ISO QUALITY SYSTEMS & CLINICAL ENGINEERING *STANDARDS OF PRACTICE*

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INTRODUCTION

This research project consisted of investigating whether an ISO Quality Management System framework could be applied over a service guideline outlined in the Canadian Medical and Biological Society's *Clinical Engineering Standards of Practice*. The intention of the project was to make recommendations to enhance the existing *Clinical Engineering Standard of Practice,* and create a best practices approach to clinical engineering (CE) service delivery in Canadian hospitals.

CLINICAL ENGINEERING RESEARCH

The research was performed between September 2006 and May 2007 and consisted of an investigation into:

- Relevant medical device ISO standards (copy of standards)
- Current CMBES *Standard of Practice* (ver.5)
- Gap analysis between ISO and CMBES *Standard of Practice* (copies of standards)
- Survey existing clinical engineering services in Canada (survey and phone interviews, 17 participants)
- Compare to other independent, manufacturing and international service providers (survey and phone interviews, 12 participants)

KEY FINDINGS

Relevant Standards

Research indicates the most current and relevant medical device quality management system in use today is ISO 13485, which supersedes the previously used ISO 9001. Now the ISO 13485 standard specifically addresses medical device service. Currently, ISO 9001:2000 and ISO 13485:2003 are the best practices quality management systems being used by a number of medical device stakeholders including: government, regulatory, manufacturer, education, research & design development; venture capital companies, independent and international service providers. Q uebec has already incorporated ISO standards into their professional association for clinical engineering, and standard of practice guidelines. Other provincial hospital clinical engineering services didn't identify themselves as being a part of a broader ISO compliant medical device and service industry.

Gap Analysis

A gap analysis between the existing CMBES *Clinical Engineering Standard of Practice* and the ISO 13485 standard showed that many ISO components were already included in the CMBES *Clinical Engineering Standard of Practice*. With some additions and restructuring, the application of ISO 13485 quality management is quite feasible.

Clinical Engineering Survey

A convincing 87% of hospital clinical engineering services reported that they *aim* to be compliant with the Canadian Medical and Biological Society's (CMBES) *Clinical Engineering Standard of Practice*. This significant acceptance, gives the CMBES *Standard of Practice* the credibility to act as a national guideline for hospital clinical engineering best practice.

However, at the national and provincial level, hospital clinical engineering services reported to have no common practice or quality management framework. Each hospital had its own interpretation of the scope of clinical engineering services and how they should be managed. Hospital clinical engineering services are providing more diverse service activities than their counterparts in private industry.

Interestingly, 60% of hospital CE services use a custom-made computerized equipment management database, implying a need for better off-the-shelf products or one Canadian CE database (preferably with ISO quality built-in). Comparisons to international and independent service providers showed that the database application is the key to their ability to integrate quality management functions.

Yet only 27% of hospital respondents said they have the resources required to implement a quality

management system, compared to 80% in private industry and 100% in the manufacturing industry.

RECOMMENDATIONS

Based on the key findings of this research project, there are five recommendations being put forward to the CMBES committee for revisions to the *Clinical Engineering Standard of Practice.*

Choose a Quality Management System

As a best practices model, I recommend that CMBES adopt the ISO 13485 quality management system as its service management framework. This would bring hospital clinical engineering services in alignment with all other medical device stakeholders. Note, ISO registration is not a requirement for hospital clinical engineering services in Canada CCHSA (Canadian Council on Health Services Accreditation) nor with the American JCAHO, (The Joint Commission on Accreditation of Healthcare Organizations).

Define the Customers and Products

Secondly, define who the customers are, what their expectations are (outcomes) and how this relates to hospital clinical engineering service delivery. Once the customers are defined, their medical device service needs can be identified as service products.

Show customers, (clinical end-users, senior management, accreditation surveyors) how the service will meet their needs, will be monitored, evaluated, and adapted to continue to meet their needs. Include the ISO 13485 customer and product quality indicators in the service delivery framework.

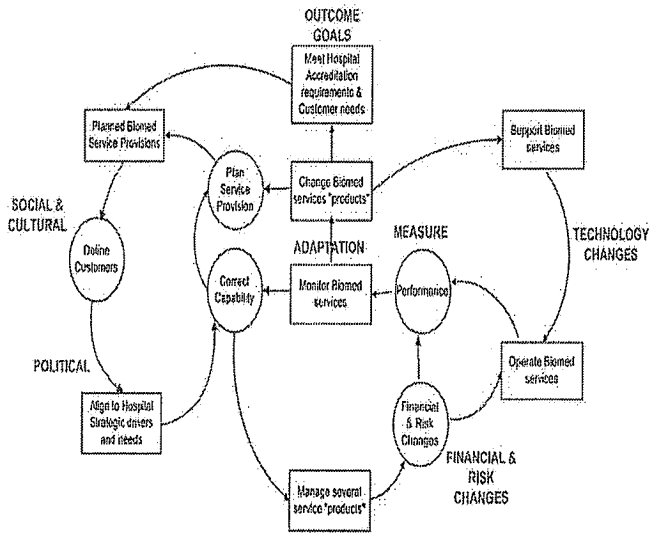

Figure 1: *Service Delivery Framework*

Separate Service Management from Service Products

Thirdly, revise the CMBES *Clinical Engineering Standard of Practice* in such a way that clearly segregates service management functions from the service activities (products) being provided.

