Clinical Engineering

Standards of Practice for Canada

September 2007
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Foreword

The original *Clinical Engineering Standards of Practice for Canada* was published in 1998. It was recognized that for this Standards of Practice document to remain relevant to Canadian Clinical Engineers, it must undergo periodic reviews and updating. This revision represents two years work by a team of dedicated CMBES members from across Canada. The work began at a session of the CMBES annual conference in Quebec City in 2005 in which suggestions for changes were solicited from the general membership. After that session a committee was assembled of the following: Mike Capuano (Hamilton), Jeremy Dann (Halifax), Murat Firat (Toronto), Bill Gentles (Toronto), Dave Gretzinger (currently Toronto but in Winnipeg during the revision process), Gord McNamee (Winnipeg).

This group took the input from the Quebec Conference and developed additions, deletions and amendments to the existing Standards. A draft of the proposed updated Standards was circulated to the membership for comment. Additional comments and suggestions from members were incorporated wherever possible.

The final draft was circulated to CMBES members to vote on in June of 2007. Of those members who voted on the Standards, 94% voted to approve them. As a result of this vote, the CMBES Executive agreed to adopt the revised Standards of Practice document and make it available to members at no charge. The cost for non-members remains unchanged from the previous document.

To order a copy of the Standards in pdf format, contact the Society Secretariat at cmbes@magma.ca or go to the CMBES web site at www.cmbes.ca.
1. **Preamble**

Clinical engineering is one of several professional disciplines contributing to safe, effective and economical health care. The role and primary responsibility of a clinical engineering service (Service) is management of medical device (Device) technology, including adherence to recognized safety, quality, cost and efficiency standards.

The following standards of practice have two goals: to define the scope and role of clinical engineering services in Canadian health care organizations (Organizations) and to define standards suitable for evaluation in a review process.

2. **Service Management**

2.1 **Objective**

To provide Service staff with leadership and resources to achieve planned Service goals and objectives.

2.2 **Standards**

2.2.1 **Organization**

2.2.1.1 Executive Communication

The Head of Service has a reporting relationship, which includes formal communication with senior administration of the Organization.

2.2.1.2 Organizational Chart

There is a current organizational chart for the Service.

2.2.2 **Personnel Requirements**

2.2.2.1 Education & Experience

All existing Service staff has attained levels of education, experience and accomplishments to meet the requirements of their position descriptions.

2.2.2.2 Recruitment of staff

Persons recruited to the service will have demonstrated competence through documented evidence of appropriate qualifications, including education, experience and accomplishments. This may also include certification by the International Certification Commission.
2.2.2.3 Titles
Any titles used by Service staff are consistent with legislation governing the professions.

2.2.2.4 Staffing levels
Staffing levels are sufficient to maintain the standards of service described in this document.

2.2.2.5 Professional Development
Time and funds are available for the professional development of Service staff.

2.2.3 Policies and Procedures

2.2.3.1 The Service maintains a mission statement and a statement of goals and objectives consistent with the mission statement of the Organization. Goals and objectives are measured for achievement and are reviewed annually.

2.2.3.2 Scope of Service
The Service clearly outlines the scope of services provided.

2.2.3.3 Strategic plans
The Service has long-range strategic plans, which are reviewed annually.

2.2.3.4 Staff Meetings
The Service conducts regular staff meetings, for which minutes are recorded.

2.2.3.5 Manual of Policies and Procedures
The Service maintains a current manual of policies and procedures.

2.2.4 Facilities

2.2.4.1 Space
The Service has sufficient space, which is adequately equipped to deliver all services within its scope.

2.2.4.2 Accessibility
The Service is accessible to its customers.

2.2.4.3 Space Planning Involvement
The Service is involved in space planning where it impacts the installation and use of Devices.
3. Medical Device Technology Management

3.1 Objective
To ensure that devices used by the Organization are safe, properly functioning and readily available at an economical cost. To provide accurate and current information on Devices.

3.2 Standards

3.2.1 Device Maintenance Management

3.2.1.1 Devices in Inventory
The Service has a documented policy for identifying those Devices appropriate to the inventory.

