FDA Background Materials

Prepared for the

October 25-26 2016

Technical Electronic Product Radiation Safety Standards Committee

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1) TEPRSSC: Scope and History

Introduction

The Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) was established by the Radiation Control for Health and Safety Act of 1968 (*see* section 534 of the Federal Food, Drug and Cosmetic Act (the "FD&C Act" or the "Act"), 21 U.S.C. § 360kk): "The Secretary shall establish a Technical Electronic Product Radiation Safety Standards Committee…which he shall consult before prescribing any standard under this section." Here "Standard" refers to performance standards for electronic products to control the emission of electronic product radiation. [1]

The TEPRSSC Charter states that the Committee provides advice and consultation to the Commissioner of Food and Drugs on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products, and may recommend electronic product radiation safety standards to the Commissioner for consideration. [2]

TEPRSSC may also make recommendations on any other matter it deems necessary or appropriate in fulfilling the purposes of the Act (21 CFR 14.122(a)(3)). [3]

Electronic products and medical devices

An Electronic Product ("product") is (21 CFR 1000.3(j)):

> (1) Any manufactured or assembled product which, when in operation:
>
> (i) Contains or acts as part of an electronic circuit and
>
> (ii) Emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or
>
> (2) Any manufactured or assembled article that is intended for use as a component, part, or accessory of a product described in paragraph (j)(1) of this section and which, when in operation, emits (or in the absence of effective shielding or other controls would emit) such radiation. [4]

Electronic product radiation is (21 CFR 1000.3(k)):

> (1) Any ionizing or nonionizing electromagnetic or particulate radiation,
>
> or

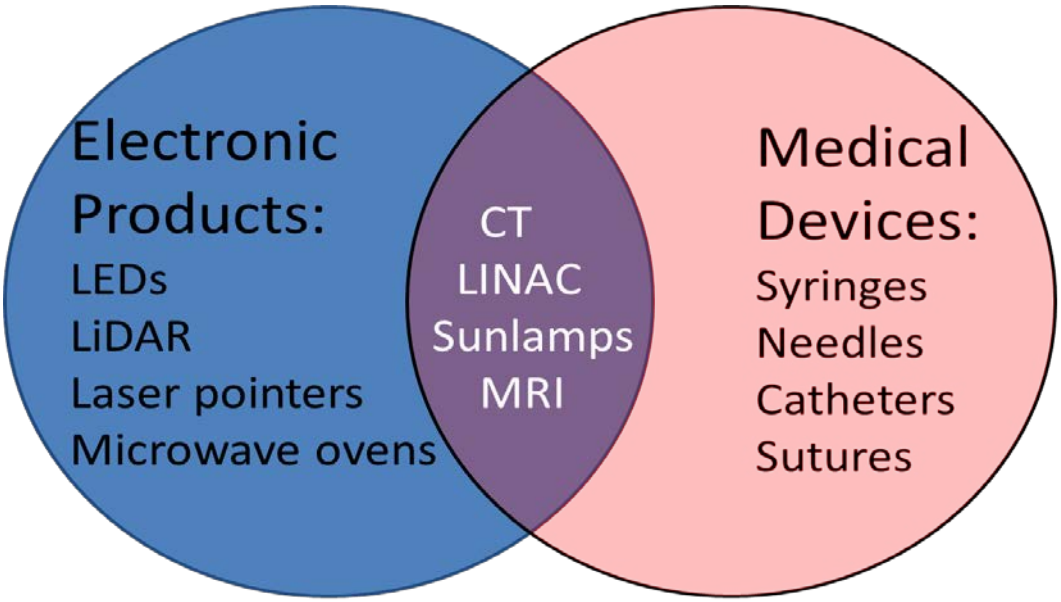
(2) Any sonic, infrasonic, or ultrasonic wave that is emitted from an electronic product as the result of the operation of an electronic circuit in such product. (4)("EPRC" is electronic product radiation control)

A Medical Device ("device") is:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is –
>
> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

(Section 201(h) of the FD&C Act, 21 U.S.C. § 321(h)) [5]

Some, but not all, medical devices are also electronic products, and are regulated as both devices and products:



With regard to medical devices that are also electronic products, TEPRSSC will only consider aspects related to control of the emission of electronic product radiation.

Recent TEPRSSC History [6]

TEPRSSC met annually from 1999-2003. Topics included the following:

1999: CT, sunlamps, security screening systems

2000: Lasers, sunlamps, security screening systems, CT

2001: CT, digital radiography, cellphones

2002: CT, sunlamps, security screening systems

2003: Six amendments to the standard for sunlamp products; amendments to the fluoroscopy standard, with a brief discussion of the possibility of using IEC standards instead of FDA performance standards; emerging issues in ionizing radiation security systems [7]

Relevant FDA activity since 2003

2005: Fluoroscopy amendments Final Rule

2007: Laser Notice No. 50 (IEC conformance)

2008: Ultrasound guidance

2013: Proposed laser amendments

2015: Draft MRI guidance

2015: Proposed sunlamp amendments

Non-regulatory efforts:

2010: Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging

2010: CT Dose Check

2012: Public Workshop: Device Improvements for Pediatric X-ray Imaging

Ongoing work with industry and national and international organizations, including professional societies and standards development organizations [8]

Agenda items for the 2016 TEPRSSC meeting

Day one: Electronic products that are not medical devices:

Radiofrequency Radiation Products

- Microwave Ovens
- Wireless Power Transfer

Laser Products

- Amendments to the Laser Rule
- LIDAR
- Remotely Controlled Mobile Systems
- Laser pointers
- Lamps for general illumination and LIPs
- Infrared Applications

Sunlamp Products

Non-Coherent Light Sources

Day two: EPRC-related issues associated with electronic products that are medical devices:

Radiation Therapy

Computed Tomography (CT)

Radiography & Fluoroscopy

Diagnostic and Therapeutic Ultrasound

IEC Standards vs. Performance Standards for Medical Devices

References

1. 21 U.S.C. § 360kk: https://www.gpo.gov/fdsys/search/pagedetails.action?collectionCode=USCODE&browsePath=Title+21%2FChapter+9%2FSubchapter+V%2FPart+C%2FSec.+360kk&granuleId=USCODE-2002-title21-chap9-subchapV-partC-sec360kk&packageId=USCODE-2002-title21&collapse=true&fromBrowse=true

2. TEPRSSC Charter (2014): http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/ucm124730.htm

3. 21 CFR 14.122: https://www.gpo.gov/fdsys/granule/CFR-2012-title21-vol1/CFR-2012-title21-vol1-sec14-122/content-detail.html

4. 21 CFR 1000.3: http://www.ecfr.gov/cgi-bin/text-idx?SID=70e16a9916743ac08a6356cb4d497680&mc=true&node=se21.8.1000_13&rgn=div8

5. 21 U.S.C. § 321: https://www.gpo.gov/fdsys/granule/USCODE-2010-title21/USCODE-2010-title21-chap9-subchapII-sec321/content-detail.html

6. Past Meeting Materials for Technical Electronic Product Radiation Safety Standards Advisory Committee. http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/ucm125347.htm

7. Brief Summary of the Technical Electronic Products Radiations Safety Standards Committee Meeting – October 1, 2003. http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/ucm125380.htm

8. The FDA and the Bonn Call for Action: Update on the Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging. http://www.fda.gov/downloads/radiation-emittingproducts/radiationsafety/radiationdosereduction/ucm439602.pdf

Summary of the Electronic Product Radiation Control Provisions of the Federal Food, Drug and Cosmetic Act

The Radiation Control apply to any "electronic product" which is defined (21 CFR 1000.3(j)) as:

any manufactured or assembled product (or component, part, or accessory of such product) which, when in operation,
(i) contains or acts as part of an electronic circuit and

(ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation.

"Electronic product radiation" is defined (21 CFR 1000.3(k)) as:

(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or
(B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

Many electronic products are also “medical devices”; many are not.
A medical device is defined (Section 201(h) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(h)) as follows:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
(3) intended to affect the structure or any function of the body of man or other animals, and
which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Examples of electronic products:

Medical devices: diagnostic x-ray or ultrasound imaging devices, microwave or ultrasound diathermy devices, microwave blood warmers or sterilizers, laser coagulators, ultrasound phacoemulsifiers, x-ray or electron accelerators, sunlamps, ultraviolet dental curing devices;

Not medical devices: microwave ovens, televisions receivers and monitors (video displays), entertainment lasers, industrial x-ray systems, cordless and cellular telephones, industrial RF sealers of plastics and laminates, laser CD players.

SUMMARY OF PERFORMANCE STANDARDS

(Please Consult 21 CFR 1000-1050 for full text)

21 CFR 1020.10. Television Receivers

applies to receivers and monitors that receive and convert a signal to display a "television picture"

limits radiation at 5 cm from the surface to 0.5 mR/hr during conditions of maximized user and service controls and a single worst-case component fault

21 CFR 1020.20. Cold-cathode Discharge Tubes

limits radiation at 30 cm to 10 mR/hr

requires user precautions labeling

21 CFR 1020.30. Diagnostic X-Ray Systems and their Major Components

applies to tube housings, generators and controls, film changers; fluoroscopic assemblies; air kerma meters; spot film and image intensifiers; cephalometric devices; image receptor support devices for mammographic systems; diagnostic systems; CT systems (in part)

limits leakage at 1 meter from the source to 100 mR in 1 hr and at 5 cm from any other components to 2 mR in 1 hr

specifies beam limitations and beam quality criteria; user and assembler instructions and technical information

21 CFR 1020.31. Radiographic Equipment

requires control and indication of technique factors; timer termination conditions; technique factor accuracy and reproducibility specifications; indication and limits on field size and alignment, etc.

limits transmission through mammographic image support system at 5 cm to 0.1 mR for each tube activation

21 CFR 1020.32. Fluoroscopic Equipment

requires primary protective barrier; field limitation; continuous pressure control; source to skin distance; timer; air kerma/air kerma rate display; limits entrance exposure rates to 5 R/min (or 10 R/min with automatic exposure rate control)

requires last-image-hold functionality to permit viewing a still image without continuous radiation

prescribes accurate alignment of x-ray field with image receptor

requires display and alerts of radiation time and display air kerma rate and cumulative air kerma to the operator. Specifies minimum accuracy of air kerma display

limits the minimum possible distance between the x-ray tube and the patient's skin to 38, 30, 20, 19, or 10 cm depending on the device's design and intended use

21 CFR 1020.33. Computed Tomography (CT) Equipment

specifies user information on dose, imaging performance and quality assurance

requires indication prior to initiation of scan, timer control to terminate or shutter the beam, indication of plane and alignment; beam on and shutter status indicators

21 CFR 1020.40. Cabinet X-Ray Systems

applies to systems with x-ray tube installed in an enclosure, including carry-on baggage inspection systems

limits radiation at 5 cm to 0.5 mR/hr under maximized operating conditions and door positions; restricts human access to the primary beam

requires 2 interlocks on each door with 1 resulting in physical disconnection of energy to the generator; key control; 2 independent x-ray on indicators; warning indicators and labels; user instructions, etc.

21 CFR 1030.10. Microwave Ovens

applies to ovens for heating and cooking food (household or commercial; not industrial food processing)

limits radiation at 5 cm to 1 mW per sq cm prior to purchase and 5 mW per sq cm throughout useful life under conditions of allowable door positions and primary interlock failure, or with conducting wire

limits access by human body to energy-containing space and to 1 of 2 required interlocks; at least 1 interlock must be "monitored" to disable the source

requires user caution label and user and service manuals

21 CFR 1040.10. Lasers and Laser Systems

applies to lasers, products containing lasers, and products intended to contain lasers

specifies classification and user logotype with precautions based on radiation accessible during use; limits radiation from viewing optics, ports and displays to less than Class I; specifies interlocks/labels based on radiation accessible during maintenance and service

requires, based on increasing hazard class, radiation indicators and safety: aperture label, beam attenuator, emission indicator (some with time delay), remote door interlock, key control, scanning safeguards, etc.

requires user, maintenance and service manuals

21 CFR 1040.11. Specific Laser Products

requires indication of power levels on medical lasers with +/- 20% accuracy

limits radiation to less than Class IIIa for surveying, leveling and alignment lasers

limits radiation to less than Class IIIa for demonstration lasers, including display or entertainment (NOTE: Variances, with extensive human access limitations, are often granted for laser light shows.)

21 CFR 1040.20. Sunlamps and Sunlamp Products

applies to products intended to produce skin tanning

limits levels of UV-C radiation and ratio of UV-A/ UV-B; requires specification of compatible lamps

requires maximum exposure time based on ultraviolet levels, timers with +/- 10% accuracy, protective eyewear, and user labeling and instructions

21 CFR 1040.30. High-intensity Mercury Vapor Discharge Lamps

requires self-extinguishing lamps to cease operating after breakage or removal of 3 sq. cm of the outer envelope

specifies lamp packaging and advertisement information

21 CFR 1050.10. Ultrasonic Therapy Products

applies to applicators or generators operating above 16 kHz for physical therapy

provides indication of radiation parameters: average and temporal peak power and/or intensity; pulse duration, pulse repetition rate; effective radiating area; beam nonuniformity and spatial distributions, etc.

requires power accuracy of +/- 20% and timer accuracy +/- 10%

SUMMARY OF REPORTING REQUIREMENTS

(Consult 21 CFR 1000-1050 for full text)

21 CFR 1010.4, 1010.5. Variances; Exemptions

manufacturers may request variances (i.e., an individual standard) for alternate, or equivalent, safety

manufacturers may request exemption from a performance standard for reason of national security, investigations, etc.

