Scientific Committee on Health, Environmental and Emerging Risks

SCHEER

Preliminary opinion on

Biological effects of UVC radiation relevant to health with particular reference to UVC lamps

The SCHEER approved this Opinion for public consultation at the 2nd plenary on 6 July 2016
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SCHEER

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All Declarations of Working Group members and supporting experts are available on the following webpage:
http://ec.europa.eu/health/scientific_committees/emerging/members wg/index_en.htm
ABSTRACT

Introduction

The part of the ultraviolet radiation (UVR) emitted in the wavelength range 280 nm – 100 nm is called UVC; this radiation is used in a growing number of applications, which include disinfection of water and air, food-industry processing, and air-conditioning. Although most appliances are sealed systems there is now increasing use of devices where consumers may be directly exposed to UVC radiation. There have been several reports of adverse dermal or ocular effects from accidental exposure or through misuse of appliances. The European Commission has requested the Scientific Committee to review recent evidence in order to better assess risks associated with UVC radiation from lamps.

Legal background

The placing on the market of UVC lamps is regulated by Directive 2014/35/EC\(^1\) on electrical equipment designed for use in defined voltage ranges\(^2\). The overarching Directive 2001/95/EC\(^3\) on General Product Safety applies to UVC lamps whenever the Low Voltage Directive (LVD) is not applicable. It requires that products intended for consumers or likely to be used by them, including in the context of a service, must provide reasonably expectable safety throughout the lifetime of the product. Member States authorities responsible for the enforcement of these Directives have an obligation to carry out controls to ensure compliance by relevant economic operators.

European harmonised standards related to UVC lamps are voluntary but, if published in the Official Journal of the European Union (OJEU), they provide presumption of conformity with the related essential requirements on safety in the relevant EU legislation. However, the applicable product standards do not yet fully address some specific safety risks of UVC lamps. For example, standard EN 60335-2-109 for UVC radiation water treatment appliances, which includes pond filters, excludes repair sets and replacement lamps from its scope. To protect workers from acute health effects, limits of the exposure to UVC radiation from devices are specified in prEN ISO DIS 15858:2014.

As an unintended side-effect or intendedly in combination with a dedicated ozone generator, UVC lamps emitting wavelengths shorter than 240 nm may generate ozone which above certain thresholds may cause adverse health effects. Limits of ambient ozone levels are defined in the Directive 2008/50/EC to avoid, prevent or reduce harmful effects on human health and the environment. The Directive recommends not using ozone generators, which are air cleaners that intentionally produce ozone at home.

Exposure

There is a wide variety of UVC lamps, working with different technologies and generating different irradiance levels and wavelengths. For most applications, the lamp is surrounded by an enclosure that prevents UVR exposure of the user in normal condition. For other applications, the UVR may be directly emitted to the environment. Most of the recently published data on exposure from UVC lamps comes from reports on accidental exposure.

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\(^1\) Directive 2014/35/EU on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits, OJ L 96, 29.03.2014, p. 357.

\(^2\) Voltage rating of between 50 and 1 000 V for alternating current and between 75 and 1 500 V for direct current.

Human Health effects

There are very few studies that have investigated potential adverse health effects in humans from sole exposure to artificial UVC radiation.

Most studies of adverse effects are case reports that report dermal or ocular effects from accidental exposure to UVC radiation from lamps through, for example, inappropriately replaced bulbs or accidental prolonged exposure that is much higher than the safe occupational exposure limit.

Depending on exposure characteristics and exposure patterns, UVC radiation from lamps may cause adverse health effects to the eye and skin, particularly in photosensitive persons.

Since the skin is composed of different layers of varying depths with different physical and chemical properties, UVR exerts different biological effects on different kinds of cells in the skin. The minimal erythema dose (MED) is highly dependent on skin type. Dose-response curves of the induction of minimal erythema show that human skin is more sensitive to 254 nm (UVC) than to 300 nm (UVB) radiation. It has not yet clearly been demonstrated to what extent UVC-induced erythema may be related to chronic and stochastic effects in the skin or/and to skin cancer development in humans.

The studies of accidental overexposure of the eye generally report that ocular symptoms usually subside within about a week. However, in severe exposure cases, ocular problems may remain for a much longer period. In contrast, most of the effects on the skin have been reported as being transient.

Cumulative exposures to intense UV radiation (which includes UVC) during welding can lead to cataract formation, retinal damage and an increased risk of melanoma, but detailed discussion is beyond the scope of this Opinion.

Exposure to ozone such as unintentionally produced by the UVC lamps emitting at wavelengths shorter than 240 nm may present an additional risk of a variety of symptoms and diseases associated with the respiratory tract, particularly in ozone-sensitive and vulnerable individuals.

Mechanistic studies

In vitro studies and human volunteer studies have reported that UVC radiation induces similar effects at the molecular level as UVB; in vitro experiments have demonstrated UV-induced DNA damage peaking in the UVC range.

It has been shown that UVC radiation reaches to the level of the upper layers of the epidermis in intact skin, but where the epidermis was thin, UVC exposure resulted in cyclobutane pyrimidine dimers (CPD) formation at the basal layer of the epidermis. These effects have been reported at low doses below the bacteriostatic effect threshold of UVC radiation with a wavelength of 222 nm.

Overall Conclusion

There are few studies of exposure to humans under normal conditions of use and insufficient data on long-term UVC exposure from UVC lamps.4

Adverse effects to the eye and skin in humans are reported mainly from accidental acute exposure to high levels of UV radiation from UVC lamps. Although mechanistic studies suggest that there are wavelength-dependent exposure thresholds for UVC regarding acute adverse effects to human eyes and skin, except for erythema, quantitative estimation of these thresholds could not be derived from currently available data. Due to the mode of action and induced DNA damage similarly to UVB, UVC can be considered

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4 UV exposure including UVC from welding is not discussed in this opinion because the exposure is not comparable with that of UVC lamps.
carcinogenic to humans. However, the currently available data do not allow quantitative
cancer risk assessment of exposure from UVC lamps.

UVC lamps emitting radiation at wavelengths shorter than 240 nm need additional risk
assessment of the associated production of ozone in the environment.

More data are needed on the exposure of general population and workers from UVC
lamps and generated ozone. Research is needed on long-term stochastic effects such as
cancer.

Keywords: UV radiation, UVC lamps, ozone, risk assessment, cancer, skin, eye.

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Preliminary Opinion on Biological effects of UVC radiation relevant to health with
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1. MANDATE

1.1 BACKGROUND

1.1.1 INTRODUCTION

UVC radiation is now used in a large range of applications, including for disinfection in water, air and surface treatment, in food-industry processing and in air-conditioning. In these situations, the systems are usually designed and built in such a way that UVC radiation cannot escape (employing protective housings) and therefore there are no direct UVC hazards for users. Servicing, maintenance and repair personnel must be instructed accordingly in the handling and use of UVC radiation, and the employer is required to provide personal protective equipment for them. Another requirement is that the UVC radiation source automatically shuts down when the protective housing is opened during operation.

Market surveillance authorities from Member States have observed that there is increasing use of UVC radiation in products for consumers and in appliances with which consumers come into contact. For example, UVC radiation is used in electrical pond filters, in electrical discharge insect control systems ("bug zappers"), in the brush attachments of electrical vacuum cleaners, in special lamps used for local disinfection, in aquariums and for surface disinfection.

These developments have led the European Commission to request the SCENIHR (currently SCHEER) to review recent evidence in order to have a better understanding of risks associated with UVC radiation coming from lamps. It should be noted that mercury-based lamps for lighting such as energy-saving lamps or fluorescent lamps, which unintentionally emit UVC radiation, are out of the scope of this mandate and are thus not assessed.

1.1.2 SCIENTIFIC BACKGROUND

The relevant literature\(^5\) indicates that UVC radiation can present a risk for both the human eye and human skin. This risk depends on a range of factors, for example, radiation intensity and duration (energy), which needs consideration in risk assessment.

There have been reports that the electrical discharge insect control systems used, for example in the hotel and catering sector, have caused skin burns to those who have been exposed to UVC. Consumers are also often unable to recognise the risks and may not take adequate precautions against emitted UVC radiation.

