

OPINION ARTICLE

Sunbeds, Skin Cancer, International Standards, and the Social Role of Dermatologists

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The carcinogen to which humans are most frequently exposed is UV radiation.¹ Acute exposure results in erythema and burns, and effects over the long term include photoaging.²

The most important source of UV radiation is the sun. To enable energy coming from the sun to be understood and managed, the United Nations adopted the solar UV index (UVI),³ calculated by multiplying by 40 the sun's effective irradiance adjusted to a standard curve for erythema. The typical maximum UVI value for tropical countries is 12 (or 0.3 W/m²), although values of up to 18 may be reached in some areas.⁴ Campaigns are conducted annually to warn people of the risks associated with exposure to the sun, and the World Health Organization (WHO) recommends avoiding exposure on days with a UVI of 8 or more³—a recommendation that has been adopted by Spain (see the Spanish Meteorology Agency website at <http://www.inm.es/uvi/>).⁵ Implicit in the WHO recommendation is the fact that the greater the solar irradiance (that is, the higher the UVI), the greater the risk of experiencing the side effects of UV radiation. However, further research is required in order to reliably determine whether, at similar doses, differences in irradiance lead to different effects.

In this scenario, an increasingly important source of UV radiation has been largely ignored, namely, sunbeds.^{1,6} Until 2002, the manufacture and sale of sunbeds in Spain was regulated by the European EN 60335-2-27:1997 standard, approved by the European Committee for Electrotechnical Standardization (CENELEC), of which the Spanish Association for Standardization and Certification (AENOR) is a member. Compliance with this standard is mandatory in Europe. This standard is the same as the international IEC 60335-2-27 standard, approved by the International Electrotechnical Commission (IEC) and accepted in most countries in the world, even though it is merely informative in nature. However, this standard places no restrictions on the irradiance produced by the sun lamps used in sunbeds; in fact, it has only been technology-imposed restrictions that have resulted in low irradiance in sunbeds.⁷

Technological advances are such, however, that the irradiance of sunbed lamps is increasingly greater. Sunbeds are now the cause of many skin cancers as a result of the similarity of their effects to those associated with solar radiation, namely immunosuppression, DNA damage, and increased production of free radicals.^{6,8} Some epidemiologic studies have found a higher incidence of skin cancer (both melanoma and non-melanoma cancer) in sunbed users, with an estimated relative risk of up to 2.25.⁹

Given this scenario, in 2002 the Spanish Ministry of Health and Consumer Affairs published Royal Decree 1002/2002, governing the sale and use of tanning equipment based on UV radiation. In its Article 3 (page 35 772) this legislation sets 2 restrictions: maximum erythemal effective irradiance for sun lamps is established as 0.3 W/m² (equivalent to a UVI of 12), and sun lamps may not emit UV-C radiation. Given the conflict between the Spanish legislation and the EN 60335-2-27:1997 standard, on 22 May 2003 Spain presented a formal objection to the effect that the European standard failed to confer the presumption of conformity. This step taken by Spain has important implications, given that the free movement of goods may not be impeded in the European Union; in other words, if an item of equipment can be used in one country, it must also be possible to use it in another.

On 25 November 2003 the European Commission met with representatives of the Spanish Ministry of Science and Technology in Madrid at a meeting in which the latter, on behalf of the Spanish National IEC Committee, defended the Spanish position against that of the tanning industry and the chairperson of IEC Technical Committee 61/Maintenance Team 16 (IEC/TC61/MT16) for the 60335-2-27 standard. Given the entrenched positions of the 2 sides, the European Commission representative requested a report from the Scientific Committee on Consumer Products of the European Union, an independent committee composed of scientists with academic affiliations. The Spanish National IEC Committee, meanwhile, appointed me to attend meetings on the subject of the IEC 60335-2-27 standard held by IEC/TC61/MT16.