21 CFR 1002.20. Accidental Radiation Occurrences

documents any actual or possible unexpected exposure during manufacturing, testing or use of ANY electronic product

reports are due immediately after the event is known (MDR/NDFC may be substituted, if applicable)

21 CFR 1002.10, 11, 12. Product Reports (also Supplements, Abbreviated)

applies to products listed in Table 1 of 1002.1 (most are subject to performance standards), unless excluded by 1002.1 or 1002.50

documents information on manner of conformity to standards, labeling, test instrumentation, test procedures, quality control, etc.; submitted prior to family of products being introduced into commerce

abbreviated reports were added in Oct 1995 to reduce burdens

21 CFR 1002.13. Annual Reports

applies to products as listed in Table 1

documents results of testing and user safety concerns; annually or quarterly updates contain model listings

21 CFR 1003.20. Notice of Defect or Noncompliance

applies to **ALL** radiation-emitting electronic products

documents safety concerns, corrective actions, and information to users for safe use

SUMMARY OF OTHER RADIATION CONTROL REGULATIONS

(Consult 21 CFR 1000-1050 for full text)

21 CFR 1003.2. Defect in an Electronic Product

applies to products not subject to performance standards and to products subject to standards if the standard does not address the specific safety issue

exists, for products that USE radiation to accomplish the purpose of the product and emissions are intended, when radiation

(1) fails to meet design specifications, or

(2) is unnecessary and creates a risk of injury, or

(3) fails to accomplish its intended purpose

exists, for products that DO NOT USE radiation to accomplish the purpose and do not intend to emit radiation, when radiation

(1) is emitted that creates a risk of injury, or

(2) fails to meet its design specifications

21 CFR 1003.10/.11. Determination of Noncompliance or Defect

FDA or manufacturer informs the other of safety concern based on product testing, inspection, research, or review of reports or other data

manufacturer notifies purchasers, dealers and distributors of the hazard and appropriate use until corrected (per 1003.21)

21 CFR 1003.30/.31. Exemption from Notification

based on data to show there is no significant risk of injury as a result of the defect or failure to comply

granted by FDA in response to written request from the manufacturer

21 CFR 1004.1/.2/.3. Repurchase, Repair, and Replacement

correction of noncompliance or defect which is neither successfully refuted nor granted an exemption

plan, including (draft) notification to users, documented by the responsible firm and approved by FDA (usually prior to implementation); may include one or more of the options to repair, replace or refund as needed

21 CFR 1005.3/.10. Importation Requirements

Form FDA 2877 is filed by importer for entry (19 CFR 12.90)
FDA samples and tests products to verify compliance if necessary

products failing to meet applicable standards are refused entry by U.S. Customs

21 CFR 1005.21 / .22 / .23 / .24 / .25. Bringing Imported Products into Compliance

under a U.S. Customs term bond, importer submits written application (usually Form FDA 766) for approval by FDA

FDA supervises activities and the importer pays fees for such supervision

21 CFR 1010.2/.3. Certification and Identification Labels

label(s) on each product subject to a standard identifying the name and address of the manufacturer and date of manufacture

label on each product subject to a standard of the manufacturer's statement that the product complies with DHHS radiation standards or similar language

SUMMARY OF COMPLIANCE ACTIONS FOR RADIATION CONTROL ACT VIOLATIONS

(Consult 21 U.S.C. 360, Subchapter C, and 21 CFR 1000-1050 for full text)

A. FDA Administrative Actions

Recall Products (corrective actions are approved and Substantiated)

Disapprove Quality Control and Testing Program (i.e., embargo products)

Import Alert, Automatic Detention and Refusal (with U.S. Customs Service)

B. Actions through U.S. District Courts

Injunction from shipping in interstate commerce or to require reporting and certification requirements

Civil (money) penalties for failure to report, failure to certify, failur

2) RF Radiation Products

a) Microwave Ovens

What is the product?

Microwave ovens were patented in 1946. The first commercial model for home use became available in 1967. By the middle of the 1970s millions of microwave ovens were being sold to consumers each year.

The necessity for a standard to protect the public health and safety became apparent after surveys by State health departments and studies by the Bureau of Radiological Health revealed that these ovens could emit excessive levels of microwave radiation. The federal performance standard for microwave ovens was based on a variety of inputs. The sources used included evaluation of the available information on the health hazards of exposure to microwave radiation, consultations with manufacturers of microwave ovens, and reviews by State health departments and other agencies.

On October 6, 1970, FDA published a radiation safety performance standard to address the potential emission of microwave radiation from microwave ovens. The microwave oven performance standard applies only to microwave ovens manufactured for use in homes, restaurants, food vending or service establishments, on interstate carriers, and in similar locations.

Microwave Oven Performance Standard

The Federal radiation safety microwave oven performance standard (21 CFR § 1030.10) applies to microwave ovens manufactured after October 6, 1971. The term “microwave oven” means (21 CFR § 1030.10(b)(1)) a device designed to heat, cook, or dry food through the application of electromagnetic energy at frequencies assigned by the Federal Communications Commission in the normal industrial, scientific, and medical (ISM) application heating bands ranging from 890 megahertz to 6,000 megahertz. As defined in this standard, "microwave ovens" are limited to those manufactured for use in homes, restaurants, food vending, or service establishments, on interstate carriers, and in similar facilities. The performance standard does not apply to industrial use of microwave heating or cooking. The performance standard establishes certain requirements, including:

- A limit for microwave power density 5 cm from the external surface of the oven. This limit allows for an increase in the allowable microwave power density at 5 cm from the external surface from 1 mW/cm^2 prior to acquisition by a purchaser to a maximum of 5 mW/cm^2 after purchase. A variety of abnormal operating conditions are specified that require compliance with the power density limit (e.g., operation with the door fixed in any position that allows generation of microwaves).
- How FDA will test for conformance of microwave ovens to the power density limit set in the performance standard. The majority of microwave ovens can be satisfactorily tested according to the procedures established in the standard.
- Safety interlocks and a means to monitor the correct functioning of those interlocks.
- Warnings, precaution labels, user instructions, and service instructions.

FDA Concerns

Wire Insertion Test Failure

Persons may be burned if they are near an operating microwave oven that has been compromised by insertion of an object that acts as an antenna. This hazard exists only if it is possible to insert a wire from the outside of the oven into interior microwave-energy-containing spaces.

21 CFR § 1030.10(2)(iv) *Safety interlocks* states: Microwave radiation emission in excess of the limits specified in paragraph (c)(1) of this section shall not be caused by insertion of an insulated wire through any opening in the external surfaces of a fully assembled oven into the cavity, waveguide, or other microwave-energy-containing spaces while the door is closed, provided the wire, when inserted, could consist of two straight segments forming an obtuse angle of not less than 170 degrees.

At the time the performance standard was being developed some ovens on the market included an uncovered mesh as microwave shielding instead of a glass- or plastic-covered mesh shield. Insertion of a wire or other object was trivially easy and could result in a significant hazard due to greatly exceeding the power density limit. From *Documentation Report for the Performance Standard for Microwave Ovens*, December 1970, p 14, "It has also been observed that some microwave oven designs permit the insertion of rods, pipe cleaners, pencils, etc., into the oven cavity through perforations in the door or wall of the cavity. These objects have been shown to act as antennae and thereby transmit excessive radiation to the outside. It has been concluded further that the standard should include performance language which protect against this type of situation."

A wire insertion test remains part of the FDA laboratory test procedure for determining compliance of microwave ovens with the performance standard. The risk of a currently-marketed microwave oven design suffering from the design flaw of an uncovered mesh is extremely low. However, our laboratory tests have identified ovens where a relatively straight wire can be inserted into a microwave cavity. For example, an oven might allow the insertion of a wire from the corner of the door or through an air vent into a microwave-energy-containing space.

FDA's laboratory test can determine if a wire insertion is possible, but at present no emission measurement is made to verify if the power density limit will be exceeded due to the inserted wire. This lack of a power density measurement is due to concern regarding the potential microwave safety hazard to the laboratory staff, because the inserted wire will act as an antenna that bypasses a microwave oven's shielding. We have found that the lack of an emission measurement is an impediment to requiring a corrective action when a microwave oven fails FDA's laboratory test for wire insertion.

FDA's intended actions

To remedy this gap in our enforcement and to verify there is truly a failure to comply, we intend to make some measurements of external power density resulting from wire insertions. We intend to determine if wire insertion always causes a significant failure to comply with the power density limit or, if this is not the case, to develop a test procedure that is not unduly hazardous.

Microwave Ovens Operate with an Open Door

21 CFR § 1030.10(2)(vi) *Safety interlocks* states: A means of monitoring one or both of the required safety interlocks shall be provided which shall cause the oven to become inoperable and remain so until repaired if

the required safety interlock(s) should fail to perform required functions as specified in this section. Interlock failures shall not disrupt the monitoring function.

[Note: The safety interlocks referenced are the two (primary and secondary) interlocks required to shut off microwave generation when the oven door is open.]

FDA has received an increased number of consumer complaints regarding microwave ovens in the last two years. In 2015-2016 we received approximately 40 microwave oven consumer complaints compared to only 10 consumer complaints in 2014. Most consumer complaints are related to microwave ovens that operate when the door is open. In these cases usually the light, fan, and turntable continue to operate even when the door is open. Consumers report this type of microwave oven failure because it appears the microwave oven continues to generate microwave radiation with the door is open. It is possible their concerns are not unfounded and that, in some cases, microwave generation continues with the door open. Serious injury could result if a microwave oven's interlocks and safety circuit fail and allow microwave generation with the door open.

A microwave oven can have a door sensing switch failure or an interlock fail that results in other functions continuing without causing a failure of the second monitored interlock. In these cases the remaining functioning interlock assures that power to the microwave generating components of the oven (traditionally, a magnetron) is disconnected when the door is open. However, we cannot be certain that an interlock and the monitoring circuit remain operational in all cases. To verify if microwave radiation is or is not being generated, a microwave power density measurement of the faulty oven is necessary. The consumer cannot distinguish between a microwave oven with an open door that is emitting microwaves and one that has functioning lights, fan and turntable, but a disconnected microwave generating component.

FDA needs access to the faulty ovens to determine if there are ovens that have failures leading to open door microwave emission. Unfortunately this has usually not been possible because the faulty oven is either no longer functional at the time of the complaint or because the oven was disposed of, either by the consumer or by a service technician. Many of these microwave oven complaints are sent to the Consumer Product Safety Commission (CPSC) and then forwarded by CPSC to FDA.

Even if none of the microwave ovens in these complaints can generate microwaves with the door open, the appearance that microwave generation with the door open is possible causes the consumer unnecessary anxiety, fear, and stress.

FDA's intended actions

We will continue to gather relevant information. We will also arrange microwave power density measurements as follow ups to these complaints when possible.

Additionally we are considering altering the performance standard, issuing guidance, or working to alter consensus standards to address this issue. For example, we could add a performance requirement to unambiguously display an indication when the oven can still generate microwaves or we could require that all functions associated with microwave production are also shut off by the same monitored interlock that disables power used to generate microwaves.

Questions for TEPRSSC

1. What other actions should FDA pursue in order to address wire insertion test failure? What are your recommendations regarding to our intended actions?

2. What changes, if any, do you recommend making to the microwave oven performance standard? What changes should we encourage in consensus standards? Would altering voluntary consensus standards (e.g., IEC standards) be preferable to amending the microwave oven performance standard? Alternatively or additionally, what sort of guidance, if any, should FDA develop?

References

1. A history of the microwave oven; Davis, Amanda; 2 May 2016; published by The Institute, "The IEEE news source"; http://theinstitute.ieee.org/tech-history/technology-history/a-history-of-the-microwave-oven

2. Elder, R.L. and Gundaker, W.E., 1971. Microwave ovens and their public health significance. *Journal of Milk and Food Technology (JMFT)*, *34*(9), pp.444-446.

3. Title 21 Code of Federal Regulations Part 1030 - Performance Standard for Microwave and Radio Frequency Emitting Products § 1030.10 Microwave ovens http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1030.10

b) Wireless Power Transfer

Wireless Power Transfer

What is the product?

The transition from physical connectors and toward wireless connectivity in portable electronic products has been steady over the past 20 years, with most of these products now having some form of wireless communications via some form of either Bluetooth [1] or WiFi [2]. However, the power connector has remained the traditional means of transferring power. Wireless Power Transfer (WPT) has the potential to eliminate this connector and eliminate both cords and the potential for connector failure from electronic products. The clinical environment also presents an important opportunity for the adoption of wireless power transfer. Hermetically sealed electronic products could be more easily sterilized and more hygienic than current products that have connectors. Eliminating cords or wires in a hospital environment could also enhance patient comfort and safety by presenting fewer tripping hazards.

The US Department of Energy (DOE), the Federal Transit Administration (FTA) and other US government entities have been researching and studying wireless power transfer and its potential impact on infrastructure needs. Specifically, wireless battery-chargers for electric and hybrid vehicle use are entering US commerce. These proximity-chargers are capable of transferring approximately 10 kW of power across a 20 cm gap for charging batteries in electric vehicles. An FTA report on wireless power transfer [3] addresses transportation needs for the most part, but similar proximity-charger technology is entering US commerce for a wide variety of applications.

Additionally, electronic products using beamed or directed power via lasers or microwaves are expected to enter the US market soon. These beamed power products could charge household devices such as smoke alarm batteries, electronic door locks or wearable electronic devices.

What are FDA's concerns?

The risk profile of wireless power transfer products can be evaluated, but only if full information about the product's electromagnetic characteristics are known. Generally, the highest power products pose a higher risk than lower power products, but near-field electromagnetic devices require more information than a power density specification.

- What happens when metal conductors such as rings, implanted medical devices or steel-toe safety shoes are placed within the gap of a proximity-charger? Are engineering controls sensitive enough and reliable enough, and do they act sufficiently quickly to prevent injury?

