WHO Technical Specifications for Medical Devices

Objectives
In developing countries there is a significant need for counseling regarding minimum specifications and requirements that should be considered before starting a process of purchase or donation of medical devices. Having this type of specification allows to improve access to medical devices of high quality, safety and efficacy, as well as planning adequately the financial, human and legal resources, among others, to be considered in the implementation, functioning and decommissioning of the devices.

Since early 2011, WHO in collaboration with a working group of experts, has been developing a global template that applies to all types of medical devices, and have started a pilot test developing 70 specifications for different kind of devices.

WHOA 60.29, 2007: “to work with interested Member States and WHO collaborating centres on the development, in a transparent and evidence-based way, of guidelines and tools, including norms, standards and a standardized glossary of definitions relating to health technologies in particular medical devices,”

Example of WHO technical specification (X-ray Imaging System)

Main categories, WHO template

1. NAME, CATEGORY
2. PURPOSE OF USE
3. TECHNICAL CHARACTERISTICS
4. PHYSICAL/CHEMICAL CHARACTERISTICS
5. UTILITY REQUIREMENTS
6. ACCESSORIES, CONSUMABLES, SPARE PARTS AND OTHER COMPONENTS
7. PACKAGING
8. ENVIRONMENTAL REQUIREMENTS
9. TRAINING, INSTALLATION AND UTILISATION
10. WARRANTY AND MAINTENANCE
11. DOCUMENTATION
12. SAFETY AND STANDARDS

Impact of Technical Specifications

Working group on WHO technical specifications:
James ABBAS, USA; Kamel ABDUL RAHIM, JORDAN; Firas ABU-DALOU, JORDAN; Roberto AYALA PERDOMO, MEXICO; Andrew GAMMIE, UK; Niranjan KHAMBETE, INDIA; Nicolas PALLIKARAKIS, GREECE; Mladen POLUTA, SOUTH AFRICA; Didier VALLENS, FRANCE; Alejandra VELEZ, MEXICO

Participants of Consultation for technical specifications for UN Commission for Life saving commodities, 10-12 June in Geneva:
Mr Alusine B. KABIA, SIERRA LEONE; Ms Rehema MARIKI, UNITED REPUBLIC OF TANZANIA; Mr Lovemore MKUKUMA, MALAWI; Mr Valentinio MVANGA, UNITED REPUBLIC OF TANZANIA; Dr Youssouf NDIAO, SENEGAL; Mr Sam. S.B. WANDA, UGANDA; Ms Indira NARAYANAN, USAID (lead convenor); Dr Nagarajan Kartik NAGESH, INDIA; Mr Keith NEROUTSOS, PATH; Mr Steve WALL, Save the Children; Ms Bidia Deperthes, UNFPA; Dr Helene MOLLER, UNICEF; Ms Hayley TRAEGER, UNFPA, Dr Jean Bosco NDIOHUKABYO, WHO Africa regional office

Contact: Laura Alejandra Velez Gaitan (velezruzgaitanla@who.int), Yukiko Nakatani (nakatanay@who.int) and Adriana Velazquez Berumen ( velazquezberumen@who.int) © WHO 2013