STANDARDS AND PRACTICE IN MANAGEMENT OF MEDICAL DEVICE

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ABSTRACT

The purpose of this paper is to raise awareness within the Biomedical and Clinical engineering community, about the issue of understanding the standards. Also, open a discussion about current practices in management of medical devices in general and laboratory equipment in particular. The paper focuses on similarities between medical electrical equipment and medical electrical laboratory equipment standards. The influence of these standards on today's technologically advanced healthcare. The paper looks at risks associates with current laboratory equipment management practices. A common practice is suggested as the next step forward. The paper also highlights some benefits of a common practice in the management of medical and laboratory equipment.

SOMMAIRE

Le but de cet article est de soulever la conscience de la communauté de génie Biomédical et Clinique, au sujet de la compréhension des normes. Aussi d'ouvrir un débat au sujet des pratiques en vigueur dans la gestion des dispositifs médicaux en général et laboratoire en particulier. Le papier se focalise sur les similarités entre les normes électriques d'équipement médical et Normes électriques d'équipement de laboratoire. L'influence de ces normes sur les soins de santé technologiquement avancés d'aujourd'hui. Le papier regarde des risques associés avec les procédures courantes de gestion de dispositif médicales. Une pratique commune est suggérée comme prochain pas en avant. Le papier suggère également quelques avantages d'une pratique commune dans la gestion de l'équipement médical et de laboratoire.

INTRODUCTION

The development of technology has provided an opportunity to re-examine current practice in management of laboratory equipment. Inconsistent use of standards and lack of common strategy in medical device management remains a challenge to health and safety improvement in healthcare. However, the acknowledgement by the International Electrotechnical Committee (IEC) and the amendments made on IEC 60601-1 appears to be more efficient, comprehensive and relevant to healthcare professionals. The inclusion of requirements for essential performance and formal risk management system was seen as a substantial change that impacted on the management of medical equipment. The future of medical device management will be influenced by this new standard. Biomedical and Clinical Engineering departments in healthcare bear a substantial responsibility for ensuring best practice in management of laboratory equipment. Because of the complexity of current technology in the development of laboratory equipment, laboratory test personnel are increasingly working under pressure to handle a large number of diagnostic test and manage the technology which rely on advanced knowledge of engineering. There is a need for Biomedical Engineering and Laboratory Test services to work together to meet safety and standards required for accreditation by the regulators.

Comparison of IEC61010 and IEC 60601 standards

In 1990, the International Electro technical Committee published the IEC 1010-1 (later re-numbered as IEC 61010-1), a standard covering safety requirements for electrical equipment for measurement control and laboratory use. The purpose was to provide adequate protection to the operator and the surrounding area against electric shock or burn, mechanical hazards, excessive temperature, fire, effects of radiation, liberated gases, explosion and implosion.

IEC61010-1 was not specifically intended for hospital applications. However, this standard was adopted by many healthcare organizations as a safety guide for operation, service, design and management of laboratory equipment.

The historic process of globalization has facilitated the harmonization of standards that relate to the care of patient. The latest edition of the basic standard, covering electrical equipment used in medicine (IEC 60601-1) was published in December 2005. The amendments answer some of the differences in the way this standard is interpreted. Although IEC 60601-1 is very expensive and Its structure very difficult to read and interpret by those who are not familiar with it. Over the years, this standard has provided healthcare with a successful base in which medical equipment are tested, serviced, maintained and managed.

The following table (figure 1) shows the vertical structure of both medical and laboratory equipment. The table illustrates the difficulty in how to follow the structures and elements, layout, terminology and presentation of the standards. As more healthcare organizations adopt these standards for safety and performance of their medical device, there is a need for a comprehensive summary written for healthcare professionals.

IEC 61010	IEC 60601
• Part 1: IEC 61010-1 General requirements	• Part 1: IEC 60601-1 General Requirements
• Part 2: EIC 61010-2 Particular Requirement (In Vitro Diagnostic)	• Part 2: IEC 60601-2 Particular Requirements
• IEC 61010-2-010 Equipment for Heating material • IEC 61010-2-020 Centrifuges • IEC 61010-2-041 Autoclaves using steam	• IEC 60601-2-2 Surgical Diathermy • IEC60601-2-3 Shortwave Therapy • IEC 60601-2-4 Cardiac Defibrillator • IEC 60601-1-32 X-Ray Equipment

Figure 1. Vertical structure of IEC 61019 and IEC 60610

Medical Device link [2] reported that: 'Although there are other national medical standards, IEC 60601-1 is the governing standard for electrical medical products. In Canada, CAN/CSA C22.2 No. 25 will be withdrawn January 1, 2005. In the United States and Canada, UL 544, UL 187, and CAN/CSA C22.2 No. 114 will all be withdrawn January 1, 2010

Adverse Incidents

Over the last decade, efforts have been made to improve the poor track record of healthcare to learn from past incidents. The Regulatory authorities and Standards organization are increasingly pushing for better safety by designing and implementing mechanisms of identification, assessment, investigation and reporting incidents.

