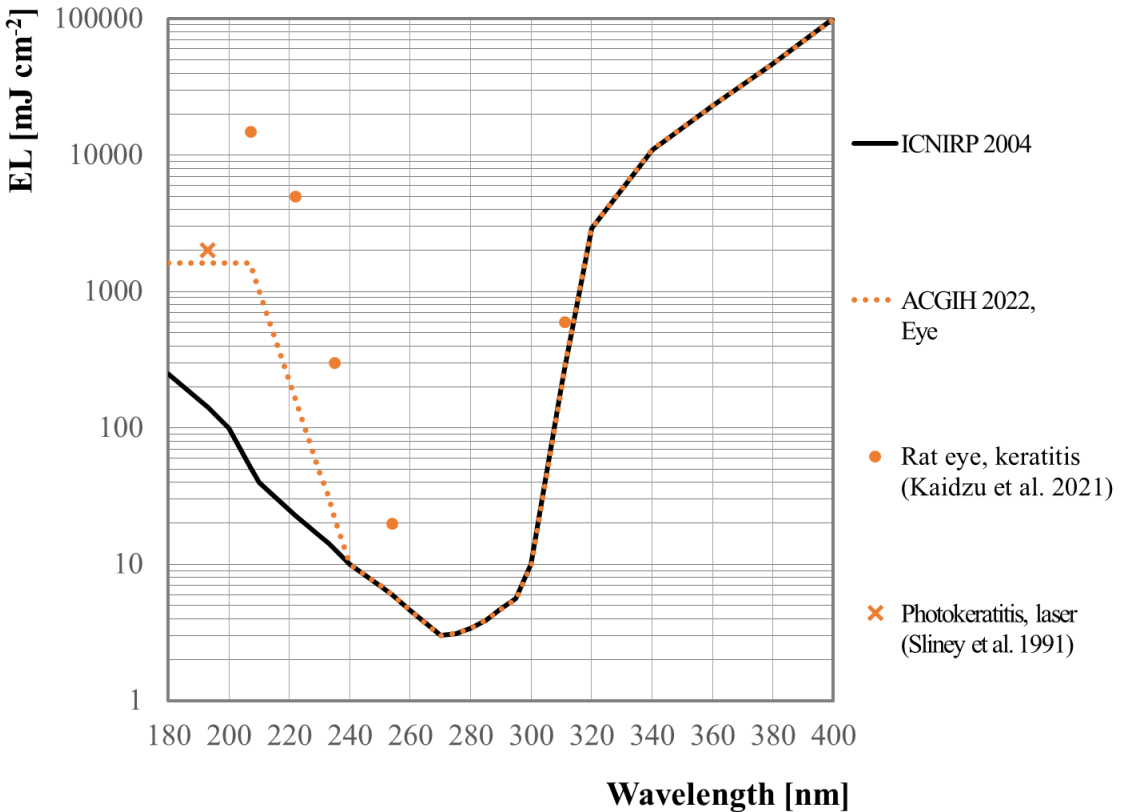


Figure 3.8: Relative action spectra of ACGIH 2022 for the skin (if the eyes are not exposed, dashed line) and the eyes (dotted line) compared to the action spectrum for the actinic UV hazard $S(\lambda)$ of ICNIRP 2004 (solid line).