UVC lamps can also be sold separately, for example, with a conventional socket (TL socket, PL socket or G23 socket) up to a rated power of 55 W. It is also possible that lamps of an even high power could be sold. Moreover, the replacement lamps fit into

\(^5\) http://peschl-ultraviolet.com/deutsch/ueber-uv/sicherheitshinweise/sicherheitshinweise.html
http://www.sterilair.com/de/kompetenz/kompetenz/wirkung-uvc.html
lamps are often not labeled adequately so that users may not be aware of risks from the UVC radiation. The intended purpose of UVC lamps is not to produce light for lighting needs but for other purpose such as disinfection or attracting and killing insects.

1.1.3 LEGAL & ENFORCEMENT BACKGROUND

At EU level, a legal framework exists that aims to address the risks posed by UVC lamps themselves. The placing on the market of UVC lamps is regulated by Directive 2014/35/EU on electrical equipment designed for use in specified voltage ranges. This Directive falls under the responsibility of Directorate General for Growth. Directive 2001/95/EC on General Product Safety applies to UVC lamps whenever the Low Voltage Directive (LVD) is not applicable (e.g. UVC lamps outside the voltage range of LVD), requiring that products intended for consumers or likely to be used by them, including in the context of a service, must provide reasonably expectable safety (throughout the lifetime of the product). The General Product Safety Directive falls under the responsibility of Directorate General for Justice. Member States’ authorities responsible for the enforcement of these Directives have an obligation to carry out controls to ensure compliance by relevant economic operators.

European harmonised standards related to UVC lamps are voluntary but, if published in the Official Journal of the European Union (OJEU), they provide presumption of conformity with the related essential requirements on safety in the relevant EU legislation. However, the applicable product standards do not yet fully address some specific safety risks of UVC lamps. For example, standard EN 60335-2-109 for UVC radiation water treatment appliances, which includes pond filters, excludes repair sets and replacement lamps from its scope. Pond filters are designed in such a way that no UVC radiation can escape from them if they have been properly installed. However, repair sets and replacement lamps, which can also be operated outside the pond filter and without any screening, are also available for such appliances. The repair sets are generally ready-wired for connection and can be operated in this state without any further safety precautions. The standard applicable to pond filters excludes repair sets and replacement lamps from its scope with the result that there is no specific safety standard for them.

To protect workers from acute health effects, limits of the exposure to UVC radiation from devices are specified in prEN ISO DIS 15858:2014.

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7 Voltage rating of between 50 and 1 000 V for alternating current and between 75 and 1 500 V for direct current


As an unintended side effect or intended in combination with a dedicated ozone generator, some UVC lamps may also generate ozone, which above certain thresholds may cause adverse health effects. Limits of ambient ozone levels are regulated by the directive 2008/50/EC; Ozone generators, which are air cleaners that intentionally produce ozone, are not recommended for home use.

1.1.4 REGULATIONS AND STANDARDS FOR WORKERS

To protect workers from acute health effects, limits of the exposure to UVC radiation from devices are recommended in prEN ISO DIS 15858:2014\textsuperscript{10}. They equal the recommendation of the National Institute of Occupational Safety and Health (NIOSH, 1992\textsuperscript{11}). Exposure during an 8-hour work day should not exceed 60 J/m\textsuperscript{2} at 254 nm. The limit of the effective irradiance at 254 nm is dependent on exposure time and shown in Figure 1. The recommended maximum exposure levels in prEN ISO DIS 15858:2014 do not protect photosensitive persons. It needs to be noted that these limits do not account for existing UVC sources emitting radiation at other wavelengths either.

![Figure 1: Recommended limits of the effective irradiance I at 254 nm in dependence on exposure time t (ISO/DIS 15858)](image)

To protect workers from acute UVR health effects based on an UVR exposure of 8 hours per day, the European Directive 2006/25/EC\textsuperscript{12} limits UVR in the wavelength range 180 - 400nm and hence also covers the relevant UVC range including the second UVC mercury emission line at 185 nm. The recommended protection levels of ICNIRP\textsuperscript{13} are also


\textsuperscript{12} EU 2006/25/EC (+EU 2007/30/EC+EC1137/2008+EU 2013/64/EU): European directive on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation)

\textsuperscript{13} ICNIRP (2004): Guidelines on limits of exposure to ultraviolet radiation of wavelength between 180nm and 400nm (incoherent optical radiation). Health Physics 87(2):171-186
intended for workers based on an exposure of 8 hours per day, but it is mentioned that this also applies to the general population (photosensitive individuals excluded). The recommended levels for protection of eyes are as follows:

\[ E_{eff} = \sum E_\lambda S(\lambda) \Delta \lambda \]

For comparison, for UVA the 8 hours exposure is limited to \( \leq 10^4 \, \text{J/m}^2 \).

Limits of ambient ozone levels are defined in the directive 2008/50/EC to avoid, prevent or reduce harmful effects on human health and the environment as a whole. Ozone generators, which are air cleaners that intentionally produce ozone, are not recommended for home use.

The European standard ambient air level for ozone is \( 120 \mu \text{g/m}^3 \), maximum daily 8 hours mean; target value entered into force 1.1.2010; permitted exceedances each year - 25 days averaged over 3 years.

\[ \text{http://ec.europa.eu/environment/air/quality/standards.htm} \]
1.2 TERMS OF REFERENCE

In view of the incidents\textsuperscript{15} due to the UVC lamps, the SCENIHR (currently SCHEER) is asked to assess the safety risks associated with the use of UVC lamps and to provide an answer to the following questions:

1. What are the potential effects on human eyes and skin if these organs are exposed to UVC radiation of varying wavelength, intensity and duration?

2. Is there a wavelength-dependent safety threshold with regard to UVC intensity and/or energy (dose) that could prevent adverse health effects to the human eyes and/or skin?

3. Are there other safety aspects that should be considered together with/instead of any possible wavelength-dependent safety threshold?

\textsuperscript{15} Some Member States have indicated accidents due to UVC lamps, e.g. in Spain insect killers installed in a public restaurant in a sport centre provoked an outbreak of an actinic conjunctivitis due to the UVC lamps included in the insect killers.
2. METHODOLOGY

The general approach by the Scientific Committee to health risk assessment is to evaluate all available evidence from human and mechanistic studies regarding effects of exposure to the agent of concern and then to weigh together this evidence across the relevant areas to generate a combined assessment. The overall quality of the studies is taken into account, as well as the relevance of the studies for the issue in question.

This combined assessment addresses the question of whether or not a hazard exists, i.e. if there is a causal relationship between exposure and some adverse health effect. The answer to this question is not necessarily a definitive 'yes' or 'no', but may express the different evidence for the existence of a hazard.

In this current Opinion, the health risks associated with the use of UVC lamps have been assessed by review of the literature on epidemiological studies, experimental studies in humans, experimental studies in animals and cell culture studies. Information has primarily been obtained from papers and reports published in international peer reviewed scientific journals in the English language. Additional sources of information have also been considered, including web-based information retrieval and other documents in the public domain e.g. from governmental bodies and authorities, non-governmental organisations (NGOs) and data sheets. A list of literature search terms used is given in Annex 1.

Throughout the Opinion, consistency and adherence to the International System of Units (SI) regarding the use of terms and units has been used.
3. DEFINITION AND USE OF UVC DEVICES

3.1 DEFINITION OF UVR AND PHYSICAL PROPERTIES

Ultraviolet radiation (UVR) is electromagnetic radiation (EM) with a wavelength from approximately 400 nm to 100 nm (respectively with frequency between 750 THz and 3 THz).

EM is characterised by its spectrum that is the distribution of radiation intensity over its wavelength (or frequency). Matter emits a characteristic broad and continuous EM spectrum, the so-called blackbody radiation, depending on its temperature. Discrete spectral peaks (lines) at certain wavelengths are characteristic of the emitting material of an EM source and can superpose or exceed the blackbody radiation.

