(ii) The text of the risk acknowledgement certification shall be at least 10-point font.

(iii) The tanning facility operator shall provide a copy of the signed acknowledgement certification to the prospective user and the tanning facility shall retain a copy of the signed risk acknowledgement certification for 1 year or until the prospective user signs a new risk acknowledgement certification, whichever is earlier.

(d) *Electronic product performance standard.* * * *

Dated: December 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–32024 Filed 12–18–15; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1002 and 1040

[Docket No. FDA–1998–N–0880 (Formerly 1998N–1170)]

RIN 0910–AG30

Sunlamp Products; Proposed Amendment to Performance Standard

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing to amend the performance standard for sunlamp products and ultraviolet (UV) lamps intended for use in these products. This standard was last amended in 1985. The current amendments seek to improve consumer safety by requiring more effective communication regarding the risks posed by these products. They also would reduce risks to consumers by updating technical requirements to reflect current science, and by adopting and incorporating by reference certain elements from the International Electrotechnical Commission (IEC) International Standard 60335–2–27, Ed. 5.0: 2009–12.

DATES: Submit either electronic or written comments on the proposed rule by March 21, 2016. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by January 21, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–1998–N–0880 for ''Sunlamp Products; Proposed Amendment to Performance Standard.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget (OMB) in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or email to *oira_submission@omb.eop.gov.* All comments should be identified with the title, ''Sunlamp Products; Proposed Amendment to Performance Standard.''

FOR FURTHER INFORMATION CONTACT: Sharon Miller, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4234, Silver Spring, MD 20993–0002, 301–796–2471.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Regulatory Action

The Safe Medical Devices Act of 1990 (Pub. L. 101–629), enacted on November 28, 1990, transferred the provisions of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602) from Title III of the Public Health Service Act to Chapter V, subchapter C of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360hh *et seq.*). Under these provisions, FDA administers an electronic product

radiation control program to protect the public health and safety. This authority provides for developing, amending, and administering radiation safety performance standards for electronic products, including sunlamp products.

A sunlamp product is a device that emits UV radiation to induce tanning. The device incorporates one or more UV lamps as a radiation source. Examples of sunlamp products are tanning beds, which are used while lying down, and tanning booths, which are used while standing. UV radiation-emitting products not used for tanning would not be affected by this proposed rule. Devices emitting UV radiation to treat dermatological disorders are regulated separately and are not part of this proposed rule. As electronic products, sunlamp products are subject to the regulations for electronic product radiation control, including parts 1000 to 1010 (21 CFR parts 1000 through 1010) and § 1040.20 (21 CFR 1040.20).

Sunlamp products emit UV radiation to induce tanning. The adverse effects of UV radiation are well known. UV radiation can cause acute injuries such as sunburns and eye irritations (*e.g.,* photokeratitis). Long-term UV exposure has been associated with skin cancer (including squamous cell carcinoma, basal cell carcinoma, and melanoma), skin aging, and cataracts. Epidemiological studies of the effects of UV radiation on incidence of cancer and other health problems are complicated by latency between exposure and disease, difficulty controlling for environmental exposure to UV radiation, and other factors. Nevertheless, a recent meta-analysis found an increase in the risk of melanoma for each additional session of sunlamp product use per year (Ref. 1).

FDA is concerned about the safety risks from UV radiation. Therefore, FDA is updating our requirements for sunlamp products which allow for indoor exposure to UV radiation. There have been many changes in our understanding of how UV radiation interacts with human skin since FDA published the document entitled ''Sunlamp Products; Performance Standard'' in the **Federal Register** of September 6, 1985 (50 FR 36548). There have also been many changes in the indoor tanning industry which affect the type of equipment on the market and the measurement techniques used by manufacturers. FDA is updating requirements for sunlamp products to bring our regulations up to date with current science. FDA also wants to improve consumers' understanding of the risks related to UV radiation exposure.

Summary of the Major Provisions of the Regulatory Action in Question

The objective of this proposed rule is to align the performance standards for sunlamp products with current scientific knowledge and our understanding of how these products are used. This proposed rule seeks to facilitate compliance, improve awareness among operators and consumers about risks of use, and ultimately improve public health.

FDA proposes to incorporate certain elements of the International Electrotechnical Commission (IEC) International Standard 60335–2–27, Ed. 5.0: 2009–12, ''Household and Similar Electrical Appliances—Safety—Part 2–27: Particular Requirements for Appliances for Skin Exposure to Ultraviolet and Infrared Radiation,'' by reference. Harmonizing the FDA standard with the current IEC standard would bring it up to date with current science and better protect consumers from the risks posed by these devices. Harmonization would have benefits for sunlamp product manufacturers as well. Currently, many firms producing sunlamp products for sale within the United States and abroad have to follow both IEC and FDA standards. Aligning these standards would mean that such firms would need to comply with a single set of rules instead of two different ones, at least for the particular clauses which are being adopted and incorporated by reference.

FDA proposes to amend the requirements of part 1002 as specified in table 1 to require that manufacturers of UV lamps intended to be used in sunlamp products are subject to the same record and reporting requirements as manufacturers of sunlamp products. FDA wants to ensure that all test data necessary to ensure compliance with § 1040.20 are collected and maintained. Currently, manufacturers of UV lamps are required to submit only product reports. Under proposed § 1002.1, manufacturers of UV lamps would also be required to submit supplemental reports and annual reports and to maintain test records and distribution records. Moreover, proposed § 1002.1 would also require that manufacturers of protective eyewear maintain test records demonstrating that the eyewear complies with applicable UV and visible transmittance requirements as well as distribution records. In addition, proposed § 1002.1 would also require that manufacturers of protective eyewear submit annual reports, supplemental reports, and product reports to FDA.

Proposed § 1040.20(c)(1) would set an absolute limit for UVC radiation. An absolute limit on UVC (200–290 nanometer (nm)) irradiance would provide greater assurance of user safety because a ratio permits higher doses of UVC (as long as they correspond to higher doses in the 260 to 320 nm range). UVC, which is not present in sunlight that reaches the Earth's surface, is potentially harmful to users while less effective for tanning than UVA or UVB. FDA has chosen not to adopt the limit for UVC radiation in Ed. 5.0 of IEC 60335–2–27 because this limit is 10 times lower than the limit in Ed. 4.2 and FDA believes that it would be difficult for some manufacturers to measure irradiance at this level.

Proposed § 1040.20(c)(2)(ii) would limit the maximum timer interval to one that would result in a biologically effective (also referred to as erythemal-effective) dose that would not exceed 500 joules/meter^2 (J/m^2) which is approximately equivalent to the 624 J/m^2 value (weighted with the CIE LYTLE action spectrum) that was specified in the 1986 FDA Policy Letter on Maximum Timer Interval and Exposure Schedule. FDA has determined that a dose of 500 J/m^2 (weighted with the CIE erythemal action spectrum) provides a biologically equivalent dose that is more closely matched to the current 624 J/m^2 value than does the IEC dose limit of 600 J/m^2.

Proposed § 1040.20(c)(3) would add a requirement that the control enabling manual termination of radiation emission (sometimes referred to as the ''panic button'' or ''emergency stop'') be easily accessible and readily identifiable to the user. This would ensure that users could easily turn the sunlamp product off for any reason.

Proposed § 1040.20(c)(4)(ii) would expand application of the performance requirements to all protective eyewear intended to be used with sunlamp products, whether sold together with a sunlamp product or sold separately. UV wavelengths can cause serious eye damage, and exposure to the shorter wavelength region of the UV spectrum is especially dangerous. The spectral transmittance requirements for protective eyewear are necessary to protect users of sunlamp products from these risks, which directly result from the UV radiation emitted by the sunlamp product.

Proposed § 1040.20(d)(1)(i) would modify the warning statement required to appear on the label of all sunlamp products. FDA believes that the current warning statement is too long, not user-friendly, and that its content and format could be improved to more effectively

communicate the risks of indoor tanning to users. Based on its analysis of the consumer testing, FDA concluded that the current warning statement could be made more effective by changing its required language, formatting, and location. FDA believes that the proposed warning statement would most effectively convey the risks of indoor tanning to users.

The proposed rule would also improve user safety by adopting the IEC's ''equivalency code'' system for ensuring compatibility between sunlamp products (*e.g.,* tanning beds and booths) and the UV lamps that are used in them. Proposed § 1040.20(d)(1)(vi) would require the label of all sunlamp products to indicate the equivalency code range of the UV lamp to be used in the sunlamp product. Proposed § 1040.20(d)(2)(ii) would require the label of each UV lamp to indicate its UV lamp equivalency code. FDA believes the adoption of the IEC's absolute rating system for replacement UV lamps would eliminate confusion regarding proper lamp replacement, facilitate the enforcement of lamp compatibility requirements, and improve the safety of sunlamp products.

Proposed § 1040.20(d)(3) would retain the requirement of the current FDA standard that the required label information must be legible and readily accessible to view by a sunlamp product user immediately prior to use. Proposed § 1040.20(d)(3)(i) would incorporate specifications into the rule regarding the location, spacing, and font of the required warning statement. FDA believes that these label specifications would ensure that users see the required warning prior to use, and would result in a more comprehensive and effective standard.

Proposed § 1040.20(e)(3) would add a requirement for the provision of the required warning statement in all catalogs, specification sheets, and descriptive brochures intended for consumers in which sunlamp products are offered for sale, and on all consumer-directed Web pages on which sunlamp products are offered for sale. This requirement would ensure that consumers are fully informed of the risks presented by sunlamp products at the time they consider purchasing it.

Proposed § 1040.20(g) is also modeled after the proposed FDA Performance Standard for Laser Products (78 FR 37723, June 24, 2013). FDA believes the addition of these requirements, which have been used successfully over the past two decades for laser products, would improve safety by ensuring that modifications that affect performance would be held to the same standards as original manufacturing.

Costs and Benefits

Estimated one-time costs are $20,917 to $113,240 and annual costs are $4,686 to $7,230. The present discounted costs are $57,181 to $151,390 at 7 percent and $61,498 to $165,883 at 3 percent. Annualized at 7 percent over 10 years, total costs are $8,141 to $21,498. At 3 percent, annualized total costs are $7,867 to $19,447.

The primary benefit of the proposed rule would be from reduced injuries, including sunburn, photokeratitis, skin cancer, cataracts and ocular melanoma, and from reduced exposure to UV radiation. We are unable to quantify the benefits, but where possible, demonstrate that they satisfy breakeven tests using very conservative assumptions. The benefits of this proposed rule would justify the costs.