- Are there electromagnetic hazard concerns when hands, feet, or head enter the gap of proximity-chargers? Is tissue detected by an engineering control when no metal is present? Are persons at risk for radiofrequency burns or electrical shock hazards from induced or contact currents? Are engineering controls (if needed) sensitive enough, reliable enough and do they act sufficiently quickly to prevent injury?

- Are new products tested to a consensus industry standard that addresses electromagnetic safety adequately? Do any other federal regulations require adherence to a standard?

- Do beamed or directed power chargers present an unacceptable risk to public safety when used for charging wearable electronic products placed in clothing or worn on the head?

What scientific evidence/published reports/recommendations from professional organizations support these concerns?

- SAE J 2954 (Society of Automotive Engineers) includes requirements for safety features that may be needed to ensure the public safety [4].
- ICNIRP http://www.icnirp.org/en/frequencies/high-frequency/index.html and Guidelines For Limiting Exposure To Time-Varying Electric and Magnetic Fields (1 Hz TO 100 kHz) [5].
- IEEE C95.1-2005 Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields [6].

What would FDA like to do?

- FDA would like to determine if there are significant risks of injury from new wireless power transfer products entering into US commerce.
- FDA would like to determine if a performance standard is necessary, or if conformance to a consensus standard is sufficient to protect public health.
- FDA wants to determine if any special requirements for medical devices or any modifications to existing standards are needed to protect patients, who represent a more vulnerable population than the general public. A concern is that the patient population and health-care workers may be exposed for longer time intervals than the general public.
- FDA would like to inform manufacturers that they are subject to the electronic product radiation control (EPRC) provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act found in 21CFR 1000-1050, in particular the regulations in 21 CFR 1003.2 pertaining to defects in an electronic product and the regulations in 21 CFR 1002.20 pertaining to accidental radiation occurrence reporting.

Why do we want to do it? How would it help?

Under the FD&C Act, FDA has a mandate to protect the public health and safety from electronic product radiation. 21 CFR 1000.15 (b) twice mentions power generating devices as examples of electronic products which may emit microwave or radio and low-frequency radiation. Wireless power transfer will only become part of the public infrastructure if the public can be assured of its safety. FDA must maintain awareness of any safety concerns related to these electronic products.

Questions for TEPRSSC

1. What is your opinion of FDA's concerns regarding the safety of wireless energy transfer?
2. What recommendations do you have regarding the regulatory path for these products, e.g., a reporting requirement, a performance standard or a voluntary consensus standard?
3. What special concerns are appropriate for wireless power transfer in clinical environments?
4. Are there any similar products or product types known to the committee that also require attention regarding radiation safety?

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3) Laser Products

a) Update to Amendments to the Laser Rule

History

The current performance standard for laser products, last updated in 1985, is based on an outdated understanding of photobiological science and no longer reflects the current state of a technologically-evolving industry, In 2013, FDA proposed to amend its regulations applicable to laser products under Chapter 1, Subchapter J of Title 21 of the Code of Federal Regulations (21 CFR) in order to update its standard. The proposed amendments were posted in the Federal Register (Vol. 78, No. 121, Docket FDA-2011-N-0070) on June 24, 2013. Through this action, FDA intended to better harmonize its standard applicable to the laser industry with the current International Electrotechnical Commission (IEC) 60825-1 standard for the safety of laser products.

In 2013, FDA received 40 comments to its proposed rule. The IEC subsequently made additional amendments to IEC 60601-2-22 Medical electrical equipment—Part 2-22 (IEC 60601-2-22:2012); IEC 60825-1 Safety of laser products--Part 1(IEC 60825-1:2014); and IEC 62471-5 Photobiological safety of lamps and lamp systems – Part 5 (IEC 62471-5:2015). In addition, the International Commission on Non-Ionizing Radiation Protection (ICNIRP) made changes to "ICNIRP Guidelines on Limits of Exposure to Incoherent Visible and Infrared Radiation," (ICNIRP:2013) published in Health Physics 105(1):74-91;2013 and the American National Standards Institute (ANSI) made changes to (ANSI Z136.1:2014) American National Standard for Safe Use of Lasers, Maximum Permissible Exposure levels.

Revised Proposed Amendments

Since 2013, FDA has been in the process of writing a revised proposed amendment. The following changes have been proposed to the amendment (listed in the approximate order in which they appear in the revised proposed rule):

- Adds Class 1C lasers. This class of laser product is designed to contact the skin for skin treatment. The applicator must be engineered to prevent ocular hazards.

- Adopts portions of the latest IEC medical equipment and laser safety standards. Adopts portions of the IEC lamp standard. References ICNIRP radiation limits and ANSI Maximum Permissible Exposure Levels.

- Improves "Children's toy laser product" definition by stating that toys have a novelty or visual entertainment use that excludes laser products that are used in professional or academic settings that may also be used by children.

- Retains FDA's collateral radiation definition because it is clearer in terms of plain English language than the IEC definition. It states clearly that collateral radiation itself is not laser radiation and gives examples.

- Retains FDA's demonstration laser definition and makes it clearer than the current definition in that it states "demonstration" is the demonstration of optical effects.

- Adds the term "Finished laser product" to define a product that is not a component or part. This term is already used in 21 CFR 1000.3(e) in the context of a laser product that has its emission affected by laser components.

- Adds the term "Installed laser product" to account for finished products that are placed in or on non-laser products. FDA wants to use this term to address the compliance of laser products that are installed in or on a non-laser product. Installed laser products are not incorporated and not intended to be incorporated into a non-laser product such that the non-laser product achieves its designed purpose by its laser emission. Rather, the installed product only provides laser functionality for which the installed product was designed.

- Adds the term "Laser illuminator" to define laser products that are designed to emit divergent light (such as auto headlamps) that emit laser light directly or laser light that is more lamp-like.

- Adds the term "Laser-illuminator image projector" to define digital image projectors.

- Adds the term "Laser (or light) distance and ranging" (LIDAR or LADAR) as a laser product for measurement of distance and range for specific purposes that include research, navigation or mapping.

- Adds the term "Laser pointer" to remove these products from the definition of "surveying, leveling or alignment" so as to apply a specific wavelength limit to the emission and to better identify what FDA means by "laser pointer", as a product with a low divergence beam with limited uses.

- Refines the term "laser product" to mean that laser products or their parts are incorporated or intended to be incorporated to achieve a laser product's intended purpose.

- Retains FDA's laser radiation definition because FDA's explicitly defines all radiation collected during measurement as laser radiation. FDA disagrees with IEC's standard that requires exclusion of collateral or non-coherent light radiation from contributing to laser classification.

- Adds the term "Laser rangefinder or speedometer" to differentiate these products from what FDA defines as LIDAR or LADAR products. Even though these are technically distance and ranging products, FDA is making them distinct products because they don't use the type of laser scanning or platforms that LIDAR uses for mapping, research and navigation. Rangefinders and speedometers are more likely to be manually operated in a "point and shoot" method rather than requiring the types of interlocks and scanning safeguards for the safe operation of other LIDAR products.

- Defines Maximum Permissible Exposures (MPE) as specifically U.S.-based ANSI MPEs and not European Union (EU) MPEs, as stated in the IEC laser safety standard.

- Adds the term "Non-laser product" to define products that are not laser products because they do not utilize their own laser emission to achieve a purpose, but may utilize the emission of an installed

finished laser product. FDA wants to make it clearer that a manufacturer of a non-laser product that is accompanied by a laser product is considered a distributor of the laser product, not a manufacturer of that laser product. For example, a manufacturer of personal computers that incorporate another manufacturer's DVD readers (an installed finished laser product) should be regulated only as a distributor of the DVD player.

- Modifies the term "Surveying, leveling or alignment" laser product to omit superfluous and confusing references to taking angular measurements and alignment of parts, and to better describe the act of using the laser emission as a straight line for positioning or adjusting.

- Adds the term "Remotely controlled mobile laser product" to define products used remotely from the operator. FDA is trying to address the emerging use of lasers on robots, autonomous automobiles, and other mobile laser emitting platforms.

- Limits laser pointers to exclude wavelengths from 410 to less than 610 nanometers.

- Excludes an additional eight IEC definitions as not applicable.

- Excludes the IEC subclause covering products designed to function as conventional lamps, because the IEC has no vertical lamp standard to support its horizontal laser standard. FDA only adopts the Risk Groups and applies them to only to laser illuminated projectors. All other lamp-like laser products are held to laser class limits, including laser illuminators.

- Improves and retains FDA's removable laser systems definition by not adopting IEC's version, which requires the design of a plug-in electrical fitting in order to qualify as "removable". FDA believes that manufacturers should not have already designed for plug-in fittings when evaluating a product for laser system removability.

- Adopts all of IEC's up-to-date Accessible Emission Limits.

- Retains FDA's collateral x-ray radiation limit, which is not addressed by the IEC standard.

- Retains FDA's useful life testing requirement for increased emissions with age and degradation. The IEC does not make this requirement clear so it FDA makes it explicit.

- Retains FDA's requirement for fail-safe or redundant interlocks. The IEC standard is not very clear on this requirement so FDA makes it explicit.

- Rejects IEC's allowance for no remote interlock connector for "handheld battery powered Class 3B laser systems". FDA will not be held to this allowance when writing variance or exemption conditions.

- Retains FDA's requirement that an emission indicator work sufficiently prior to the emission to allow appropriate action. The IEC has no such "prior to" requirement.

- Requires an additional warning label to caution against viewing 1M or 2M radiation with optical instruments.

- Clarifies and adds “incorporation” to the standard in context. Laser products are defined as incorporating lasers or laser systems. This section explicitly says that incorporation does not mean incorporation when a finished laser product is placed or intended to be placed in or on a non-laser product. This solves the issues of installed laser products being “incorporated” and therefore the host manufactured product being deemed a laser product itself (even if it does not utilize laser emissions to achieve its purpose, such as a ship or plane). It also solves the issue of some manufacturer’s claiming that an installed laser product must be considered to be a component due to its “incorporation”.

- Updates adopted clauses in IEC’s Medical equipment standard.

- Adds 1M and 2M class limits under specific purpose laser products, and adds the following products as having specific purpose class limits: Laser Illuminated Projectors (LIPs), Remote Controlled Mobile Laser Products (RCMLPs), Laser (Light) Distance and Ranging (LIDAR / LADAR), Laser rangefinders or speedometers, Laser pointers, and Laser illuminators. These class limits exist to protect the public from accessible exposure to 1M, 2M, Class 3B and 4 emissions from products used for LIDAR mapping, LIDAR navigation, range finding, speed measurement, pointing and laser or lamp-type illumination.

- Adds LIPs as Demonstration laser products, adds qualifying conditions and test conditions for LIPs, and allows LIPS to be limited to Risk Groups 0, 1, or 2 without a variance.

- Clarifies that a children’s toy laser product is considered to fail if it fails due to disassembly or breakage. This is in response to a comment.

- Adds “electric toys” because IEC has a standard for these in its laser standard, but FDA makes clear that if they are laser products they have applicable requirements and are not subject to IEC 62115 Electric Toys, because FDA does not recognize IEC 62115.

- Requires that RCMLP have a specific requirement for an emission indicator and beam stop or attenuator on the mobile product controller and a means of preventing human access upon loss of operational control, which includes signal, vision or guidance system failure. This addresses the increasing use of drones and other remotely controlled products that have a laser emission that is likely to be beyond line-of-sight.

- Limits laser pointer products to certain visible wavelengths to decrease the flash blinding effect, particularly for aircraft pilots.

- Removes FDA’s omission of tests that must be made under each and every reasonably foreseeable single fault condition. FDA accepts single fault conditions to allow international consistency in the approach to laser product design.

- Removes FDA’s security master key control requirement because it is now covered by an IEC standard.

- Removes FDA’s Class 3B or 4 beam stop requirement because it is now covered by an IEC standard.

- Removes FDA's exception to the IEC standard's environmental conditions clause. We accept the environmental tests in edition 3.0 of the IEC standard.

- Removes alternate labeling. FDA removes this alternative labeling scheme because it differs substantially from the labels specified in the IEC standard and would add complexity to FDA's compliance evaluations.

- Removes FDA's user information section because it is now adequately covered by the IEC standard.

Question for TEPRSSC:

1. Does TEPRSSC have any comments on the proposed amendments?

b) Laser LiDAR, Remotely Controlled Mobile Laser Products, and Laser Pointers

Laser Hazard Classifications

Lasers are classified numerically to communicate the eye and skin hazard from the laser emission. There are two hazard classification systems applicable to FDA's laser performance standard, FDA's system and the International Electrotechnical Commission's (IEC) system. This table shows how the systems are comparable and how they differ. Each hazard class has a maximum power limit in milliwatts (mW) except class IV (4) which has no limit.

FDA/CDRH	International Electrotechnical Commission (IEC)	Classification Description
I	1	Not recognized as hazardous
	1M	Do not expose users of telescopic optics
	1C	Users must follow instructions
IIa		Hazardous when looking directly for long periods
II	2	Hazardous – do not stare into the beam
	2M	Hazardous – do not stare into the beam or expose users of telescopic optics
IIIa		Avoid exposure to the beam
	3R	Avoid exposure to the beam
IIIb	3B	Direct eye or skin exposure hazard
IV	4	Hazardous for direct or scattered exposure

Trends

Laser products intentionally or collaterally expose people to invisible laser radiation, so that laser radiation exposures are generally not noticeable. Laser emissions are increasingly encountered outdoors and in the home, as opposed to academic or work environments. In the future, exposure to laser light radiation will be as commonplace as exposure to electromagnetic radiation from communication systems.

LiDAR

LiDAR stands for "Laser light (Li) Distance (or Detection) and Ranging (DAR)." These are laser products for distance, detection or ranging measurements. LiDAR products generate a range-based dataset in 1, 2 or 3 dimensions. During operation, some of these products may intentionally or unintentionally expose people to hazardous levels of laser radiation.

