



**CSA
Group**

What Makes a Standard Great ???

DITTA Workshop on Standardization

The benefits of international standards for regulatory conformity

Monday 18 September 2017 from 12:00 to 16:00

Location: Lord Elgin Hotel in Ottawa, Canada

Conformity Assessment Body – CSA Group

Speaker: Michel Brossoit, P Eng.



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The goal of safety and essential performance standards for medical electrical equipment are to improve safety in the use of such equipment.

This goal should be achieved by developing standards which assist:

- a) manufacturers in designing and assembling safe and effective medical products;
- b) manufacturers, test houses and regulatory authorities in assessing compliance with requirements; and
- c) health care professionals in managing risks associated with the use of these medical products.

What determines the quality and regulatory use of a standard ?



The quality of a safety standard is mainly based on the expert members participation.

Regulatory authorities have the freedom to select standards which will be referenced and used for regulatory purposes.
Note: They have the authority to make standards normative

There are different regulatory stakeholders. For medical electrical equipment (medical device) we have to meet, Quality, Safety and Medical Licencing.

The word "consensus" is an important word since it represents a common viewpoint of those parties concerned with its provisions, namely producers, users, consumers and general interest groups.

IEC's International Standards are reached by international consensus among the IEC's members (National Committees).

Any member of the IEC may participate in the preparatory work of an International Standard, and any international, governmental and non-governmental organization liaising with the IEC also participates in this preparation.

Note: Without the word consensus odds are that safety standards would probably never reach their objectives.

Consensus process - the development and approval procedures followed to achieve consensus.

A consensus process includes applying the following four principles underlying consensus processes:

- (a) inclusive, not exclusive, participation;
- (b) respect for diverse interests;
- (c) accountability; and
- (d) consensus achievement.

Who are the beneficiaries of standards and why ?



- 1- Safety Standards are written for medical manufacturers to meet. Regulatory Bodies will verify and validate if the medical safety standard has been met. A Test Laboratory will test and provide certification for the medical manufacturer.
- 2- The benefit of medical safety standard is to address the most common known basic safety hazards and essential performances. These hazards will be mitigated through testing or through risk management. Safety Standards are all about mitigating all foreseeable hazards.
- 3- A safety standard will ensure that all medical electrical equipment will have to meet minimum safety requirements. These electrical safety standards also create a good level of confidence that the medical electrical equipment is safe!

- Well-balanced, multi-disciplinary matrix of expert members, to ensure all different points of interest and concerns will be captured and addressed.
- Open, rule-based and consensus driven process standards.
- Addressing the most common known basic safety hazards and essential performances.
- Provides a Good level of confidence that the medical electrical equipment is safe!
- The greatest safety standards are safety standards integrating a Risk Management Process. A Risk Management Process addressess throughout the life cycle of these products foreseeable and possible/future hazards in a proactive way!

My future recommendation is to be open minded towards new technologies, have passion and vision to make a safer world.

My future wish is to have safety standards address safety for children (IEC/ISO Guide 50) and safety for elderly persons (Aging Population, IEC/ISO Guide 71).

The majority of safety standards today address primarily adult safety, which is the lowest risk. Upcoming safety standards will need to address children and elderly persons.

Safety First !





Any Questions?