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I. Background

The Safe Medical Devices Act of 1990 (Pub. L. 101–629), enacted on November 28, 1990, transferred the provisions of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602) from Title III of the Public Health Service Act to Chapter V, subchapter C of the FD&C Act (21 U.S.C. 360hh *et seq.*). Under these provisions, FDA administers an electronic product radiation control program to protect the public health and safety. This authority provides for developing, amending, and administering radiation safety performance standards for electronic products, including sunlamp products.

Until recently, sunlamp products intended for tanning were class I medical devices and exempt from premarket notification requirements, subject to the limitation in 21 CFR 878.9 (see 53 FR 23856, June 24, 1988; 59 FR 63005, December 7, 1994). On March 25, 2010, FDA held a meeting of the General and Plastic Surgery Devices Panel of the FDA/Center for Devices and Radiological Health (CDRH) Medical Devices Advisory committee to seek input on whether the classification or regulatory controls needed to be changed. For a summary of this meeting, see *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GeneralandPlasticSurgeryDevicesPanel/UCM206522.pdf.* On June 2, 2014, based on the panel's recommendations, among other things, FDA reclassified UV lamps intended to tan the skin from class I and exempt from premarket notification to class II and subject to premarket notification, and renamed them sunlamp products and UV lamps intended for use in sunlamp products (see 21 CFR 878.4635; 79 FR 31205, June 2, 2014).

As electronic products, sunlamp products are subject to the regulations for electronic product radiation control, including parts 1000 through 1010 and § 1040.20. The sunlamp products performance standard in § 1040.20 was originally published in the **Federal Register** on November 9, 1979 (44 FR 65352). In the **Federal Register** of September 6, 1985 (50 FR 36548), FDA amended § 1040.20 and made it applicable to all sunlamp products manufactured on or after September 8, 1986.

FDA also issued several policy letters pertaining to specific aspects of its regulation of sunlamp products. On June 25, 1985, FDA issued a policy letter entitled ''Policy on Warning Label Required on Sunlamp Products'' (available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095333.pdf*) (Ref. 2). This document pertained to the location, spacing, and legibility of the required warning label. On August 21, 1986, FDA issued a policy letter entitled ''Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products'' (available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095333.pdf*) (Ref. 3). This document explained the criteria FDA uses to evaluate the adequacy of the exposure schedule and the recommended maximum exposure time for sunlamp products. On September 2, 1986, FDA issued another policy letter entitled ''Policy on Lamp Compatibility,'' (available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095325.pdf*) (Ref. 4). This document listed the criteria FDA uses to

evaluate appropriate replacement lamps for sunlamp products.

Before prescribing any electronic product performance standards, FDA is required to consult a statutory advisory committee, the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC). See section 534(f)(1)(A) of the FD&C Act (21 U.S.C. 360kk(f)(1)(A)). At the September 23 and 24, 1998, meeting of TEPRSSC, FDA presented general concepts for amendments to the performance standard for sunlamp products, which are embodied in this proposed rule. The committee recommended that FDA pursue development of the amendments.

On February 9, 1999, CDRH published an Advance Notice of Proposed Rulemaking (ANPRM) (Docket No. 98N–1170), 64 FR 6288 (February 9, 1999), for the following reasons:

1. FDA was concerned that inadequate attention was being given to recommended exposure schedules, which are designed to minimize consumer risk.

2. FDA was concerned that the warnings for sunlamp products were not reaching many users of sunlamp products prior to their purchase and use, and that purchasers may not be aware of the risks associated with UV exposure from sunlamp products.

3. Sunlamp products technology has changed since the FDA Performance Standard was amended in 1985. These changes can affect both the intensity and spectral characteristics of the UV emission from sunlamps.

4. Because there is no uniform grading/rating system, choosing a replacement lamp can be confusing for sunlamp product owners and tanning facilities. It also makes the job of tanning facility inspectors more difficult because they cannot easily verify whether the correct lamps are installed in the sunlamp products. The use of incorrect replacement lamps can lead to sunburns.

The specific amendments under consideration were as follows:

1. Harmonizing the sunlamp product performance standard with IEC Standard 60335–2–27;

2. Revising and updating the August 21, 1986, guidance entitled ''Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products,'' and incorporating the updated guidance into the sunlamp product performance standard;

3. Adding a provision clarifying that ''manufacturing'' under the FD&C Act includes a modification of a sunlamp product that affects any aspect of its performance or intended function for which § 1040.20 has an applicable requirement;

4. Updating the warning statement required by § 1040.20(d)(1)(i) to simplify the wording and to highlight the risk of developing skin cancers;

5. Requiring reproduction of the text of the warning statement specified in § 1040.20(d)(1)(i) in catalogs, specification sheets, and brochures; and

6. Developing a biological efficacy rating scale for UV lamps intended for use in sunlamp products to simplify appropriate lamp replacement.

In response to this ANPRM, FDA received 26 comments from State and local radiation control agencies, manufacturers, the American Academy of Dermatology, the Skin Cancer Foundation, an industry educational association, a tanning facility owner, and a trade organization. FDA considered these comments in developing this proposal.

FDA presented recommendations for amendments to the sunlamp performance standard to TEPRSSC on June 21, 2000. FDA explained to TEPRSSC that it was prepared to move forward with some of the amendments at that time, but did not have sufficient scientific data to move forward with the lamp classification or the exposure schedule amendment. TEPRSSC advised FDA to develop scientifically-based exposure schedule guidelines before incorporating these requirements into the Performance Standard itself. FDA scientists obtained special funding from FDA's Office of Women's Health to conduct this research. Upon completion, FDA presented guidelines for exposure schedules to the IEC TC (Technical Committee) 61, MT (Maintenance Team) 16 that is responsible for developing standards for these products. The IEC accepted these guidelines and incorporated them into IEC 60335–2–27 standard (Ed. 5.0), which published on December 14, 2009.

In February 2002, FDA held a 2-day meeting with the indoor tanning industry and representatives from the U.S. Army Environmental Hygiene Agency, Health Canada, the Swedish Radiation Protection Institute, and the North Carolina Department of Radiation Protection. The purpose of this meeting was to solicit input from the affected parties on the lamp equivalence issue and other possible amendments to the FDA Performance Standard for Sunlamp Products, which we considered in the development of this proposed rule.

The IEC TC 61, MT 16 committee met in October 2002, and decided to work with IEC SC (subcommittee) 34A to develop practical standardized test methods and a classification scheme for low-pressure, fluorescent tanning lamps to facilitate replacement of these lamps when they wear out. IEC SC 34A has responsibility for the IEC 61228 standard entitled ''Fluorescent Ultraviolet Lamps Used for Tanning—Measurement and Specification Method'' (Ref. 5). At their meeting in 2003, IEC TC 61, MT 16 and IEC SC 34A reached a consensus position on lamp testing and classification. This position has now been incorporated into the IEC 60335–2–27, Ed. 5.0 standard (Ref. 6) and the IEC 61228, Ed. 2.0 standard (Ref. 5).

In October 2003, FDA presented six amendments to TEPRSSC and all were approved with modifications to two of the proposals. These six amendments, along with others, are being presented in this proposed rule and are outlined in section II.

In addition, FDA has informed radiological health representatives from the states of our intentions to amend the Sunlamp Products Performance Standard through semi-annual meetings with the state Conference of Radiation Control Program Directors. See Web site at *http://www.crcpd.org/.*

FDA is concerned about the safety risks from UV radiation. Therefore, FDA is updating our requirements for sunlamp products—which allow for indoor exposure to UV radiation.

FDA is undertaking three initiatives to address the risks associated with sunlamp products. First, in a final reclassification order that issued June 2, 2014 (79 FR 31205 at 31213), FDA reclassified sunlamp products and UV lamps intended for use in sunlamp products from class I to class II, and established special controls and premarket notification (510(k)) requirements under the medical device authorities of the FD&C Act. The special controls include performance testing and labeling requirements, including a warning that sunlamp products are not to be used on persons under the age of 18 years.

Second, and simultaneously with this proposed rule, FDA is proposing device restrictions under section 520(e) of the FD&C Act (21 U.S.C. 360j(e)), which authorizes FDA to issue regulations imposing restrictions on the sale, distribution or use of a device, if, because of its potentiality for harmful effects or the collateral measures necessary to its use, FDA determines that absent such restrictions, there cannot be a reasonable assurance of its safety and effectiveness. As explained elsewhere in this issue of the **Federal Register**, the proposed device restrictions would require that:

1. Tanning facility operators permit use of sunlamp products only if the prospective user is age 18 or older;

2. Tanning facility operators, upon request by the user or prospective user, provide a copy of the sunlamp product user manual or name and address of the manufacturer or distributor from who a user manual may be obtained;

3. 510(k) holders assure that a user manual accompanies each sunlamp product and, upon request, provide a copy of the user manual to any tanning facility operator, user or prospective user; and

4. Tanning facility operators obtain each prospective user's signature on a risk acknowledgement certification before use that states that they have been informed of the risks to health that may result from use of these devices.

These device restrictions would primarily apply to tanning facility operators, and to a lesser extent, device manufacturers and distributors. FDA would not consider people who use their own tanning beds (home users) to be tanning facility operators.

Finally, in this action, FDA is proposing amendments to the sunlamp products and UV lamps performance standard at § 1040.20 (21 CFR 1040.20) (last updated in 1985), which includes technical and labeling requirements issued under the radiological health provisions of the FD&C Act. FDA is taking this action to reflect current scientific knowledge related to sunlamp product use, harmonize it more closely with IEC International Standard 60335–2–27, Ed. 5.0: 2009–12, and strengthen the warning statement required by § 1040.20(d)(1)(i) in accordance with the results of the study FDA conducted under section 230 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85).

II. Contents of the Proposed Regulation

A. Overview

This preamble will focus on the proposed changes to § 1002.1 and § 1040.20, which include:

- Requiring that UV lamp manufacturers follow the same reporting requirements as sunlamp product manufacturers,
- Requiring that protective eyewear manufacturers maintain distribution records and test records relating to the UV and visible transmittance of the eyewear as well as requiring the submission of annual reports, supplemental reports, and product reports to FDA,
- Changing the content, format, and location of the required warning statement to make it more effective at communicating the risks of indoor tanning to consumers,
- Replacing the current limit on the ratio of UVC to UVB irradiance with an absolute limit on UVC irradiance,
- Limiting the maximum timer interval to one that would not exceed a maximum dose of 500 J/m^2, weighted with the CIE Reference Action Spectrum for Erythema (1999),
- Adopting the IEC ''equivalency code'' system for labeling and measuring the strength of replacement lamps to prevent original lamps being replaced with more powerful lamps, which can lead to sunburn,
- Changing the current subjective requirement regarding the visible transmittance of protective eyewear to an objective, quantitative requirement, adopted from the IEC standard,
- Adding a cap on the amount of visible transmittance allowed through the protective eyewear, to protect the users' retina from intense visible light,
- Updating the guidelines for the required manufacturer-recommended exposure schedule, by requiring conformity to the IEC standard, which is based on current science,
- Requiring that a reproduction of the warning label be provided in all catalogs, specification sheets, brochures, and consumer-directed Web pages on which sunlamp products are offered for sale, and
- Requiring that persons involved in significant modification of sunlamp products re-certify the product just as the manufacturer of a new product would. This requirement currently exists in the FDA Laser Standard (21 CFR 1040.10(i)).

