MP 54—2012

Miscellaneous Publication

Survey of standards environment for telehealth devices

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PREFACE

This document has been prepared by Sub-committee IT-014-12, Telehealth for Standards Australia Committee IT-014, Health Informatics.

This document assumes some reader familiarity with health informatics knowledge and standards concepts. Given the convergence of information, communication and medical technology in devices (i.e. ‘telehealth’ and ‘telemedicine’ devices) the need for new standards terminology appropriate for future healthcare communication is also assumed but not specifically developed in this document.

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GLOSSARY OF TERMS

Medical device (Australian Regulatory Definition)

A medical device is any material instrument, apparatus, machine implement, contrivance, implant etc., including any component, part or accessory that is used in health care and includes in-vitro diagnostics.

REFERENCE: Australian Government, Department of Health and Ageing, Therapeutic Goods Administration. *Medical device adverse event reporting by medical device users*. http://www.tga.gov.au/docs/html/forms/iris_udir.htm, accessed 19 April 2007.

Medical device

Any instrument, apparatus, appliance, material … including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of … diagnosis, prevention, monitoring, treatment or alleviation of disease…

REFERENCE: ISO 13485, *Quality systems—Medical devices—Particular requirements for the application of ISO 9001*. As cited in 'Developing Software for Medical Devices' ©ResMed 2004 (page 9). http://www.ict.csiro.au/MU/Trends/Presentations/medical_software.pdf

Medical device software

(a) Software used as a component of a medical device.

(b) Software that is a medical device.

(c) Software used in the production of a device.

(d) Software used to manufacture a device.

(e) Software used in the implementation of the quality system.

The key difference for medical device software: Safety.

REFERENCE: General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Jan 2002. cited in 'Developing Software for Medical Devices' ©ResMed 2004 (page 9) http://www.ict.csiro.au/MU/Trends/Presentations/medical_software.pdf

Telehealth

The International Organization for Standardization defines telehealth as the 'use of telecommunication techniques for the purpose of providing telemedicine, medical education, and health education over a distance', while drawing a distinction between this and telemedicine, which is defined as the 'use of advanced telecommunication technologies to exchange health information and provide health care services across geographic, time, social and cultural barriers'.

REFERENCE: ISO/TR 16056:2004, *Interoperability of telehealth systems and networks*, ISO TC 215.

In 1997 the World Health Organization (WHO) in 1997 defined telehealth as 'the delivery of healthcare services, where distance is a critical factor, by healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, and for the continuing education of healthcare providers as well as research and evaluation, all in the interests of advancing health of individuals and their communities'.

REFERENCE: Suleiman, A. *Telemedicine and Telehealth Networks: National Networks*. Presentation at Ann Arbor, 23–25 August 2001.

STANDARDS AUSTRALIA

Miscellaneous Publication

Survey of standards environment for telehealth devices

SECTION 1 OVERVIEW

This project aimed to conduct a survey of the existing standards environments that would affect the further development of standards to apply to devices used for telehealth purposes, and in so doing to identify gaps in the existing standards base. The findings noted in this discussion paper will provide a context for Standards Australia's future development focus in the area of telehealth devices standards activities.