Table 1: Definition of different spectral regions of electromagnetic radiation

<table>
<thead>
<tr>
<th>Region</th>
<th>Wavelength (nanometers, (nm))</th>
<th>Frequency (Hz)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radio waves</td>
<td>$10^{13} - 10^9$</td>
<td>$3.10^8 - 3.10^{11}$</td>
</tr>
<tr>
<td>Microwaves</td>
<td>$10^9 - 10^6$</td>
<td>$3.10^8 - 3.10^{11}$</td>
</tr>
<tr>
<td>Infrared light</td>
<td>$10^6 - 780$</td>
<td>$3.10^{11} - 3.8.10^{14}$</td>
</tr>
<tr>
<td>Visible light</td>
<td>780 - 400</td>
<td>$3.8.10^{14} - 7.5.10^{14}$</td>
</tr>
<tr>
<td>Ultraviolet radiation</td>
<td>400 – 100</td>
<td>$7.5.10^{14} - 3.10^{15}$</td>
</tr>
<tr>
<td>X-rays</td>
<td>&lt; 10</td>
<td>&gt; $3.10^{16}$</td>
</tr>
</tbody>
</table>

Wavelengths of UVR are shorter than those of visible light but longer than X-rays, i.e. UVR wavelengths are in the region 400-100 nm (Table 1). UVR is found in sunlight and can be produced by electric arcs, sunbeds and some technical devices such as water and air disinfectors. To account for different physical and biological effects, the UVR wavelength range is subdivided into three main ranges A, B and C. The following ISO-21348 definitions are used in this Opinion:

- UVA (400 nm – 315 nm)
- UVB (315 nm – 280 nm)
- UVC (280 nm – 100 nm)

The UVC range is frequently subdivided into:

- far UV (FUV) (280 nm – 200 nm),
Sunlight is absorbed as it propagates through the earth’s atmosphere. As a result, radiation with wavelengths below 280 nm (UVC) is filtered out by the stratospheric ozone layer and the UV radiation that reaches the earth’s surface is largely composed of UVA and UVB. The amount and spectrum of UV radiation that reaches the Earth’s surface varies widely around the globe and varies with altitude and season\textsuperscript{16}.

3.2 UVC-LAMPS TECHNOLOGY

3.2.1 MERCURY CONTAINING LAMPS

The lamps of this technology are called mercury or amalgam lamps, because they contain tiny solid quantities of either pure mercury or an amalgam, i.e., an alloy of mercury with another element, typically indium and gallium (although bismuth may also be used). The aim of this additive is to control mercury vapour pressure. Together with mercury vapour, a starter gas, usually argon, is contained in the lamp. There are two categories of lamps in this technology, based on the pressure at which mercury vapour is kept:

- low-pressure lamps, which work with approximately 1 Pa, and
- medium- or high-pressure lamps, for which the pressure is higher than 100 kPa.

The low-pressure mercury lamps generate UV radiation in a narrower spectrum (with peaks at 185 nm and 254 nm, the two mercury resonance lines) compared to the high-pressure lamps, which are also called high intensity discharge (HID) lamps and generate high levels of UV radiation in a broad-spectral range.

Low-pressure mercury lamps used for UVC generation are similar to fluorescent lamps, which are also low-pressure mercury discharge lamps. Common ballasts and pin types for UV and fluorescent lamps allow the use of the same fixtures. Although this may be very convenient in many cases, it may comprise a hazard in others, especially when replacing a lamp with the wrong type. The main difference between mercury/amalgam and fluorescent lamps is their glass wall coating. Their operation is common with the ballast providing the necessary voltage across the electrodes of the lamp to initiate a current, which heats up mercury vapour, thus stimulating electronic transitions that result in emission in the UV and visible spectrum. However, in the fluorescent lamps the glass wall is coated with phosphors which absorb UV radiation and re-emit radiation in the range of visible light.

The phosphor coating is missing in the UVC lamps: the glass used, typically quartz, is transparent to all UV wavelengths and allows the radiation of the two mercury peaks at UVC to be emitted. However, it is possible to use another type of glass, i.e. soft glass (sodium-barium glass), which absorbs the 185 nm peak and transmits only the 254 nm radiation peak. The UVC radiation near 185 nm can produce ozone; therefore, it is also quite common to categorise low-pressure mercury lamps with this criterion into:

- ozone-free lamps, with a peak wavelength of 254 nm (high efficiency) only, and

ozone-generating lamps, with a peak wavelength at 185 nm (low efficiency),

However, there are also ozone generators used in conjunction with UVC lamps\textsuperscript{17}.

The most common type of mercury lamp is a hot cathode lamp, although lamps with cold cathodes also exist. The cathodes are usually coated with electron emissive material which erodes when the lamp is first used and continues to evaporate during lamp use. The lifetime of a hot cathode lamp is determined by the rate of loss of this electron emissive coating. The lamp reaches the end of its lifetime when the coating is completely removed from at least one of the electrodes, so that a current cannot be established.

### 3.2.2 EXCIMER TECHNOLOGY

UVC lamps operating with the excimer technology are mercury-free. The word excimer originates from the expression 'excited dimer', which is a short-lived dimeric or heterodimeric molecule formed from two species, at least one of which has a completely filled electron valence shell - for example, noble gases. In this case, formation of molecules is possible only if the noble gas atom is in an excited state. Excimers are often diatomic and are composed of two atoms or molecules that would not bond if both were in the ground state. The lifetime of an excimer is very short, in the order of nanoseconds. Such excimers can form in a dielectric barrier discharge, i.e., an electrical discharge between two electrodes separated by an insulating dielectric barrier. Such a discharge can be achieved with high AC voltage electric fields, ranging from lower RF to microwave frequencies. The dielectric barrier can be formed, for example, by a quartz glass body filled with xenon (Xe) gas, giving rise to Xe\textsubscript{2} excimers. The electrodes are placed on the surface of the glass body to prevent short-circuiting from the plasma gas created.

In UVC lamps, the excimers produced are heterodimeric (exciplex technology), depending on the type of rare gas and halogen used inside the dielectric barrier. For example, the KrCl\textsuperscript{*} excimer lamps radiate at 222nm and XeBr\textsuperscript{*} emit at 282nm. Excimer lamps are 'instant-on' (there is no need to warm up) but have low efficiency.

Lasers are another light source based on the exciplex technology at the UVC spectrum, which, like the ArF\textsuperscript{*}, emit a wavelength of 193 nm and a KrF\textsuperscript{*} at 248 nm. They are used in high-resolution photolithography for producing semiconductor integrated circuits, industrial micromachining, and for eye surgery and scientific research.

### 3.2.3 UVC LIGHT EMITTING DIODES (UVC-LEDS)

A light-emitting diode (LED) is a compact light source consisting of compound semiconductor materials like gallium arsenide (GaAs), gallium phosphide (GaP) indium phosphide (InP) and aluminum nitride (AlN), which also emit in the UV part of the electromagnetic spectrum. Doping can shift the emitted spectral lines into the UVC region. For instance, AlGaN LED lamps emit in the wavelength range of 247 – 280 nm; AlBN LED lamps emit at 214 nm.

\textsuperscript{17} http://www.ozonegenerator.com/ozone_generators/ozone_generators.php
UVC-LEDs are operated with low DC voltages. They are cheap and environmentally friendly, but they are not yet as highly effective as mercury lamps that achieve 40% to generate the required 400 J/m² for water disinfection.

3.2.4 PULSED UV LAMPS

Pulsed UV lamps may be subtypes of flashtubes (or flashlamps) or light-emitting diodes (LEDs).

Flashtubes are electric arc lamps designed to produce extremely intense, incoherent, full-spectrum white light for very short durations. Flashtubes are made of lengthy glass tubing (envelope) with electrodes at either end and are filled with a gas that, when triggered by a high voltage pulse, ionises and produces radiation. The pulse of Xenon and Krypton flashtubes lasts from μs to ms with high intensity spectral peaks which, depending on the lamp type, lie in the range of ultraviolet to infrared. They are capable of operating at high repetition rates (>120 Hz) and can have peak wavelengths in the UVC range (220-275 nm) for synthetic quartz enclosures (quartz is transparent down to 160 nm).

3.3 UVC LAMP APPLICATIONS

There is a wide variety of UVC lamps, working with different technologies and generating variable irradiance levels and peak wavelengths. The choice of a lamp for a specific application depends on the optimisation of cost, spectrum requirements and operating conditions. For some applications, the lamp is inserted in a closed system with no UVR exposure of the user in normal conditions and for other applications; the radiation is directly emitted to the environment.

Low-pressure mercury lamps are often used for water treatment at small or medium flow rates for disinfection and/or oxidation processes; such applications include a wide range of water types (drinking and domestic water, ground water, industrial and waste water, ultrapure water and public pool water). Soft glass lamps are mainly used for drinking water disinfection systems and domestic water treatment systems (aquaria, fishponds, private pools, etc.), transilluminators and sterilising equipment because of their small flow rates and low cost. HID lamps of increased UV-flux are also used for water treatment, usually with the exception of residential drinking water systems.