B. Changes to § 1002.1

FDA proposes to amend the requirements of part 1002 as specified in table 1 to require that manufacturers of UV lamps intended to be used in sunlamp products are subject to the same record and reporting requirements as manufacturers of sunlamp products. When table 1 was first codified, it was common for the manufacturers of UV lamps to be the same entity that manufactured the sunlamp product. Today, the market has changed and there are some manufacturers that manufacture only UV lamps. FDA wants to ensure that all test data necessary to ensure compliance with § 1040.20 are collected and maintained. Currently, manufacturers of UV lamps are required to submit only product reports. Under proposed § 1002.1, manufacturers of UV lamps would also be required to submit supplemental reports and annual reports and to maintain test records and distribution records. In addition, manufacturers of protective eyewear would also need to maintain distribution records as well as test records demonstrating that the eyewear complies with applicable UV and visible transmittance requirements. Proposed § 1002.1 would also require that manufacturers of protective eyewear submit annual reports, supplemental reports, and product reports to FDA.

C. Changes to § 1040.20

1. Incorporation by Reference

FDA proposes to incorporate certain elements of the IEC International Standard 60335–2–27, Ed. 5.0: 2009–12 entitled ''Household and Similar Electrical Appliances—Safety—Part 2–27: Particular Requirements for Appliances for Skin Exposure to Ultraviolet and Infrared Radiation,'' by reference (Ref. 6). See proposed § 1040.20(a)(2). A similar approach has been used successfully with the FDA standard for laser products, § 1040.10, see FDA Guidance, ''Laser Products—Conformance With IEC 60825–1 and IEC 60601–2–22'' (Ref. 7), and FDA has proposed to incorporate by reference several provisions of IEC 60825–1, Ed. 2, into the laser products performance standard (78 FR 37723). Harmonizing the FDA standard with the current IEC standard would bring it up to date with current science and better protect consumers from the risks posed by these devices. FDA has representation on the IEC committee and has had significant influence on changes made to the IEC standard over the past decade. Working with this committee, which includes representatives from industry, government, and the medical community, has provided FDA with useful expertise and perspectives to which it may not otherwise have access.

Harmonization would have benefits for sunlamp product manufacturers as well. Currently, many firms producing sunlamp products for sale within the United States and abroad have to follow both IEC and FDA standards. Aligning these standards would mean that such firms would need to comply with a single set of rules instead of two different ones, at least for the particular clauses which are being adopted and incorporated by reference.

2. Definitions

''Protective goggles'' would be added to the definition of ''protective eyewear'' in proposed § 1040.20(b) since this is the synonymous term used in the IEC standard.

The definition of ''sunlamp product'' would be amended to make clear that

tanning beds and tanning booths are included within this term.

We propose adding a definition for ''tanning course.'' This term is used in Annex DD of IEC 60335–2–27, Ed. 5.0, to aid the manufacturer in the development of its exposure schedule. In the context of exposure schedules, ''tanning course'' means the period of time over which a tan is developed, starting with the first short exposure and building up to longer exposures over time, usually requiring a period of 3 to 4 weeks. In an effort to ensure that a useful recommendation is provided to the user about maximum annual exposure, this concept is utilized in the exposure schedule requirements at proposed § 1040.20(d)(1)(iv) and the example exposure schedule provided therein. FDA is uncertain how users might best keep track of their exposure over many weeks and months, and is particularly interested in comments on the best approach for informing users about limiting their annual exposure.

3. Performance Requirements

Proposed § 1040.20(c)(1) would set the irradiance limit for UVC radiation (200–290 nm) at 0.03 Watts/meter^2 (W/m^2) at the shortest recommended exposure distance from the sunlamp product. This limit is the same as the one in the previous version of IEC 60335–2–27 (Ed. 4.2: 2007–04). This requirement would replace the current limit on the ratio of irradiance in the 200 to 260 nm wavelength range to the irradiance in the 260 to 320 nm wavelength range (see § 1040.20(c)(1)). One of the comments received in response to the 1999 ANPRM recommended that the current ratio limit in § 1040.20(c)(1) be dropped since it is no longer necessary, considering current low-pressure lamp technology, and because a limit on the UVC/UVB ratio provides less safety than an absolute limit on the UVC emissions from a sunlamp product. FDA agrees with this comment. An absolute limit on UVC (200–290 nm) irradiance would provide greater assurance of user safety because a ratio permits higher doses of UVC (as long as they correspond to higher doses in the 260 to 320 nm range). UVC, which is not present in sunlight that reaches the Earth's surface, is potentially harmful to users while less effective for tanning than UVA or UVB. FDA has chosen not to adopt the limit for UVC radiation in Ed. 5.0 of IEC 60335–2–27 because this limit is 10 times lower than the limit in Ed. 4.2 and FDA believes that it would be difficult for some manufacturers to measure irradiance at this level. FDA is particularly interested in comments on this proposal.

FDA proposes to change § 1040.20(c)(2) by adding a dose-based limit similar to the one in FDA's 1986 FDA Policy Letter on Maximum Timer Interval and Exposure Schedule (Ref. 3) to the maximum timer interval requirement in paragraph (c)(2)(ii). FDA also proposes to remove paragraph (v) from § 1040.20(c)(2).

Proposed § 1040.20(c)(2)(ii) would incorporate by reference the action spectrum used in figure 103 of IEC 60335–2–27, Ed. 5.0 for calculating the effective dose that defines the maximum timer interval. This method uses the internationally-accepted CIE Reference Action Spectrum for Erythema (Ref. 8) instead of the CIE LYTLE action spectrum that was defined in the 1986 FDA Policy Letter on Maximum Timer Interval and Exposure Schedule (Ref. 3). Since 1986, the CIE Action Spectrum for Erythema has been verified and accepted by research laboratories across the globe. As a result, it is used worldwide in the calculation of the UV Index.

The 1986 FDA Policy Letter on Maximum Timer Interval and Exposure Schedule also recommends the use of the Parrish 1982 melanogenesis action spectrum, in addition to the CIE LYTLE erythema action spectrum, as a secondary means of calculating the maximum timer interval. As it has been found that the two action spectra are highly correlated, this calculation does not provide independent characterization data and the requirement is redundant. Therefore, proposed § 1040.20(c)(2)(ii) would not require a second calculation of the maximum timer interval.

Proposed § 1040.20(c)(2)(ii) would limit the maximum timer interval to one that would result in a biologically-effective (also referred to as erythemal-effective) dose that would not exceed 500 J/m^2, which is approximately equivalent to the 624 J/m^2 value (weighted with the CIE LYTLE action spectrum) that was specified in the 1986 FDA Policy Letter on Maximum Timer Interval and Exposure Schedule (Ref. 3). Although the FDA would like to harmonize its standard as much as possible with the IEC standard, consumer safety is our main concern. Based on spectral irradiance data submitted to the Agency and on data presented at the 2004 Commission Internationale de l'Eclairage (CIE) Symposium on ''Light and Health: Non-visual effects'' (Ref. 10), FDA has determined that a dose of 500 J/m^2 (weighted with the CIE erythemal action spectrum) provides a biologically-equivalent dose that is more closely matched to the current 624 J/m^2 value than does the IEC dose limit of 600 J/m^2. FDA invites comment on this proposal.

Proposed § 1040.20(c)(3) would add a requirement that the control enabling manual termination of radiation emission (sometimes referred to as the ''panic button'' or ''emergency stop'') be easily accessible and readily identifiable to the user. This would ensure that users can easily turn the sunlamp product off for any reason.

Proposed § 1040.20(c)(4)(ii) would expand application of the performance requirements to all protective eyewear intended to be used with sunlamp products, whether sold together with a sunlamp product or sold separately. As we have previously explained, UV wavelengths can cause serious eye damage, and exposure to the shorter wavelength region of the UV spectrum is especially dangerous. (See 42 FR 65189 at 65191, December 30, 1977.) Short-term risks include photokeratitis, which is very painful and causes temporary loss of vision, and there is also a risk of retinal damage from short-term or long-term exposure, which could cause blind spots to form in the retina. Repeated, long-term UV exposure increases the risk of cataracts, and there is evidence of an association between UV exposure and ocular melanoma (Ref. 11).

The spectral transmittance requirements for protective eyewear are necessary to protect users of sunlamp products from these risks, which directly result from the UV radiation emitted by the sunlamp product. Users of sunlamp products, especially those who tan in tanning facilities, often use protective eyewear manufactured by an entity other than the manufacturer of the sunlamp product. Use of sunlamp products with eyewear that does not meet these requirements would increase the risk posed by the radiation emitted by the sunlamp product and undermine the protection provided by the performance standard. Therefore it is necessary to apply the standard to all protective eyewear intended to be used with sunlamp products.

The proposal would also modify the protective eyewear transmittance requirements of § 1040.20(c)(4)(ii) to better ensure user safety and achieve harmony with the IEC standard. (See clause 32.102 of IEC 60335–2–27, Ed. 5.0.) The requirements for spectral transmittance in the UV range of 200–400 nm would remain the same as in the current FDA standard. The proposed rule would adopt the limit of 5 percent on the visible transmittance in the range

of 400–550 nm from clause 32.102 of the IEC standard. This requirement would provide additional safety to protect the retina from intense visible light. Currently, there is no such requirement included in the FDA standard. The proposed rule would abandon the current requirement that spectral transmittance shall be sufficient over the wavelength range greater than 400 nm to provide visibility to the user, and instead adopt the lower limit of 1 percent on luminous transmission from clause 32.102 of the IEC standard. Replacing the subjective standard with an objective one would make compliance easier to verify and improve uniformity and consistency.

4. Label Requirements

Proposed § 1040.20(d)(1)(i) would modify the warning statement required to appear on the label of all sunlamp products. FDA believes that the current warning statement is too long, not user-friendly, and that its content and format could be improved to more effectively communicate the risks of indoor tanning to users. As discussed in section I, FDA has been considering updating the required warning since 1999. In 2007, Congress required FDA to conduct consumer focus group testing to evaluate the adequacy of sunlamp product warning labels in conveying certain risk information to consumers, including the risk of skin cancer. (See section 230 of the Food and Drug Administration Amendments Act of 2007, Pub. L. 110–85.) Based on its analysis of the consumer testing, FDA concluded that the current warning statement could be made more effective by changing its required language, formatting, and location. See the FDA Report to Congress entitled ''Labeling Information on the Relationship Between the Use of Indoor Tanning Devices and Development of Skin Cancer or Other Skin Damage'' (Ref. 12).