LiDAR platforms include fixed and rotary wing aircraft, marine vessels, ground-based, and autonomous vehicles. LiDAR are not considered Specific Purpose Laser Products. Under 21 CFR 1040.10(b)(39) specific purpose laser products have certain surveying, leveling or alignment (SLA) uses. Under 21 CFR 1040.11(b) SLA products are limited to no higher than Class IIIa or the CDRH recognized equivalent, IEC Class 3R. The Preamble at 39 Federal Register 32098 (September 4, 1974) states, in relation to SLA products: "Imposition of the requirements (class limit) of §1040.11(b) on distance measurement laser products is not appropriate since substantially higher powers and different beam configurations are required for ranging purposes." CDRH interprets this exclusion from the class limit as specific to LiDAR applications.

LiDAR safety concerns

There is no class limit for LiDAR products. The public may be exposed to these emissions. There is no pre-market safety review of the products, so they enter into commerce as designed by the manufacturer. There is difficulty in detecting or associating injuries with the product due to the invisible emissions. Injured individuals would have difficulty associating the injury with an exposure.

As a safety plan, manufacturers may instruct the LiDAR operator to terminate the emissions under unsafe conditions. However, this is an administrative control and is not reliable.

What does FDA want to do?

FDA wants to amend the performance standard for LiDAR products. The amendment would lessen the hazard from anticipated exposures to 1M, 2M, IIIb (3B) or IV (4) emissions. FDA proposes that LiDAR products integrate as many interlocks as are necessary for safe operation during intended uses. These interlocks are intended to limit exposure to no greater than Class IIIa or 3R accessible emissions. FDA also proposes that specific LiDAR products (rangefinders and speed detectors) shall not be either Class 1M or 2M and shall be limited to no higher than Class IIIa or 3R.

Questions for TEPRSSC

1. What is your opinion of FDA's LiDAR safety concerns (no class limit, public access to the emission, no pre-market review, and difficulty in detecting or associating injuries with the product due to invisible emissions, reliance on operator control)?

2. What is your opinion of a Class IIIa / 3R limit?

3. What is your opinion on the viewing hazard that will require no allowable 1M and 2M accessible emissions, and is it appropriate for rangefinders and speed detectors?

Remotely Controlled Mobile Laser Products (RCMLP)

Remotely Controlled Mobile Laser Products (RCMLP) are mobile laser products that require remote operational control of the emission. Examples of RCMLP include mobile vehicles and drones.

RCMLP Safety Concerns

FDA is concerned about potential public exposure to laser emission that may require the operator to judge and maintain safe distances between the RCMLP and the public. There is no pre-market safety review of these products, so they enter into commerce as designed by the manufacturer. There is difficulty in detecting or associating injuries with the product due to the invisible emissions. Injured individuals would have difficulty associating the injury with an exposure.

As a safety plan, manufacturers may instruct the RCMLP operator to terminate the emissions under unsafe conditions. However, this is an administrative control and is not reliable.

Another concern is the consequence of the loss of communication/control of the product. The operator of a RCMLP is not required to have a controller-based means of beam attenuation. Currently, the attenuator shall be provided with "one or more" permanently attached means. Further, upon signal loss, the operator cannot monitor the beam attenuation and without manual reset, the product could emit laser radiation continuously or upon restart.

What Does FDA Want to Do?

FDA wants RCMLP's to have a IIIa/3R class limit and exclude classes 1M and 2M, because these products attract attention and are likely to be viewed with optical aids such as binoculars or a telescope.

RCMLP Emission Indicator Requirement

Currently, under 21 CFR 1040.10(f)(5): (Paraphrased)

> Laser products such as RCMLP "that have separately housed laser and operation control"…"shall incorporate an emission indicator"…"if the laser or operation control can be operated at a separation distance greater than 2 meters"…"from any other separately housed portion of the (RCMLP) incorporating an emission indicator."

What Does FDA Want to Do?

We propose an amendment to the performance standard that requires a beam attenuator on the RCMLP and a beam attenuator actuator on the operation control, regardless of separation distance, and an emission indicator on both the RCMLP and operation control, regardless of separation distance. We propose an amendment that the RCMLP must not permit human access to laser radiation in excess of the accessible emission limits of Class IIIa (3R) upon loss of operation control, including signal, machine vision or electronic guidance system failure. We also propose to exclude Classes 1M and 2M because these products are likely to be viewed through viewing optics.

Questions for TEPRSSC

1. For laser products designed to be remote controlled, what is your opinion regarding (1) not requiring a separation distance of 2 meters, (2) a requirement to have an emission indicator on both the operation control and RCMLP, and (3) a requirement to have a beam attenuator actuator on the operation control that controls the beam attenuator on the RCMLP?

2. What is your opinion of the Class IIIa / 3R limit for RCMLP?

3. What is your opinion on the likelihood that RCMLP will be observed using optics that increase the observer's risk of injury?

Laser Pointers

We propose to define laser pointers

Laser Pointers may be defined as handheld laser products designed for battery-powered operation that are manufactured, designed, intended or promoted to provide illumination, designation of a target or point of origin, or sighting, with no associated technological or scientific purpose for the laser's emission. Laser products are not excluded as laser pointers when used for visual entertainment, vision disruption or startle or novelty purposes.

Laser pointer safety concerns

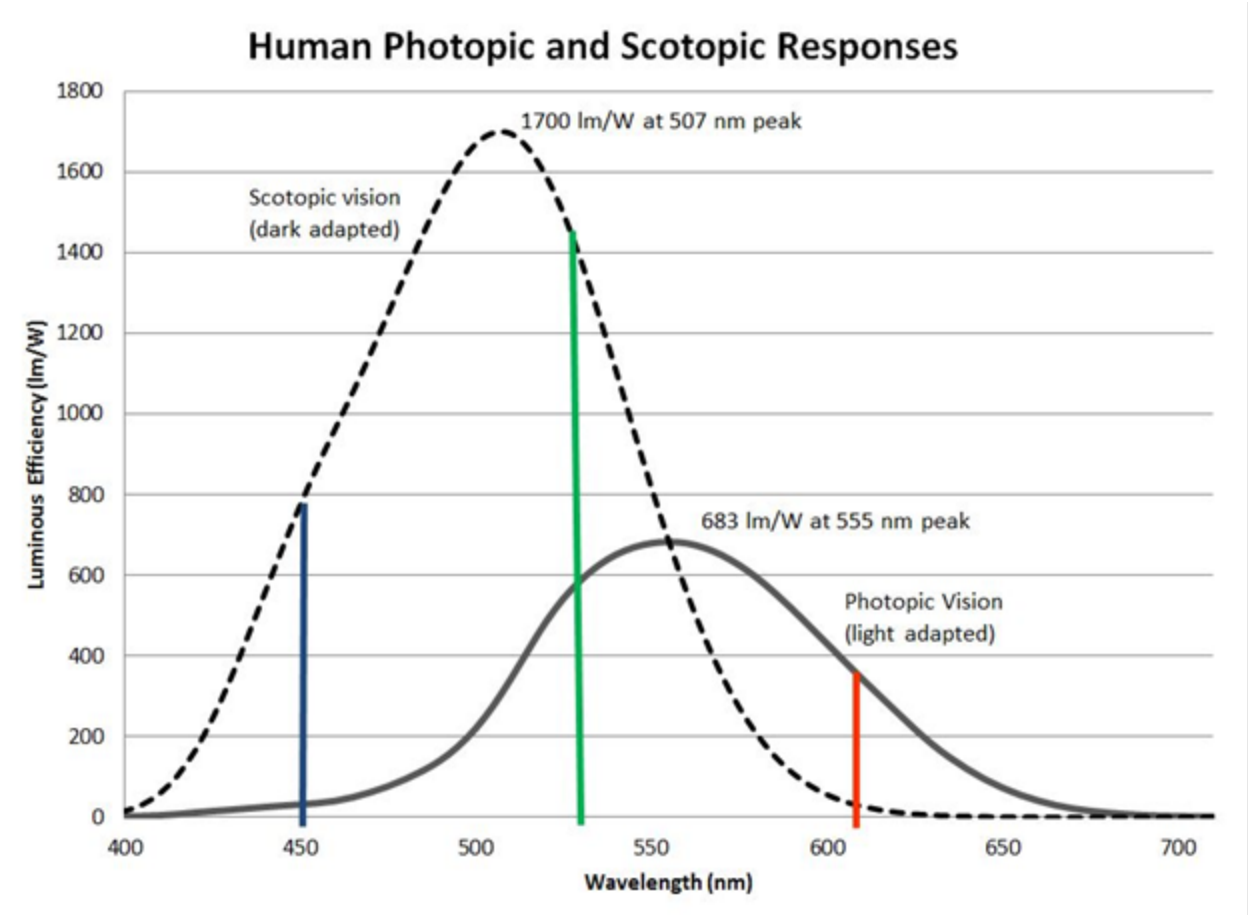
Laser Pointer "illuminations" in the visible wavelengths from 400 nm to less than 610 nm are a significant vision safety hazard to operators of marine vessels, aircraft, and motor vehicles. According to an FAA study entitled "*Laser Illumination of Flight Crew Personnel by Month, Day of Week, and Time of Day for a 5-Year Study Period: 2004-2008*" most illuminations occur at night (around 7 to 11 p.m.) by green lasers (88% of all illuminations) that are 28 times brighter than equivalently powered red laser pointers. Illuminations cause startle, distraction, glare, flash blindness, and a persistent afterimage of a reverse contrast shadow in the visual field, lasting minutes. This effect renders operators of aircraft particularly vulnerable since they rely heavily on reading flight instruments. Pilots of rotary wing aircraft who fly at low altitudes must also rely on night-adapted vision to identify airborne and ground-based hazards.

Since 2006, there has been an eighty-fold increase in reported incidents of aircraft illuminations from laser pointers, according to FDA analysis of FAA public data (http://www.faa.gov/about/initiatives/lasers/). FDA has received numerous letters from Congress requesting action on laser pointer illuminations of aircraft.

Changes in Technology

Due to recent technological advances, laser pointers with green or blue laser diode systems are now available. Previously, laser pointers emitted only red laser light. It is well established that humans are most visually sensitive to green light. Humans are also far more sensitive to green light at night. As a result, green laser pointers are a much more significant safety hazard than red laser pointers. Due to a 50 nm shift in color sensitivity toward the blue wavelengths and away from the red wavelengths at night,

blue light also appears to be much, much brighter than red light at a comparable power output (see illustration below).



The hazard from flash blinding is substantially reduced when laser pointers emit red/orange wavelengths at 615 nm or longer. The hazard from laser aircraft illuminations would be effectively eliminated if green and blue laser pointers were not available. Colors at 615 nm and longer, viewed with night adapted vision, are only 1.4% as bright appearing as green at the commonly manufactured 532 nm wavelength.

Blue and green pointers are defective as applicable to electronic products

Currently, under 21 CFR 1003.2: (Paraphrased)

> An electronic product "shall be considered to have a defect which relates to the safety of use by reason of the emission of radiation if:"
>
> …"(b) It is a product which utilizes electronic product radiation to accomplish its primary purpose and from which such emissions are intended"…and…
>
> …"(2) Without regard to the design specifications of the product, emits electronic product radiation unnecessary to the accomplishment of its primary purpose which creates a risk of injury, including genetic injury to any person."

What does FDA want to do?

FDA would like to amend the performance standard to require that laser pointer products must not emit laser radiation in the visible wavelengths from 400 nm to less than 610 nm (deep violet to orange-red).

Questions for TEPRSSC

1. What do you think of the laser pointer definition?
2. In your opinion, did a startle and flash blinding hazard exist when laser pointers were only available in red?
3. Does the startle and flash blinding hazard with green and blue laser pointers justify calling them "defective"?
4. What is your opinion regarding the exclusion of wavelengths from 400 to less than 610 nm for laser pointers?

c) Laser Lamps for General Illumination and Image Projectors

Laser Lamps

Laser lamps are a new type of white-light source that can be more efficient than light emitting diodes (LED) at higher output levels. A type of solid state lighting (SSL), like LEDs, laser lamps are finding increased use in lamps used in cinema and other image projectors, spotlights, stadium lighting, and car headlights. Solid-state lighting is also the subject of the US Department of Energy (DOE) Office of Energy Efficiency and Renewable Energy (EERE) Solid-State Lighting Program (http://energy.gov/eere/ssl/about-solid-state-lighting-program).

The Energy Policy Act of 2005 (EPACT 2005) and the Energy Independence and Security Act of 2007 (EISA 2007) issued directives to the Secretary of Energy to carry out a Next Generation Lighting Initiative to support SSL research and development. The legislation directed DOE to support research, development, demonstration, and commercial application activities related to advanced SSL technologies. One topic DOE has been investigating is the basic mechanism of LED "efficiency droop", an impediment to making brighter LEDs. Practically, "efficiency droop" reduces the efficiency of electrical-to-optical power conversion at higher drive currents. Laser lamps do not experience efficiency droop, because laser light is generated using stimulated emission, which converts input energy into light more efficiently at high current levels.

There are clear benefits to laser lamp technology as compared to traditional incandescent or fluorescent lamp technologies. These include energy savings, longer lamp lifetimes, new lighting formats and aesthetics, and the ability to more effectively project video images onto walls in public spaces for art and information. There are also safety benefits to this technology such fewer ladder accidents and no injuries from broken lamp glass. Work-related falls from ladders caused 113 deaths and almost 15,500 nonfatal injuries that resulted in at least one day away from work in 2011, according to researchers from the Centers for Disease Control and Prevention (CDC). The US Consumer Product Safety Commission (CPSC) National Electronic Injury Surveillance System (NEISS) indicated that 20 eye injuries occurred during 2015 from broken glass light bulbs in just the NEISS sample of hospital emergency room visits.