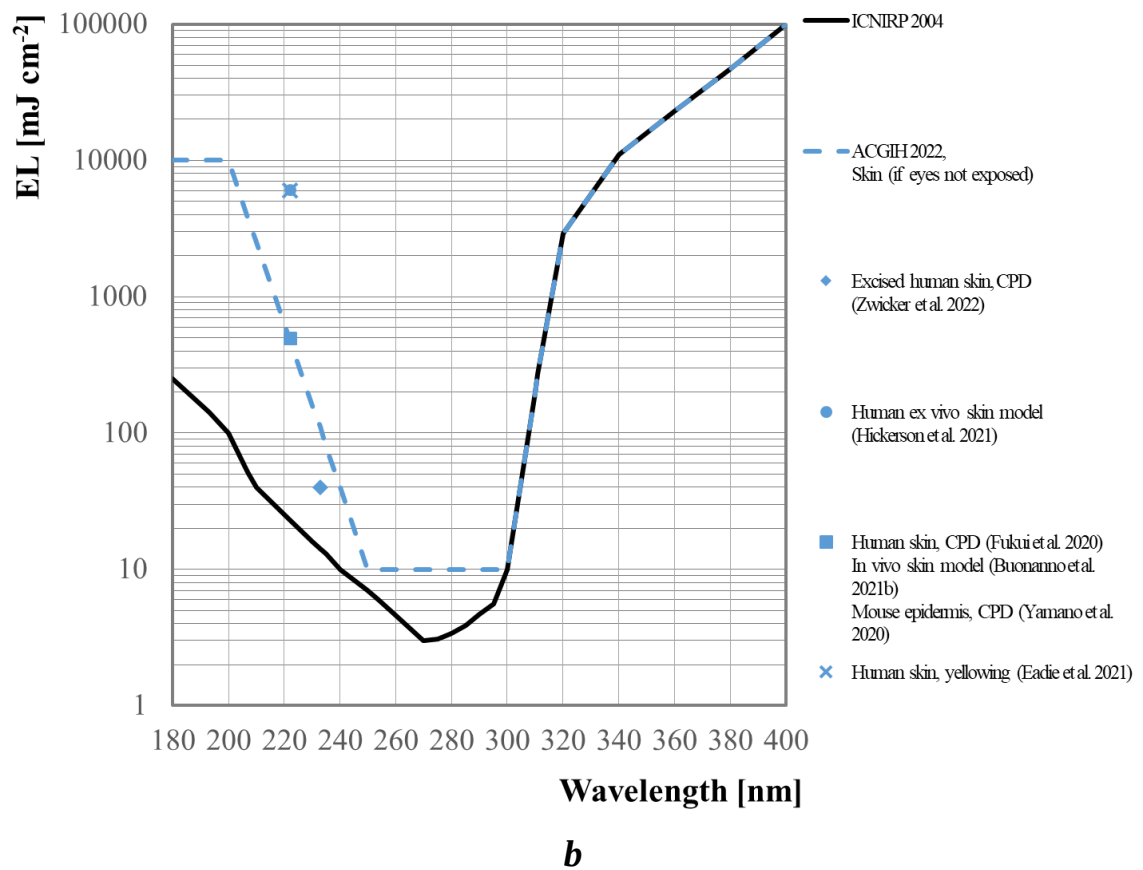


Figure 3.9: *ELs for monochromatic radiation according to ACGIH 2022 to protect the eyes (a, dotted line) and the skin, if the eyes are not exposed (b, dashed line), compared with the ELs of ICNIRP 2004 (solid line). In addition, the maximum doses are given from some studies where no notable damage from UV radiation was observed.*

Table 3.6: *ELs of ACGIH 2022 and ICNIRP 2004 for protecting the eyes and the skin from monochromatic radiation at selected wavelengths.*

λ [nm]	EL [mJ cm ⁻²] (ICNIRP 2004)	EL eye [mJ cm ⁻²] (ACGIH 2022)	EL skin [mJ cm ⁻²] (ACGIH 2022)
180	250	1,626	10,000
190	160	1,626	10,000
200	100	1,626	10,000
207*	49.5	1,626	3,802
210	40	1,023	2,512
220	25	218	631.0
222*	22.7	160.7	479
230	16	46.8	158.5
240	10	10	39.8
250	7	7.0	10
254	6	6.0	10
260	4.6	4.6	10
270	3.0	3.0	10
280	3.4	3.4	10

* Values taken from Sliney and Stuck (2021)

Conclusion

The argument of Sliney and Stuck (2021), according to which the ELs specified to date were estimated very conservatively, in particular due to the insufficient data situation with high measurement uncertainties, at first appears to be justified. However, the SSK is of the opinion, that the more recent studies cited by the authors do not sufficiently improve the data situation. In the case of some studies, the question must be raised whether the radiometric measurements were performed correctly. For example, Kaidzu et al. (2021) stated that a broadband radiometer (model USHIO VUV S172), which is usually calibrated by the manufacturer to 172 nm, was used for the measurements at 222 nm. In other studies, self-experiments were conducted (Eadie et al. 2021) or only a small number of subjects were examined (Fukui et al. 2020).

Sliney and Stuck (2021) state that there are hardly any recent studies into the effect of UVC radiation on the eye. A self-experiment is then described which resulted in a sensation of dry eye and ultimately tear production at high doses. The authors proposed two curves that were adopted by the ACGIH. Neither of the curves is supported by sufficiently robust data, however. To assess the risk from UV radiation exposure in the far-UVC range, comprehensive studies are still essential – especially with respect to the effects on the eye.