FDA would like to harmonize its standard as much as possible with the IEC 60335–2–27 Ed. 5.0 standard. However, based on the results of the focus group testing, we believe it is appropriate for some differences to remain between the FDA warning statement and the IEC warning statement, especially since the IEC warning statement provides only the general substance to be conveyed (since it is intended for use in multiple languages) and does not provide formatting specifications. FDA believes that the proposed warning statement would most effectively convey the risks of indoor tanning to users. Specifically, the label of each sunlamp product would have to contain a warning statement with the following language and format:

''DANGER—Ultraviolet Radiation (UV)

UV can cause:

- Skin Cancer
- Skin Burns
- Premature Skin Aging such as wrinkles and age spots
- Eye Damage (both short- and long-term)

Wear FDA-compliant protective eyewear to prevent eye damage, such as burns or cataracts.

Follow the recommended exposure schedule to avoid severe skin burns.

Talk to your doctor or pharmacist before tanning if you use medicines and/or cosmetics. Some of these products can make you more sensitive to skin and eye damage from UV.''

Currently, § 1040.20(d)(1)(iv) requires sunlamp product labels to include a recommended exposure schedule containing certain information. FDA proposes to add a requirement that the exposure schedule be developed in accordance with the specific parameters in IEC 60335–2–27, Ed. 5.0, Annex DD, which would be incorporated by reference. The proposed rule provides an example of a recommended exposure schedule that would meet the guidelines/parameters in IEC 60335–2–27, Ed. 5.0, Annex DD. See proposed § 1040.20(d)(1)(iv). These parameters are different from those provided in the 1986 FDA Policy Letter on Maximum Timer Interval and Exposure Schedule (Ref. 3), and are based on current science, including recent human research conducted at FDA. This requirement is aimed at reducing the cumulative UV dose to sunlamp product users and attaining closer harmonization of FDA and the IEC standard.

Proposed § 1040.20(d)(1)(iv) would also require a warning to appear either directly above or below the exposure schedule stating ''Skin Type I individuals (always burns, never tans) should never use sunlamp products.'' This warning is based on years of published research showing that Skin Type I individuals sunburn easily and cannot tan and are therefore at the greatest risk for skin cancer. By ''Skin Type'' we are referring to the historical Fitzpatrick skin typing system (Ref. 13) developed in 1975 by dermatologist Thomas Fitzpatrick to predict skin reactivity in phototherapy. Under this categorization scheme, Skin Type I is the fairest and most sensitive while Skin Type VI is the darkest and least sensitive to UV radiation. The Skin Types that are most likely to tan through the use of sunlamp products are Skin Types II through IV. It has been shown (Ref. 14) that Skin Types III and IV can attain a tan with UV doses that are similar to what is needed for Skin Type II. Thus, the same dose can be used to develop and maintain a tan for all three Skin Types. This was confirmed in clinical studies performed at FDA (Ref. 15). This is a change from the approach of the 1986 Policy Letter, which called for exposure schedules to be differentiated by Skin Type.

The proposed rule would also improve user safety by adopting the IEC's ''equivalency code'' system for ensuring compatibility between sunlamp products (*e.g.,* tanning beds and booths) and the UV lamps (sometimes referred to as light bulbs) that are used in them. Proposed § 1040.20(d)(1)(vi) would require the label of all sunlamp products to indicate the equivalency code range of the UV lamp to be used in the sunlamp product. The equivalency code range would have to be determined in accordance with clause 22.111 and Annex CC of IEC 60335–2–27, Ed. 5.0, which would be incorporated by reference. Proposed § 1040.20(d)(2)(ii) would require the label of each UV lamp to indicate its UV lamp equivalency code, as defined in Annex CC of IEC 60335–2–27, Ed. 5.0. In determining the ''UV code'' component of the UV lamp equivalency code, output would have to be measured in accordance with IEC 61228, Ed. 2.0, ''Fluorescent Ultraviolet Lamps used for Tanning—Measurement and Specification Method,'' (Ref. 5) which would be incorporated by reference.

FDA believes the adoption of the IEC's absolute rating system for replacement lamps would eliminate confusion regarding proper lamp replacement, facilitate the enforcement of lamp compatibility requirements, and improve the safety of sunlamp products. Currently, FDA relies on a relative system in which the lamp manufacturer has to provide to FDA and to users a list of lamps with which the manufacturer's lamp is compatible. (See §§ 1002.10 and 1040.20(e)(2)(iii).) As new lamp manufacturers and new lamp models enter the marketplace, while other manufacturers abandon old models of lamps or leave the marketplace, it is increasingly cumbersome to keep track of which lamps are compatible with the lamps originally provided with the sunlamp product. This can cause confusion for tanning facility owners, FDA, and State or local inspectors. When incorrect lamps are used as replacements, the erythema-effective intensity may be greater, resulting in burns. Therefore, FDA has decided that an absolute rating system is needed,

which would require that a code be printed on the lamp to indicate its erythema-effective output, and a code range be printed on the sunlamp product, to indicate which lamps to use with it. Another advantage of adopting the provisions in both of these IEC standards is that they provide detailed measurement specifications, which would ensure consistency among manufacturers.

Proposed § 1040.20(d)(3) would retain the requirement of the current FDA standard that the required label information must be legible and readily accessible to view by a sunlamp product user immediately prior to use. FDA provided details regarding compliance with this requirement in its June 25, 1985, policy letter entitled ''Policy on Warning Label Required on Sunlamp Products'' (Ref. 2). Proposed § 1040.20(d)(3)(i) would incorporate similar specifications into the rule regarding the location, spacing, and font of the required warning statement. The proposal specifies that the warning statement would have to be readily accessible to view whether the tanning bed canopy or tanning booth door is open or closed when the user approaches, which may necessitate that it appear in more than one location on the sunlamp product. FDA believes that these label specifications would ensure that users see the required warning prior to use, and would result in a more comprehensive and effective standard.

Proposed § 1040.20(d)(3)(ii) specifies that required UV lamp information would have to appear on the packaging of the lamp in addition to being permanently affixed or inscribed on the lamp itself. This would ensure that anyone replacing a UV lamp would be aware of the lamp equivalency code and required warnings before and after purchase.

We propose revising § 1040.20(d)(3)(iv) to achieve consistency with the requirement in the device labeling regulations at 21 CFR 801.15(c)(1) that all words, statements, and other information required by or under authority of the FD&C Act to appear on the label or labeling of a device must appear in the English language (or a foreign language for articles distributed solely in Puerto Rico or in a Territory where the predominant language is not English). Since the labeling of UV lamps must comply with the labeling requirements of part 801 and § 1040.20, we propose to remove the language in § 1040.20(d)(3)(iv) that permits the manufacturer to express the manufacturer's name and month and year of manufacture as code or symbols. FDA is not aware of any request to use symbols or codes for this purpose in the past.

5. User Information

The proposal would remove § 1040.20(e)(1)(iv) since the recommended exposure schedule no longer needs to be differentiated by skin type and would be required to be prominently displayed at the beginning of the users' instructions under proposed § 1040.20(e)(1)(i).

Proposed § 1040.20(e)(1)(v) would add a requirement for the provision of instructions and warnings regarding assembly, operation, and maintenance, which is modeled on the proposed FDA Performance Standard for Laser Products (78 FR 37723). This would better protect individuals who assemble, test, and maintain sunlamp products.

Proposed § 1040.20(e)(3) would add a requirement for the provision of the required warning statement in all catalogs, specification sheets, and descriptive brochures intended for consumers in which sunlamp products are offered for sale, and on all consumer-directed Web pages on which sunlamp products are offered for sale. This requirement would ensure that consumers are fully informed of the risks presented by sunlamp products at the time they consider purchasing it.

6. Test for Determination of Compliance

Proposed § 1040.20(f) would add a requirement that the performance requirements for the measuring instrument in clause 32.101 of IEC 60335–2–27 Ed. 5.0 would apply.

7. Modification of Certified Sunlamp Products

Proposed § 1040.20(g) is also modeled after the proposed FDA Performance Standard for Laser Products (78 FR 37723). FDA believes the addition of these requirements, which have been used successfully over the past 2 decades for laser products, would improve safety by ensuring that modifications that affect performance would be held to the same standards as original manufacturing.

III. Legal Authority

Section 532 of the FD&C Act (21 U.S.C. 360ii) authorizes FDA to establish and administer an electronic product radiation control program to protect the public health and safety. Section 534 of the FD&C Act gives FDA authority to issue regulations establishing performance standards for electronic products to control their emission of radiation. These standards may include requirements for product testing and radiation measurement, the attachment of warning signs and labels, and the provision of instructions for product installation, operation, and use. Section 1003(b)(2)(E) of the FD&C Act (21 U.S.C. 393(b)(2)(E)) requires FDA to ensure that public health and safety are protected from electronic product radiation. In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) authorizes the Agency to issue regulations for the efficient enforcement of the FD&C Act.

Section 230 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) directed FDA to determine whether changes to the warning statement would more effectively communicate the risks of indoor tanning, such as skin cancer, and to submit a report that includes an explanation of the measures being implemented to significantly reduce the risks associated with indoor tanning devices. As explained in section II, based on consumer testing, FDA determined that the proposed warning statement would better communicate the risks of indoor tanning to consumers, and is proposing these amendments to the sunlamp products performance standard to significantly reduce the risks associated with these products.

IV. Proposed Effective Date

FDA proposes that any final rule issued based on this proposal become effective 1 year after the date of publication of the final rule in the **Federal Register**.

V. Environmental Impact, No Significant Impact

The Agency has determined under 21 CFR 25.34(c) that this proposed action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environment impact statement is required.

VI. Economic Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have

developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. We do not believe this proposed rule would result in a significant impact on a substantial number of small entities, but the impacts are uncertain so we are explicitly seeking comment on the impacts.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

The proposed rule would affect several aspects of the performance standards to reduce risks associated with use. The costs are summarized in table 1. Estimated one-time costs are $20,917 to $113,240 and annual costs are $4,686 to $7,230. The present discounted costs are $57,181 to $151,390 at 7 percent and $61,498 to $165,883 at 3 percent. Annualized at 7 percent over 10 years, total costs are $8,141 to $21,498. At 3 percent, annualized total costs are $7,867 to $19,447.

