

CLINICAL ENGINEERING STANDARDS OF PRACTICE FOR CANADA

PreSurvey Questionnaire

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 format of the questionnaire is such that the standards statements and related criteria appear in a column to the left of the page. The right-hand column is to be completed by the service being surveyed. The responses should include a self-rating for each point, along with a narrative justifying the rating. Use one of the five ratings: N/A(Not applicable), N(Non-compliant), M(Minimally compliant), P(Partially compliant), S(Substantially compliant).

Demographic information

Name of Organization _____

Name of service _____

Primary Contact Person _____

Phone _____ Fax _____ E-mail _____

Details of service staff

Name	Title	Years on staff
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Scoring codes. Enter one of the following codes in the right hand column for each of the standards.	N/A	N (Non-compliant)	M (Minimally Compliant)	P (Partially Compliant)	S (Substantially Compliant)
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	In-house	External	Final
2. Service Management			
2.1 Objective To provide Service staff with vision, leadership and resources to achieve planned Service goals and objectives			
2.2 Standards			
2.2.1 Organization			
2.2.1.1 The Head of Service has a reporting relationship which includes formal communication with senior administration of the Organization.			
2.2.1.2 There is a current organizational chart for the Service.			
2.2.2 Personnel Requirements			
2.2.2.1 All Service staff have attained levels of education, experience, and accomplishment to meet the requirements of their position descriptions.			
2.2.2.2 Any titles used by Service staff are consistent with Provincial legislation governing the professions.			
2.2.2.3 Staffing levels are sufficient to maintain the standards of service described in this document.			

2.2.2.4	Persons recruited to the service will have demonstrated competence through documented evidence of appropriate education, experience, and accomplishment.			
2.2.2.5	Time and funds are available for the professional development of Service staff.			
2.2.2.6	Annual performance appraisals are conducted for each Service staff member. Each individual's performance is evaluated by direct supervisors, the individual, and other Organization staff members interacting with the Service.			
2.2.3.1	The Service maintains 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	The Service clearly outlines the scope of services provided.			
2.2.3.3	The Service has long range strategic plans which are reviewed annually.			
2.2.3.4	The Service conducts regular staff meetings, for which minutes are recorded.			
2.2.3.5	The Service maintains a current manual of policies and procedures.			
2.2.4	Facilities			
2.2.4.1	The Service has sufficient space for its activities.			
2.2.4.2	The Service is accessible to its customers.			
2.2.4.3	The Service is involved in space planning where it impacts the installation and use of Devices.			

<p>3. Medical Device Technology Management</p> <p>3.1 Objective To provide safe, properly functioning, and readily available Devices to the Organization at an economical cost. To provide accurate and current information on Devices.</p>			
<p>3.2 Standards</p> <p>3.2.1 Device Tracking and Inventory 3.2.1.1 The Service has a documented policy for identifying those Devices appropriate to the inventory.</p>			
<p>3.2.1.2 The Service uses electronic databases for Device inventory management, which permit efficient analysis of Device performance and rapid retrieval of risk management information.</p>			
<p>3.2.1.3 Each Device has a unique identification code.</p>			
<p>3.2.1.4 Reports on Device work orders, performance history, and summary reports are available to Organization staff on request.</p>			
<p>3.2.1.5 Device inventory audits are conducted to maintain accuracy of the inventory.</p>			
<p>3.2.1.6 After Device retirement, documentation related to Device history is maintained for a period consistent with the record retention policy of the Organization.</p>			
<p>3.2.2 Acquisition 3.2.2.1 A Service representative participates in Organization processes for capital equipment budgeting and planning.</p>			
<p>3.2.2.2 The Service offers documented policies for Device acquisition. These policies describe preferred approaches</p>			

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, and service training.			
3.2.2.3 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 The Service assists with production of detailed written specifications for Device purchases.			
3.2.2.5 Incoming inspection and acceptance testing are performed on all medical devices introduced into the Organization.			
3.2.3 Unscheduled Maintenance			
3.2.3.1 The Service provides an unscheduled maintenance program to deal with Device malfunctions, breakdowns, or operator errors.			
3.2.3.2 There is a process to have qualified Service staff available for urgent situations after regular business hours			
3.2.3.3 All unscheduled maintenance actions are documented.			
3.2.4 Scheduled Maintenance			
3.2.4.1 A scheduled maintenance program promotes optimum performance, safe operation, minimum downtime, and maximum useful life from each Device or system of Devices.			