Air treatment may include disinfecting and oxidising processes. In air conditioning, low pressure mercury lamps are used to disinfect the cooling coils or the air stream directly. Fixed installations of low-pressure mercury lamps are used for air disinfection in sensitive areas within hospitals (e.g. operating theaters), laboratories, thin-layer chromatography (TLC) viewing cabinets, cadmium/mercury lamps, phospholuminescence equipment, clean rooms, storage rooms, and in heavily frequented areas, such as airports, cinemas, homeless shelters, etc. Air oxidation via UV is used for odour removal (in sewage plants, rest rooms, hotels, restaurants, catering, senior citizen

18 The choice should be meaningful because the level of disinfection is not always proportional to the product of irradiation intensity (E) and exposure time (t). Proportionality may not be valid for a wide range of E and t. For a long period of time (t) at low irradiation intensity (E), the microorganism will be able to reproduce themselves with a high rate at the beginning, resulting in lower disinfection level.
homes, caravan trailers, cars, etc. and industrial exhausts). Ozone-generating, low-pressure mercury lamps are used at temperatures below 40°C, whereas amalgam lamps can be used at higher air temperatures up to 120°C.

### 3.4 UV LAMPS MAINTENANCE

UV lamps are housed within lamp sleeves. Their role is to keep the lamp at optimal operating temperature and to protect it from breaking. Lamp sleeves are usually tubes of quartz or vitreous silica. The sleeves must be long enough to include the lamp and its associated electrical connections. Sleeve walls are typically 2 to 3 mm thick.

Lamp sleeves can fracture and foul. Fractures can occur from internal stress and external mechanical forces (such as resonant vibration or impact by objects). Microscopic fractures may also occur if lamp sleeves are not handled properly when removed for manual cleaning. When the sleeves are replaced, the manufacturer's procedure should be closely followed, because the lamp sleeve can crack and break from overtightening of the compression nuts that hold it in place. If the sleeve fractures while in service, the lamp becomes vulnerable to breakage. Lamp breakage is undesirable, due to potential for mercury release (depending on the lamp technology, section 3.2).

In addition to internal and external fouling, when various substances come in contact with the surface of the sleeve, exposure of quartz contaminated with metal cations can cause solarisation, as lamp sleeves age. Both fouling and solarisation can decrease the UV transmittance of the sleeve, which may appear as changes in the lamp spectra or changes in dose calculation (Jin et al., 2007; Schmalwieser et al., 2014). Sleeves should be replaced every 3 to 5 years or when damage, cracks or excessive fouling diminishes UV intensity to the minimum validated intensity level, whichever occurs first.

However, aging affects not only lamp sleeves, but the lamps themselves (Jin et al., 2007; Schmalwieser et al., 2014). Lamp degradation occurs with both low- and medium-pressure lamps and is a function of the number of hours in operation, number of on/off cycles, power applied per unit (lamp) length and heat transfer from lamps. The reduction in output occurs at all wavelengths across the germicidal range. Any deposits on the inner or outer surfaces of the lamp envelope and metallic impurities within the envelope can absorb UV light and cause premature lamp aging. Electrode sputtering during start-up can also coat the inside surface of the lamp envelope with tungsten as the lamp ages. The tungsten coating is black, non-uniform, concentrated close to the electrode, and can absorb UV light. If the lamps are not sufficiently cooled during operation, electrode material in medium-pressure lamps may evaporate and condense on the inside of the envelope. Electrode sputtering can also be reduced by designing lamps that pre-heat the electrode before applying the start voltage, are driven by a sinusoidal current waveform, or have a higher argon (inert gas) content.

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19 This subsection is based on the guidance provided in EPA (2003) and EPA (2006)
4. EXPOSURE

The Maximum Permissible Exposure (MPE) is set for 8 hours for 180-400 nm (UVA, and UVB, and UVC) $H_{\text{eff}}=30 \text{ J/m}^2$ \{H_{\text{eff}} is effective radiant exposure: radiant exposure spectrally weighted by S (\lambda), expressed in joules per square metre\} and for UVA (315-400 nm) $H_{\text{UVA}}=10^4 \text{ J/m}^2$ (Directive 2006/25/EC). These MPEs may be lower if someone is photosensitised e.g. by pathology, medication or diet.

4.1 WATER DISINFECTION

Since the beginning of the 20th century, UV irradiation of water has been used as a means of disinfection (Henry et al., 1910). This was possible because of the new technologies using low-pressure mercury vapour lamps and quartz tubes around these lamps. This technology is now widely used in drinking water plants for water disinfection, especially because of its activity against chlorine-resistant parasites like Cryptosporidium and Giardia.

Different UVC devices are used today (low-pressure, medium-pressure mercury) and these are protected by a quartz tube (doped or not) inserted into a metallic reactor allowing the irradiation of water as a flowing small layer around the quartz tube (a minimum of 400 J/m$^2$ is necessary for obtaining a 3-log reduction with a contact time of 1-15 sec). The reactor is always closed, except during the maintenance phases where the lamps are turned off, thus there is no possible exposure of the workers inside the water treatment plants.

Some small devices for UV water disinfection are sold for the general public but, excepting eventual cases of accidental irradiation linked to misuses, there should be no UVC exposure to users. However, data on UVC exposure in water disinfection are lacking.

4.2 AIR DISINFECTION AND INSECT KILLERS

Information on the exposures experienced from the use of UVC lamps for air disinfection is available from some of the case reports reviewed in section 5 in relation to the adverse health effects that occurred.

Accidental high exposure to UVC irradiation experienced by 26 medical students from germicidal (UVC) lamps was calculated to be approximately 70 J/m$^2$ absorbed energy (Trevisan et al., 2006). The actual radiation emitted by the lamps was estimated to be 1.4 W/m$^2$ (the radiometric measurements confirmed this, because the effective irradiance measured from the height of the autopsy table to about 1 m under the UVC lamp varied from 0.5 to 2.5 W/m$^2$) but, more likely, the effective energy absorbed, according to skin phototype and symptoms, was between 5 and 10 J/m$^2$.

An electric insect killer (bug zapper) is a device that attracts and kills flying insects that are attracted by light. A light source attracts insects to an electrical grid, which electrocutes the insects. The device is housed in a protective cage of plastic or grounded metal bars to prevent people or animals from touching the high-voltage grid. A light source is fitted inside, often a fluorescent lamp designed to emit violet and ultraviolet light, which is visible to insects and attracts them. Usually these devices do not emit UVC
but in some cases they do. A report of accidental radiation effects includes exposure measurement data from electric fly killers (Forsythe 1991). The effective irradiance ranged from 0.3 to 4.6 mW/m². UVA radiation was found to be within the current occupational limits but both UVB and UVC levels exceeded the 8-hour maximum occupational exposure. 10 of the 16 tubes were non-standard and were designed to emit UVC for germicidal purposes.

Measurements of one UVC tube mistakenly fitted in an electric fly killer were made at a distance of 30 cm using a Bentham DM150 double grating spectroradiometer (Oliver et al., 2005). The tube was found to emit strongly in the UVC region; total irradiance from the tube (200–600 nm) was found to be 4.6 W/m². Erythemal weighting of the UVC tube spectra revealed that the erythemal effective irradiance was 4.5 W/m². The authors note that midday Southern European summer sun has an erythemally effective irradiance of 0.27 W/m².

Zaffina et al. (2012) reported on the overexposure of two health care workers (nurses) from a germicidal lamp. In particular, for UVC radiation the maximum exposure measured at the eyes and skin after the accident was 3.36 W/m² (which resulted in an absorbed dose of 5822 J/m² in skin). It was calculated that this exposure must have resulted in an overexposure of the skin and the eyes by 194 and 126 times respectively compared to the daily 8-hour limit in the Directive 2006/25/EC.

In a case report of adverse eye symptoms in Botswana, the lamp of concern was secured to the ceiling (at 3 m) and provided direct irradiation of the area below; no louvres or reflectors were in place (Talbot et al., 2002). Twenty-five centimetres from the UV germicidal lamp, UV irradiation levels ranged from 1.79 to 1.82 W/m². The resulting permissible exposure time was therefore estimated as 34 to 33 seconds. At eye level (about 1.7 m) underneath the lamp, UV irradiation ranged from 0.573 to 0.899 W/m², which corresponded to a permissible exposure time of 105 to 67 seconds. At seated level at one workstation, UV irradiation ranged from 0.20 to 0.222 W/m² (6 to 5 minutes). At the other workstation, UV irradiation ranged from 0.343 to 0.499 W/m² (3 to 2 minutes).