The primary benefit of the proposed rule would be from reduced injuries, including sunburn, photokeratitis, skin cancer, cataracts and ocular melanoma and from reduced exposure to UV radiation. We are unable to quantify the benefits, but demonstrate that they satisfy breakeven tests using very conservative assumptions. The benefits of this proposed rule would justify the costs.

TABLE 1—PRESENT DISCOUNTED COSTS OF THE PROPOSED RULE

Year	Low cost scenario	High cost scenario
Discounted @7 percent	$57,181	$151,390
Discounted @3 percent	61,498	165,883
10-Year Annualized @7 percent	8,141	21,498
10-Year Annualized @3 percent	7,867	19,447

The full assessment of the economic analysis is available in Docket FDA–1998–N–0880 and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm* (Ref. 16).

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Federal law includes an express preemption provision at section 542 of the FD&C Act (21 U.S.C. 360ss) that preempts the States from establishing, or continuing in effect, any standard with respect to an electronic product which is applicable to the same aspect of product performance as a Federal standard prescribed under section 534 of the FD&C Act and which is not identical to the Federal standard. If this proposed rule is made final, the final rule would prescribe a Federal standard under section 534 of the FD&C Act. However, section 542 of the FD&C Act does not ''prevent the Federal Government or the government of any State or political subdivision thereof from establishing a requirement with respect to emission of radiation from electronic products procured for its own use if such requirement imposes a more restrictive standard than that required to comply with the otherwise applicable Federal standard.'' (Section 542 of the FD&C Act.)

VIII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in the paragraphs that follow with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Sunlamp Products; Proposed Amendment to § 1002.1 (Record and Reporting Requirements) and § 1040.20 (Performance Standard).

Description: The Safe Medical Devices Act of 1990 (Pub. L. 101–629) transferred the provisions of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602) from Title III of the Public Health Service Act (42 U.S.C. 201 *et seq.*) to Chapter V, subchapter C of the FD&C Act (21 U.S.C. 301 *et seq.*). Under the FD&C Act, FDA administers an electronic product radiation control program to protect the public health and safety. FDA also develops and administers radiation safety performance standards for electronic products, including sunlamp products.

Current § 1002.1 requires that sunlamp product manufacturers submit product reports, supplemental reports, and annual reports and requires that test records and distribution records are maintained, used for summary data submitted in the annual report, and made available upon request. In addition, current § 1002.1 requires UV

lamp manufacturers to submit product reports. Proposed § 1002.1 would require that manufacturers of UV lamps also submit supplemental reports and annual reports and maintain test records and distribution records.

Proposed § 1002.1 would also require that manufacturers of protective eyewear maintain test records and distribution records as well as submit annual reports, supplemental reports, and product reports. The eyewear must meet certain transmittance limits in the UV and visible wavelength range. Both manufacturers of sunlamp products that include eyewear with their products and manufacturers of protective eyewear that is sold separately would be responsible for maintaining records of the results yielded by the testing and reporting these results to FDA. (See § 1002.1.) There are no operating and maintenance costs associated with testing the eyewear because this requirement reflects current market practices.

Proposed § 1040.20(d)(2)(ii) would require that the UV lamp labeling include a replacement lamp code instead of a list of compatible replacement lamps. Although the single UV lamp manufacturer in the United States is already required to conduct spectral irradiance testing of lamps in order to demonstrate compatibility with other model lamps (whether made by that company or other manufacturers), proposed § 1040.20(d)(2)(ii) would require testing in accordance with test methods as specified in IEC 61228, Ed. 2.0, ''Fluorescent Ultraviolet Lamps Used for Tanning—Measurement and Specification Method.'' The spectral irradiance data obtained is used to calculate the UV code that would be required to be printed on the lamp by proposed § 1040.20(d)(2)(ii). Manufacturers would be responsible for maintaining and reporting records of the results yielded by the testing as well as imprinting the lamp with the replacement lamp code.

Proposed § 1040.20(d)(2)(iii) would require that each UV lamp have a label containing the model identification of the lamp, if applicable. Manufacturers would be responsible for printing the model number on the lamp itself.

Proposed § 1040.20(d)(3)(iii) would permit the manufacturer of the sunlamp product or UV lamp to submit a request to the Director, Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health for an approval of alternate labeling if the size, configuration, design, or function of the sunlamp product or UV lamp would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective. In these circumstances, manufacturers would be responsible for reporting the request to FDA. The operating and maintenance costs associated with this provision are based on correspondence costs (postage) for non-email communications.

Proposed § 1040.20(d)(3)(iv) would permit manufacturers of UV lamps to permanently affix or inscribe the tags or labels required by §§ 1010.2(b) and 1010.3(a) on the lamp packaging associated with the UV lamps, rather than the UV lamps themselves. The third party disclosure burden of this provision would be the time it takes to inscribe the label or tag on the UV lamp packaging.

Proposed § 1040.20(e)(1)(v) would require instructions for sunlamp ''assembly, operation, and maintenance,'' and would include a schedule of maintenance. This information would also protect those maintaining and assembling sunlamp products from inadvertent exposure to UV radiation by providing adequate instructions to avoid UV exposure during assembly or maintenance. We presume that the maintenance schedules would be developed from known information about how to properly maintain these devices. The third party disclosure burden of this provision would be the time spent bringing this known information into a user-friendly format and disclosing it to users. We also assume that this information would be identical for all units of a given model of sunlamp products.

Proposed § 1040.20(g) would require that those who change the function or performance characteristics of a sunlamp are manufacturers and would need to recertify and re-identify the device. This requirement applies only if the modification affects any aspect of the product's performance or intended function(s) for which § 1040.20 has an applicable requirement. We believe some sunlamp owners (*e.g.,* tanning facility owners) view such modifications as a less expensive alternative to purchasing a new sunlamp product. We believe some owners, otherwise inclined to alter their sunlamp's performance characteristics, would be deterred from doing so by our proposal because recertification would cost a tanning facility owner more than $30,000 in operating and maintenance costs since tanning facility owners do not typically have the equipment necessary to recertify sunlamp products. However, if a tanning facility owner chooses to recertify the sunlamp product, documentation must be submitted to FDA.

Description of Respondents: Respondents for these information collections are manufacturers of sunlamp products and UV lamps intended for use in sunlamp products, and manufacturers of protective eyewear that is intended to be used with sunlamp products.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Capital and operating and maintenance costs
1002.1(b)—Lamp only	1	9	9	2	18	
1002.1(b)—Protective eyewear	5	4	20	0.5	10	
1040.20(d)(2)(ii)	1	1	1	1	1	
1040.20(d)(3)(iii)	1	1	1	.17	.17 (10 minutes)	
1040.20(g)	1	1	1	8	8	$43,000
Total					37	$43,000

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours	Capital and operating and maintenance costs
1002.1(b)—Lamp only	1	2	2	2.5	5.	
1002.1(b)—Protective eyewear	5	3	15	7	105.	
1040.20(d)(2)(ii)	1	75	75	0.8	60	$30,000
Total					170	$30,000

TABLE 4—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
1040.20(d)(1)(vi)	5	5,200	26,000	.0034	88
1040.20(d)(2)(ii)	1	286,000	286,000	.0017	486
1040.20(d)(2)(iii)	1	286,000	286,000	.0017	486
1040.20(d)(3)(ii)	1	286,000	286,000	.0017	486
1040.20(d)(3)(iv)	1	23,833	23,833	.0017	41
1040.20(e)(1)(v)	5	10	50	12	600
Total					2,187

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

A. Reporting Burden

For § 1002.1(b)—Lamp only, we estimate the single U.S.-based manufacturer of UV lamps would need to submit 2 new types of reports (supplemental reports and an annual report) for the 75 models. Based on previous submissions, we estimate that nine supplemental reports would be submitted per year. Annual reports are submitted once per year. We estimate that it takes approximately 2 hours to complete each report for a total of 18 burden hours.

For § 1002.1(b)—Protective eyewear, we estimate that the five respondents would need to report the information annually and that each of the manufacturers produces two models of protective eyewear. Manufacturers are not required to produce two types of eyewear; however, FDA estimates that each of the five respondents produces two types of eyewear that could be made available with sunlamp products. Manufacturers would fill out and submit the annual, supplemental, and product reports demonstrating conformance to the performance standard, and this process is estimated to take 30 minutes per report for a total of 10 hours.

For § 1040.20(d)(2)(ii), we estimate that the single U.S.-based manufacturer of UV lamps would test 75 UV lamps and that the time needed to incorporate the data into the product report is 1 hour.

For § 1040.20(d)(3)(iii), we estimate that one sunlamp product and UV lamp manufacturer would submit a request for alternate labeling approval to FDA. This task is expected to be performed by clerical staff that prepare the request and submit it to FDA. This process is expected to take 10 minutes (.17 hours) to type the request and email it. The request is expected to be submitted electronically and does not involve any operating and maintenance cost.

For § 1040.20(g), we estimate that, at most, one respondent per year would decide to re-certify a sunlamp product with the Agency, instead of the less expensive alternative of purchasing a new sunlamp product. The $43,000 capital costs for recertifying the sunlamp product includes the required instrumentation and calibration light sources such as a double-grating spectroradiometer with integrating sphere and software. We estimate the time needed to make the necessary spectral measurements and compile them into a report that would be sent to FDA to take 8 hours.

B. Recordkeeping Burden

For § 1002.1(b)—Lamp only, we estimate the single U.S.-based manufacturer of UV lamps would need to maintain 2 types of records (test records and distribution records) for each of the 75 models and that it takes approximately 2 minutes per model per record for a total of 300 minutes, or 5 burden hours.

For § 1002.1(b)—Protective eyewear, we estimate that there are five U.S. manufacturers of protective eyewear that would be affected by this amendment. However, this number is uncertain and we welcome comment on this issue. We estimate that each of the manufacturers produces 2 models of protective eyewear and the manufacturer would sample approximately 10 units per model. The time required to perform the necessary testing, including time to verify the instrument, set up the test and prepare and file a report takes approximately 7 hours per model. Protective eyewear manufacturers would also be required to maintain distribution records for their products. We estimate that 7 hours per year would be necessary for the manufacturer to log and file the distribution data. We estimate a total of 105 hours for each manufacturer to maintain the single distribution record for both models of protective eyewear as well as perform the testing for the individual test records that are to be maintained for each model of protective eyewear.

