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Safety requirements for UV-C equipment used for room air and surface disinfection

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UNE Specification 0068

Safety requirements for UV-C equipment used for room air and surface disinfection

Requisitos de seguridad para aparatos UV-C utilizados para la desinfección de aire de locales y superficies.

Exigences de sécurité pour les équipements UV-C utilisés pour la désinfection de l'air de locaux et surfaces.

This standard is the English version of Especificación UNE 0068:2020.

In case of disputes concerning the accuracy of this translation into English, the Spanish original version should be consulted.

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0 Introduction

Due to the pandemic caused by COVID-19, a multitude of products is entering the Spanish market intended for room air and surface disinfection that use UV-C light sources as a germicidal element. UV-C radiation is not visible to humans and exposure to it may have effects on their health. There are standards that ensure the quality and safety of certain types of these products, however others have been detected that are not completely covered by the existing standards.

The Spanish Association for Standardization, UNE, has developed this Specification in order to determine the minimum safety requirements applicable to such products not covered by a standard, encompassing from the technical requirements of the product to installation and maintenance requirements, intended for ensuring a safe and efficient use.

This document has been prepared by a Working Group created specifically for this purpose.

The Spanish Association for Standardization, UNE, undertakes this initiative in accordance with its purpose of contributing to the competitiveness and safety of businesses, as well as their products, services and processes, the protection of people, consumers and the environment, the integration of persons with disabilities, the promotion of Social Responsibility and the improvement of business risk control, thus contributing to achieve business excellence and the welfare of society.

1 Scope

This UNE Specification covers product, installation and maintenance requirements, intended for a safe and efficient use of professional-use apparatus for room air and surface disinfection that use UV-C radiation.

2 Normative references

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

UNE-EN 60335-2-65:2005, *Household and similar electrical appliances. Safety. Part 2-65: Particular requirements for air-cleaning appliances.*
UNE-EN 60335-2-65:2005/A1:2008
UNE-EN 60335-2-65:2005/A11:2013
PNE-EN 60335-2-65:2003/FprAA[1)]
PNE-EN 60335-2-65:2003/FprA2[1)]

UNE-EN ISO 15858:2017, *UV-C Devices. Safety information. Permissible human exposure (ISO 15858:2016).*

UNE-EN 62471:2009, *Photobiological safety of lamps and lamp system.*

1) In preparation at the date of publication of this document.

3 Requirements

3.1 General requirements

The apparatus or equipment with UV-C radiation shall include in the product documentation an EU Declaration of Conformity in order to provide the information required on the compliance with the applicable regulation, including at least the following Directives:

- Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization 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;

- Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to electromagnetic compatibility;

- Directive 2011/65/EU of the European Parliament and of the Council, of 8 June 2011, on the restriction of the use of certain hazardous substances in electrical and electronic equipment;

- Directive 2012/19/EU of the European Parliament and of the Council, of 4 July 2012 on waste electrical and electronic equipment (WEEE);

- Directive 2006/25/EC of the European Parliament and of the Council, of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation).

In addition to these Directives, the declaration of conformity shall also include any other harmonised legislation applicable to the product based on its specific characteristics.

3.2 Safety requirements

This type of apparatus that incorporate a series of UV-C radiation emitting sources is electrical equipment designed to operate within certain voltage limits, and shall be in accordance with the safety objectives of the Low Voltage Directive (2014/35/EU) described in its Annex I - Principal elements of the safety objectives for electrical equipment designed for use within certain voltage limits.

These safety objectives are as follows:

1 General conditions

a) The essential characteristics, the recognition and observance of which will ensure that electrical equipment will be used safely and in applications for which it was made, shall be marked on the electrical equipment, or, if this is not possible, on an accompanying document.

b) The electrical equipment, together with its component parts, shall be made in such a way as to ensure that it can be safely and properly assembled and connected.

c) The electrical equipment shall be so designed and manufactured as to ensure that protection against the hazards set out in points 2 and 3 is assured, providing that the equipment is used in applications for which it was made and is adequately maintained.

2 Protection against hazards arising from the electrical equipment

Measures of a technical nature shall be laid down in accordance with point 1, in order to ensure that:

a) persons and domestic animals are adequately protected against the danger of physical injury or other harm which might be caused by direct or indirect contact;

b) temperatures, arcs or radiation which would cause a danger, are not produced;

c) persons, domestic animals and property are adequately protected against non-electrical dangers caused by electrical equipment which are revealed by experience;

d) the insulation is suitable for the foreseeable conditions.

