CONTINUING EVOLUTION OF STANDARDS IN HEALTH CARE AND WHAT YOU MUST DO TO IMPROVE THEM

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DRIVING FORCES AND ACTIONS

Many new devices began to appear in hospitals in the 1960s and 70s.
Many had faults and hazards
Hazards were notably electrical
Many devices did not function properly

Standard CSA C22.2 No.125 was published in 1984 to prevent electrical hazards that were found with previous devices (No. 114 also).
Performance as a Safety Requirement was included - this was revolutionary!
Previous safety standards had no requirement for performance. CSA, in past years had been forced to certify devices that were safe, but had no effect on the patient. We were able to demonstrate that proper function of an electromedical device was a safety requirement.

CSA certified devices to the standards so hospitals could be assured of device safety.

Quality Assurance standards for Device and Drug manufacturing were developed to control manufacturing processes. Good Manufacturing Practises were adopted by Health Canada for evaluating device production.

Other organizations were allowed to certify devices to the CSA standards

CSA Z32 (1989) was redeveloped for electrical safety - a change from preventing explosions and fires from Flammable Anaesthetics

The Canadian Electrical Code - CEC, Sec 24 - was rewritten to meet Changing Medical Practise in hospitals - (2002).

The standards and codes were updated several times for new versions in accordance with their schedules to align with changes in health care and medical prectise.

THEN A MAJOR CHANGE ! ADOPTION OF IEC AND ISO STANDARDS

international harmonization of trade
IEC - International Electrotechnical Commission - 6060-1 and others
ISO - International Organization for Standardization - ISO 9000, (originally developed from a CSA quality management standard)

Previous CSA standards for medical devices were removed in 2005 - only IEC used now.

A Major Change in Attitude and Methods Was Required !

Previously, only a single basic standard was needed - C22.2 No. 125 - and Particular Standards could be stricter that the basic standard, but not less strict.

IEC particular standards for devices may amend, modify, and/or supercede parts of the requirements of the basic standard.

Now you require all the individual standards for each type of device, and you must examine them to understand the differences for safety requirements.

THE CHANGES IN HOW STANDARDS ARE WRITTEN AND ADOPTED

In Canada, once a need is identified, and funding is arranged with the standards organization, committee members are sought to represent the various interests - regulators, device manufacturers, facility designers, health care representatives. They are regarded as the experts in their fields.

Members propose wording to limit existing

hazards, or ones they can imagine. After debate, members agree on the wording they think is agreeable for that time, and CSA reviews it to ensure it meets their mandate, and publishes it.

Standards are to be reviewed, modified or corrected every 3 or 5 years. Changes to standards are allowed to meet new conditions or correct errors. Proposals for change may be made by members or other individuals.

The international standards require an entirely different and more formal process. Each country must have an official organization to represent the country to IEC and ISO. The Standards Council of Canada (SCC) is the Canadian representative, and sets up committees corresponding to the IEC committees to review ongoing work and propose new work or changes to existing standards, and to recommend adoption or refusal of a standard for Canada. An international standard may be adopted by the SCC directly as a Canadian Standard or with revisions to meet Canadian conditions. The SCC committee on a particular standard could, or not, harmonise with a CSA committee on a similar standard - now there is an effort to have them the same.

An SCC committee may develop a proposal for a change to a standard, and submit it to the SCC. If the SCC finds that the proposal fits its mandate, it will propose it to the international committee; and the international committee will distribute it for discussion and a vote. It will only be accepted if a majority of the countries accept it. At the International level, a proposal from just one country does not usually gather support, so countries collaborate if they have a common goal for change. You must recognise that at the international level the representatives are representing the interests of their countries, and may not have any direct involvement with the topic being discussed, so changes will be slow.

A major factor to recognise is that once a requirement exists in a standard, even if it was for an hazard that did not exist in medical practise, it is very difficult to remove it just because it is now useless or is an impediment to good practise.

USE OF THE STANDARDS

Many people in health care feel that the standards are imposed upon them, and since some are incorporated as regulations, they must comply. In the health care field, most people assume that the standards are fixed, and written by experts who know more than they do - even when following the standards sometimes creates difficulties for them. Unless a major cost issue or bad public attention is brought to their notice, hospital managements are not interested to even try to change the problem caused by the standard - they just live with the problem (after all it may only be one of the many problems they have to deal with).