For § 1040.20(d)(2)(ii), we expect that the single U.S.-based lamp manufacturer does not use IEC UV codes and would have to test and label its models under the proposed rule. The manufacturer has an estimated 30 to 120 models and we chose the mean number of models (75) for our calculations. The mean cost of testing each model is $350 and the cost for an ink stamp is $50 per model,

yielding an approximate $30,000 in operating and maintenance cost for § 1040.20(d)(2)(ii). Manufacturers are already performing similar spectral irradiance testing to determine lamp compatibility. We estimate that it would take 0.8 hours per model to modify the test setup to measure spectral irradiance in order to determine the UV code as well as file the results, for a total of 60 hours. We estimate that the single U.S.-based lamp manufacturer is already maintaining records of these tests, so there should be no additional cost associated with proposed § 1002.1 that requires lamp manufacturers now also to maintain test records, although FDA is seeking comment on this understanding.

C. Third Party Disclosure Burden

For § 1040.20(d)(1)(vi), we estimate that the five respondents would need to list the code range that can be used in each of the 5,200 sunlamp products produced annually. We estimate 2 minutes to print and affix this label on each the 26,000 sunlamp products, for a total of 88 hours.

For § 1040.20(d)(2)(ii), the single U.S.-based lamp manufacturer would need to inscribe the UV lamp equivalency code onto each lamp. We estimate it would take 1 minute to ink stamp 10 lamps with the new UV lamp equivalency code. The operating and maintenance costs for this information collection are subsumed in the recordkeeping burden estimate for § 1040.20(d)(2)(ii). The lamp manufacturer produces 286,000 new lamps per year so this process is expected to take approximately 28,600 minutes per year, or about 486 hours.

For § 1040.20(d)(2)(iii), the single U.S.-based lamp manufacturer would need to inscribe the model identification onto each lamp. We estimate it would take 1 minute to ink stamp ten lamps with the model identifier. The operating and maintenance costs for this information collection are subsumed in the recordkeeping burden estimate for § 1040.20(d)(2)(ii). The lamp manufacturer produces 286,000 new lamps per year so this process is expected to take approximately 28,600 minutes per year, or about 486 hours.

For § 1040.20(d)(3)(iv), we estimate that the single U.S.-based lamp manufacturer would permanently affix or inscribe the tags or labels required by §§ 1010.2(b) and 1010.3(a) on the packaging of all the UV lamps rather than the lamps themselves. Since lamps are typically packaged and sold in cases of 12, this yields 23,833 packages that must bear the third party disclosure required by § 1040.20(d)(3)(iv). We estimate it would take 1 minute to ink stamp 10 lamp packages with the tags or labels required by §§ 1010.2(b) and 1010.3(a) for a total of 41 hours.

For § 1040.20(d)(3)(ii), the single U.S.-based lamp manufacturer would need to inscribe or affix the UV lamp equivalency code on the packaging of each lamp. We estimate it would take 1 minute to ink stamp 10 lamp packages with the new UV lamp equivalency code. The lamp manufacturer produces 286,000 new lamps per year so this process is expected to take 28,600 minutes per year, or about 486 hours.

For § 1040.20(e)(1)(v), we estimate the 5 respondents would need to go through this reporting exercise once for each of their 10 models of sunlamp products. We estimate that 10 hours of a technician's time would be required to collect all the necessary information regarding maintenance and assembly and 2 hours of a manager's time to review this information once it is re-formatted into the user instructions. Thus, we estimate a total of 12 hours per model of sunlamp product would be required for a total of 600 hours. This would be a one-time cost.

This proposed rule also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information found in proposed § 1040.20(d)(1)(ii); (d)(1)(iii); (d)(1)(iv), 1st sentence; (d)(1)(v); (e)(1)(i) to (e)(1)(iv); (e)(2)(i), and (e)(2)(ii) have been approved under OMB control number 0910–0025 (expires January 1, 2017); the collections of information found in § 1040.20(d)(3)(v) have been approved under OMB control number 0910–0485 (expires February 28, 2015).

In addition, FDA concludes that proposed § 1040.20(d)(1)(i); (d)(1)(iv), 2nd and 3rd sentences; (d)(2)(i); (d)(2)(iv); (d)(3)(i); and (e)(3) do not constitute ''collection[s] of information'' under the PRA. Rather, the labeling statements are ''public disclosure[s] of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public.'' (5 CFR 1320.3(c)(2).)

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB (see **ADDRESSES**). All comments should be identified with the title ''Sunlamp Products; Proposed Amendment to § 1002.1 (Record and Reporting Requirements) and § 1040.20 (Performance Standard).''

In compliance with the PRA (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

IX. Incorporation by Reference

FDA is proposing to incorporate by reference certain portions of the IEC International Standards 60335–2–27, Ed. 5.0: 2009–12 entitled ''Household and Similar Electrical Appliances—Safety—Part 2–27: Particular Requirements for Appliances for Skin Exposure to Ultraviolet and Infrared Radiation''; and 61228, Ed. 2.0, ''Fluorescent Ultraviolet Lamps Used for Tanning—Measurement and Specification Method.'' You may purchase a copy of these materials from the International Electrotechnical Commission (EC Central Office), 3 rue de Varembe, CH–1211 Geneva 20, Switzerland, call +41 22–919–02–11, *https://webstore.iec.ch/*. FDA is also proposing to incorporate by reference the American National Standard C81.10–1976, entitled ''Specifications for Electric Lamp Bases and Holders—Screw-Shell Types.'' You may purchase a copy of the material from the American National Standards Institute, 1889 L St. NW., 11th Floor, Washington, DC 20036, call 202–293–8020, *www.ansi.org*.

The IEC 60335 standard describes technical specifications that address the safety of electrical appliances that incorporate emitters for exposing the skin to UV and infrared radiation, including those found in tanning salons or other facilities. The IEC 61228 standard describes the method to measure, evaluate, and specify the characteristics of fluorescent UV lamps that are used in appliances for tanning purposes. The ANSI standard describes technical specifications that will help ensure only appropriate bulbs can be fitted to the appliance.

X. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). FDA is explicitly seeking comment on how the proposed requirements would impact small entities.

Comments on the following two proposals listed are of special interest to FDA:

1. The Use of the Limit on UVC Irradiance of 0.03 W/cm^2 in IEC 60335–

2–27, Ed. 4.2: 2007–4 Instead of the Limit of 0.003 W/cm² in IEC 60335–2–27, Ed. 5.0: 2009–12.

2. The Use of a Limit of 500 J/m² on the Maximum Dose Used to Calculate the Maximum Timer Limit, Instead of the 600 J/m² Limit in IEC 60335–2–27, Ed. 5.0: 2009–12.

XI. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Boniol, M., P. Autier, P. Boyle, and S. Gandini, ''Cutaneous Melanoma Attributable to Sunbed Use: Systematic Review and Meta-analysis,'' *British Medical Journal,* 345:e8503, December 2012.
2. FDA, Policy on Warning Label Required on Sunlamp Products, Department of Health and Human Services, Center for Devices and Radiological Health, Rockville, MD, June 25, 1985, *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095333.pdf.*
3. FDA, Policy on Maximum Timer Intervals and Exposure Schedule for Sunlamps, Department of Health and Human Services, Center for Devices and Radiological Health, Rockville, MD, August 21, 1986, *http://www.fda.gov/downloads/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/UCM192707.pdf.*
4. FDA, Policy on Lamp Compatibility, Department of Health and Human Services, Center for Devices and Radiological Health, Rockville, MD, September 2, 1986, *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095325.pdf.*
5. IEC 61228, Ed. 2.0, ''Fluorescent Ultraviolet Lamps Used for Tanning—Measurement and Specification Method,'' IEC, Geneva, Switzerland.
6. IEC 60335–2–27, Ed. 5.0, ''Household and Similar Electrical Appliances—Safety—Part 2–27: Particular Requirements for Appliances for Skin Exposure to Ultraviolet and Infrared Radiation,'' IEC, Geneva, Switzerland, 2009.
7. FDA Guidance for Industry and FDA Staff, ''Laser Products—Conformance With IEC 60825–1 and IEC 60601–2–22 (Laser Notice No. 50),'' June 24, 2007, available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094366.pdf.*
8. CIE S 007/E–1998/ISO 17166: 1999(E) Erythemal Reference Action Spectrum and Standard Erythema Dose, CIE Vienna, Austria.
9. ''Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph,'' FDA, Department of Health and Human Services, 64 FR 27666, May 21, 1999.
10. Dowdy, J.C. and R.M. Sayre, ''Comparison of IEC and U.S. FDA Sunlamp Standards: Critical Discrepancies in Exposure Timers and Annual Exposure Limits,'' Proceedings of the CIE Symposium 2004 on Light and Health: Non-Visual Effects, Vienna, Austria, pp. 183–188.
11. Vajdic, C.M., A. Kricker, M. Giblin, et al, ''Sun Exposure Predicts Risk of Ocular Melanoma in Australia,'' *International Journal of Cancer,* 101(2): 175–182, September 2002.
12. FDA, ''Report to Congress: Labeling Information on the Relationship Between the Use of Indoor Tanning Devices and Development of Skin Cancer or Other Skin Damage,'' submitted December 2008, available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109288.htm.*
13. Fitzpatrick, T.B., ''The Validity and Practicality of Sun-Reactive Skin Type I Through VI,'' *Archives of Dermatology,* 124: 869–871, 1988.
14. Pathak, M.A. and D.L. Fanselow, ''Photobiology of Melanin Pigmentation: Dose/Response of Skin to Sunlight and its Contents,'' *Journal of the American Academy of Dermatology,* 9: 724–733, 1983.
15. Miller, S.A., S.G. Coelho, S.W. Miller, et al., ''Evidence for a New Paradigm for UV Exposure: A Universal Schedule That is Skin Phototype-Independent,'' *Photoderm Photoimm Photomed,* 28: 187–195, 2012.
16. *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects

21 CFR Part 1002

Electronic products, Radiation protection, Reporting and recordkeeping requirements.

21 CFR Part 1040

Electronic products, Incorporation by reference, Labeling, Lasers, Medical devices, Radiation protection, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 1002 and 1040 be amended as follows:

PART 1002—RECORDS AND REPORTS

■ 1. The authority citation for part 1002 is revised to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 360hh–360ss, 371, 374, 393.

■ 2. Section 1002.1 is amended by revising Table 1 to read as follows:

§ 1002.1 Applicability.

