

MINISTRY OF HEALTH

National Policy for Management of Medical Devices in Albania





SWEDISH INTERNATIONAL DEVELOPMENT
COOPERATION AGENCY

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MINISTRY OF HEALTH

**National Policy for
Management of Medical
Devices in Albania**



REPUBLIC OF ALBANIA
Ministry of Health
MINISTER

No. 3272 Prot.
11.09.2007

Tirana,

ORDER

No. 356, Date 10.09.2007

FOR

**The Approval of the National Policy for the Management of
Medical Devices
in Albania**

In support to article 102, paragraph 4 of the Constitutional Law of Republic of Albania and in the implementation of the long term Strategy for the development of the Albanian healthcare system

I ORDER

1. The approval of the National Policy for the Management of Medical Devices in Albania.
2. The General Directorate of Policy and Healthcare Planning, the Directorate of Human Resources, the Directorate of Procurement in the Ministry of Health, the National Biomedical Center and hospital institutions, are requested to implement this Order.

This order enters into power with immediate effect.

THE MINISTER

Nard Ndoka

Signed and sealed

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Abbreviations

AER	Adverse events reporting
ALL	Albanian Lek
BENC	Biomedical Engineering Centre
BSc	Bachelor of Science
CE	Clinical Engineering
CEU	Clinical engineering units
CRT	Cathode ray tubes
EBM	Evidence based medicine
EC	European Commission
ECB	European Central Bank
ECRI	Emergency Care Research Institute, AER reporting institution etc.
EU	European Union
GDP	Gross domestic product
HII	Health Insurance Institute
HMIS	Health management information system
HSR	Health sector reforms
ICU	Intensive Care Unit
INSTAT	Albania's National Institute of Statistics
IPH	Institute of Public Health
LCC	Life-cycle costs
LTHSD	Long-term Strategy for the Development of the Albanian Health System
MDD	Medical Device Directive
MDIS	Medical Device Information System
MDMS	Medical Devices Management Sector
MOES	Ministry of Education and Science
MoH	Ministry of Health
MOLGD	Ministry of Local Governments and Decentralisation
SAMD	State Agency of Medical Devices
NGO	Non-governmental organization
NCQSA	National Centre of Quality, Safety and Accreditation of Health Institutions
PCB	Polychlorated biphenyles
PHC	Primary health care
PHM	Public health management
PPA	Public Procurement Agency
PPL	Public Procurement Law
PRSP	Poverty reduction strategy and policy
SAA	Stabilization and Association Agreement
SEK	Swedish Kroner
Sida	Swedish International Development Assistance
TOR	Terms of reference
TOT	Training of trainers
UNESCO	United Nations Educational and Social Council
UNDP	United Nations Development Programme
WB	World Bank
WEEE	European Directive on Electrical and Electronic Waste
WHO	World Health Organization

1. Introduction and background

1.1 Purpose of Policy Document

This document describes the health sector policy in the field of management of medical devices in Albania. It reflects the Long Term Strategy for the Development of the Albanian Health System (LTHSD) developed by the Ministry of Health (MoH) and approved by the Council of Ministers in 2004 as well as the Stabilization and Association Agreement (SAA) signed by the Government of Albania and the European Union (EU) in 2006.

In 2004 the Ministry of Health initiated the development of this document with support from Sida and Swedish Health Care. It has been approved by the Ministry of Health in August 2007.

The document describes the technology infrastructure and competence necessary for the use of modern medical devices in the Albanian health care system. It shall serve as a base for development of future legislation concerning medical devices. Also based on this policy document, hospitals and other health care providers will be encouraged to build a local technology infrastructure to support safe and efficient use of medical devices. These guidelines are in line with the European legislative framework for medical devices.

1.2 Scope of Policy Document

Over the recent decade Albania has adopted a wide variety of health policy documents and the Ministry of Health has identified a number of health policy goals, but none of them

have specifically addressed the issues of safe and efficient use of medical devices in Albania. Reorganisation of the health services and modernisation of hospitals and health centres are necessary and important steps on the road to a health care that meets European standards. Modernization of the health care services should ensure that medical devices and other capital investments are used properly and that they are maintained in a good way, so that expected lifetimes are ensured and patient safety not violated.

This policy document describes all organizational changes and specific regulations and guidelines required to ensure a better management of medical devices and their safe and efficient use. The organizational issues addressed in this document include the organizational and operational plan of the Medical Devices Management Sector (MDMS) in the MoH, organization and functioning of the Clinical Engineering Units (CEU) at the Albanian hospitals, and the role and functioning of the State Agency of Medical Devices (SAMD) at national level. (Refer to chapter 2). Some important systems to support a technology infrastructure are described in chapter 3. Policies, guidelines, rules and regulations, intended to cover all stages of clinical use of medical devices (life-cycle management) in Albania, are developed in detail in chapter 4, while chapter 5 focuses on health technology assessment.

1.3 The Medical Technology Challenge

Due to many donations and national investments in Albanian hospitals a rapid change of medical care is at hand. It gives the medical staff access to modern technology with a possibility for better treatment of diseases. Effective modern health care depends both on highly skilled staff for safe and efficient use of medical devices but also on safe and efficient medical devices which must be available and prepared to produce results during their entire lifetime.

This development is making life easier for both medical staff and patients if everything is going according to plans. But all

medical devices have a limited life-expectancy and will sooner or later suffer from break-downs. Investments in new technology without investments in an infrastructure to run it will only result in short life expectancies for the technology, and cause frustration among the staff using it, resulting in inefficient and ineffective medical care. There is consequently a need to focus on support for medical technology management.

All kinds of medical devices, even new ones, must fit into a technology infrastructure managed by professionals since they require safe procedures and guidelines on how to use the device and conduct preventive maintenance. It is no longer just about the repair of faulty devices as new medical devices tend to be more complex than older inventions and must be carefully selected and introduced to fit the user. The devices are often integrated into advanced medical systems that require an understanding of computers, medical applications and specialised maintenance.

Dealing with modern medical technology therefore requires specially trained clinical engineers. Providing proper maintenance for medical devices is a cost-effective way of ensuring not only that the devices last longer, but more importantly that they provide safety for patients. The Albanian health care sector has in the past suffered due to availability of complex devices that requires specialists for repair and maintenance. Support has increasingly been required from external experts. This situation is not sustainable as it creates important budget constraints, may bring frustrations due to non-working equipment or additional costs hiring expertise for service. In the worst case, patients miss out on important examinations or treatments due to faulty medical devices.

2. Organization of Clinical Engineering in Albania

2.1 Medical Devices Management Sector (MDMS) in Ministry of Health

2.1.1 Introduction and Background

To design and monitor the technology infrastructure in the Albanian health care the MoH must take the lead. The adoption of the EU legislative framework for medical devices also requires special attention. Since special competence is needed, a special unit within MoH must be set up.

Such a unit is the Medical Devices Management Sector (MDMS) in the MoH, which is responsible for the overall supervision and monitoring of the use of medical devices in the health care sector. Continuous training of clinical engineers is also required and standards must be set for the regulation of their work.

This section of the policy document describes the mission, policy, strategy and scope of work for the MDMS, for which a work plan shall be elaborated and continuously updated.

2.1.2 Mission

The mission of the MDMS is to increase patient safety and safety for the user when medical devices are used.

MDMS shall function as the Albanian Competent Authority: Introduce EU legislation and institutionalize the mutual report with pertinent facilities of European Council as well as with Competent Authorities of members of European Union

A Competent Authority according to EU medical device directives is responsible for:

- designating Notified Bodies to carry out conformity assessment procedures.
- handling applications for clinical investigations.
- ensuring adverse incidents are reported within appropriate time scales and evaluated.
- the withdrawal of unsafe devices from the market.
- effecting the Directives into law through statutory instruments.
- ensuring only those devices bearing the CE marking are allowed onto the market.

2.1.3 Policy and strategy

- Provide patients, users and third parties with a high level of safety and health protection and attain the performance levels attributed to them by legislation and the manufacturer of medical devices
- In order to be accepted by professionals the MDMS must be highly competent in its field of work. The Unit must also work efficiently, be independent and act in a transparent way.
- For control and monitoring of the market and adverse events MDMS shall assume an executive role.

2.1.4 Scope of work

- a. Introduce EU legislation and function as a Competent Authority. Update the regulatory framework: amendments/completion/new formulation
- b. Monitor, analyse and issue relevant national and international safety information on medical devices and their use.
- c. Set up an Adverse Event Reporting System (AER, refer to section 3.1) on medical devices.
- d. Set up the structures at the national level: State Agency of Medical Devices (SAMD) and Clinical Engineering Units

(CEU), and monitor their functioning and effectiveness.
 e. Document the procedures and act according to them.

2.1.5 Human Resources and Competence of MDMS

To meet the objectives of the MDMS a spectrum of competence is needed. Focus is on clinical engineering and users of medical devices. But also knowledge on national legislation is of importance. Therefore at least the following competences shall be represented by the MDMS in the MoH: clinical engineer, medical doctor, preferably with a background in intensive care, and a lawyer. A network of other competences must be built up and used when needed, e.g with nurses and suppliers of medical devices.

2.1.6 MDMS Organisation

A chart of the MDMS organisation and network is drawn in figure 2-1.

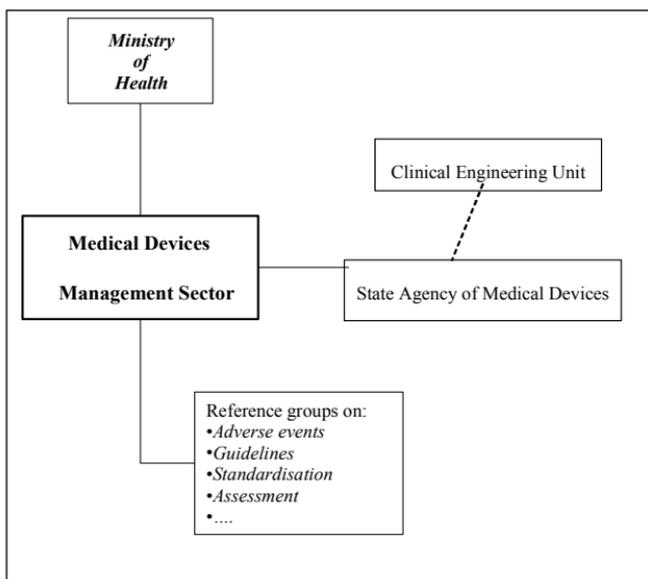


Figure 2-1. Proposed organizational chart for the Medical Devices Management Sector (MDMS)

2.2 State Agency of Medical Devices

2.2.1 Introduction and Background

The Biomedical Engineering Centre (BENC) is an existing national workshop for maintenance of medical devices. It supports health care institutions in Albania with maintenance of medical devices. When the local hospital clinical engineering unit (CEU) need experts to repair a medical device or lacks a CEU, it is sent to BENC in Tirana for repair or a BENC employee is asked to visit the institution for repair. Up till today most of the technical staff employed at hospitals are not trained in clinical engineering and need support from BENC.

Medical devices of many brands are entering Albania in various ways. New devices may be found underutilized or inappropriately used due to factors such as lack of consumables, lack of maintenance and insufficient competence of users. To improve utilisation of medical devices additional competence is needed. Such competence is organised in the State Agency of Medical Devices (SAMD). The existing BENC will be transformed into the State Agency of Medical Devices in order to provide the highest level of competence in clinical engineering in support of modern medical technology of the Albanian Health Care system.

This chapter describes the State Agency of Medical Devices (SAMD), representing a high level of clinical engineering competence that shall be able to support Albanian health care with a proper technology infrastructure for modern medical devices. SAMD and CEU's (ref chapter 3.2) will work in close cooperation with the existing BENC

2.2.2 Mission

To provide patients, users and third parties the safety as well as with a high level of protection and attain the performance levels attributed to them by the manufacturer of medical devices. It shall help users to take advantage of all opportunities

that modern medical devices can produce and consider cost-effectiveness.

2.2.3 Policy and Strategies

SAMD shall work with increasing competence and cost-effectiveness in an organisation with high motivation and behave proactively in order to support the Albanian health care system with the highest competence in clinical engineering.

The SAMD budget shall be accommodated within the MoH overall budget and SAMD services shall be free of charge for public hospitals.

2.2.4 Scope of Work of SAMD

The SAMD shall be responsible for:

- a. Managing the National Medical Device Information System (MDIS, refer to section 3.2).
- b. Managing the database of persons placing medical devices on market and database of adverse events.
- c. Ensuring accessibility of information and communication with the European database of medical devices
- d. Provision the clinical evaluation of medical devices
- e. Medical devices classification according to MDD.
- f. Information and investigation of adverse incidents including the communication/collaboration with European Commission and member states of European Economic Zone related to them.
- g. State Supervision over compliance with the requirements set by the medical devices law and legislation established on the basis of it: market supervision, notified bodies, manufacturers, supervision over the notification and investigation of adverse events, the organisation of clinical investigations; deciding on application of the rule for classification of medical devices in the event of a dispute between the manufacturer and notified body.
- h. Inspection of conformity of medical devices to requirements.
- i. Contestation of precept or act.

- j. Set up national standards for the most frequently used medical devices.

2.2.5 SAMD organisation

The State Agency for Medical Devices (SAMD) will be an agency of the Ministry of Health, financed by the state budget. It will be composed by four separate sectors in charge of the following areas:

- a. Registration implying the database of medical devices, persons placing medical devices on market etc;
- b. Information and investigation of adverse incidents;
- c. Clinical investigation;
- d. Inspection of conformity of medical devices to requirements.

2.3.6 Competence

The SAMD shall develop advanced competence in specialised medical areas in order to provide users, clinical engineers, medical doctors and procurement officers with professional service and advice. Specialist competence is required in the strategic planning for medical devices such as procurement and also when it comes to safety checks, service contracts, maintenance, safe use and disposal of medical devices.

Medical specialties for SAMD to focus on are the following:

- Intensive Care.
- Surgery.
- Infection control.
- Diagnostic radiology.
- Physiology.
- Laboratory.
- Neonatal care.
- Dialyses.

2.3 Clinical Engineering Units (CEU)

2.3.1 Introduction and Background

Clinical Engineering is an expert field and most hospitals using medical devices need this kind of support. The occupation has developed over the years and gradually become more sophisticated and specialised. Traditionally medical devices have often been handled by the technical maintenance staff at the hospitals at a level of repairing equipment failure.

Modern medical devices are much more complex. Today a wide range of devices are computer based and medical devices interconnected with each other. Devices can often also be portable or implantable, patient-activated or have built-in intelligence. This requires a wide range of technical skills, some basic medical knowledge and a high degree of understanding of the concept of risk management since the technology is applied on the human body.

A clinical engineer works with both practical and advisory tasks, often in close collaboration with the medical staff. The clinical engineer is a very important communication link between medicine and technology. Providing expertise in procurement, development of new methods, integration of systems, organising efficient repair and spare-part supplies, preventive maintenance of medical devices, training of staff concerning safe use and installing new equipment belong to the scope of tasks of the clinical engineer. Qualified clinical engineers shall have the sufficient and necessary education and training for carrying out needed tasks at a hospital.

In order to provide the hospitals in Albania with clinical engineering competence, Clinical Engineering Units (CEU) shall be established at the hospital level.

2.3.2 Mission

The mission of a Clinical Engineering Unit is to monitor and develop the technical safety of devices in medical care in fa-

in favour of the patient and users and to minimise the cost of use in favour of the hospital and the patient.

2.3.3 Policy and Strategies

A Clinical Engineering Unit shall be represented with adequate competence with regards to medical devices within the hospital and is consulted in all handling of medical devices and tasks with regards to purchase, safe use and relocation of medical devices.

A Clinical Engineering Unit shall have expert knowledge when it comes to laws, regulations, advices, standards and recommendations within the field and is an advisory resource in issues concerning the field of medical devices.

A Clinical Engineering Unit (CEU) shall provide professionally performed technical support to the health care sector at the hospital level. Clinical engineering support involves all tasks required in the process of purchase, acceptance test, use, maintenance, relocation and disposal of medical devices. The purpose is that the medical device during its entire life cycle shall fulfil the requirements of:

- Safety for the patient, personnel and environment.
- Availability.
- Reliability.
- Economy.

