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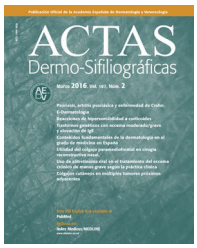

OPINION ARTICLE

# Safety of UV Lamps for Cosmetic Use: Regulatory Considerations☆

## La seguridad de las lámparas emisoras de radiación ultravioleta de uso cosmético desde el punto de vista de su regulación legal

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## 1. Current Regulatory Framework in Spain

The classification of devices that emit UV radiation as electrical appliances is being updated under European harmonised standard EN 60335-2-27, which establishes specific requirements for appliances used to expose the skin to UV and infrared radiation.[1]

Until they were first regulated by Royal Decree (RD) 1002/2002,[2] tanning devices in Spain were classified as home appliances equipped with UV emitters. As the use of tanning devices became generalized, several studies and extensive reviews, such as that published by the International Agency for Research on Cancer, have shown that these devices constitute a dermatologic and carcinogenic risk to the health and safety of users[3,4] and the World Health Organisation has issued a warning concerning their use.[5] These developments have made it essential to regulate the use of these devices and, therefore, to impose a series of obligations on the owners of tanning facilities based on a set of minimum requirements: compliance with technical standards and specifications, proper training of indoor tanning professionals in the use and operation of the devices, and the inspection and certification of such equipment as defined in Table 1. In Spain, competence for the regulation and control of indoor tanning facilities has been devolved to the Autonomous Communities (ACs). The appropriate regulatory body in each AC shall require operators to demonstrate that the equipment has passed technical inspections and meets the required standards by displaying the regulatory compliance notice affixed to the device in a position clearly visible to the user and, if applicable, a detailed description of the nature and compliance of any components that have been replaced (types and models) and new elements that have been installed.

Under RD 1002/2002, the implementation of these regulations in accordance with Spanish law is the responsibility of the governments of the ACs, and implementation is currently a very difference stages throughout the country. The transfer of legal competence has not been an easy task and is not yet complete. Table 2 shows the date of implementation of the RD in each AC. It indicates which ACs have implemented the regulation and have established regular inspections, and the lack of action on the part of regional governments in other parts of the country. Table 3 lists the

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**Table 1** Technical Testing and Inspection of Tanning Lamps and Compliance Report.

| | |
|---|---|
| Technical Requirements | Effective irradiance $\leq$ 0.30 W/m$^2$ [a]<br>Wavelength $\geq$ 295 nm[b] |
| Compliance report (national authorities) | Pass: If the tanning device passes inspection, the accredited body will affix a label indicating compliance on the device in a visible position. It will also provide a report certifying that the equipment has been inspected and has passed all required tests.<br>Fail: If the device does not pass the inspection, the label affixed to the device will indicate this (Failed Inspection - Out of Service).[c] |

[a] Effective irradiance is the relative biological response corresponding to each of the wavelengths emitted by the UV lamps, and is the same as the dose received/time of exposure.

[b] RD 1002/2002 does not establish a quantifiable numerical value for the threshold for detection of radiation for $\lambda$ <2 95 nm, leaving this limit to be defined by the Autonomous Communities. By common agreement the ACs have fixed a limit of 0.03 W/m$^2$, either explicitly (e.g. Balearic Islands and the Basque Country) or by omission (administrative silence) in other ACs.

[c] The device may not be used until the deficiencies are remedied. If the device is not repaired to the appropriate standard it should be removed from use definitely and this action should be notified to the competent authority responsible for maintaining the register of tanning devices.

**Table 3** Common Requirements for Tanning Salons Fixed by the Spanish Autonomous Communities.

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|---|
| Registration of any business involving the use of sun tanning devices |
| A report providing a description of all the equipment on the premises |
| Protocol for the cleaning and disinfection of the premises and equipment |
| Technical description of the tanning machines in use |
| Protocol for daily operation and work methods |
| Name of the authorized maintenance company |
| Operator training certificates |
| Technical inspection by an accredited body and monitoring of the limits of UV radiation exposure |
| Provision of protective eyewear (goggles) |
| All clients must read and sign an informed consent form before using tanning devices for the first time. These forms must be retained by the salon for 5 years. |
| A personal record must be kept for each client, including information on the sessions received and the total and partial doses administered, specific recommendations corresponding to the client's skin phototype and other appropriate advice. |
| A series of warning notices must be displayed in a prominent position. These include: Ultraviolet radiation can cause skin cancer and seriously damage your eyes; Protective eyewear must be worn; Certain drugs and cosmetic products can cause undesirable effects; Use of tanning beds by people under 18 years of age is prohibited; Tanning bed use is not advised during pregnancy; Maximum exposure times and intervals between exposures corresponding to your skin phototype must be respected. |

common requirements that must be complied with by all tanning facilities located in the ACs that have implemented the regulation.

It is important to note, with respect to safety, that the RD establishes a system of monitoring by which the entity or person legally responsible for operating a tanning facility assumes responsibility for passing at least 1 technical inspection each year for all the devices in use and additional inspections whenever consumables are changed. These tests and inspections must be performed by officially accredited companies authorized by a public resolution issued by the competent authority. This means that inspectors may come from different areas of expertise and testing may differ from one AC to another.