3.2.1.2 Database of Devices
The Service uses a computerized maintenance management system (CMMS) for management of device inventory, device service history parts inventory and productivity.

3.2.1.3 Unique Device Identifier
Each Device has a unique identification code.

3.2.1.4 Reports Available on Request
Reports on Device work orders, performance history, and summary reports are available to Organization staff on request.

3.2.1.5 Inventory Audits
Device inventory audits are conducted to maintain accuracy of the inventory.

3.2.1.6 Retirement of Devices
After Device retirement, documentation related to Device history is maintained for a period consistent with the record retention policy of the Organization.

3.2.1.7 Third Party Service Monitoring
For devices that are within its scope, the service monitors the work of third party organizations for timeliness, completeness and accuracy of information.

3.2.1.8 Technical Documentation
The service acquires technical documentation required to support the equipment for which it is responsible and maintains an accessible list of technical documentation, and their locations.

3.2.1.9 Replacement Parts Policy
There is a policy on substituting alternative replacement parts to those suggested by the manufacturer.

3.2.1.10 Spare Parts Management

The Service has a documented policy for the management of spare parts.

3.2.2 Acquisition

3.2.2.1 Capital Equipment Acquisition

A Service representative participates in Organization processes for capital equipment acquisition.

3.2.2.2 Policies for Device Acquisition

The Service offers documented policies for Device acquisition. These policies describe preferred approaches throughout the acquisition phases of capital planning, pre-purchase evaluation, definition of clinical or user needs, technical specifications, site visits, tenders, installation, acceptance, user training, service documentation and service training.

3.2.2.3 Input into Device Acquisition Process

Specific Service input to the Device acquisition process includes assessing safety and performance, reviewing alerts and published product comparisons, examining compatibility, considering life cycle issues, assessing maintainability, and identifying training needs.

3.2.2.4 Specification Writing

The Service assists with production of detailed written specifications for Device purchases.

3.2.2.5 Incoming Inspection & Acceptance Testing

The service performs and documents or manages incoming inspection and acceptance testing on all medical devices within its scope before they are introduced into the Organization.

3.2.2.6 Government regulations

The service takes an active role in ensuring that all devices acquired by the organization conform to applicable government regulations.

3.2.3 Unscheduled Maintenance

3.2.3.1 Unscheduled Maintenance Program

The Service provides an unscheduled maintenance program to deal with Device malfunctions, breakdowns, or operator errors.

3.2.3.2 After Hours Support

The Service ensures that a process is in place to cover urgent situations after regular business hours.
3.2.3.3 Documentation of Unscheduled Maintenance
All unscheduled maintenance actions are documented.

3.2.3.4 Customer Access
There is a clearly defined and widely communicated process for customers to access the Service.

3.2.4 Scheduled Maintenance
3.2.4.1 Scheduled Maintenance Program
The Service ensures that a scheduled maintenance program is in place for all medical devices.

3.2.4.2 Maintenance Intervals
The Service establishes minimum scheduled maintenance intervals based on manufacturer-recommended frequencies, established industry norms and user experience.

3.2.4.3 Modification of Maintenance Intervals
There is a process to monitor and modify, if necessary, maintenance frequencies consistent with risk management practice.

3.2.4.4 Documentation of Scheduled Maintenance
All scheduled maintenance actions are documented.

3.2.4.5 Calibration of Test Equipment
Test and measurement equipment is calibrated using traceable standards.

3.2.4.6 Calibration Intervals for Test Equipment
Calibration intervals are specified for test and measurement equipment.

3.2.5 Disposal of Equipment
3.2.5.1 Service Involvement in Equipment Disposal
The service takes an active role in ensuring that the process for disposing of equipment that is no longer required by the organization conforms to applicable government regulations.

3.2.6 Wireless Spectrum Management
The service has an active involvement in keeping track of the frequencies used by all wireless devices in the organization and ensures government regulations relating to wireless devices are adhered to.
4. Technology Planning and Evaluation

4.1 Objective
To collect, evaluate and provide the Organization with relevant information pertaining to medical device technology assessment. To promote Organization strategic planning awareness of internal and external technological factors influencing health care.