The following figure illustrates the trends in adverse incident reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) [6] in the United Kingdom. Over three year's period, an increase of almost 60% of incidents reported in the In Vitro Diagnostics (IVD) device group. This alarming result is due to the full implementation of the European Union IVD directive at the end of 2003. Also a good cooperation and communication between laboratory staff, Biomedical Engineering, Adverse incident reporting team and risk management team within hospitals is needed.

Despite what can be learned from incidents reported, fears of potential liability, blame or loss of job make it difficult to find out the details behind serious equipment malfunction. Constant effort is required to reduce the rate at which adverse incidents occur. This is only possible by the commitment of healthcare workers responsible for the management of diagnostic and therapeutic services.

Although valuable, accurate and equally important information is provided for patient diagnostic and treatment, laboratory equipment still not submitted to the same service program as medical equipment. The unbalanced in maintenance, service and management of laboratory equipment contribute to the increase number of adverse incidents.

As opposed to Biomedical engineering services in the hospital environment, laboratory equipment professionals are not only overloaded by the number of tests to perform, but they have to manage Laboratory equipment service program with minimum resources and lack of up to date engineering expertise in some cases.

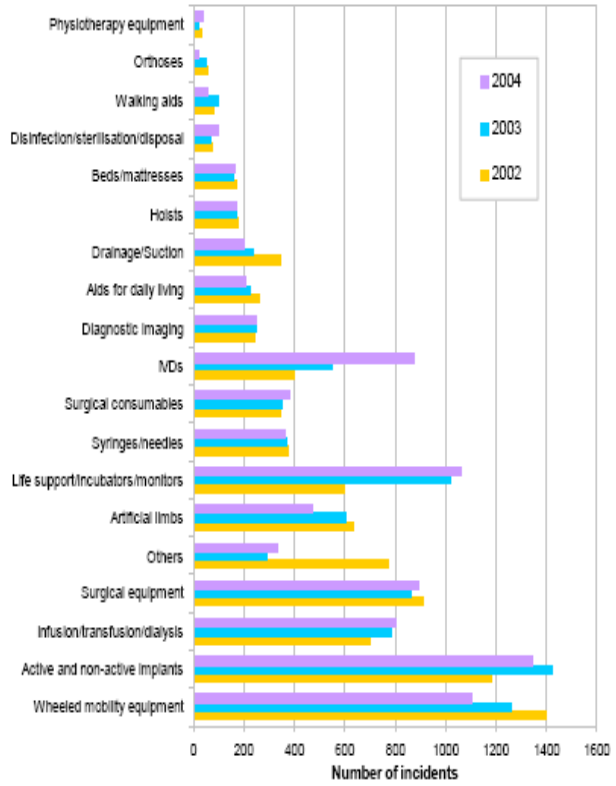

Figure 2. Incident reports by devices
Source: Adverse Incident Reports 2004 MHRA DB2005(2), UK.

Risk Assessment

Even though most laboratory equipment would not directly cause harm to patients, equipment failure could trigger a chain of events that ultimately results in patient harm. [1] For example, an IVD failure can cause the clinical laboratory to report inaccurate results, which can contribute to erroneous medical decisions that lead to injury or death of the patient. Equipment related hazards to Clinical laboratory workers and service personnel, such as electric shocks, unguarded moving parts, or waste solutions can have a major outcome to the user. [3] Preventive maintenance, repair, refurbishment, upgrade etc., are sometimes ignored in order to reduce cost. Risk related to laboratory equipment is significant and the outcome can be catastrophic. Patient, public and workers safety should not be compromised at any time.

CONCLUSION

There is a need for a comprehensive summary of electrical safety standards designed for healthcare. Also there is a need for common practice in the management of medical equipment and laboratory equipment in order to meet the challenges imposed on us by the fast pace in development of technology for both medical and laboratory equipment. This new way of work will allow laboratories and Biomedical engineering departments to work together to improve quality of healthcare delivery. This opportunity will provide a better diagnostic system where laboratory managers will concentrate in producing better diagnosis. Clinical, Medical and/or Biomedical Engineering will provide a good equipment management and support to laboratory equipment as well as medical equipment.

The long term benefit of this system will be cost reduction, better monitoring of quality of service and lower risk of erroneous test results.

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