The Clinical Engineering Unit shall carry out tasks based on:

- Standards.
- Regulations.
- Medical profession's demands.
- Manufacturers' recommendations.

2.3.4 Scope of Work of Clinical Engineering Unit (CEU)

The CEU shall be responsible for:

- a. The technical safety of medical devices close to the patient, connected to the patient and medical devices necessary for

treatment or diagnosis.

- b. Carrying out service and repair, as specified in Box 1.
- c. Planning and performing preventive maintenance according to the manufacturers' instructions.
- d. Performance of regular safety checks to ensure that the medical devices conform to issued standards and are safe to use.
- e. Acceptance test and delivery checks with regards to function, safety and to confirm delivery status according to purchase order.
- f. Securing that procurement, service and maintenance are carried out in accordance in the most cost effective way for the health care organisation.
- g. Support and give technical advice during the procurement process of medical devices regarding technical requirements, life cycle costs and evaluation of tenders.
- h. Project management during installation and provision of technical advice in planning of new projects.
- i. Communication with suppliers to the health care institution.
- j. Supervising tasks that are carried out by service contract companies or by suppliers.
- k. Hands-on training and support in safety aspects regarding use and handling of medical devices.
- l. Support the clinic in the design of procedures including medical devices and special attention to the risk management.
- m. Carry out risk assessment, control that essential requirements can be met and produce documentation in accordance with MDD for In-house products.
- n. Disposal of medical devices not in use or not appropriate for use.
- o. Development of quality programme within the clinical engineering field.
- p. Register all medical devices which are used at the hospital in the Medical Device Information System (MDIS, refer to 3.2) and update it regularly with maintenance and incident information.
- q. Adverse event inquiry (AER, refer to 3.1) and reports when medical devices are involved. The manager of the depart-

ment reports to the authority concerned according to documented routines.

- r. Organise service training of medical devices

Box 1: Service and maintenance include:

- Safety control and risk management.
- Quality control regarding performance and function.
- Preventive maintenance.
- Repair.
- Contacts with external companies and management of service contracts.
- Modifications and adaptations.

2.3.5 CEU Organisation

The Clinical Engineer is employed by the Director of the Hospital to the Clinical Engineering Unit (CEU) and is responsible to the manager of the CEU.

The Manager of the CEU must be direct responsible to the Director of the Hospital

2.3.6 Competence and Resources

Necessary resources in the CEU are:

- a. Staff and clinical engineering competence
- b. Financial budget including resources for spare parts and training.
- c. Tools, Test equipment and Facility

Competence:

A CEU needs to have trained and qualified Clinical Engineers, but can also include other staff such as technicians that are working with medical devices. The number of clinical engineers necessary at a hospital depends on the amount and complexity of medical care and devices a hospital performs.

A qualified clinical engineer is an engineer trained in the field according to the European university programme, with a BSc

in engineering as a base. Such training has been performed in Albania, and course materials exist in order to implement the training in the Albanian university training programme. Additional competence, master's programme, can be achieved in some European universities.

No clinical engineer is able to be an expert on all medical devices and therefore clinical engineers shall seek to work in networks with other colleagues that have other areas of competences.

The development of medical devices and associated technology is rapidly changing and the CEU need to have a competence development plan how to match the future need. A budget needs to be set aside for competence training.

The CEU shall also seek expert knowledge at the BENC and SAMD when appropriate.

Budget and Resources:

In order to run a CEU with prompt and efficient service a budget is needed for service handbooks, components, spare parts, tools and training. Some maintenance and repair can only be carried out by third party contractors such as suppliers and service contract holders and the appropriate budget for such service shall be calculated when the medical device is procured. The size of the budget to run a CEU shall match the clinical need at the hospital.

Tools and Facility:

Minimum requirements for facility and service equipment to run a CEU:

- a. Room for workshop in connection to or located in a clean area of the hospital. Close to the intensive care unit (ICU), operating theatre and radiology department.
- b. Workshop with workbench, electric power, medical gases, soldering station etc., spare parts, tools and test equipment.
- c. Office with desk and chairs, internal and external telephone lines, PC with internet connection and office programme and MDIS software.

3. Technical infrastructure support systems

The technology infrastructure for the use of medical devices in Albania must be improved in order to strengthen the Albanian health services. To be able to use medical devices in a safe and efficient way in the public and private health sector it is important to understand the components of such an infrastructure. In order to handle this infrastructure properly, knowledge and skills in technology management among staff must be ensured.

One tool to assure efficiency and safety of medical devices is to use technical support systems implemented on a national level. An Adverse Event Reporting System (AER) is a report system that shall be used to monitor the use of medical devices, learn from mistakes and prevent accidents from reoccurring. It is aimed for the safety of staff and patients and it also involves the responsibility of the manufacturer. A Medical Device Information System (MDIS) is an inventory system that shall be used to administrate, organise and follow up technical matters with medical devices. It is a helpful tool for procurement officers, clinical engineers and hospital management to achieve efficiency of medical devices. The following chapter focuses on the description of these vital support systems.

3.1 Guidelines on Adverse Event reporting system on medical devices.

3.1.1 Introduction and Background

An adverse event with a medical device is defined as an accident and/or incident that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, users or other persons and involves the use of a

medical device. Adverse incidents with medical devices may arise due to:

- a. Shortcomings in the design or manufacture of the device itself.
- b. Inadequate instructions for use.
- c. Inadequate servicing and maintenance.
- d. Locally initiated modifications or adjustments.
- e. Inappropriate user practices (which may in turn result from inadequate training).
- f. Inappropriate management procedures.
- g. The environment in which a device is used or stored.
- h. Selection of the incorrect device for the purpose.

The conditions of use may also give rise to adverse incidents:

- Environmental conditions (e.g. electromagnetic interference).
- Location (e.g. devices designed for hospitals may not be suitable for use in the community or ambulances).

3.1.2 Definitions and concepts

A medical device is defined as any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease or compensation for an injury or handicap, or for control of conception. The medical device, by definition, does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.

An accessory is defined as an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

Blame free culture is defined as management of technology to

be controlled by a quality assurance system. It is important to monitor failures in the system, technical as well as user faults, as input for improvements. Reports on faults shall therefore be encouraged and not seen as the first step to find someone to blame. An adverse event reporting system can thus be seen as one of the means to improve technology. Therefore a blame free culture must be created to encourage adverse event reporting in order to improve the medical device and the use of it, and thus promote patient safety.

3.1.3 Actions to be taken by Hospital Management

- a. Establish and maintain procedures to ensure the prompt reporting of adverse incidents relating to medical devices to MDMS in accordance with this document.
- b. Appoint a hospital manager (medical doctor) to co-ordinate the reporting of the incidents and the local dissemination of MDMS safety warnings.
- c. Keep MDMS informed of this person and changes to his/her contact details.
- d. Review regularly local procedures and update those as necessary.

3.1.4 Responsibilities

It is the responsibility of the hospital manager:

- to design a procedure for adverse event reporting and reception of safety alerts with medical devices, and make the procedure known to all medical staff.

It is the responsibility of the head of a clinic:

- to participate and control that the staff has been trained in reporting adverse events. He/she shall also participate in reporting, investigating and follow up of reported adverse events and create a blame free culture for reporting.

It is the responsibility of all users of medical devices:

- to report adverse events where a medical device has been involved, whether the device have caused the accident/incident or not. The adverse event must in one way or another have jeopardised the patient or others safety.

3.1.5 Rules and Regulations for Local Reporting

Any adverse event, accident/incident, involving a medical device, including products for single use and their accessories shall be reported to the Medical Devices Management Sector (MDMS) at the Ministry of Health, especially if the incident has led to or could lead to death, life-threatening illness or injury, deterioration in health or permanent impairment of body structure or function. Also events which have led to or could lead to the necessity for medical or surgical intervention or has required in-patient hospitalisation or prolongation of existing hospitalisation or given rise to unreliable test results leading to inappropriate diagnosis or therapy shall be reported.

It is also obligatory to report any other device-related adverse incidents or minor faults and discrepancies to the MDMS, since those incidents may take on a greater significance when aggregated with other similar events as they may help to demonstrate trends or may indicate inadequate quality assurance on the part of the manufacturer or supplier.

Also reports of adverse incidents that appear to be caused by human error shall be reported. The error may be partly or fully due to deficiencies in the design of the device or instructions for use. Reporting will help to prevent repetition of mistakes, possibly by promulgation of advice or through improvements to the design of future devices.

3.1.6 When a Report shall be made

All incidents shall be reported as soon as possible after the occurrence. Serious cases shall be reported to MDMS by the fastest means available, preferably on-line, fax or e-mail, followed up by a confirmatory telephone call. Telephone reports should be followed up as soon as possible by a written report. The initial report of an incident should contain as much relevant detail as is immediately available, but should not be delayed for the sake of gathering additional information. Refer flow chart in box 2. for necessary steps in the local reporting of adverse events.

Box 2. Flowchart for Local Reporting of Adverse Events

- An adverse event with a medical device is discovered
- Patient is rescued and the device is taken out of use and put in quarantine
- The report form shall be completed by the user
- The report form is sent to the head of clinic and the case is discussed among collaborators.
- Clinic management controls that the report form has been sent to hospital management.
- Hospital management completes the report and sends it to MDMS as soon as possible
- Reporter (user of medical devices) and clinic management receives a copy of the completed report from hospital management
- The head of clinic take actions to prevent the event from occurring again.
- MDMS receives the report and register it
- MDMS consider if a complementary investigation shall be performed, and sends a receipt that the case is received and inform about further investigation.
- When appropriate MDMS informs the clinic about what has been learned from the case and when the medical device can be repaired and taken into use again.
- Hospital management/clinic management shall change procedures according to MDMS suggestions to prevent the event from occurring again
- The clinic management informs the staff about the case and the necessity to take action to prevent recurrence of event

3.1.7 How to Report

The report shall be in writing. The generic report form, attached to this document (refer annex 6) will facilitate the reporting. The report shall without delay be sent to the head of the clinic for further handling. Serious cases shall be reported to MDMS by the fastest means available.

3.1.8 How to handle defective or contaminated items

Infected items shall initially be quarantined where possible and should not be repaired (either in-house or by a third party), or returned to the manufacturer/supplier unless otherwise agreed with MDMS. Neither shall they be discarded before MDMS has been given the opportunity to carry out an investigation itself. The manufacturer or supplier shall be informed promptly, and allowed to inspect the items if accompanied by an appropriate person. To facilitate an investigation, it may be possible to provide the manufacturer with a sample of unused stock from a large batch. However, until advised to the contrary by the MDMS, the manufacturer must not be allowed to exchange, interfere with, or remove any part of the product implicated in the incident if this would prejudice subsequent investigations by the MDMS or by other official bodies. Once the MDMS has indicated that an item may be returned to the manufacturer, the manufacturer shall be contacted to ensure that correct forms of documentation and transport are arranged.

If devices are required for use, defective parts may be removed so that the medical device can be repaired. Any parts removed under such circumstances must be quarantined and securely stored pending investigation. MDMS advice shall be sought and, in all cases, the defective parts shall be clearly identified and kept secure. If it is not possible to remove defective parts or withdraw the medical device from use, staff shall be made aware of the need for increased vigilance and extra caution during use.

In case of contaminated devices, which may constitute a bio-hazard, MDMS will provide advice where necessary, particu-

larly as to whether arrangements should be made for the item to be examined prior to any decontamination.

Where decontamination/cleaning would destroy vital evidence, the item shall be placed in protective containment, labelled and placed in quarantine. MDMS and the manufacturer/supplier shall be contacted for advice prior to any further action being taken.

3.2 Guidelines on Medical device information system

3.2.1 Introduction and Background

The following guidelines describe the procedures required at the national level in order to organise and monitor all medical devices in clinical use within the health care sector in a systematic manner.

A Medical Device Information System, MDIS, is a necessity in the modern health care system for efficient planning and monitoring of health care services. It is an essential tool for medical, technical as well as administrative staff at various levels in the health care sector. With the help of MDIS, hospital management and the MoH will be able to provide cost-effective health care services, maintenance and capital investment planning. It also simplifies the procedures when it comes to reporting and monitoring adverse events that have occurred with medical devices.

A computerised information system makes it easier to retrieve data and to get various types of lists and statistics. The advantage is more obvious when you have several thousands of items registered. When MDIS works as a national system that includes several hospitals, it may serve as a very useful tool for those engaged in situation analyses and health planning.

Introduction of a computerised MDIS-system at the health institution level facilitates planning and follow up of medical devices. At any point in time the hospital will have full control over its resources and costs. It is easy to moni-

tor the condition of the medical devices in a hospital where there is a MDIS system in use. By storing all information from each hospital in a common database, vital information can be shared and potential accidents may be prevented.

If there are any reports about medical devices with risks from Albania or from other reporting systems around the world it is easy to identify potential risks also in Albania. If a high level of breakdowns occurs with a given model of devices in one hospital, it is easy to find out where the same types of medical devices are in use in other hospitals, and preventive actions may be taken to eliminate future problems. If a medical device needs to be withdrawn, because it is faulty and poses a risk to users or patients, it is possible to list locations of all the relevant medical devices and appropriate actions can be implemented. A withdrawal action can be requested by SAMD or a manufacturer.

There are several ways to organise this information depending on the size of hospitals and clinics. But a minimum of information requirements that shall be processed when working with medical devices are the following:

- Inventory of Medical Devices
- Preventive Maintenance and service planning
- Tracking of MD history and carried out service

Keeping track of medical devices and being able to plan for future activities with medical devices is an activity that clinical engineers perform in their daily work. When a new medical device arrives in a clinic, the clinical engineer shall make acceptance test and at the same time register the device in a system. A well working and continuously updated Medical Device Information System is necessary for future maintenance and service, but also for the efficient regular purchase of consumables as well as for the development of plans for future replacements and other new investments.

The system shall be designed and organised in such a way that it can be a useful tool for medical, technical as well as adminis-

trative staff at various levels of the health care system. It will offer competent authorities a possibility to monitor medical devices that are in use at various clinics and hospitals in Albania. Registered data can be presented in many ways and adapted to various needs. A computerised system is more efficient when it involves many medical devices, but staff working in smaller hospitals can use paper records for registration and printouts. The principles of registering data shall be the same whether the information is stored in a manual system, such as paper records, or in a computer.

3.2.2 Policy

All health care providers within the health care sector must have a system to organise, plan and monitor medical devices that are in clinical use. The devices shall preferably be registered in a national computerised inventory system, referred to as the Medical Device Information System (MDIS), or if not possible in a local manual inventory system. Information regarding medical devices shall be developed, monitored and updated in a systematic manner.

The system owner of MDIS shall be the MoH-MDMS. But SAMD can be appointed to keep and run the system.

The MDIS includes features that allow monitoring of medical devices from the hospitals with regard to issues such as cost, safety, efficient use and needs of replacement.

3.2.3 Responsibilities

It is the responsibility of Ministry of Health:

- to provide a system that fulfils the requirements for registration, monitoring and data for planning of medical devices in public health care facilities.

It is the responsibility of the State Agency of Medical Devices (SAMD):

- to run, maintain and update the MDIS as well as to customise the interface for different users and make the information retrievable for relevant users.

- to develop an inventory tag system that offers unique identification numbers to be used on the medical devices in Albania.
- to offer education and training for the proper use of the MDIS.
- classify the medical devices in accordance with a standardised nomenclature.
- design and update routines for safety backup on all data in the system on regular basis.
- for setting authorization levels and keeping records of authorization levels for users.
- assist hospitals to register medical device data, which do not have a clinical engineering unit.

It is the responsibility of the hospital manager:

- to monitor the medical device information deriving from the medical devices in their hospital. The organisation of work with MDIS, including routines and responsibilities, shall be established and documented in each hospital.
- is to inform all users of medical devices that only registered medical devices shall be in clinical use.

It is the responsibility of the clinical engineering unit (CEU):

- to register the basic medical device data and also to keep records about repairs and maintenance/service that have been carried out and other essential information about the medical device.
- to ensure that all records relating to the repair and maintenance of any medical device are accurate, detailed and readily accessible.
- to ensure that all registered medical devices remain identifiable.