4.2 Standards
4.2.1 Service Involvement in Equipment Planning
The Service participates in the process of equipment planning.

4.2.2 Assessment of Devices
Assessments of safety, efficacy, feasibility, indications for use, cost and cost effectiveness are provided for Devices under consideration for use by the Organization.

4.2.3 Staff Development
The Service staff continually updates their knowledge concerning emergent technologies.

4.2.4 Health Technology Assessment Data
The service utilizes health technology assessment data in equipment planning and decision-making.

5. Patient Safety and Risk Management

5.1 Objective
To minimize Device-related risk to patients and staff and on the financial, physical resources and reputation of the Organization.

5.2 Standards
5.2.1 There is a process that ensures that Devices conform to relevant regulations and safety standards.

5.2.2 Involvement in Policy Development
The Service is involved in developing Organization policy such as reuse of single use Devices, loaned devices and the safe use of wireless communication devices.

5.2.3 Management of Hazard Alerts and Recalls
The Service is involved in processes for managing hazard reports, alerts, and recalls received by the Organization. This includes notifying relevant staff of action required and organizing Service follow-up to confirm that proper actions are taken.

5.2.4 Involvement in Patient Safety
The Service participates in Organization’s patient safety and risk management activities.

5.2.5 Incident Investigation

The Service has a defined and collaborative role in the investigation of incidents involving Devices.

5.2.5.1 Incident Investigation Activities

The Service carries out, or oversees, the following functions as part of Organization procedures in dealing with incidents involving Devices:

(a) Preparing or reviewing incident documentation.
(b) Retaining and quarantining implicated Devices and supplies.
(c) Communicating progress and follow-up to appropriate staff.
(d) Taking and recommending remedial action to minimize possibility of recurrence.
(e) Reporting to regulatory agencies and manufacturers.
(f) Releasing quarantined equipment.

6. Quality Management

6.1 Objective

To satisfy recipients of service consistent with professional standards and ethics and continuous improvement of service.

6.2 Standards

6.2.1 Quality Goals

The Service defines its ongoing commitment to quality and identifies tangible goals.

6.2.2 Customer Feedback

The Service incorporates customer (e.g. nursing) input for identifying areas for improvement. Input is obtained from surveys and interviews.

6.2.3 Quality Program

The Service has a quality program for the effective control, evaluation, and improvement of services. Quality targets are set and reviewed annually as part of this program.

6.2.4 Integration with Organization Quality Program

The Service quality programs are integrated with Organization wide quality programs.
6.2.5 **Staff Training on Quality**
Service staff receives training on quality issues

6.2.6 **Analysis of Device Failures**
A documented process is used to analyze the cause and impact of device failure, to implement corrective action, and to monitor quality indicators.

6.2.7 **Annual Review of Quality Program**
There is a documented annual internal review of the quality management program. Quality targets are reviewed and new targets are developed on an annual basis.

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**7. Education**

7.1 **Objective**
To maintain a high level of technical competence among Service staff. To develop awareness of the appropriate use of Devices throughout the Organization. To provide appropriate training for Service interns.

7.2 **Standards**

7.2.1 **Service Staff**

7.2.1.1 **Education Program for Service Staff**
The Service has an active education program for development of its staff.

7.2.1.2 **Training of Service Staff**
The Service arranges for on-the-job training and for training by commercial or Organization providers.

7.2.1.3 **Documentation of Training**
Documentation is maintained to show that Service staff is trained to perform the tasks assigned to them.

7.2.1.4 **Continuing Education and Certification**
Service staff is encouraged to engage in continuing education activities which may include preparation for certification by internationally recognized certifying organizations.

7.2.2 **In-service Education**

7.2.2.1 **User Training**
Service staff is involved in appropriate user training on new Devices as they are introduced into the Organization.

7.2.2.2 **Refresher Training**
Service staff coordinates refresher training for Device users according to identified needs.