However, reports on the use of UVC radiation for air disinfection without any reported adverse health effect were also found in the literature reviewed. First et al. (2005) have reported measurements of UVC radiation exposure for 19 different scenarios of subjects in four environments (hospital, homeless shelter, university, school). The subjects carried the dosimeter at the height of the chest. The radiation peak was essentially at 254 nm, since the authors reported that systems were low pressure mercury lamps. The measured doses exhibited a large variation from 0.2 to 200 mJ/m² with the maximum eye-level irradiance ranging between 0.2 and 12 mW/m². The authors concluded that an eye-level irradiance up to 4 mW/m² could have been used to increase the efficiency of disinfection lamps without causing overexposure.

4.3 SUMMARY

Most of the recently published data on exposure from UVC lamps comes from reports involving accidental misuse of the lamps. Some of the studies compare the exposures observed with limits applicable at the time of the incident. Many find exceedances, with varying results between UVA, UVB and UVC, e.g. UVA radiation being found to be within
current occupational limits but both UVB and UVC levels exceeding the 8-hour maximum occupational exposure. It has to be noted that the effective irradiance reported in the different studies ranged from 0.3 mW/m² to 4.6 W/m², which is rather high. The variation in exposures with distance from the source is also highlighted in some studies.

It should also be noted that in one study in which measurements of UVC were made in some premises, the disinfection systems had been installed and operating for more than 15 years, without any side effects for the workers in these environments.
5. HUMAN HEALTH EFFECTS

UVC radiation is the most damaging range of UV radiation. However it is highly absorbed by chromophores in the outer layer of the epidermis. As an example, only 5% of incident 254 nm UVC penetrates to the top viable cell layer, compared to 15% of 365 nm UVA and 50% of 297 nm UVB (Bruls et al., 1984). In contrast, the cornea has no such outer layer. Consequently, the cells of the cornea are at higher risk of injury from exposure to UVC irradiation. Thus when fixtures of UVC lamps are improperly installed or when accidental high-intensity exposure occurs to room occupants, UVC can result in photodermatitis and, more commonly, in photokeratitis and photoconjunctivitis (Nardell et al., 2008; Verma et al., 2007).

The following sections review literature on skin and ocular effects from UVC exposure from lamps. In addition, because UVC radiation exposure may be experienced during welding operations, a short overview of the adverse health effects from welding is given in section 5.2. It should be noted that the exposures from welding are usually in combination with UVA and UVB exposure and occur repeatedly at high levels for a short duration; these are thus not directly comparable with the exposures from UVC lamps. As the UVC lamps emitting radiation with wavelengths shorter than 240 nm produce ozone, a brief review of the adverse health effect of ozone is given in section 5.4.

5.1 SKIN AND OCULAR EFFECTS FROM UVC EXPOSURE FROM LAMPS

There are very few recent studies that investigate potential adverse health effects in humans from exposure to UV radiation from UVC lamps. Most are case reports of dermal or ocular effects from accidental exposure (section 5.1.1). There are a few papers reporting small volunteer studies on skin tolerability (section 5.1.2) and gene expression changes (section 6).

5.1.1 CASE REPORTS

There were a handful of reports on the adverse health effects of UVC radiation before the 1990s, for example, a report of acute sunburn due to accidental UVC irradiation in the butcher's department of a meat processing firm (Forsythe et al., 1991). Fifteen employees complained of sunburn and gritty eyes; symptoms improved on holidays and recurred on return to work.

Two health-care workers in a hospital pharmacy received accidental overexposure to UVC radiation produced by a germicidal lamp which was accidentally turned on instead of the supplied fluorescent neon light (Zaffina et al., 2012). A few hours after the exposure, the two subjects reported symptoms of ocular itching and conjunctival injection, along with facial erythema; they were both wearing gloves so their hands were not affected. After 30 days, the ocular signs of actinic keratitis associated with conjunctival injection, disorders of accommodation and blurred vision were still present. The dermatology specialist check, performed about 60 days after the accident, showed first degree erythema (skin dyschromia and desquamation) in both operators. The publication reported that both continued having significant clinical signs for over 2 years.
In another hospital setting in Botswana, two nurses and one housekeeper complained of eye discomfort, ‘like sand in the eyes’, after working in an administrative office. The following day, one employee noted facial skin peeling (Talbot et al., 2002). All symptoms resolved over 2–4 days without sequelae. Six weeks later, the syndrome recurred for all three employees. A workplace investigation revealed that the office had been converted from a hospital sputum induction room and that an unshielded 36W UV lamp was still installed and operational. The on/off switch for the UV lamp was immediately adjacent to the fluorescent bulb on/off switch and did not have a locking mechanism. In the office, UV measurements at eye level and looking directly at the UV lamp ranged from a low of 0.2 J/m² when seated to a high of 0.49 J/m² when standing. The US National Institute for Occupational Safety and Health recommends that exposure to UVC (254 nm) be less than 60 J/m² over a daily 8-hour period for unprotected skin or eyes. These radiant exposure levels result in allowable exposure times of 300 and 120 seconds, respectively.

A 90-minute accidental exposure to similar levels of UVC radiation as reported by Zaffina et al. was experienced by 26 medical school students from germicidal lamps that were lit due to a malfunctioning of the timer system (Trevisan et al., 2006). Several hours after irradiation exposure, all subjects reported the onset of ocular symptoms, subsequently diagnosed as photokeratitis, and skin damage to the face, scalp and neck. While the ocular symptoms lasted 2–4 days, the exposure produced significant erythema followed by deep skin exfoliation. The ocular and skin effects produced by such a high irradiation appeared reversible within a short time – several days. It should be noted that the exposure to the 254 nm UVC radiation should not exceed 21.4 seconds in order to keep the dose below 60 J/m² as recommended by the American Conference of Governmental Industrial Hygienists.

In another example of misuse of UVC exposure, two electric fly killers positioned on the ceiling and sidewalls of a hotel kitchen were found to be incorrectly fitted with UVC tubes (Oliver et al., 2005). Eight cooks reported having painful red skin on their face, eyelids and the side and front of their neck as well as burning, gritty eyes, and a clinical examination diagnosed conjunctivitis and sunburn-like erythema.

In contrast to the above reports, the study by First et al. (2005) described in section 4.2 points out that the disinfection systems had been installed and operating for more than 15 years, without any side effects for the workers in these environments. Similar results were reported by Nardell et al. (2008) in their homeless shelter study where irradiance at eye level reached values as high as 13 mW/m². The authors interviewed 3,611 subjects for eye and skin complaints and concluded that there was a 6% incidence rate of some type of related symptom. However, an analysis of the interviews showed that there was not a statistically significant correlation between the symptoms and the activity of the disinfection lamps.

**5.1.2 VOLUNTEER STUDIES**

Results for the gene expression part of these studies are reported in section 6.

The buttock skin of humans (n = 16) was irradiated with 5-fold MED of UVC and the time course of hyperalgesia (increased sensitivity to pain) and axon reflex erythema (redness of the skin) was monitored (Weinkauf et al., 2012). Skin biopsies were assessed for
gene expression levels (reported in section 6). No side effects of the irradiation such as blisters, infection or scarring were observed. In addition, a lasting pigmentation as regularly reported after a 3-fold minimum erythema dose (MED) UV-B irradiation was not observed upon UVC exposure. Among the individuals, no correlation between the individual UVC irradiation dose required for the 5-fold MED and the mechanical or thermal hyperalgesia was found. Hyperalgesia due to mechanical stimuli delivered at an impact velocity of 12 m/s and heat (48°C) stimuli was significant at 6 hours (p<0.05 and p<0.01) and 24 hours (p<0.005 and p<0.01) after irradiation. Axon reflex erythema upon mechanical and thermal stimuli significantly increased 3 hours after irradiation and was particularly strong 6 hours after irradiation.

A ‘Sterilray’ disinfectant source (222 nm) conventionally used to sterilise equipment and work surfaces was assessed for tolerability in four healthy volunteers with phototype I and II skin (Woods et al., 2015). The MED was determined using an escalating dosage study methodology. Biopsies of irradiated sites (on the back) were stained for cyclobutane pyrimidine dimers (CPD) and the degree of CPD was compared with that in biopsies from unexposed skin and from areas exposed to UVB (280–315 nm) radiation (section 6.1.3). Calibrated spectral measurements revealed emission at a peak wavelength of 222 nm with 97% emission at wavelengths less than 250 nm. For UVC, the MED values in the four volunteers tested were either 400 J/m² or 500 J/m², i.e. at low doses, below the threshold bacteriostatic effect; the source was capable of inducing both erythema and CPD formation in human skin.

