



ENGINEERS AUSTRALIA

Standards of Practice
Clinical Engineering

Foreword to this Edition

This document has been developed from one prepared for clinical engineers in Canada. The authors of the original document were Dr Anthony Easty, Mr Ted McLeod and Dr William Gentles. Their work has been modified for local regulations and terminology by a working party of the VHA Biomedical Engineering Focus Group, Victoria. This version has been endorsed by the National Panel of Clinical Engineers, College of Biomedical Engineers, Engineers Australia.

The aim of this document is to provide some direction to biomedical engineers working in Clinical Engineering both in defining the scope and role of clinical engineering in Australian health care organisations, and setting standards suitable for measurement and evaluation of performance.

Foreword to Clinical Engineering Standards of practice for Canada

This Clinical Engineering Standards of Practice document is the culmination of two and one half years of work by a dedicated group of clinical engineers and biomedical engineering technologists and technicians.

Successful completion of the Standards of Practice document was possible only through the strong and determined leadership of Dr. Anthony Easty and Dr. William Gentles, and the efforts of Mr. Ted McLeod.

The need for a Clinical Engineering Standards of Practice was realised at CMBEC 22 in Vancouver in 1994. The original concept evolved gradually into the final written document through regular consultation with a broad group of clinical engineering professionals from across Canada. The document was overwhelmingly accepted by the *Canadian Medical & Biological Engineering Society*, by way of a general membership vote held during November 1996.

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GLOSSARY

Credentialing of CE Practitioners

The means by which people practicing within the field may be evaluated and endorsed as being competent to do so.

Biomedical Engineer

Qualified engineer with training and experience in life sciences. Major fields of biomedical engineering are clinical engineering and rehabilitation engineering.

Clinical Engineering Service

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

Medical Device

Any instrument or apparatus (including software) used alone or in combination, including accessories, that is used for the purpose of diagnosis, treatment, monitoring or alleviation of disease or injury.

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.

Life Cycle Issues

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

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 Organisation, 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.

Patient Treatment Area (Area)

A Room or Area that has safety devices to prevent electrocution of patients or staff by medical devices.

Organisation

The administered organisation 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 organisation, direction, planning, and representation of the Service.

Technology Assessment and Planning for Medical Devices

Process to examine and report Device properties such as safety, efficacy, feasibility, indications for use, cost, and cost effectiveness, and to optimise Device acquisitions.

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 and Patient Treatment Areas (Areas), including adherence to recognised safety, quality, cost, and efficiency standards.

The following standards of practice have two goals:

1. to define the scope and role of clinical engineering in Australian health care organisations (Organisations), and
2. to define standards suitable for measurement and evaluation.

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 Organisation

2.2.1.1

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

2.2.1.2

There is a current organisational chart for the Service.

2.2.2 Personnel Requirements

2.2.2.1

A position description exists which outlines qualifications, experience, authorities and responsibilities for each position.

2.2.2.2

All Service staff have attained levels of education, experience, and accomplishment to meet the requirements of the position descriptions.

2.2.2.3

Any titles used by Service staff are consistent with state and federal legislation governing the professions.

2.2.2.4

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

2.2.2.5

Persons recruited to the Service will have demonstrated competence through documented evidence of appropriate education, experience, and accomplishment

2.2.2.6

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

2.2.2.7

Annual performance appraisals against position descriptions are conducted for each Service staff member. Each individual's performance is evaluated by direct supervisors, the individual, and other Organisation staff members interacting with the Service.

2.2.3 Policies and Procedures

2.2.3.1

The Service maintains a statement of goals and objective consistent with the mission statement of the Organisation. 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.

2.4.2 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.

3. MEDICAL DEVICE TECHNOLOGY MANAGEMENT

3.1 OBJECTIVE

To provide safe, properly functioning, and readily available Devices and Areas to the Organisation at an economical cost. To provide accurate and current information on Devices and Areas

3.2 STANDARDS

3.2.1 Device Tracking and Inventory

3.2.1.1

The Service has a documented policy for identifying those Devices and Areas appropriate to Inventory. This policy addresses issues of loan, demonstration and research equipment and responsibility for maintenance of same.

3.2.1.2

The Service uses electronic databases for Device and Area inventory management which permit efficient analysis of performance and rapid retrieval of risk management information.

3.2.1.3

Each Device and Area has a unique identification code.

3.2.1.4

Reports on Device and Area work orders, performance history, and summary reports are available to Organisation staff.

3.2.1.5

Device and Area inventory audits are conducted to maintain accuracy of the inventory.

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 Organisation.

3.2.2 Acquisition

3.2.3.1

A Service Representative participates in Organisation processes for capital equipment, budgeting and planning.

3.2.2.2

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, 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 and Areas introduced into the Organisation.

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 operations, 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 Organisation with relevant information pertaining to medical device technology assessment. To promote Organisation 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 and Area 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 Organisation.

4.2.3

The Service participates in long range Device and Area planning.

4.2.4

The Service staff continually update their knowledge concerning emerging technologies.

5. RISK MANAGEMENT

5.1 OBJECTIVE

To minimise the impact of Device-related Service risk on patients and staff, and on the financial and physical resources and reputation of the Organisation.

5.2 STANDARDS

5.2.1

There is a process to confirm that Devices and Areas conform to relevant safety standards.

5.2.2

The Service is involved in developing Organisation policy regarding reuse of single use Devices.

5.2.3

There are processes for managing hazard reports, alerts, and recalls received by the Organisation. This includes notifying relevant staff of action required, and organising Service follow up to confirm, that proper action is taken.

5.2.4

The Service participates in Organisation risk management processes.

5.2.5

Service staff have a defined and collaborative role in the investigation of incidents involving Devices and Areas

5.2.5.1

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

- (a) Preparing or reviewing incident documentation.
- (b) Retaining and quarantining Device and supplies.
- (c) Communicating progress and follow-up to appropriate staff.
- (d) Taking and recommending remedial action to minimise 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

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

6.2.2

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

6.2.3

Management has a quality system structure for the effective control, evaluation and improvement of the Service

6.2.4

The Service quality programs are integrated with Organisation wide quality programs.

6.2.5

Service staff receive training on quality issues.

6.2.6

A documented process is used to analyse 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 and Areas throughout the Organisation. 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 Organisation 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.

7.2.2 In-service Education

7.2.2.1

Service staff provide for appropriate user training on new Devices as they are introduced into the Organisation.

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 Organisation mission through a commitment to research, involvement in design and modification of Devices, and assessment of Devices and Device utilisation.

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 Organisation 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 Organisation 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.

9. APPENDIX - RELEVANT NATIONAL STANDARDS FOR THE MANAGEMENT OF CLINICAL ENGINEERING.

AS/NZS 3551: Technical Management Programs for Medical Devices

AS/NZS 3003: Electrical Installations – Patient Treatment Areas of Hospitals and Medical and Dental Practices

AS/NZS 2500: Guide to the Safe Use of Electricity in Patient Care

AS/NZS 3200: Approval and Test Specification – Medical Electrical Equipment

AS/NZS 4187: Cleaning, disinfecting and sterilising reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities

AS/NZS 4360: Risk Management.