Invited Speaker

EXPERIENCE GAINED IN APPLYING IEC 80001-1 PRINCIPLES TO A MEDICAL IT NETWORK SUPPORTING A CLINICAL INFORMATION SYSTEM.

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INTRODUCTION

IEC 80001-1:2010 [1] recognises that medical devices are incorporated into IT-networks to achieve desirable benefits1. The standard defines the roles, responsibilities and activities that are necessary for the risk management of IT-networks incorporating medical devices to address safety, effectiveness and data and system security. It applies throughout the life cycle of IT-networks incorporating medical devices and applies to responsible organizations, medical device manufacturers and providers of other information technology. IEC 80001-1:2010 draws on processes set out in ISO 14971:2007 [2] intended to be used by equipment manufacturers to identify hazards associated with medical devices. It also draws on ISO/IEC 20000-1:2011 [3] which specifies the requirements for an IT service provider to meet when implementing an IT service management system.

DISCUSSION

A Process Assessment Model (PAM) based on IEC 80001 has been developed by the Regulated Software Research Centre (RSRC). We used this PAM to review the existing processes used to support the ICU Clinical Information System in the hospital environment which incorporates a complex Medical IT Network and medical devices from a number of vendors. In doing so, we identified where these processes could be improved. We will discuss the difficulties encountered in applying the PAM, to a Hospital setting. We will give examples of where the intent set out in IEC 80001-1 was met within the hospital using processes usually predicated on multidisciplinary management of clinical processes and healthcare technology management. We propose that Clinical Engineers in hospitals can play a significant role in interpreting 80001-1:2010 for the hospital environment and in doing so ensure that Clinical Information Systems are managed appropriately.

1. IEC, IEC 80001-1 - Application of Risk Management for IT-Networks incorporating Medical Devices - Part 1: Roles, responsibilities and activities. 2010, International Electrotechnical Commission: Geneva, Switzerland.

2. ISO, ISO 14971:2007 - Medical Devices - Application of Risk to Medical Devices. 2007, International Organisation for Standardization: Geneva, Switzerland.

3. ISO/IEC, ISO/IEC 20000-1:2011 - Information technology —Service management Part 1: Service management system requirements. 2011: Geneva, Switzerland.