It should not be forgotten that, under RD 1002/2002, the use of and access to tanning devices is prohibited for persons under 18 years of age. Furthermore, tanning facilities are prohibited from supplying any products—whether chemical, dermatological or cosmetic—intended to accelerate tanning, act as sunscreen, or make possible longer exposures to ultraviolet radiation.

The mandatory training of indoor tanning professionals is an important aspect of user safety; the RD specifies that any person responsible for the operation of any device emitting UV radiation must undergo training and delegates the responsibility for making such training available to the Health Department in each AC. These courses, which vary in content and can last for anything between 15 to 25 hours,

**Table 2** Implementation of RD 1002/2002 by the Spanish Autonomous Communities.

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|---|---|---|
| Aragon, 2007[6] | Asturias, 2005[7] | Balearic Islands, 2004[8] |
| Cantabria, 2011[9] | Castile-La Mancha, 2004[10] | Catalonia, 2003[11] [a] |
| Extremadura, 2004[12] | Galicia, 2004[13] | Madrid, 2007[14] |
| Navarre, 2004[15] | Basque Country, 2003[16] | Other Autonomous Communities, not yet implemented[b] |

[a] The Catalan government (Generalitat) drafted an initial decree[17] in 2001 before RD 1002/2002 was introduced.

[b] Andalusia and Castille-Leon have carried out inspections, but not with the required regularity; Melilla and Murcia have approved training courses and certified inspection companies; Valencia has submitted courses for approval; La Rioja, the Canary Islands, and Ceuta have not done anything to create a regulatory or a surveillance system.

have been provided since the RD went into effect. This training helps to ensure that employees will correctly determine the appropriate duration of exposure for each user at each session depending on the maximum emission of the lamps after irradiance has been properly verified. Maximum tanning time for each user is determined according to their skin type, which must first be established. Courses must also inform trainees about the risks and side effects of UV radiation and instruct them on how to complete the user's record form (including a targeted questionnaire on the client's health and possible contraindications) and how to check and maintain tanning devices to ensure that all the elements are operating correctly.

## 2. The Impact of European Regulation

In June 2016, the Council of the European Union passed a proposal for a regulation on medical devices[18] that has been under discussion since 2012. Regulations are lengthy and complex documents that are slow to implement from both the legal and the technical standpoint. Moreover, since proposals have binding legal force throughout the EU, unlike directives, they do not have to be incorporated into national legislation in each member country but rather become effective immediately. The legal framework created by the proposal effectively guarantees the protection of health, consistent with the rapid pace of technological developments in the sector, as well as greater transparency, supervision, and cooperation on the part of health authorities. It is important to note that medical appliances are currently classified as therapeutic devices so that the designation includes any instrument, apparatus, or other article to be used in humans for, among others, the purpose of diagnosis, prevention, monitoring, treatment, or alleviation of a disease, or to compensate for a deficiency, which does not achieve its principal intended action by pharmacological or metabolic means.[19] Depending on the intrinsic risk associated with the use of a product, the Council of the European Union has established explicit rules concerning the responsibility of manufacturers to monitor quality and to provide an after-sales service scheme and a strong monitoring system for the authorities.

The aim of this new proposal is to expand the scope of the designation of a medical device beyond that of the current definition to include other products which we consider to be of interest to dermatologists. Indeed, the scant consideration of the safety of tanning lamps outside of our borders may now be corrected by the EU authorities because Annex XV of the future regulation, for the first time, expands the definition of the term *medical device* to include products with no intended medical purpose. The annex includes, among other things, a series of high intensity electromagnetic radiation (infrared, visible, and UV) emitting equipment for use on the human body, including monochromatic and broad spectrum light sources, such as lasers (single wavelength, approx. 800 nm) and intense pulsed light equipment (e.g. between 450-1200 nm) used for skin resurfacing, cosmetic treatments, and hair or tattoo removal. Given their photothermal activity, they act on skin chromophores such as melanin. While in the USA these appliances are considered to be medical devices and are regulated by the FDA,[20] in Europe, they currently have to comply with the standards of the International Electrotechnical Commission ratified by the European Committee for Electrotechnical Standardization. However, the European political authorities have been no less concerned to ensure the proper use of such equipment.[21] The proposed regulation deems that these products, despite having a cosmetic rather than medical purpose, nonetheless have a particular functionality and risk profile. Therefore, we believe that it will also apply to tanning lamps. It is our understanding that this change will improve the safety guarantees of equipment intended for cosmetic use and will help to prevent the repetition of adverse incidents through the collection, evaluation, and dissemination of information and by adopting appropriate corrective measures.

## 3. Conclusions

People who use tanning facilities must have guarantees during sessions that they are receiving an appropriate dose, taking into account the maximum emission of UV radiation of the equipment on the market and the user's skin phototype, as defined by the AC. Although, the Spanish ACs are now the competent authorities in the areas of industry, commerce, and health, some of them have not yet adequately implemented RD 1002/2002, and in those areas there is currently no control of this activity by any competent bodies. There are also differences in the way the RD has been implemented in different ACs, for instance in the training of operating personnel and the type of company that has been certified to perform mandatory inspections.

It is our view that the new approach to the regulation of medical devices in the European proposal will, although this is not explicitly stated, include the lamps that emit UV radiation which are used in tanning devices, thus enhancing the safety of users. Given the high degree of concern in Spain about this activity, what is important at this point is to consolidate and expand the inspection of tanning equipment in tanning facilities by accredited bodies and to eliminate the differences between different regions in the country.

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