IMDRF International Medical Device Regulators Forum

Final Document

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Title: Statement regarding Use of ISO 11137-1:2006 "Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices"

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Use of ISO 11137-1:2006 "Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices" in each jurisdiction

Australia Therapeutic Goods Administration (TGA)	*Therapeutics Goods (Manufacturing Principles), Determination No. 1 of 2013, MP1/2013* requires medical devices labelled 'Sterile' to be manufactured in accordance with EN 556. For terminally sterilized medical devices, EN 556, Part 1 applies (i.e. an SAL of 10^{-6} is required). The TGA's non-mandatory *Medical Devices Standards Order (Standards for medical devices required to be sterile)*, 2008 (MDSO) specifies ISO 11137-1:2006 as a standard for the purpose of deeming compliance with *Medical Devices Essential Principle Checklist*, sub clause 8.3(3) - *Medical devices to be supplied in a sterile state*. The TGA can accept an alternative approach to a radiation sterilization process provided it is at least equivalent to ISO 11137-1. The TGA adopts the same approach to ISO 11137-2 and ISO 11137-3 as the other applicable parts of the radiation sterilization suite of standards as listed in the MDSO.
Brazil National Health Surveillance Agency (ANVISA)	Special processes (e.g., sterilization) must be validated according to preset standards. Companies must periodically check their processes and establish the frequency of revalidation, when applicable, according to requirements 5.5.1 and 5.5.3 of Anvisa Resolution RDC 16/2013. ISO 13485:2003 has the same requirements for sterile products. The Brazilian pharmacopeia has established that, in case the process of sterilization is consistent and has been validated, it may provide precise information for the approval of products which undergo terminal sterilization. ISO 11137-1:2006 may be used as a technical guide for sterile medical devices.
Canada Health Canada (HC)	In Canada, conformance to specific standards is not mandatory. However, evidence of conformity to recognised standards can be submitted to demonstrate that specific requirements of the Medical Devices Regulations have been met. HC publishes a list of recognised standards, and the level of evidence expected is "equivalent or better" to these recognised standards. ISO 11137-1:2006 is currently a recognised standard. Health Canada relies on this standard in the assessment of irradiation sterilization validations.
China China Food and Drug Administration (CFDA)	CFDA just translated the ISO11137:1995 into china national standard GB 18280-2000 equally and the standard are waiting for the approval by Standardization Administration of the People's Republic of China(SAC), So it isn't implemented in china till it will

	be approved by SAC.
Europe European Commission (EC)	The corresponding European standard EN ISO 11137-1:2006, is a harmonized standard which provides presumption of conformity with the legal requirements regarding appropriate design and manufacturing procedures and validated method for device sterilization. The use of this standard (to the extent specified in its Annex ZZ) provides one solution for compliance with the relevant legal requirements. Compliance with the legal requirements can however be ensured also by other means.
Japan Ministry of Health, Labour and Welfare (MHLW) Pharmaceuticals and Medical Devices Agency (PMDA)	All medical devices are required to satisfy the EPs that align with those defined in GHTF/SG1/N68:2012 *Essential Principles of Safety and Performance of Medical Devices*. ISO 11137-1 can be used for its purpose, especially in case of sterilized medical devices, which is clearly referred to in checklist of EPs or certification/approval standards for each medical device. And validation of sterilization process is required as particular requirements for sterile medical device in the QMS ordinance in Japan, as is the same as ISO13485. The guidance on the standards for its validation issued on 18 December 2014 (No. 1218-4) clearly indicates ISO 11137-1:2006 or equivalent/more strict standards shall be followed.
Russia Russian Ministry of Health Roszdravnadzor	In current regulation using of standards is voluntary in premarket MD evaluation. And Regulator does not recognize any standard which could provide presumption of conformity. But when on the market, some types of MD have to be certified for particular mandatory standards (list of mandatory standards and types of MD is available on Regulator's web site). It should be noted, that this regulation is to be canceled on 01/01/2016.
The United States of America US Food and Drug Administration (US FDA)	ISO 11137-1:2006(R)2010 is recognized by the US FDA medical device program as a consensus standard for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirements to which a standard is applicable. Sterilization is a process that requires validation under 21 CFR §820. US FDA by recognizing ISO 11137-1:2006(R)2010 , allows firms to demonstrate they have validated the radiation sterilization process per the requirements outlined in the standard. ISO 11137 is broken into 3 parts. US FDA also recognizes, Part 2 – Establishing the Sterilization Dose, and Part 3 – Guidance on Dosimetric Aspects which are referenced in Part 1 of the standard.