The standards are used by manufacturers to enable them to sell their products. Manufacturers, when they determine that a requirement in a standard limits their sales, will propose changes to remove the impediment, and usually are quite successful in convincing others that it should be done, so long as it does not reduce the safety defined by the standard.

The Effects of How Standards Are Financed

All standards organizations are businesses that must make a profit to exist.

Standards organizations are non-profit - members do not obtain money from the

organization, but it must make money to grow and pay for its costs - staff, publishing, advertising, and all the normal expenses of running a standards company.

The committee members 'volunteer' their time and activities - most are paid for committee work by the organizations they work for - to represent the interests of their companies. While they represent the interests of their employers, they do an admirable job of ensuring that safety is the priority of the committee.

In the 1960s and 70s CSA obtained funds directly from the federal and provincial governments, and earned money from certifying equipment and selling standards. Today, the provincial health care field is much more constrained for funds than before, so fewer Biomedical / Clinical Engineering people can afford to be committee members.

Manufacturers can and do support wide membership of their people in the committees because they represent the interests of the company, and the manufacturers are becoming larger international companies.

Therefore, now, the committees are composed primarily of people from government and organizations who can afford to support the standards work, and there are fewer actual health care professionals. International Manufacturers have staff in different countries and are active in the standards committees - they can provide a single viewpoint in many countries at once.

Sales of standards are an important income for the standards organizations, so advertising is becoming more important. And new versions of the standards provide income.

WHAT YOU MUST DO TO ENSURE THE STANDARDS MEET YOUR NEEDS

1. Be aware of the standards that affect your work or are associated with your activities.

2. Examine them to see if they actually achieve their intent.

3. Identify any requirements that do not seem to fit with the intent of the standard.

4. Identify any requirements that do not fit the existing practises, even though they were necessary in previous years.

5. Identify any existing needs that are not covered in the standards, and propose wording to meet the need.

6. Check with others in your field to determine if they identify the same things.

7. When you find a potential need for change identify it, explain it clearly, and propose it to the standards organization in the defined format. And, have at least two other individuals make a similar proposal. (a proposal from one individual may just indicate a singular idea that may not receive adequate attention, but three proposals on the same topic is noteworthy)

8. If it fits with the CMBES mandate, ensure that it is brought to the attention of the CMBES representative to the standards organization.

9. If a change is necessary, but the official formal route through the international standards organization is taking too long, approach the local authority having jurisdiction to make a local variation.

EXAMPLES OF CHANGES THAT DROVE CHANGES IN STANDARDS AND CODES

Change from Flammable Gaseous Anaesthetics to Non-Flammables

This factor made hospitals and provincial governments look at the other growing needs in hospital operating rooms. Without the need to protect against explosions, there was no special need for isolated power systems or conductive floors and their expensive upkeep. So the electrical code (Sec. 24) was rewritten to make isolated power systems optional, not required, and Z32 was changed. Some provinces were reluctant to make a change, and so kept some of the original requirements.

The introduction of Cardiac Pacing

A direct metallic connection to the heart made people aware of the risk of electrocution by voltage and current levels that they would not even be aware of at the skin surface. This factor led to studies of a 'safe current' for the heart. That value became the existing value recognised as a safe current, because that was the only 'safe' small current then recognised. (In subsequent years no one has found funding to determine if the value for safe current to the heart is also the correct value for newer nerve studies.)

This factor lead to the development of CSA C22.2 No. 125 and IEC 60601-1 for devices that would protect the heart, and the CSA Z32 standard purpose was changed from prevention of explosion to provision of electrical safety.

Auxiliary Bonding Conductor in Conduit

The inclusion of an auxiliary green bonding conductor in wiring protected by conduit was introduced by the CEC Sec 24 committee to meet a specific need. During the initial discussions about the advantages of EMT conduit to minimize voltage differences during a fault to ground, representatives from the East Coast Provinces reported that they had a major problem with uncoated steel conduit - the salty air caused corrosion of the conduit, sometimes so sever that portions of conduit disappeared, and the bonding to ground was interrupted. Therefore the committee decided that it made sense to require an insulated copper bonding conductor (green) within the conduit, run with the circuit conductors. This would provide back-up if the conduit was affected, and being insulated along its length, would permit investigation of the integrity of the conduit if required.