3.2.4.2 Minimum scheduled maintenance intervals are based on manufacturer-recommended frequencies, established industry norms, and user experience			
3.2.4.3 There is a process to monitor and modify, if necessary, maintenance frequencies consistent with risk management practice.			
3.2.4.4 All scheduled maintenance actions are documented.			
3.2.4.5 Services provided by manufacturers, vendors, or third parties are monitored by the Service.			
3.2.4.6 Manufacturer, vendor and third party service reports meet standards equivalent to those of the Service.			
3.2.4.7 There is a policy on substituting alternative replacement parts to those suggested by the manufacturer.			
3.2.4.8 Test and measurement equipment is calibrated using traceable standards.			
3.2.4.9 Calibration intervals are specified for test and measurement equipment.			
3.2.4.10 The Service has a documented policy for the management of spare parts.			
4. Technology Assessment and Planning			
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 The Service participates in the process of equipment planning and pre-purchase equipment evaluation.			
4.2.2 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 The Service participates in long range Device planning.			
4.2.4 The Service staff continually update their knowledge concerning emergent technologies.			
5. Risk Management 5.1 Objective To minimize the impact of Device-related risk on patients and staff, and on the financial and physical resources and reputation of the Organization.			
5.2 Standards 5.2.1 There is a process to confirm that Devices conform to relevant safety standards.			
5.2.2 The Service is involved in developing Organization policy regarding reuse of single use Devices			
5.2.3 There are 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 The Service participates in Organization risk management processes.			
5.2.5 Service staff have a defined and collaborative role in			

the investigation of incidents involving Devices.			
<p>5.2.5.1 The Service carries out, or oversees, the following functions as part of Organization procedures in dealing with incidents involving Devices:</p> <p>(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.</p>			
<p>6. Quality Management</p> <p>6.1 Objective To satisfy recipients of service, consistent with professional standards and ethics, and continuous improvement of service.</p>			
<p>6.2 Standards</p> <p>6.2.1 The Service defines its ongoing commitment to quality, and identifies tangible goals.</p>			
<p>6.2.2 The Service incorporates customer (e.g. nursing) input for identifying areas for improvement. Input is obtained from surveys and interviews</p>			
<p>6.2.3 Management has a quality system structure for the effective control, evaluation, and improvement of the Service.</p>			

6.2.4 The Service quality programs are integrated with Organization wide quality programs.			
6.2.5 Service staff receive training on quality issues			
6.2.6 A documented process is used to analyze the cause of device failure, to implement corrective action, and to monitor quality indicators.			
6.2.7 There is a documented annual internal review of the quality management program.			
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 The Service has an active education program for development of its staff.			
7.2.1.2 The Service arranges for on the job training and for training by commercial or Organization providers.			
7.2.1.3 Documentation is maintained to show that Service staff are trained to perform the tasks assigned to them.			
7.2.1.4 Service staff are encouraged to engage in continuing education activities which may include preparation for certification by the International Certification Commission			
7.2.2 Inservice Education			

7.2.2.1 Service staff provide for appropriate user training on new Devices as they are introduced into the Organization.			
7.2.2.2 Periodic refresher training is provided to Device users according to identified needs.			
7.2.3 Clinical Engineering Service Interns and Students			
7.2.3.1 The Service supplies a valid experience to interns and students.			
7.2.3.2 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 The Service identifies the scope of its involvement in research and development.			
8.2.2 The Service has aligned its research and development goals with the Organization mission and goals.			
8.2.3 Service staff are encouraged to participate in these activities, as appropriate.			
8.2.4 Service staff participate where appropriate in the publication of peer-reviewed research material and presentation of work at conferences and meetings.			

8.2.5 All research activities comply with Organization ethics committee requirements.			
8.2.6 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 The Service encourages user involvement in the design, development, or modification of medical devices.			