3.5.5 Applicability of the exposure limits to vulnerable groups (groups requiring UV protection)

Individuals who are especially sensitive to UV radiation on account of their physical development, genetics, (pre-existing) illnesses or for other reasons are considered to be

vulnerable groups. This applies to the following groups of people who are sensitive to UV radiation (people requiring UV protection according to Technical Specification DIN/TS 67506:2022-02, section 10.4) and also does not rule out any potential vulnerability to far-UVC radiation:

- Children: the eyes and skin of children are generally more sensitive to UV radiation than in adults. A detailed description of these differences can be found in the SSK Recommendation “Protection of man against the hazards of solar UV radiation and UV radiation in solaria” (SSK 2016). In the case of the cornea of the eye and corneal layer of the skin affected by UVC radiation, studies demonstrate that the corneal thickness varies considerably in children depending on different factors and from birth and until roughly the age of four years is thinner than in adults (Fiethen 2019). With respect to the corneal layer of the skin, one study shows that the stratum corneum can be 30% thinner and the epidermis 20% thinner in infants than in adults (Stamatas et al. 2010). Furthermore, the basal membrane of the epidermis can sometimes be much closer to the surface of the skin in children than in adults (SSK 2016). Given these differences, it can be assumed that a child’s eyes and skin will be more sensitive to UVC radiation and thus require special protection as a preventive measure.
- Individuals with congenital, acquired (especially age-dependent) or transient changes in the cornea or thinner stratum corneum.
- Individuals with pre-existing conditions that cause changes in the cornea of the eye or the stratum corneum of the skin.
- Individuals with pre-existing eye and skin conditions and/or injuries (also due to surgery); individuals who have previously had skin cancer are at increased risk of developing skin cancer again.
- Individuals lacking any ability to recover from UV-induced skin damage (e.g. xeroderma pigmentosum patients).
- Individuals with skin that generally exhibits above-average photosensitivity.
- Individuals taking medicines or herbal products that increase photosensitivity.
- Individuals coming into contact with photosensitising substances, such as touching certain plants (hypericins in St John’s wort, furocoumarins in umbels).

The ELs defined by the EU and Germany generally apply to the protection of workers against risks from eight hours of exposure to UV radiation. They are not intended to protect vulnerable groups of people, however, nor are they applicable. These individuals may also be harmed at levels below the ELs presented in section 3.5.1. For this reason, occupational safety aimed at these groups is generally subject to the obligation to provide information on occupational health advice and the obligation to provide instruction on optional and mandatory health care with the possibility to establish individual protective measures (TROS IOS 2013).

While individually adapted protective measures are foreseen for vulnerable individuals in the workplace, this cannot be guaranteed for people in public spaces. Whereas workers are largely healthy adults within a limited age range, the general population also includes other age groups such as children and the elderly. It is highly likely, at least in the elderly population, that other vulnerable groups will exist, such as individuals with pre-existing conditions or injuries to the eyes and skin (also due to surgery) as well as individuals taking photosensitising medication. None of these individuals would be aware of UVC exposure in public spaces without the relevant information, e.g. warnings, and would not take any protective action.

4 Open questions and the need for research

The lack of data as described in the recommendation (Chapter 2) gives rise to the following research need:

- The majority of studies to date address the effects of short-term exposure to far-UVC radiation. To investigate the effect of far-UVC radiation when used in public spaces with people present, studies with chronic irradiation must be performed.
- Such additional studies must also include investigations into the human eye and injured or damaged skin. Furthermore, these studies also need to consider potentially vulnerable groups, such as children, the elderly and individuals with pre-existing skin or eye diseases, and the effect of far-UVC irradiation when taking photosensitising medication.
- The ability of UVC₂₂₂ to eradicate (unwanted) germs on the skin has been demonstrated by Fukui et al. (2020). It can be assumed that far-UVC radiation alters the microbiome of the skin. As the importance of the microbiome to healthy skin and protecting the body against external influences is becoming increasingly apparent, the effect of far-UVC radiation on the skin microbiome should be investigated more closely.
- Since the absorption of UVC₂₂₂, especially by proteins, is high, part of the inactivating effect, particularly in viruses, is attributed to the damage caused to proteins (e.g. Beck et al. 2018). The inhibition of enzyme activities by UVC has been demonstrated in studies conducted by the food industry, where UVC irradiation is used, e.g. to prevent fruit juices from turning brown (Yannam et al. 2020). The inhibition of the activity of enzymes could play a role in the absorption of far-UVC radiation in tear fluid. The inhibition and underlying photochemical mechanism has not been fully explained and should be investigated further (Rathinasamy and Augenstein 1968, Setlow and Doyle 1957).

