Inspection and Field Testing of Radiation-Emitting Electronic Products: Attachment C: Specific Instructions for Sunlamp Product Inspections and Tests

Background

A sunlamp product is an electronic product designed to use one or more ultraviolet lamp(s) and is intended for irradiation of any part of the living human body by ultraviolet radiation within a specified range of wavelengths to induce skin tanning. The ultraviolet lamps, subject to the performance standard, produce radiation within a prescribed range of wavelengths and are intended for use in sunlamp products.

Sunlamp products include portable home units, table top models, tanning beds and tanning booths. These units may incorporate different types of fluorescent lamps, reflector spot (RS) or High Intensity Discharge (HID) with different levels of energy output and radiation at different wavelengths.

Since sunlamp products are radiation-emitting electronic products as defined by Section 531 of Subchapter C-Electronic Product Radiation Control (EPRC) formerly the Radiation Control for Health and Safety Act (RCHSA) and medical devices as defined by Section 201(h)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA, the Act), they are regulated under both laws.

Under authority of Section 534 of the (EPRC), a performance standard for sunlamp products and ultraviolet lamps intended for use in these products was promulgated effective May 7, 1980 (21 CFR 1040.20). The standard was intended to reduce sunlamp related injuries by reducing unnecessary exposure and overexposure to sunlamp radiation by: (1) limiting shorter wavelength emissions that are not necessary and pose unreasonable risk, (2) providing for adequate warning label and user instructions containing safety information, and (3) requiring special lamp bases, protective eyewear, timers, and controls to help users limit the duration and amount of exposure.

This performance standard was promulgated when the common sunlamp product was a table-top, home portable unit incorporating one or two RS lamps having a large part of their radiation output in the wavelength range of 260 to 320 nanometers (UVB). In 1979-80, a new-wave of sunlamp products came onto the market. These products, commonly referred to as Tanning Booths, usually measured 3'x3'x7' and contained one or two fluorescent ultraviolet lamps in each corner. These products also had relatively high UVB output.

Around early 1983, another product in the shape of a bed and/or canopy entered the market with fluorescent lamps that emit radiation mainly in the 320-400 nanometer range (UVA), with usually less than 5% in-the UVB range. This type of product requires longer exposure times to achieve its intended purpose and the risk of chronic sunburn is reduced relative to the older type of products. Most manufacturers requested variance under 21 CFR 1010.4 to equip the products with timers which would allow exposure in excess of ten minutes. Since the products usually required 30 minutes to achieve their intended result, the variances were granted with two conditions: (1) the maximum timer interval shall not exceed the maximum recommended exposure time specified in the required product label, and (2) the UVB to UVA ratio shall not exceed .05 (no more than 5% UVB). The manufacturers are required to specify the variance number and effective date on the product).

Some of these products incorporate High Intensity Discharge (HID) lamps. These lamps are usually used for facial tanning, although some whole body exposure systems use such lamps exclusively. In most cases, however, these lamps are used in conjunction with ultraviolet fluorescent lamps. The HID lamps are much smaller than fluorescent lamps, (usually about 1/2" in diameter by 3" in length) and they usually incorporate an outer, clear, glass envelope.

On September 6, 1985, amendments to the performance standard were published and became effective in September 8, 1986. The purpose of the amendments is to accommodate new products employing design concepts significantly different from those for which the original standard was developed. Also, FDA experience in applying the original standard indicated that some requirements were either inappropriate for or not applicable to some products. The amendments are intended to establish a standard that is appropriate for the present technology of tanning and new sunlamp product designs. This revised program offers guidance for testing products against the original standard or revised standard, as appropriate.

Specific Instructions

Some electro-optics specialists, x-ray auditors and other radiological health specialists have been trained in general EPRC requirements and also may have specialized training in the sunlamp product performance standards. Only trained individuals should perform these inspections and field tests and may train additional field staff or accompany a medical device investigator to conduct joint EPRC/medical device inspections. If an EOS has training in both EPRC and QSIT inspections, a single EOS may conduct both portions of the inspection.

The District Offices have the authority (delegated under 21 CFR 5.37 and 5.89) to make declarations of noncompliance and/or defect for sunlamp products. The field also has the authority to approve sunlamp manufacturer corrective action plans under 21 CFR 1004 and to grant exemptions (from notification and product repair) in accordance with 21 CFR 1003.31. Consult CDRH for assistance in determining appropriate enforcement action or other support. A copy of any letter issued to a manufacturer must be sent to HFZ-240.