It is the responsibility of the head of clinical services:

- to ensure that only medical devices that are registered in the Medical Device Information System, as indicated by the inventory tag, are in clinical use in his/her clinic.

It is the responsibility of the user:

- to use only medical devices that carry the inventory tag.

3.2.4 Procedures and Routines

Each Hospital must keep track of their medical devices, and for that must have procedures for registration of medical devices in MDIS. These procedures shall be organised and documented and be made available to clinical engineering staff that maintains medical devices. All procedures shall continuously be monitored, reviewed and updated in order to assure its efficiency, correctness and applicability.

3.2.5 Medical Devices to register in an MDIS System

- a. All medical devices in a hospital and/or health care facility that are in clinical use shall be registered in the system. The definition follows the EU definition found in the Medical Device Directives. They are quoted in box 3. below.
- b. Single use items, accessories and disposable medical devices shall be excluded and not be registered. Medical devices that are part of a medical device system shall be registered.
- c. The MDIS system shall only contain medical devices newer than 1995, or medical devices in working condition that are in clinical use.
- d. In-house products intended to be used on humans shall be included in the system. An in-house medical device must comply with the same safety rules as a for manufactures devices.
- e. Devices for research and development shall be registered. Medical devices shall be registered due to economic value, safety reason or other reason that makes the registration important.

Box 3. Definition of medical devices according to MDD 93/42 EC

A medical device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such mean

3.2.6 Who shall register Medical Device Data

The registration work shall be carried out by staff from the clinical engineering unit at the hospital with help from the clinic. Hospitals without clinical engineers shall have assistance from SAMD staff. Prior to registration in the system an acceptance testing, which includes function and safety control of the medical device must be carried out. All new medical devices that are to be installed and put into service must be registered in the MDIS prior to any clinical use. The registration shall be carried out at the time of acceptance test when obtaining new medical devices. A registration card may be used as a checklist at registration of new medical devices.

3.2.7 Classification of Medical Devices

Medical devices registered in the system shall be classified in accordance with a national standardised nomenclature. The nomenclature shall offer a description of the type of device in either English or Albanian language. With a nomenclature, authorities receiving the pre-marketing registration of devices will have a much greater opportunity to build up a database useable for their coming tasks. In order to make registration an activity useful for the future, a proper generic description of the device, together with its make and model, is essential. The nomenclature must be comprehensive and cover all the devices put on the market or considered a device at a global level, and provide a definition suitable for a correct classification of the device in question. The nomenclature shall be monitored and updated continuously in order to match new classifications of medical devices.

3.2.8 Unique Registration Number

Each medical device shall be marked with a unique registration number, referred to as inventory tag. The tags shall be organised in a logical number sequence. SAMD shall be responsible for allocating a number sequence to each hospital for the labelling according to the hospital need. There shall only be one type of inventory tag on the medical device. Two pieces of devices can not have the same number. The inventory tag shall be placed clearly visibly on the medical device. It shall be easy to identify for the user. The material of the inventory tag should resist conventional cleaning agents.

3.2.9 Information to be registered

In the medical device information system all important information about medical devices shall be registered. Medical device registration data shall be registered so that information can be retrieved for economical, maintenance or safety reason. Essential data is specific data about each medical device and historic data over each medical device lifetime.

Each hospital shall register, either in paper format or on a computer, the complete history of the device, including the:

- a. Manufacturer or supplier.
- b. Serial number or other unique identifier.
- c. Acquisition date.
- d. Value (real or estimated).
- e. Current location.
- f. Planned maintenance and recommended intervals.
- g. Repair and maintenance history data.

All medical devices in clinical use shall be included in a maintenance system.

The medical device system shall be a tool for planning, prioritizing and follow up maintenance of medical devices. The Clinical Engineering Unit must establish routines and ongoing planning for how and when maintenance is going to be carried out. Data on the repair history should be relevant and comprehensive. Data shall be easy to find by using well defined search words.

Service and maintenance data shall be in sufficient detail to allow the clinical engineer to monitor performed services and maintenance and to determine the contribution of planned maintenance. In order to track the completed repair and maintenance for each medical device, the following information shall be registered:

- a. Name of person who has performed the repair/maintenance.
- b. Name of person who reported a problem with a medical device.
- c. General description of the problem or service need.
- d. The spare parts used during the repair/maintenance.
- e. Name of company if the work has been carried out by such, and in
- f. Sufficient detail to determine that the work is in accordance with the agreed specification and to the level of detail agreed.
- g. Information on service-contract and when such involvement appears, including relevant data to determine that

the work is carried out in accordance with the agreement.

3.2.10 Access Rights to Medical Device Data

All system users that are authorised by SAMD to have access to the medical device information system shall be documented and with which level of retrieval. Responsibilities for assigning authorised use shall be documented and be decided by the SAMD in cooperation with the hospital management.

3.2.11 Removal of Medical Device Data

Obsolete medical devices shall be treated as disposed medical devices in accordance with the Guidelines of Disposal of Medical Devices (refer to section 4.5). Disposed medical devices shall have the inventory tag removed and the MDIS must be updated with the new status of the device.

Medical device data shall remain in the system, offering access to historical data.

Samples of information to be registered in a Medical Device Information System are listed in annex 5.

4. Medical Device Guidelines for Local and Regional Hospitals

The following guidelines are set up to cover important safety aspects of the life cycle of medical devices at hospital level starting with the acquisition of a medical device and ending with its disposal. The complete life cycle of a medical device at a hospital can be described as illustrated in figure 4-1. Each hospital needs to set up its own procedures, with the help of these recommendations as set out in the following guidelines. Necessary competence to administer these routines and technology infrastructure is described in each guideline. These Guidelines are mainly intended for the use of:

- Hospital management
- Medical device users
- Clinical engineers

To achieve good clinical engineering practice in larger hospitals, the guidelines assume the existence of a Clinical Engineering Unit (CEU). The guidelines can however be used by other organisations, such as BENC for instance, or hospitals that consults individuals with Clinical Engineering competence where no existing CEU is available at the hospital.

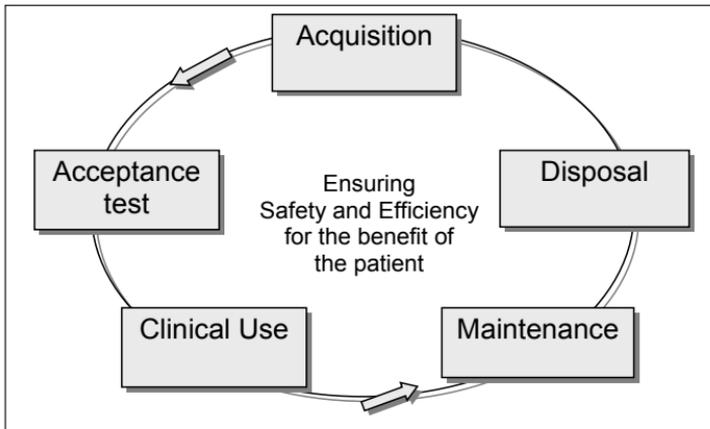


Figure 4-1. The life cycle of a medical device at hospital level

4.1 Guidelines on Acquisition of Medical Devices

4.1.1 Introduction and Background

Correct procurement of a medical device is the basic parameter in the modern technology infrastructure for health care. It is essential for safe and efficient use of medical devices. Therefore it is important to follow defined procedures for obtainment that are based on these guidelines. If a medical device with a minor quality has been obtained it will cause more problems and costs later when used and interfere with estimated production results.

This section describes the procurement procedures and activities in the technology infrastructure that need to be applied in order to assure safe and efficient use of medical devices at hospital level. The acquisition guidelines cover 5 different situations:

- Procurement of new medical devices
- Spare parts and consumables
- In-house production
- Change of ownership
- Donation

Irrespective of the origin and mode of acquisition of a medical device it shall be procured according to these guidelines.

The health care sector shall obtain and introduce new medical devices in a safe and correct way such that EU directives and national laws are respected and cost effectiveness is ensured. The guidelines in this section advice on how acquisition processes can guarantee that safe products for intended use on patients are acquired and that proper instructions for use, training of users and technical documentation is ensured.

4.1.2 Policy

- a. Only CE-marked medical devices and consumables shall be accepted for use on patients.
- b. If not possible to provide CE-marked medical devices in any given situation, in-house production can be accepted.

But devices produced in-house must meet the same specifications of safety as CE-marked products.

- c. All new medical devices must pass an acceptance test before they are used on patients.
- d. The procurement procedures must include introduction of users and appropriate technical training such that the competence of medical staff is adequate to ensure safe use of the medical device on patients.

4.1.3 Responsibilities of Parties involved in the Acquisition Process

It is the responsibility of Hospital management.

- to design a procurement procedure, organize the process and support the process with a purchase officer. No procurement processes shall be initiated unless management has accepted to finance it.

It is the responsibility of Clinical management:

- to set and control the medical needs and participate according to decided procedure.

It is the responsibility of Clinical engineers:

- to set and control technical specification, the risk analyses, compliance with MDD, carry out acceptance test, prepare for maintenance and other needs to support the process.

4.1.4 Procurement of Medical Devices

The requirements must be based on clinical needs. The procurement procedure can be divided in several consecutive activities.

- a. The procurement procedure of capital investments of medical devices starts with describing the needs of a medical device and ends with an acceptance test of it. Flowcharts for procurement of medical devices are outlined in figures 4-2 and 4-3.
- b. Medical needs formulated by user and decision by management.

- c. Technology assessment
- d. Specification of product requirements
- e. Purchase (Tender procedure)
- f. Acceptance of tender and decision by management
- g. Contracting the selected supplier
- h. Delivery and installation
- i. Acceptance testing and technical control
- j. Clinical implementation - training of user and acceptance reported to management which gives clearance to pay.
- k. Payment by fiscal department
- l. Warranty

The management of the clinic is responsible for defining the clinical needs and ensuring that all aspects of use and viewpoints of all staff are considered. Cost benefit analyses and the level of improvement of patient treatment are also important factors to consider. When clinical needs are accurately defined the financial manager must accept to continue with the procurement procedure. This indicates that the manager is willing to pay for obtainment of the device later. Next step includes an assessment of the devices available on the market and specification of the product requirements. Such requirements must be based on the intended use as defined by the manufacturer. International standards inform about most technical requirements on a medical device if intended use is specified. What shall come with the device must be specified like service costs and training. Also the procedure of evaluation of tenders must be specified. This work covers several areas of competence and the work must be organized in a multi professional team to ensure best purchase and quality.

If specification is accepted by all parties involved in the procurement, purchase can start. Purchase must follow Albanian law, which since January 2007 complies with the European, and shall be controlled by a purchase officer locally or at the national level.

The legislative framework for public procurement in Albania is described in annex 1.

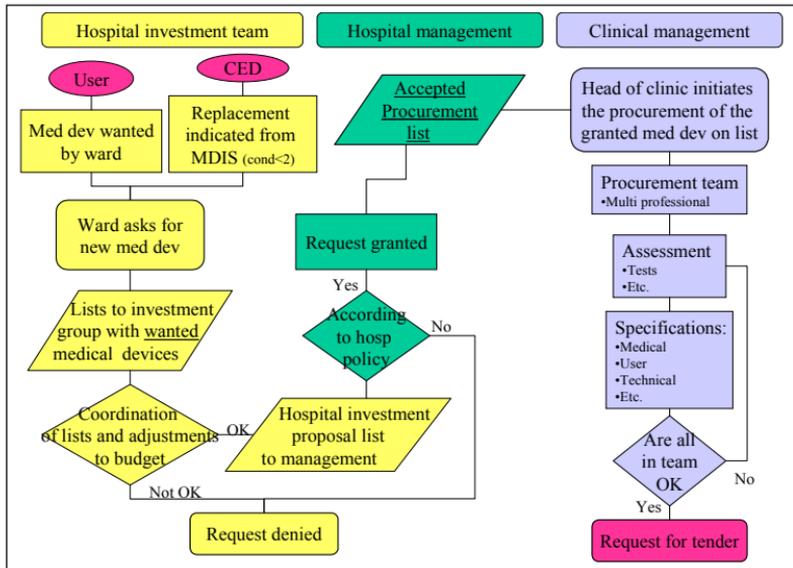


Figure 4-2 Initial phase of procurement of Medical Devices

When tenders have been submitted from different suppliers, a selection process starts which to a high degree is controlled by the law (refer annex 1). The selection shall be done by the multi professional team like the one setting up the specifications. The work shall be characterised by objectivity and transparency of the process towards all suppliers. Suppliers shall be treated fairly and equally. When costs are calculated several parameters must be considered and the life cycle costs (LCC) of the device can be estimated. Such parameters are:

- Capital investment costs.
- Costs of consumables.
- Cost of testing for acceptance.
- Staff cost (training and use).
- Maintenance costs and estimated spare parts.

Since documentation in user and technical manuals is considered part of the device it must be evaluated as well as the device itself. Introduction and staff training must also be evaluated. There are many parameters to be considered in selecting a tender from a supplier or manufacturer. First all requirements set up in the re-

quest for tender must be fulfilled. The life cycle costs and support from suppliers during the expected lifetime of the product must be considered. An important factor is the relation between the supplier and manufacturer. The supplier must have access to the same information about the product as the manufacturer, such that he can provide prompt services for the product. When a supplier has been selected by the evaluation team and acceptance from management has been obtained the purchase contract can be signed by the purchase officer.

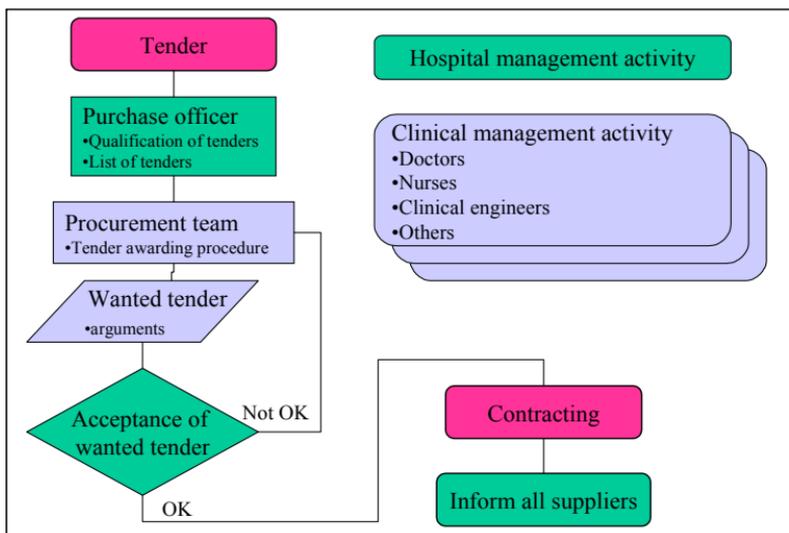


Figure 4-3 Procurement of Medical Devices

Delivery and installation is done by the supplier and the hospital shall support him in order to facilitate the process and reduce costs. Included in installation costs is contracted training of the staff. Acceptance tests shall be performed according to the procedure as described in section 4.2 and in accordance with the contract. A report shall be issued and inform about anything missing, if appropriate, and when the warranty period starts. After accepted delivery, payment is done unless otherwise stated in the contract. Warranty period starts according to the contract and result of the test report.

A checklist of questions to be addressed prior to procurement of medical devices is attached to this document (refer annex 2). A list of requirements for inclusion in the invitation for tenders is also attached (refer annex 3).

4.1.5 Procurement of Consumables, Accessories and Spare Parts

Consumables and accessories that are part of medical devices and that shall be used in combination with such shall be purchased according to the recommendation of the manufacturer of the device. Only when the manufacturer's recommendation is followed he can guarantee the safety and performance of the medical device.

The purchase of accessories other than those recommended by the manufacturer must be prevented. If not possible they must be handled as in-house production (refer to 4.1.6). When procuring a new medical device, a list of associated accessories and consumables shall be requested from the supplier or the manufacturer. All consumables, single-use items and accessories shall be accompanied by instructions for use, either stated on the device or on the package or have a separate instruction included with the packing. Information shall be in a language understood by the intended user.

Consumables that are not used together with a medical device shall bear the CE mark and be marked with a lot (batch) number if in sterile condition. Items with expiration dates shall not be procured in such big quantities that normal stock holding will compromise the expiration time. When procuring items with expiration time the tender from the supplier shall include information about remaining time of use. Consumables and single-use items which have passed the expiration date must not be used.