Since 2003, the Spanish stance in regard to the maximum erythemal effective irradiance of 0.3 W/m² and the absence of UV-C radiation emissions from sunbeds—not to mention the inclusion of a number of safe-use guidelines—have all been defended in IEC/TC61/MT16 and CENELEC meetings

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and in various IEC and CENELEC voting rounds in relation to 60335-2-27 standard amendments. The Spanish position has been supported by countries such as Sweden, Norway, Finland, Belgium, France, and Denmark in voting rounds in both the IEC and CENELEC. Nonetheless, developments in these 2 bodies have unfolded in very different ways.

Within the IEC, in 2004 IEC/TC61/MT16 adopted a first modification of the standard as Amendment 1, which for the first time defined an upper irradiance limit for sun lamps used in sunbeds. However, this limit was established as 1 W/m² of effective irradiance determined according to the non-melanoma standard curve. It is difficult to compare effective irradiance measured using the non-melanoma curve with effective irradiance measured using the erythral curve, as equivalence depends on the sun lamp spectrum, and different lamps will have different spectra. A rough calculation of effective irradiance of 1 W/m² according to the non-melanoma curve, however, would give an approximate UVI of 35. Amendment 1, furthermore, fails to place any restriction on the emission of UV-C radiation from sunbeds. The IEC recently approved a second amendment to the standard, by means of which the UV-C irradiance limit was established as 0.03 W/m² and certain safety aspects were improved. Even so, the safety standards and limits established for sunbed irradiance are inadequate.

In terms of composition, IEC/TC61/MT16 is dominated by representatives of the tanning industry and by experts in radiological protection (physicists and chemists); the fact that there is just 1 dermatologist (myself) in IEC/TC61/MT16 leaves our profession very under-represented. Once the IEC/TC61/MT16 approves an amendment, this is voted on by the national committees of each country. National committees in most countries are typically composed of public employees and so do not include photobiology specialists, never mind dermatologists. This would explain why most countries vote in favor of any new amendment that has already been approved by the IEC.

As for CENELEC, Spain ensured, firstly, that amendment of the standard would not be implemented until the conclusions of the Scientific Committee on Consumer Products of the European Union had been made available, and secondly, that a specific working group would be created to make the necessary adaptations to the EN 60335-2-27 standard once the conclusions were published. On July 6, 2005, the definitive version of the report of the Scientific Committee on Consumer Products was published (http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_031b.pdf). It took account of many of the Spanish National Committee requests, most importantly, the maximum limit of 0.3 W/m² for erythral effective irradiance for sun lamps used in sunbeds and a prohibition on UV-C radiation from tanning equipment. By means of the publication of an official mandate, the European Commission formally commissioned CENELEC with the task of amending the EN 60335-2-27 standard. In the voting to elect a chairperson-

secretary for this working group, I had the honor of being elected over the chairperson of the IEC/TC61/MT16 (who happened to be a representative of the tanning industry). In March 2007 this working group completed the process of adapting the European standard governing the manufacture of sunbeds, and in January 2008, the amended standard was approved by individual member states.

However, although the standard may have been modified and approved, much remains to be achieved. Standards have to be continually revised and amended in line with any new scientific evidence that comes to light. In fact, IEC/TC61/MT16 is exerting a great deal of pressure on the European Union to ensure that the European standard remains equivalent to the standard published by the IEC—in other words, with a higher irradiance limit for sun lamps. Since I have moved to Australia, there is no longer a dermatologist or photobiologist in CENELEC to defend the position of our profession regarding sunbed radiation. This means that the issue will once again be dealt with exclusively by public employees, physicists, and members of the tanning industry. Although my intention is to continue my efforts in this field in Australia (my appointment to the Australian National IEC Committee is imminent), I wish to encourage my colleagues to continue working through the Spanish National IEC Committee. It is necessary to carry on the battle behind the scenes, as this ultimately may have further reaching consequences and implications.

Conflicts of Interest

The author declares no conflicts of interest.

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