There are two lamp types featured in this presentation: Remote Phosphor Pumped by Blue Laser and Direct Multi-Color Laser:

Remote Phosphor Pumped by Blue Laser

This laser lamp works by using a blue laser to pump a remote, yellow phosphor to produce white light. This is very similar to LED lamp technology, but the laser-pumped lamp can be brighter due to the higher output of blue lasers. LEDs tend to have phosphors that are located very close to the blue light source. The phosphors in these lamps can be located at a considerable distance from the blue light source because beam collimation is possible. Fiber optics can be used to deliver the blue pumped-laser light to the phosphor for conversion to white light. Uses for laser-pumped phosphor illuminators include laser illuminated projectors (LIPs), stadium lighting and automotive headlamps.

Lamp Type: Direct Multi-Color Laser

These laser lamps works by directly combining three or four laser colors combine to produce white light. Direct combination results in higher efficiencies and no limited lifetime issues as compared to lamps that use phosphors. Currently, higher-power green lasers are produced by up-conversion using a non-linear optical crystal, but direct high-power green lasers are now available. Individual laser colors can be delivered through optical fibers into medical instruments such as endoscopes for viewing internal structures during medical procedures. For general illumination applications, recent US DOE studies at Sandia National Laboratory showed that 4-color (tetrachromic) laser illumination was visually pleasing despite preconceived notions that the quality of illumination would be perceived as unpleasant [1].

Laser Lamp Safety Concerns

Like any bright lamp, laser lamps can present both retinal thermal hazards and photochemical, blue-light hazards. These hazards are discussed in the IEC 62471: 2006 lamp standard [2]. Under the IEC's classification procedure, LIPs are assigned a Risk Group (RG) of 0, 1, 2, or 3, where higher RGs correspond to higher radiation outputs and a higher potential to pose serious danger if used improperly.

Laser lamp technology also presents the laser exposure-related health risks encountered with other laser applications. For example, should the laser burn through the phosphor or diffusers or suffer some other failure in the protective housing, there may be a risk of exposure to source hot spots or coherent laser light. This emphasizes the importance of performing and reporting component lifetime testing as required in product reports in 21 CFR 1002.10.

Another factor related to health risks is the reliability of the human physiological response to laser and other bright lights. Reidenbach [3] conducted two research projects on human aversion responses and concluded that fewer than 29% of test subjects reacted with a protective aversion response to bright laser and other light. Previously, it had been assumed that the blink reflex would provide sufficient protection from Class II laser exposures.

Additionally, concerns have been voiced by the Council on Science and Public Health (CSAPH) in a report on human and environmental effects of LEDs [4] that blue light emitted from LEDs may disrupt circadian rhythms. The American Medical Association also shared these concerns when it adopted a community guidance document to reduce the harmful effects of high-intensity street lighting [5]. A logical concern is whether laser lamps also produce the same harmful effects.

Laser Illuminated Projectors (LIPs)

Regulatory history:

Upon the introduction of laser illuminated projectors (LIPs), the International Electrotechnical Commission (IEC) included Clause 4.4 - "Laser Products designed to function as conventional lamps" of the IEC 60825-1:2014 [6] laser performance standard to utilize the IEC 62471 lamp standard for its risk group classification system. FDA is in the process of rulemaking in which FDA will amend its laser performance standard in 21 CFR 1040.10 and 1040.11 by harmonizing it with IEC 60825-1:2014. However, FDA did not find Clause 4.4 regarding LIP laser products to be adequate to protect public health.

Instead, FDA published a guidance document, "Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors (LIPs): Guidance for Industry and Food and Drug Administration Staff", published February 18, 2015 [7]. In this guidance document, FDA maintained the IEC 60825-1:2014 concept of using the IEC 62471 lamp standard, in which a risk group (RG) classification system is used. One important aspect of this guidance document is that RG 3 projectors are considered to be equivalent to Laser Class IIIb and IV projectors, requiring manufacturers to apply for a variance because these projectors exceed Laser Class IIIa limits; the only RG 3 LIPs considered in the document were cinema projectors. Industry representatives have asked FDA to consider how non-cinema RG 3 projectors as defined by the FDA guidance could be entered into US commerce.

What does FDA want to do and how will this help?

FDA wants to implement requirements for engineering controls in the laser performance standard to prevent laser lamps from operating should a failure of the protective housing occur. This engineering control requirement would apply to both LIPs and laser lamps. There is precedent under 21 CFR 1040.30 for Type T mercury vapor lamps. These lamps are required to have engineering controls to protect against hazardous protective housing and optical component failures.

FDA is considering a requirement for engineering controls for non-cinema RG 3 LIPs in fixed and non-fixed installations, which could provide a virtual protective housing to protect the nominal ocular hazard distance in front of a projector lens. Virtual protective housings have been found to be acceptable in some variances when used to protect the nominal ocular hazard distance of certain surveying, leveling, and alignment products. Such controls for LIPs would relieve industry from being required to apply for a variance for non-cinema RG 3 LIPs.

Questions for TEPRSSC

1. What are your concerns regarding protective housing and optical component failures in these products and resulting safety issues?

2. What is the best way to assure the safety of these products (e.g. the existing FDA performance standard, a combination of the FDA performance standard and a lamp standard)?

3. What is the Committee's opinion of the FDA virtual protective housing approach using engineering controls to protect the nominal ocular hazard zone from human access?

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d) Infrared applications

Near infrared (NIR) laser illuminators used in surveillance

What is the product?

The Center for Devices and Radiological Health (CDRH) is aware that the use of near infrared (NIR) lasers as illuminators for use in surveillance systems is growing. NIR laser illuminators may present a public safety hazard when used in surveillance applications by exposing public to radiation that may be an ocular hazard. These lasers also present a regulatory burden for industry that will be discussed below. CDRH would like input from TEPRSSC regarding the safe use of these products and recommendations for how to best regulate them.

Long-range surveillance (more than 50 m) in environments with low ambient light and/or atmospheric interference is a useful capability for many applications. Until recently, surveillance systems with these capabilities were prohibitively expensive or not available outside of the defense market. NIR surveillance systems can be fixed in location, (e.g., mounted on a building or bridge), or can be mobile (e.g., mounted on a vehicle, aircraft or unmanned aerial vehicle (UAV)). Long-range surveillance applications span a broad range of fields that include:

- Traffic monitoring
- Airport/seaport security
- Building complex security
- General public space monitoring
- Police surveillance
- Aid in firefighting
- Professional sports
- Border protection
- Military/defense

NIR laser illuminators typically have the following characteristics:

- Solid-state, continuous wave
- 810-940 nm
- 100 mW – 5 W (Class IIIb or IV)
- Variable divergence
- Nominal Ocular Hazard Distance (NOHD): 1 m – 2.5 km

If people are exposed to NIR laser within the NOHD, they can potentially suffer eye injury.

How is the product currently regulated?

NIR lasers used in surveillance applications are categorized as survey, levelling and alignment (SLA) lasers. These lasers are class limited to Laser Class IIIa (21 CFR 1040.11(b)). For the relevant spectral range, Class IIIa is equivalent to Class I which is approximately 0.1 mW. For comparison purposes, Class 1 according to IEC 60825-1 (2007) is approximately 35 mW. Since most NIR laser illuminators used for surveillance are more powerful than 35 mW, most of these products do not meet the class IIIa limitation. Historically, the

FDA has only permitted law enforcement and the military to use more powerful NIR surveillance systems, and then only after CDRH approves a variance to the performance standard.

What are our concerns?

When the eye focuses NIR light onto the retina, photothermal damage can occur, and may result in permanent detrimental effects to vision. Since humans cannot perceive NIR radiation, those exposed to hazardous levels will not know that they are being exposed and cannot react to avoid exposure. Labelling and signage cannot always be relied upon to inform the public of hazardous areas, nor would it be practical in many cases (e.g., UAV-based NIR surveillance). In addition, entry into hazardous areas cannot always be prevented or predicted. Training of laser operators may prevent some hazardous exposures in predictable situations, but cannot be relied upon—unforeseen situations are possible and these lasers often operate in an automated mode. For these reasons, FDA does not think administrative controls would be an effective solution.

What would FDA like to do, and why?

CDRH is proposing that we do not enforce the SLA class limitation on NIR illuminators used for surveillance if engineering controls are incorporated that provide a virtual protective housing that prevents exposures within the NOHD of the laser. For example, a laser range finder may be incorporated into a NIR surveillance system that reduces the power of the NIR laser whenever an object is sensed at a distance closer than the NOHD. This would accomplish three important things: a virtual protective housing would protect the public from hazardous exposures to NIR laser radiation, it would eliminate the variance process, thereby reducing the burden on industry and CDRH, and it would allow the public to obtain NIR surveillance products.

Questions for TEPRSSC

1. What is your opinion regarding the potential public safety hazard associated with NIR illuminators used in surveillance applications?
2. What is your opinion regarding the effectiveness of using an engineering control to create a virtual protective housing to prevent hazardous exposures to NIR radiation?
3. Can you suggest another type of engineering control or alternative solution that would better protect the public?

4) Sunlamp Products and Other Non-Coherent Light Sources

a. Update on Amendments to Performance Standard for Sunlamp Products.

Background:

The FDA Performance Standard for Sunlamp Products (21 CFR 1040.20) was published in 1979 and updated in 1985 to accommodate UVA-emitting lamps. We have been working on the amendments to this Performance Standard since the 2003 TEPRSSC meeting. The following proposals were presented and accepted at the 2003 TEPRSSC meeting:

- Strengthen language in the Warning Label and make it easier to read
- Require a Warning Label to be included in sales material targeted to consumers
- Specify that modification of a Sunlamp Product that results in a change to safety constitutes manufacturing
- Change requirements for Protective Eyewear to include a cap on transmittance in visible region and a quantitative floor on luminous transmittance (from IEC) and extend requirements to ALL eyewear intended to be used with Sunlamp Products
- Replace current erythema action spectrum with universally-recognized CIE Reference Action Spectrum for Erythema AND change maximum dose limit accordingly (from IEC, modified)
- Adopt the UV code approach (from IEC) for measuring and labeling replacement lamps
- Change approach for limiting UVC radiation exposure from current 'ratio' to an 'absolute' limit (from IEC)
- Update guidelines for Recommended Exposure Schedule to reduce cumulative UV burden (from IEC)

Recent Actions:

In May, 2014, FDA published a Final Order (Appendix A) to reclassify Sunlamp Products as Class II Medical Devices and require 510(k) submissions (Sunlamp Products were previously classified as Class I Devices and 510(k)-exempt).

In December 2015, FDA published the proposed amendments (Appendix B) and we hope to finalize them by the end of 2016.

Question for TEPRSSC

1. Does TEPRSSC have any comments or concerns about our proposed amendments?

b. New Initiatives for Non-Coherent Light Sources

Background:

In 1979, FDA developed Performance Standards for two types of non-coherent light sources/lamps:

- Sunlamp Products (amended in 1985)
- High-intensity Mercury Vapor Lamps

Health concerns and possible solutions for:

A. LEDs

Light-emitting diodes (LEDs) are semiconductor diodes that emit light when electrical current is applied. The bandgap determines the wavelength of the emitted light. All radiation-emitting (including light-emitting) products are subject to regulation by the FDA. LEDs are different from lasers in that they are less intense, do not have as narrow a bandwidth as a laser and do not emit 'coherent' radiation.

'White' LEDs are usually created through the use of a blue LED and a phosphor. These LEDs have become more widely available to consumers in recent years and are expected to replace traditional light sources, e.g. fluorescent and high intensity discharge lamps, in the near future due to their higher energy efficiency.

The potential adverse effects of exposure to humans to the light from LEDs are:

- Blue light damage to the retina, due to the high blue content of some LEDs and the high luminance or hot spot emission pattern [1]
- Glare (especially at night) from street lighting, due to increased scatter of the shorter wavelength emissions compared to traditional street lighting
- Disruption of circadian rhythm, leading to disturbed sleep which can have short and long-term health consequences

In 2010, the French Agency for Food, Environmental and Occupational Health and Safety (ANSES), a public body reporting to the French Ministers for Health, organized a task group which consisted of physicists, lighting and metrology specialists, retinal biologists and ophthalmologists. ANSES conducted a study (Appendix C), following the ANSI/IEC 62471 Standard, and evaluated the Risk Group (RG) of dozens of LEDs and traditional lamps. ANSES found that some 'white' LEDs fell into RG 2, the 'moderate' risk group, similarly to high pressure mercury vapor/metal halide lamps. The 'safe' exposure times for the most intense 'white' LEDs were 10 – 30 seconds; it was only a few seconds for blue LEDs. Most other lamps were RG 1, or low risk. Typical sources of human exposure to LED light include (1) general illumination at home or work; (2) tablets and E-readers; and (3) outdoor lighting. Chang *et al*., 2015 [2] showed that reading from these devices for 4 hrs just prior to sleep can suppress and shift melatonin secretion. Also, some citizens have complained of debilitating after-images from exposure to LED street lights.[3]

Based on their findings, ANSES recommended:

- Manufacturers classify and label their LEDs by RG, but noted that IEC 62471 needs to be updated to provide more guidance on evaluating LEDs, specifically
- Limit LEDs for general public to $\leq$ RG1
- Provide distance at which product $\leq$ RG0
- Require that LED systems of > RG1 be installed only by professionals
- Recommending that manufacturers design lighting systems that provide only indirect light to reduce glare

ANSES notes that there is uncertainty regarding the chronic effects of low doses of blue light on age-related macular degeneration (AMD), but it is known that chronic exposure to intense sunlight is a risk factor for AMD. There is some evidence that exposure to light levels below the published 'safe' thresholds can produce retinal damage.[4]

The American Medical Association (AMA) has also expressed concerns about the effects of excessive blue light emitted from LEDs in street lighting [5]. In their 2016 report (Appendix D), they note that there is a strong economic incentive to overhaul existing street lighting and convert to LED lighting. The early LED designs emitted excessive blue light, which contributes to disability glare and visual impairment. The first generation of LEDs had a 'Correlated Color Temperature (CCT) index of 4000 K. Current outdoor lighting (typically sodium lamps) has a CCT of 2100 K. Newer LEDs are ca. 3000K, which is slightly warmer in tone and has less impact on humans and wildlife. The AMA is also concerned about increased glare from outdoor LED lighting compared to conventional outdoor lighting. They note that this glare can be minimized by proper shielding and CCT control. Lastly, like ANSES, the AMA is concerned about the high blue content of 'white' LEDs and the possible effects on circadian disruption.

