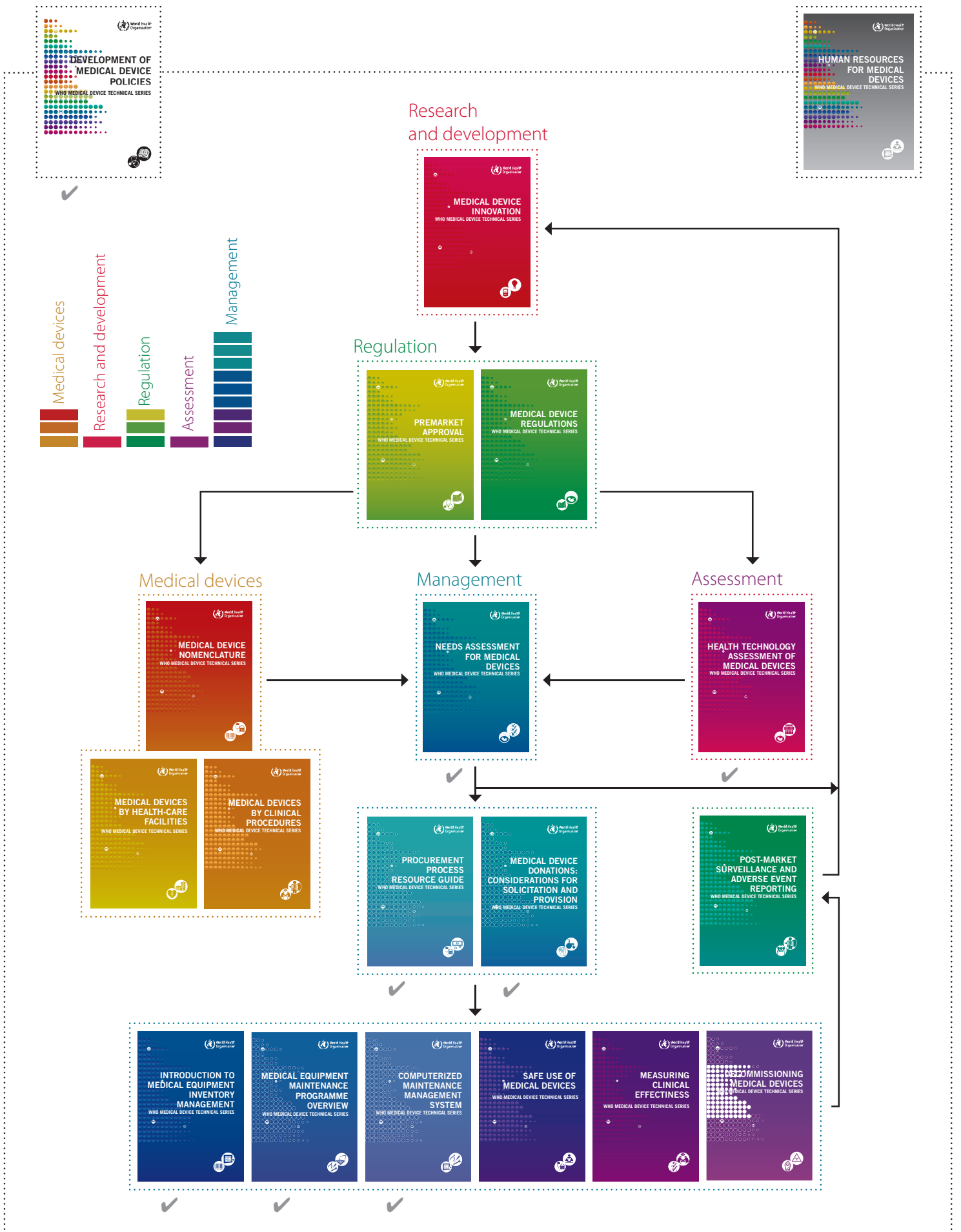




Medical equipment maintenance programme overview

WHO Medical device technical series





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Preface

Health technologies are essential for a functioning health system. Medical devices in particular are crucial in the prevention, diagnosis, and treatment of illness and disease, as well as patient rehabilitation. Recognizing this important role of health technologies, the World Health Assembly adopted resolution WHA60.29 in May 2007. The resolution covers issues arising from the inappropriate deployment and use of health technologies, and the need to establish priorities in the selection and management of health technologies, specifically medical devices. By adopting this resolution, delegations from Member States acknowledged the importance of health technologies for achieving health-related development goals; urged expansion of expertise in the field of health technologies, in particular medical devices; and requested that the World Health Organization (WHO) take specific actions to support Member States.

One of WHO's strategic objectives is to "ensure improved access, quality and use of medical products and technologies." This objective, together with the World Health Assembly resolution, formed the basis for establishing the Global Initiative on Health Technologies (GIHT), with funding from the Bill & Melinda Gates Foundation. GIHT aims to make core health technologies available at an affordable price, particularly to communities in resource-limited settings, to effectively control important health problems. It has two specific objectives:

- to challenge the international community to establish a framework for the development of national essential health technology programmes that will have a positive impact on the burden of disease and ensure effective use of resources;
- to challenge the business and scientific communities to identify and adapt innovative technologies that can have a significant impact on public health.

To meet these objectives, WHO and partners have been working towards devising an agenda, an action plan, tools and guidelines to increase access to appropriate medical devices. This document is part of a series of reference documents being developed for use at the country level. The series will include the following subject areas:

- policy framework for health technology
- medical device regulations
- health technology assessment
- health technology management
 - › needs assessment of medical devices
 - › medical device procurement
 - › medical equipment donations
 - › medical equipment inventory management
 - › medical equipment maintenance
 - › computerized maintenance management systems
- medical device data
 - › medical device nomenclature
 - › medical devices by health-care setting
 - › medical devices by clinical procedures
- medical device innovation, research and development.

These documents are intended for use by biomedical engineers, health managers, donors, nongovernmental organizations and academic institutions involved in health technology at the district, national, regional or global levels.

Maintenance series and external guidance

Three documents in this technical series have been developed specifically to aid a health facility or a national ministry of health to establish or improve a medical equipment maintenance programme. The documents address medical equipment inventory management, maintenance, and computerized maintenance management systems. Each of these documents can be used as a stand-alone document, but together they present all of the factors to consider when developing a medical equipment maintenance programme. Furthermore, a six-volume comprehensive series of manuals for the management of healthcare technology, known as the 'How To Manage' series, exists for people who work for, or assist, health service provider organizations in developing countries and are publicly available.¹

Methodology

The documents in this series were written by international experts in their respective fields, and reviewed by members of the Technical Advisory Group on Health Technology (TAGHT). The TAGHT was established in 2009 to provide a forum for both experienced professionals and country representatives to develop and implement the appropriate tools and documents to meet the objectives of the GIHT. The group has met on three occasions. The first meeting was held in Geneva in April 2009 to prioritize which tools and topics most required updating or developing. A second meeting was held in Rio de Janeiro in November 2009 to share progress on the health technology management tools under development since April 2009, to review the current challenges and strategies facing the pilot countries, and to hold an interactive session for the group to present proposals for new tools, based on information gathered from the earlier presentations and discussions. The last meeting was held in Cairo in June 2010 to finalize the documents and to help countries develop action plans for their implementation. In addition to these meetings, experts and advisers have collaborated through an online community to provide feedback on the development of the documents. The concepts were discussed further during the First WHO Global Forum on Medical Devices in September 2010. Stakeholders from 106 countries made recommendations on how to implement the information covered in this series of documents at the country level.²

All meeting participants and people involved in the development of these documents were asked to complete a declaration of interest form, and no conflicts were identified.

¹ Available at http://www.healthpartners-int.co.uk/our_expertise/how_to_manage_series.html

² *First WHO Global Forum on Medical Devices: context, outcomes, and future actions* is available at: http://www.who.int/medical_devices/gfmd_report_final.pdf (accessed March 2011)

Definitions

Recognizing that there are multiple interpretations for the terms listed below, they are defined as follows for the purposes of this technical series.

Health technology: The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life.³ It is used interchangeably with health-care technology.

Medical device: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.⁴

Medical equipment: Medical devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

³ World Health Assembly resolution WHA60.29, May 2007 (http://www.who.int/medical_devices/resolution_wha60_29-en1.pdf, accessed March 2011).

⁴ Information document concerning the definition of the term “medical device”. Global Harmonization Task Force, 2005 (<http://www.ghtf.org/documents/sg1/sg1n29r162005.pdf>, accessed March 2011).

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Declarations of interests

Conflict of interest statements were collected from all contributors and reviewers to the document development. No conflicts of interest were declared.

Acronyms and abbreviations

AAMI	Association for Advancement of Medical Instrumentation
ACCE	American College of Clinical Engineering
BMET	biomedical equipment technician
CIMV	conventional intermittent mandatory ventilation
CM	corrective maintenance
CMMS	computerized maintenance management system
ECG	electrocardiograph
EM	equipment management
FDA	Food and Drug Administration
GIHT	Global Initiative on Health Technologies
HEPA	high efficiency particulate air
HTM	health/health-care technology management
IPM	inspection and preventive maintenance
ISO	independent service organization
MRI	magnetic resonance imaging
NFPA	National Fire Protection Association
PM	preventive maintenance
PPE	personal protective equipment
SIMV	synchronized intermittent mandatory ventilation
TAGHT	Technical Advisory Group on Health Technology
UPS	uninterruptable power supply
WHO	World Health Organization

Executive summary

Medical devices are assets that directly affect human lives. They are considerable investments and in many cases have high maintenance costs. It is important, therefore, to have a well planned and managed maintenance programme that is able to keep the medical equipment in a health-care institution reliable, safe and available for use when it is needed for diagnostic procedures, therapy, treatments and monitoring of patients. In addition, such a programme prolongs the useful life of the equipment and minimizes the cost of equipment ownership.

A maintenance strategy includes procedures for inspection, as well as preventive and corrective maintenance. Performance inspections ensure that equipment is operating correctly, safety inspections ensure the equipment is safe for both patients and operators, and preventive maintenance (PM) aims to extend the life of the equipment and reduce failure rates. Additionally, some hidden problems may be discovered during a scheduled inspection. However, performing inspections of equipment only ensures that the device is in good operating condition at the time of inspection and cannot eliminate the possibility of failure during future use; the nature of most electrical and mechanical components is that they can potentially fail at any time. Corrective maintenance (CM) restores the function of a failed device and allows it to be put back into service.

An effective medical equipment maintenance programme consists of adequate planning, management and implementation. Planning considers the financial, physical and human resources required to adequately implement the maintenance activities. Once the programme has been defined, financial, personnel and operational aspects are continually examined and managed to ensure the programme continues uninterrupted and improves as necessary. Ultimately, proper implementation of the programme is key to ensuring optimal equipment functionality.

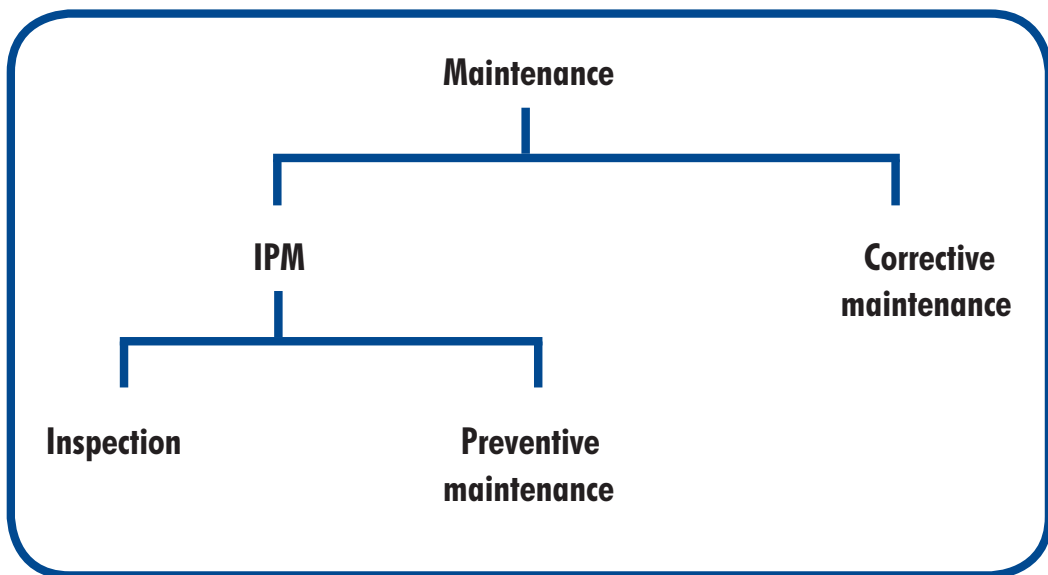
1 Introduction

Medical equipment maintenance can be divided into two major categories: inspection and preventive maintenance (IPM), and corrective maintenance (CM) (see Figure 1). IPM includes all scheduled activities that ensure equipment functionality and prevent breakdowns or failures. Performance and safety inspections are straightforward procedures that verify proper functionality and safe use of a device. Preventive maintenance (PM) refers to scheduled activities performed to extend the life of a device and prevent failure (i.e. by calibration, part replacement, lubrication, cleaning, etc). Inspection can be conducted as a stand-alone activity and in conjunction

with PM to ensure functionality; this is important as PM can be fairly invasive in that components are removed, cleaned or replaced.

It is essential for any health-care facility, regardless of its size, to implement a maintenance programme for medical equipment. The complexity of the programme depends on the size and type of facility, its location, and the resources required. However, the principles of a good maintenance programme will be the same if it is in an urban area in a high-income country or a rural setting in a low- to middle-income country.

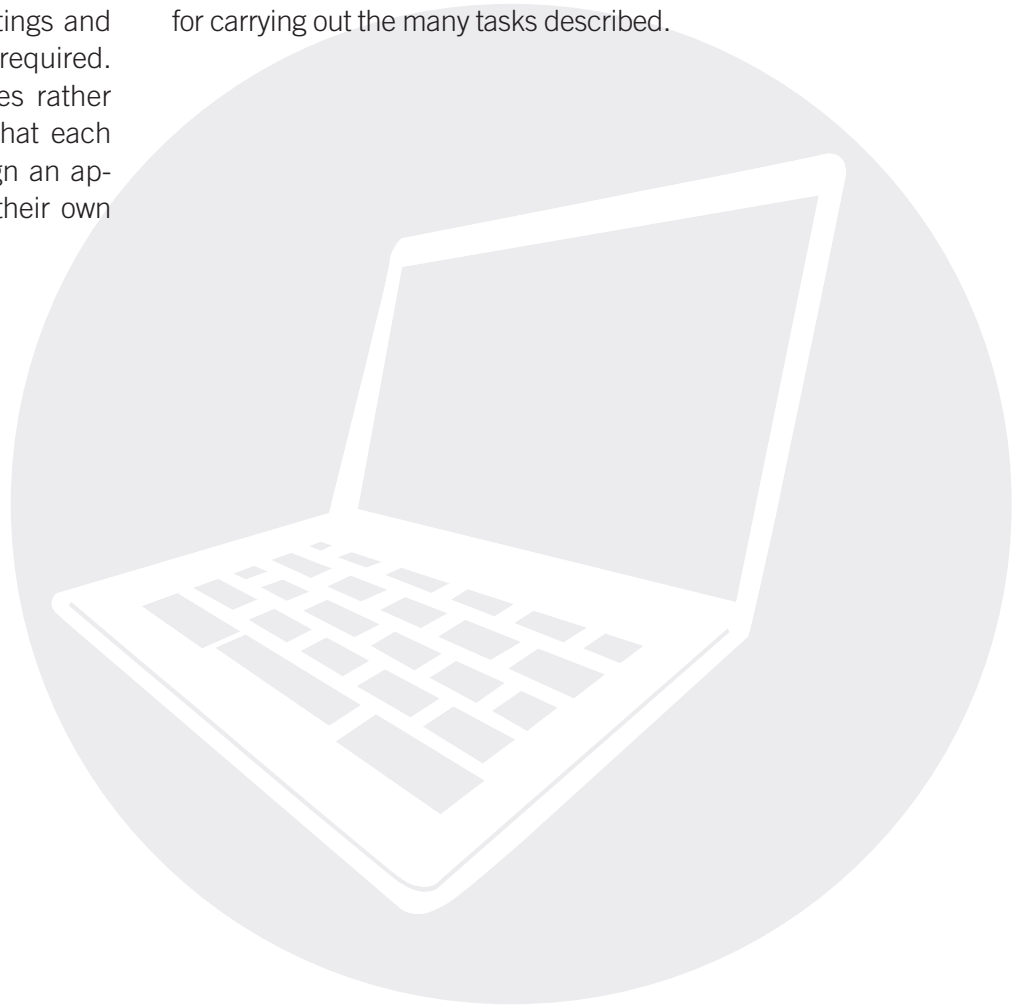
Figure 1. Components of a maintenance programme



2 Purpose

The objective of this document is to provide information regarding the components of an effective medical equipment maintenance programme. It can assist health-care organizations, especially those in developing countries, with planning, managing and implementing the maintenance of medical equipment. It is intended to be concise and flexible, and may be adapted to various settings and levels of technical resources as required. It focuses on general principles rather than being a rigid model, so that each country or institution can design an appropriate programme to meet their own specific requirements.

The document is intended for those responsible for planning, managing and implementing health technology management services at the facility, local, regional and national levels, particularly in resource-constrained countries where such services may not yet be fully established. It may also be of value to engineers and technicians responsible for carrying out the many tasks described.



3 Maintenance related definitions

Key terms used in the discussion of medical equipment maintenance are defined below.

Term	Definition
Acceptance testing	The initial inspection performed on a piece of medical equipment prior to it being put into service. When the device first arrives in the health-care facility, it is checked to ensure it matches the purchase order, it is functioning as specified, the training for users has been arranged and it is installed correctly. If a computerized maintenance management system (CMMS) is available, it is registered into the CMMS.
Calibration	Some medical equipment, particularly those with therapeutic energy output (e.g. defibrillators, electrosurgical units, physical therapy stimulators, etc.), needs to be calibrated periodically. This means that energy levels are to be measured and if there is a discrepancy from the indicated levels, adjustments must be made until the device functions within specifications. Devices that take measurements (e.g. electrocardiographs, laboratory equipment, patient scales, pulmonary function analysers, etc.) also require periodic <i>calibration</i> to ensure accuracy compared to known standards.
Clinical engineer	A professional who supports and advances patient care by applying engineering and managerial skills to health-care technology (American College of Clinical Engineering). While a <i>clinical engineer</i> is a specialized biomedical engineer, the terms are often used interchangeably.
Clinical engineering department/group	Engineer/technician or team of engineers/technicians responsible for the management and maintenance of medical equipment. Depending on the context and country, this department or team may be referred to by a wide variety of names. Some alternative names include: 'biomedical engineering department', 'medical equipment maintenance department', 'medical equipment management unit', etc. In this document, we refer most often to <i>clinical engineering department</i> .
Common descriptive nomenclature	The terminology used to describe a device. Using common universal descriptive names from a single internationally accepted source ¹ is key to comparing inspection procedures, inspection times, failure rates, service costs and other important maintenance management information from facility to facility. Although manufacturers have specific names for devices, it is important to store the common name of the device as listed in the nomenclature system (e.g. nomenclature name: electrosurgical system, monopolar/bipolar; vendor name for the device: electrosurgical generator; vendor model name: Radiolase).
Corrective maintenance (CM)	A process used to restore the physical integrity, safety and/or performance of a device after a <i>failure</i> . <i>Corrective maintenance</i> and <i>unscheduled maintenance</i> are regarded as equivalent to the term <i>repair</i> . This document uses these terms interchangeably.
Failure	The condition of not meeting intended performance or safety requirements, and/or a breach of physical integrity. A <i>failure</i> is corrected by <i>repair</i> and/or <i>calibration</i> .
Inspection	<i>Inspection</i> refers to scheduled activities necessary to ensure a piece of medical equipment is functioning correctly. It includes both <i>performance inspections</i> and <i>safety inspections</i> . These occur in conjunction with <i>preventive maintenance</i> , <i>corrective maintenance</i> , or <i>calibration</i> but can also be completed as a stand-alone activity scheduled at specific intervals.
Inspection and preventive maintenance (IPM)	IPM refers to all the scheduled activity necessary to ensure a piece of medical equipment is functioning correctly and is well maintained. IPM therefore includes <i>inspection</i> and <i>preventive maintenance (PM)</i> .

¹ Two common nomenclatures are the Global Medical Device Nomenclature (<http://www.gmdnagency.com/>) and the Universal Medical Device Nomenclature System (<https://www.ecri.org/Products/Pages/UMDNS.aspx>)

Performance inspections	These activities are designed to test the operating status of a medical device. Tests compare the performance of the device to technical specifications established by the manufacturer in their maintenance or service manual. These inspections are not meant to extend the life of equipment, but merely to assess its current condition. <i>Performance inspections</i> are sometimes referred to as 'performance assurance inspections'.
Predictive maintenance	This activity involves a forecasting technique to determine the rate of failure of certain types of replaceable components (e.g. batteries, valves, pumps, seals). The maintenance interval is then set so components are replaced before they fail, ensuring the equipment continues to operate reliably. In health care this is primarily done in a facility that has a large number of medical devices from a single manufacturer or model.
Preventive maintenance (PM)	PM involves maintenance performed to extend the life of the device and prevent <i>failure</i> . PM is usually scheduled at specific intervals and includes specific maintenance activities such as lubrication, cleaning (e.g. filters) or replacing parts that are expected to wear (e.g. bearings) or which have a finite life (e.g. tubing). The procedures and intervals are usually established by the manufacturer. In special cases the user may change the frequency to accommodate local environmental conditions. <i>Preventive maintenance</i> is sometimes referred to as 'planned maintenance' or 'scheduled maintenance'. This document uses these terms interchangeably.
Repair	A process used to restore the physical integrity, safety, and/or performance of a device after a <i>failure</i> . Used interchangeably with <i>corrective maintenance</i> .
Safety inspections	These are performed to ensure the device is electrically and mechanically safe. These inspections may also include checks for radiation safety or dangerous gas or chemical pollutants. When these inspections are done, the results are compared to country or regional standards as well as to manufacturer's specifications. The frequency of safety inspections may be different than planned maintenance and <i>performance inspections</i> , and are usually based on regulatory requirements.

4 Maintenance programme planning

Planning a maintenance programme is part of a broader effort to establish a comprehensive programme for health-care technology management (HTM). This planning process includes a review of critical factors, as shown in Figure 2. The challenge for planners is to balance these factors to design a maintenance programme that is appropriate and cost-effective for their situation.

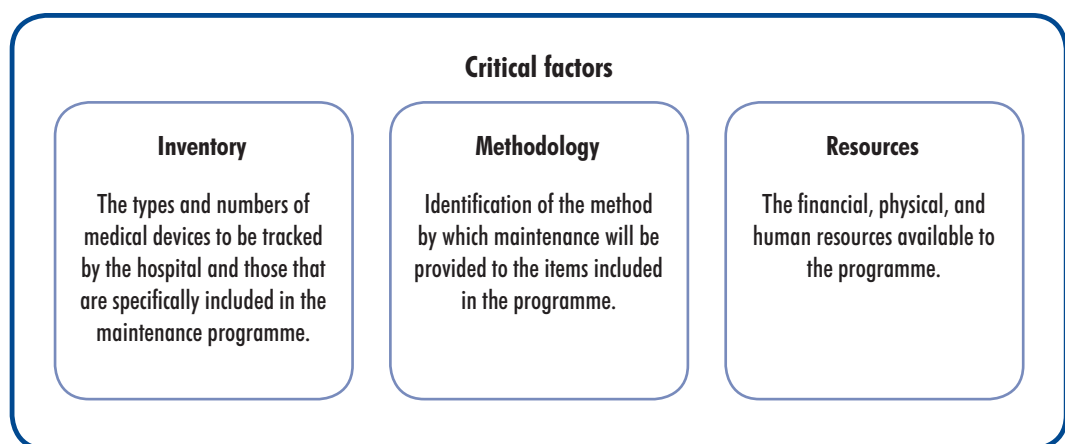
4.1 Inventory

Medical devices range from relatively simple to highly complex. For example, manual devices to measure blood pressure (sphygmomanometers) have only few components and are easily repaired, assuming that parts, calibration instruments and basic hand tools are available. At the other extreme are advanced imaging and laboratory devices. Repair of a magnetic resonance imaging system requires extensive financial, physical and human resources. Between

these extremes are infusion pumps, defibrillators, ECG (electrocardiograph) machines, and hundreds of other types of medical devices of varying complexity. Early in the process of planning a maintenance programme, it is essential to determine the types of devices that need to be included in the programme. This will depend on the types of facilities to be covered by the programme, ranging from primary care clinics to tertiary hospitals, and the range of devices in those facilities.

The clinical engineering department should identify and select the devices to be included in the inventory, and which of those to include in the maintenance programme. While some may prefer to record all equipment in the facility (and some government agencies may require this), studies have shown that not all equipment needs to be tracked in an inventory, inspected or maintained, and very few hospitals or health-care organizations have the manpower to accomplish this level of effort. Approaches

Figure 2. Critical factors in planning a maintenance programme



to selecting equipment to record in an inventory and a maintenance programme are important. Section 5.3.4 discusses methods for prioritizing work, which are also helpful in the selection of equipment for inclusion in an inventory. Appendix A.1 outlines one specific method in greater detail.

The clinical engineering department is responsible for developing and maintaining the inventory. They are responsible for routinely checking that all the equipment being tracked within a health-care facility is in the inventory and that all the equipment listed in the inventory can be located. The team may find it convenient to perform an inventory while carrying out routine inspections or PM activities. Furthermore, when new equipment arrives it should be inspected and then added to the inventory. Appendix A.2 outlines a policy for initial testing and evaluation, while Appendix D.1 provides a sample form for new equipment received. Please also refer to *Introduction to medical equipment inventory management* in this technical series for further information.

4.2 Methodology

A maintenance programme can be implemented in any number of ways so it is important to consider the variety of methodologies that are available. For example, it is possible for a health-care organization to establish service contracts with device manufacturers, independent service organizations (ISOs), or a combination of both. In such cases it is essential for the health-care organization to have personnel to monitor

and manage the activities of these service contractors. In practice, the typical approach is to establish some level of management and technical capability within the health-care organization. Some of the maintenance activities may also be conducted by employees of the health-care organization. Other maintenance activities may be conducted by service contractors or other external service providers. One of the most important management activities is to decide which services should be provided by which combination of internal and external service providers, based on the capacity of the facility and its staff. Further details on management and implementation are found in sections 5 and 6, which help in designing an appropriate methodology for a given context.

4.3 Resources

Resources needed for maintenance are difficult to project. This requires a maintenance history, calculations of the staff requirement and knowledge of when a piece of equipment might fail. Maintenance also requires appropriate staff skills, education and experience. Outside vendors are necessary for the maintenance of complex equipment.

Maintenance requires access to equipment parts which may be difficult to obtain due to budget limitations and procurement difficulties, particularly when purchasing from abroad. To prepare for such challenges, it is important to consider in advance the financial, physical and human resources necessary to properly execute the intended activities.

4.3.1 Financial resources

The financial resources required for a maintenance programme (as one component of a comprehensive HTM programme) fall into two categories: initial costs and operating costs. Initial costs are investments that must be made before the programme begins. Operating costs are ongoing expenses required to keep the programme in operation. Table 1 summarizes the major items within each category.

Table 1. Financial resources required for a maintenance programme

	Initial costs	Operating costs
Physical resources	Space, tools, test equipment, computer resources, vehicles.	Operation, utilities, maintenance, calibration.
Human resources	Recruiting, initial training.	Salaries, benefits, turnover, continuing education.
Direct maintenance	(not applicable)	Service contracts, parts and materials, travel, shipping.

The first step in calculating costs is to specify the physical and human resources needed, based on the number and types of medical equipment in the inventory, and on the level and type of maintenance methodology selected. The initial and operating costs are then calculated using the applicable rates in the country or region. For the IPM component specifically, it is helpful to estimate the workload required by the programme. This is a relatively straightforward process if the estimated time for inspections is known. By counting the number of devices of each type (each common nomenclature type) and multiplying it by the estimated time, it is possible to determine an estimated total workload for the IPM programme. Administrative time to create the IPM forms, preparation time

in getting ready to do inspections, time to obtain the equipment to be inspected (either bringing it to a central work area or going to the location of the equipment), time to document the work done and re-order PM parts used, are all activities that should be added to the total workload calculation. An example can be found in Appendix C.

Direct maintenance costs can be difficult to estimate initially, but will improve with time and experience. Service contract costs, however, can be determined by negotiation with external service providers. These types of services can be acquired on a time and materials basis or by contracting over a set period at a fixed rate. In either case, the cost must be planned in advance and included in related budgets. Section 5.2.1 discusses further the issues surrounding engagement of service vendors.

The cost of service ratio is a useful measure in determining the financial effectiveness of a maintenance programme. This ratio is calculated by dividing the total annual cost of operating a medical equipment maintenance programme by the value (initial cost) of medical equipment in the inventory. In the United States, for example, the cost of service ratio is between 5% and 10% (1). This ratio is achievable only when substantial supporting resources are available, and only after an extended period of performance improvement. For planning purposes in developing countries, this measure may be much higher, especially for new programmes in resource-constrained environments. However, the cost of service ratio, should be monitored over time and be used as a guide for performance improvement efforts.

Over time there will be opportunities to make additional investments in the maintenance programme. For example,

the programme may consider providing service for a particular type of equipment by using internal resources and staffing rather than outsourcing the work. At each such opportunity, a simple business plan should be drawn up that includes the initial and operating costs of the proposal. Then the costs and benefits of the current situation and the new proposal can be compared. This decision-making process for new investments is particularly effective when it is informed by actual data from the programme.

4.3.2 Physical resources

A maintenance programme relies on a number of physical resources. These include the workspace, tools and test equipment, supplies, replacement parts, and operation and service manuals needed to perform maintenance. When planning a maintenance programme each of these should be considered individually as follows.

Workspace

The location in which maintenance will take place should be considered when planning the programme. One option is in the location where the equipment usually resides. For some types of equipment such as X-ray systems, laboratory analysers, sterilizers, and surgical lights, going to the equipment is the only option. In this case, planning to take essential tools and test equipment to the work site or equipping a space closer to the equipment is necessary.

The second option is to transport the equipment to the clinical engineering department's repair shop to have the IPM or CM performed. This may be a time consuming process, but the clinical engineering department may be the only location where some maintenance can be performed. A good workspace is clean and well-organized. It provides good lighting and access to utility systems required by the equipment (electricity

and medical gases, for example). It includes work benches and storage space for tools and test equipment, repair parts and supplies, and equipment awaiting repair. It also includes space for records and documentation, service and operator manuals, and access to whatever computer resources are required.

Inclusion of computer resources in the workspace is also important to consider. Basic documentation may be maintained with paper records but the use of a computer spreadsheet, database programme, or computerized maintenance management system (CMMS) supports good record-keeping, performance monitoring and performance improvement (see section 5.3.6 for more information). Additionally, when internet access is available, it can be a valuable resource. Many technical resources are available online at little or no cost, and online educational programmes may be an option to further technical knowledge and facilitate training.¹ Furthermore, inexpensive voice communication and e-mail communication enable effective collaboration across wide distances. However, where internet communication is unreliable, keeping in touch by mobile phone can be an effective alternative.

The clinical engineering workshop is typically found within the facility itself, but if the programme includes multiple facilities it may be more economical to establish a centralized repair depot.

Tools and test equipment

The productivity of biomedical equipment technicians (BMETs) will be limited without appropriate tools and test equipment. As purchases are planned, it should be noted that investment in tools and test equipment results in

¹ An example of an online educational opportunity is the series of courses developed by the University of Vermont in USA (<http://its.uvm.edu/medtech/index.html>). Spanish language versions of the courses are offered through Universidad CES (Colombia) and Pontificia Universidad Católica de Peru.

reduced maintenance costs. In addition, having the right equipment will greatly increase the reliability of the readings, the accuracy of the calibrations, and the margin of safety for the patients and staff, as well as the efficiency of the staff doing the maintenance.

Various tools and test equipment are required to perform IPM and/or CM procedures, depending on the type of equipment in service. It is possible to perform a large proportion of IPM and CM procedures satisfactorily with a basic set of electronic service tools and test equipment (e.g. temperature meter, volt meter, force gauge, oscilloscope, resistance and capacitance substitution boxes, an electrical safety meter). Small hospitals or clinics with a limited amount of medical equipment can run their programme with just several pieces of basic test equipment (e.g. a physiological simulator, safety analyser and some basic tools). In larger facilities with more complex equipment, more advanced tools and test equipment may be necessary. For example, in a large hospital with more than a few operating rooms and modern electrosurgery equipment, an electrosurgical analyser may be a prudent purchase. Purchasing more advanced tools and test equipment will enable clinical engineering technical staff to calibrate, maintain and repair a wider variety of medical equipment. If it is not possible to procure and maintain certain test equipment, it may not be appropriate to take responsibility for the maintenance of the associated device.

The life of tools and test equipment may exceed ten years if they are carefully maintained. Typically, test equipment can be used for about seven years. Highly specialized items, such as troubleshooting software and laptop computers to connect to computer-based laboratory or imaging equipment, may have a shorter useful lifespan because the laboratory and imaging technology changes so quickly.

Tools and, in particular, test equipment must themselves be appropriately maintained. They should be kept in good physical condition, calibrated at appropriate intervals, and repaired as required.

Where resources are constrained, creativity is required; establishing a network of technicians and engineers may mean that tools can be shared. Facilities with few financial resources can consider renting or sharing expensive test equipment and tools with other hospitals in the surrounding area. *Medical instrumentation in the developing world* recommends a minimum set of tools and test equipment for low-resource settings (2). These recommendations represent the most basic level of investment in tools and test equipment that can enable meaningful service for medical devices.

Initial funding to start a programme is necessary, but so too is providing additional ongoing funding to purchase, calibrate and service test equipment for new medical equipment the hospital may acquire in the future, or for test equipment needed to expand the scope of the maintenance programme.

A detailed list of test equipment and the devices they are required for is provided in Appendix F.

Supplies

These primarily consist of cleaning and lubricating supplies, and need to be acquired in sufficient quantities. The manufacturers' service manuals give cautions about using the wrong cleaning agents, which can damage labelling and the plastic surfaces of some equipment.

Replacement parts

When planning an IPM programme, it is possible to forecast in advance what parts need to be replaced and how often, by referring to the manufacturer's

guidelines. Thus, based on the number of devices at the facility, the replacement parts (or parts kits) to be used during preventive maintenance (e.g. batteries, filters, valves, tubing, seals, etc.) can be ordered many months in advance, optimizing any volume discounts and minimizing shipping costs. Most importantly, the replacement parts will be on hand when needed. This practice will improve reliability and availability of the equipment and increase the productivity of the staff performing the maintenance.

In many countries the problem of obtaining replacement parts at a reasonable cost and in a timely manner can be substantial. However, knowing what will be needed and the associated costs will help in planning maintenance and informing management in advance. This may lead to funds being redirected to critical areas. The use of generic parts instead of the manufacturer's parts is an option if the quality and characteristics of each part is carefully analysed. Purchasing generic parts from specialty medical equipment parts suppliers – who do the engineering analysis and guarantee the parts they sell – is a reasonable solution in many cases, but associated risks (e.g. loss of manufacturer guarantee, non-compliance with equipment specifications that leads to device failure) must be carefully considered beforehand.

Operation and service manuals

Ideally, the maintenance programme will have an operation (user) manual and a service manual for each model of medical equipment. The operation manual is valuable not only for equipment users but also for equipment technicians who need to understand in detail how the equipment is used in clinical practice. The service manual is essential for inspection, preventive maintenance, repair, and calibration.

Unfortunately, operation manuals and service manuals are not always available, or may be in a language not spoken by equipment technicians. Therefore, it is important that a clinical engineering department take steps that allow them access to such manuals. For existing equipment, the manuals may be borrowed from other local hospitals or obtained online. Clinical engineering department managers should, if possible, have access to high-speed Internet service for this purpose. Manuals or advice may be found among the wider health technology management community, such as the Infratech mailing list.²

For new equipment, it is important that these manuals are included as part of the purchase agreement. All manufacturers who sell equipment are required to provide detailed IPM procedures for use by those who buy their equipment. These procedures are usually written very clearly and in many cases with illustrations for performing complete and appropriate IPM. However, manufacturers may not provide specific IPM procedures, maintenance and service manuals, troubleshooting guidelines, parts lists and schematics unless the owner requires them to do so at the time of purchase. Even if the hospital staff does not plan to do maintenance on a particular piece of equipment, having maintenance and service manuals enables the hospital to provide the manuals to external maintenance providers or do the repairs themselves in the future if circumstances change.

For donated equipment, when manuals have not been provided and due to the age or type of equipment are impossible to access, the instincts and know-how of the staff will be the primary resource. However,

² Instructions on how to join the Infratech listserv are found at http://infratechonline.net/?page_id=38

the clinical engineering department should consider developing their own guidelines and emphasizing the importance of including operation and service manuals with every donation. Developing countries should work with responsible donor agencies and insist on adherence to appropriate guidelines. Please refer to *Medical device donations: considerations for solicitation and provision* in this technical series for more information.

In all cases, it is important to discuss with the supplier if manuals are available, or can be made available, in the local language, perhaps at an additional cost.

4.3.3 Human resources

Developing the human resources necessary to operate an effective maintenance programme is a slow and steady process. The first step is to identify the number and type staff that a facility (or group of facilities) requires. For example, a small health-care facility may have a single technician who provides services for a small inventory of relatively simple equipment. On the other hand, a clinical engineering department serving a large number of health-care facilities, especially when those facilities include higher level hospitals, will have a large number of technical and management personnel, including specialists in particular technologies, with multiple levels of supervision. In general, however, there are two categories of clinical engineering personnel: technical and management.

Technical Personnel

Within the category of technical personnel are engineers and technicians. Biomedical or clinical engineers, are educated in general engineering principles, the physical and biological sciences and their application to medical technology. Similarly, technicians receive technical training with a primary focus on medical equipment maintenance. Biomedical or clinical engineers come into the position

after completion of a four to five year bachelor's degree programme, while biomedical equipment technicians often come into the position with two year's post-graduate training and a degree or certificate in biomedical electronics or biomedical equipment technology.

Alternatively, particularly in countries with fewer specialized training programmes, engineers and technicians may be trained in a related field (such as industrial engineering or electrical technology) and have taken certificate courses, received training or completed an apprenticeship enabling them to work in the area of medical equipment. Engineers or technicians must have this additional training because medical equipment is highly specialized and if improperly maintained or repaired may have adverse consequences on human life. This type of engineer or technician is usually easier to find in the employment marketplace, but will need more supervision and training to effectively accomplish their work. Overtime and with experience, technicians may become qualified to take a position as a biomedical equipment technician. However, for engineers to become qualified as a biomedical or clinical engineer, they must receive the relevant higher education and degree. Table 2 provides a classification of the types of technical personnel and their typical duties.

In many countries there is a shortage of qualified clinical engineers and biomedical equipment technicians. A long-term solution is to develop the educational infrastructure so that qualified technical personnel can be created within the country or region. It may be a good idea to include universities within the country or region in human resource planning as they can develop formal degree programmes and provide continuing education for technical personnel. In the short-term it is necessary to recruit

Table 2. Classification and roles of technical personnel

Personnel	Title	Role
Engineer	Biomedical engineer or clinical engineer	Management, specialized maintenance, supervision of external service provider, needs assessment, planning, and user training.
	Other related fields (e.g. electrical engineer, mechanical engineer)	Require a training course and certificates to work in the medical device field. Primary focus is on the maintenance of medical equipment and sometimes managerial positions.
Technician	Biomedical equipment technicians	Primary focus on specialized medical equipment repair and maintenance.
	Other related fields (e.g. electrical or medical technologist, polyvalent technician)	Preventive maintenance and repair of less complex equipment. It is important that they receive specialized training for high-risk medical devices.
Service provider	Engineer or technician	Provide maintenance that cannot be performed in house. They are product-oriented and specialized in a certain field.

engineers and technicians from other disciplines, as outlined above, and to provide them with training related to medical technology.³

The size of a health-care organization, the number and type of medical equipment in the maintenance programme, the skills found in the local marketplace, and the financial capacity of the organization will be the basis for identifying the correct blend of engineers and technicians. Almost all maintenance programmes will find it necessary to complement the internal staff with external service providers (either the vendor/manufacturer's service representatives or third-party service representatives). Such providers may perform the IPM and CM for equipment that internal staff are not able to complete. Furthermore, repair work on the most sophisticated medical equipment is only accomplished

by highly trained specialists who focus on a single technology or small group of technologies. These outside vendors should operate under the supervision of in-house biomedical equipment technicians for the purpose of service management, cost control and the opportunity to become increasingly familiar with other equipment.

Having some lower level general staff to undertake less technical work is acceptable, but most of the maintenance staff will need to have electronics training and an understanding of the functioning of test equipment, concepts of electronic calibrations and the operating principles of the medical equipment in order to do the job effectively. In addition, investing in higher level technicians may allow the clinical engineering department to eventually provide in-house service on even the highest level laboratory, surgical and imaging equipment. In general, the more the work that can be undertaken by in-house technical staff helps to limit the overall cost of maintaining the hospital's medical equipment. Hiring well trained and qualified biomedical equipment technicians, who can assume more

³ In addition to numerous workshops conducted by the World Health Organization (WHO) in Nepal and the Russian Federation, as well as in various African and Baltic nations, etc., the Pan American Health Organization has conducted numerous workshops on clinical engineering and HTM in countries throughout Latin America and the Caribbean, in cooperation with ACCE (www.accenet.org). Engineering World Health (www.ewh.org) also conducts technical training programmes in Costa Rica and Kenya. ORBIS International conducts similar programmes in Bangladesh, China, Ethiopia, India, Peru and Viet Nam.

responsibility, will reduce the cost of maintaining a hospital's equipment.

Where substantial resources are available to support technical personnel, it is typical that one technical person may be responsible for the maintenance of several hundred medical devices. However, in countries without such support resources, the number of devices per technical person must be greatly reduced. This is especially true in the early stages of implementing a health technology management programme. Over time, performance improvement efforts will increase the productivity of individual personnel. Care should be taken, however, to avoid overburdening technical personnel at the outset of new programmes.

Management Personnel

Engineering management staff provide leadership for the maintenance programme. In concert with hospital administration, they set department policies, provide budget recommendations,

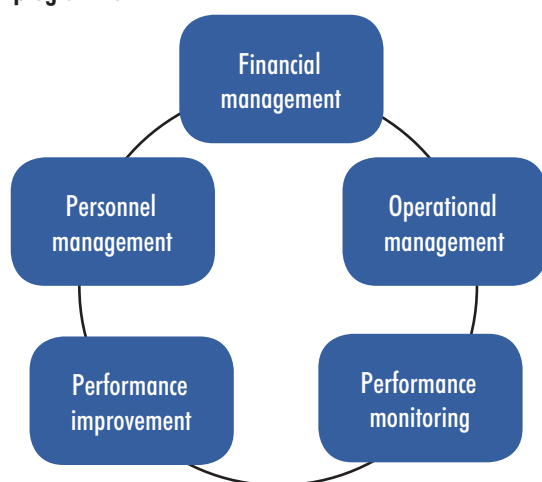
supervise technical staff, arrange for training, set priorities for the department activities and administer the overall programme. The background of those in this position may include a technical degree (two years) with many years of experience in medical equipment service, but a preferable combination would be someone with a four-year engineering degree and familiarity with the health-care environment and health-care technology. Management personnel can also have a combination of business and technical training. They may be engineers or technicians who have additional training and experience in management and supervision. The number of management personnel required in a clinical engineering group depends on the size and structure of the group and is based primarily on maintaining an appropriate 'span of control' for each supervisor and manager.

Sample job descriptions for the positions outlined above are provided in Appendix G.

5 Management

Once established, it is essential to manage the programme in an effective and economical manner. Programme management has several aspects that are typically addressed concurrently, as seen in Figure 3.

Figure 3. Management aspects of a maintenance programme



5.1 Financial management

Financial management for a maintenance programme focuses primarily on two tasks: *monitoring costs and managing the budget*.

Costs are monitored by accurately documenting all of the time and expenses associated with maintenance activities. For work performed by technical personnel, this is typically accomplished by recording this information on a work order document, followed by entry into the CMMS, if available. Specifically for work performed by external service providers, the contract costs (or the itemized costs for service) are recorded on the work order, or into the CMMS. The result is that for each medical device in the inventory there is a history of all time and expenses associated with maintaining that device.

This information may be used to calculate the cost of service ratio described in section 4.3.1.

Managing the maintenance budget is not unlike managing any other organizational budget. The established budget represents the target or benchmark for the programme. Actual costs are compared to the budget. Any difference between actual and budget data triggers a review of the reasons for the variance. Budgeting can be problematic with regard to CM costs because such costs are unpredictable. An unexpected and expensive repair required for a critical medical device can cause a substantial budget variance. However, expenses of this type must be anticipated as much as possible so that, over time, the average level of CM expenses remains within the target budget. It is a good idea to allocate the cost of repair to a separate account from the IPM work. This will allow for accurate cost accounting and future budgeting for IPM and more accurate repair accounting. Additionally, it is important to consider adjusting the maintenance budget after acquisition of new equipment or removal of existing equipment as this affects costs associated with both IPM and CM.

5.2 Personnel management

The purpose of personnel management is to provide support to the maintenance programme's human resources so that programme objectives are achieved. Work assignments should be made to match the skills of the technical personnel and to promote efficiency. Typically, technical personnel will be assigned a combination of IPM and CM responsibilities. However, there may be cases where emphasis on one or the other types of maintenance

activities is appropriate. Section 5.3.3 specifically discusses the various aspects of scheduling maintenance activities.

Personnel management also includes monitoring service vendors when maintenance must be outsourced (see 5.2.1 below). It is important to monitor the productivity of internal and outsourced technical personnel on a regular basis. When applied to individual in-house technicians, productivity monitoring can identify those technicians needing additional support or training. When applied to the maintenance programme as a whole, productivity monitoring can identify opportunities to improve the cost-effectiveness of the programme. More details on performance monitoring and improvement are found in sections 5.4 and 5.5.

The most important aspect of personnel management is the ability to ensure adequate training. Training on new equipment, as well as routine refresher training on existing hardware, is necessary to ensure that technical staff are capable of properly maintaining and repairing the medical equipment included within the scope of the programme. Section 5.2.2 discusses training in further detail.

5.2.1 Service vendors

As mentioned, it is often not possible to provide all maintenance services in-house. In such circumstances, it may be necessary to make use of external service providers for a significant portion of the maintenance activities.

There are generally two categories of external service providers: *equipment manufacturers and independent service organizations*. Many equipment manufacturers offer scheduled and unscheduled maintenance services for the equipment they manufacture. Some also offer maintenance services for

equipment from other manufacturers, in some cases extending to all the medical equipment in a health-care organization. Independent service organizations range in size; some specialize in a particular type of medical equipment and others offer maintenance services for a wide variety of equipment types.

In some parts of the world there are many external service providers, which offer the clinical engineering department manager a wide variety of options. However, in other parts of the world the number of external service providers is much more limited. In some cases these companies find it uneconomical to offer services in remote areas with small inventories of equipment. They are more likely to expand their service areas if it possible to negotiate a contract that covers a large inventory of equipment, especially if that inventory has a reasonable level of standardization in terms of manufacturer and model. In some cases, it may be reasonable to consider liaising with other health-care facilities in order to provide better justification for the external service providers to enter the local market.

There are several types of service agreements as outlined in Table 3. Service agreements can include various levels of scheduled maintenance, unscheduled maintenance, or a combination of the two. Flexibility in the terms of service agreements is valuable to the clinical engineering department manager, but care must be taken to fully understand those terms before entering into a formal agreement. Additionally it is advisable to check the references of any outside vendor prior to hiring them.

After a service agreement is in place, it is essential to monitor the performance of the service provider. This is necessary to make sure that the terms of the agreement are being met and that the health-care organization is receiving the services it

Table 3. Service agreement types

Type	Description	Rates (cost)
Full service	Quick response available at all times	Fixed
Time and material service	Varying response time available as needed	Hourly charge plus cost of parts
Shared responsibility	Internal staff provides initial response and repair. External staff follows up as and when required.	

needs. All maintenance activities they perform and associated costs should also be recorded (i.e. in a CMMS, if available) and reviewed on a regular basis.

5.2.2 Training

For the safety of the patient and the user, proper training is critical for both the user and the technical staff. The technical staff and the clinical engineering department manager have dual responsibility for ensuring that the technical personnel as well as the clinical users are informed, trained and versed on their specific responsibilities. Training and education is not a one-time activity but a continual process. Enabling staff to see that learning is important and a constant feature of their job will improve reliability and success in future problem solving. This section describes the training of technical personnel and section 5.3.9 briefly discusses user training.

Training of technical personnel can be provided inside the health-care organization through:

- Self-study:
 - › reading the equipment service and training manuals;
 - › using additional self-study materials provided by the manufacturer;
 - › using materials provided by a third party.
- One-to-one training provided by a more experienced person from

inside the organization. This may be a clinician teaching biomedical equipment technicians how the device works, for example, or a technician who is familiar with the device guiding others about maintenance and operation.

- The biomedical equipment technician taking part in a education class for nurses or other clinical users to learn about the operation of the equipment.
- The clinical engineering department bringing in a specialized outside trainer to teach staff about maintenance of a particular piece or type of equipment.
- The clinical engineering department bringing in one of the manufacturer's trainers to present to biomedical equipment technicians about maintenance and operation.

Or training can take place outside the organization at:

- Third-party training programmes designed to explain several models of a specific technology.
- Manufacturer's training programmes specifically designed for equipment technicians.

The methods of training suggested above, progress from the least expensive to the most expensive to implement. So depending on hospital resources, local availability of information sources and the ability to coordinate with other hospitals who might have technicians to train as well, the hospital can choose a methodology that best matches their resources. It should be noted however that the most effective training methods for sophisticated equipment are the more expensive options.

The most sophisticated equipment in hospital settings consists of computer-based multi-component systems.

Most of the performance inspection and verification of this equipment is performed by software-based inspection systems built into the equipment itself. Obtaining access to the computer codes and understanding how to maintain this equipment may only come with training provided by the manufacturer or vendor for a fee. If the hospital has developed a competent staff of biomedical equipment technicians, service training by the vendor is a good investment as it enables the hospital to eliminate vendor-related costs and may also lead to the hospital being able to assume repair responsibilities.

5.3 Operational management

5.3.1 Developing or changing IPM procedures

For IPM to be conducted properly, procedures are either selected or written so they provide sufficient testing and maintenance for specific devices and their features. The process of selecting or writing must begin with a good understanding of the technology in general, and the relevant model of equipment.

When developing new procedures for either old or new equipment, it is best to take the most conservative approach and use the manufacturer's IPM procedure manual as a baseline. The equipment owner should expect IPM procedures from the manufacturer to:

- Be well designed and easy to understand.
- Clearly explain every step in the procedure.
- Explain what test equipment is required.
- Explain what the upper and lower limits for measurements the biomedical equipment technician will take.
- Show how to replace parts.

- Explain the required frequency of specific steps.
- Provide recommended forms to be used for the IPM procedure.
- Be provided in the predominant major language of the region/country. If this is not possible, the department will then have to consider if this is the best purchase for them or if they can afford to translate the manuals themselves.

Procedures should not be changed until the owner has some experience with the device. Then, based on inputs from biomedical equipment technicians and/or other organizations who also own the equipment (or industry recommendations), IPM procedures can be changed. If this is done, the justification for deviating from the manufacturer's suggested IPM procedure should be thoroughly documented for future reference. The decision to make this change should also be reviewed periodically (e.g. annually) to make sure the conditions leading to the change persist.

In most cases, the unique characteristics and features of devices require unique inspection steps for each different model. However, in some cases, a generic procedure for all manufacturers and models (e.g. oto/ophthalmoscope, fibre optic light source, microscope) can be used. While using available generic procedures may be very convenient, it must be done with understanding and discernment as some are written with the intention of providing only the most basic steps in an inspection. Appendix B contains a procedure template and a few sample generic procedures.

5.3.2 Setting IPM frequency

The frequency of IPM is specified by the manufacturer of the equipment in the maintenance manual. In cases where there is sufficient familiarity with

the equipment or because of resource constraints, the clinical engineering department manager may prefer to modify what equipment to inspect, how often maintenance should be performed and what parts should be replaced. Before changing the inspection frequency of a medical device, the manager should consider the regulatory environment, the physical environment, the level of user training, the reliability of the equipment, the frequency of use, how much wear the equipment receives during normal use, and the number and types of technical staff available. This information could then be presented to a multidisciplinary safety committee (if available) or hospital management, to make the final decision. In this way, the decision-making responsibility is spread to a broader group of interested parties. When the clinical engineering department is unfamiliar with the equipment, it is best to simply follow the manufacturer's recommendations and adjust the procedures and frequency only after familiarity increases. Where a level less than the manufacturer's specification is determined, this should be noted in the equipment's maintenance record.

5.3.3 Scheduling maintenance

Efficient use of technician time will reduce down-time of equipment and minimize overall expenses. The most appropriate method for scheduling maintenance in a particular health-care facility should be chosen. For inspections, one approach is to plan for the equipment in a given clinical department to be inspected at the same time. This works very well for equipment that does not move from the department. Another approach would be to schedule inspection of equipment of a given type (e.g. defibrillators) simultaneously. For preventive maintenance, equipment may be scheduled by calendar dates depending on the manufacturer's recommendation (e.g. once every 3 months etc.). Alternatively, it can be

scheduled by hours of usage (e.g. for volume ventilators). In this case, creating a method for the users to communicate the device's elapsed usage time to the clinical engineering department is important. See section 5.3.8 for more on effective communication. Because they are unscheduled, CM activities will increase or decrease with demand. Therefore it is important to have a prioritization scheme in place so that CM resources are directed toward the most critical needs (see section 5.3.4 for more information on prioritization).

For IPM, the workload is best scheduled over the calendar year so that the work schedule and staff capacity can be aligned. However, during vacation or holiday periods where staffing levels in the department may be reduced, consideration can be given to reduce the IPM workload by moving IPM inspections to another time. Measuring the workload created by scheduled IPM helps identify where adjustments may be needed. Appendix C explains how the IPM workload can be calculated and related to staff time so they can be matched as closely as possible.

Work can be assigned manually by management personnel or automatically by the CMMS, using rules established by management. Greater efficiency can be gained by creating a system where IPM technicians can focus on the work at hand without interruption. This will require sufficient staff to be able to handle repairs or service calls that may be unrelated to IPM work.

5.3.4 Prioritization of work

Exact matches between workload for the equipment in the hospital and the staff available to do the work are rare. So, rather than plan a programme with the goal to inspect and maintain all the equipment and then not completing the scheduled work, (thus leaving some

of the critical, high risk or life support equipment not serviced), it is better to carefully identify the equipment in the health-care facility that is the most important to inspect and maintain, and schedule this work as a priority. Creating such a 'tiered process', where the most important equipment is dealt with first, is a better use of limited resources. When additional staff is added and their training completed, the next lower tier of equipment can be added to the schedule. Managing the process in this manner gives the manager more control over both the work and the outcome. The following are examples of how maintenance may be prioritized.

Risk-based prioritization

One method used to prioritize medical equipment IPM is based on assigning the highest priority to equipment with the highest likelihood of causing patient injury if it fails. Categorizing devices by maintenance priority, and identifying those that are of such a low risk that maintenance is not necessary, requires a systematic approach. For over 20 years the Joint Commission for the Accreditation of Healthcare Organizations has required a risk-based approach to prioritizing IPM of medical equipment (3). An example of how this risk-based technique is implemented is shown in Appendix A.1.

Mission-based prioritization (4)

This methodology is based on the question: Which devices are most important to us in providing the majority of our patient care? For example, if the hospital's priorities were caring for people living with HIV and caring for pregnant women and their children, the equipment used in this type of care would become the priority. The second priority after this work is completed would then be those devices with the highest risk (as described by the method listed in the previous section).

Maintenance-based prioritization (5)

This methodology analyses which devices have a significant potential to harm a patient if they do not function properly and have a significant potential to function improperly if they are not provided with an adequate level of IPM. Devices excluded are those for which there is no evidence that they benefit from scheduled IPM.

Resource-based prioritization

This methodology uses any of the three prioritization models (see above), in combination with knowledge about the staffing and resource levels of the particular facility or region, in order to define maintenance priorities. In this way, the devices with the highest risk, most important to the work of the hospital or that are maintenance critical would be maintained first, and other devices with a lower prioritization rank would be maintained if resources permitted.

In addition to these methods, priority may be given to IPM and CM of equipment that generates revenue for the health-care organization. The same is true when the non-availability of equipment incurs higher costs for the organization (due to the costs of temporary rental of replacement equipment, for example).

5.3.5 Keeping records

The record for each device should include identifying data such as a brief description, manufacturer, model, serial number, and location (see *Introduction to medical equipment inventory management* in this technical series for more details). It is helpful to also include data regarding the time and expense of providing scheduled and unscheduled maintenance services for the device. These data are typically contained in work order records that provide documentation of every maintenance task performed on the device. As a result, the inventory database will contain the entire technical and financial history for each device in the inventory. Appendix

A.4 provides a sample policy outlining how to manage a work order system for corrective maintenance and Appendix D.3 provides an example of an actual work order form.

From a regulatory point of view, work that was not documented is work that was never performed. Additionally, when a problem with a piece of equipment occurs, it is helpful to see what previous work was done and what the measurement values were. Therefore, it is invaluable to have thorough documentation of all service events which have taken place over the life of the equipment. Being able to keep this in a CMMS for electronic retrieval is ideal, but simply having the information available in a paper format is still useful.

The maintenance programme must strive for accurate records of both the total list of equipment requiring maintenance as well as an accurate accounting of the specific work completed. Using an organized CMMS system to print appropriate procedures for each scheduled activity, and a good system of annotations and coding to record the results of the IPM (for quality control and productivity analysis purposes), are good methods to keep records. Another important aspect of equipment control and tracking is keeping accurate records of locations of equipment to facilitate quick location of equipment for procedures. If attention is given to keeping accurate records and information, many hours can be saved in trying to locate equipment that was recently removed from service, disposed of, put in storage or was moved to a different department. Keeping database information updated is an ongoing task, which is well worth the effort when striving for good programme management.

5.3.6 Computerized maintenance management systems

In most modern health-care facilities, the number of pieces of medical equipment

and the number of service events are so large that keeping and organizing this information can only be done by a computer system. Thus, a computerized maintenance management system (CMMS), a software tool that is able to run on a stand-alone computer, can be very useful in managing the medical equipment maintenance programme.

In an effort to effectively manage a good programme, a CMMS system may provide the following capabilities:

- Keep an inventory of each device in the facility, including the ability to easily add or change the equipment information.
- Keep track of past service events (e.g. IPM, CM, recalls, software updates etc.) and retrieve or print them if needed.
- Store IPM procedures and related information.
- Schedule IPM procedures, change the schedule of IPM procedures and print a summary list of what has been scheduled.
- Print individual IPM forms with the appropriate procedure, the past few service events (for reference), and the expected IPM completion date/time.
- Record and store the results of the IPM inspection procedures – including tasks that passed or failed, the measurements taken and the acceptable range of measured values.
- Record the CM activity including the problem with the device, time spent in the repair process, a description of the work done and the list of parts used.
- Produce summary reports of:
 - › IPM completion rates;
 - › IPM that failed and required repair work;
 - › IPM actual versus expected completion times;
 - › Inventory lists of equipment by

- location, owner or device type;
- › Repairs completed in a certain time period;
- › List of parts used to repair equipment over a certain time period.

In some countries where there is a shortage of staff, and particularly of adequately trained staff, the process of implementing a CMMS may begin as a dual system. The initial inventory is taken on computer but also on paper, so that there is a back-up option, and staff can be confident that there is a form of record keeping available with which they feel comfortable. The active development of an inventory may also function as an extended training period. Once the initial inventory is established, and staff are more comfortable with computers and with the inventory system, the paper records can be phased out.

Computerized maintenance management system in this technical series is a good resource when ready to implement such a system, as it provides details on the key elements of an effective CMMS. In cases where a CMMS may not be possible or is not necessary (e.g. health centre, small hospital), *Introduction to medical equipment inventory management* in this technical series is a good resource on getting started with tracking current inventory and equipment maintenance in a paper-based way.

5.3.7 Tags and labels

It is good practice to label each piece of medical equipment with a unique identification number. This number will be used by the users to communicate with the medical equipment maintenance department so there is no confusion about which specific piece of equipment is being reported.

When doing IPM procedures, a label indicating the date the work was done and the procedure that was performed

should be applied to the equipment for two reasons:

- To communicate with clinicians and others that the device was recently inspected or maintained;
- To identify to IPM technicians which devices have been completed and which are still due for IPM.

When taking power measurements on equipment that have an output, the measurements are recorded on the inspection form but many hospitals also choose to record these readings on a sticker which is placed on the equipment for future reference. See Appendix D.2 and Appendix E for examples of inspection forms and labels.

Some hospitals use coloured inspection stickers to indicate when the device was last inspected in (e.g. yellow – this year, blue – last year, pink – two years ago, etc). This helps readily identify which equipment is next due for inspection.

5.3.8 Communication

Keeping in mind that the ultimate objective of a maintenance programme is to improve patient care, it is essential to develop strong working relationships with clinicians and to understand their needs. The user will know what to expect from the clinical engineering department and vice versa. Respect is shown to the user for their role in helping to complete the maintenance, resulting in appreciation for the work and responsibilities of the clinical engineering unit. Furthermore, having an effective dispatch communication system in place will ensure that repair requests from users are promptly relayed to technical personnel for timely response. Many maintenance programmes have also found it helpful for technical personnel to regularly contact clinical personnel, preferably in person, to inquire about any equipment-related problems they are experiencing. In this way the

technical personnel become accepted as part of the clinical team.

Ultimately, effective communication with the clinical users leads to:

- Clinical staff understanding the reason behind inspecting and maintaining equipment and the benefits of such a programme.
- The clinical engineering department being kept well informed of a device's elapsed usage time for the determination of PM frequency.
- The clinical users being alert to changes or issues with the equipment and immediately contacting the clinical engineering department when such problems are detected.
- The clinical staff being able to locate all essential equipment, and inform technical personnel of location.
- Devices in storage being brought out for inspection.
- Minimal time being spent in the department.
- An improved working relationship with the clinical department.

Providing clinical users with a list of the scheduled IPM work a few weeks in advance, a copy of IPM results, or a list of problems identified, solved or remain to be addressed, are just a few examples of good communication practice.

5.3.9 Managing use and user error

The work of clinicians, including the use of health technology, can be viewed as a series of activities intended to achieve a particular clinical objective: diagnosis, treatment, monitoring or life support. However, a user may be unable to meet this objective due to 'use error', a problem related to the use of a medical device. This is distinct from the term 'user error', which implies that the user of the device caused the problem. Investigation of use error includes consideration of the user, the patient, the device, the environment and

other systemic factors that may block the achievement of a clinical objective. The root cause of user error is typically easier to identify. However, in both cases clinical engineers and biomedical equipment technician can be instrumental in working with clinicians to resolve these issues. They are responsible for providing them with adequate training (or retraining if appropriate) on the operation of a device and working with the users to identify factors leading to use error.

A well-trained user is aware that when preventive maintenance, performance or safety inspections are done, the equipment is adjusted to test its various modes of operation. Therefore, the settings that the user may be used to having left untouched on their equipment will have been changed and they should check the settings and adjustments before using it with patients once again.

Additionally, if users are expected to provide basic, routine maintenance on a device, the clinical engineering department is responsible for training them on the correct procedures. The overall result will be a user who feels ownership for the equipment, takes good care of the equipment, operates (and maintains) it well, leading to a reduced workload for the clinical engineering department and improved lifespan for the equipment.

5.3.10 Travel

Travel is an important component of an effective maintenance programme. If extensive travel between facilities is required or the accessibility of facilities is difficult, there will be significant effects on work assignments, productivity standards, vehicle and other travel expenses, etc. For example, in remote areas, it may take a day or more to travel to a local clinic. Thus, travel time should be considered when planning maintenance activities. However, it may be also reasonable to develop and support user maintenance where it may be

difficult to transport the tools, equipment, and technician to the site.

5.4 Performance monitoring

For effective management of the maintenance programme, it is important to measure performance. Most performance measures do not have a standard or benchmark to compare with. In such cases the manager should monitor performance over time, investigate any significant trends, and identify opportunities for improvement. It is also important to communicate regularly with colleagues who are managing similar programmes. By comparing performance data, managers can identify and take advantage of improvement opportunities. Those with the financial resources may consider subscribing to a benchmarking service that will support detailed performance monitoring.¹

Several important performance measures are described below, but note that without a CMMS it is very difficult to calculate some of these measures. However it is important to conduct some sort of performance monitoring on a regular basis in order to identify opportunities for improvement.

5.4.1 Completion rate of assigned IPM

The completion rate is percentage of procedures completed. It can be measured at the end of an assignment period (e.g. monthly, bi-monthly or quarterly). A good completion rate goal is to be above 90%. This measure could also be calculated to evaluate the completion rate of each priority group, starting with the highest priority group. The highest

priority devices should have the highest completion rate goal, e.g., over 95%, with lower priority groups having lower goals. This indicator is used to measure the productivity and effectiveness of the IPM staff, the ability of the technical personnel, and the adequacy of the staffing levels. IPM completion rates for each technician must take into consideration the expected time it takes to complete an IPM procedure, so the technician is not overloaded, or underloaded, with work.

5.4.2 Equipment location rate

The proportion of equipment scheduled to be inspected in the assignment period but not located before the end of the inspection period is known as the equipment location rate. This indicator primarily measures the accuracy of the inventory database in the CMMS system. It also provides an indication of the effectiveness of the policies to keep the inventory accurate, as well as measuring the quality of communications between clinicians and the medical equipment maintenance department, particularly when equipment is moved, loaned or put into storage.

5.4.3 IPM yield

IPM yield is the percent of scheduled IPM procedures performed where problems were found that affected equipment operation or safety (note: cosmetic problems which do not affect function or safety are not included). This indicator measures the general reliability of the medical equipment at the facility. When individual models of equipment are analysed it can be useful to compare the reliability of one model against another. Furthermore, it is a measure of the effectiveness of the maintenance programme; if equipment is being well-maintained the percentage will be low. Alternatively, if problems are discovered upon inspection that should have been detected by the user, the percentage will be higher than anticipated. As such, IPM

¹ The Association for the Advancement of Medical Instrumentation offers *AAMI's Benchmarking Solution*, which is an online self-assessment tool for clinical engineering (www.aami.org/abs). It supports performance monitoring, assessment of best practices, and performance improvement. ECRI Institute (www.ecri.org) offers *Biomedical Benchmark*, which provides several valuable tools for medical technology management, including detailed benchmarking capabilities for medical equipment maintenance activities.

yield may also indicate how well clinicians report problems they find with equipment.

5.4.4 IPM productivity

The productivity and effectiveness of the IPM staff is an important management measure. By modifying department policies, levels of training, test equipment, and/or forms or procedures, great improvements in individual or group productivity can be achieved. However, this can be managed only if targeted activities are measured. The most important IPM productivity measurement in use today is IPM productivity.

IPM productivity is an expression of the actual time it takes an individual to complete a single scheduled IPM procedure divided by the time the IPM procedure is expected to take. The actual time taken does not include preparation or set-up time, merely the actual time it takes the technician to perform the individual procedure on each device. The results from individual inspections can then be added up to measure the daily, weekly or monthly productivity levels. The number for all technicians can be added to calculate the results for an entire maintenance programme. The expected IPM completion time is initially obtained from outside sources such as the manufacturer's maintenance manual. Eventually, after several years of experience and collecting accurate data, you can use past experience to guide expected completion times.

5.4.5 CM performance measures

In addition to the measures already mentioned, there are certain measures that may be recorded to specifically monitor CM performance. For example:

- *Mean time between failures.* The average time elapsed between failures.
- *Repeated failures.* The number of failures within a specified period of time.

- *Response time.* The time between a request for service and the start of repair.
- *Repair time.* The time between the start and finish of repair.
- *Downtime.* The percentage of time that a device is out of service.
- *Delinquent work orders.* Work orders not completed within 30 days.

5.5 Performance improvement

For a maintenance programme, performance improvement applies to every aspect of the programme, with the ultimate objective of improving patient care. The performance improvement process has the following steps:

1. *Identify opportunities for improvement.* This is one of the outcomes of careful and thorough performance monitoring as described above.
2. *Identify best practices.* These are actions that have been recognized within the profession as leading to improved performance. They are found in clinical engineering literature and through collaboration with professional colleagues.
3. *Improve performance.* Performance improvement projects should be based on best practices. The aspect of performance selected for improvement should be closely monitored until the desired level of performance is achieved.

Specific changes should be measured systematically to determine if the changes improve performance and quality. This can be done by: a) carefully measuring the performance and quality indicators for several measurement periods (months or quarters); b) making a change in the way things are done; and c) continuing to measure the performance and quality. If the new procedures demonstrate positive improvements then the change

was an effective one. If indicators do not improve, revisit the original performance analysis, adjust accordingly and repeat the process. This systematic approach of managing programme performance improvement can have a very positive impact over a period of several years.

Additionally by measuring the improvement in performance and quality after

making changes to the system in which the technicians operate (e.g. install a remote workshop, purchase automated test equipment, upgrade to a CMMS system etc.), the cost of these changes can be justified, the changes will be well accepted by the staff, and further systemic changes can continue to be made.



6 Implementation

6.1 Inspection and preventive maintenance

6.1.1 IPM procedures

Using the correct and appropriate procedures for equipment maintenance can make the difference between having reliable and properly functioning equipment and not. As discussed in section 5.3.1, the procedures used in performing IPM activities should be defined prior to execution of the inspection or maintenance work, through a careful review of each type of equipment (or model).

Most IPM procedures are completed by technical personnel from the clinical engineering department. In some cases, however, routine and easy to perform tasks are completed by the user. This saves time for technical personnel to perform more technically complex and critical tasks and also provides the user with a sense of ownership. The type of inspection the user might perform would be pre-use or daily checks, where required. Examples of this might be daily calibration of portable blood glucose monitors, daily testing of defibrillators or checking the standard calibration of laboratory equipment. It is the responsibility of the clinical engineering department to train the user to perform these tasks. See section 5.3.9 for further information on user interaction.

Appendix A.3 provides a sample policy on inspection and preventive maintenance procedure.

6.1.2 Problem identification

When IPM identifies a problem, the device can either be set aside for later repair, so the IPM work can continue on schedule, or the repair can be completed as part of

the IPM process. If the IPM activities or related repairs are not accomplished in a certain pre-defined period, the work order should be left open and the staff should inspect or repair the device as soon as reasonably possible. Higher priority devices not inspected in previous IPM periods should be located and inspected first. Appendix A.5 presents a sample policy regarding corrective actions identified during preventive maintenance.

6.2 Corrective maintenance

6.2.1 Troubleshooting and repair

Identification of a device failure occurs when a device user has reported a problem with the device. As mentioned earlier, it may also occur when a technician in the clinical engineering department finds that a device is not performing as expected during IPM.

In order to return equipment to service as quickly as possible, efficient troubleshooting is required to verify the failure and determine its origin. In some cases the technician will find that the device itself has failed and must be repaired. The technician then determines what steps are necessary to correct the problem and return the device to full functionality. The technician initiates the corrective maintenance, performing some steps themselves and making use of in-house expertise or external service providers when necessary. This corrective maintenance may be accomplished at various levels:

- *Component level.* Component-level troubleshooting and repair isolates the failure to a single, replaceable component. In electrical devices, mechanical devices, and for discreet

components of electronic devices (such as resistors or capacitors in an electronic circuit, or fuses) this is often the most effective repair approach. In relation to electronic devices, however, component-level repair may be time-consuming and difficult. Modern electronic circuit boards (digital circuit boards, especially) are frequently not repairable at the component level. In those cases board-level or even system-level repair need to be considered.

- *Board level.* For electronic devices, it is common to isolate failures to a particular circuit board and to replace the entire circuit board rather than a given electronic component.
- *Device or system level.* In some cases even board-level troubleshooting and repair is too difficult or time-consuming. In such cases it can be more cost-effective to replace the entire device or subsystem.

It is important to choose an appropriate level of maintenance for each situation. This is dependent on the availability of financial, physical and human resources as well as on the urgency of a particular repair request. For high-priority cases, for example, device-level repairs may be preferred. When more time is available, board- or component-level repair may be feasible. If component-level repair is proposed, part replacement may be necessary. For this approach, there are a few options from which to choose. The replacement can be made with specialized parts from the manufacturer, with generic parts of the same or higher specifications (e.g. fuses), or with spares reclaimed from non-functional or obsolete equipment (only after thorough risk-assessment and permission of the clinical engineering manager).

In some cases, the technician will find that the device performs within its

design specifications, as defined by the manufacturer. In such instances, it is necessary to communicate with the device user and examine the work environment to determine why the device did not function as expected. See section 5.3.8 on managing use error and section 6.2.2 on factors affecting equipment failure for further information.

6.2.2 Factors affecting equipment failures

When investigating an unexplained failure, environmental factors should be taken into due consideration. For example, medical devices that require electrical power may be adversely affected by power issues. Ideally, electrical power should have a steady voltage (of the appropriate value); be free of transient distortions, such as voltage spikes, surges or dropouts; and be reliable, with only rare loss of power. Unfortunately, these ideal characteristics do not always exist in many developing countries. Technical personnel should collaborate with those responsible for the electrical power system in the health-care organization to help make the system function as effectively as possible. This may include purchasing voltage regulators, installing uninterruptable power supplies (UPS), using surge protectors, and avoiding connecting extension leads/plug boards in series. Furthermore, technical personnel should work with the facility personnel to ensure that a functional back-up generator is in place and that the switch to auxiliary power is made in under 10 seconds. Another alternative may be to select and purchase equipment that is battery operated. When considering acquiring new equipment, it is also important for the technical personnel to ensure that the electrical power system is capable of supporting it. When it cannot, it often makes sense to opt for less sophisticated and more robust equipment.

Similarly, technical personnel should be aware of how medical devices interact with other utility systems (e.g. medical gas and vacuum systems, temperature control and ventilation systems, water supply, information technology and communication infrastructure, etc.). And, once again, they should collaborate with others in the organization to optimize the ability of the utility systems to support medical equipment.¹

Unique aspects of the physical environment, such as high temperature and humidity, can adversely affect medical equipment designed for use in temperate climates or controlled environments. Maintenance procedures in a particular country or region may need to be adjusted based on these local factors.

The age and condition of the health-care facility may also play a role in medical equipment failure. Over time, utilities systems will degrade and may become overloaded and/or outdated. Older facilities will have been built to older standards. Even new facilities may not meet all applicable standards. Therefore, it is often necessary to test the utility infrastructure rather than to assume it is functioning appropriately.

6.2.3 Inspection and return to service

After completion of repair, it is essential to conduct a performance and safety inspection, and in some cases a recalibration may be required. These activities will measure the performance of the device and allow for any adjustments necessary to return the equipment to full functionality. Once this is complete, the device may be returned to use in patient care.

¹ It is important for clinical engineers and biomedical equipment technicians to have a working knowledge of utility systems and facility infrastructure. An article that provides an overview of these topics can be found in Issue 4 of *Revista Ingeniería Biomédica* (Colombia) (<http://revistabme.eia.edu.co/numeros/4/index.html>).

6.3 Reporting

For IPM activities, the technician typically has a detailed checklist to follow in order to record the results. Having such a checklist also serves as a reminder of each step in the IPM process and thus helps avoid skipping or overlooking specific steps. Recording measurements and documenting the final results (either as 'pass/fail' or numeric values) aids in the execution of future maintenance work, including repairs. Having the last few sets of IPM checklists on-hand for reference during maintenance is extremely helpful for decision-making. For example, for equipment with therapeutic energy output, including the energy readings from the last few inspections on the next inspection form helps identify potential problems, as equipment energy levels may slowly drift over time. Additionally, knowing when routine maintenance parts were last replaced helps identify if or when the parts should be replaced again, and helps explain the condition of the parts during the current inspection.

For CM, the technician records what actions were taken, including the time and the cost of those actions.

6.4 Safety

There are various safety aspects to consider when implementing a successful and effective maintenance programme, such as the safety of technical personnel while performing maintenance, safety of the user following maintenance, and general infection control.

The safety of equipment maintenance personnel is fundamental. Therefore, it is important to have a lock out/tag out policy to protect personnel from unexpected activation of equipment and release of stored energy. This policy ensures that when working on electrical equipment

it is essential to disconnect it from the electrical power source. One or more physical locks may be applied to keep the power source disconnected ('lock out') so that it is not inadvertently reconnected before the repair is completed. When it is not possible to physically lock out the power source, prominent signage should be posted ('tag out').

Furthermore, personnel should be aware, prior to performing maintenance work, of particular medical technologies that may present special hazards such as chemical hazards from chemotherapeutic agents and from other sources, radiation hazards from radiation-generating equipment and radiopharmaceuticals, magnetic field hazards from magnetic resonance imaging (MRI) equipment, hazards from compressed gas cylinders, etc. Training in personal protective equipment (PPE) and techniques that will allow technical personnel to work safely in hazardous conditions are critical. It is preferable to have PPE readily available within the clinical engineering department for hazardous maintenance.

Following maintenance, especially after procedures that may have affected the safety features of a medical device, technical personnel should verify that the device is safe to use, mechanically and electrically. Particular attention is given to electrical safety for medical devices such that ground resistance and leakage currents are measured to ensure that they are within applicable limits. (In the absence of electrical safety test equipment, technical personnel must

rely on careful repair techniques and simple electrical tests to verify device integrity). Clinicians should be advised to check the settings of the device and to perform basic operational checks prior to using the device with patients. When direct communication is not possible, a prominent note should be placed on the device so that it is not used without being checked by the clinician.

Lastly, when working in the clinical environment, technical personnel should be aware of infection control risks that they might encounter (patients with airborne infections such as tuberculosis, for example) and, if there is any doubt, they should ask clinicians in the area. In particular, if asked to work on a medical device that appears to be contaminated, they should request assistance in cleaning the device from the clinical user, who will have knowledge regarding the potential contaminants and their associated hazards. Additionally, technical personnel should be aware of infection hazards that their work might create for patients. For example, patients with compromised immune systems (certain organ transplant patients, patients with AIDS, and others) or otherwise susceptible to infection (such as premature infants) can be severely affected by moulds and spores disturbed and dispersed by maintenance activities in the clinical environment. Again, when in doubt, equipment maintainers should communicate with clinicians about potential risks and ways to manage those risks. See Appendix A.6 for a sample infection control policy.

7 Concluding remarks

Timely and economical maintenance activities maximize the value of health technology resources, which is especially important when resources are limited. When the various financial, physical and human resource aspects are carefully examined, even with certain resource constraints, a successful programme that suits the needs of a particular context

can be designed and executed. However, the programme must be considered an integral part of health-care delivery with a minimum set of resources designated to fulfil the tasks outlined by the programme. Only in this way will patients have access to the medical equipment that can provide them with an accurate diagnosis, effective treatment or appropriate rehabilitation.



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Useful resources

All URLs accessed 29th April 2011

Association for the Advancement of Medical Instrumentation (www.aami.org):

- *AAMI benchmarking solution* (www.aami.org/abs)
- *Electrical safety manual* (www.aami.org/publications/books/esm.html)
- *Computerized maintenance management systems* (www.aami.org/publications/books/cmms.html)
- *Medical equipment management manual* (www.aami.org/publications/books/mem.html)
- *Medical electrical equipment standard 60601-1* (www.aami.org/publications/standards/60601.html)

ECRI Institute (www.ecri.org):

- *Health devices system* (www.ecri.org/Products/Pages/Health_Devices_System.aspx)
- *Biomedical benchmark* (www.ecri.org/Products/Pages/BiomedicalBenchmark.aspx)

Joint Commission/Joint Commission International:

- *Accreditation standards, United States* (www.jointcommission.org)
- *Accreditation standards, international* (www.jointcommissioninternational.org)

National Fire Protection Association (www.nfpa.org):

- *Standard for health care facilities* (NFPA 99)
- *National electrical code* (NFPA 70)

Other online resources:

- 24x7 (www.24x7mag.com)
- American College of Clinical Engineering (www.accenet.org)
- American Hospital Association (www.aha.org)
- Biomedical Instrumentation and Technology (www.aami.org/publications/BIT/)
- El Hospital (www.elhospital.com)
- Engineering World Health (www.ewh.org)
- International Electrotechnical Commission (www.iec.ch)
- Journal of Clinical Engineering (journals.lww.com/jcejournal)

Online discussion groups:

- *Infratech* (infratechonline.net)
- *Biomedtalk* (www.ecri.org/biomedtalk)

Books and articles:

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WHO Medical device technical series:

- *Introduction to medical equipment inventory management*. Geneva, World Health Organization, 2011.
- *Computerized maintenance management system*. Geneva, World Health Organization, 2011.
- *Medical device donations: considerations for solicitation and provision*. Geneva, World Health Organization, 2011.



Appendix A

Sample policies and procedures

The following samples are provided to support the development of medical equipment maintenance policies and procedures in a hospital, health centre or other health facilities. The samples should be adapted and modified according to the specific needs and circumstances of any given institution, the relevant resource context and local environment.

A.1 Risk-based biomedical equipment management programme

A.2 Initial testing and evaluation

A.3 Inspection and preventive maintenance procedure

A.4 Work order system for corrective maintenance

A.5 Corrective actions identified during preventive maintenance

A.6 Infection control

Appendix A.1

Risk-based biomedical equipment management programme

Equipment inclusion criteria have been developed to evaluate each piece of equipment in use at a hospital or health facility. The following details a modified version of the Fennigkoh and Smith model (see reference 6) where a numerical value has been assigned to each device type by classifying its equipment function, clinical application and required maintenance. Adding the number from each subgroup and adding or subtracting a factor based on equipment failure history yields an equipment management (EM) number.

EM number equation:

$$EM \# = \text{Function \#} + \text{Application \#} + \text{Maintenance \#} + \text{History \#}$$

Equipment function

Includes various areas in which therapeutic, diagnostic, analytical and miscellaneous equipment is used.

Category	Function description	Point score
Therapeutic	Life support	10
	Surgical and intensive care	9
	Physical therapy and treatment	8
Diagnostic	Surgical and intensive care monitoring	7
	Additional physiological monitoring and diagnostic	6
Analytical	Analytical laboratory	5
	Laboratory accessories	4
	Computers and related	3
Miscellaneous	Patient related and other	2

Physical risk associated with clinical application

Lists the potential patient or equipment risk during use.

Description of use risk	Point score
Potential patient death	5
Potential patient or operator injury	4
Inappropriate therapy or misdiagnosis	3
Equipment damage	2
No significant identified risk	1

Maintenance requirements

Describes the level and frequency of maintenance required as noted by the manufacturer or through experience.

Maintenance requirement	Point score
Extensive: routine calibration and part replacement required	5
Above-average	4
Average: performance verification and safety testing	3
Below-average	2
Minimal: visual inspection	1

Equipment incident history

Any information available regarding service history that can be considered when evaluating the device type to determine an EM number.

Average equipment failures	Factor
Significant: more than one every 6 months	+2
Moderate: one every 6–9 months	+1
Average: one every 9–18 months	0
Minimal: one every 18–30 months	-1
Insignificant: less than one in the past 30 months	-2

Included devices

All devices with a total EM number of 12 or more will be included in the programme and scheduled for inspections and preventive maintenance. During the acceptance testing, any new device will be included in the programme if the device has been previously evaluated and classified for inclusion. If the device has not been previously evaluated, a new device classification will be created. It will be evaluated according to the outlined procedure to produce an EM number and will be included in the programme if appropriate. If included, a performance assurance inspection and preventive maintenance procedure will be written for the new device.

Maintenance interval

The maintenance requirement values are also used to determine the interval between each inspection and maintenance procedure for each device type.

- All devices classified as extensive (characteristic value of 4 or 5) are given a preventive maintenance interval of six months.
- Devices with average or minimal requirements (values of 3, 2 or 1) are scheduled for preventive maintenance annually.
- Devices with an EM number of 15 or above will be scheduled for inspection at least every six months.
- Devices with an EM number of 19 or 20 will be given an inspection interval of four months.

Devices not included in the programme

All patient care-related equipment including therapeutic, monitoring, diagnostic or analytical equipment not included in the programme, because it did not receive an EM number of 12 or above, may still be included in the hospital's biomedical equipment inventory and be covered on a repair-only basis.



Equipment classification examples

Device description	Equipment function	Clinical application	Maintenance requirement	Incident history	EM #	Class	Inspection frequency
Anaesthesia machine	10	5	5	0	20	I	T
Anaesthesia vaporizer (enflurane/ethrane)	9	5	3	-2	15	I	S
Arthroscopic surgical unit	9	4	2	-2	13	I	A
Breast pump	3	4	3	-2	8	N	-
Aspirator, mobile	8	5	4	-1	16	I	S
Blood warmer	9	4	3	-1	15	I	S
Bone saw	9	4	2	-2	3	I	A
Blood pressure module	7	3	2	0	12	I	A
Camera, video, medical	6	3	3	0	12	I	A
Cast cutter	2	4	3	-2	7	N	-
Cast cutter vacuum	2	2	3	-2	5	N	-
Cardiac output computer	7	3	2	0	12	I	A
Computer, micro (pc)	3	3	1	-2	5	N	-
Cryosurgical unit	9	4	3	-1	15	I	S
Defibrillator/monitor	9	5	4	0	18	I	S
Electrocardiograph, 3-channel	6	3	5	2	16	I	S
Endoscopic video system	6	3	3	0	12	I	A
Electrosurgical unit	9	4	3	0	16	I	S
Fetal monitor	7	3	3	0	13	I	A
Humidifier, heated	8	3	3	1	15	I	S
Hypo/hyperthermia machine	9	4	5	0	18	I	S
Light, surgical portable	2	4	3	-1	8	N	-
Light source, fibre optic	7	3	3	-2	11	N	-
Microscope, ophthalmic slit lamp	6	3	3	-2	10	N	-

Class

I = Included
N = Not included

Inspection frequency

A = Annual T = Three-yearly
S = Semi-annual

SAMPLE

Appendix A.2

Initial testing and evaluation

Purpose

To assure that all clinical equipment is inspected prior to its initial use.

Policy

All clinical equipment coming into the hospital is tested before initial use and appropriately added to an inventory. These tests, evaluations and inventories are documented. All clinical equipment falling under the responsibility of the clinical engineering department is covered by this policy, regardless of ownership, and must pass the incoming inspection before it will be allowed into the hospital. Examples of ownership categories are:

- Rental/leased equipment
- Physician-owned equipment
- Donated/loaned equipment
- Hospital-owned equipment

Procedures

A. Hospital-owned equipment:

1. When notified that new clinical equipment is received in the hospital, the clinical engineering department will initiate a work order.
2. The clinical engineering department will ensure that the new equipment is inspected for:
 - a. Presence of all accessories required for proper operation.
 - b. Presence of operators' manuals and technical service manuals, and schematics, if applicable.
 - c. Proper operation of the equipment. Performance specifications in the manufacturer's service literature should be used if available.
 - d. Clinical alarm functionality and audibility, if applicable.
 - e. Passage of electrical safety requirements, if applicable.
 - f. Inclusion into, or exclusion from, the equipment management programme.
 - g. Compliance on labelling of equipment, to ensure that the equipment has been evaluated for safety and suitability for intended use by a nationally or internationally recognized testing laboratory.
3. If equipment passes all required inspections, the technician will affix a clinical equipment maintenance inspection sticker, or other means of identification, in a visible location on the device.

4. The clinical engineering technician who performs the inspection is responsible for ensuring the completion of the initial inspection documentation. If the technician determines that an in-service orientation/training would be beneficial, the technician will make a recommendation to the hospital education department or the department manager. Should a manufacturer in-service demonstration be required, the technician will assist in coordinating this effort with the hospital education department.

B. Testing of devices brought in for demonstration or trial evaluation

The hospital is responsible for the safety of all patients, staff, and visitors; equipment for loan, evaluation or demonstration is tested prior to its use in the hospital, unless an emergency dictates otherwise. In this instance, the user should ensure with reasonable certainty that the equipment is in safe working condition before operating. If the equipment is to remain in the hospital subsequent to its emergency use, it must be safety tested by the clinical engineering department.

1. All electrical equipment that passes the clinical engineering safety inspection will have a clinical equipment maintenance sticker affixed in a visible location, or equivalent, indicating that it has been inspected, and is safe for use in the hospital. (Certain battery-operated devices may be excluded from the preventive maintenance programme, and will not have a sticker affixed. Devices included in the programme, but that do not require regular preventive maintenance, will also receive a “PM Exempt” sticker).
2. Any equipment that fails the clinical engineering safety inspection will be returned to its originating source with a description of the failure. Such equipment/device will be prohibited from being used in the facility until it has been repaired and satisfactorily passes the safety inspection.

C. Equipment intended for use in a clinical laboratory application

Vendor provided equipment in exchange for the purchase of reagents or consumables must be approved by hospital management, the clinical laboratory, or pathology department manager and safety tested prior to being placed into service. Hospital technical staff is not responsible for the maintenance of this equipment.

SAMPLE

Appendix A.3

Inspection and preventive maintenance procedure

Equipment to be covered by the programme will typically include: life support equipment, laboratory equipment, surgical and critical care equipment, imaging equipment, equipment which could cause patient injury or death if it fails, equipment required to be maintained by regulations, equipment on an outside vendor maintenance programme, equipment under lease where maintenance is part of the lease, and equipment under warranty.

Procedure

1. All equipment due for maintenance needs to be identified one month prior to the maintenance date. The list of maintenance tasks can be generated automatically by a computerized maintenance management system (CMMS), if in place.
2. Parts required for preventive maintenance are ordered and made available for the equipment in this period.
3. The inspection and preventive maintenance (IPM) tasks will be assigned to specific biomedical technicians.
4. Work orders will be generated and distributed to the assigned technicians.
5. Maintenance will be performed in accordance with the established IPM procedure. These IPM procedures will be based on manufacturer's recommendations, industry recommendations and facility experience.
6. The assigned technician will document on the work order the inspections and maintenance performed and any other important observations.
7. When the IPM is completed successfully, the equipment will receive an IPM sticker or other identification denoting its maintenance status.
8. When the IPM and documentation is completed, the work order will be updated in the records and/or the CMMS.
9. If scheduled work cannot be completed (i.e. parts are needed, equipment is in use, equipment cannot be located), the reason is documented on a work order. This work will be followed up at a later date.
10. When scheduled maintenance is performed by an outside vendor, the biomedical engineering department will notify the vendor and schedule the maintenance service. When maintenance and documentation is completed, the work order is subsequently updated in the records and/or the CMMS.

11. Life support equipment due for maintenance but still in use by patients will be scheduled for maintenance after it is removed from the patient. The technician will work closely with the clinical department to schedule the maintenance as soon as possible.
12. Equipment scheduled for IPM but which cannot be located, can be identified as “could not locate” only after a concerted effort to locate the device has been made, the equipment owners have made every attempt to locate it and the biomedical engineering supervisor/manager has approved the device to be marked in this way.
13. If the equipment has not been located for two consecutive maintenance cycles, it will be removed from service and deleted from the records, and/or deactivated in the CMMS.
14. To assure IPM quality technician competency and the correct execution of IPM, procedures and practices need to be evaluated by clinical engineering management.
15. Maintenance completion rates, lists of equipment unable to be located, PM yield rates and other quality or performance related statistics will be reported to the relevant safety committee and the clinical engineering department staff at least quarterly.

Longer or shorter preventive maintenance intervals are adopted after documented justification based on previous PM yield data, relevant safety information and other service history records.



Appendix A.4

Work order system for corrective maintenance

The clinical engineering department has adopted a standard work order system for all departments requesting maintenance on clinical equipment. When a malfunction occurs with a piece of clinical equipment that is encompassed within the programme of the clinical engineering department, the user department shall notify clinical engineering by telephone, on-line/web request, interdepartmental mail or bringing the device to the clinical engineering office.

Purpose

To provide guidelines for the receipt and processing of clinical engineering service requests.

Procedure

1. Upon receipt of the request, a work order will be initiated. This includes priority designation and delegation of the work order to a technician for completion. Both will normally be determined by the appropriate clinical engineering manager. Input from users is encouraged with regard to priority assignment. The priority categories are as follows:
 - I. Emergency urgent
 - This describes situations of dire need and severe safety concerns for patients, visitors or staff. The lack of immediate action could lead to severe consequences for the hospital and/or potential loss of life or disability.
 - Emergency requests are accepted by phone or verbally and will be addressed by the chief biomedical engineer.
 - Under such circumstances, documentation will be completed at the earliest possible opportunity.
 - Should an outside vendor be required to rectify the problem, the chief biomedical engineer will test and evaluate the equipment upon return, prior to being taken into service.
 - II. Urgent
 - This category is used for failures that require immediate attention because the operation of the hospital/facility is compromised.
 - A work order can be hand-carried to the clinical engineering department. The response to the request will be as soon as possible, only an emergency request will pre-empt this work order.
 - III. Routine
 - This describes an action that needs to be taken, but the situation does not compromise the primary function of the hospital/facility.

- Routine work orders can be sent through the hospital/facility interdepartmental mail system.
- The requesting department will be notified once the order has been received and the work has been scheduled.

IV. Deferred

- Routine requests may be deferred based on workload or priority. No work order may be deferred for more than 10 normal working days without the approval of the clinical engineering manager.

2. Information to identify the equipment, the respective department and to describe the problem should be provided on the work request, by the person originating the request for service, or by the technician. This may include the following:
 - a. Inventory identification number
 - b. Cost center (usually the user department)
 - c. Equipment description
 - d. Telephone number
 - e. Name of contact
 - f. Location of equipment
 - g. Description of the problem

Upon completion of the work, the technician will complete the work order within one day, including all information relating to the service request. All work orders are dated and logged for record keeping. In the event that a work order cannot be completed in the requested time, or within twelve business days, the technician will notify the request originator or department manager and inform them of the reasons that the equipment repair will be delayed, and provide them with an estimated time of repair. It is the responsibility of each clinical engineering technician to follow-up on such situations as needed and personally contact the request originator or department manager if necessary.

SAMPLE

Appendix A.5

Corrective actions identified during preventive maintenance

The clinical engineering department performs preventive maintenance procedures on a timely basis as part of the hospital's equipment management plan. Corrective actions arising during preventive maintenance procedures will be documented appropriately.

Purpose

To ensure corrective actions are performed and documented appropriately when found during preventive maintenance procedures.

Procedure

A. No problem found during preventive maintenance of a medical device

1. Once the preventive maintenance procedure is performed, the technician will complete the preventive maintenance work order form.
2. The technician will affix an updated maintenance sticker, or other record of inspection, on the device.

Note: if the PM work request is completed in a month later than the scheduled month, the technician will date the sticker to correspond with the month the work request was completed.
3. The technician will return the device to service.

B. Problem found during preventive maintenance of a medical device

1. If a problem is determined to be minor, the preventive maintenance procedure can be completed and the device cannot be returned to service (e.g. a power cord has a cut in the covering), the technician should follow these steps:
 - a. Perform the preventive maintenance procedure.
 - b. Complete the PM work order form.
 - c. Affix an updated sticker on the device.

Note: if the PM work request is completed in a month after the scheduled month, the technician will date the sticker to correspond with the month the work request was completed. The due date should reflect the next due date based upon the last due month and the appropriate interval for the device.
 - d. Initiate a corrective work order request, affix a label to the device indicating it is out of service and inform the user department of the delay in return to service of the device.
2. If a problem is determined to be minor, the preventive maintenance procedure can be completed and the device can be returned to service (e.g. a hose bracket for an anaesthesia machine is broken or a cosmetic label has fallen off), the technician should follow these steps:
 - a. Perform the preventive maintenance procedure.

- b. Complete the PM work order form.
 - c. Affix an updated maintenance sticker on the device.

Note: if the PM work request is completed in a month after the scheduled month, the technician will date the sticker to correspond with the month the work request was completed. The due date should reflect the next due date based upon the last due month and the appropriate interval for the device.
 - d. Return the unit to service.
 - e. Initiate a corrective work order for eventual follow-up action when the device is available and take appropriate actions to complete the request.
3. If a problem is determined to be more than minor and the preventive maintenance procedure cannot be completed (e.g., the flow control module on a mechanical ventilator is damaged), the technician should follow these steps:
- a. Initiate a corrective work order referencing the preventive work request number, affix a label to the device indicating it is out of service and inform the user department of the delay in return to service of the device.
 - b. Complete the preventive maintenance work order and must reference the corrective work order number.
 - c. Upon completion of the corrective action, resume the preventive maintenance procedure, document that a preventive maintenance procedure was completed and then complete the corrective work request.
 - d. Affix an updated maintenance sticker on the device.

Note: the completion date will be the date the PM work request documentation is completed in the work order system. For example, a PM work request was completed in October and the CM work request was opened and carried over into November. The PM sticker should reflect the October date coinciding with the PM work order. The due date should reflect the next due date based upon the last due month and the appropriate interval for the device. The technician will complete the CM work order and document the date the CM work was done.
 - e. Return the device to service.

Appendix A.6

Infection control

All clinical engineering employees will be aware of current hospital policies regarding infection control. Employees will not knowingly expose themselves or others to any types of infectious waste.

Purpose

To provide all employees with a safe, clean working environment, to protect clinical engineering technicians from contaminated equipment.

Procedure

General precautions

1. Visibly contaminated equipment will not be accepted for repair until adequately cleaned by the appropriate department. Appropriate personal protective equipment is worn to handle equipment.
2. All clinical engineering technicians will observe isolation guidelines as well as the dress and scrub procedures for the area in which they are working. Clinical engineering technicians should not enter 'isolation rooms' or 'restricted areas' without obtaining permission from the charge nurse.
3. All clinical engineering employees will attend annual infection control education. This training will be documented in the employees' personal training record in the clinical engineering department.
4. Hand-washing is required whenever:
 - a. Hands become contaminated with blood or body fluids.
 - b. Protective gloves are removed.
 - c. Between patient contacts.
 - d. Eating, drinking, applying cosmetics and handling contact lenses are prohibited in areas where there is a risk of occupational exposure to blood or body fluids.

Personal protective equipment (PPE)

1. Disposable gloves are available, within the clinical engineering department, for all workers at risk of exposure for use at their discretion or as required.
2. Eye protection and/or a facemask will be worn whenever handling equipment that puts the employee at risk of occupational exposure to blood or body fluids through splashing.

3. Personal protective equipment, (i.e. gowns, gloves, masks and goggles) will be supplied by the user department whenever needed.
4. Contaminated supplies, (i.e. gowns, gloves, masks and absorbent towels) are to be placed in sturdy, plastic bags and tightly closed for appropriate disposal.

Equipment precautions

1. All equipment containing serviced filters will have the filters cleaned or replaced according to manufacturer recommendations.
2. Gloves will be worn during non-HEPA (high-efficiency particulate air) filter changes. These filters will be placed in normal waste.
3. Any equipment containing a HEPA filter requires that gloves, particulate respirator, gown, and protective eyewear are worn. These filters will be disposed of as infectious waste.
4. All replaced filters from the clinical laboratory should be considered contaminated and disposed of as infectious waste. Appropriate PPE will be worn.
5. All equipment that needs to be opened and vacuumed or blown clean will be done away from patient care or employee work areas whenever possible. Equipment that can be carried or rolled easily will be removed to the clinical engineering workshop for cleaning. Clinical engineering personnel will wear masks to eliminate the risk of breathing the dust from any machine.

All equipment that cannot be moved from the employee work area will be vacuumed (as opposed to blown clean), so as not to contaminate the work environment.

SAMPLE

Appendix B

Examples of inspection and preventive maintenance procedures

B.1 Procedure template

B.2 Anaesthesia/analgesia unit (gas machine)

B.3 Centrifuge, table top

B.4 Monitor, ECG

B.5 Pump, infusion

B.6 X-ray system, mobile



Appendix B.1

Procedure template

Equipment type	<i>Name and/or type of equipment</i>		
Risk score	<i>Available from the national regulatory agency, or consult the United States Food and Drug Administration (FDA)</i>	Safety inspections/year	<i>Refer to manufacturer's service manual</i>
Programme risk (EM number)	<i>Refer to Appendix A.1 to determine risk EM number</i>	Performance inspections/year	<i>Refer to manufacturer's service manual</i>
Risk group (equipment function category)	<i>Refer to Appendix A.1 to determine category</i>	PM checks/year	<i>Refer to manufacturer's service manual</i>

Procedures:

List the steps to be taken to perform inspection and preventive maintenance.

Appendix B.2

Anaesthesia/analgesia unit (gas machine)

FDA risk: 2

Programme risk score:

Risk group: Life support

Safety insp./yr.: 2

Perf. insp./yr.: 12

PM checks/yr.: 12

Procedure

1. Inspect exterior of equipment for damage or missing hardware.
2. Inspect the power cord, strain relief and plug/s for any signs of damage.
3. Turn unit off, open user-accessible covers and inspect unit for damage.
4. Clean unit interior components and exterior with vacuum or compressed air.
5. Inspect interior for signs of corrosion or missing hardware. Repair as required.
6. Inspect electrical components for signs of excessive heat or deterioration.
7. Inspect all external quick disconnect O-rings.
8. Inspect condition of all tubing, replace if necessary.
9. Inspect all cables for excessive wear.
10. Inspect inspiratory and expiratory flow valves.
11. Inspect internal circuits by leak testing.
12. Verify correct operation of gas scavenger systems.
13. Verify correct vaporizer calibration.
14. Verify correct flow meter calibration.
15. Verify correct operation of ventilator (rate, volume, flow).
16. Verify correct operation of all buttons, controls, displays and/or indicators.
17. Verify correct operation of unit in all functional modalities.
18. Clean exterior of unit including all accessories, cables, controls and displays.

Appendix B.3

Centrifuge, table top

FDA risk: 1
Programme risk score:
Risk group: Diagnostic

Safety insp./yr.: 1
Perf. insp./yr.: 4
PM checks/yr.: 4

Procedure

1. Inspect exterior of equipment for damage or missing hardware.
2. Inspect the power cord, strain relief and plug/s for any signs of damage.
3. Turn unit off, open user-accessible covers and inspect unit for damage.
4. Clean unit interior components and exterior with vacuum or compressed air.
5. Clean motor with compressed air. Check brushes if applicable.
6. Inspect interior for signs of corrosion or missing hardware. Repair as required.
7. Inspect electrical components for signs of excessive heat or deterioration.
8. Verify correct operation of lid and safety mechanism. Inspect lid gasket.
9. Verify smooth operation of the timer and correct operation of braking.
10. Verify correct operation of tachometer if applicable.
11. Verify head balance. Check for vibrations and excess noise.
12. Verify correct operation of refrigeration and thermostat if applicable.
13. Verify speed setting using a test photo-tachometer.
14. Inspect motor brushes and armature for wear. Clean out carbon build-up.
15. Lubricate motor and mechanical parts where applicable.
16. Verify correct operation of all buttons, controls, displays and indicators.
17. Verify correct operation of unit in all functional modalities.
18. Clean exterior of unit including all accessories, cables, controls and displays.

Appendix B.4

Monitor, ECG

FDA risk: 2

Programme risk score:

Risk group: Diagnostic

Safety insp./yr.: 2

Perf. insp./yr.: 2

PM checks/yr.: 2

Procedure

1. Inspect exterior of equipment for damage or missing hardware.
2. Inspect the power cord, strain relief and plug/s for any signs of damage.
3. Turn unit off, open user-accessible covers and inspect unit for damage.
4. Clean unit interior components and exterior with vacuum or compressed air.
5. Inspect interior for signs of corrosion or missing hardware. Repair as required.
6. Inspect electrical components for signs of excessive heat or deterioration.
7. Inspect patient cable and connectors for mechanical or electrical damage.
8. Verify correct detenting and lead shorting of lead selector switch.
9. Verify vertical gain and calibration pulse. Inspect monitor/diagnostic switch.
10. Verify correct sweep size, linearity, centring, speed and vertical spacing.
11. Verify correct amplifier frequency response and common mode rejection.
12. Verify correct brightness and focus of trace.
13. Verify correct operation of freeze and cascade controls if applicable.
14. Verify accuracy of heart rate meter at 3 points for $\pm 3\%$ accuracy.
15. Verify operation of high and low alarms for correct trigger and response time.
16. Cycle alarms and verify correct operation of audio and visual indicators.
17. Verify correct operation of all buttons, controls, displays and/or indicators.
18. Verify correct operation of unit in all functional modalities.
19. Clean exterior of unit including all accessories, cables, controls and displays.

Appendix B.5

Pump, infusion

FDA risk: 2

Programme risk score:

Risk group: Patient support

Safety insp./yr.: 2

Perf. insp./yr.: 2

PM checks/yr.: 2

Procedure

1. Inspect exterior of equipment for damage or missing hardware.
2. Inspect the power cord, strain relief and plug/s for any signs of damage.
3. Turn unit off, open user-accessible covers and inspect unit for damage.
4. Clean unit interior components and exterior with vacuum or compressed air.
5. Inspect interior for signs of corrosion or missing hardware. Repair as required.
6. Inspect electrical components for signs of excessive heat or deterioration.
7. Perform battery operation test.
8. Test instrument service/test mode.
9. Verify pressure calibration.
10. Perform auto pinch-off test.
11. Verify rate accuracy.
12. Verify correct operation of all buttons, controls, displays and/or indicators.
13. Verify correct operation of unit in all functional modalities.

Appendix B.6

X-ray system, mobile

FDA risk: 11

Programme risk score:

Risk group: Diagnostic

Safety insp./yr.: 1

Perf. insp./yr.: 2

PM checks/yr.: 2

Procedure

1. Inspect exterior of equipment for damage or missing hardware.
2. Inspect the power cord, strain relief and plug/s for any signs of damage.
3. Turn unit off, open user-accessible covers and inspect unit for damage.
4. Clean unit interior components and exterior with vacuum or compressed air.
5. Inspect interior for signs of corrosion or missing hardware. Repair as required.
6. Inspect electrical components for signs of excessive heat or deterioration.
7. Verify accuracy of kVp, mA-time, per manufacturer's specifications.
8. Verify correct operation of electrical locks (tube and table).
9. Verify correct operation of other electrical functions.
10. Inspect batteries if applicable; service as required.
11. Verify correct support and travel of stationary and movable rails.
12. Verify smooth operation of the drive system.
13. Verify correct operation of display devices if applicable.
14. Verify correct operation within specifications of collimators (auto and manual).
15. Verify correct calibration using manufacturer's specifications.
16. Verify correct operation of all buttons, controls, displays and/or indicators.
17. Verify correct operation of unit in all functional modalities.
18. Clean exterior of unit including all accessories, cables, controls and displays.

Appendix C

Calculating IPM workload

The following procedure and charts are used to calculate IPM workload. This mathematical methodology is used by service companies to calculate the IPM workload of the accounts they bid on. If the clinical engineering department calculates the actual work needed to accomplish this task and acquires the staff to do this work, the more likely the work will be accomplished and the goals achieved. The steps are as follows:

1. Identify the areas to be covered for IPM (a group of equipment, a department, a new wing, a whole facility).
2. Create a complete inventory of each item to be covered for IPM.
3. Record time it takes a technician to perform the inspection procedure. Each piece of equipment should be analysed, the inspection frequency and times entered into a spreadsheet and the total annual time for inspection and preventive maintenance calculated for the list of equipment to be covered. An example of this is provided in Chart A.

Chart A: Calculating IPM workload, detailed method

Medical equipment	Minor IPM frequency (per year)	Minor IPM time (hours)	Major IPM frequency (per year)	Major IPM time (hours)	Total time (hours/year)
Laboratory chemistry department					
Laboratory blood refrigerator	11	0.2	1	0.5	0.7
Laboratory specimen refrigerator	1	0.5	1	0.5	1
Heating block	2	0.25	0	0	0.5
Spectrophotometer	3	0.5	1	0.75	2.25
Bilirubin analyser	2	0.75	1	1.0	2.5
Chemistry analyser	3	3.0	1	4.0	13.0
Printer module	2	0.3	0	0	0.6
Computer printer	2	0.3	0	0	0.6
Computer monitor	1	0.25	0	0	0.25
Chemistry analyser	3	4.5	1	6.0	19.5
Microscope	1	0.5	1	1.5	2.0
Laboratory freezer	1	0.3	1	0.5	0.8
Laboratory mixer	2	0.25	0	0	0.5
Centrifuge	2	0.5	1	1.0	2.0

Chemistry analyser	3	3.0	1	5.0	14.0
Refrigerator	1	0.3	1	0.4	0.7
Chemistry analyser	3	3.0	1	4.0	13.0
Water purification system	1	1.0	1	2.0	3.0
Total					76.9 hrs.
Labour and delivery department					
Fetal monitor	4	0.75	0	0	3.0
Ultrasound scanner	1	3.0	1	5.0	8.0
Video monitor	1	0.5	0	0	0.5
Infant radiant warmer	2	0.75	1	1.0	2.5
Infant radiant warmer	2	0.75	1	1.0	2.5
Pulse oximeter	1	0.3	1	0.4	0.7
Warming blanket	1	0.5	1	1.0	1.5
Fetal monitor	4	0.75	0	0	3.0
Physiological monitor	1	0.75	1	1.0	1.75
Doppler blood flow probe	2	0.3	0	0	0.6
Syringe pump	1	0.5	1	0.75	1.25
Electrosurgical unit	1	1.0	1	1.0	2.0
Fetal monitor	4	0.75	0	0	3.0
Fetal blood gas monitor	2	1.5	1	2.0	5.0
Fetal monitor	4	0.75	0	0	3.0
Fetal blood gas monitor	2	1.5	1	2.0	5.0
Total					43.3 hrs.

An alternate, simplified method to do this is to generally categorize each device into one of three classifications:

1. Simple device – inspected once per year with no PM required;
2. Intermediate devices – inspected once or twice per year, some PM may be required;
3. Advanced systems – inspected 2–4 times per year, extensive PM required.

This method requires some familiarity with the equipment and maintenance procedures. The approximate inspection times and frequencies for each class of equipment is entered into the chart and the calculations are done to yield the total IPM work time. An example of this method is found in Chart B.

Chart B: Determining workload

(This example uses the chemistry and delivery room inventory above)

Equipment type	Simple devices	Intermediate devices	Advanced systems
Number of devices	5 Chemistry 1 Delivery	8 Chemistry 14 Delivery	4 Chemistry 3 Delivery
Total number of devices	6.0	22.0	7.0
Hours/inspection	0.3	0.5	1.0
Inspections/year	1.0	1.5	4.0
Total hours inspecting equipment	1.8	16.5	28.0
Total Workload = 46.3			

This method yields the total time needed to provide complete inspection and preventive maintenance on this inventory. This example did not take into account the time needed to travel to the clinical site to perform the work, the time to get ready for work in a particular area (gather correct paperwork, test equipment, tools and PM parts) or the time it takes to complete the paperwork after the work is done. These tasks are variable depending where the department is located with respect to the clinical areas, where the work takes place and what type of equipment will be maintained. Additionally time should be taken out of the normal work day for lunch, short breaks and short conversations with the clinical staff to build rapport and to learn about how the equipment has been functioning. All things considered, this example yields about two weeks of work for a single technician to accomplish this work in a careful and thorough manner.

Appendix D

Examples of inventory and inspection forms

D.1 New equipment received form

D.2 Equipment inspection forms

D.3 Work order form



Appendix D.1

New equipment received form

Date: _____

Tech name: _____

Equipment _____ Category _____

Floor _____ Unit _____ Dept. _____

Details	
Note:	
Asset #	
Model #	
Serial #	
Vendor #	
Manufacturer	
Functional units	
Function score	
Risk score	
Maintenance score	

Purchase Info	
Arrival date	/ /
Installation date	/ /
Warranty date	/ /
Purchase price	\$
Replacement cost	\$

Life expectancy _____ yrs

PM schedule _____
(monthly, annual, etc.)

Work order # _____

Purchase order # _____

Incoming # _____

Comments _____

SAMPLE

Appendix D.2

Equipment inspection forms

Hyper/Hypothermia Machine				
Functional check and inspection form				
Location: _____		Control number: _____		
Manufacturer: _____		Model: _____		
Item	OK? (Y/N)	Action needed	Action taken (date/initials)	
a. Condition of chassis?				
b. Condition of attachment plug?				
c. Condition of line cord and strain relief?				
d. Condition of indicator lights and alarms				
e. Flow	Mode	GPM		
	Heating			
	Cooling			
	Flow switch activation			
f. Level switch activation				
g. Cold water reservoir controls				
h. Blanket water temperature controller	Set point	Display	Thermometer	
	55 deg F			
	77 deg F			
	105 deg F			
	Display within 1 deg C (1.8 F) of set point			
Thermometer within 1 deg C (1.8 F) of set point				
i.	High temperature back-up thermostat			
	Shut down relay set point			
j. Thermometer verification test				
k. Patient temperature display test	Probe resistance	Patient temp display		
	1355	37 ° C ± 0.3 ° C		
	1667	32 ° C ± 0.3 ° C		
L. Low temperature backup thermostat				
m. Ground resistance less than 0.5 ohm				
n. Leakage current	Chassis (grounded)		10 uA	
	Chassis (ungrounded)		100 uA	
	Patient probe		50 uA	

Adapted from Medi-Therm III hyper/hypothermia service manual, 2008

QA inspection form
Volume ventilator inspection

Date: _____ Inspected by: _____ Equipment owner: _____

Device type: _____ Manufacturer: _____

Control no: _____ Model no: _____ Serial no: _____

Hour meter: _____ Location: _____

ITEM	PASS	N/A	QUALITATIVE TASK
1.1			chassis / case
1.2			mounting hardware
1.3			wheels / breaks
1.4			line cord
1.5			strain relief
1.6			circuit breaker/fuse
1.7			tubes/hoses
1.8			cables
1.9			connectors
1.10			transducers
1.11			filters
1.12			controls
1.13			heater/humidifier
1.14			motor/pump/fan
1.15			battery/charger
1.16			indicators/displays
1.17			user cal/self-test
1.18			alarms/interlocks
1.19			audible signals
1.20			labelling
1.21			accessories

ITEM	PASS	N/A	QUANTITATIVE TASKS
3.1			relief valve
3.2			sensitivity
3.3			apnea alarm
3.4			low oxygen pressure alarm
3.5			low exhale alarm
3.6			minute volume alarm
3.7			low PEEP alarm
3.8			low CPAP alarm
3.9			high rate alarm
3.10			temperature alarm
3.11			high oxygen % alarm
3.12			low oxygen % alarm
3.13			fail to cycle alarm
3.14			vent INOP alarm
3.15			I:E ratio alarm
3.16			low air pressure alarm
3.17			
3.18			
3.19			
3.20			
3.21			

2.1			ground resistance
2.2			max leakage current
2.3			leak test
2.4			control mode
2.5			assist control mode
2.6			SIMV mode
2.7			CPAP mode
2.8			pressure support
2.9			nebulizer function
2.10			rates (CIMV / SIMV)
2.11			
2.12			rates (SIGH)
2.13			SIGH function

4.1			additional tasks
4.2			clean
4.3			lubricate
4.4			calibrate
4.5			calibrate regulators
4.6			calibrate switches
4.7			calibrate transducers
4.8			calibrate compressor cutout
4.9			replace air/O2 filters
4.10			replace compressor filters
4.11			record parts used
4.12			
4.13			
4.14			

Adapted from MEDIQ/PRN quality assurance programme form, ventilator service report, 1998

SAMPLE

Appendix D.3

Work order form

Request for service

Department: _____

Date: _____

Clinician/technician reporting problem: _____

Location of device: _____

Problem description: _____

Date/time: _____

Service record

Service engineer name: _____ Date/time responded: _____

Action taken: _____

Has the problem been corrected? _____

Is follow-up work necessary? _____

When will follow-up work be performed? _____

Follow-up action

Service engineer name: _____ Date/time responded: _____

Action taken: _____

Has the problem been corrected? _____

Is further follow-up work necessary? _____

(If so, describe on reverse side of this form.)