7.2.3 Service Interns and Students

7.2.3.1 Intern and Student Experience
The Service supplies a valid experience to interns and students.

7.2.3.2 Intern and Student Evaluation
The Service evaluates intern and student experiences.

8. Research and Development and the Modification of Medical Devices

8.1 Objective
To support the Organization mission through a commitment to research, involvement in design and modification of Devices and assessment of Devices and Device utilization.

8.2 Standards

8.2.1 Scope of involvement in Research
The Service identifies the scope of its involvement in research and development.

8.2.2 Research Goals
The Service has aligned its research and development goals with the Organization mission and goals.

8.2.3 Staff Involvement
Service staff is encouraged to participate in these activities, as appropriate.

8.2.4 Publications
Service staff participates where appropriate in the publication of peer-reviewed research material and presentation of work at conferences and meetings.

8.2.5 Ethics Committee Requirements
All research activities comply with Organization ethics committee requirements.

8.2.6 Development & Modification of Devices
The design, development or modification of medical devices is properly documented, tested for safety and efficacy to appropriate standards, and approved by a designated Service member.

8.2.7 User Involvement
The Service encourages user involvement in the design, development, or modification of medical devices.
9. **Workplace Safety**

9.1 **Workplace Hazard Management**

The service complies with government standards surrounding hazardous materials in the workplace.

9.2 **Contaminated Equipment**

Staff follows organizational policy detailing precautions to be taken when working with contaminated equipment.

9.3 **Waste Management**

The service participates in the management of dangerous and hazardous waste materials, such as batteries, found in instrumentation as well as general office and workshop waste.

9.4 **Hazardous Equipment**

The service has a documented policy dealing with service staff safety when working with hazardous equipment such as lasers or machine tools.
10. GLOSSARY

Certification
Certification as a Clinical Engineer or Biomedical Engineering Technologist to the standards set by organizations such as the International Certification Commission (ICC).

Clinical Engineering Service
Technical service supporting and advancing health care through application of engineering, scientific and management knowledge to Devices.

Device
(Medical Device) Item used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition.

Device Development
Application of current knowledge to development of new Devices or modification of existing Devices.

Education
The upgrading of Service skills and knowledge, delivery of user training, and support of the intern experience.

Incident
An incident is an event implicating a Device in the injury or potential injury of a person.

International Certification Commission
An international body which oversees the process of certifying engineers and technologists in the field of Clinical Engineering based on education, professional registration, and experience.

Life Cycle Issues
Analysis of costs and benefits of a Device throughout its operating life.

Maintenance
Any activity carried out on a device in order to ensure that it continues to perform its intended function. This may include repair, inspection, lubrication, scheduled parts replacement, testing against specifications, calibration.

Medical Devices Technology Management
Process which ensures that the acquisition and operation of medical device technology is consistent with the policies and procedures of the Organization, and relevant regulations and standards. This includes involvement in equipment selection and purchasing; life cycle analysis; technical support; supplying equipment information and training; monitoring and evaluating equipment performance; documenting equipment; incident investigation; alerts review and follow-up.
**Organization**  
(Healthcare organization) The administered organization which assigns Device support responsibilities.

**Quality Management**  
A strategic management system for achieving customer satisfaction by involving all Service staff in the application of quantitative methods, leading to continuous improvement of processes.

**Research**  
Generation of new knowledge using accepted methods and ethical principles.

**Risk Management**  
Ongoing process of identifying risks, assessing their threat, instituting countermeasures, and evaluating countermeasure effectiveness.

**Service Management**  
Human and other resources required for effective and efficient organization, direction, planning, and representation of the Service.

**Scheduled Maintenance**  
Any maintenance work that has been included on an approved maintenance schedule prior to its commencement. Sometimes called preventive maintenance, preventative maintenance or predictive maintenance.

**Technology Assessment for Medical Devices**  
Process to examine and report Device properties such as safety, efficacy, feasibility, indications for use, cost, and cost effectiveness, and to optimize Device acquisitions.

**Unscheduled Maintenance**  
Any maintenance work that has not been included on an approved maintenance schedule prior to its commencement.

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