Brief Summary of the Technical Electronic Product Radiation Safety Standards Committee Meeting – October 25-26, 2016

Introduction:

The Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) met on October 25-26, 2016.

The general function of the committee is to provide advice and recommendations to the Agency 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 Agency for consideration.

On October 25, 2016, the committee discussed and made recommendations regarding possible FDA performance standards for the following topics: Radiofrequency (RF) radiation products, such as microwave ovens and wireless power transfer; laser products, including an update to amendments to the laser rule, light detection and ranging (LIDAR), laser data (Light Fidelity-LiFi)/energy transfer, illumination applications and infrared applications; sunlamp products including an update on the performance standards amendments; and noncoherent light sources (e.g., LEDs and UVC lamps) including new initiatives.

On October 26, 2016, the committee discussed and made recommendations regarding possible FDA performance standards for the following topics: International Electrotechnical Commission (IEC) standards versus performance standards for medical devices; computed tomography (CT); radiography and fluoroscopy; diagnostic and therapeutic ultrasound; and radiation therapy.

The following presentations/discussions were given:

1. TEPRSSC: Scope and History

   The Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) 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. Some, but not all, medical devices are also electronic products, and are regulated as both medical devices and electronic products. At the 2016 TEPRSSC meeting, the committee considered questions related to a wide variety of electronic products, including electronic product radiation control-related issues associated with electronic products that are medical devices.

2. RF Radiation Products (Microwave Ovens and Wireless Power Transfer)

   FDA presented on an issue with the microwave oven performance standard that may need adjustment regarding the requirement related to wire insertion leading to excessive emissions and elimination of the appearance of microwave generation with the door open due to a failure. The committee was split regarding wire insertion with suggestions ranging from making the requirement contingent only on the possibility of wire insertion to a recommendation that the requirement should be eliminated because it is no longer relevant with current

technology. The committee was supportive of FDA's proposed revisions to require open door operation to be unambiguous regarding the possibility of microwave generation. FDA also presented on wireless power transfer as an emerging product area that is capable of charging battery-powered products from mobile phones to electric cars. FDA is interested in gathering information about these products to evaluate their safety profile and regulatory environment. The committee concurred that FDA should monitor this product area for safety concerns.

3. Laser Products

   Updates, safety concerns and proposed solutions were presented to the committee regarding the amendments to the performance standard for laser products, light detection and ranging (LIDAR) systems, remotely controlled mobile laser systems, laser pointers, laser lamps, laser illuminated projectors (LIPs), and infrared surveillance systems. There was significant discussion about the best approach to reduce risks associated with laser pointers. There was also discussion related to the safety concerns and engineering controls for LIPs. Members of the committee generally agreed with FDA's proposals, while also raising concerns that FDA should note for further consideration.

4. Sunlamp Products—Performance Standard Amendments Update and Non-Coherent Light Sources—New Initiatives

   FDA provided the committee with an update on the proposed amendments to the sunlamp performance standard and changes under the device medical authority. FDA did not present specific questions, but in response to public speakers, several committee members expressed that the topic was important and that FDA should pay close attention to the most recent and relevant science. FDA presented concerns related to light emitting diodes (LED) that include blue light hazard; disruption of circadian rhythm; glare and chronic, low-dose exposures; and UVC lamps that include erythema, photokeratitus, DNA damage and ozone production and requested input from the committee. There was general discussion by the committee regarding support for FDA's concerns.

5. Radiation Therapy

   FDA presented background information on radiation therapy systems that fall under EPRC (Electronic Product Radiation Control) regulations, related IEC standards. FDA sought comments from the committee on establishing performance standards for electronic products used for radiation therapy. Generally, the committee was aware of the significant safety risks posed by the products, and was supportive of FDA's involvement in the product review and consensus standards.

6. Computed Tomography

   FDA discussed regulation of CT and cone-beam CT (CBCT) equipment under the performance standard 21 CFR 1020.33, last updated in 1985. FDA noted that new safety issues created by subsequent changes in CT usage and technology (including the emergence of CBCT) have rendered the performance standard obsolete. FDA proposed the use of voluntary consensus standards, rather than updating the performance standard for these products. The committee discussed potential ramifications of such a change and provided additional recommendations for FDA consideration, including an emphasis on the importance of addressing pediatric imaging concerns.

7. Radiography & Fluoroscopy

   FDA presented the Agency's current thinking regarding the regulation of radiography and fluoroscopy equipment under 21 CFR 1020.30, 1020.31, and 1020.32. Particular topics that were presented include additional possible equipment standards to address misuse and unnecessary radiation exposure, including additional quality control information for the end user, size specific protocols for imaging patients of varying sizes, sufficient shielding for hand-held x-ray units, adequate integration information for 3rd party components, and implementation of Radiation Dose Structured Reports (RDSR). In addition to supporting FDA's specific proposals, the committee suggested that FDA work with the states (such as CRCPD and AAPM end users) to address issues related to access to consensus standards and QC recommendations that do not conflict with the states. The committee also recommended focusing on devices/features that represent the greatest risk of harm which probably requires first focusing on accurate and consistent dose reporting, and support for size-based pediatric protocol requirements.

8. Diagnostic and Therapeutic Ultrasound

   FDA presented the Agency's current policy for EPRC reporting requirements under 21 CFR 1002.1 for medical and nonmedical ultrasound products and informed the committee about 21 CFR 1050.10, the sole performance standard for ultrasonic therapy products for use in physical therapy. FDA asked the committee's opinion about relying on medical device premarket reviews to address safety concerns with medical ultrasound devices if the agency no longer required EPRC product report monitoring. FDA also asked if the committee was aware of any nonmedical ultrasound device safety concerns that warrant continuing the EPRC requirement for abbreviated product reports. Members of the committee were cautiously fine with the proposed approach; however, FDA must continue reviewing the safety of these devices during premarket review process. Regarding abbreviated reporting of nonmedical products, some members agreed there may not be value in the receipt and review of these reports.

9. IEC Standards vs. Performance Standards for Medical Devices

   FDA proposed accepting conformance with IEC standards in lieu of conformance to certain EPRC performance standards for diagnostic x-ray systems (21 CFR 1020.30-1020.33). FDA would consider a manufacturer that submits a declaration of conformity to applicable IEC standards to have met certain EPRC performance standards and reporting requirements. FDA proposed that conformance to these standards would provide the same or improved protection of public health and safety as EPRC performance standards. The committee supported FDA's proposal to accept conformance with IEC standards in lieu of conformance to certain EPRC performance standards as practical to the current regulatory environment with some reservations and recommendations to ensure the needs of all stakeholders were addressed.

Public Speakers

The following Open Public Speakers attended the meeting: Jim Shepherd, on behalf of Sperti Sunlamps; Alan Miller, on behalf of Palm Beach Tan; Dr. Frank Richarz, on behalf of JK Holdings and KBL; Sonali

Gunawardhana and Jerome E. Dennis on behalf of the Laser Illuminated Projector Association; Sarah E McKenney and Alan B. Cohen on behalf of the American Association of Physicists in Medicine (AAPM); Jamie Wolzon and Stan Mansfield on behalf of Advamed; Alan B. Cohen on behalf of himself; Megan A. Hayes on behalf of Medical Imaging & Technology Alliance (MITA); and Elisabeth George on behalf of Phillips Medical Systems.

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