Partial Amendment to the 'Interpretation on the Range, etc. of Electrical Appliances and Materials (Outlines)

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1. Current Regulatory Status

Direct current power supply units are designated as specified electrical appliances and materials under the Electrical Appliances and Material Safety Act (Law No.234 of 1961), which was established aiming at preventing hazards and accidents generated by electrical appliances. Under the law, name of manufacturers/importers must be notified to the regulatory agency, units are subject to inspections and must be in conformity with the designated technical criteria, conformity assessments by registered inspection agencies and attachment of a PSE mark, etc.

On the other hand, the Pharmaceutical and Medical Device Act (Law No. 145 of 1960, hereinafter referred to as PMD Act) (Note) regulates medical electrical equipment by requiring governmental approvals for market authorization, approvals for manufacturing business, obtaining approvals of specially controlled medical devices by the minister of MHLW, certification of controlled medical devices by a 3rd party certification body, or notification of general medical devices to the minister of MHLW, and prohibiting sale and manufacture of devices that fail to meet the criteria designated in order to ensure appropriate property, quality and performance of them.

As electric/electronic technologies advance, medical electrical equipment have been more functional and efficient as well as smaller in size and lighter in weight. More medical electrical equipment have a separate direct current power unit, because the unit tends to relatively large and heavy. A direct current power supply unit, designed and manufactured for integrated use as medical electrical equipment is considered as a part of the medical electrical equipment and is regulated under PMD Act.

(Note) After a law to partially amend the Pharmaceutical Affairs Act (Law No. 84 of 2013) was established and has been in effective since November 25, 2014, the former Pharmaceutical Affairs Act was renamed as PMD Act.

2. Demand for a Regulatory Reform

A meeting of the Council for Regulatory Reform established in January 2013 took up safety of parts used for medical electrical equipment (i.e. AC adapters, etc.) doubly checked by the Pharmaceutical Affairs Act and the Electrical Appliances and Material Safety Act. After a report on the subject was issued on June 5, 2013, the following sentence was added to an action plan on regulatory reform which was resolved at a cabinet meeting on June 14: 'For parts (AC adapters, etc.), used for electrically driven medical devices, omission of necessary inspections required under the Electrical Appliances and Material Safety Act will be considered, provided that they meet at least the same level of electric safety required by certification and approval under the Pharmaceutical Affairs Act and the same level of qualification procedures as required by the Electrical Appliances and Material Safety Act .'

3. Assuring Electric Safety under the Pharmaceutical Affairs Act (PMD Act)

PMD Act requires to demonstrate compliance with JIS T 0601-1 (Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance) for approval of specially controlled medical devices, etc., and certification of controlled medical devices. This is a JIS standard made by combining an international standard designated for each medical electrical equipment and requirements peculiar to Japan and is the same as or at least in the similar category as those listed in Annex 12 of 'Interpretation of the Ordinance related to Technical Criteria of Electrical Appliances (No.3 dated June 5, 2013 of Commerce and Information Policy Bureau),' to be deemed as meeting technical criteria stipulated in the 'ordinance on designating technical criteria for electrical appliances' (METI Ordinance No. 34 in 2013)

4. Action Policy

The criteria (standard) applied by PMD Act for securing safety of medical electrical equipment are the same or in the same category as the criteria (standard) employed by the Electrical Appliances and Material Safety Act and compliance with the stipulation of the former Act ensures at least the same level of safety under the latter Act. The procedures for approval of specially controlled medical devices, etc. or certification of controlled medical devices required by PMD Act are at least in the same level as those applied to specified electrical appliances and materials under the Electrical Appliances and Material Safety Act, considering the relatively rigid regulatory structure of the Act.

As such, direct current power supply units designed and manufactured for integrated use as specially controlled medical devices and controlled medical devices will be excluded from the application of Electrical Appliances and Material Safety Act. Accordingly, 'Interpretation on the Range, etc. of

Electrical Appliances and Materials (No.1 dated March 21, 2012 of Commerce and Information Policy Bureau)' has been amended appropriately.