3 Protection against hazards which may be caused by external influences on the electrical equipment

Technical measures shall be laid down in accordance with point 1, in order to ensure that the electrical equipment:

a) meets the expected mechanical requirements in such a way that persons, domestic animals and property are not endangered;

b) is resistant to non-mechanical influences in expected environmental conditions, in such a way that persons, domestic animals and property are not endangered;

c) does not endanger persons, domestic animals and property in foreseeable conditions of overload.

Conformity with these requirements is presumed, provided they are in accordance with harmonised standards published in the OJEU (cf. Articles 12 and 13 of the Directive). In this sense, there is a standard that establishes the safety aspects of the apparatus or equipment incorporating UV-C emitters used as germicides. This is UNE-EN 60335-2-65. Additionally, another standard (UNE-EN ISO 15858) was prepared as a response to a worldwide demand for minimum safety UV-C specifications for apparatus using UV-C lamps, mainly intended for air disinfection.

None of the previous standards are directly applicable to the apparatus covered by this specification, but both standards may be used as a basis for the analysis that shall be performed by the manufacturers of apparatus with these characteristics to comply with the safety objectives described in Articles 2b) and 2c) of aforementioned Annex I.

NOTE UNE-EN 60335-2-65 covers air cleaning equipment that uses a UV-C emitting source as a germicidal element, but totally enclosed and in which the radiation is not allowed to be emitted outside. For its part, UNE-EN ISO 15858 covers the safety requirements relative to exposure to UV-C radiation, but does not cover other safety requirements, such as electrical ones.

These standards contain the hazardous UV-C radiation limits that should be met.

NOTE The International Commission on Non-Ionizing Radiation Protection (ICNIRP, 2004) has provided a guide on the occupational exposure to UV radiation, including UV-C radiation: the exposure to UV radiation in the eyes/skin should not exceed 30 J/m^2 for a radiation of 270 nm, the maximum wavelength of the spectral weighting function for the actinic danger of UV for the skin and eyes. As the hazardous effect of UV depends on the wavelength, the maximum exposure limit for radiation with a wavelength of 254 nm is 60 J/m^2. For radiations of 222 nm, the maximum exposure limit (UV actinic risk) is even greater, around 240 J/m^2. This wavelength has been studied for germicidal purposes. The previous (daily) UV exposure limits are given in UNE-EN 62471 for the photobiological safety of products that use lamps.

Compatibility of the materials and components of the equipment with UV radiation shall also be considered, so that their characteristics (insulations, durability, resistance, etc.) are not affected by the presence of this type of radiation, whether directly or indirectly through the reflections off the different materials.

On the other hand, there is also a standard, that is harmonised for the Low Voltage Directive, on the photobiological safety of lamps (UNE-EN 62471) which includes the classification and radiation exposure limits, and states verbatim "*Within Europe those limiting values are already covered by the Artificial Optical Radiation Directive (2006/25/EC). Thus, the limits of the directive have to be applied instead of those fixed in IEC 62471:2006*". Therefore, conformity shall be given with the limits included in the Artificial Optical Radiation directive (2006/25/EC), Annex I.

The components that are replaceable shall be those specified by the manufacturer in its instructions.

The enclosure elements and optical systems used in these apparatus shall ensure they remain within the admissible values and not hinder the transmission of UV-C radiation. They shall also ensure no deterioration takes place in these parts at least during the warranty period established by the manufacturer.

At present, in the equipment that is equipped, for example, with low pressure mercury lamps, materials that modify their spectral and transmittance characteristic shall not be used for the optical system. Regular cleaning of insects and dust from the luminaire may be required, as specified by the manufacturer in its maintenance instructions.

The apparatus shall have labels warning of the danger and harm it may cause. These warnings shall also appear in all the communications of the products.

There are three disinfection systems that may be used using UV-C (germicide) in closed spaces:

- Indirect radiation, placing the equipment above 2.3 m from the ground and directing its ray horizontally and towards the ceiling. There may be people inside the room, as long as the ultraviolet radiation that affects them does not exceed the maximum permissible amounts defined in UNE-EN 62471. It acts as an air germicide in the radiated area. In order to increase its effectiveness, the use of systems for directing the room air flow to this upper radiated part is recommended.

