

Attachment 1



PUBLIC HEALTH DIVISION
Radiation Protection Services

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Authority

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ENFORCEMENT BULLETIN 2012-03

To: Tanning Registrants
From: David M. Howe, Section Manager
Radiation Protection Services
RE: **Use of red light therapy (633 nm) lamps in tanning devices**

The State of Oregon Radiation Protection Services (RPS) is issuing this informational bulletin to inform registrants that replacing UV tanning lamps with red light therapy lamps is not allowed. RPS and the U.S. Food and Drug Administration (FDA) have become aware that operators of tanning devices are replacing Ultraviolet (UV) lamps with red light therapy lamps. Per U.S. Food and Drug Administration Code of Federal Regulation (CFR), tanning devices made for UV light must not install lamps that exceed 400 nano meter output. Currently red light lamps are rated at 633 nm.

Oregon Administrative Rule 333-119-0010(22) defines a Tanning Device as any equipment used for tanning of the skin, that emits electromagnetic radiation with wavelengths in the air between 200 and 400 nanometers including, but not limited to, a sunlamp, UV Lamp, tanning booth, facial unit, UVA wand, or tanning bed. In addition, Oregon Administrative Rule 333-119-0100 and 21 CFR 1040.20 directs the registrant to use only lamps with a type intended for use in the device and shall be of the same UV range (A or B) and shall be the original lamp type as specified by the manufacturer, or certified as an equivalent lamp.

In order to meet the conditions of the OARs, the manufacturer of the device must have the device cleared by the FDA. This is accomplished when the manufacturer submits a declaration that their device is equivalent to a device that is already on the market in order to receive pre-market approval for public use. Replacing UV tanning lamps with red light therapy lamps is not allowed and registrants may be subject to civil penalties for violations of the rules.

We appreciate your cooperation in complying with the enforcement bulletin. Please feel free to contact Todd Carpenter @ 971-673-0500 for further information.