* * * * *

TABLE 1—RECORD AND REPORTING REQUIREMENTS BY PRODUCT

Products	Manufacturer						Dealer and distributor
	Product reports § 1002.10	Supplemental reports § 1002.11	Abbreviated reports § 1002.12	Annual reports § 1002.13	Test records § 1002.30(a) [1]	Distribution records § 1002.30(b) [2]	Distribution records §§ 1002.40 and 1002.41
DIAGNOSTIC X-RAY [3] (§§ 1020.30, 1020.31, 1020.32, and 1020.33):							
Computed tomography	X	X		X	X	X	X
X-ray system [4]	X	X		X	X	X	X
Tube housing assembly	X	X		X	X	X	
X-ray control	X	X		X	X	X	X
X-ray high voltage generator	X	X		X	X	X	X
X-ray table or cradle			X		X	X	X
X-ray film changer			X		X	X	

TABLE 1—RECORD AND REPORTING REQUIREMENTS BY PRODUCT—Continued

Products	Manufacturer						Dealer and distributor
	Product reports § 1002.10	Supplemental reports § 1002.11	Abbreviated reports § 1002.12	Annual reports § 1002.13	Test records § 1002.30(a) [1]	Distribution records § 1002.30(b) [2]	Distribution records §§ 1002.40 and 1002.41
Vertical cassette holders mounted in a fixed location and cassette holders with front panels	.....	.....	X	.....	X	X	X
Beam-limiting devices	X	X	.....	X	X	X	X
Spot-film devices and image intensifiers manufactured after April 26, 1977	X	X	.....	X	X	X	X
Cephalometric devices manufactured after February 25, 1978	.....	.....	X	.....	X	X	.....
Image receptor support devices for mammographic X-ray systems manufactured after September 5, 1978	.....	.....	X	.....	X	X	X
CABINET X RAY (§ 1020.40):							
Baggage inspection	X	X	.....	X	X	X	X
Other	X	X	.....	X	X	X	.....
PRODUCTS INTENDED TO PRODUCE PARTICULATE RADIATION OR X-RAYS OTHER THAN DIAGNOSTIC OR CABINET DIAGNOSTIC X-RAY:							
Medical	.....	.....	X	X	X	X	.....
Analytical	.....	.....	X	X	X	X	.....
Industrial	.....	.....	X	X	X	X	.....
TELEVISION PRODUCTS (§ 1020.10):							
<25 kilovolt (kV) and <0.1 milliroentgen per hour (mR/hr IRLC [5 6]	.....	.....	X	X [6]	.....	.....	.....
≥25kV and <0.1mR/hr IRLC [5]	X	X	.....	X	.....	.....	.....
≥0.1mR/hr IRLC [5]	X	X	.....	X	X	X	.....
MICROWAVE/RF:							
MW ovens (§ 1030.10)	X	X	.....	X	X	X	.....
MW diathermy	.....	.....	X	.....	.....	.....	.....
MW heating, drying, security systems	.....	.....	X	.....	.....	.....	.....
RF sealers, electromagnetic induction and heating equipment, dielectric heaters (2–500 megahertz)	.....	.....	X	.....	.....	.....	.....
OPTICAL:							
Phototherapy products	X	X	.....	.....	.....	.....	.....
Laser products (§§ 1040.10 and 1040.11)	.....	.....	.....	.....	.....	.....	.....
Class I lasers and products containing such lasers [7]	X	.....	.....	X	X	.....	.....
Class I laser products containing class IIa, II, IIIa, lasers [7]	X	.....	.....	X	X	X	.....
Class IIa, II, IIIa lasers and products other than class I products containing such lasers [7]	X	X	.....	X	X	X	X
Class IIIb and IV lasers and products containing such lasers [7]	X	X	.....	X	X	X	X
Sunlamp products (§ 1040.20).							
Lamps only	X	X	.....	X	X	X	.....
Sunlamp products	X	X	.....	X	X	X	X
Protective eyewear	X	X	.....	X	X	X	.....

TABLE 1—RECORD AND REPORTING REQUIREMENTS BY PRODUCT—Continued

Products	Manufacturer						Dealer and distributor
	Product reports § 1002.10	Supplemental reports § 1002.11	Abbreviated reports § 1002.12	Annual reports § 1002.13	Test records § 1002.30(a) [1]	Distribution records § 1002.30(b) [2]	Distribution records §§ 1002.40 and 1002.41
Mercury vapor lamps (§ 1040.30)							
T lamps	X	X		X			
R lamps			X				
ACOUSTIC:							
Ultrasonic therapy (§ 1050.10)	X	X		X	X	X	X
Diagnostic ultrasound			X				
Medical ultrasound other than therapy or diagnostic	X	X					
Nonmedical ultrasound			X				

[1] However, authority to inspect all appropriate documents supporting the adequacy of a manufacturer's compliance testing program is retained.
[2] The requirement includes §§ 1002.31 and 1002.42, if applicable.
[3] Report of Assembly (Form FDA 2579) is required for diagnostic x-ray components; see § 1020.30(d)(1) through (d)(3).
[4] Systems records and reports are required if a manufacturer exercises the option and certifies the system as permitted in § 1020.30(c).
[5] Determined using the isoexposure rate limit curve (IRLC) under phase III test conditions (§ 1020.10(c)(3)(iii)).
[6] Annual report is for production status information only.
[7] Determination of the applicable reporting category for a laser product hall be based on the worst-case hazard present within the laser product.

PART 1040—PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

■ 1. The authority citation for 21 CFR part 1040 is revised to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e–360j, 360hh–360ss, 371, 381, 393.

■ 2. Section 1040.20 is revised to read as follows:

§ 1040.20 Sunlamp products and ultraviolet lamps intended for use in sunlamp products.

(a) *Applicability.* The provisions of this section, as amended, are applicable as specified to all sunlamp products and ultraviolet lamps intended for use in sunlamp products not later than [*A DATE WILL BE ADDED 1 YEAR AFTER DATE OF PUBLICATION OF A FUTURE FINAL RULE IN THE* **Federal Register**].

(b) *Definitions.* As used in this section, the following definitions apply:

Exposure position means any position, distance, orientation, or location relative to the radiating surfaces of the sunlamp product at which the user is intended to be exposed to ultraviolet radiation from the sunlamp product, as recommended by the manufacturer.

Irradiance means the radiant power incident on a surface at a specified location and orientation relative to the radiating surface divided by the area of the surface, as the area becomes vanishingly small, expressed in units of watts per square centimeter (W/cm^2).

Maximum exposure time (Te) means the greatest continuous exposure time interval recommended by the manufacturer of the sunlamp product.

Maximum timer interval means the greatest time interval setting on the timer of a sunlamp product.

Protective eyewear or protective goggles means any device designed to be worn by users of a sunlamp product to reduce exposure of the eyes to radiation emitted by the product.

Spectral irradiance (Eλ) means the irradiance resulting from radiation within a wavelength range divided by the wavelength range as the range becomes vanishingly small, expressed in units of watts per square centimeter per nanometer ($W/(cm^2/nm)$).

Spectral transmittance (Tλ) means the spectral irradiance transmitted through protective eyewear divided by the spectral irradiance incident on the protective eyewear.

Sunlamp product means any device designed to incorporate one or more ultraviolet lamps intended for irradiation of any part of the living human body, by ultraviolet radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning. This definition includes tanning beds and tanning booths.

Tanning course means a consecutive series of tanning exposures until a tan is developed, usually spanning a period of 3 to 4 weeks.

Timer means any device incorporated into a sunlamp product that terminates radiation emission after a preset time interval.

Ultraviolet lamp means any lamp that produces ultraviolet radiation in the wavelength interval of 200 to 400 nanometers in air and that is intended for use in any sunlamp product.

(c) *Performance requirements*—(1) *UVC (200–290 nm) irradiance.* The total irradiance emitted by a sunlamp product in the wavelength range between 200 and 290 nm (UVC) shall not exceed 0.03 W/m^2. UVC irradiance shall be measured at the shortest exposure distance recommended by the manufacturer, as required to be provided on the label of the sunlamp product by paragraph (d)(1)(ii) of this section. UVC irradiance shall be calculated using the following formula:

$$E = \sum_{200\,nm}^{290\,nm} E_\lambda \Delta_\lambda$$

Where:

E is the total irradiance over the wavelength range of interest
Eλ is the spectral irradiance in $W/(m^2\text{-nm})$
Δλ is the wavelength interval (nm).
The wavelength interval shall be 1 nm or less.

(2) *Timer system.* (i) Each sunlamp product shall incorporate a timer system with multiple timer settings adequate for the recommended exposure time intervals for different exposure positions and expected results of the products as specified in the label information required by paragraph (e) of this section.

(ii) The maximum timer interval may not exceed the manufacturer's recommended maximum exposure time

(Te) that is indicated on the label, as required by paragraph (d)(1)(iv) of this section. In addition, the maximum timer interval shall not result in a biologically-effective dose that exceeds 500 J/m², weighted with the erythema action spectrum provided in figure 103 of IEC 60335–2–27, Ed. 5.0, which is incorporated by reference. The manufacturer's recommended maximum exposure time (Te) shall be determined using the following formula:

$$Te = \frac{500\ ^{J}/_{m^2}}{\sum_{250\,nm}^{400\,nm} S_\lambda E_\lambda \Delta_\lambda}$$

Where:

Sλ is the erythema action spectrum in figure 103 of IEC 60335–2–27, Ed. 5.0
Eλ is the spectral irradiance in W/(m²-nm)
Δλ is the wavelength interval (nm).
The wavelength interval shall be 1 nm or less.

(iii) No timer interval may have an error greater than 10 percent of the maximum timer interval of the sunlamp product.

(iv) The timer may not automatically reset and cause radiation emission to resume for a period greater than the unused portion of the timer cycle, when emission from the sunlamp product has been prematurely terminated.

(3) *Control for termination of radiation emission.* Each sunlamp product shall incorporate a control on the product to enable the person being exposed to manually terminate radiation emission from the product at any time without disconnecting the electrical plug or removing the ultraviolet lamp. This control shall be easily accessible to the user and be readily identified by touch and sight.

(4) *Protective eyewear.* (i) Each sunlamp product shall be accompanied by the number of sets of protective eyewear that is equal to the maximum number of persons that the instructions provided under paragraph (e)(1)(ii) of this section recommend to be exposed simultaneously to radiation from such product.

(ii) The spectral transmittance to the eye of all protective eyewear intended to be used with the sunlamp product shall not exceed a value of 0.001 over the wavelength range of greater than 200 nm through 320 nm, shall not exceed a value of 0.01 over the wavelength range of greater than 320 nm through 400 nm, and shall not exceed a value of 0.05 over the wavelength range of greater than 400 nm through 550 nm. In order to ensure adequate visibility through the protective eyewear, the luminous transmittance shall not be less than 1.0 percent. Spectral transmittance and luminous transmittance must be measured in accordance with clause 32.102 of IEC 60335–2–27, Ed. 5.0, which is incorporated by reference.

(5) *Compatibility of lamps.* An ultraviolet lamp shall not be capable of insertion and operation in either the ''single-contact medium screw'' or the ''double-contact medium screw'' lampholders described in C81.10–1976, which is incorporated by reference.