- Direct radiation, to all the surfaces in the room. There can be no people in the room during the time of radiation because the permissible limits may be exceeded. This radiation disinfects the air but only surfaces directly radiated, not shadow areas. There may be mixed systems so that the indirect part is generally activated and only when there are no persons, the direct part can also be radiated.

- Radiating the inside of air conditioning system ducts, in this case UNE-EN ISO 15858 is applied.

Although within the safety objectives of the Low Voltage Directive, Annex I, point 1a), it is established that "the essential characteristics, the recognition and observance of which will ensure that electrical equipment will be used safely and in applications for which it was made, shall be marked on the electrical equipment, or, if this is not possible, on an accompanying document", in the case of this type of apparatus of particular relevance are the strict safety measures that shall be applied when used, as well as the additional measures that shall be provided during usage to operators, maintainers or other persons.

The risk analysis that shall be carried out for this type of apparatus shall include all essential means and possible incorrect or abnormal operation in order to keep its operation safe without affecting people.

In this sense, a series of minimum requirements shall be established (for example, interlocks, presence safety detectors, impossibility of putting it into operation if the safety and protection of the operators, maintainers or other persons that may be subject to radiations are not met, etc.) to ensure an adequate operation and maintenance of the equipment.

The apparatus that are incorporated into installations that emit UV-C shall visibly include mandatory markings on their packaging and on the product itself clearly and unmistakably indicating that it emits UV-C radiation. The accompanying documentation shall include the possible harm it may cause to health.

Only products that actually and mainly emit this radiation may be marked with the UV-C label, and those that emit more than 10% in wavelengths between 280 nm and 400 nm shall especially not be marked as UV-C apparatus.

The products shall be differentiated according to whether they are designed for direct, indirect and mixed radiation.

It shall be ensured that the installations meet the safety requirements that are applicable when the radiation is direct and indirect.

The apparatus for direct radiation shall not be in operation if there are persons within the radiation field. The apparatus and/or installation shall be equipped with safety and warning elements if it is installed in spaces with the presence of persons (movement or presence sensors, visual and sound signals etc.), as well as a mechanism which, if any of the systems fail, disconnects the equipment when persons are detected. In anticipation of the failure of this safety equipment there shall be a protocol that prevents the usage of said UV-C radiation installation. To do this the installer shall perform a risk analysis of the installation and usage of the system. The presence sensor used shall be catalogued as a functional safety sensor and be in accordance with the relevant standards (for example, standard series UNE-EN 61508 or equivalent ones).

The product documentation shall include a data sheet thereof.

Taking Article 6 of Directive 2006/25/EC as a reference, the owner of the installation shall ensure that workers who are exposed to risks from radiation receive any necessary information and training relating to the outcome of the risk assessment (including the use of personal protective equipment in accordance with UNE-EN 170, for example, or any other applicable standard).

Clear and concise instructions shall be provided to place at the entrances to the rooms with installations of UV-C apparatus.

Once the system is installed it shall be verified that it meets this specification, as regards safety systems. Particular verification shall be made, in the indirect radiation installations, that the area occupied by persons does not exceed the established UV radiation levels mentioned beforehand.

Regular measurements shall be made (at least every six months) of the installations with UV-C apparatus.

Portable type apparatus or that may have different application locations shall also meet the following requirements:

- they shall have an on and off timer, in order to program a time for the start up that enables the user to leave the radiation area and ensure the operation of the apparatus during the required time without the need for manipulating the machine to turn it off when it's in operation;

- they shall have a presence detector incorporated in the apparatus itself, that ensures the apparatus does not start operating when the presence of persons is detected in the radiation area.

NOTE UV-C radiation is useful for disinfecting air and surfaces or for disinfecting water. Particularly with low pressure mercury vapor energy sources with radiation predominantly at 254 nm. However, the ICD and WHO advise against the use of UV lamps to disinfect the hands or any other area of the skin (WHO, 2020).

UV-C radiation may cause the photodegradation of materials and this shall be considered where susceptible materials, such as plastics, textiles, paints, etc., are located in the exposed environment.

For an adequate assessment of the UV radiation of the disinfection equipment and its risk management, the on-site measures shall be performed with calibrated and traceable equipment using them adequately in the installation and in its maintenance.

4 Bibliography

UNE-EN 170:2003, *Personal eye-protection. Ultraviolet filters. Transmittance requirements and recommended use.*

UNE-EN 61508 (series), *Functional safety of electrical/electronic/programmable electronic safety-related systems.*

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