5.2 STUDIES OF WELDERS

Occupational exposure to artificial UV radiation, including UVC, during welding is common in the construction industry and in many manufacturing industries. Electric welding arcs emit radiation within a radius of several meters, thus people working nearby, not just welders themselves, can suffer from overexposure. Gas welding and cutting torches also produce UV radiation but at a much lower level; this process mainly consists of exposure to infrared radiation. Arc welding processing scatters bright light with UVR emission over the full UV spectrum (UVA, UVB, and UVC). The worst case of irradiance measurement from 50 cm arc welding reported by Peng et al (2007) showed a broadened UVR spectrum with 33% UVC, 19% UVB, and 48% UVA distributions. As the distance increased the percentage of UVA increased while the percentages of both UVB and UVC radiation decreased.

5.2.1 OCULAR HAZARDS IN WELDERS

Ocular hazards experienced by welders include photophthalmia (welder’s flash), keratoconjunctivitis and cataracts caused by UVR emitted from welding arcs. The condition of ‘arc-eye’, a sensation of sand in the eyes, is a result from excessive eye exposure to UV welding due to the damage to eye lens (Dixon and Dixon 2004; Magnavita 2002). Photokeratoconjunctivitis cases from work-related welding process have been observed in occupational ophthalmological emergencies in Taiwan (Yen et al. 2004).
An increased risk of eye melanoma associated with welding has also been observed (reviewed in IARC 2010; HSE 2012). Studies which related specifically to working as a welder or sheet metal worker (as opposed to working in proximity to welding) found a strong association between increased risk and increased duration of welding (years welding or lifetime hours welding) (Holly et al., 1996; Guenel et al., 2001; Vajdic et al., 2004). A meta-analysis included 5 studies and found a statistically significant meta-OR of 2.05 (95%CI=1.20-3.51) (Shah et al., 2005). There was significant heterogeneity between studies due to two that included iris melanomas, as well as choroids and ciliary body melanomas, reporting higher ORs. The authors concluded that welding was a significant risk factor for the development of uveal melanoma, but due to the relatively small number of studies available, potentially under-powering the analysis, the results should be interpreted with caution.

Sections 5.2.1 and 5.2.2 briefly review literature on skin and ocular effects from welding. It should be noted, however, that these studies do not specifically evaluate the risk from exposure to the UVC from welding.

5.2.2 SKIN EFFECTS IN WELDERS

There have been several case reports of welders experiencing skin effects following welding (Bruze et al., 1994; Donoghue and Sinclair 1999; Roelandts and Huys 1993). A 1-year history of recurrent, severe facial dermatitis, mainly involving the right side of the face, neck and right ear was described in a patient employed in a steel fabrication plant where a considerable part of the workload was the welding of steel bars and plates (Shehade et al., 1987). A 71-year-old woman experienced numerous squamous cell carcinomas (SCCs) on her hands after she had frequently experienced ‘sunburn’ on her hands after assisting her son with his welding business (Dixon 2007). A 32-year-old welder showed atopic dermatitis repeatedly upon occupational exposure to UVC, which subsided only after the patient was removed from the welding site (Elsner and Hassam 1996).

A case-control study compared acute and chronic photo-damage and the incidence of malignant skin disorders between a group of welders, a group of other trades exposed to welding operations and a non-exposed group (Emmett et al., 1981). There were no significant differences among the groups in regard to the prevalence of various dermatoses, skin tumours, changes in visual acuity, clinical ocular abnormalities or the prevalence of actinic elastosis. The degree of elastosis was significantly associated with type of complexion, original hair color, eye colour, childhood freckling, poor ability to tan and ease of sun burning. However, cutaneous erythema and cutaneous scars were more frequent in welders. In addition, a large number of the examined welders showed UV-related acute erythema with blistering in the area of the neck, nose, the rest of the face, arms, chest and throat.

5.3 HEALTH AND WELLBEING

A pilot study tested whether installation and operation of germicidal UVC lamps in central ventilation systems would be feasible, without adverse effects, undetected by building occupants, and effective in eliminating microbial contamination (Menzies et al.,
Germicidal UV lamps were installed in the ventilation systems serving three floors of an office building and were turned on and off during a total of four alternating 3-week periods. Workers reported their environmental satisfaction, symptoms, as well as absences due to sickness, without knowledge of whether the lamps were on or off. The indoor environment was measured in detail including airborne and surface bacteria and fungi. The intensity (irradiance) of UV light, measured at the cooling coils of the lights, exceeded 5.5 mW/m². Airborne bacteria and fungi were not significantly different, whether the UVC lights were on or off, but were virtually eliminated from the surfaces of the ventilation system after the UVC lamps were operated for 3 weeks. Of the other environmental variables measured, only total airborne particulates were significantly different under the two experimental conditions — higher with UV lamps on than off. Of 113 eligible workers, 104 (87%) participated; their environmental satisfaction ratings were the same, whether or not UVC lamps were on or off. With UVC lamps on, headaches, difficulties concentrating and eye irritation occurred less often, whereas skin rash or irritation was more common. Overall, the average number of work-related symptoms reported was similar whether or not the UV lamps were on or off. Overall it was concluded that UV lamps can be installed and working in central heating, ventilation and air conditioning systems of office buildings without workers noticing any different and without resulting in any adverse effects.

Another field trial (double-blind, placebo-controlled) was carried out to evaluate whether the use of upper-room (i.e. mounted high on the wall or on the ceiling) UVC germicidal irradiation could prevent transmission of tuberculosis at 14 homeless shelters in six U.S. cities from 1997 to 2004 (Nardell et al., 2008). As part of this trial, the safety of room occupants was evaluated through administering questionnaires regarding eye and skin irritation to a total of 3,611 staff and homeless study subjects. Approximately every 12 months, the unblended head of the data safety and monitoring committee randomly assigned each shelter to either a placebo or active UV status. Overall there were 3611 questionnaires administered, with 223 (6%) reports of eye or skin symptoms. Of the 223 complaints, 95 occurred in the active UV periods and 92 during the placebo period; in the 36 remaining cases it was unclear which period they occurred in. There was no statistically significant difference in the number of reports of symptoms between the active and placebo periods. One definite occurrence of UV-related keratoconjunctivitis occurred, resulting from a placement of a bunk bed in a dormitory where a single bed had been used when the UV fixtures were first installed. The authors concluded that effective use of upper-room UV germicidal irradiation can be achieved without an apparent increase in the incidence of the most common side effects of accidental UV overexposure.

### 5.4 HEALTH EFFECTS OF OZONE

Ozone is a highly reactive substance and adverse health effects are usually found at the sites of initial contact especially the respiratory tract (nose, throat and airways), the lungs, and at higher concentrations, the eyes. The principal health effects are produced by irritation of and damage to the small airways of the lung. However, people's sensitivity to ozone exposure varies considerably (Lippmann 1989). Studies of the adverse health effects of ozone include volunteer studies, studies of 'natural exposure' of ozone in ambient air and hospital-based studies to investigate longer-term chronic effects. Symptoms from short-term transient exposures include coughing and wheezing,
pain when taking a deep breath and breathing difficulties during exercise or outdoor activities.

Volunteer studies have shown reductions in lung function following ozone exposure in healthy children and adults and also in asthmatics. Studies of ozone exposure as a component of ambient air pollution have identified associations with respiratory mortality (both short-term and long-term exposure); short-term exposure has also been shown to be associated with respiratory symptoms, asthma and COPD (EPA 2014).

At risk groups include children and adults who are active outdoors, outdoor workers, people with respiratory diseases such as asthma or emphysema and people with unusual susceptibility to ozone.

The EPA advises that the UVC lamps that emit ozone should not be used in closed premises without ventilation (EPA, 2013)

5.5 SUMMARY

There are very few studies that investigate potential adverse health effects in humans from exposure to UV radiation from UVC lamps when used as intended. Most are case reports that report dermal or ocular effects from accidental exposure through, for example, use of inappropriate bulbs or accidental prolonged exposure. UVC radiation can damage the superficial tissues of the eye. However, in general it is reported that while eye exposure to UVC from lamps may cause extreme discomfort, the symptoms subside within about a week. However, one study reported that, following UVC lamp exposure which caused more immediate first degree erythema and ocular problems, ocular problems remained for up to 2 years after exposure. In contrast, most of the effects on the skin have been reported as being of short duration.