Devices labelled for single use are designed with the intention by manufacturers that they will not be re-used. Re-use of single-use items will compromise the safety of the patient and

staff. Suppliers that sell refurbished single-use items shall not be considered unless in-house production can be guaranteed.

When procuring a new medical device a spare part budget shall be set aside matching the future need for that medical device. A Life cycle cost (LCC) analysis shall be performed in order to estimate associated costs and the spare parts needed for a medical device.

In case of an immediate need for spare parts, the decision regarding which spare parts to buy shall be made with the assistance of a clinical engineer and in collaboration with hospital management. Prior to procuring a spare part, sufficient trouble shooting must have been carried out on the medical device. Spare parts shall always match those specified by the manufacturer.

Refurbished spare parts shall be avoided unless they can be guaranteed to work safely and satisfactorily by the manufacturer. The use of a refurbished or an alternative spare part must be demonstrated to be equivalent and must take into account all risks to patients and users and be fully documented. In this case the CE-mark has no value but an in-house production is at hand. A risk analysis must be carried out if this option is considered. Procurement of pirate spare parts is dangerous and will compromise the safety for both the patient and staff and must therefore be prevented.

Procurement of spare parts shall be seen to be ad-hoc, since it is not possible to foresee what is going to break down in advance. With a big variety of different types of medical devices in the hospitals it is not efficient, or even possible, to build up a standard spare part stock. Therefore unique spare parts shall normally not be held in stock. Most manufacturers and suppliers shall be prompted to provide fast delivery of such spare parts. Only spare parts that are identified as critical in the Maintenance system shall be hold in stock.

When procuring a medical device the tender from the sup-

plier shall include information about delivery time of spare part and prices. For medical devices that are crucial and where no down-time can be accepted there shall be spare part stock within accessible reach. Such spare parts shall be identified by the manufacturer or supplier. There shall be efficient routines so that when a spare part is needed it must be possible to order without long waiting time. Having broken medical devices waiting for spare parts must be prevented and is considered inefficient, since the device can not be used during that time.

4.1.6 In-house Production of Medical Devices

Sometimes health care institutions need to use products not intended for medical use or to use medical devices in manner, not originally intended. Those may be simple devices for common use, but not intended for use in health care by the manufacturer. An example is cotton bands used to help surgeons strap healthy tissues away from the surgical field. Such a product can be called an in-house product. An in-house product can also be a complex medical device that is used in a manner not originally defined by the manufacturer, e.g. an insulin pump for the intended use of injecting an insulin inhibitor. All use of devices on humans, simple or complex, in a manner not originally intended by the manufacturer, is done with the responsibility of the user and not the manufacturer. By doing so the user must guarantee the safety of the device. In-house products must meet the same safety level as CE-marked medical devices. If such a safety level can be ensured, products may be accepted for use on patients and considered to be in-house products not intended to be put on the market. Hospital management is responsible for development of local procedures in order to ensure the same level of safety for in-house products as for CE-marked products. Management shall also allocate technical competence to support this procedure.

In-house medical devices shall comply with essential requirements in the Medical Device Directives (MDD), be accompanied by a user manual in the Albanian language, be marked with an identification number but not marked with a CE-

mark. The medically responsible person shall confirm that the product meets the essential quality requirements and is suitable for use on patients. This confirmation includes an assessment that benefits exceed risks and that staff using the device is adequately trained. Clinical engineering competence shall document that the device is technically safe. This includes a risk analyses and acceptance control. The documentation to document safety must be stored in a safe place as long as the device is used as well as during the two subsequent years.

If the use of an in-house Product on a patient can be questioned, the medically responsible person must apply for acceptance by an ethical committee at the health institution in question. In annex 7 a roadmap to design and commission in-house products is outlined.

4.1.7 Change of Ownership

It is possible that a used medical device, which no longer fulfils a clinical need in one public hospital, could be fit for use in a different public hospital. Such a medical device may be transferred to another user in the same health care organisation. According to the EU legislation a medical device can not be put on the market unless a CE marking procedure has been performed. When changing owner in the organisation high safety requirements shall be considered and a life-cycle cost (LCC) assessment shall be made before accepting a medical device in order to assess future maintenance costs. It is important to keep in mind that when a medical device is resold the manufacturer is no longer fully responsible. The responsibilities only apply when the medical devices are initially marketed as new or fully reconditioned. Such device shall be treated as In-house production and a risk-assessment shall always be carried out.

Before sale, donation or transfer of ownership of a medical device, both parties should thoroughly investigate the legal liability aspect in consultation with a legal advisor. For example, the new user may inherit the liability for previous incidents or unpaid hire or purchase costs if appropriate

contracts are not used. The former user may request the new owner to sign a disclaimer, to the effect that the former owner has no future responsibility for the medical device.

Essential requirement of the Medical Devices Directives (MDD) requires the original manufacturer to provide all the information needed to verify whether the medical device can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely at all times. In order to ensure good practice, the former user should apply this principle to the sale, donation or change of ownership of medical devices, to ensure device safety. This information should be available to the new user before change of ownership and be supplied with the medical device on delivery.

The original user manuals should be supplied along with the medical device, in order to ensure clear and safe use of the medical device. Recommendations on any other necessary training should be given. The original medical device manufacturer should be able to provide this information. If manuals and training information are not available, the medical device shall be considered unsuitable for passing on to a new user.

Any updates which have been issued since the medical device was manufactured should be included in the delivery. The new user should in addition ensure that there is a method to keep up to date with any safety updates from the manufacturer in the future. This is because the manufacturer may not be aware who are the present owners of their medical device, and will not put them on their mailing list for safety updates. A medical device log book and service history record should be supplied with the medical device and passed on to the new user. By means of the log book it will be possible to track the medical device backwards throughout its life. Before the new user takes the medical device into clinical use an acceptance test should be carried out by a clinical engineer. The medical device shall also be registered in the Medical Device Information System and have a plan for maintenance.

4.1.8 Donation of Medical Devices

Donation of medical devices is a desired option that many health care organisations strive towards. Even so, a donation of medical devices needs to comply with the same policies and standards as new medical devices being procured. In general there should be no difference whether the medical device is donated or procured through a regular procedure, as described in section 4.1.4 above. It is preferable if the donated medical device is new and can get delivered directly from the manufacturer, since the manufacturer then can guarantee safety of the CE-marked device. In any other cases the medical device needs to be treated as In-House products, as specified in section 4.1.6. However, since the donor also has some control over a donation there is a need to establish clear procedures on how to handle a possible donation and be prepared to formulate relevant questions. When a recipient of a donated medical device accepts a medical device as a donation the recipient will be responsible that the medical device can be used in a safe and efficient way. In order to be clear about what future economic impact a donated medical device will have, a thorough assessment with a life-cycle-cost analyse should always be carried out.

Donation Policy

The Albanian policy for donations of medical devices is stipulated in the following text:

- a. A medical device that is proposed for donation should be effectively evaluated and should fulfil a clinical need before it is accepted.
- b. A donated medical device should be cost-effective for operation, repair and maintenance.
- c. A donated medical device should only be accepted if it can be properly installed, operated, maintained and appropriately used.
- d. A donated medical device, new or used, should be tested by the donor before shipment and all essential parts, accessories and working materials shall be included in the shipment.

- e. A donated medical device should be CE-marked and be accompanied by a user manual, preferably in the Albanian language.
- f. Acceptance testing and registration should be carried out on all donated medical devices. Donated medical devices shall be included in a maintenance system.
- g. Before accepting a refurbished or used medical device it should be established that the manufacturer continues to provide spare parts, and the life expectancy of the medical device should be indicated.
- h. Old, broken, outmoded, and redundant medical devices for which spare parts and consumables are no longer available or medical devices which are no longer supported by the manufacturer should not be accepted as a donation.
- i. A National Donation Plan shall be available indicating which medical devices that are desired and which technical support is available for specific types and brands.

Responsibilities of parties involved in Donation activities

It is the responsibility of the MoH

- to formulate a clear policy, regulations and administrative routines for accepting donated medical devices and to communicate this policy to potential donors.

It is the responsibility of the recipient:

- to adhere to the policy on donations set out by Ministry of Health. The recipient is also responsible for specifying the requirements for accepting a donated medical device and shall communicate these requirements effectively to the donor. Further it is the responsibility of the recipient to turn down an offer of a proposed donation if a medical device is not safe for use, can not be used in its intended way or does not fulfil the requirements.

It is the responsibility of the donor:

- to ensure that a donated medical device fulfils the requirements set out by the recipient as well as following applicable regulations and laws in Albania. The donor further has the responsibility for ensuring that a donated medical

device is safe for use and is fully functional when it is delivered. The donor is also responsible for the delivery of the donated medical devices, including a reasonable amount of accessories and consumables as well as necessary accompanying documents.

Procedures and Routines

There shall be a documented procedure that settles the relationship between the donor and recipient. The donor and recipient shall seek to act as equal partners where both parties respect each others needs, possibilities and requirements.

Each party in a donation process shall know which procedures to follow. These procedures shall be organised and documented and be made available to donor and recipients as well as to supportive clinical engineering staff that maintains medical devices. All procedures shall continuously be monitored, reviewed and updated in order to assure their efficiency, correctness and applicability.

Annex 4 describes the procedures and activities needed in order to acquire successful donations of medical devices in the public health care sector. It aims at both the donor and the recipient and point outs what procedures need to be established for successful donation.

The donation guidelines are developed in compliance with the recommendations formulated in the World Health Organization (WHO) guidelines for health care equipment donations.

4.2 Guidelines on Acceptance Test of Medical Devices

4.2.1 Introduction and Background

The aim of an acceptance test is to ensure that a medical device has been delivered according to the contract and fulfils the MDD safety criteria. All newly obtained medical devices must pass an acceptance test before they can be used on patients. Hospital management must organize a local procedure to se-

sure that this requirement is respected. The Clinical Engineering Unit (CEU) is a competent body to execute this test alone or in collaboration with the supplier. If very complex devices are obtained it may require a third party to perform the acceptance test. In such a case clinical engineering shall monitor the test procedure. How acceptance tests shall be performed must be stated in the procurement documents.

The acceptance test shall assure that the medical device:

- Is delivered complete and is in good condition without visible defects
- Is delivered in full working order and performs as expected in accordance with intended use
- Passes the safety controls and tests used in the clinical engineering unit (including electrical safety tests)
- Is delivered with a full set of documentation including a user manual in a national language
- Is delivered with necessary training of users and engineers such that the user can operate the device safely and the engineer can manage necessary maintenance.

4.2.2 Policy

- a. Each hospital shall have routines so that no new medical devices may be used prior to acceptance testing.
- b. Acceptance testing shall be performed by a clinical engineer that checks the delivery, makes appropriate tests and marks the medical device with an inventory tag before it is approved for use.
- c. Only medical devices that are approved for use shall bear the inventory tag on the device.
- d. Medical devices that do not bear the inventory tag shall not be used.
- e. All medical devices in a hospital shall be registered in a Medical Device Information System (MDIS) maintained by a clinical engineer.

4.2.3 Responsibilities

It is the responsibility of hospital management

- to make sure that no newly obtained medical devices are put into clinical service without successful acceptance test carried out by a Clinical Engineer.

It is the responsibility of the head of clinical services

- to ensure that only medical devices that are registered in the Medical Device Information System, as indicated by the inventory tag, are in clinical use in his/her clinic.

It is the responsibility of Clinical Engineering Unit:

- to carry out the acceptance test in a professional way and to register the medical device in a Medical Device Information System without delay.

It is the responsibility of the user

- to use only medical devices that carry the inventory tag.

4.2.4 Procedures and Routines

When a new medical device is ordered as a capital investment a copy of the order shall be sent to the testing body, i.e. the CEU. The unit prepares for an acceptance test to be initiated when the device is scheduled to arrive to the hospital or when the supplier is ready with installation and gives a notice. The test shall be performed within ten days of arrival of the device or notice. A roadmap, designed to assist the CEU to pass a device is outlined **in box 4**. When the acceptance test provides clearance for the device to be used it is shown on the medical device with an inventory tag.

• **Box 4. Roadmap designed to assist the CEU to pass a new medical device (acceptance testing).**

- Check that medical device and accessories comply with purchase documentation (all parts delivered).
- Check CE mark/applicable standards and intended use.
- Examine whether the user's manual is acceptable and in national language.
- Examine whether technical documentation is adequate.
- Examine whether labelling is made in accordance with relevant standards and the marking adequate.
- Perform a safety control (electricity, gas).
- Register the device in the hospital Medical Device Information System (inventory tag).
- Install and perform a function control (with user).
- Check and/or perform training of staff, if found necessary.
- Plan for spare parts and preventive maintenance.

4.2.5 Registration of Medical Devices

After acceptance tests the medical device shall be registered in an inventory and maintenance system (MDIS). Registration and record keeping is an important tool for effective medical device management. Having organised all medical devices in a systematic manner is helpful for efficient planning and when problems may arise. Registration and record keeping of a medical device are needed in order to:

- a. give the medical device a unique identifier,
- b. provide data for inventory, planned maintenance and historic device data,
- c. provide information about running costs,

- d. take appropriate action following a manufacturer's withdrawal, and
- e. trace medical devices that have been used in patient accidents.

All medical devices that have passed acceptance testing and are planned to be in clinical use shall be registered and be given a unique registration number, same as stated on the inventory tag. Inventory tags can be obtained from the State Agency of Medical Devices (SAMD) or the CEU. The inventory tag shall be fixed on the medical device. Only medical devices that are marked with an inventory tag are accepted for clinical use and can be used on patients.

All important information about medical devices shall be registered as described in section 3.2.

The Clinical Engineering Unit in each hospital should have the task to carry out registration, maintain records and keep track of medical devices. There should be efficient routines established so that the CEU gets relevant information in the procurement process. In order to get efficient coordination of medical devices on a national level, a Medical Device Information System (MDIS) shall be designed, implemented, operated and maintained by the State Agency of Medical Devices (SAMD). The CEU shall follow the recommendation from SAMD in respect to what information shall be registered and how the system shall be updated. Hospitals without CEU's shall consult with SAMD for assistance. Refer to Chapter 3.2 for details.

4.3 Guidelines on Clinical Use of Medical Devices

4.3.1 Introduction and Background

The majority of incidents and accidents with medical devices are due to human mistakes or bad usage. Procedures of how to operate medical devices therefore are of great importance for the safety of the patient. Modern medical care often involves use of several medical devices at the same time or even systems of devices, which increases the patient risk dramati-

cally. There must be documented and tested procedures for use, but no procedures are safe if staff using the system is not adequately competent. There also has to be a programme for maintenance. To learn about and improve safety a feed back system on adverse events is necessary. Also disposal of medical devices in a controlled manner is important. All procedures and requirements necessary must be documented. Together they form the basis of a quality system.

Many studies and common experience show that problems with medical devices often occur because staff is not familiar with the proper functioning of the device. Most users have in fact never achieved any training. Yet they are put in dramatic and stressful situations and are expected to know how the medical devices are functioning. The lack of training is both a risk for the patient as well as for the staff. More often a medical device is reported faulty due to user errors or misunderstandings. This causes problems for the clinical engineer that uses resources to look for problems that are non-existing. By carrying out proper user training on all medical devices these mistakes can be reduced.

However, medical devices will - as all technology - sooner or later break down. Therefore the user of devices must prepare for such a situation. Alternative devices and methods must be available.

This section describes the procedures which need to be established at the hospital level in order for using or handling medical devices in a safe and efficient way.

4.3.2 Policy

- a. All staff within the Hospital that handles and/or uses medical devices must have gained sufficient knowledge and training in handling medical devices in a safe, efficient and appropriate way.
- b. All medical devices shall be used and handled by qualified

- staff in its intended way.
- c. All staff within the Hospital must be aware of associated and potential risks when using or handling medical devices, directly or indirectly on a patient, and have the proper knowledge in how to mitigate risks.
 - d. All medical devices, in-house or from medical device manufacturer, must be approved for use by a clinical engineer prior to any use on patients.
 - e. Training shall be provided to medical staff regarding the safe and efficient use of applicable medical device.
 - f. All medical devices shall be accompanied by user manuals, preferably in the Albanian language.
 - g. Faulty or non-functioning medical devices must be prevented from being used.
 - h. Accidents and adverse events with medical devices shall be reported and investigated.
 - i. All staff within the Hospital that uses diagnostic or therapeutic medical devices on a patient, directly or indirectly, as well as clinical engineers who are maintaining the medical devices shall be aware of the content in this section.