Service Management

The separation of service management functions defines the requirements to operate a quality-based service. Customers can be assured that background management of the clinical engineering service is formalized, controlled, and structured. Service management functions can be modeled directly from the ISO 13485 standard, by integrating specific ISO process inputs and outputs:

- Service provision
- Document control
- Record keeping
- Internal audit
- Planning
- Training
- Monitoring
- Measurement
- Regulatory
- Continual improvement
- Internal communication
- Customer communication
- Customer needs assessment
- Non-conformance management

Other departmental management functions such as budgets, human resources, and workplace safety are organization dependent. This excludes them as a national *standard of practice* capable of being measured or surveyed.

Service Products

Service products can be sub-divided into two main categories: core services and complementary services.

The *core services* are baseline medical device management activities suited for smaller departments with limited resources and staff. Medical Device Management would include the following baseline (core) service activities:

- Commissioning New Equipment
- Equipment Tracking
- Scheduled Maintenance (preventive maintenance)
- Corrective Maintenance (repair)
- End-of-Life Removal (disposal)

Complementary service products incorporate the whole "equipment life-cycle model" and increase the service activities to match the more complex needs of larger healthcare organizations. These activities increase value and the cost/benefit of in-house hospital clinical engineering services when compared to the limited service activities of external (independent and manufacturer) service providers.

Complementary service products would include:

Risk Management

- Acceptance Inspection & Testing
- Patient & Staff Safety
- Device Alerts/Hazards/Recalls
- Incident Reporting & Investigation
- Consultation to Organization Risk Policies

Capital Equipment Procurement

- Life-Cycle Planning
- Appropriate Technology (Clinical Needs vs. Technical Needs)
- Regulatory & Standards Requirements
- Technical Market Analysis
- Writing Technical Specifications
- Tender Submission Review

Education

- New Equipment User In-services
- Equipment User Credentialing
- Equipment User Review & Ongoing In-services

Health Technology Management

- Wireless Spectrum Management
- Network & Software Management (Medical Devices)
- Service Contract Management
- New Technology Assessment

Identify Quality Measures

Within the CMBES *Clinical Engineering Standard of Practice*, clearly identify the benchmarks, key performance indicators and measurables to be used to monitor clinical engineering service delivery. Quality indicators should measure service management processes as well as service product delivery (outcomes). By providing a common way of measuring and quantifying the variables related to service delivery, hospital clinical engineering services can then benchmark themselves to their peers across the country and use this as a means of acquiring the necessary resources to fulfill customer and practice expectations.

Link the CMBES *Standard of Practice* to Hospital Accreditation

Fifthly, a revised CMBES *Clinical Engineering Standard of Practice* would align precisely into the key quality, risk, and patient safety goals of CCHSA's (Canadian Council on Health Services Accreditation). With benchmarks, a revised *Standard of Practice* would provide the CCHSA survey team with a tool with which all hospital clinical engineering services could be measured as an independent technical support service. Currently, CCHSA surveys hospital Facilities (Plant) and Information Management & Technology departments as independent support services, why not clinical engineering?

RISK ANALYSIS

Professional Credibility

Without a shared quality framework and a centralized practice, the credibility of clinical engineering's' professional contribution to the goals and objectives of healthcare organizations is at risk for the following reasons:

- No cohesive national professional association (e.g. CMBES and Québec professional association)
- No consistency in service activities provided
- No linkage to medical device service industry in Canada, United States and Internationally
- No linkage to governmental and regulatory bodies
- No accountability of hospital clinical engineering services in relation to hospital accreditation

Service Provision Risk

As a part of good manufacturing practices, both in Canada and United States (international harmonized standards), medical device manufacturers are required to follow through on post-market surveillance of their products. This means that the manufacturer has to have a procedure in place to address complaints handling, problem reporting, and vigilance reporting.

As a part of this post-market scrutiny, I predict there will be more focus placed on who is providing services to medical devices after deployment. Eventually, Clinical Engineering services will need to comply with the same quality standards as the manufacturers if they intend to continue to offer technical support services for their products. Since a large majority of the medical devices purchased in

Canada originates from United States, the medical device manufacturers, FDA and eventually the Canadian Health Protection Branch will need assurances that::

- staff are factory trained and qualified
- "non-conforming" devices are reported such as: user errors, repairs, incidents, adverse events
- repair work and parts are tracked per device
- documented procedures are followed
- records are kept and shared back to the manufacturer

Without doing so, the hospital clinical engineering service may be at risk or denied access to OEM (original equipment manufacturer) service training; parts; software and documentation. This would in effect disable the hospital clinical engineering service from performing many technical support services. Rather than be a "problem" as a non-ISO compliant service, turn it around and become ISO 13485 compliant. Hospital (in-house) clinical engineering services have an important role to play in the larger context of Post-Market Problem Identification, Assessment, and Response. There is tremendous potential to cooperate with manufacturers and regulatory agencies from a unique front-line perspective by:

- reporting adverse events associated with medical devices
- reporting PM compliance
- reporting risks, faults, misuse, any additional signals
- reporting educational needs for patient safety (e.g. need for staff training on safe use of medical devices)
- reporting human factors issues with medical device design

CONCLUSION

As healthcare evolves with technology embedded into clinical practices, the professional engineers and technologists of the clinical engineering services in Canadian hospitals need to dedicate themselves to continually improving their front-line support to healthcare administrators and clinical end-users. With open discussions across the country, let's reform the CMBES *Clinical Engineering Standard of Practice* so that hospital services can be unified, relevant and provide excellent service value for their healthcare organizations. By working together, we can move the Canadian clinical engineering profession up to a new level of integrity and quality.

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