The AMA makes the following recommendations:

- Encourages use of < 3000 K CCT lighting for outdoor installations
- Encourages use of proper shielding of LEDs to reduce glare
- Encourages use of dimming in off-peak times

Question for TEPRSSC

1. Does TEPRSSC have any comments or concerns about the ANSES/AMA proposals?

B. UVC Lamps

UVC lamps are light sources which emit optical radiation in the 100 to 280 nm wavelength range. Traditional, low-pressure, mercury-based lamps had a peak emission at 253.7 nm. The widespread availability of UV-emitting LEDs in the past decade is cause for concern. UVC lamps are also known as 'germicidal' lamps due to their ability to kill bacteria and other organisms.

Exposure to UVC can cause:

- sunburn of cornea (photokeratitis)
- skin sunburn/erythema
- DNA damage – leading to long-term effects, e.g. skin cancer

- UVC lamps also produce ozone which is irritating to the respiratory system

Common uses for UVC lamps:

- Air Disinfection
- Water Disinfection
- Food Processing Hygiene
- Laboratory Hygiene
- Medical Device Sterilization
- Consumer use for home sterilization – both for air and on surfaces

There is currently no mandatory US standard for these types of lamps that would warn consumers of the potential hazards. Adoption of either the ANSI standard or the IEC 62471-1 standard (currently in draft form) for Photobiological Safety of Lamps would provide for uniform testing and risk classification and provide consumers with information about the potential hazards of these lamps through labeling. Requiring that all lamp manufacturers comply with either the ANSI or IEC standard would ensure that consumers are informed about potential hazards from UV, intense visible or infrared emissions from lamps.

Another potential danger from UVC lamps is the risk of incorrect installation. There have been reports of incorrect replacement of UVA lamps with the more dangerous UVC lamps, usually in 'insect trap' fixtures, with resultant injuries. There have also been warnings about the potential for incorrect replacement of UVC lamps into UV nail curing appliances which are designed to use UVA lamps. The International Electrotechnical Commission is beginning a project on specifying unique lampholders and fixtures for UVC lamps to avoid this problem in the future.

Question for TEPRSSC:

1. Does TEPRSSC have any comments about the best way to deal with potential hazards of UVC lamps, including the risk of incorrect installation?

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Day Two

1) Radiation Therapy

What are the products?

The Electronic Product Radiation Control (EPRC) regulations apply to radiation therapy products where the radiation is produced using an electronic circuit (e.g., particle accelerators, x-ray tubes, brachytherapy using miniature x-ray tubes). The EPRC regulations do not apply to radiation therapy devices that use inherently radioactive material as their radiation source (e.g., brachytherapy using radioactive seeds, gamma rays). Accessories to radiation therapy systems may or may not be subject to EPRC regulations. All of these products, systems and accessories are also medical devices and are subject to the medical device regulations.

Radiation therapy (external beam or brachytherapy) is widely used to treat cancer [1-2]. External beam radiation therapy is performed with x-rays, gamma rays, electrons, or particle beams (protons) and uses large doses of radiation to destroy cancerous cells. Brachytherapy is performed by placing radiation sources inside or on the body and can be given at high and low dose rates. Over the past 30 years, radiation therapy technology has rapidly advanced and now includes devices that use software and image-guided techniques to treat patients. Additionally, the development of methods such as image-guided radiotherapy (IGRT), stereotactic radiosurgery (SRS), stereotactic body radiotherapy (SBRT), proton therapy, and the accompanying ability to modulate the energy, size, and shape of the radiation beam in real-time during delivery has led to shorter fractionation schemes employing higher doses of radiation per fraction.

To ensure the safe use of these devices and treat patients accurately, quality assurance devices have been designed to validate dose calibration and delivery. Treatment planning software has been created to automate practices that can control the radiation beam that have become too complex to be done manually. Numerous accessories, such as beam-limiting collimators, patient positioning systems, and patient motion tracking systems are currently in use and have a substantial impact on the safe delivery of the radiation treatment beam.

What are our concerns?

The trend in the design of radiation therapy systems is to incorporate automation and multiple features into what was formerly a manually controlled, stand-alone treatment unit. These features now include multi-modality imaging systems such as cone-beam CT and MRI, robotic couches that can move during treatment, and multi-leaf collimators. Additionally, with numerous accessories available, the user often has the ability to add third-party components to design a system that meets their specific requirements and enables more complex and specialized treatments. With these advancements in technology, physicians can use higher doses of radiation per fraction, and use imaging to control the beam in real-time. However, if this radiation is delivered incorrectly, it can have severe adverse consequences for the patient.

In part due to the complexity of radiation therapy devices, the FDA has seen reports of adverse events from mistreatment resulting from improper hardware and software designs. We are also aware of numerous near-miss events. These events are related to both the products that generate and deliver the treatment beam and the accessories intended to assure that those treatment beams deliver the correct dose to the correct locations.

Currently, there is no specific performance standard under Title 21 CFR Subchapter J Radiological Health that applies to the electronic products used for ionizing radiation therapy. FDA relies on voluntary international consensus standards to assess manufacturers' premarket submissions for radiation therapy devices. We are proactively working with standards development organizations such as the International Electrotechnical Commission (IEC) to develop and improve voluntary standards for radiation therapy delivery systems and their associated accessories. As radiation therapy systems become more complex, it will be desirable for these products to have standard requirements for safety features such as: dual-channel dosimetry systems, safety interlocks, limits on radiation leakage, verification of beam properties, and pre-set tolerance limits.

What scientific evidence/published reports/ recommendations from professional organizations supports these concerns?

Currently, there are a number of existing IEC standards for linear accelerators and particle beam therapy systems. These are listed in the Appendix. Additionally, manufacturers are working together with professional societies to develop standards that provide specific requirements and guidance for the design and manufacture of equipment intended for use in external beam radiation therapy. These standards reference existing IEC standards and also identify additional pre-treatment checks which could further improve patient safety [4].

Two professional societies whose members are involved in the use of radiation therapy to treat patients, the American Society for Radiation Oncology (ASTRO) and the American Association of Physicists in Medicine (AAPM) have developed the Radiation Oncology Incident Learning System (RO-ILS), a secure reporting system that allows radiation oncology centers to track safety incidents and near-misses in radiation therapy that occur at their facilities. The system was launched in June 2014 with the intent of making the radiation oncology community aware of safety issues occurring across the country and to help educate users about how to prevent errors [3].

What would FDA like to do?

At present, FDA relies solely on the medical device premarket review of safety and effectiveness, which is based on guidance documents and recognized voluntary consensus standards for these products. FDA supports the efforts of international bodies, industry groups, and professional societies (e.g., IEC, AAPM) in the development of consensus standards addressing safety, performance, and testing of radiation therapy devices. We encourage manufacturers to adopt features that promote patient safety and to follow existing voluntary consensus standards. We could develop additional guidance to facilitate and encourage the use of the relevant consensus standards. We are considering developing specific mandatory performance standards applicable to electronic products used for radiation therapy.

Why do we want to do it? Why would it help?

We believe that assuring that there are clearly defined, relevant, and consistent standards for electronic products used for radiation therapy will help ensure the safety of patients and health care professionals.

Questions for TEPRSSC

1. Currently, FDA does not have performance standards for radiation therapy systems, specifically for linear accelerators and particle accelerators systems used to deliver external photon or particle radiation. What is the committee's opinion on the desirability of establishing performance standards for electronic products used for radiation therapy?

2. Are mandatory performance standards necessary for electronic products used for radiation therapy, or is it sufficient to develop and encourage the use of voluntary consensus radiation safety standards?

3. If FDA develops performance standards for electronic products used for radiation therapy, what functions, systems, products, etc. should we focus on to achieve the largest public health benefit?

4. Currently, there are no specific FDA performance standards for accessories to radiation therapy systems, such as treatment planning software, quality assurance equipment and software, patient positioning systems, and patient motion tracking systems that can control the quality, quantity, or direction of the radiation beam. What is the committee's opinion on the desirability of establishing performance standards for accessories to radiation therapy systems?

5. Are mandatory performance standards necessary for accessories to radiation therapy systems, or is it sufficient to develop and encourage the use of voluntary consensus radiation safety standards?

6. If FDA develops performance standards for accessories to radiation therapy systems, what functions, systems, products, etc. should we focus on to achieve the largest public health benefit?

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1. National Cancer Institute, Types of Treatment, Radiation Therapy webpage (https://www.cancer.gov/about-cancer/treatment/types/radiation-therapy)

2. National Cancer Institute Radiation Therapy for Cancer webpage (https://www.cancer.gov/about-cancer/treatment/types/radiation-therapy/radiation-fact-sheet)

3. ASTRO RO-ILS Database webpage (https://www.astro.org/RO-ILS.aspx)

4. Press release for Radiation Therapy Readiness Check Initiative (http://www.medicalimaging.org/2010/06/09/manufacturers-unveil-radiation-therapy-readiness-check-initiative/)

Appendix: IEC and other voluntary standards relevant to radiation therapy recognized by FDA

Document Number	**FDA Recognition Number**	**Title**
IEC 62083 Edition 2.0 2009	12-217	Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems
IEC 62274 Edition 1.0 2005	12-241	Medical electrical equipment - Safety of radiotherapy record and verify
IEC 61217 Edition 2.0 2011	12-267	Radiotherapy equipment - Coordinates, movements, and scales
IEC 60731 Edition 3.0 2011	12-235	Amendment 1, Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy
AAMI / ANSI / ISO 14971:2007/(R)2010	5-70	Medical devices - applications of risk management to medical devices
IEC 60601-1-6 Edition 3.0 2013	5-89	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
IEC 62366 Edition 1.1 2014	5-87	Medical devices - Application of usability engineering to medical devices
IEC 60601-2-54 Edition 1.0 2009	1-82	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC 60601-1-3 Edition 2.1 2013	12-269	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-2-28 Edition 2.0 2010	12-204	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
IEC 60601-2-68:2014	NA	Electrical medical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided

(not yet FDA-recognized)		radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment
AAMI ANSI IEC 62304:2006	13-32	Medical device software - Software life cycle processes
AAMI ANSI ES 60601-1 :2005/(R)2012 and C1:2009/(R)2012 and, A2:2010/(R)2012	19-5	Medical electrical equipment - part 1: general requirements for basic safety and essential performance
AAMI ANSI IEC 60601-1-2:2007/(R)2012	19-2	Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests (edition 3)
AAMI ANSI IEC 60601-1-2:2014	19-8	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (edition 4)
IEC 60601-2-64:2014 (not yet FDA-recognized)	NA	Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment
IEC 62667 Ed. 1.0 (not yet FDA-recognized)	NA	Medical electrical equipment - Light ion beam medical equipment - Performance characteristics
IEC 60825-1 Edition 2.0 2007	12-273	Safety of laser products - Part 1: Equipment classification, and requirements
IEC 60976 Edition 2.0 2007-10	12-253	Medical electrical equipment - Medical electron accelerators - Functional performance characteristics
IEC 60601-2-11 Edition 3.0 2013-01	12-255	Medical electrical equipment - Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment
IEC 60601-2-1 Edition 3.1 2014-07	12-285	Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV

2) Computed Tomography

What is the product?

Computed Tomography (CT) is a non-invasive medical examination or procedure that uses specialized X-ray equipment to produce cross-sectional images (slices) of the body [1]. These images are used for a variety of diagnostic and therapeutic purposes. Over the past 30 years, CT technology has rapidly advanced and now includes such performance and safety features as rapid helical scanning, automatic tube-current modulation, various methods of incorporating multiple energy spectra acquisitions for added physical information in reconstructed images[2], the development of cone-beam x-ray sources with flat-panel detectors (cone-beam CT; CBCT), non-linear iterative reconstruction algorithms for improved image quality or reduced radiation dose [3], and others. These new technological features have greatly expanded the frequency with which such exams are performed, with an estimated 10% annual growth in number of CT exams until recently [4].

What are our concerns?

FDA is concerned with ensuring that the radiation dose incurred by patients during CT examinations is appropriate for acquiring the necessary medical information, but no greater than necessary. The rapid expansion of CT use, while offering exciting opportunities to provide rapid and accurate diagnostic information for the health of patients, has also led to a large increase in the total amount of ionizing radiation that an average patient receives in a year.

Moreover, we are aware that when operators of CT devices do not have access to safety features and accurate patient dose information, incidents of harmful over-exposure to patients can occur. One prominent example occurred in 2009, when CT scanners used for CT brain perfusion studies in suspected stroke patients were unintentionally set to acquisition parameters that exposed patients to excessive radiation doses. [5] As a direct result of this incident, FDA and industry saw the importance of implementing device safety features such as establishing dose notification and dose alert levels as part of the Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging.[6]

What scientific evidence/published reports/ recommendations from professional organizations supports these concerns?

Numerous publications and recommendations from expert bodies support FDA's concerns about the potential risks of ionizing radiation and increased patient exposure to ionizing radiation from medical procedures. Some selected resources include:

- The NCI's fact sheet on CT: http://www.cancer.gov/about-cancer/diagnosis-staging/ct-scans-fact-sheet
- NCRP Report No. 160: Ionizing Radiation Exposure of the Population of the United States National Council on Radiation Protection and Measurements, Bethesda, MD (2009)
- FDA Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging (2010) [6]
- ACR White Paper on Radiation Dose in Medicine [http://www.acr.org/~/media/ACR/Documents/PDF/QualitySafety/Radiation%20Safety/WhitePaperRadiationDose.pdf]

What would FDA like to do?