4.3.3 Responsibilities

It is the responsibility of MoH to:

- Provide for the resources needed to assure that each unit/clinic in any public hospital can use applicable medical devices in a safe and appropriate way.
- Be directly accountable for the use and handling of all medical devices within the Hospital.

It is the responsibility of the hospital management to :

- Provide for necessary resources so that relevant staff can get sufficient training in how to use the medical devices in a safe and appropriate way.
- Provide for the necessary resources in order to implement appropriate procedures at each unit/clinic.
- Control that the appropriate procedures are implemented in each unit/clinic and to monitor its effectiveness.

It is the responsibility of the head of clinic to :

- Assure that the medical devices are being used in a safe and proper way and that the staff gets sufficient training in how to use the medical devices.
- Make sure that the medical devices are being used in accordance with its intended way and by qualified staff, as specified by the manufacturer.
- Implement appropriate procedures at each unit/clinic.

It is the responsibility of the user to:

- Use the medical device only in its intended way and to follow the procedures of use as well as the instructions in the user manual.
- Be aware of their direct actions on the patient with a medical device for which they are directly responsible for.
- Inform the head of clinic in case he/she needs training on a medical device or have problems with operating a medical device.
- Report accidents or incidents with a medical device to the Head of Clinic.

4.3.4 Procedures and Routines

Each unit/clinic within the hospital that handles/uses medical device shall have procedures for the safe and correct handling of medical devices. These procedures should be organised and documented and be made available to all staff that handles medical devices. All procedures should continuously be monitored, reviewed and updated in order to assure their efficiency, correctness and applicability.

There shall be an appointed focal point (medical device coordinator) for the medical devices at each unit/clinic. The medical device coordinator shall assist in reporting problems and incidents, making user manuals available, organizing training activities for users, making requests for service, contacting the clinical engineer, and coordinating the utilization of the medical devices. It shall also be documented, and made known, which staff that has authorization to use which medi-

cal device. Staff that uses medical devices shall have the appropriate education and training to use the device in a safe and efficient way and if stated in accordance with specification of the manufacturer (found in user manuals).

4.3.5 Introduction of new Medical Devices, updated Systems and Software and Training upon Delivery

Upon delivery of new medical devices the supplier of a medical device shall provide training for all staff that is going to use the medical device. The supplier shall also give necessary training to the responsible clinical engineer that is going to maintain the medical device in the future. Such training can be performed as a service course on-site or be carried out at the manufacturer's premises. User manuals must be made available in the Albanian language by the supplier. The conditions for the obligations of the supplier shall be stated and specified in the procurement process. Before new medical devices are brought into service, acceptance testing and registration must be performed by a qualified clinical engineer. Installation of medical devices that are carried out by the supplier must have acceptance test clearance by a clinical engineer.

4.3.6 Training after Update

Medical devices and systems where software is part of the device may be subjected to updates in a way that the user interface and functions can be changed. After such updates, relevant staff must be trained and be made aware on changed functions. Medical devices that get updated with new functions, controls, software or alarms shall not be taken into clinical use unless necessary training is provided. Such training can be provided by a clinical engineer or the supplier/manufacturer. It is the responsibility of the head of the unit/clinic to make sure that the information gets known to relevant staff.

4.3.7 User Manuals

There shall be routines to assure that all medical devices that

are being obtained are accompanied with a user manual. All users shall read and understand the user manual prior to any use. User manuals shall be kept and stored in a known location which is easily accessible by the applicable staff.

4.3.8 Continuous Training

Medical devices that require continuous training shall be defined by head of clinic/clinical engineer. There shall be procedures for continuously monitoring the need for training of medical staff. Clinical engineers shall inform the head of clinic about any specific type of medical devices that require extra user training in order to sustain its safe and effective use. Where there are user problems related to a medical device, extra user training shall be made available to relevant staff. Clinical engineers shall work closely with each unit/clinic that handles/uses medical devices in order to co-ordinate and make available user training for relevant staff. The training shall be made available regularly, when needed or upon request from the user. Performed training should be documented.

4.3.9 Procedures for Use

All medical devices are part of a diagnostic or therapeutic procedure. As such the unit/clinic must have developed procedures for safe and efficient work on patients. When medical devices are used it is very important that these procedures are well known followed. More complex procedures must be documented and shall contain a risk analyses and actions on how to mitigate the known risks.

4.3.10 Function Test

There shall be routines at the unit/clinic to make sure that a medical device that is planned to being used on a patient (diagnose or therapy) must be checked prior to each use. A function test shall be carried out in accordance with the description in the user manual or in accordance with instructions from a clinical engineer. A function test shall at least contain a visual

inspection. If the medical device does not pass the function test it shall not be used on the patient.

4.3.11 Critical Devices

Medical devices that are critical to use or complicated may require special license to use. The determination of what a critical medical device is shall be specified by the head of clinic. Routines shall be documented and specify in what extend training is needed, for which staff and how the knowledge is maintained. A user license may be granted after successful training.

4.3.12 Accessories

Medical devices that need accessories shall have sufficient supply of accessories available. Only accessories that have been recommended by the manufacturer shall be used. Use of other accessories may only be used if the safety and performance of the medical device can be guaranteed by a qualified clinical engineer. Prior to such use a risk assessment should be performed by a clinical engineer.

4.3.13 Medical Device Malfunction

Medical devices that have detected problems or are suspected to have malfunctions must be reported to the clinical engineer. The medical device shall be taken out of service and be tagged with a warning note that it can not be used. Applicable users of the medical device must be informed of the device status. The medical device may not be used in any ongoing procedures until the problem is solved. If a medical device is awaiting service or spare parts, it must be stored in a separate location. Such location shall be defined and the location must be organized in such a way that functioning medical devices can not get mixed up with non-functioning. If the medical device has been used where an accident, or a suspected accident, has occurred it must be reported in accordance with the rules for reporting of accidents and incidents (refer to AER Guidelines section 3.1)

4.3.14 Accidents and Incidents

Medical devices which have been used where accidents or patient injuries have occurred, or could have occurred, should be subjected to investigation. Such medical devices must be taken out of service and be tagged with a warning note so that it can not be used. Applicable staff must be informed of the device status. The medical device may not be used until it is clear that the investigation is finished and a functional test has been carried out by a clinical engineer. The procedure for reporting accidents and incidents shall be made known to all staff. The procedure shall comply with the recommendations in the adverse event reporting (AER) system. Please refer to chapter 3.1 for guidelines on AER.

4.3.15 Maintenance

The Unit/Clinic shall have a system implemented to monitor safety and performance on the medical device on a continuous basis, preferably supervised by a clinical engineer. If an abnormal amount of repair calls result from operator error, misuse or abuse, a clinical engineer shall assist in the training or recommend user training by the appropriate source. All medical devices shall be organised in a maintenance program and have defined procedures for preventive maintenance. The maintenance programme can be supervised by a clinical engineer.

4.3.16 Use of In-house produced Medical Devices

There shall be documented routines for in-house production of medical devices if such are to be used (refer section 4.1.6). These routines shall also apply if any device is modified in a way which is not in accordance with original manufacturer's recommendations of that medical device. In-house medical devices must be approved and tested by a clinical engineer prior to any use. The clinical engineer shall be responsible so that adequate procedures for safe medical devices are being applied. In-house medical devices that are accepted shall bear the inventory tag and have the user manuals written in the Albanian language.

4.3.17 Disposal of Medical Devices

Medical devices that are deemed unsafe or unreliable shall be taken out of service. At the end of a medical devices life it shall be disposed. Disposal of medical devices shall be made in accordance with recommended routines and with the assistance of a clinical engineer. Disposed medical devices may not be used in any ongoing procedures. The disposal must be environmentally safe and be carried out in accordance with the national procedures for waste management, outlined in chapter 4.5 of this document.

4.4 Guidelines on Maintenance of Medical Devices

4.4.1 Introduction and Background

All technical systems or devices must be exposed to maintenance procedures in order to function as intended and in a safe way for everybody concerned. The maintenance also has economic impact on the output that is expected. Therefore maintenance procedures are of great importance for safety and efficiency.

4.4.2 Policy

- a. Maintenance of medical devices shall be performed in a professional and cost-effective way such that the accessibility, performance and safety are maintained during the lifetime of the product.
- b. All maintenance of medical devices must be planned, prioritised, performed and documented professionally and in close collaboration with the clinic that uses the device.
- c. All, in-house as well as subcontracted, maintenance shall be performed under the responsibility and supervision of a clinical engineer.
- d. Evaluation and decisions regarding preventive maintenance procedures, the mode of maintenance, whether in-house or subcontractor, and a documented maintenance

- plan for each specific medical device shall be made during the procurement process.
- e. In order to assure reliability regarding function and safety, preventive maintenance is based on requirements and demands from:
 - The law.
 - Other regulations.
 - Manufacturer's recommendation.
 - The user.
 - f. Maintenance shall be planned and performed such that the clinical work is influenced as little as possible.
 - g. All maintenance must be documented and recorded in MDIS.

4.4.4 Preventive Maintenance Tasks

Preventive maintenance (planned service) involves assessment with inspection and replacement of critical spare parts before break down, and is based on various parameters to obtain cost-effectiveness, e.g.

- recommendations from the manufacturer,
- operational time,
- chronological time,
- documented technical experience,
- clinical needs,
- risk analysis
- accessible resources

Preventive maintenance may be executed in total, or in part by the CEU or through a contract with the external supplier of the medical device services. This decision shall be based on a risk and cost-effective analysis. Often this relation is regulated by a business contract or a so called Service contract.

During planned preventive maintenance corrective actions shall be performed, if and as appropriate. This action shall be considered and reported as a corrective maintenance.

All medical devices in health care must be evaluated if they should be included in a system for preventive maintenance. The evaluation shall be based on maintenance requirements

and risks. After maintenance the medical devices shall be marked with the time for next preventive maintenance. The clinical user must be informed when preventive maintenance shall be performed and about the result of the maintenance.

4.4.5 Corrective Maintenance Tasks

Corrective maintenance (unplanned breakdown) and repair can be executed in total, or in part by the CEU or through a contract to an external supplier. The clinical engineer shall evaluate whether the repair is reasonable considering the value of the device and the cost of the repair. Decisions on repair shall be made in co-operation with the user, including when services from external suppliers are needed. Documentation of all activities performed includes observations made, replacement of spare parts and follow up on previous sessions, including economic parameters shall be performed.

4.4.6 Safety and Function Control

After all maintenance procedures, in-house as well as subcontracted, a safety and function control must be performed and documented before the device is taken into use. If patient or user safety is endangered due to technical problems, discovered during maintenance, it shall be reported according to the adverse event reporting system. Refer to AER in section 3.1

4.4.7 Registration

All activities experienced during maintenance, safety and functional control must be documented, including observations, replaced spare parts and their cost. The information documented shall be sufficient for evaluation of the need of preventive maintenance, economic consequences, replacement of the medical device, warranty aspects, needs for spare parts supply and modifications. Documentation and results of the preventive maintenance programme shall be obtained, controlled and reviewed on electronic media, e.g. MDIS, for the purpose of traceability. The documentation collated shall

be evaluated and adjusted at least once a year to obtain continuous improvement and cost-effectiveness of the preventive maintenance plan.

4.4.8 Competence and Responsibility

Ministry of Health is responsible for maintenance in public health care. The Ministry of Health has delegated the responsibility of performance to hospital directors. The hospital director can delegate the performance to the hospital CEU, BENC or both if CEU needs support. Delegation of the responsibility must include delegation of resources to carry out the task. Maintenance is performed either by hospital clinical engineering personnel, BENC or personnel from a supplier under clinical engineering control. In some cases the device is sent to supplier or taken to BENC to be maintained. Qualified clinical engineers shall have documented sufficient and necessary education and training for carrying out maintenance.

4.4.9 Priority of Maintenance of Medical Devices

Preventive maintenance shall be performed in the following order:

- a. Life supporting equipment where it is important to keep up function, safety and reliability
- b. Laboratory equipment with special requirements for quality.
- c. X-ray and other heavy equipment mounted in the ceiling where it is important to keep up function, safety and reliability.
- d. Other equipment where unplanned stops will be unacceptably costly or damage the equipment.

4.5 Guidelines on Disposal of Medical Devices

4.5.1 Introduction and Background

There are many reasons why a medical device can be subjected to disposal. First of all it might have problems that can not be repaired, or the repair itself may be more expensive than actually acquiring a new medical device. It may also have permanent fatal safety problems that can not be corrected, such as to high leakage current and radiation. Such medical devices must be prevented from being used. Some medical devices become outdated and they might not be needed in the ongoing procedures. Such medical devices do not necessarily need to be disposed by disassembling. But if they are going to be kept, the same safety reasons shall apply to the outdated medical device as to the new. Quite often new medical devices are obtained to replace old medical devices and when the new device is delivered staff often wants to keep the old medical device as well. If the medical device was replaced due to the fact that it was unfit it shall be taken out of service. The disposal of a medical device may cause conflict in a clinic and is typically a situation where the clinical engineer may end up disagreeing with staff. The safety issue must be prioritised before financial interests. The clinical engineer must have a role where he or she can point out safety issues with the consequences that the medical device is taken out of service.

In the process of taking care of disposed medical devices, health aspects of humans and environmental safety must be a priority. Since medical devices contain many types of material the actual handling and recycling of parts from these products fall under several regulations.

Medical devices can typically contain organic parts, chemicals and fluids, radioactive substances, electrical and electronic parts, batteries and toxic plastics to mention some items that are hazardous and may require extra care.

Furthermore the medical device itself may also have associ-

ated consumables, accessories and single-use items that are being used together with the medical device. These parts are in fact by definition part of a medical device and should be treated as medical devices.

Medical devices also generate or process specimens, organic material, blood samples, infectious and non-infectious clinical waste. These items shall not be considered as disposal of medical devices and will not be covered in this section. The operator's manual of such devices will often give recommendations on how to take care of such items and these recommendations shall always be followed. Additionally any local waste management plan at the hospital shall always be followed.

This section gives guidance and points out the responsibilities in a chain that needs to be established in the health care environment for medical devices that are unfit for use. Medical devices can not be treated in the same way as household waste and need their own routines and framework. Environmental impact is something that must to be considered in all aspects when dealing with medical devices starting from the need when obtaining it, through effective maintenance to make the medical device last longer and finally the actual disposal in proper ways. In order to establish an effective waste management chain it also requires that there will operators that will take care of collected waste outside the health care environment. The implementation of such functions shall be considered a national and governmental responsibility.

This section describes the procedures that need to be established on a hospital level in order to ensure the safe and proper disposal of medical devices. It also describes the prerequisites a decision as to when a medical device shall be considered to be disposed.

4.5.2 Policy

- a. Only medical devices providing the intended functions are used in the intended way and that carries the "Inventory tag" must be in clinical use.

- b. Medical devices that are suspected to overloading, mis-handling, have suspect results or safety deviations, are replaced, has expired its date of use, has been shown by verification or otherwise to be defective for use must be prevented from being used.
- c. Disposal of medical devices must comply with laws, regulations, and recommendations of the manufacturer as well as applicable rules of hospital waste management plans. Equally applies to any consumables, accessories and/or single-use items which are part of a medical device.
- d. Collected disposed medical devices must be destructed and stored in a safe way and must not be mixed up with medical devices that are in clinical use.
- e. Each hospital shall have a waste management plan for disposed medical devices and ensure that the plan conforms to the national waste management plans and regulations.
- f. All staff within the Hospital that disposes medical devices, or parts thereof, must be aware of the hospital waste management plan.

4.5.3 Responsibilities

It is the responsibility of the MoH:

- to provide for necessary resources needed to collect and take care of disposed medical devices, and parts thereof, in a safe and environmentally proper way.
- to define what is considered waste, the categories of waste and how different waste shall be handled.