5 Further questions on the use of far-UVC radiation

This advisory mandate focuses on the use of far-UVC radiation for disinfection in the presence of people and the associated risks to human skin and eyes. The potential use of far-UVC radiation through unshielded, open sources of radiation in public spaces gives rise to further questions, however, that also need to be considered, e.g. the possible emergence of UVC-resistant bacterial variants, the effect on flora and fauna, the long-term influence on materials/plastics in interior spaces, or the possible emergence of harmful chemical compounds indoors. Some of these questions are briefly addressed below.

Possible emergence of UVC-resistant bacterial variants

Choi et al. (Choi et al. 2022) investigated whether antibiotic-resistant bacteria can acquire resistance to UV radiation after repeated exposure. They exposed methicillin-resistant *Staphylococcus aureus* (MRSA), carbapenemase-producing *Klebsiella pneumoniae* and metallo-beta-lactamase-producing *Klebsiella pneumoniae* to the UV radiation of a mercury vapour lamp (UVC₂₅₄ radiation) and a xenon lamp. After 25 cycles of UV irradiation, no significant genetic changes were found in these three bacterial strains upon sequencing analyses of the entire genome. Very high UV doses were used in this study, however: 56,160 mJ cm⁻² (irradiance 93.6 mW cm⁻² for 10 min) in the case of the mercury vapour lamp and 11,430 mJ cm⁻² (irradiance 38.1 mW cm⁻² for 5 min) with the xenon lamp. If the UV doses applied are sufficient to eradicate the entire bacterial population, the emergence of UV-resistant bacterial variants can

be prevented. In studies by Alcantara-Diaz et al. (2004) and Shibai et al. (2017), *Escherichia coli* bacteria were repeatedly exposed to lower doses of UV radiation (up to 15 mW cm⁻² and 10 mW cm⁻²) from a mercury vapour lamp. The *Escherichia coli* did in fact produce mutant strains that were more resistant to UV radiation than the parental strains. When using far-UVC radiation in public spaces – especially at greater distances from the radiation source – doses sufficient to completely eradicate bacterial populations cannot be guaranteed. Hence, consideration must be given to the possible emergence of UVC-resistant bacterial variants as a result of repeated exposure to such radiation.

Effect on other organisms

Otake et al. (2021) investigated the influence of UVC₂₂₂ and UVC₂₅₄ radiation on *Arabidopsis* plants by irradiating seedlings that were seven days old. In plants exposed to UVC₂₂₂ radiation, the following was observed four days after irradiation: The leaves curled after a dose of 100 mJ cm⁻² and were significantly bleached at 1,000 mJ cm⁻². These effects were not observed in non-irradiated plants or plants exposed to UVC₂₅₄ radiation. Furthermore, functional guard cells (which are important to the plant for gas exchange with the surrounding air) were found in the leaves of non-irradiated plants and plants exposed to UVC₂₅₄ doses of 100 mJ cm⁻² and 500 mJ cm⁻². Conversely, most guard cells were deformed after the same dose of UVC₂₂₂ radiation. The studies indicated that mitochondria are inactivated or fragmented and that chloroplasts are damaged. The authors conclude that the UVC₂₂₂ radiation severely damages the guard and epidermal cells and that such damage can inhibit growth.

Yoshiyama et al. (2023) conducted experiments on the transparent model organism *Caenorhabditis elegans* (a nematode). At irradiation doses of just 20 mJ cm⁻² and 40 mJ cm⁻² UVC₂₂₂ and UVC₂₅₄, only UVC₂₂₂ was found to cause serious neurodegenerative effects and neuronal damage in the sensory neurons located just 1-2 µm below the surface. The authors assume that UVC₂₂₂-induced ROS are primarily responsible for this. Comparable damage to the neurons was not observed with UVC₂₅₄ at such doses, but damage to the oocytes located 20 µm to 60 µm below the surface was reported.

Possible emergence of harmful chemical compounds indoors

Peng et al. (2023) investigated the impact of far-UVC radiation on indoor air quality. They conducted a model evaluation of the secondary chemistry initiated by UVC₂₅₄ and UVC₂₂₂ in a characteristic indoor environment for different ventilation levels. The evaluation revealed that the UVC₂₅₄ radiation can photolyse ozone molecules (O₃) and produce OH radicals. They oxidise volatile organic compounds (VOCs) and lead to the production of oxygen-containing VOCs (OVOCs) and a secondary organic aerosol (SOA), which can have negative effects on the health (Collins and Farmer 2021). UVC₂₂₂ radiation, which exhibits the same virus-inactivation rate, has less impact on the quality of room air at moderate to high ventilation levels, mainly due to the lower UV irradiance required and the less efficient OH-producing photolysis, moreover, than is the case with UVC₂₅₄ radiation. If the ventilation level is poor (which can frequently be the case, e.g. in schools), however, UVC₂₂₂ radiation has a greater impact on room air quality than UVC₂₅₄ radiation due to the low but significant photochemical production of O₃ at 222 nm. The authors stress that only a very limited number of chemical substances were modelled in the study and that further studies are required to better assess the toxicity of gas-phase products. Consideration must also be given to interiors with polluted air where the concentration of VOCs can be very high.