References

Sunlamp Products, Performance Standard – 21 CFR 1040.20.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1040.20 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1040.20)

Quality Control Guide for Sunlamp Products (/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM119279.pdf).
(Publication; FDA 84-8234)

Policy on Warning Label Required on Sunlamp Products (/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095333.pdf) (6/25/85)
Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products (/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095333.pdf) (8/21/86)

Policy on Lamp Compatibility (/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095325.pdf) (9/2/86).

Sunlamp Products Reporting Guide (/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081575.pdf), (dated September, 1995).

Refer to the sunlamp products main page (/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/ucm116447.htm) for additional information.

Sunlamp Product Codes

Translation of 2-Digit Code	Product Name	Product Code		CFR	Definition
Sunlamp Products (Certified)	Suntan Booth	79	LEJ	1040.20	
Sunlamp Products (Certified)	Suntan Bed, Sunlamp Products (Certified), Non-Medical	95	REF	1040.20	A bed or other platform that is designed to incorporate one or more ultraviolet lamps and intended for irradiation of any part of the human body, by ultraviolet radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning with no medical claims.
Sunlamp Products (Certified)	Suntan Lamp, Sunlamp Products (Certified), Non-Medical	95	REG	1040.20	A lamp that produces ultraviolet radiation in the wavelength range of 200 to 400 nanometers in air and that is intended for use in any sunlamp product or fixture with no medical claims.
Sunlamp Products (Certified)	Tabletop Sunlamp System (Certified), Non-Medical	95	REH	1040.20	A sunlamp system that sits on a table, primarily intended to tan the face by ultraviolet radiation with wavelengths in air between 200 and 400 nanometers with no medical claims.
Sunlamp Products (Certified)	Other	95	RZZ	Unk	Sunlamp product means any electronic product designed to incorporate one or more ultraviolet lamps and intended for irradiation of any part of the human body, by ultraviolet radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning.

Classification of Non-compliant Items

Performance Requirements			
1040.20(c)(1)	Fails to comply with the irradiance ratio limits for UVC over UVB cannot exceed 0.003	Minor	Class B
1040.20(c)(2)(i)	Fails to incorporate a timer system with multiple timer settings adequate for recommended exposure time intervals	Major	Class A
1040.20(c)(2)(ii)	Maximum timer interval(s) is more than 3 times greater than the manufacturer's recommended maximum exposure time(s) as indicated on label	Major	Class A
1040.20(c)(2)(ii)	Maximum timer interval(s) is 2 – 3 times greater than the manufacturer's recommended maximum exposure time(s) as indicated on label	Minor	Class B
1040.20(c)(2)(ii)	Maximum timer interval(s) is less than 2 times greater than the manufacturer's recommended maximum exposure time(s) as indicated on label	Concern	Class C
1040.20(c)(2)(iii)	Maximum timer interval error > 30 percent	Major	Class A
1040.20(c)(2)(iii)	Maximum timer interval error > 20 and < 30 percent	Minor	Class B
1040.20(c)(2)(iii)	Maximum timer interval error > 10 and < 20 percent	Concern	Class C
1040.20(c)(2)(iv)	Timer automatically resets and causes radiation to resume.	Major	Class A
1040.20(c)(3)	Fails to incorporate a control for termination of radiation emission (at minimum a timer system)	Major	Class A
1040.20(c)(4)(i)	Fails to have protective eyewear	Minor	Class B