One of the volunteer studies found no lasting pigmentation after irradiation with 5-fold MED of UVC and no side effects of the irradiation such as blisters, infection or scarring were observed. The other volunteer study found that 222 nm UVC radiation at low doses (below the bacteriostatic effect threshold) was capable of inducing both erythema and CPD formation in human skin.

Two intervention trials found no difference in eye or skin irritation between periods when germicidal UV lights were switched on and periods when they were off, nor any difference in symptoms of health and well-being, such as headache and difficulty concentrating.

Exposure to ozone presents a risk of a variety of symptoms and diseases associated with the respiratory tract, particularly in sensitive individuals.

Ocular hazards experienced by welders include ‘arc-eye’ (a sensation like sand in the eyes), photophthalmia (welder's flash), keratoconjunctivitis, cataracts caused by the wide spectrum of UVR (including UVC) emitted from welding arcs and an increased risk from ocular melanoma. UV-related acute erythema with blistering has also been reported in welders.
6. BIOLOGICAL EFFECTS

6.1 BIOLOGICAL EFFECTS OF UV RADIATION

6.1.1 GENERAL OVERVIEW

As UVC from solar radiation is effectively filtered by the atmosphere, in particular the ozone layer, there is normally negligible exposure to this type of radiation on the earth’s surface. However, artificial UVC radiation is now used in a large range of applications.

The penetration of UV radiation in the eye and the skin tissues largely depends on the wavelength. Since the spectrum of UVC lamps may also contain some UVB, biological effects of both UVC and UVB radiation are also discussed in this chapter.

UV radiation can damage the eyes (Bova et al., 2001). One of the most common ocular conditions associated with UVA and UVB exposure is cataract development. A crystalline lens is made up of proteins. These proteins can be altered or denatured by exposure to UV radiation. In fact, all three layers of the lens — nucleus, cortex and capsule — can have alterations in their protein structures. Figure 2 shows that UV light with wavelengths larger than 315 nm penetrates up to the lens, with the UVC wavelengths being absorbed at the surface of the cornea - both the corneal epithelium and endothelium (which cannot regenerate) are vulnerable to UV radiation. Mallet and Rochette (2013) have shown ex vivo that UVB- and UVC-induced CPDs are concentrated in the corneal epithelium and do not penetrate deeply beyond this corneal layer.

![Figure 2: Variation of penetration depth in the eye with UV radiation wavelength.](http://www.laser2000.co.uk/safety_guidance.php)

It has been shown by Meinhardt et al. (2008) that the penetration depth of UV radiation into the skin depends on the body site and the skin phototype. Usually UVC does not
penetrate deeper than the horny layer in the intact skin as illustrated in Figure 3. It should be noted that skin thickness exhibits a large variation both interpersonally as well as intrapersonally, and varies with age.

**Figure 3:** Variation of penetration depth in a standard skin with wavelength. It is clearly shown by the isoparametric transmission contours that less than 10% of the radiation at UVC wavelengths reaches depths below the upper two skin layers, whereas 10 to 50% of radiation at UVA wavelengths reaches the basal cell layer and the corium. (Source: Bezzant JL, Penetration of human skin by ultraviolet light, M.D. [http://library.med.utah.edu/kw/derm/pages/meet_2.htm](http://library.med.utah.edu/kw/derm/pages/meet_2.htm))

The harmful effects from exposure to UV radiation include acute effects on the human skin, like photodermatosis, photosensitisation and erythema (inflammation/sunburn) as well as chronic and stochastic effects like premature aging of the skin, suppression of the immune system and skin cancer. UVA radiation effects are not considered here (for details see the SCENIHR Preliminary Opinion on sunbeds).

Artificial UVC is also known to induce erythema in human skin. For erythema that is just perceptible to the eye, the dose is approximately one thousand fold higher for 360 nm radiation (UVA) than for 300 nm (UVB) or 254 nm (UVC) radiation (Diffey and Farr, 1991). The development of measurement techniques to quantify UVR erythema has allowed the response of normal skin to UVR of different wavelengths to be defined in terms of its dose-response relationship, rather than the conventional and limited visual threshold assessment of minimal erythema. This has facilitated investigation of the biochemical processes of ultraviolet erythema in normal skin (Diffey et al., 1984). The time course of ultraviolet erythema was measured at exposure to six different doses of UVC and UVB radiation in each of eight adult subjects (Farr et al., 1988). The intensity of erythema was measured by reflectance spectrophotometry at 4, 8, 24, 36, and 48 hours after irradiation. In five subjects, there was no significant difference between the form of the UVB and UVC erythema time course. A significant difference was observed in three subjects, but this was random rather than systematic between subjects.

The dose-response curve for UVC (253.7 nm) erythema in human skin has been shown to be significantly less steep than for UVB (300 nm) (Farr PM, Diffey BL. 1985, Diffey and Farr, 1991). The degree of erythema increases more rapidly with equal increments
of dose above the MED for irradiation with UVA or UVB than for UVC radiation. The significant difference in slope of the dose-response curve at these two wavelengths (254 nm and 300 nm) means that, when compared in this fashion at doses greater than the MED, UVC erythema will always be of much greater intensity.

Diffey and Farr (1991) also point out that the criterion used to judge the erythema could be a major factor in the reported variability of erythematic sensitivity to wavelengths of 280 nm or less. Since the slope of the dose-response curve at 254 and 280 nm is much shallower than at 300, 313 or 365 nm, they suggest that appreciable uncertainty is possible in the estimation of the MED at these shorter wavelengths depending on the exact degree of erythema observed. They show that this means that although the skin is more sensitive to 254 than 300 nm radiation in terms of minimal erythema, the reverse is the case for moderate or severe erythema.

IARC classified UV radiation as carcinogenic to humans (Group 1 carcinogen) (IARC 1992; IARC 2010). The group 1 classification for UVC was based on experimental evidence in mice causing squamous cell carcinoma of the skin and mechanistic considerations that UVC is carcinogenic in human cells (IARC 2010). The main source for UV-induced skin cancer is DNA damage. In addition, suppression of the immune system resulting from exposure to UV radiation is considered to be an important contributor to the development of non-melanoma skin cancers.

6.1.2 ANIMAL STUDIES

Yel et al. (2014) investigated the ultrastructural effects of UVC radiation on the stratum corneum of mole rats. The control group did not receive any radiation while the animals of the treated groups were irradiated with UV radiation (254 nm) for 14, 28, or 60 days, corresponding to 52, 112 and 168 h. The total dosage was reported to be 2,822.4 J/m², 5,644.8 J/m² or 8,647.2 J/m², respectively.

Skin samples were prepared and analysed by transmission electron microscopy. Depending on dosage and exposal period, ultrastructural changes occurred in mole rats' skin. An increase in the keratohyalin and the formation of vacuoles in the cytoplasm were among the remarkable changes induced by UVC. It was found that the transformation of granular cells into horny cells was not completed in the stratum corneum. Pathological aggregations of tonofilaments were formed in the desmosomes. Lacunae formations and unkeratinised cytoplasmic residues were observed within the horny cells.

6.1.3 HUMAN STUDIES

In the study of 4 volunteers using a ‘Sterilray’ disinfectant source (Woods et al., 2015), described in detail in 5.1.2, the histopathology results showed evidence of CPD formation after irradiation with ‘Sterilray’ UVC at 222 nm. In two volunteers with epithelial thinning over the suprapapillary plates, UVC exposure resulted in basal CPD formation where the epidermis was thinned.

These events occur at ‘Sterilray’ dosage levels below the threshold for bacteriostatic/cidal effects. The authors concluded that in hand skin, if UVC exposure was employed to reduce microsurface organisms, potentially mutagenic damage to the
basal layer keratinocytes would occur during use of this disinfection source, particularly within the thinned suprapapillary plates. There might be some filtering out of the damaging effects of UVC by the thicker corneal layer on palmar skin, but DNA damage might still occur at other less cornified sites such as the dorsal hands and wrists.

In the study of volunteers irradiated in the buttocks (Weinkauf et al., 2012), described in section 5.1.2, skin biopsies were assessed for expression patterns of 31 gene levels by RT-PCR analysis. Twenty-three of those genes could be reliably quantified. A modulated gene expression pattern was found in the irradiated skin for e.g. bradykinin receptor 1, chemokine ligand CCL-2, COX-2, NGF and its high affinity receptor TrkA. Analysing the individual pain responses upon heat and mechanical stimuli with the individual mRNA expression patterns, a correlation between COX-2 and PGES levels at 6 h and heat evoked erythema was found, and in addition a possible role of Nav1.7 (gene SCN9A) for mechanical hyperalgesia was identified.