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7 List of abbreviations

ACGIH	<u>A</u> merican <u>C</u> onference of <u>G</u> overnmental <u>I</u> ndustrial <u>H</u> ygienists
BMUV	<u>B</u> undes <u>m</u> inisterium für <u>U</u> mwelt, Naturschutz, nukleare Sicherheit und Verbraucherschutz (Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection)
CCD	<u>C</u> harge- <u>c</u> oupled <u>d</u> evice
CFU	<u>C</u> olony- <u>f</u> orming <u>u</u> nit
CMOS	<u>C</u> omplementary <u>m</u> etal- <u>o</u> xide <u>s</u> emiconductor
CPD	<u>C</u> yclobutane pyrimidine <u>d</u> imer
DNA	<u>D</u> esoxyribon <u>n</u> ucleic <u>a</u> cid
6-4PP photoproduct	<u>6</u> -pyrimidine- <u>4</u> -pyrimidone <u>p</u> hotop <u>ro</u> duct
EL	<u>E</u> xposure <u>l</u> imit(s)
ICNIRP	<u>I</u> nternational <u>C</u> ommission on <u>N</u> on- <u>I</u> onizing <u>R</u> adiation <u>P</u> rotection
KrCl	Krypton chloride
LED	<u>L</u> ight- <u>e</u> mitting <u>d</u> iode
MMP	<u>M</u> atrix <u>m</u> etalloproteinases
MRSA	<u>M</u> ethicillin- <u>r</u> esistant <u>S</u> taphylococcus <u>a</u> ureus
OH radical	Hydroxyl radical
OStrV	Verordnung zum Schutz der Beschäftigten vor Gefährdungen durch künstliche optische Strahlung (Arbeitsschutzverordnung zu künstlicher optischer Strahlung – OStrV) (Occupational Safety and Health Ordinance on Artificial Optical Radiation)
OVOC	<u>O</u> xygenated <u>v</u> olatile <u>o</u> rganic <u>c</u> ompound
PFU	<u>P</u> laque- <u>f</u> orming <u>u</u> nits
ProdSG	Gesetz über die Bereitstellung von Produkten auf dem Markt (<u>P</u> rodukt <u>s</u> icherheitsgesetz – ProdSG) (Act on Making Products Available on the Market (Product Safety Act – ProdSG))
VAC system	<u>V</u> entilation and <u>a</u> ir- <u>c</u> onditioning system
RNA	<u>R</u> ibon <u>n</u> ucleic <u>a</u> cid

ROS	<u>R</u> eactive <u>o</u> xygen <u>s</u> pecies
RHS	<u>R</u> econstructed <u>h</u> uman <u>s</u> kin
SCT	<u>S</u> tratum <u>c</u> orneum <u>t</u> hickness
SOA	<u>S</u> econdary <u>o</u> rganic <u>a</u> erosol
SSK	<u>S</u> trahlenschutz <u>k</u> ommission (Commission on Radiological Protection)
TCID ₅₀	50 % <u>T</u> issue <u>C</u> ulture <u>I</u> nfectious <u>D</u> ose (<i>Median tissue infectious dose</i>)
TIMP-1	<u>T</u> issue <u>i</u> nhibitor of <u>m</u> etalloproteinase 1 (<i>metallopeptidase inhibitor 1</i>)
TROS	<u>T</u> echnische <u>R</u> egel zur Arbeitsschutzverordnung zu künstlicher <u>o</u> ptischer <u>S</u> trahlung (<u>T</u> echnical <u>R</u> ules for Occupational Safety and Health Ordinance on Artificial <u>O</u> ptical <u>R</u> adiation)
TROS IOS	<u>T</u> echnische <u>R</u> egel zur Arbeitsschutzverordnung zu künstlicher <u>o</u> ptischer <u>S</u> trahlung – TROS <u>I</u> nkohärente <u>O</u> ptische <u>S</u> trahlung (Technical Rules for Occupational Safety and Health Ordinance on Artificial Optical Radiation – TROS Incoherent Optical Radiation)
UV radiation	<u>U</u> ltraviolet radiation
UVC ₂₅₄	UVC radiation at a wavelength of 254 nm (example)
VOC	<u>V</u> olatile <u>o</u> rganic <u>c</u> ompound