1040.20(c)(4)(ii)	Spectral transmittance of the protective eyewear exceeds a value of 0.001 over the wavelength UVC and UVB(200nm to 320nm)	Minor	Class B
1040.20(c)(4)(ii)	Spectral transmittance of the protective eyewear exceeds a value of 0.01 over the wavelength UVA (>320nm to 400nm)	Minor	Class B
1040.20(c)(4)(ii)	Spectral transmittance (>400nm) of protective eyewear does not allow user to clearly see to reset the timer	Minor	Class B
1040.20(c)(5)	UV lamp capable of insertion and operation in either the “single-contact medium screw” or the “double-contact medium screw” lamp holders.	Major	Class A
Label Requirements for Sunlamp Products			
1040.20(d)(1)(i)	Fails to have warning statement “Danger UV radiation…”	Minor	Class B
1040.20(d)(1)(ii)	Fails to have recommended exposure position(s)	Minor	Class B
1040.20(d)(1)(iii)	Fails to have directions for recommended exposure position(s) and warning other positions may result in overexposure	Minor	Class B
1040.20(d)(1)(iv)	Fails to have recommended exposure schedule	Minor	Class B
1040.20(d)(1)(v)	Fails to have time before expected results statement	Concern	Class C
1040.20(d)(1)(vi)	Fails to have ultraviolet lamp designation	Minor	Class B
Label Requirements for Ultraviolet Lamps			
1040.20(d)(2)(i)	Fails to have “Sunlamp-DANGER-Ultraviolet radiation. Follow Instructions”	Minor	Class B
1040.20(d)(2)(ii)	Fails to have model identification	Minor	Class B
1040.20(d)(2)(iii)	Fails to have “Use ONLY in fixture equipped with timer”	Minor	Class B
Label Specifications for Sunlamp Products and Ultraviolet Lamps			
1040.20(d)(3)(i)	Fails to be permanently affixed or inscribed on the exterior surface of sunlamp product when fully assembled for use so as to be legible and readily accessible to view by person being exposed immediately before use of product	Minor	Class B
1040.20(d)(3)(ii)	Fails to be permanently affixed or inscribed on the ultraviolet lamp so as to be legible or readily accessible to view	Minor	Class B
1040.20(d)(3)(iv)	Fails to have identification and certification labels on shelf package of ultraviolet lamps and coded mfr name and date of mfr on ultraviolet lamp	Minor	Class B
1040.20(d)(3)(v)	Labels contain statements or illustrations that are false or misleading, diminish the impact of the required statements, or are prohibited by this chapter.	Major	Class A
Instructions to be provided to users of Sunlamp Products			
1040.20(e)	Inadequate instructions for use to avoid or minimize potential injury provided to purchaser	Minor	Class B
1040.20(e)(1)(i)	Failed to have reproduction of “Danger Ultraviolet Radiation warning statement…”	Minor	Class B
1040.20(e)(1)(ii)	Failed to have a statement of the maximum number of users and warning that only that number of protective eyewear was provided	Concern	Class C
1040.20(e)(1)(iii)	Failed to have instructions on the proper operations of the product including function, use, and setting of the timer and other controls , and use of the protective eyewear	Minor	Class B
1040.20(e)	Failed to have instructions determining the correct exposure time and schedule for persons according to skin	Minor	Class B

(1)(iv)	type.		
1040.20(e)(1)(v)	Failed to have instructions for obtaining repairs and recommended replacement components and accessories which are compatible with the product, including compatible protective eyewear, ultraviolet lamps, timers, reflectors, and filters, if installed or used as instructed would result in continued compliance with the standard.	Minor	Class B
1040.20(e)(2)(i)	User instructions for ultraviolet lamps not sold with sunlamp products failed to have a reproduction of the “Danger Ultraviolet Radiations…warning statement and the “Sunlamp-DANGER Ultraviolet radiation. Follow Instructions” and “Use ONLY in a fixture equipped with a timer” label	Minor	Class B
1040.20(e)(2)(ii)	User instructions for ultraviolet lamps not sold with sunlamp products failed to have a warning that instructions should be followed to avoid or minimize potential injury	Minor	Class B
1040.20(e)(2)(iii)	User instructions for ultraviolet lamps not sold with sunlamp products failed to have a clear identification by brand and model designation of all lamps models for which replacement lamps are promoted	Minor	Class B
Tests for Determination of Compliance			
1040.20(f)	Fail to account for all errors and statistical uncertainties in the process for changes in radiation emission or degradation in radiation safety with age of the product.	Minor	Class B
1040.20(f)	Fail to make measurements for certification under operational conditions as recommended by the manufacturer.	Minor	Class B
1040.20(f)	Fail to position measuring instrument at recommended exposure position and oriented to result in maximum detection of the radiation	Minor	Class B

Sample Sunlamp Product Inspection and Field Test Checklist

INSPECTIONAL FIELD TEST CHECKLIST REPORT FOR SUNLAMP PRODUCTS MANUFACTURED AFTER SEPTEMBER 8, 1986

(Including Pertinent Parts of the Regulation)

FACILITY NAME:

PERSON INTERVIEWED:

ADDRESS:

TELEPHONE NUMBER

FIELD TEST DATE

WARNING LABEL [21 CFR 1040.20(d)(1)]

Accessible To View: Yes / No Legible From One Meter: Yes / No Exposure Position: Yes / No "DANGER" Statement:: Yes / No

If "NO" to any of the above,
Explain:_____

Exposure Schedule times: Minimum ____min. / Maximum ____min. Warning Label Location:_____

List All Lamp Types Designated On Unit Labeling:_____

CERTIFICATION LABEL [21 CFR 1040.20(d) & 21 CFR 1010.2]

Adequate Certification: Yes / No Written In English: Yes / No Legible: Yes / No

If "NO" to any of the above,
Explain:_____

IDENTIFICATION LABEL [21 CFR 1040.20(d) & 21 CFR 1010.3] (AS APPEARS ON LABEL)