Some of the reported gene modulations are already known to occur in human skin after UVB radiation: (1) Bradykinin receptor 1 is correlated with an increased sensitivity in human sunburn as an increased B1 and B2 receptor mediated hypersensitivity, and additionally, enhanced local vasodilatation upon B1-receptor activation has been previously described in UV-B irradiated human skin. (2) Following UVC exposure, COX-2 was upregulated and this is in-line with the well-known anti-inflammatory and analgesic effect of COX-2 inhibitors in human sunburn. (3) The strong increase of the chemokine (C-C motif) ligand 2 (CCL-2) in UVC skin is in accordance with recent findings exploring the cytokine profile after UVB irradiation in human skin.

6.2 SUMMARY

UVC is mostly absorbed in the horny layer of human epidermis. Both histopathological and genetic investigations show alterations like CPD formation and gene modulations induced by UVC. UVC exposure resulted in basal CPD formation where the epidermis was thinned even at low doses below the threshold bacteriostatic effects.

UVC from solar radiation is effectively filtered by the ozone layer and there is normally negligible exposure to UVC from the sun on the earth’s surface. Artificial UVC radiation has been shown to induce erythema in human skin. The time course of UV-induced erythema appears not to be significantly different between UVC and UVB radiation. However, the dose response curve for UVC erythema in human skin is less steep than for UVB. As the mechanisms for DNA damage at molecular level are comparable to those known for UVB, UVC is considered carcinogenic.
7. OPINION

The Scientific Committee has been asked to assess the safety risks associated with the use of UVC lamps and to provide an answer to the following questions:

Q1. What are the potential effects on human eyes and skin if these organs are exposed to UVC radiation of varying wavelength, intensity and duration?

Epidemiological data

There are few studies of UVC exposure to humans from lamps under normal conditions of use, most data on both exposure and adverse health effects comes from reports on accidental misuse of UVC lamps. Depending on exposure characteristics and exposure patterns, UVC radiation from lamps may cause different adverse health effects in the eyes and the skin. UVC radiation can damage the superficial tissues of the eye. The studies of accidental overexposure of the eye generally report that ocular symptoms usually subside within about a week. However, at high exposure, ocular problems may remain for much longer.

Most of the acute effects on skin, such as erythema, have been reported as being transient.

Exposure to UVR from welding is outside the scope of the Opinion.²⁰

Mechanistic data

Information about the mode of action regarding DNA damage by UVC radiation is well documented and is available from in vitro studies and human volunteer studies. UVC is mainly absorbed by the horny layer of human epidermis. Histopathological and genetic investigations show alterations such as CPD formation and gene modulations induced by UVC. UVC exposure was shown to result in basal CPD formation where the epidermis was thinned, i.e. in deeper skin parts than the usual horny layer. These changes have been reported to occur at a dose lower than the threshold bacteriostatic effects of UVC.

The dose response curve for UVC erythema in human skin is significantly less steep than for UVB. Since the slope of the dose-response curve at UVC wavelengths is much shallower than at UVB wavelengths, it suggests that appreciable uncertainty is possible in the estimation of the MED at these shorter wavelengths depending on the exact degree of erythema observed.

The mechanisms for DNA damage at molecular level from UVC exposure are comparable to those known for UVB. The mode of action of UVC radiation is similar to UVB radiation and capable of inducing skin cancer. Due to the mode of action and induced DNA damage similarly to UVB, UVC can be considered carcinogenic to humans. However, the currently available data do not allow quantitative cancer risk assessment of exposure from UVC lamps.

Q2. Is there a wavelength-dependent safety threshold with regard to UVC intensity and/or energy (dose) that could prevent adverse health effects to human eyes and/or skin?

²⁰ Cumulative exposures to acute intense UV radiation (including some UVC) during welding can lead to cataract formation, retinal damage and an increased risk of melanoma.
Adverse effects to the eye and skin in humans are reported mainly from accidental acute exposure to UVC radiation from UVC lamps. There are wavelength-dependent exposure thresholds in the UVC range for acute adverse effects to human eyes and skin. However, due to the lack of data, including dosimetry, no quantitative values can be given.

Q3. Are there other safety aspects that should be considered together with/instead of any possible wavelength-dependent safety threshold?

Ozone may be produced from UVC lamps emitting UVC at wavelengths shorter than 240 nm. Exposure to ozone, above threshold levels, presents a risk of a variety of symptoms and diseases associated with the respiratory tract, particularly in sensitive individuals.

UVC lamps capable of producing ozone in the environment need critical assessment. Other unintended side-effects such as safety-relevant material degradation are outside the scope of this Opinion.
8. RECOMMENDATIONS FOR FURTHER WORK

Research is needed on medium- and long-term health effects from exposure to UVC from lamps to both workers and the general public, in particular children. Little is known about exposures from private use of UVC lamps. Exposure data are scarce for the use of UVC irradiation in disinfection of water.

Although mechanistic studies suggest that there are wavelength-dependent exposure thresholds for UVC regarding acute adverse effects to human eyes and skin, except for erythema, quantitative estimation of these thresholds could not be derived from currently available data. In addition, there are no quantitative data on dose responses of stochastic effects such as skin cancer or ocular cancer, neither with regard to UVC intensity or irradiance nor with regard to cumulated absorbed radiation energy. Therefore, more research is needed on these issues.
9. MINORITY OPINION

None.
10. ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>Aluminum nitride</td>
<td>AlN</td>
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<tr>
<td>Basal cell carcinoma</td>
<td>BCC</td>
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<tr>
<td>Cyclobutane-pyrimidine dimers</td>
<td>CPDs</td>
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<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>COPD</td>
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<tr>
<td>Electromagnetic radiation</td>
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<tr>
<td>Far UV</td>
<td>FUV</td>
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<td>Gallium arsenide</td>
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<td>Gallium phosphide</td>
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<tr>
<td>Germicidal UV lamps</td>
<td>GUV lamps</td>
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<tr>
<td>High intensity discharge</td>
<td>HID</td>
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<tr>
<td>International Commission on Non-Ionizing Radiation Protection</td>
<td>ICNIRP</td>
</tr>
<tr>
<td>Indium phosphide</td>
<td>InP</td>
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<tr>
<td>International System of Units</td>
<td>SI</td>
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<tr>
<td>Light emitting diode</td>
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<tr>
<td>Low Voltage Directive</td>
<td>LVD</td>
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<tr>
<td>Minimal erythema dose</td>
<td>MED</td>
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<tr>
<td>Maximum Permissible Exposure</td>
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<tr>
<td>National Institute of Occupational Safety and Health</td>
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<td>Official Journal of the European Union</td>
<td>OJEU</td>
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Scientific Committee on Emerging and Newly Identified Health Risks  SCENIHR

Scientific Committee on Health, Environmental and Emerging Risks  SCHEER

Squamous cell carcinoma  SCC

Ultraviolet radiation  UVR

United States Environmental Protection Agency  EPA

Vacuum UV  VUV
ANNEX 1

Literature review on the biological effects of UVC radiation relevant to health with particular reference to UVC lamps

The purpose of the literature review was to assess the scientific literature papers to allow the assessment of the scientific evidence concerning the biological effects of UVR relevant to human health with particular reference to UVC radiation and lamps.

Method
PubMed was used as the main database for searching. Since no MeSH heading includes the term ‘UVC’, the terms used in the searches are given in the table below (Table A.1), together with their results. The searches covered the period until 31 March 2016. Some of the publications included in the list of references have appeared in the results of more than one search terms combinations (lines in Table A.1).

The majority of the studies identified did not pertain to the work towards the current Opinion, i.e., they could not be used for risk assessment of UVC lamps. The most common subject of research were the disinfecting properties of UVC radiation, its use in clinical practice and protective measures to reduce damage during exposure to it. Some studies were not used for risk assessment because it was not possible to differentiate between exposures to distinct ranges (UVA, UVB, UVC) of the UV spectrum or they were lacking the corresponding dosimetry.

The studies on welders/welding were not systematically reviewed or considered, for the reasons mentioned in section 5. The same holds for the occupational risks of exposure to ozone.

Table A.1. Literature search terms and results (PubMed)

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<thead>
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<th>Search term</th>
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<th>Human studies</th>
<th>Number of references included</th>
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<td>UVC light</td>
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<tr>
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<tr>
<td>UVC risk occupational</td>
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