(d) *Label requirements.* In addition to the labeling requirements in part 801 of this chapter and the certification and identification requirements of §§ 1010.2 and 1010.3 of this chapter, each sunlamp product and ultraviolet lamp is subject to the labeling requirements prescribed in this paragraph and paragraph (e) of this section.

(1) *Labels for sunlamp products.* Each sunlamp product shall have labels which contain:

(i) A warning statement with the following language and format:

''DANGER - Ultraviolet Radiation (UV)

UV can cause:

- **Skin Cancer**
- **Skin Burns**
- **Premature Skin Aging**
- **Eye Damage (both short- and long-term)**

Wear FDA-compliant protective eyewear to prevent eye damage, such as burns or cataracts.

Follow the recommended exposure schedule to avoid severe skin burns.

Talk to your doctor or pharmacist before tanning if you use medicines and/or cosmetics. Some of these products can make you more sensitive to skin and eye damage from UV.''

(ii) Exposure position(s) that may be expressed either in terms of a distance specified both in meters and in feet (or in inches) or through the use of markings or other means to indicate clearly the recommended exposure position.

(iii) Directions for achieving the recommended exposure position(s) and a warning that the use of other positions may result in overexposure.

(iv) The manufacturer's recommended exposure schedule, including maximum exposure times per session, and overall maximum exposure time, in minutes, and spacing of sequential exposures. This schedule, with the following exceptions, must be developed in accordance with Annex DD of IEC 60335–2–27, Ed. 5.0, which is incorporated by reference.:

(A) The maximum single dose (which corresponds to the maximum timer interval at 1040.20(c)(2)(ii)) is 500 J/m² (not 600 J/m² as stated in Annex DD).

(B) Information regarding the maximum number of exposures per year must be based on a maximum yearly dose of 15 kJ/m², weighted according to the erythema action spectrum shown in figure 103 of IEC 60335–2–27, Ed. 5.0.

(C) The exposure schedule must also include the following warning: ''Skin Type I individuals (always burns, never tans) should never use sunlamp products.'' The exposure schedule must also include the statement: ''Maximum sessions per week = 2.''

(D) *Example schedule.* For a sunlamp product whose maximum exposure time (Te) = 20 minutes, the following table provides an example of what the exposure schedule might look like where a single tanning course covers a 4-week period:

Manufacturer-Recommended Exposure Schedule							
Maximum exposure time must not exceed 20 minutes							
Session #							
1	2	3	4	5	6	7	8
Minutes (maximum) per session							
4	6	8	10	13	16	20	20
Minimum time between exposures = 48 hours Maximum sessions per week = 2 Maximum tanning courses per year = 6							
Skin Type I individuals (always burns, never tans) should never use sunlamp products							

(v) A statement indicating the time it may take before the expected results appear.

(vi) The designation of the ultraviolet lamp equivalency code range to be used in the sunlamp product as defined in Clause 22.111 and Annex CC of IEC 60335–2–27, Ed. 5.0, which is incorporated by reference.

(2) *Labels for ultraviolet lamps.* Each ultraviolet lamp shall have a label which contains:

(i) The warning: ''Sunlamp—DANGER—Ultraviolet radiation. Follow instructions.''

(ii) The UV lamp equivalency code as defined in Annex CC of IEC 60335–2–27, Ed. 5.0, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (i) of this section. In determining the ''UV code'' component of the UV lamp equivalency code, output must be measured in accordance with IEC 61228, Ed. 2.0 (iii) The model identification, if applicable.

(iv) The words ''Use ONLY in fixture equipped with a timer.''

(3) *Label specifications.* (i) The labels prescribed in paragraph (d)(1) of this section for sunlamp products shall 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 immediately before the use of the product. The labels shall be of sufficient durability to remain legible throughout the expected lifetime of the product. To be legible and readily accessible to view, the sunlamp product warning statement required by paragraph (d)(1)(i) of this section shall comply with the following:

(A) It shall appear on a prominent part or panel displayed 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;

(B) It shall be physically separate and visually distinct from the other required label information;

(C) It shall meet the following font size and font color requirements: The lettering in the word ''DANGER'' shall be at least 10 millimeters (height), at least double the height of the other words in the warning statement, in all capital letters, and in red or another font color that is legible and distinct from the other words in the warning statement. The lettering in the other words in the warning statement shall be at least 5 millimeters (height) and in lower case or title case.

(ii) The information prescribed in paragraph (d)(2) of this section for ultraviolet lamps shall be permanently affixed or inscribed on the lamp itself so as to be legible and readily accessible to view, as well as on the packaging of the lamp.

(iii) If the size, configuration, design, or function of the sunlamp product or ultraviolet lamp would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, the Director, Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health, on the Director's own initiative or upon written application by the manufacturer, may approve alternate means of providing such information or alternate wording for such label, as appropriate.

(iv) In lieu of permanently affixing or inscribing tags or labels on the ultraviolet lamp as required by §§ 1010.2(b) and 1010.3(a) of this chapter, the manufacturer of the ultraviolet lamp may permanently affix or inscribe such required tags or labels on the lamp packaging uniquely associated with the lamp, if the name of the manufacturer and month and year of manufacture are permanently affixed or inscribed on the exterior surface of the ultraviolet lamp so as to be legible and readily accessible to view.

(v) A label may contain statements or illustrations in addition to those required by this paragraph if the additional statements are not false or misleading in any particular, *e.g.,* if they do not diminish the impact of the required statements, and are not prohibited by this chapter.

(e) *Informational requirements—User information.* Each manufacturer of a sunlamp product or ultraviolet lamp shall provide or cause to be provided to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, adequate instructions for use to minimize the potential for injury to the user, including the following information:

(1) *Sunlamp Products.* The users' instructions for a sunlamp product shall contain:

(i) A reproduction of all the label information required by paragraph (d)(1) of this section prominently displayed at the beginning of the instructions.

(ii) A statement of the maximum number of people who may be exposed to the sunlamp product at the same time and a warning that only that number of protective eyewear has been provided.

(iii) Instructions for the proper operation of the sunlamp product including the function, use, and setting

of the timer and other controls, and the use of protective eyewear.

(iv) Instructions for obtaining repairs and recommended replacement components and accessories which are compatible with the sunlamp product, including compatible protective eyewear, ultraviolet lamps, timers, reflectors, and filters, which will, when installed and used as instructed, result in continued compliance with the standard.

(v) Manufacturers of sunlamp products shall provide as an integral part of any user instruction or operation manual that is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each sunlamp product: Adequate instructions for assembly, operation, and maintenance, including clear warnings concerning precautions to avoid possible exposure to ultraviolet radiation during assembly, testing, and maintenance, and a schedule of maintenance necessary to keep the sunlamp product in compliance with this section.

(2) *Ultraviolet lamps.* The users' instructions for an ultraviolet lamp not accompanying a sunlamp product shall contain:

(i) A reproduction of the label information required in paragraph (d)(2) of this section, prominently displayed at the beginning of the instructions.

(ii) A warning that the instructions accompanying the sunlamp product must always be followed to avoid or to minimize potential injury.

(3) *Promotional materials.* Manufacturers of sunlamp products shall provide or cause to be provided in all catalogs, specification sheets, and descriptive brochures intended for consumers in which sunlamp products are offered for sale, and on all consumer-directed Web pages on which sunlamp products are offered for sale, a legible reproduction (color optional) of the warning statement required by paragraph (d)(1)(i) of this section.

(f) *Test for determination of compliance.* Tests on which certification under § 1010.2 of this chapter is based shall account for all errors and statistical uncertainties in the process and, wherever applicable, for changes in radiation emission or degradation in radiation safety with age of the sunlamp product. Measurements for certification purposes shall be made under those operational conditions, lamp voltage, current, and position as recommended by the manufacturer. For these measurements, the measuring instrument shall be positioned at the recommended exposure position and so oriented as to result in the maximum detection of the radiation by the instrument. The performance requirements for the measuring instrument specified in IEC 60335–2–27, Ed. 5.0 Clause 32.101, which is incorporated by reference, shall apply.

(g) *Modification of certified sunlamp products.* The modification of a sunlamp product, previously certified under § 1010.2 of this chapter, constitutes manufacturing under the Federal Food, Drug, and Cosmetic Act if the modification affects any aspect of the product's performance or intended function(s) for which this section has an applicable requirement. The person who performs such modification shall recertify and re-identify the sunlamp product in accordance with the provisions of §§ 1010.2 and 1010.3 of this chapter.

(h) *Medical device classification regulation.* Sunlamp products and ultraviolet lamps intended for use in sunlamp products are subject to special controls and restrictions on sale, distribution, and use as set forth in § 878.4635 of this chapter.

(i) *Incorporation by reference.* The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Food and Drug Administration, Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available from the following sources. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) American National Standards Institute (ANSI), 1889 L St. NW., 11th Floor, Washington, DC 20036, *storemanager@ansi.org, www.ansi.org,* 202–293–8020.

(i) ANSI C81.10–1976, ''Specifications for Electric Lamp Bases and Holders—Screw-Shell Types,'' dated September 1976.

(ii) [Reserved]

(2) International Electrotechnical Commission (IEC), EC Central Office, 3 rue de Varembe, CH–1211 Geneva 20, Switzerland, *www.iec.ch,* call 41–22–919–02–11.

(i) IEC 60335–2–27, Ed. 5.0: 2009–12, ''Household and Similar Electrical Appliances—Safety—Part 2–27: Particular Requirements for Appliances for Skin Exposure to Ultraviolet and Infrared Radiation,'' dated December 2009.

(ii) IEC 61228, Ed. 2.0, ''Fluorescent Ultraviolet Lamps Used for Tanning—Measurement and Specification Method,'' dated January 2008.

Dated: December 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 655

[FHWA Docket No. FHWA–2015–0028]

National Standards for Traffic Control Devices; the Manual on Uniform Traffic Control Devices for Streets and Highways; Request for Comment

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Request for Comments (RFC).

SUMMARY: The Manual on Uniform Traffic Control Devices for Streets and Highways (MUTCD) is incorporated in our regulations, approved by FHWA, and recognized as the national standard for traffic control devices used on all streets, highways, bikeways, and private roads open to public travel. This document asks for responses to a series of questions regarding the future direction of the MUTCD. Specific topic areas include target audience/intended user, content and organization, process for introducing new traffic control devices, and frequency of MUTCD editions.

DATES: Comments must be received on or before February 18, 2016.

ADDRESSES: Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, or fax comments to (202) 493–2251. Alternatively, comments may be submitted to the Federal eRulemaking portal at *http://www.regulations.gov.* All comments must include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments