تقديم

الهيئة العامة للغذاء والدواء جهة مستقلة الغرض الأساسي لها هو القيام بتنظيم ومراقبة الغذاء والدواء والأجهزة والمنتجات الطبية والتشخيصية، ومن مهامها وضع اللوائح الفنية والمواصفات في مجالات الغذاء والدواء والأجهزة والمنتجات الطبية سواءً كانت مستوردة أو مصنعة محلياً بواسطة لجان فنية متخصصة، وقد قام قطاع الأجهزة والمنتجات الطبية بالهيئة ضمن برنامج عمل الفريق رقم (SFDA/MDS/TC 62) "فريق عمل مواصفات الأجهزة الكهربائية في التطبيقات الطبية" بتبني المواصـــفة الدولية رقم (IEC 80001-1:2010) " تطبيق إدارة الخطر لشبكات الاتصالات وتقنية المعلومات المستخدمة مع الأجهزة الطبية – الجزء الأول: الأدوار والمسؤوليات والأنشطة" ، والتي أصدرتها " المنظمة الدولية الكهروتقنية " وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالمطابقة بلغتها الأصلية وذلك في اجتماع مجلس الإدارة رقم ( ) والذي عقد بتاريخ (../../..14 هـ) الموافق (../../..20 م).

Foreword

Saudi Food and Drug Authority (SFDA) is an independent organization with main purpose of regulating and monitoring of foods, drugs and medical devices. One of SFDA functions is to issue national Standards /Technical Regulation in the fields of foods, drugs and medical devices, whether imported or manufactured locally, through specialized technical committees (TCs).SFDA medical devices sector through the work program of technical committee (SFDA/MDS/TC62) " Electrical equipment in medical practice" has adopted the International Standard No. (IEC 80001-1:2010) "Application of risk management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities" issued by "International electrotechnical Commission "in its original language. This standard is identically adopted in its original language and has been approved as national standard by SFDA board of directors in its meeting No ( ) Held on (../../14..AH), agreed with (../../20..G).

1 Scope

Recognizing that MEDICAL DEVICES are incorporated into IT-NETWORKS to achieve desirable benefits (for example, INTEROPERABILITY), this international standard defines the roles, responsibilities and activities that are necessary for RISK MANAGEMENT of IT-NETWORKS incorporating MEDICAL DEVICES to address SAFETY, EFFECTIVENESS and DATA AND SYSTEM SECURITY (the KEY PROPERTIES). This international standard does not specify acceptable RISK levels.

NOTE 1 The RISK MANAGEMENT activities described in this standard are derived from those in ISO 14971 **Error! Reference source not found.**. The relationship between ISO 14971 and this standard is described in **Error! Reference source not found.**.

This standard applies after a MEDICAL DEVICE has been acquired by a RESPONSIBLE ORGANIZATION and is a candidate for incorporation into an IT-NETWORK.

NOTE 2 This standard does not cover pre-market RISK MANAGEMENT.

This standard applies throughout the life cycle of IT-NETWORKS incorporating MEDICAL DEVICES.

NOTE 3 The life cycle management activities described in this standard are very similar to those of ISO/IEC 20000-2 **Error! Reference source not found.**. The relationship between ISO/IEC 20000-2 and this standard is described in **Error! Reference source not found.**.

This standard applies where there is no single MEDICAL DEVICE manufacturer assuming responsibility for addressing the KEY PROPERTIES of the IT-NETWORK incorporating a MEDICAL DEVICE.

NOTE 4 If a single manufacturer specifies a complete MEDICAL DEVICE that includes a network, the installation or assembly of the MEDICAL DEVICE according to the manufacturer's ACCOMPANYING DOCUMENTS is not subject to the provisions of this standard regardless of who installs or assembles the MEDICAL DEVICE.

NOTE 5 If a single manufacturer specifies a complete MEDICAL DEVICE that includes a network, additions to that MEDICAL DEVICE or modification of the configuration of that MEDICAL DEVICE, other than as specified by the manufacturer, is subject to the provisions of this standard.

This standard applies to RESPONSIBLE ORGANIZATIONS, MEDICAL DEVICE manufacturers and providers of other information technology for the purpose of RISK MANAGEMENT of an IT-NETWORK incorporating MEDICAL DEVICES as specified by the RESPONSIBLE ORGANIZATION.

This standard does not apply to personal use applications where the patient, OPERATOR and RESPONSIBLE ORGANIZATION are one and the same person.

NOTE 6 In cases where a MEDICAL DEVICE is used at home under the supervision or instruction of the provider, that provider is deemed to be the RESPONSIBLE ORGANIZATION. Personal use where the patient acquires and uses a MEDICAL DEVICE without the supervision or instruction of a provider is out of scope of this standard.

This standard does not address regulatory or legal requirements.