Note: Keep this form in the active file for at least 15 days after the completion of final repairs.

Adapted from: Medical Consultants Network Inc., Reference# 1004 Biomedical Engineering

Appendix E

Samples of inspection labels

E.1 Record of inspection

E.2 Record of inspection (test) results

E.3 Notification of defect



Appendix E.1

Record of inspection

This type of label indicates the date the device was serviced or inspected and may indicate when the next service is due. These tags are sometimes printed in different colours, one for each year or inspection cycle so that it is easier to identify devices that are due for inspection. This tag may be covered with plastic adhesive/cover to protect it from being defaced during the cleaning process.

BIOMEDICAL ENGINEERING DEPT.
SAFETY CHECKED
 By _____
 Date _____

SERVICED
 Date _____ by _____
 Due _____
 Service Performed CAL PM PT ST

 DO NOT REMOVE LABEL

CLINICAL ENGINEERING
 INSPECTION PASSED
 TECH _____ I.D. _____
 DATE DUE _____

INSPECTED
 DATE _____ BY _____
 DUE _____

Approved For Use By
Biomedical Engineering Dept.
 Date Inspected _____
 Inspected by _____
 Inspection Due _____

ELECTRICAL SAFETY CHECK
NON-HOSPITAL OWNED DEVICE
 RENTAL LOANER EVAL. OTHER
 BY _____ DATE _____
 Next Inspection Due _____

BATTERY
 Dates
 Checked _____
 Replaced _____
 By _____

INSPECTED
CLINICAL ENGINEERING
 Date _____ By _____
 Location _____

Appendix E.2

Record of inspection (test) results

This label provides space to record the output readings taken during the performance assurance inspection. These can be used to record outputs on many energy-producing devices including ultrasound therapy equipment, lasers, defibrillators, electrocurrent therapy devices, nerve stimulators, etc.

CLINICAL ENGINEERING PERFORMANCE TEST RESULTS			
DATE		TECH	

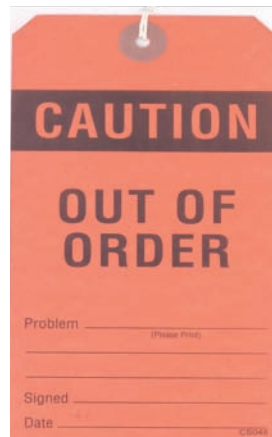
ULTRASOUND OUTPUT	
ID NO. _____	DATE _____
TESTED BY _____	
ULTRASOUND SETTING (WATTS)	ACTUAL OUTPUT (WATTS)
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

DEFIBRILLATOR CALIBRATION	
INDICATED	DELIVERED
WS	WS
WS	WS
WS	WS
WS	WS
WS	WS
MAX.	
DATE _____	BY _____
NEXT INSPECTION DUE _____	

Appendix E.3

Notification of defect

This label is placed on medical equipment that has been inspected by the clinical engineering staff and found to be defective. It is printed on very brightly coloured paper to attract the clinician's visual attention and prevent inadvertent use of the device.



CAUTION

OUT OF ORDER

Problem _____
(Please Print)

Signed _____

Date _____

UAL BE764



DO NOT USE

Control Number: _____

Date (problem) _____ Time (problem) _____ and/pm

Location (at time of problem) _____

Description of Problem (explain) _____

Service was requested: yes no

Engineering (Ext. 44200)

Clinical Engineering (Ext. 43382)

_____ (Ext. _____)

Occurrence Report generated: yes no

User _____ Date _____

Department _____ Ext. _____



REMOVED FROM SERVICE

DATE INITIALS

MUST RECEIVE PM/ELECTRICAL
SAFETY INSPECTION PRIOR TO
RETURNING TO SERVICE



**DEFECTIVE
DO NOT USE**

DATE: _____

BY: _____

DO NOT REMOVE
THIS LABEL



Appendix F

Test equipment per medical device category

Medical device category	Test equipment required
Electrosurgical units	Radio frequency electrosurgical analyser
Defibrillators	Defibrillator analyser
All electrical equipment	Electrical safety analyser
Anaesthesia machines, ventilators	Test lung
Anaesthesia machines, ventilators	Ventilation analyser
Heart lung machines, hyper/hypothermia machines, warming pad pumps, dialysis machines	Fluid flow meter
Anaesthesia machines, ventilators, CO ₂ insufflators, vacuum regulators, air-O ₂ blenders, lasers	Gas flow meters
Physiological monitors, intra-aortic balloon pumps, defibrillators, EEG machines, EKG machines	Physiological simulators
ICU monitors, EKG machines	Arrhythmia simulators
IV pump, surgical irrigation pump	Graduated cylinder
Radiographic and fluoroscopic equipment	Ionization chamber/radiation analyser/kVp meter
Surgical and ophthalmic lasers	Laser power meter/laser thermal imaging plates
Most electronic equipment	Multimeter/oscilloscope/function generator
Radiographic, mammography, ultrasound, CT, MR	Phantoms
Air-O ₂ blenders, anaesthesia machines, medical gas systems	Oxygen analyser
Pacemakers	Pacemaker analyser
Scales, traction units	Scales, spring scale, floor scale, balance, weights
Ventilators, heart-lung machine, anaesthesia machine	Pneumatic tester, pneumatic flow meter
Medical gas systems, insufflators, lasers, haemodialysis machines, suction regulators	Pressure meter
Incubators, infant warmers, laboratory ovens	Temperature probe/thermometers
Infusion pumps, traction units	Stop watch/timers
Centrifuges	Photo or contact tachometer
Electrical outlets	Receptacle testers
Isolated power systems	Isolated power tester
Non-invasive blood pressure monitors	Non-invasive blood pressure simulator
Dialysis machine	pH/conductivity meter
Various	Variable resistance box, variable capacitance box

Appendix G

Examples of job descriptions

G.1 Biomedical equipment technician – entry-level

G.2 Biomedical equipment technician – mid-level

G.3 Biomedical equipment technician – senior-level

G.4 Clinical engineering supervisor/manager



Appendix G.1

Biomedical equipment technician – entry-level

Job description:

Performs tasks involving the installation and maintenance of therapeutic, diagnostic and monitoring medical equipment.

These activities include:

1. Installation, maintenance and repair of a diverse range of medical equipment.
2. Performing electrical safety inspections on medical equipment using specialized test equipment.
3. Assisting in the systematic preventive maintenance programme of medical equipment.
4. Documenting all work performed including new equipment inspections, corrective and preventive maintenance and special requests as required. Maintaining documentation in an accurate and timely manner.
5. Assisting hospital clinical and technical staff in the proper operation and maintenance of clinical equipment.
6. Communication with users regarding status of repairs. Meeting the needs of clinical departments and obtaining loaner or replacement equipment as required.
7. Acceptance testing on new clinical equipment per department policy.
8. Being aware of patient- and work-safety issues, reports problems found and assists with correction of issues as required.
9. Identifying and recommending medical equipment that is obsolete, has an extensive repair history, no longer has service support from the manufacturer or has identified safety problems.
10. Providing good customer service, answering phones in a pleasant manner, screening and referring calls as appropriate and providing information to staff, visitors and patients, upon request.
11. Maintaining a professional appearance and approach to work.
12. Maintaining good relationships with fellow workers, clinical staff and other hospital workers.
13. Maintaining a high level of productivity. Making suggestions to improve department productivity when appropriate.
14. Maintaining a clean and safe work place.
15. Following all departmental policies and procedures.

Education: Two-year degree or equivalent training in electronics, biomedical equipment technology or a related field is required.

Experience: No experience required above minimum education. One-year experience as a biomedical equipment technician in a health-care setting preferred.

SAMPLE

Appendix G.2

Biomedical equipment technician – mid-level

Job description:

Performs tasks involving the installation and maintenance of therapeutic, diagnostic and monitoring medical equipment.

These activities include:

1. Performance of both routine and complex tasks associated with the installation, maintenance, and repair of a diverse range of clinical equipment including life support equipment.
2. Working independently in both routine and complex tasks. Being able to prioritize work and initiate new work and tasks.
3. Being able to effectively work with clinicians to troubleshoot clinical problems with medical equipment. Being able to solve technology problems for the clinicians.
4. Providing training, mentoring and guidance for entry level technicians.
5. Participation in committees as requested.
6. Coordination of initial inspection and installation of new equipment as requested.
7. Coordination and management of projects from start to completion, performing any necessary communication and follow-up with owner department.
8. Assisting with pre-purchase evaluations of equipment as required. Participation in incident investigations as requested and provides follow-up to management.

Education: Two-year degree or equivalent training in electronics, biomedical equipment technology or a related field is required.

Experience: At least three years experience as a biomedical equipment technician or a minimum of five years experience in electronic, mechanical or electromechanical repair or equivalent, preferably in a healthcare setting.

Appendix G.3

Biomedical equipment technician – senior-level

Job description:

Performs tasks involving the installation and maintenance of therapeutic, diagnostic and monitoring medical equipment.

These activities include:

1. Being able to consistently perform a wide variety of routine, complex and specialized tasks associated with the installation, maintenance and repair of a wide range of clinical equipment including life support equipment.
2. Training, mentoring and guidance to entry-level and mid-level technicians.
3. Conducting training sessions for department staff covering safe operation and maintenance of equipment for entry-level and mid-level technicians.
4. Assisting in developing technical specifications for equipment purchases.
5. Routinely coordinating and managing projects, performing any necessary communication and follow-up with the department.
6. Leadership and prioritization of work in the absence of the manager.

Education: Two-year degree or equivalent training in electronics, biomedical equipment technology or a related field is required.

Experience: Requires a minimum of four years experience as a biomedical equipment technician.

SAMPLE

Appendix G.4

Clinical engineering supervisor/manager

Job description:

Responsible for directing and managing clinical engineering activities directly related to safe and effective medical equipment.

These activities include:

1. Acquisition, maintenance and repair of the medical equipment.
2. Assisting and overseeing writing specifications for new equipment.
3. Evaluation and assistance in acquiring new technology for patient care.
4. Coordination of preventive maintenance and repairs by outside service personnel.
5. Evaluation of possible service contracts and outside vendor relationships.
6. Maintaining familiarity with regulatory codes and standards.
7. Collaboration with clinical staff to provide the highest level of patient safety.
8. Ensuring that applicable accreditation standards are met.
9. Ensuring departmental policies and procedures are followed.
10. Managing other projects as assigned.
11. Managing department productivity and performance improvement initiatives.
12. Assistance in the management of the computerized maintenance management system.
13. Ensuring the timely completion and documentation of all maintenance activities.
14. Maintaining the stock of repair parts to ensure appropriate maintenance of equipment.
15. Ensuring timely completion of preventive maintenance.
16. Representing clinical engineering at meetings as assigned.
17. Instructing hospital personnel on safe and proper operation and maintenance of medical equipment.

Education: Requires a two-year degree in clinical/biomedical engineering or equivalent. A four-year degree in clinical/biomedical engineering is preferred.

Experience: Work requires minimum of three years of clinical/biomedical technology experience including management and leadership experience.

Appendix H

Examples of actions performed when developing maintenance programmes at the facility level

H.1 Planning a maintenance programme at a district hospital

H.2 Managing a maintenance programme at a district hospital

H.3 Planning a maintenance programme within a regional health system

H.4 Managing a maintenance programme within a regional health system



Appendix H.1

Planning a maintenance programme at a district hospital

Critical factor	Action	Responsible party
Inventory	<ul style="list-style-type: none"> • Create an inventory of all medical equipment in the hospital using a computer spreadsheet or simple CMMS software. 	Clinical engineering department
Methodology	<ul style="list-style-type: none"> • Identify current resources • Define maintenance methodologies: <ul style="list-style-type: none"> – Simple maintenance tasks – hospital staff – critical equipment of greater complexity – service contracts 	Clinical engineering department manager
Financial resources	<ul style="list-style-type: none"> • Plan for service contracts. • Develop the budget for implementing the programme. • Develop the budget for operating the programme. • Identify budget sources. 	Clinical engineering department manager
Physical resources	<ul style="list-style-type: none"> • Plan for build-out of space and acquisition of tools and equipment. 	Architect
	<ul style="list-style-type: none"> • Plan for basic computer resources. 	Administrator
Human resources	<ul style="list-style-type: none"> • Plan additional training for technicians. • Identify managerial capabilities within the hospital for management of the programme. • Develop links to external resources. 	Clinical engineering department manager/administrator

Appendix H.2

Managing a maintenance programme at a district hospital

Management component	Action	Responsible party
Personnel management	<ul style="list-style-type: none"> Assign scheduled and unscheduled work to the repair person. Monitor hours worked by the technician and timely completion of scheduled and unscheduled work assignments. 	Clinical engineering department manager
	<ul style="list-style-type: none"> Document work on work order forms and, if available, in the CMMS software. 	Technician
Financial management	<ul style="list-style-type: none"> Monitor costs associated with service contracts and with work carried out by the technician. Compare costs to budget, review variances, plan for future budgets. 	Clinical engineering department manager
Operational management	<ul style="list-style-type: none"> Develop procedures and schedules for inspection and preventive maintenance. Develop policies for prioritizing corrective maintenance activities. Monitor services provided under service contracts. 	Clinical engineering department manager
	<ul style="list-style-type: none"> Work closely with clinicians. 	Clinical engineering department manager/technician
Performance monitoring	<ul style="list-style-type: none"> Monitor performance measures. 	Clinical engineering department manager
Performance improvement	<ul style="list-style-type: none"> Compare performance to objectives annually; identify opportunities for improvement. 	Clinical engineering department manager

Appendix H.3

Planning a maintenance programme within a regional health system

Critical factor	Action	Responsible person
Inventory	<ul style="list-style-type: none"> • Create inventory of all medical equipment in the system using full-featured CMMS software. 	Clinical engineering department
Methodology	<ul style="list-style-type: none"> • Define maintenance methodologies: <ul style="list-style-type: none"> – simple and moderate maintenance tasks – hospital staff – critical equipment of greater complexity – service contracts, with “first look” by hospital staff 	Clinical engineering department manager
Financial resources	<ul style="list-style-type: none"> • Identify financial resources (moderate). • Plan for service contracts. • Develop budget for implementing the programme. • Develop budget for operating the programme. • Identify budget sources. 	Clinical engineering department manager
Physical resources	<ul style="list-style-type: none"> • Identify physical resources (some space, tools, and equipment). 	Clinical engineering department manager
	<ul style="list-style-type: none"> • Plan for build-out of space and acquisition of tools and equipment. 	Architect
	<ul style="list-style-type: none"> • Plan for basic computer resources. 	Administrator
	<ul style="list-style-type: none"> • Plan for transportation among hospitals and clinics. 	Administrator/transport services officer
	<ul style="list-style-type: none"> • Plan for service request dispatching and clerical support. 	Administrator
Human resources	<ul style="list-style-type: none"> • Identify current human resources (one engineer and a few technicians with varying skills). 	Clinical engineering department manager
	<ul style="list-style-type: none"> • Plan additional general and specialised training for technicians. • Plan management training for the engineer. • Develop links to external resources. 	Clinical engineering department manager/administrator

Appendix H.4

Managing a maintenance programme within a regional health system

Management component	Action	Responsible person
Personnel management	<ul style="list-style-type: none"> • CMMS assigns scheduled and unscheduled work using defined protocols. • Monitor hours worked by the technical staff and timely completion of scheduled and unscheduled work assignments. 	Clinical engineering department manager
	<ul style="list-style-type: none"> • Technical personnel document work on work order forms and in the CMMS software. 	Technician
Financial management	<ul style="list-style-type: none"> • Monitor costs associated with service contracts and with work carried out by technical staff. • Compare costs to budget, review variances, plan for future budgets. 	Clinical engineering department manager
Operational management	<ul style="list-style-type: none"> • Develop procedures and schedules for inspection and preventive maintenance. • Develop policies for prioritizing corrective maintenance activities. • Monitor services provided under service contracts. • Participate in medical equipment planning, incident investigation and committee activities. 	Clinical engineering department manager
	<ul style="list-style-type: none"> • Work closely with clinicians and conduct customer satisfaction surveys. 	Clinical engineering department manager/technician
Performance monitoring	<ul style="list-style-type: none"> • Monitor performance measures plus additional measures supported by the CMMS. • Manage compliance with applicable standards, performance benchmarking, and implementation of 'best practices.' 	Clinical engineering department manager
Performance improvement	<ul style="list-style-type: none"> • Prepare written report comparing performance to objectives and identifying opportunities for improvement. • Implement performance improvement initiatives and monitor for success. 	Clinical engineering department manager



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