It is the responsibility of the hospital manager:

- to assess that all medical devices within the Hospital are fit for use and that disposed medical devices can not be used.
- to provide for resources for implementing a Hospital waste management plan that includes medical devices, consumables, single-use items and accessories which are part of a medical device.
- to provide for the necessary resources in order to implement appropriate procedures for safe and proper disposal and disassemble of medical devices at the clinical engineer-

ing unit or at other relevant department with clinical engineering competence.

- to formally discard a medical device based on the recommendations from a clinical engineer and to request clinical engineering unit to take care of the discarded medical devices out of service.

It is the responsibility of the head of clinic/unit:

- to implement routines in accordance with the hospitals waste management plan for safe disposal of consumables, single-use items and accessories which are part of a medical device.
- to make sure that the medical device in his/her clinic is safe to use and that regular maintenance is carried out in accordance with manufacturer's recommendations and/or by the suggestions of a clinical engineer.

It is the responsibility of the user:

- to contact a clinical engineer if a medical device is suspected to overloading, mishandling, have suspect results or safety deviations, has expired its date of use or seems to be defective for use.
- to follow the hospital waste management plan for accessories, consumables and single-use items that are part of a medical device.

It is the responsibility of the clinical engineer:

- to advice the Hospital Directory about medical devices that are subjected to disposal.
- to take out of service, and degrade for other applications, a medical device that is decided to be disposed.
- to clearly identify a disposed medical device, destruct it for use and store it in a specified place.
- to update the Medical Device Information System, or service log books, on the current status of the disposed medical device.

4.5.4 Procedures

There shall be documented routines at the clinical engineering unit for correct and safe disposal of medical devices. Each clinic/unit within the hospital that disposes consumables, accessories and single-use items that are part of a medical device shall have routines for the safe and proper disposal. All routines shall be organised and documented and be made available to all staff that disposes medical devices or parts thereof. All procedures shall continuously be monitored, reviewed and updated in order to assure its efficiency, correctness and applicability. Required procedures for correct and safe disposal of medical devices are the following:

4.5.5 Disposal of Consumables, Accessories and Single-use Items

Each clinic/unit within the hospital organisation that handles consumables, accessories and single-use items shall have routines for the safe and correct disposal. The routines must be made known to the relevant staff at the clinic/department. Consumables, accessories and single-use items shall be disposed and stored in a location which is safe for staff and patients. Disposal must be made in an environmentally safe way and be in accordance with the hospital waste management plan and the national policy for environmental safety. Removal of collected disposed items shall be made regularly with contracted organisations/companies.

4.5.6 Monitoring of medical devices

The clinical engineering unit shall continuously monitor the status of medical devices with respect to disposal. Any device that has been subjected to overloading, mishandling, suspect results, safety deviation or replaced due to changes in medical procedure, expired its date of use, has been shown by verification or otherwise to be defective for use shall be taken out of clinical use and be degraded for other applications. Such device shall be clearly identified and stored in a specified loca-

tion. The clinical engineering unit shall register the new device status in the Medical Device Information System (MDIS).

4.5.7 Investigation

A clinical engineer shall carry out an investigation on the medical device that is subjected to disposal. This shall be carried out in collaboration with Head of clinic which is responsible for the use of medical device and that it's safe. Such investigation shall consider if the medical device is possible to repair, what kind of disassembly method that is required, re-cycling of possible spare parts, investigation if the clinical method is outdated and a suggestion if a new medical device is to be obtained. If there are medical devices with similar problems they should also be considered to be disposed. The result from the investigation shall be documented and can be presented as a simple report. Supportive information from the service log books (or Medical Device Information System) can be attached. The documentation shall include a recommendation from a clinical engineer and shall specify the risks or reasons why the medical device is considered unfit for use.

4.5.8 Disposal Certificate for a Medical Device

When a medical device is considered to be unfit to be used, in accordance with the description above, it may not be used in any ongoing procedures. The clinical engineer must take precautions to prevent the medical device from being used and inform hospital manager of this new device status. The result from the investigation shall be presented to the hospital manager who will have the responsibility to take the final decision. A medical device with the recommendation of a clinical engineer that it has associated risks must not be used. Hospital manager shall sign a disposal certificate, which will act as the formal decision, and hand it over to the clinical engineer with a request to take the medical device out of service.

4.5.9 Take the medical device out of service

The clinical engineering unit (CEU) shall have routines for ensuring that the disposed medical device can not be used in any ongoing clinical procedures. The disposed medical device shall be destructed in a way that it can not be used. The destruction must be permanent but need not include all parts in the medical device. Typically the internal electrical wiring may be cut. It is not enough to just remove the power cord or the internal batteries. Parts that can be used for spare parts can be recovered if the quality is good and a clinical engineer can be sure that the spare part is functioning properly.

4.5.10. Medical Device Information System

When a medical device is disposed it shall no longer exist as an active device in the inventory system or the Medical Device Information System (MDIS). Historical data about the medical device can be kept in order for future reference, but the medical device shall no longer exist as an inventory item. The system shall be updated and the inventory tag must be removed from the unit and destructed. Serial number and other markings may remain on the unit. A medical device that does not bear the inventory tag is by definition not approved for use.

4.5.11 Disassembly of disposed medical devices

The clinical engineering unit (CEU) shall have routines for safe disassembly for medical devices. Health aspects when working with different material and parts must be considered. The following items require special precautions and documented routines:

a. Fluids

Fluids are typically found in heating and cooling appliances, such as fridges and freezers (coolant circuit) and oil-filled radiators. Fridges and freezers containing hydrocarbons should have their fluids removed under safe conditions. Fridges and freezers identified as containing ammonia must have the ammonia extracted and transferred to a suitable container pend-

ing disposal. Ammonia is potentially hazardous to the environment, is toxic to humans and can present a risk of fire and explosion. Oils that can typically be found in X-ray generators are polychlorinated biphenyls (PCB). Such oil shall be removed and collected in separate containers. Special precautions must be taken when dealing with PCB and it need to be removed and disposed of at an appropriately licensed facility.

b. Mercury containing components

Mercury is used in gas discharge lamps, in medical devices, data transmission, telecommunications, and mobile phones. It has also been used in batteries, thermostats, position sensors, relays and switches. Its use in electrical and electronic equipment has declined significantly in recent years. Apart from batteries, most mercury containing items are likely to be found on a circuit board. Thus, removing the circuit board would result in the removal of most mercury containing components such as switches. Mercury containing components and where identified should remove these items and store them in appropriate labelled containers.

c. Batteries

Batteries and battery packs occur in many medical devices and they can also be soldered on printed circuit boards. Batteries should be removed intact in such a way that they are clearly recognisable as batteries. Removed batteries should be stored in appropriate labelled containers having due regard to the potential fire risk that batteries can present.

d. Circuit Boards

Circuit boards must be removed as whole circuit boards or as large pieces. Once removed, they must be stored in suitably labelled containers so as to be able to be sent for specialist recovery.

e. Cathode Ray Tubes

Cathode ray tubes (CRT) are mainly used in either computer monitors or television sets. Handling of CRTs can present a danger of implosion. As a consequence, safe systems of work

will need to be used to control the risk. CRTs have fluorescent coating that should be removed to ensure that it does not cause pollution or harm. CRTs shall be sent to specialist recovery.

f. Liquid Crystal Displays

Liquid crystals are embedded between thin layers of glass and electrical control Elements. LCDs are used in monitors (and in LCD televisions) and are often back-lighted with gas discharge lamps. These will need to be removed, and the backlights will then need to be separated from the LCD. Removed gas discharge back-lights and LCDs should be stored separately in appropriate labelled containers.

g. Components containing Radioactive Substances

Radioactive substances are typically found in some medical devices and test instruments. There are special precautions to take in to consideration and certain regulations that need to be followed when working with radioactive substances, please refer to Law 1825 Radiation Protection Act.

h. Capacitors containing Polychlorinated Biphenyls

Historically, polychlorinated biphenyls (PCBs) were extensively used in electrical equipment such as capacitors and transformers. However, their use in open applications was widely banned in 1972 and they have not been used in the manufacture of new equipment since 1986. Thus, unless an appliance is more than 20 years old, the risk that it contains capacitors containing PCBs is very remote. PCBs can harm the environment and human health. Any capacitor, identified as containing PCBs, will need to be removed and disposed of at an appropriately licensed facility.

i. Electrolyte Capacitors

Capacitors are used typically as smoothing capacitors in power supplies that use a transformer. Currently there is no definition of substances of concern, and modern electrolyte capacitors are unlikely to contain any hazardous substances. Nearly all capacitors are now mounted directly on the circuit board,

and thus would be removed if the circuit board is removed.

4.5.12 Storage and Collection

Appropriate storage must be in place for disassembled parts. The storage shall offer appropriate spillage collection containers, be safe for health of staff and patients and be safe for fire and explosion dangers. All containers with disposed items or disassembled parts shall be clearly marked.

Appropriate containers shall exist for storage of batteries, capacitors containing PCBs and other hazardous waste such as radioactive waste. All batteries should be handled and stored with regard to the potential fire risk associated with them. Parts (e.g. motors and compressors) that contain oil and/or other fluids must be appropriately disaggregated and stored in containers that are secured such that oil and other fluids cannot escape from them. These containers must be stored on an area with an impermeable surface and a sealed drainage system. Toxic waste must be stored in double containers and shall bear correct marking. The hazardous clinical waste is of two types: infectious and non-infectious (chemicals). The non-infectious hazardous clinical waste will be regulated under a specific Law on hazardous waste management and is outside the scope of this document, once it has been separated from the other wastes.

Medical devices that are awaiting removal or are to be disposed as whole units must be kept separately from clinical areas. They should be stored in lockable storage room. It may not be stored in the clinics, corridors, waiting rooms, offices and examination rooms. It must be clear that the device is taken out of service. A separate tag indicating not for use shall be noticeable on the device. The device must be internally destructed.

4.5.13 Planning for Replacement of Medical Devices

If reinvestment is considered necessary, the information from the investigation process shall be incorporated into the invest-

ment planning activity. The requirement specification, when acquiring a new medical device, shall request information on the proper disposal of a medical device. The manufacturer and/or the distributor shall offer to have a take-back scheme in place so that they collect old medical devices, in accordance with the European Directive on Electrical and Electronic Waste (WEEE).

5. Health Technology Assessment

5.1 Vision

The Ministry of Health vision on health technology assessment (HTA) is consistent with the World Health Organization's concept of quality development in health systems, which should consider all existing alternatives and components of health technologies already used or recently proposed for use in health systems: organizations, processes, procedures, devices and drugs.

- a. The HTA will ensure the systematic assessment and comparison of health technology in terms of its health outcomes, safety and costs.
- b. The objective of a health technology assessment is to provide to the decision makers the most reliable scientific evidence as basis for their political, financial and clinical decisions and choices with regard to the appropriate use of HTA
- c. The Institutionalization of HTA aims to reduce the over-use, misuse or under use of health technologies and to maximally improve the health gain, safety and the cost effectiveness of the health systems. It helps to shift from an obsolete decision process based on opinions to a new approach of evidence based decision making.
- d. Institutionalization is referred to as promoting structures and processes suitable for producing systematic technology assessments with the power to guide policy and clinical practice towards the best possible health and cost outcomes.

5.2 Institutionalization of HTA

Institutionalization of HTA shall be developed in two parallel and synergetic approaches: a top-down and a bottom-up one.

The top-down approach includes the establishment of a National Centre responsible to carry out HTA and to produce the necessary requested evidence or answers concerning specific issues or questions addressed to the HTA centre. In the Albanian context this HTA institutionalization has already been initiated within the structure of the National Centre of Quality, Safety and Accreditation of Health Institutions (NCQSA) where a department is dealing with HTA, Evidence Based Medicine (EBM) and the Guidelines of Best Clinical Practices. The NCQSA will act as a consulting agency to the Ministry of Health during all decision-making processes with regard to health technology assessment.

The bottom-up approach refers to a system of periodical assessments, comparison and evaluation of the outcomes, safety and cost of the health technologies used daily in current clinical practice. This kind of HTA is expected to be conducted by means of quality information systems, systematic auditing, and comparison of quality indicators, accreditation, patient safety and patient satisfaction. This approach may have a significant impact in the reduction of unnecessary use of health technology, on minimization of its overuse, misuse or under use, on replacement of inefficient health technology and the introduction by a new and more effective one.

Bottom-up approaches to HTA need to be based on professional motivation toward the best practice and continuous quality of care development approaches. Future activities shall ensure that appropriate data sources and systems are to be utilized in HTA. Conversely, HTA shall include recommendations on necessary databases and quality development measures accordingly. More cooperation in the scientific community as well as collaboration and exchange of information with other countries is needed. Albanian HTA programmers shall take part in international activities and networks.

Cooperation at the national level involves:

- a. Coordination of activities of interested parties.
- b. Establishment of a central body with a legal mandate for

- coordination and priority-setting.
- c. Decentralization of HTA research itself as well as funding.
 - d. Creation of a platform for information exchange on HTA for all interested parties.
 - e. Multidisciplinarity of HTA.
 - f. Establishment of formal links to health policy.

Cooperation at the international networking level involves:

- a. Participation in joint projects;
- b. Cross-national issues should be given high priority;
- c. Exchange of information, project reports, and other materials.

The capacity building and systematic training on HTA and EBM are prerequisites for Institutionalization of HTA in Albania. Training and education in HTA shall target expertise, organization and staff qualification. Any training and education strategy shall include health care institutions, professional associations, industry, medical device manufacturers, academic institutions, health care reimbursement and funding agencies, and policy-making institutions. Implementation of HTA results shall also be based on empowerment of decision-makers by means of training and education.

Other issues for further development in HTA include targeting users and beneficiaries more effectively, developing a common European terminology and methodology for HTA and development of transparent and systematic methods for integrating observational studies and registry data.

Annexes

Annex 1

The Legislative Framework for Public Procurement in Albania

The activity of public hospitals in Albania is based on the Law Number 9106, dated 17 July 2003, *On the hospital care in the Republic of Albania*. This act regulates all aspects of hospital care and the management and planning of activities in hospitals.

The act regulates the following issues:

- Hospital planning at central and regional level.
- Hospital management.
- The operation of private hospitals.
- Anticipates the licensing (authorization) of hospitals by MoH.

Each hospital has in its structure a medical commission which is a technical body that gives technical advice to the board of directors of the regional hospital authority. It is composed of directors of hospitals, chiefs of the services as well as representatives elected from these services and functions within the hospital authority. Among other functions the commission can propose to the board of directors of the hospital the medical, diagnostic and therapeutic equipments that should be purchased. According to this law, the public hospitals are financed by:

- The Ministry of Health.
- Health insurance institutions.
- Local authorities.
- Domestic and foreign donors.

Hospitals exert their financial activity in line with the laws and legal acts in force for the institution with independent budget. In the procurement field, they are compelled to operate under the Public Procurement Legislation.

The public procurement in Albania is based on following acts:

- The Law Number 9643, dated 20 November 2006 *On Public Procurement*, entered into force by 1 January 2007 through approval by the People's Assembly of the Republic of Albania.
- The Decision Number 1, dated 10 January 2007 *On approved of rules on public procurement*, entered into force on 20 January 2007 through approval by the Council of Ministers.

The Public Procurement Law (PPL) sets out the rules applying to the procurement of goods, works and services by contracting authorities. This law is based on the EU regulations for procurement procedures. The objectives of the law are:

- To promote efficiency and efficacy in public procurement procedures carried on by contracting authorities.
- To ensure a better use of public funds and reduce procedural costs.
- To encourage economic operators to participate in public procurement procedures.
- To promote competition among economic operators.
- To guarantee an equal and non-discriminatory treatment for all economic operators participating in public procurement procedures.
- To guarantee integrity, public trust and transparency in public procurement procedures.

The law foresees the general awarding principles such as:

- non discrimination and equality of treatment of actual and potential tenderers,
- transparency of procurement procedures, and proportionality of requirements and obligations imposed to actual and potential tenderers.

The PPL applies to all awarding procedures. The only applicable exceptions are those which are regulated with other laws and some other cases regarding defence procurement, secret contracts and contracts requiring special security measures and

service contracts awarded on the basis of an exclusive right which they enjoy pursuant to the published legislation.

A new procedure in this law is the centralized purchasing. This occurs when more than one contracting authority needs the same kind of goods, works or services. In these cases authorities may decide to have centralized purchasing in either of two ways:

- Assign to one of them the task of procuring such items on behalf of the others.
- Instruct the Central Purchasing Body established pursuant to the procurement regulations to carry out the relevant awarding procedures.

Contracting authorities may ask the central purchasing body to carry out a specific awarding procedure or a series of awarding procedures on their behalf when centralized purchasing would benefit from substantial economies of scale, for instance regarding supplies of homogeneous goods which are offered on the market under similar conditions. In carrying out the awarding procedures assigned to it, the Central Purchasing Body is subject to the provisions of the PPL.

The public procurement organization is based on responsibility of the contracting authority (hospitals). Each contracting authority is responsible for procurement with public funds at its disposal subject to the provisions of the PPL, to any further conditions set forth in the procurement regulations.

All procurement processes are built on some common procurement rules such as:

- Non-discrimination.
- Access to relevant information.
- Forms of communication.
- Technical specifications.
- Termination of an awarding procedure.
- Confidentiality.
- Avoidance of corruption and conflict of interests.
- Methods for calculating the estimated value of public contracts.

- Thresholds.

According to PPL, technical specifications shall clearly describe the contracting authority's requirements by reference to:

- National standards transposing international accepted standards, international accepted technical approvals, common technical specifications, international standards, other technical reference systems established by international standardization bodies or, when these do not exist, to national standards, national technical approvals or national technical specifications relating to the design, calculation and execution of the works and use of the products.
- Requirements in terms of performance, even when this requires making a reference to national or international standards as means of presuming conformity with such performance or functional requirements.
- Both methods for different products, services or works included in the same contract.

If needed, the description of works, goods or services shall contain the technical specifications to be achieved, including plans, drawings and models. In cases of functional description of works or goods, the technical specifications should clearly and neutrally describe the scope of the works, in order to indicate all the conditions and circumstances which are important to the preparation of the bid. The description shall indicate not only the scope of work, but also the requirements related to the named work from the technical, economic, aesthetic and functional aspect. In order to guarantee the comparison of bids in relation to the contract object's requirements for these goods or for their functions, the competitors and bidders shall be provided with precise requirements for the functions or performance, thus helping them during the bid preparation. Specifications for the supply of appropriate goods or services for the environment shall also be indicated in the description of works.

There shall be no requirement or reference in the technical specifications to a particular trademark or name, patent, design or type, specific origin, producer or service provider, unless there is no sufficiently precise or intelligible way of

describing the procurement requirements and provided that words such as *or equivalent* are included in the specifications.

The applicable thresholds for the purposes of the PPL are:

- High value thresholds which are ALL 600 000 000 for public labour contracts and ALL 100 000 000 for public contracts of services and goods.
- Low value thresholds which are ALL 3 000 000 for public labour contracts and ALL 2 000 000 for public contracts of services and goods.

In awarding their public contracts, contracting authorities shall apply the procedures set forth in the PPL.

The types of procedures to be used for the award of public procurement contracts shall be:

- Open procedures.
- Restricted procedures.
- Negotiated procedures, with or without prior publication of a contract notice.
- Request for proposals.
- Design contests.

For all contracts, open procedures can always be used. For contracts above the low value thresholds, contracting authorities shall use open procedures, restricted procedures, design contests. For contracts of a value lower than the low value thresholds, contracting authorities may use negotiated procedures with or without prior publication and requests for proposals. For small value purchase of goods, services or works, below the low threshold, contracting authorities may use simplified procedures.

Contracting authorities wishing to award a public contract by open, restricted or negotiated procedure shall make known their intention by means of contract notices. Contract notices for contracts of a value above the high value thresholds shall be published on the Public Procurement Bulletin, and on at least one newspaper of European distribution. Contract no-

tices for contracts of a value lower than the high value thresholds, but above the low value thresholds, shall be published on the Public Procurement Bulletin.

Time-limits for receipt of requests to participate and for receipt of tenders vary depending of different kind of procedures and thresholds. So these go from ten up to 52 days from the date when the contract notice is published. Therefore in case of procurement of service maintenance of medical devices, when these services are not procured together with the medical device the administrative rules and regulations do not favour this kind of procedure.

Contract Award Criteria

Contracting authorities may *award public contracts* to the offer which meets the qualification criteria and is the responsive offer with the lowest price. Contracting authorities may use various criteria, for example: quality, price, technical merit, aesthetic and functional characteristics, environmental characteristics, running costs, cost effectiveness, after-sales service and technical assistance, delivery date and delivery period or period of completion, provided these criteria are:

- Closely linked to the subject-matter of the public contract to be awarded.
- Objective, proportionate and non-discriminatory.
- Clearly set out in the contract notice or in the tender documents.
- Clearly set out in quantity and quality terms aiming at the evaluation of tenders, and expressed in monetary terms or using the *fail/pass criteria*.

If, for a given contract, one or more tenders appear to be abnormally low in relation to the goods, works or services, contracting authorities shall, before they may reject those tenders, request in writing details related to:

- The economics of the construction method, the manufacturing process or the services provided.

- The technical solutions chosen and/or any exceptionally favourable conditions available to the tenderer for the execution of the work, for the supply of the goods or services.
- The originality of the work, supplies or services proposed by the tenderer.
- Compliance with the provisions relating to employment protection and working conditions in force at the place where the work, service or supply is to be performed.

Contracting authorities shall verify those constituent elements and may reject it, if they are not satisfied that the tender is regular in all relevant aspects.

Notice of the award of the contract shall be given promptly to the tenderer who has submitted the tender identified as the successful tender. Within ten days from the notification of award, contracting authorities shall send a notice to the Public Procurement Agency for publication in the Public Procurement Bulletin. The notice shall contain as follows:

- The names of the candidates.
- The prices of their offers.
- The names of disqualified tenderers and their offered prices.
- The name of the successful tenderer and his offered price.

The contracting authority and the tenderer shall sign the contract within 30 days after the publication of award in the Public Procurement Bulletin. The period shall not be considered reasonable if it exceeds the period of effectiveness of the tender, as set in the contract notice or the tender documents. When the contract is signed before the deadline for the classification notice or before termination of the administrative review, the contract is considered null and void.

The terms of the contract awarded pursuant to the PPL shall not differ from the prescriptions established in the tender documents and in the successful tender. Without prejudice of the provisions of the PPL and any other legislative provisions applicable to contracting authorities, contracts awarded pursuant to the PPL shall be subject to Albanian civil law.

Administrative review procedures

Any person having or having had an interest in obtaining a public contract and who has been or risks being harmed by a decision taken by a contracting authority which infringes the PPL, may challenge such decision. Objections shall be filed in the first instance with the concerned contracting authority in writing within 5 days from the day the complainant became aware or should have become aware of the alleged breach of the PPL.

Upon receiving the complainant's written objection, the contracting authority shall suspend the ongoing contract award procedure until the objection is fully examined and must, if needed, extend the time-limit of the contract award procedure for the period of suspension.

The contracting authority must examine the objection and take a justified decision within 5 days after the receipt of the objection and must inform the complainant of the taken decision and the justification thereof not later than on the next working day.

If the contracting authority fails to examine the objection within 5 days, or rejects the objection, the complainant may file a written appeal with the Public Procurement Agency (PPA) within the next five days. The complaint to the PPA should be completed using the respective template, containing the name and address of the complainant, the reference to the concrete procedure, the legal ground and a description of the violation. The above elements are essential to the examination of complaints. The PPA examines the complaint, following this law, the Code of Administrative Procedures and the public procurement rules. Failure in following all complaining stages makes the named complaint invalid.

Upon receiving the complainant's written appeal, the contracting authority shall suspend the ongoing contract award procedure. Upon receiving the complainant's written appeal, the Public Procurement Agency shall respond within five days. When the contracting authority requires information for the review of the complaint, the Agency shall respond in writing, in accordance with the public procurement rules, but not later than 20 days.

Upon receiving the complainant's written appeal, the PPA shall assure itself that the contracting authority has suspended the ongoing contract award procedure. Prior to the conclusion of a public procurement contract, PPA has the power to:

- Make a declaration with regard to the legal rules or principles which apply to the subject matter of the complaint.
- Annul the whole or part of any act or decision of the contracting authority inconsistent with the PPL. This includes the power to remove any technical or other type of specifications, which do not comply with the PPL.
- Instruct the contracting authority to correct any breaches and to proceed with the contract award procedure, after such correction.
- Order the termination of the contract award procedure.

Following the conclusion of the public procurement contract, PPA has the power to:

- Make a declaration with regard to the legal rules or principles which apply to the subject matter of the complaint.
- Issue a declaratory decision based on which the complainant who suffered loss or damage, as a result of a breach of the PPL may claim damages before the Court.
- Take measures against responsible persons: it is entitled to put fines with a value from ALL 50.000 to ALL 100.000 and to propose disciplinary measures to the head of the contracting authority.

Following the notification of the decision or the termination of the determined time limit, as provided in article 63 of the PPL, when the PPA did not examine the complaint, the complainant shall have the right to denounce the administrative conflict in the District Court of Tirana. The examination of this complaint by the Court shall not make the grounds for suspension of procurement procedures, for the conclusion of public contract for goods, services and works by the contracting authorities, or for the execution of obligations, according to the procurement contract between the parties.

A new institution is the Public Procurement Advocate. Based on a complaint, or on its own initiative, the Public Procurement Advocate may start an investigation procedure, if he/she observes or suspects that there has been an infringement of the PPL. The PP Advocate notifies its decision to open an investigation to all interested persons and to the PPA within five days from the receipt of the complaint, or immediately after the decision to start an investigation on his/her own initiative is taken. If the Public Procurement Advocate realises that the grounds for infringements of public procurement procedures lay in the content of the PPL itself or other legislative provisions, and not in its implementation, he/she has the right to:

- Recommend proposals for change, amendments and/or improvements to the laws.
- Propose amendments or improvement of administrative regulations to contracting authorities that adopted them, when such regulations are in violation with the PPL.

Refusal of the civil servant or contracting authorities' representatives, or public authority to cooperate with the Public Procurement Advocate constitutes the grounds for the Public Procurement Advocate to require from the competent authorities to start administrative procedures and take disciplinary measures.

The law is consistent with the EU regulations on the conduct of the procedures such as notice, invitation to tender, standard tender documents, general time limits to participate in the tender, qualification and disqualification of tenders, tender security, opening and examination of tenders, and contract award criteria and notification of award and signing of contract. The enforcement of the competences of the PPA and the introduction of the new institution of Public Procurement Advocate can unintentionally cause the extension of tender procedure conclusion as well as put in a passive position the contracting authority when a tenderer start a complaint at one of the above mentioned institutions.

Annex 2

Checklist of Questions to be addressed prior to Procurement of Medical Devices

Question	Applicable Yes/No	Extra cost?	Specify
Regulatory			
Which test house has certified the CE-mark (not for class I product).			
If the device is not CE-marked with which safety standards does the medical device comply? (Standard, Test House, Certificate)			
What is the intended use according to the manufacturer?			
Installation			
Is installation included?			
Within what time from ordering date will installation be completed?			
Does the medical device require special facilities or constructions in the premises, such as ventilation, water, sewerage and electrical wiring			
Training			
What kind of training is offered for users?			
What kind of education level is needed from the operator?			
What kind of service training is offered for a clinical engineer?			
Consumables			
Are there consumables and accessories available in stock?			
What other brands of consumables and accessories are safe to use according to the manufacturer?			
Maintenance			
What kind of maintenance is required by a clinical engineer?			
What kind of maintenance and/or cleaning is required from the operator?			
Are there any critical spare parts or items that need to be replaced regularly?			
Is there a supply of all spare parts available?			
Does the device require calibration, and if so how is that carried out? Calibration kits?			
For how many years from the date of last manufacture is the supply of spare parts			

guaranteed?			
What kind of training does the manufacturer provide for the supplier?			
Software			
Does the medical device include software, and if so in which user language?			
Is software for fault finding provided?			
Are there any service or maintenance restrictions, or functions that require pass words which are not accessible.			
Are upgrades for software driven devices available and free of charge?			
Is there a remote diagnostic support service? If so, how is this operated and supported? Is the support via a modem link?			
Offered services			
Is service contract offered, and at which levels?			
How fast service can be offered on equipment-down-time?			
Are all service and the most common spare parts available in Albania?			
Are there loan service to replace medical device that is undergoing repair or maintenance?			
Are there 24-hour services, if not how is out of hours repairs handled?			
What is the response time for both off-site and on-site repairs?			
What other service options can be provided?			
Is the supplier's maintenance organisation currently registered to a quality system standard?			
Documentation			
Does the service manual include circuit diagrams, preventative maintenance schedules, trouble shooting hints, repair procedures, parts lists, special tools?			
Is the user manual in Albanian and suitable for the end-user?			
Disposal			
What is the estimated life time for the medical device?			
Does the medical device contain or generate materials that need special			

environmental safety procedures? Recycling?			
If decontamination is required is specific equipment needed? If so specify equipment type and parameters of operation (eg. temperature, pressure, etc)			
What kind of routines are required when disposing the medical device?			

Annex 3

List of Requirements for Inclusion in the Invitation for Tenders

To be included in the offer:	Applicable:	Details:
CE-marked product		
EC declaration of conformity		
Installation		
Service course for clinical engineer		
User training		
Spare part list		
User manual in Albanian		
Service manual in English		
List of accessories and consumables		
1 year warranty		

Annex 4

Procedures required for the Process of Procuring Medical Devices through Donation

Donor and Recipient shall respect the *four basic principles for donation*, as formulated by the World Health Organization (WHO):

Basic principle 1: There must be maximum benefit to the recipient: The primary principle is that a health care donation shall benefit the recipient to the maximum extent possible. This implies that all donations shall be based on an expressed need and that medical device donations are to be discouraged if they are of little use to the recipient.

Basic principle 2: There must be respect for wishes and authority of the recipient: A donation should be made with full

respect for the wishes and authority of the recipient, and be supportive of existing government health policies and administrative arrangements.

Basic principle 3: There must be no double standards in quality: There shall be no double standards in quality. If the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.

Basic principle 4: There must be effective communication between donor and recipient. All donations shall be based on an expressed need and shall not be sent unannounced.

Administrative routines

In order to acquire successful donations efficient administrative routines need to be prepared and maintained at a national level. The administrative routines shall be communicated to potential donors in due time. In general, donations of medical devices shall involve similar activities which are closely connected or identical to procurement of new medical devices. Administrative routines shall include procedures and instructions on shipment, regulations, import taxes and customs.

National Donation plan and coordination

In order for donations to be efficiently targeted and be of maximum use to recipients, efforts should be invested into examining what are the general needs and desires in Albania. A national donation plan shall be prepared with the help of hospital management, physicians and clinical engineering competence in order to facilitate for both future donors and future recipients. Such a plan shall include a needs assessment and a list of standardized medical devices that can be technically supported. The national donation plan shall be updated on regular intervals.

Needs Assessment

A needs assessment with a recommendation of desired medical devices shall be prepared and maintained at a national level. Needs and desires shall regularly be monitored by the MoH. This task shall be carried out by a donation coordinator at the MoH. There shall be procedures so that suggested medical devices for procurement, which are turned down due to lack of finance, can be listed for donation possibilities.

Standardized Medical Device List

A list of standardized medical devices that have technical support possibilities shall be prepared and maintained. The list shall include what type of medical devices that can be supported from a technical point of view. Equipping a medical unit is more than simply obtaining the medical device. Maintenance is vital, and maintaining a vast array of different medical devices can be problematic and costly. There shall be routines so that the State Agency of Medical Devices will maintain a national Standardized Medical Device List with medical devices that the SAMD or the CEU at hospital level can support. Such a list is useful because:

- Medical devices included on the list can be fully supported in terms of spare parts, maintenance and operating instructions.
- Installation and operation arrangements for users and maintenance procedures for technical personnel are simplified.
- It lowers prices due to that bulk purchasing of consumables is possible, and planning for storage space is easier.