CT technology has continued to expand rapidly and evolve over recent decades. As electronic product radiation control (EPRC) performance standards for CT have not changed since 1985, FDA is interested in pursuing updated performance standards or other regulatory mechanisms for this product. As a broad goal, FDA wants to ensure that appropriate safety features and essential user safety information are available for all CT devices.

FDA currently supports the efforts of international and industry groups (e.g. IEC and NEMA) in the development of standards addressing safety, performance, and testing of CT devices. We recognize conformance to such standards and encourage manufacturers to adopt features that promote patient safety; however, FDA's EPRC performance standards for CT have not been updated to address either the new nature of the technology or to mandate new safety and user information features present in these standards. In addition, neither EPRC performance standards nor CT consensus standards currently address all of the safety concerns FDA is aware of for different CT technologies, especially CBCT. [7]

During an FDA public meeting in 2010 to establish an Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging, FDA received numerous comments related to increasing the safety of CT systems. This feedback has been incorporated into the proposals which FDA wishes to discuss with TEPRSSC at the October 2016 meeting.

Many safety features and user information proposals have been recommended which could address our concerns and benefit public health and safety:

- Dose Check - a pre-scanning alert which occurs if dose is expected to exceed limits – prepopulated by manufacturer, can be adjusted by user
- Automatic Exposure Control (variation in tube current during a scan to reduce unnecessary dose)
- Details of reference clinical protocols supplied with the system, included in user manuals
- Detailed dose information in a centralized user manual

Why do we want to do it? Why would it help?

- Reduce Unnecessary Pediatric Patient Dose
    - While experts agree that the benefits of a medically-indicated CT scan far outweigh the risks, the possibility exists that low levels of radiation from CT scans could slightly increase lifetime cancer risk. For pediatric patients, the cancer risk per unit radiation dose is higher than for adults. Thus, medical professionals should seek to use the lowest doses achievable for imaging examinations that provide the necessary information, and should perform imaging examinations only when necessary. [8]
    - Image Gently recommends that unnecessary patient dose can be reduced by ensuring that CT procedures are performed only when medically necessary (justification), using only the amount of radiation necessary to provide adequate image quality (optimization). [9]

- Dose reduction efforts require access to accurate size-scaled dose estimates, detailed dose reporting, and availability of safety features on all CT scanners which are used to image pediatrics.

- **Avoid Misuse and Unintentional Overexposure**

  - Many of the CT features/requirements we suggest were developed as a response to CT brain perfusion over-exposure incidents, to prevent such occurrences in the future.

What does the panel think about our concerns? What does the panel recommend?

FDA questions for TEPRSSC on CT technologies:

1. CT manufacturers have worked on a number of U.S. NEMA standards to improve the safety of multidetector CT equipment, including CT Dose Check, Access Controls, and user information for CT systems. While some of these safety features have already been incorporated into the IEC standard, access controls and the user information recommendations have not. How should FDA approach these types of safety features and requirements which are contained in NEMA standards but are not included in an FDA performance standard?

2. In 2012, FDA received public comments on recommendations to address concerns for imaging of pediatric patients. The IEC CT committee is currently working on one of the top identified priorities, a standard to include size-specific dose estimates to better report dose for patients of all sizes. Are there other specific recommendations to address pediatric safety concerns that should be considered for multidetector or CBCT systems, and if so what would you recommend?

3. The IEC standard for multidetector CT (IEC 60601-2-44) includes a significant safety feature—radiation dose structured reporting--that allows for tracking dose for facility quality assurance. The IEC standard covering dental CBCT does not contain such a requirement. FDA performance standards for CT do not currently require structured dose reporting. How does TEPRSSC recommend that FDA ensure that such reporting and other radiation safety features are available in all CT products?

References:

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Cone-beam CT

What is the product?

Cone-beam CT (CBCT) is a means of capturing and displaying volumetric x-ray data using a methodology that is similar to that for conventional CT. Conventional CT systems employ a fan-shaped beam that is scanned along the patient length. These systems are routinely characterized by the acquisition slice thickness and the number of simultaneous channels of data acquired per gantry rotation.

In CBCT the concept of beam slice thickness and number of detector channels simultaneously acquired do not apply. A very broad beam is employed, of sufficient breadth to entirely encompass the anatomy of interest without the need to scan along the patient. A single rotation of the CT gantry is sufficient to collect the entire set of imaging data. [1]

CBCT is now available either as an add-on feature for certain fluoroscopic systems or as a stand-alone, dedicated device. [2,3] As dedicated systems, CBCT devices are finding widespread use in dentistry as well as with ENT and extremity imaging. There were an estimated 20 manufacturers of CBCT equipment in the U.S., Japan, Korea and several European countries in 2013.[4] A more recent estimate by FDA found there to be approximately 25 such manufacturers with devices available in the U.S.[5] The FDA website includes a page that provides information on dental CBCT equipment for patients, dental professionals, and manufacturers. [6]

This summary is directed at dedicated CBCT systems such as those indicated for use in dental or ENT practices, or for imaging of specific anatomical areas such as the extremities. These devices are classified as medical devices by FDA as CT devices under 21 CFR 892.1750 and are also regulated as electronic products under 21 CFR 1020.33. Devices such as fluoroscopic equipment that provide a means for acquiring CT images via a CBCT-like mode of operation are usually classified according to their primary mode of x-ray operation.

What are FDA's electronic product regulatory challenges regarding CBCT?

The federal performance standard defines Computed Tomography in 1020.30 as follows:

"Computed Tomography (CT) means the production of a tomogram by the acquisition and computer processing of x-ray transmission data."

Therefore, although as compared to conventional CT scanners, CBCT devices have a notably different means by which tomographic data are acquired, the scope of this definition of computed tomography includes new CBCT equipment and the associated performance standards specified under 1020.33 are applicable to these devices.

The federal performance standards for CT equipment (1020.33) provide requirements, many of which are not applicable to new CBCT equipment. These requirements include:

- CTDI--the specific dose metric for CT equipment--is defined for conventional, narrow-beam CT scanners under 1020.33(b)(1). This means for measuring and specifying CT dose is not applicable to most new CBCT devices.

- Specification of a specific dosimetry phantom—the particular phantom specified under 1020.33(b)(6) is specific to the measurement of CTDI as defined in the federal standard.

- Labeling requirements—include providing dose information to users, including values for CTDI and dose profile for nominal slice thicknesses. Manufacturers are also required to specify a Quality Assurance program and phantom for assessment of image quality.

The federal performance requirement (1020.33) that specifies the use of the dose metric CTDI was intended for narrow-beam, conventional CT systems that are used to image the head and body. These units have a well-defined tomographic slice thickness or beam collimation (referred to as nT in 1020.33) for each scanning configuration, and acquire data via the translation of the patient through the CT gantry bore. New CBCT devices do not specify a beam width as intended in the performance standard. The CT phantom specified in the federal performance standard was also intended for older, narrow-beam geometry. These two specifications in the federal performance standard are therefore problematic for application to new CBCT systems. Currently, CBCT manufacturers request variances for parts of 21 CFR 1020.33 that do not apply to their systems.

FDA's challenges are therefore the following:

1. To develop a clear definition of CBCT equipment intended for regulatory classification.
2. To review and consider regulatory approaches to ensuring these devices are safe and perform acceptably for their intended use, including both dosimetry and image quality issues.

What would FDA like to do, and why?

To ensure public safety, FDA develops and enforces performance standards for these products to ensure they perform safely. However the lack of a clear electronic product performance standard that addresses all the unique aspects of this technology forces FDA to seek alternative means to assess their performance. Recognized international standards such as those published by the International Electrotechnical Commission (IEC) are often consulted, and are used by device manufacturers as a means of establishing safe and effective device performance. (Note that IEC 60601-2-63 includes CBCT devices explicitly in its scope.)

Certain types of medical x-ray imaging equipment that operate in a DICOM-compliant environment can be configured to provide a means for capturing essential dose-related information as a distinct record. This

DICOM feature, called *Radiation Dose Structured Report* (RDSR), reports the dosimetric output of x-ray devices (it does NOT report patient dose values). Although not a requirement in the federal performance standard, RDSR is a requirement for the IEC standard applying to multidetector CT systems (IEC 60601-2-44); currently, IEC 60601-2-63 does not include a requirement for RDSR for CBCT. An RDSR on a specific device could capture all data required to assess patient dose. When a standard dose metric for CBCT devices becomes recognized and accepted by the imaging community, this metric could also become a part of the RDSR record. ICRP recommended, in Publication 129, that equipment used for both fluoroscopy and CBCT include the capture of imaging data via a RDSR. (1) A DICOM working group (WG 28) is also working on RDSR for CBCT. [7]

While the current performance standard for CT equipment (1020.33) does not specify acceptable imaging performance, it does require that imaging performance data be provided to end users in product labeling documents. However, the imaging performance parameters specified in 1020.33 are specific to conventional CT equipment (e.g., specification of nominal tomographic slice thicknesses and the associated modulation transfer functions (MTF) for those thicknesses [see 1020.33(c)(3), *Imaging Performance Information*]). The Agency believes that a similar approach can be taken to provide imaging information to users of CBCT equipment.

What regulatory actions does the panel recommend to FDA regarding CBCT, specifically:

1. How would you recommend defining CBCT equipment in order that FDA could proceed to specify standards that apply to these devices?

2. Should FDA develop standards that include the specification of image quality and dosimetry metrics specific to CBCT? If so, should FDA require their inclusion with device labeling as currently is done for conventional CT equipment in 21 CFR 1020.33? (Note: 21 CFR 1020.33 is currently applied to CBCT.)

3. Are there specific pediatric safety concerns that should be included in standards for CBCT equipment?

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3) Radiography & Fluoroscopy

What is the product?

Radiographic x-ray systems produce two-dimensional images of the body's internal structures. X-rays are produced by an x-ray tube, pass through the desired portion of the body, are partially absorbed by the body, and reach an image receptor. The varying intensities of x-rays which exit the body are reflective of the composition and densities of the body structures. Radiographic exams routinely consist of a small number of individual images.

Historically, radiographic x-ray systems used x-ray film as the image receptor. Increasingly, film is being replaced by digital image receptors which can be reused many times and offer many imaging performance improvements. Third-party manufacturers have introduced devices consisting of a digital image receptor and associated software to allow an x-ray film system to be "upgraded" with a digital image receptor. Digital systems may take over functions from the existing x-ray system such as user input of x-ray settings, initiating the exposure (exposure switch), and terminating an exposure once adequate radiation has been received at the image receptor.

A hand-held x-ray system is a radiographic system which is portable and handheld. This type of device can be used for dental procedures and imaging extremities. Hand-held x-ray systems have unique concerns related to operator safety that can be addressed through shielding and labeling safety requirements.

Fluoroscopic x-ray systems employ the same basic concepts of image production as other radiographic x-ray systems. However, fluoroscopic systems produce these images repeatedly and in real time. This produces real-time images of the structures and contents of the in motion. Fluoroscopic x-ray systems can also be used to image materials and devices that are placed in the body during clinical procedures. These include, but are not limited to, imaging an ingested liquid as it passes through the digestive tract and monitoring the location of devices such as biopsy needles and instruments such as catheters, stents, blood clot filters, and other devices as they are moved through the vascular system. Fluoroscopic procedures can vary greatly in duration from a few seconds to minutes or even hours of x-ray exposure depending on the complexity of the procedure.

What are our concerns?

X-ray dose: Exposure to x-rays in high doses is known to cause direct tissue damage such as cataracts, skin damage, and hair loss, as well as long term effects including an increased risk of cancer. These risks increase as the x-ray dose increases. FDA is concerned that existing technologies that may reduce the amount of x-ray radiation necessary for an exam are not present in all new x-ray systems. In addition, FDA is concerned with potential x-ray exposure to the operator from leakage and backscatter radiation, which is of special concern for handheld x-ray devices.

Image Quality and Reliability: X-ray systems require continual monitoring, testing, and adjustment in order to maintain consistent imaging performance. This testing requires specialized knowledge and tools as well as access to system settings that are not always available to the system owner. Also, with the introduction of add-on (third party) digital image receptor systems, questions arise regarding their compatibility with the existing x-ray system due to non-standardized integration methods. The installation of upgraded/replacement components may require modifications such as disabling safety features, splicing wires, or altering printed circuit boards. This raises concerns that these modifications may inadvertently decrease the imaging performance or reliability of the x-ray system leading to misdiagnosis, unnecessary exposure, and/or delay of treatment.

Evidence to support these concerns

1) NCRP, 2010, Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures, NCRP Report 168.
2) NCRP, 2009, Ionizing Radiation Exposure of the Population of the United States, NCRP Report 160.
3) NCRP, 2003, Radiation Protection in Dentistry, NCRP Report 145.
4) Food and Drug Administration White Paper: Initiative to Reduce Unnecessary Radiation Exposure form Medical Imaging. http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm2007191.htm
5) Food and Drug Administration. Website publication regarding integration of third party components: http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM385149.pdf. Accessed on September 9, 2016.
6) Code of Federal Regulations, Title 21 (Food and Drugs), Part 1020 (Performance Standards for Ionizing Radiation Emitting Products), Sections 1020.30-1020.33.
7) International Standard IEC 60601-1-3, Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment, Edition 2.0, (International Electrotechnical Commission, Geneva, 2008).
8) Suggested State Regulations for the Control of Radiation,(Conference of Radiation Control Program Directors, 2008).
9) Food and Drug Administration Guidance, Radiation Safety Considerations for X-Ray Equipment Designed for Hand-Held Use. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094345.htm
10) Food and Drug Administration webpage: Medical X-ray Imaging. http://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/medicalx-rays/
11) Food and Drug Administration webpage: Fluoroscopy. http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115354.htm

What would FDA like to do, and why?

In addition to several requirements for x-ray systems that were amended in the Performance Standard effective 2006, FDA would like to see many additional features included in radiographic and fluoroscopic x-ray systems:

- Thorough testing and information disclosure of 3rd party integrated components, based on whether the device affects the quantity, quality, or direction of radiation. This information would include disclosing to FDA how electrical and mechanical connections are made and public disclosure of itemized lists of compatible x-ray systems.
- Providing owners with both a User's Manual that includes Quality Control procedures and a testing device (phantom) that can be used with those procedures to obtain reliable and consistent results.
- Access to a "physics mode" in which x-ray settings can be . adjusted manually and independently of each other to facilitate quality control testing.
- Safety features which reduce dose to pediatric patients, who are at higher long term risk for development of cancer as a result of radiation exposure.
- User access controls that permit only specific, qualified personnel to access and change certain system settings affecting dose.
- Clear information in the User's Manual on parameters affecting image quality and radiation dose.
- Standardized quality control testing procedures by device type to eliminate different testing procedures across multiple manufacturers and models.

- Size specific presets (S, M, L) of x-ray settings (or automatic exposure control) to improve radiation use when imaging pediatric patients.
- Skin dose mapping that tracks absorbed dose to individual regions of the skin during interventional fluoroscopy procedures in order to help physicians avoid or minimize radiation-induced skin injuries from complex, lengthy procedures.
- Radiation Dose Structured Report (RDSR) that outputs information in a standardized format to aid in patient and facility dose tracking.

There are a number of regulations, consensus safety standards, and radiation protection guidelines governing the performance and use of diagnostic x-ray equipment. States regulate the use of x-ray equipment under their own regulations, often based on the *Suggested State Regulations for the Control of Radiation*, published by the Conference of Radiation Control Program Directors (CRCPD). However, there is no performance standard specific to hand-held x-ray units. FDA would like to see safety procedures provided to the end user to promote safe use of hand-held x-ray equipment and development of a performance standard for hand-held x-ray systems that includes certain requirements:

- Shield the unit housing as required by the Federal standard.
- Identify necessary safety precautions as required by the Federal standard.
- Provide external shielding or a means to increase distance between the operator and the unit.
- Measure typical exposures near and around the unit.

Questions for TEPRSSC

1. What is your opinion of the value of requiring manufacturers to include a QC phantom with radiographic and/or fluoroscopic x-ray systems (similar to CT) as standard equipment?

2. What is the committee's opinion on including the features proposed above for radiography and fluoroscopy systems in a performance standard?

3. Are there additional safety improvements that should be pursued for radiography and fluoroscopy?

4. What information is necessary to ensure adequate integration of third-party components? Should third-party component integration issues be addressed in a performance standard?

5. What is the committee's opinion of the importance of regulating hand-held x-ray systems through a specific performance standard? Does the committee have any additional concerns with the use of hand-held devices?

6. Should FDA include requirements for structured dose reports (RDSRs) for all imaging equipment (radiographic, fluoroscopic, CT, and dental CBCT) in performance standards?

4) Diagnostic and Therapeutic Ultrasound

What are the products?

FDA's regulatory authority over radiation emitting electronic products includes products that emit acoustic radiation. The table below, from 21 CFR 1002.1, displays the reporting requirements for four categories of acoustic products: ultrasonic therapy, diagnostic ultrasound, medical ultrasound other than therapy or diagnostic, and nonmedical ultrasound. 21 CFR 1050 is the performance standard category for sonic, infrasonic, and ultrasound radiation emitting products.

	Manufacturer						Dealer & Distributor
Products	**Product reports 1002.10**	**Supplemental reports 1002.11**	**Abbreviated reports 1002.12**	**Annual reports 1002.13**	**Test records 1002.30(a)**	**Distribution records 1002.30(b)**	**Distribution records 1002.40 and 1002.41**
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				

Ultrasonic therapy
There is only one performance standard for ultrasonic therapy products, 21 CFR 1050.10, which as specified in 21 CFR 1050.10(a) is only applicable to ultrasonic therapy products for use in physical therapy. Physical therapy products, also known as diathermy products, are intended to deliver gentle therapeutic heat to tissues. Ultrasonic diathermy devices are capable of heating deep tissue to a therapeutic temperature range of 40-45°C for treatment of pain, muscle spasms, and joint contractures. While ultrasonic diathermy devices are typically used only for physical therapy purposes, they can also be used in combination with radiation treatment protocols.

Diagnostic Ultrasound
Diagnostic ultrasound uses high frequency sound waves for real-time visualization of structures inside the body. Diagnostic ultrasound systems can provide greyscale images of most soft tissues, such as the liver, heart, musculoskeletal structures, and other organs and structures. Diagnostic ultrasound in combination with doppler ultrasound can be used to visualize blood flow. Doppler fetal heart rate monitors are used to monitor the fetus. Bone sonometry is utilized to assess bone fragility. Diagnostic ultrasound products have a long history of safe use dating back to the 1940s.

Medical ultrasound other than therapy or diagnostic
Medical ultrasound other than therapy or diagnostic includes high intensity ultrasound devices for therapies other than diathermy and physical therapy. These include devices that use high intensity ultrasound energy that is focused to ablate tissue. High intensity ultrasound devices are used for treatment of cancer such as

prostate tumors as well as treatment of benign tumors such as symptomatic uterine leiomyomas (fibroids). Therapeutic ultrasound devices that use high intensity focused ultrasound to ablate diseased tissue include risk mitigations to prevent ablating non-target tissues.

Nonmedical ultrasound
Nonmedical ultrasound includes a variety of products, such as pest repellants, industrial cleaning systems, and distance sensors used in cars. Pest repellants use high frequency sound waves (> 20 kHz) which humans are unable to hear to repel animals capable of hearing high frequencies. In industrial cleaning systems, sound waves cause cavitation (bubble formation) in a cleaning solvent (e.g., water) to aid cleaning. The ultrasonic sensor in ultrasonic distance locators generate and detect the echo of high frequency sound waves. The length of time between the sound pulse and of the echo from an object is used to calculate the distance of the object from the sensor.

What are our concerns?

Medical ultrasound
Ultrasound energy has the potential to produce biological effects such as heating the tissue or creating bubbles in body fluids or tissue (cavitation). Safety issues are considered during the premarket review of the safety and effectiveness of these as medical devices.

Nonmedical ultrasound
FDA has received only received a few adverse event reports for these products.

What are FDA's current approaches?

Medical ultrasound
The safety profile of medical ultrasound products is considered acceptable when they are operated for their intended uses by trained professionals who follow the manufacturer's labeling. Safety issues have been and will continue to be handled through medical device premarket regulatory processes as well as under other medical device regulatory authorities.

Since February 24, 1986, under the authority of 21 CFR 1002.50(b), FDA has exempted all manufacturers and importers of diagnostic ultrasound products from EPRC initial and model change report requirements under 21 CFR 1002.10 and 1002.12 if they have submitted a premarket notification (510(k)) as required by the medical device regulations. [http://www.fda.gov/downloads/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/ucm509874.pdf]

Nonmedical ultrasound
There is minimal benefit to the receipt and review of the abbreviated reports given the lack of performance standards for nonmedical ultrasound and the limited evidence of safety concerns.

What would FDA like to do, and why?

FDA would like to update the reporting requirements under 21 CFR 1002.1 to no longer require product reports, supplemental reports, abbreviated reports, annual reports, test records, or distribution records for medical and nonmedical acoustic products. FDA believes the current reporting requirements and performance standard is an unnecessary burden and a source of confusion for these products. The reporting is redundant to

medical device premarket submissions and there is no nonmedical performance standard to consider for reviewing nonmedical reports.

FDA believes that the performance standard in 21 CFR 1050.10 is outdated compared with more recently published guidance documents and standards. For this and other medical ultrasonic products, FDA proposes to continue to rely on the premarket review of safety and effectiveness based on guidance documents and recognized consensus standards. The premarket medical device review allows an in-depth review of the safety and effectiveness of the design, labeling, and performance.

A disadvantage to eliminating EPRC reporting is the inability to track nonmedical ultrasound products, but we have received very few adverse event reports for these types of commercial devices and don't have evidence to support continued tracking.

Nonmedical and medical ultrasound devices would still be required to make certain reports under the following regulations: CFR 1002.20 (Reporting of Accidental Radiation Occurrences), 21 CFR 1003 (Notification of Defects or Failure to Comply), and 1004 (Repurchase, Repair, or Replacement of Electronic Products).

Questions for TEPRSSC

1. What is the committee's opinion of the strategy of relying on medical device premarket reviews to address safety concerns with medical ultrasound devices and no longer requiring the EPRC product report monitoring specified in 21 CFR 1002.1 and performance standard?

2. Is the committee aware of any nonmedical ultrasound device safety concerns that warrant continuing the EPRC requirement for abbreviated product reports for nonmedical ultrasound?

5) IEC Standards vs. Performance Standards for Medical Devices

The Electronic Product Radiation Control (EPRC) regulations are aimed at protecting the public from hazardous and unnecessary exposure to radiation from electronic products. FDA has identified nine types of electronic products, including diagnostic x-ray systems and their major components, and established mandatory performance standards for those products to control radiation. The Agency is proposing to accept conformance to applicable international consensus standards in place of conformance to certain FDA performance standards for diagnostic x-ray systems and their major components. FDA believes conformance to applicable International Electrotechnical Commission (IEC) standards would provide the same level of or improved protection of the public health and safety from electronic radiation as certain EPRC performance standards.

FDA EPRC Performance Standards for Diagnostic X-ray Systems

The performance standards for diagnostic x-ray systems and their major components, Radiographic Equipment, Fluoroscopic Equipment, and Computed Tomography (CT) equipment are listed in 21 CFR 1020.30, 1020.31, 1020.32, and 1020.33 respectively. These performance standards address aspects of radiation safety including control and indication of technique factors, reproducibility of technique factors, visual definition of the x-ray field, field alignment, source to skin distance, display of air kerma rates (AKR), Computed Tomography Dose Index (CTDI), information to be provided in the product labeling, and warning statements that must accompany the product. Historically, the EPRC performance standards for these products have been updated infrequently. For example, the performance standard for Computed Tomography Systems was last updated in the 1980's. Despite being outdated, the performance standards remain a requirement for diagnostic x-ray systems sold in the United States.

International Consensus Standards

International standards organizations also develop standards for diagnostic x-ray systems that address radiation safety. The IEC publishes safety and essential performance standards for various types of x-ray equipment. These particular standards build on a general standard for medical electrical equipment safety and essential performance and collateral standards that cover topics such as electromagnetic disturbances and radiation safety. The particular standards build on the general and collateral standards by adding or replacing requirements specific to that particular device type. The IEC standards are consensus standards, with a large international group of stakeholders participating in their development including industry, academia, end users and often FDA. IEC standards are also usually reviewed every five years to determine if updates are necessary.

Comparison of FDA and International Consensus Standards for Diagnostic X-ray Systems

There are several ways in which conformance to relevant IEC standards can offer improvements in safety and performance as compared to FDA EPRC performance standards. For example, the IEC standards are more comprehensive than the FDA performance standards. While the FDA performance standards focus on radiation safety, the IEC standards for particular devices also include other aspects of device safety and performance, including protection against mechanical, electrical and thermal hazards. The IEC standards are also updated more frequently than the FDA performance standards. The higher frequency of updates to the IEC standards enables them to address advances in technology and features that are not included in previous

editions relatively quickly. This results in a standard that is more up-to-date than the FDA performance standards in many aspects. The IEC standards also include direct input from a broader group of stakeholders than the FDA performance standards. This broader group has more breadth and depth of experience than FDA, resulting in standards that are more likely to address up-to-date real-world performance and safety.

The Use of Consensus Standards at FDA and Other Regulatory Bodies

IEC standards are currently used in the regulatory framework of the FDA and European Medical Device Authorities. The FDA incorporates standards into the US regulatory framework through a standards recognition program. Once a consensus standard has been published, it can be recognized in whole or in part by FDA. Conformance to an FDA recognized standard can then be used by a manufacturer voluntarily to streamline regulatory review for medical device premarket submissions. As part of this program, FDA staff participates in the development of relevant IEC standards. In the European Union and China, medical device manufacturers are required to manufacture their devices so that they conform to relevant IEC standards.

FDA Proposal

In August 2016 FDA published draft guidance proposing to accept conformance to applicable IEC standards in place of conformance to certain FDA performance standards for diagnostic x-ray systems and their major components in 21 CFR 1020.30, 120.31, 1020.32, and 1020.33. FDA made this proposal because the Agency believes conformance to applicable IEC standards would provide the same level of or improved protection of the public health and safety from electronic radiation as compared to certain EPRC performance standards. In particular, IEC standards are more comprehensive and up-to date than FDA's performance standards. Additionally, FDA's participation in the development of IEC standards and its authority to recognize standards in whole or in part gives the agency the ability to ensure that FDA-recognized IEC standards maintain or improve protection of the public health and safety from electronic radiation. FDA is requesting feedback on this approach to performance standards for electronic products.

Questions for TEPRSSC

1. What benefits and challenges do you see in the proposal to accept conformance and declaration of conformity to applicable recognized IEC standards in lieu of conformance to FDA performance standards and FDA product reporting requirements?

2. How do these benefits and challenges change if the policy to accept conformance to IEC standards were implemented as a mandatory requirement instead of as an option for manufacturers?

3. There are other electronic products that are also medical devices but don't have EPRC performance standards (e.g., MRI systems). If these products have IEC standards for safety and performance, how should FDA approach the implementation of new performance standards?