North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

MEMORANDUM

TO: Office of State Budget & Management

FROM: Nadine Pfeiffer, DHSR Rule-making Coordinator

DATE: May 13, 2015

RE: Federal Certification for Radiation Protection Rule Amendments

Rule-making Coordinator's Certificate

As Required by GS 150B-19.1(g)
For Proposed Permanent and Temporary Rules Adopted to
Implement a Federal Law or which upon Receipt of Federal Funds is Conditioned

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Rules 10A NCAC 15 .1414 and .1415 are proposed for amendment in order to be compatible with federal regulations in compliance with the Food and Drug Administration (FDA). These rules apply to business entities in North Carolina that require the use of ultraviolet (UV) tanning equipment.

The amendment of the above-named rules is necessary to comply with 21 CFR 878.4635. Under these provisions, the FDA administers an electronic product radiation control program to protect the public health and safety.

Rule 10A NCAC 15 .1415 has been amended to include 21 CFR Part 878.4635(b)(6)(i) as part of the equipment requirements for the tanning devices. This rule must be amended in order for the state of N.C. to enforce the new FDA requirements. § 878.4635(b)(6)(i)(A) states:

> "The warning statement below must appear on all sunlamp product fixtures. This statement must be permanently affixed or inscribed on the product when fully assembled for use so as to be legible and readily accessible to view by the person who will be exposed to UV radiation immediately before the use of the product. It shall be of sufficient durability to remain legible throughout the expected lifetime of the product. It shall appear on a part or panel displayed prominently under normal conditions of use so that it is readily accessible to view whether the tanning bed canopy (or tanning booth door) is open or closed

when the person who will be exposed approaches the equipment and the text shall be at least 10 millimeters (height). Labeling on the device must include the following statement: "**Attention: This sunlamp product should not be used on persons under the age of 18 years.**"”

Rule 10A NCAC 15 .1414 has been amended to include the FDA’s new warning language regarding the use of UV tanning devices. It is not required that this rule is changed in order to enforce the new FDA rules. However, the Radiation Protection Commission approved amending the current language found on the Warning Sign and on the Consumer Statement to reflect the FDA’s new warning found in 21 CFR Part 878.4635(b)(6)(ii) which states:

“(ii) Manufacturers of sunlamp products shall provide or cause to be provided in the user instructions for a sunlamp product as well as all catalogs, specification sheets, and descriptive brochures intended for consumers in which sunlamp products are offered for sale, and on all consumer-directed webpages on which sunlamp products are offered for sale, the following contraindication and warning statements:
(A) "Contraindication: This sunlamp product is contraindicated for use on persons under the age of 18 years."
(B) "Contraindication: This sunlamp product must not be used if skin lesions or open wounds are present."
(C) "Warning: This sunlamp product should not be used on individuals who have had skin cancer or have a family history of skin cancer."
(D) "Warning: Persons repeatedly exposed to ultraviolet sunlamp products should be regularly evaluated for skin cancer."”

No rule amendments are required in order to receive federal funding.