BOTSWANA NATIONAL HEALTH QUALITY STANDARDS FOR HOSPITALS

Republic of Botswana

31.Medical Equipment Management Service

These forms are designed to be used by both hospital personnel and external surveyors. The following information must be provided after each survey, before submitting the completed survey forms.

1.NAME OF HOSPITAL/CLINIC/FACILITY:_____

2. BASELINE/INTERNAL SURVEY INFORMATION:

Title and name of person who completed this document: _____

Post and position held: _____

Date of survey: _____

3. EXTERNAL SURVEY INFORMATION:

Name of external surveyor: _____

Date of external survey: _____

GUIDE TO COMPLETION OF FORM

N.B. Hospital staff are please to use BLACK ink at all times. The external surveyors are requested to use RED ink at all times.

Please circle the rated compliance with the criterion, e.g. NA (Not applicable), NC (Non-compliant), PC (Partially compliant), C (Compliant).

The default category affected is designated on the form for each criterion as follows:

1. patient and staff safety
2. legality
3. patient care
4. efficiency
5. structure
6. basic management
7. basic process
8. evaluation

The seriousness of the default is designated on the form for each criterion as follows:

1. mild
2. moderate
3. serious
4. very serious

Documents Checked

Surveyor: .....

Surveyor: .....

31.1 Medical Equipment Support

31.1.1 Standard

Adequate human resources are available for the Medical Equipment Management Services (MEMS) to ensure safety and the correct management, usage and operation of medical equipment.

Standard Intent: Healthcare organisations have a responsibility to ensure that appropriate medical equipment is available and ready for use at all times. Suitably qualified or trained individuals take responsibility for ensuring the provision, maintenance, checking and servicing of medical equipment. These responsibilities are defined in writing.

There is an accountable systematic approach to ensure that cost-effective, safe, efficacious and appropriate medical equipment is available to meet the demands of quality patient care.

The mission and objectives of the organisation, level of technology and geographic location determine the scope of medical equipment support which may include:

- an in-house medical equipment management and maintenance service, or
- a medical equipment management and maintenance service at a national or district level, or
- the use of outside service providers for equipment maintenance and repairs.

The management of this service can only take place if there is adequate documentation of protocols to provide support and guidance.

Policies and procedures are developed in line with current legislation and include the acquisition, allocation, utilisation and technical support for MEMS.

- Policies and procedures relating to the acquisition of equipment include technical support requirements and spares, regulatory compliance (compliance with IEC [International Electrotechnical Commission]) and other international and/or national standards and where are applicable for the equipment under consideration.
- Policies and procedures for equipment acquisition also consider compatibility with other equipment suitability for the stated clinical function(s), life cycle costing/cost of ownership, supplier evaluation, past experience and accessories.
- Policies and procedures relating to deployment of equipment include availability and preparation of facilities, installation and commissioning, safety checks, final acceptance checks, connectivity, integration, interfacing, user training and storage and usage of disposables/consumables with limited shelf life.

Where the organisation employs its own clinical engineering personnel (an in-house clinical engineering department) the medical equipment manager would refer to a clinical engineer, clinical engineering technician, medical equipment technician or other suitably trained and/or experienced person, as permitted by legislation.

Matters relating to healthcare technology and the management thereof normally fall within the general ambit of Clinical Engineering (CE). In-house CE departments (CEDs) vary in both size and level of capability according to the size and category of the institution concerned.

For the purposes of this document, the description "Clinical Engineering Department" (or its acronym "CED") shall be taken to mean any formally organised in-house facility or service intended to actively manage, maintain or repair medical and/or surgical equipment, devices and instrumentation regardless of the organisation's internal description for such a facility or service.

The onus is on the organisation's management to ensure that personnel are suitably qualified/competent and that CEDs are appropriately equipped to perform all functions expected of them. This should be according to any requirements as may be laid down by legislation and/or included in guidelines provided by relevant standards, organisations and/or recognised professional bodies.

Large tertiary-level institutions are likely to have a CED consisting of separate departments

or workshops for each of the main equipment categories (e.g. anaesthesia-related, life-support and resuscitation, respiratory, surgical instrumentation and radiology). In some cases this level of CED serves the needs of a number of other hospitals as well as its own.

CEDs at smaller regional and district level hospitals may vary from small multidisciplinary workshops to a mere CE presence, the main functions of which would be to handle first line emergencies, implement risk management, monitor the activities of outside service providers and be involved in user training. This system may also apply in smaller private hospitals.

Whatever the size and complexity of the in-house CED, a suitably qualified and experienced person is responsible for ensuring the safety, correct management, usage and operation of the medical equipment within the institution concerned.

	Criterion	Comments Recommendations
Criterion 31.1.1.1 Critical: .. Catg: Basic Management + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	A medical equipment maintenance manager is designated by the organisation.	
Criterion 31.1.1.2 Critical: .. Catg: Basic Management + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	The responsibilities of the medical equipment maintenance manager are defined in writing.	
Criterion 31.1.1.3 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	A Multidisciplinary advisory committee is appointed to represent managers and clinical and technical personnel involved in the management and use of medical equipment.	
Criterion 31.1.1.4 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	Members of the committee are appointed in writing based on their competence in the area of healthcare technology management.	

Criterion 31.1.1.5 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	The responsibilities of the committee are documented.	
Criterion 31.1.1.6 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	The committee meets regularly to discuss and advise on issues relating to healthcare technology management and these meetings are minuted.	
Criterion 31.1.1.7 Critical: .. Catg: Basic Management + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The committee has ready access to a reliable source of expertise relating to healthcare technology.	

31.2 Medical Equipment Management

31.2.1 Standard

Medical equipment is managed and maintained throughout the organisation.

Standard Intent: To ensure that medical equipment is available for use and is functioning properly the organisation:

- performs an audit on available medical equipment
- takes an inventory of medical equipment which includes description, make, manufacturer, model, serial number, tracing number, date of purchase, purchase price, list of accessories, supplier details and guarantee expiry dates.
- conducts regular inspections of medical equipment
- tests medical equipment, as appropriate to its use and requirements, and
- provides for a preventive maintenance plan.

Equipment is inspected and tested when new and then on an on-going basis as appropriate to the age and use of the equipment or based on the manufacturer's instructions. Inspections, testing results and any maintenance are documented. This helps to ensure the continuity of the maintenance process and helps when capital planning for replacements, upgrades and other changes is being undertaken.

	Criterion	Comments Recommendations
Criterion 31.2.1.1 Critical: .. Catg: Basic Process + Efficiency **Compliance** **NA NC PC C** Default Severity for NC or PC = 4 Very Serious	An audit of medical equipment is conducted.	
Criterion 31.2.1.2 Critical: .. Catg: Basic Process + Efficiency **Compliance** **NA NC PC C** Default Severity for NC or PC = 4 Very Serious	There is a comprehensive inventory of all medical equipment which lists equipment type, make, model, serial number, location and supplier/service provider, date of purchase and service requirements.	
Criterion 31.2.1.3 Critical: .. Catg: Basic Process + Efficiency **Compliance** **NA NC PC C** Default Severity for NC or PC = 3 Serious	Operator and/or service manuals are available to operators and technicians at all times.	

Criterion 31.2.1.4 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	Initial commissioning records are available for all high-risk medical equipment which include details of tests performed and training given.	
Criterion 31.2.1.5 Critical: þ Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The organisation plans and implements a planned preventive inspection and maintenance system according to the service requirements specified by the manufacturers.	
Criterion 31.2.1.6 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	There is a service history for each piece of equipment which includes signed and dated job-cards detailing all procedures carried out, parts fitted, etc.	
Criterion 31.2.1.7 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	Departmental managers have access to information on service and repairs of equipment.	
Criterion 31.2.1.8 Critical: þ Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	A documented system, known to all relevant persons, is in place which addresses the provision of basic technical support in first-line emergency situations.	

31.3 Personnel Training

31.3.1 Standard

There are systems in place to ensure that all users of medical equipment and devices are competent in the use thereof.

Standard Intent: The complexity of medical equipment requires that all users and operators receive training and education in its operation. Also those ancillary personnel who impact on technology utilisation and/or availability (e.g. stores department personnel) should receive basic appropriate training, which may include identification of medical equipment, devices, accessories and common spare parts.

All personnel need to be trained in risk management, infection control and resuscitation. Those persons involved in medical equipment management participate in the organisation's in-service training programme on these issues and also ensure that education and training are provided, which is specific for their own department.

The organisation has a responsibility to facilitate professional development and competence of its personnel in matters relating to medical equipment management and personnel have a responsibility to maintain their own competence and current knowledge.

	Criterion	Comments Recommendations
Criterion 31.3.1.1 Critical: .. Catg: Basic Process + Efficiency **Compliance** **NA NC PC C** Default Severity for NC or PC = 4 Very Serious	Training is provided for all users of basic medical equipment with a record of all such training given and successfully completed.	
Criterion 31.3.1.2 Critical: .. Catg: Basic Process + Efficiency **Compliance** **NA NC PC C** Default Severity for NC or PC = 4 Very Serious	Training is provided for all users of complex and/or critical life-support equipment with a record of all such training given and successfully completed.	
Criterion 31.3.1.3 Critical: .. Catg: Basic Process + Efficiency **Compliance** **NA NC PC C** Default Severity for NC or PC = 4 Very Serious	All users of medical equipment are provided with training in basic infection control and decontamination procedures.	

Criterion 31.3.1.4 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Training in basic electrical safety is provided to all personnel involved in the use of electrically-operated equipment.	
Criterion 31.3.1.5 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Where clinical engineering personnel are employed, they are provided with appropriate training in respect of all medical equipment, devices and instruments which they are expected to maintain and/or repair.	
Criterion 31.3.1.6 Critical: .. Catg: Basic Process + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 3 Serious	Where clinical engineering personnel are employed, they are encouraged and assisted by management to attend seminars, congresses, conferences and training sessions which could improve their knowledge of and proficiency in medical technology matters.	

31.4 Equipment Safety

31.4.1 Standard

Where clinical engineering personnel are employed, systems are in place to ensure safe working conditions and the safety of equipment in clinical engineering workshops.

Standard Intent: Personnel ensure that equipment is tested and maintained in a safe working environment. Risk management includes identifying possible hazards to both patients and personnel and formulating and implementing processes or procedures that could minimise the risks associated with these hazards. Those working with equipment are responsible for ensuring that the environment is safe.

Such hazards can arise from faulty or out-of-calibration equipment or user error as a result of unfamiliarity with the operation of a specific device. It is the responsibility of those working with equipment to ensure that both it and the environment are safe.

Regardless of whether there is an in-house clinical engineering department/service or not the medical equipment management committee, together with the management of the organisation, is responsible for ensuring that safety standards are maintained.

It is of the utmost importance to note that safety and risk management considerations go beyond just the medical devices themselves and include all hazards associated with the usage, maintenance, repair, storage and disposal of such devices/equipment with regard to the patient, user/operator, other personnel and the general public. Examples of such hazards would include gases such as ethylene oxide, nitrous oxide, nitric oxide (and its by-product nitrogen dioxide), mercury, mercury vapour and the vapours of volatile anaesthetic agents and cleaning fluids such as benzene, trichloroethylene, thinners.

In order to ensure that personnel are aware of their responsibilities regarding the handling and disposal of hazardous substances it is necessary that they are familiar with both the possible dangers and the requirements of the relevant country-specific legislation. To this end personnel need to have ready access to pertinent documentation such as a toxicology or material safety data sheet (MSDS) for each substance and copies of all relevant acts, regulations and standards.

(MSDS: A fact sheet summarising information about material identification, hazardous ingredients, health, physical and fire hazards, first aid, chemical reactions and incompatibilities, spill, leak and disposal procedures, protective measures required for safe handling and storage).

Copies of relevant Acts and regulations would include those controlling the occupational health and safety, the hazardous substances and environment conservation.

	Criterion	Comments Recommendations
Criterion 31.4.1.1 Critical: b Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Clinical engineering personnel implement risk management processes in terms of the organisational risk management systems.	

Criterion 31.4.1.2 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	There is an adequate scavenging system for the removal of nitrous oxide and volatile anaesthetic agents in the medical equipment workshop.	
Criterion 31.4.1.3 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Where anaesthetic vaporisers are tested and serviced in the workshop, a suitable fume extraction chamber is provided.	
Criterion 31.4.1.4 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Where extensive soldering work is undertaken, soldering stations are provided with a suitable fume extraction system.	
Criterion 31.4.1.5 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Where volatile cleaning agents are used, an appropriate fume extraction chamber is provided for the safe dispersal of hazardous vapours, e.g. ether.	
Criterion 31.4.1.6 Critical: .. Catg: Basic Management + Physical Struct **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The medical equipment workshop has adequate 15 ampere surge-protected electrical power outlets.	

Criterion 31.4.1.7 Critical: .. Catg: Basic Management + Physical Struct **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The medical equipment workshop is fitted with air-conditioning capable of maintaining a year-round constant temperature of 21 °C.	

31.5 Quality Improvement

31.5.1 Standard

A formalised proactive quality improvement approach is maintained in the service.

Standard Intent: This refers to the implementation of organisational quality improvement processes (Service Element 8).

It is the responsibility of management of the organisation to ensure that standards are set throughout the organisation. Within each department or service, it is the responsibility of managers to ensure that standards are set for the particular department. This requires coordination with the organisation's central/management/coordinating quality improvement structures/ or systems. Departmental managers use available data and information to identify priority areas for quality monitoring and improvement.

Quality monitoring could include:
a) frequency and duration of use
b) user acceptance
c) user training and training evaluation
d) equipment downtime
e) number and type of faults, failures, incidents, and
f) cost-effectiveness.

The following will be evaluated:
- problems identified in this service for which quality improvement activities were initiated
- the processes put in place to resolve the problems
- the identification of indicators to measure improvement
- the tool(s) used to evaluate these indicators
- the monitoring of these indicators and corrective steps taken when goals were not achieved, and
- graphed and/or tabled results, as appropriate.

	Criterion	Comments Recommendations
Criterion 31.5.1.1 Critical: .. Catg: Evaluation + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	There are formalised quality improvement processes for the service that are developed and agreed upon by the personnel of the service.	

Criterion 31.5.1.2 Critical: .. Catg: Evaluation + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Indicators of performance are identified to evaluate the quality of the service.	
Criterion 31.5.1.3 Critical: .. Catg: Evaluation + Efficiency **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The quality improvement cycle includes the monitoring and evaluation of the standards set and remedial action implemented.	

31.6 Prevention and Control of Infection

31.6.1 Standard

The department/service implements infection prevention and control processes.

Standard Intent: This refers to the implementation of organisational processes for infection prevention and control (Service Element 9).

	Criterion	Comments Recommendations
Criterion 31.6.1.1 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The department identifies the procedures and processes associated with the risk of infection and implements strategies to reduce risk.	
Criterion 31.6.1.2 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Infection control processes include prevention of infection by using appropriate protective clothing in high risk clinical area.	

Criterion 31.6.1.3 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Infection control processes include effective hand-washing procedures.	

31.7 Risk Management

31.7.1 Standard

The department/service implements risk management processes.

Standard Intent: This refers to the implementation of organisational processes for risk management (Service Element 7).

	Criterion	Comments Recommendations
Criterion 31.7.1.1 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	The department conducts on-going monitoring of risks through documented assessments as part of organisational risk management processes.	
Criterion 31.7.1.2 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	A system for the monitoring of negative incidents/near misses/ adverse (sentinel) events is available which includes the documentation of interventions and responses to recorded incidents.	
Criterion 31.7.1.3 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Security measures are in place and implemented to safeguard and protect personnel.	

Criterion 31.7.1.4 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Fire safety measures are implemented.	
Criterion 31.7.1.5 Critical: .. Catg: Basic Process + Pat & Staff Safety **Compliance** NA NC PC C Default Severity for NC or PC = 4 Very Serious	Organisation policy on handling, segregation, storage and disposal of waste is implemented.	