Name & Address of Manufacturer:_____

Model #:_____ Serial #:_____ Date of Manufacture:_____

PROTECTIVE EYEWEAR [21 CFR 1040.20(C) (4)]

Maximum Number of Users for Sunlamp Product:_____

Number of pairs:_____ Model Type:_____
Manufacture:_____

Number of pairs:_____ Model Type:_____
Manufacture:_____

LAMPS IN UNIT [21 CFR 1040.20(d) (1) & (d) (2)] & LAMP COMPATIBLITY [21 CFR 1040.20 (e) 2 (iii)]

Total Number of Lamps in Unit:_____ Lamp Compatibility Information : YES / NO / N/A

Lamp Model Designation:_____ Number of Lamps: _____
Manufacture:_____

Lamp Model Designation:_____ Number of Lamps: _____
Manufacture:_____

Facilities Lamp Supplier(s) (name, address, fax & phone #):_____

TIMER [21 CFR 1040.20 (C)(2)]

Type of Timer: Digital / Electro-mechanical / Spring Wound / Token / Other:_____

Timer Capabilities:_____(Minimum Time) _____(Maximum Time) Timer Interval (i.e. 1min increments): _____

Timer Interval Compatible with Exposure Schedule: YES / NO, If "NO",
Explain:_____

Timer Manufacturer Name and Address:_____

Timer Accuracy: 10%: _____min _____sec, 50%: _____min _____sec, 100%:_____min _____sec

(Note: Record Timer Accuracy in minutes and seconds for 10%, 50% and 100% of Maximum Timer Capability for the Sunlamp Product. Remote timers are acceptable provided all other requirements of (C)(2)/(3) are maintained.)

TERMINATION CONTROL [21 CFR 1040.20 (C)(3)]

Presence: YES / NO Description: Toggle / Push Pull / Push Button / Other:_____

How is exposure re-initiated:_____

USER INSTRUCTIONS [21 CFR 1040.20 (e) (1)] (i.e. owner manual / operator manual)

Provided by the Manufacturer: YES /NO, Available to Patrons: YES / NO, Contains Instructions To Determine Exposure Schedule and Skin Types: YES / NO, Contains Reproduction of "WARNING LABEL" : YES / NO, Contains Instructions for Obtaining Replacement

Parts and Repairs: YES / NO, If "NO" to any, Explain:_____

_____
INSPECTING DISTRICT

_____
NAME OF PERSON AND TITLE

INSPECTIONAL CHECKLIST REPORT
FOR SUNLAMP PRODUCTS MANUFACTURED PRIOR TO SEPTEMBER 8, 1986
(Including Pertinent Parts of the Regulation)

Facility Name:

Person Interviewed:

Address:

Telephone:

Field Test Date:

Mfr. Name:

Mfr. Address:

Home District_____ CFN/FEI_____Product Type:_____

Model_____Serial Number Date_____ Manufactured _____ / _____ / _____

Lamps: UV-A_____UV-B _____HID _____Properly labeled _____Mfr/Model:_____

Max Timer Setting _____Gradations_____Consistent w/exposure schedule:_____

Timer Exceed Max. Recom. Exp._____Accuracy @ 10%_____ 50%_____ 100%_____

Type of Timer_____ (e.g. Token) Mfr. of Timer_____How can user terminate exposure? _____

How is exposure re-initiated? _____ Eyewear_____Sufficient #_____

Labeling visible w/eyewear ____ Eyewear Mfr. and Model_____

Certification Label: _____ (Va_____)Permanently affixed_____ Viewable_____

Location_____ Properly Worded____ Mfr. I.D. Label_____ Viewable_____

Full Name/Address_____ Date Mfrd._____ Place Mfrd._____

Warning Label: Readily Viewable_____ Location_____ Danger Statement _____

Lamp Type_____ Min. exposure distance_____ How measured _____Warning: Min. exposure distance_____

Warning: Protective Eyewear _____ Warning: Max. exposure time_____ Exposure Schedule _____

Time before results can be expected_____ Any misleading statements? _____

User's Instructions: Provided by the Mfr. _____ Available to patrons _____

Contains copy of warning label_____ Instructions for replacement parts _____ Statement of # of people/eyewear _____

Equipment Recommendations: User position indicated _____ Timer error less than 10% _____ Temperature Control _____

Electrical Safety_____ Mechanical Safety_____ Protection from Lamps_____ Access and Support _____

_____
Name and Title

_____
Inspecting District

More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)