The Standardized Medical Device list shall address issues like:

- *Staff experience and training* required for installation, operation, and maintenance. Consider both the clinical staff and the technical service staff required to operate the equipment.
- *Climatic and environmental conditions*, such as heat (temperature), humidity, dust, ventilation, disposal and needed

waste management routines.

- *Utilities*: power supply (electric, gas, generator, fossil fuel, wood fuel, solar, windmill or biogas), reliability of supply (fluctuating power, interruptions, rationing, etc.), type of power (voltage, frequency, phase, AC/DC); type of water (polluted, salty, hard, soft, etc.) and the means of delivery (piped, stored, well, river and rain).
- *Support services* required for operation, procedures, and clinical use of the medical device. Keep in mind that modern medical devices may offer a wide variety of operational modes and may simplify the performance of certain procedures but it is often very expensive, and may need both health specialists and a manufacturers' service network for maintenance and repair. When these are available, spare parts and special maintenance tools that are costly may be required. Sophisticated medical devices often have very sensitive parts. Also remember that sophisticated modes offered by the medical devices are often not utilized.
- *Maintenance costs* in terms of spare parts, downtime during normal servicing and level of expertise of technical staff required.
- *Availability of consumables*. Some equipment may require consumables which are not available locally, for example, special papers, films, filters, etc. These are recurrent cost items and their availability must be assured.
- *Other specific requirements* related to the equipment. For example, whether a new addition will conform with existing equipment, whether a cold room is required for computerized equipment, or especially solid walls for x-ray machines, or a boiler for autoclaves or power stabilizers for electronic equipment.
- *Experience of others* with similar equipment, brands, or sources. Check whether equipment is manufactured locally or imported on a regular basis. This list shall aim at providing criteria to help define medical devices that are technologically and clinically appropriate to the intended use. By following this list, the final choice of medical devices is likely to be of high quality, solid and robust and of a standard that will withstand both environmental and operational conditions.

Procedure for Recipients

Before making a request, the recipient shall be advised to check whether the requested medical device is on the national Standardized Medical Device list. If the device is not on the list it is advisable to develop one for the unit or hospital, or working as a team, for a related group of hospitals. Associations or coordinating agencies may make a list for their members. Such cooperation encourages sharing of resources and experiences.

Specification of Items to Accompany the Medical Device

All medical devices must be provided with a full set of technical documents. That is, documentation for installation, for user operation, for repair and maintenance (manuals), a list of spare parts and diagrams and technical data. Clearly indicate the language in which documents should be made available. If documents cannot be made available in Albanian, these should be made available in another language understood by the user, for instance Italian or English.

All medical devices must be accompanied by a reasonable quantity of spare parts and consumable items. This should take into account the *lead period* (i.e. period between placing an order and receipt of spare parts). If the lead period is two years then spare parts and consumables are needed to cover that period. All new medical devices must be accompanied by documents of warranty (guarantee). A legal expert can be used to read and interpret the conditions if necessary.

Compiling a Check-list

Compiling a check-list will include consideration of all issues discussed above. It will ensure that the donor receives all the information required in order to make an appropriate donation. A generic check-list is outlined in box annex 4 below.

Consult with Clinical Engineers

Prior to accepting a medical device for donation technical/clinical engineer personnel must be involved. As experts, they will consider and advise upon:

- All aspects of the requirements for installation, operation, and maintenance.
- Essential spare parts and other special requirements, their availability, and costs.
- Availability of technical personnel and level of training required.
- Estimated lifespan of the equipment based on the model, year of manufacture and whether it is new or recondition.
- Appropriateness of equipment in terms of running costs and design.
- Local support from suppliers or manufacturers.

Box Annex 4: Sample of Check List of Requirements to be Used Prior to Donation.

- Name of equipment
- Description of equipment
- Equipment type included on national Standardized Medical Device List
- Technical specifications
- Functions required
- Special requirements
- Staff available for:
 - Installation
 - Operation
 - Maintenance
 - Other (Specify)
- Location:
 - Site
 - Size
 - Accessibility
 - Type of building
 - Other factors (specify)
- Climate:
 - Temperature range - Day / Night
 - Humidity - Maximum / Minimum
 - Ventilation system
 - Other factors
- Utilities:
 - Power supply
 - Fuel type
 - Voltage
 - Frequency
 - Phase
 - Other issues
- Water system
 - Water type

Communicate Alternative Preferences

If a financial contribution to allow local or regional purchase would be more appropriate, cheaper or easier, state this information clearly. Issues on which the donor is unable to comply can then be discussed. The solution should be understood and agreed upon by both parties. As a result, the donors will not substitute items believing that such alternatives would be equally suitable. If donations of medical devices that are not needed are received, the donor must be informed immediately.

Procedure for Donors

A donated medical device will only be useful if it is properly installed, operated, maintained, and appropriately used. Therefore the donor should be advised to comply with the following requirements:

Communicate with the Recipient

Before supplying any medical device the donor shall request for a comprehensive description of the medical device required by the recipient (including their check-list). The donor should ensure that the conditions that cannot be fulfilled are communicated to the recipient. An agreement on all conditions should be reached before shipping the medical device. This ensures that the medical device supplied is clinically, economically, and technologically appropriate.

Supply safe and fully operational medical devices

Medical devices whether new, refurbished or used, should be tested and all essential parts, accessories and working materials included before shipment. A basic list of all components must be provided to the recipient.

New medical devices shall fulfil the same requirements as if the medical device was going to be procured through regular procedure. Even if the tendering process may not be needed it

should be established that the medical device fulfils all criteria as when procuring, such as complying with intended use and regulatory requirements.

For new medical devices the manufacturer should provide all the information needed to verify whether the medical device can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely at all times.

Refurbished medical devices should be fully rebuilt or reconditioned. It should be established that the manufacturer continues to produce spare parts, and the “life expectancy” of the equipment should be indicated. Refurbishers of medical devices, who are responsible for restoring medical devices to its original working condition for the purpose of re-sale, are subject to general principles of liability. They are expected to restore medical devices to the manufacturer’s original specifications and follow the essential requirements in the Medical Device Directive. Suppliers of refurbished medical devices shall bear the same responsibilities as the original manufacturer.

Used medical devices shall be fully operational and safe for use. As in the case with new medical devices it should be proved that all the information from the original manufacturer can be obtained. This information is needed to verify whether the medical device can operate correctly and safely. In order to ensure good practice, the donor should apply this principle as to as far extent possible upon donation of a used medical device to ensure safety. This information should be available for the recipient to view before donation and be supplied with the medical device on completion of the donation.

On donation of used medical devices the following should be supplied with the medical device to the recipient:

- A clear statement that the medical device is not new.
- Documentation of decontamination (when applicable, see below).
- User manuals and training requirements.
- Service manual.
- Medical device history log book.

Old, broken, outmoded, and redundant devices for which spare parts and consumables are no longer available, or devices which is no longer supported by the manufacturer, should be considered as useless. If it is difficult for the donor to service the medical device, it will be impossible for the recipient. Such items should not be supplied for donation.

If applicable, used medical devices should be decontaminated before they are shipped to the donor. Manufacturer guidelines normally indicate if this is applicable and the method that should be adopted. All used medical devices that are subject for decontamination should be supplied with a certificate of decontamination

Supply all Technical Documents

These include all installation, operation, maintenance and service manuals. It is particularly important to include technical diagrams as the symbols used are usually international. The technical documents and service manuals should be supplied in either Albanian or English language.

Supply an Initial Requirement of Consumables and Spare Parts

Recipients often face lengthy and complicated procurement procedures. Medical devices should therefore be supplied with an initial consignment of consumables and spare parts expected to last at least two years (or as requested), and a full list of spare parts. The list must clearly indicate the part name and number, and full name and address (including phone, telex and fax numbers, if possible) of the manufacturer or authorized dealer. Vagueness over the description and source of spare parts can cause months of delay in an already long process.

Ensure Proper Packaging

The consignment is likely to endure long periods in ships, airplanes, trains, motor vehicles, bicycles and even on animal

backs or by hand. The packaging must therefore be strong and sturdy to withstand rough handling and to minimize damage during transportation. It should also include a clear packing list identifying all components and be of a size that can be handled using simple mechanical devices and manual labour.

Supply Shipping Documents Promptly

Consignments have been known to remain at ports for months, facing possible damage and accumulating demurrage charges (penalty for delayed action) due to late submission of shipping documents. Prompt submission of documents is essential and should be sent by express insured mail. If possible, send advance copies by fax. A copy of shipping details should also be sent to responsible Clinical Engineer.

Offer Technical Assistance

The donor shall, where possible, promote, recommend and provide training for the use and maintenance of the medical device. On site training is usually very useful.

Understand import regulations of the recipient country

There may be regulations which restrict who can receive donations, and which indicate taxes and other charges. It is important to get informed in advance about these conditions. It is also important to assess the ability of the recipient to pay the accompanying local costs. The donor should find out if there are any sales tax, customs or other fees to be paid and the routines for such.

Annex 5

Sample of Medical Devices to be registered Devices to be registered in the Medical Device Inventory

Radiological equipment

X-ray machine
Control unit
HT-Block
Stand and table
TV-chain
Mobile X-ray machine
CT-scanner
Cobalt machine
Scintigraph
Gamma camera
Film processing machine
Film viewer
MR camera

Pajisje radiologjike

Aparat rrezesh X
Tabela e komandes
Blloku i tensionit te larte
Stativ dhe shtrat
Zinxhir televiziv
Aparat portativ rrezesh X
Skaner
Aparat kobaltoterapie
Shintograf
Gama kamera
Procesor filmi
Negativoskop
Aparat i rezonances magnetike

Diagnostic Ultrasound equipment

Echocardiograph
Ultrasound, gynecology
Ultrasound, internal
medicine/obstetrics
Ultrasound, surgery

Aparate diagnostikuese me ultratinguj

Ekokardiograf
Eko gjinekologjike
Eko per semundjet
e brendshme/obstetri
Eko kirurgjikale

Physiology and neurophysiology lab equipment

ECG recorder
EEG recorder
EMG recorder
Spirometer
Peak flow meter
Ergometer

Pajisje laboratorike fiziologjike dhe neurofiziologjike

Elektrokardiograf
Elektroencefalograf
Elektromiograf
Spirometer
Mates i prurjes maksimale te frymes
Biçiklete ergometrike

Instruments for Clinical Chemistry Hematology lab, Bacteriology lab, and Pathology lab

Hb-meter
 Photometer
 Spectrophotometer
 Flarnphotometer
 Colorimeter
 Blood gas analyzer
 Oximeter
 pH-meter
 Electrolytemeter
 Microscope
 Waterbath
 Laboratory incubator
 Centrifuge, several types
 Balance
 Water distillatory
 Autoanalyzer
 Cell counter
 Electrophoresis equipment
 Cromatograph
 Clean air cabinet
 Refrigerator
 Freezer
 Microtome
 Staining equipment
 Paraffin dispenser
 Refractometer
 Vacuum pump
 CO₂ analyzer
 Shaker
 Stirrer
 Digital thermometer

Instrumenta per laboratorin e kimise klinike, laboratorin e hematologjise, laboratorin e bakterilogjise dhe laboratorin e patologjise

Hb-meter
 Fotometer
 Spektrofotometer
 Fiamfotometer
 Kolorimeter
 Analizator gjaku
 Oksimeter
 pH-meter
 Elektrolitmeter
 Mikroskop
 Banjomari
 Inkubator laboratorik
 Centrifuga te llojeve te ndryshme
 Peshore analitike
 Distilator uji
 Autoanalizator
 Numerues qelizash
 Elektroforeze
 Kromatograf
 Ndarje me ajer te paster
 Frigorifer
 Ngrirës
 Mikrotomi
 Pajisje ngjyrimiper qelizat
 Pajisje per shperndarjen e parafines
 Rejraktometer
 Pompevakuumi
 Analizator CO₂
 Tundes
 Perzieres
 Termometer shifror

Blood bank equipment

Blood refrigerator
 Blood freezer
 Centrifuge
 Blood test instrument

Pajisje te bankave te gjakut

Frigorifer gjaku
 Ngrires gjaku
 Centrifuge
 Instrument i testimit te g/akut

Equipment for operating theatre and Intensive care

Patient monitoring system
 Anesthesia machine
 Anesthesia evaporator (nebulizer)
 Ventilator
 Respirator
 Gastroscope, flexible with cold light source
 Bronchoscope, cytoscope etcetera
 Laparoscope
 Pulse oximeter
 Monitoring systems, various types
 Operating microscope
 Suction pump
 Infusion pump
 Syringe pump
 Defibrillator
 Diathermy equipment (electro-surgical unit)
 Blood warmer
 Pacemaker, external
 Saw, electric or pneumatic
 Drilling machine, electric or pneumatic
 Operating table
 Operating light
 Delivery bed

Pajisje per sallat e operacionit unit dhe per Reanimacionin

Monitor pacienti
 Sistem anestezie
 Avullues (nebulizator) anestezie
 Ventilator
 Respirator
 Gastroskop, fleksibel me bunm ante te ftohte
 Bronkoskope, citoskope etj
 Laparoskop
 Puls oksimeter
 Sisteme monitorimi, tipe te ndryshem
 Mikroskop kirurgjikal
 Aspirator
 Pompe infuzione
 Pompe shiringe
 Defibrilator
 Diatermi (elektrobisturi)
 Ngrohes gjaku
 Peismeiker, ijashtem
 Sharre, elektrike ose pneumatike
 Trapano, elektrike ose pneumatike
 Shtrat operacioni
 Llampe operacioni
 Shtrat lindjeje

Cardiotocograph	Kardiotokograf
Incubator	Inkubator
Heating lamp	Llampe ngrohese
Hemodialysis equipment	Hemodialize
Oxygen concentrator	Perqendrues oksigjeni
Compressed air machine	Kompresor
Lithotripter	Litotripter
Surgical equipment (Usually not to be registered in this inventory)	Instrumente kirurgjikale (zakonisht nuk duhen perfshire ne kete inventor)

Equipment for the out-patient department

Examination lamp
Eye tonometer, advanced type
Perimeter
Audiometer
Thermometer, electrical
Scale
(Otosopes, ophthalmoscopes
etceteras shall normally
not be registered)

Pajisje per ambulancat

Llampe ekzaminimi
Tonometer, te tipeve te avancuar
Perimeter
Audiometer
Termometer elektrik
Peshore
(Otoskopet. oftalmoskopet etj,
normalisht nuk do te regjistohen)

Physiotherapy

Short wave apparatus
Ultrasound apparatus
Electrostimulation equipment
IR- and UV-lamps
Tubs for hydrotherapy

Fizioterapi

Ngrohesh mefrekuence te larte
Ngrohesh me ultratinguj
Elektrostimulator
Llampa IR dhe UV
Vaske per hidroterapi

Dental equipment and instruments

Dental X-ray machine
Drilling machine
Suction pump
Dental chair

Pajisje dhe instrumenta dentare

Aparat per graft dentare
Freze
Aspirator dentar
Poltron dentar

Dental light	Reflektor dentar
Amalgam mixer	Perzieres amalgame
Photopolymerizator	Llampe fotopolimerizuese
Laboratory micromotor	Mikromotor laboratory
Porcelain oven	Furre porcelani
Polymerization oven	Furre polimerizimi me presion
High frequency oven	Furre efrekuences se larte

Sterilization equipment

Autoclave
UV-lamp
Instrument boiler
Desinfector
Aerosterile
Other sterilization
equipment

Pajisje steriUzimi

Autoklave
Llampe UV
Zieres instrumentash
Dezinfektues
Aerosteril
Pajisje te tjera sterilizuese

Computer system for medical use

PC
Printer
Scanner
Other microprocessor systems
Back-UPS
Stabilizer

Sisteme kompjuteri

Kompjuter
Printer
Skaner
Sisteme te tjera me mikroprocesor
UPS
Stabilizator

Annex 6

Adverse Event Reporting

Annex 6.1 Roles and Responsibilities of Health Care Providers, MDMS and its Advisory Board

Introduction and Background

Patient safety when using medical devices is a complex matter. It is dependent on many factors such as safety of the device and the use of the device but also the technology infrastructure in which the device is part of procurement and maintenance. To improve patient safety when medical devices are at hand it is important to have detailed knowledge about the weaknesses of this technology system. Therefore an adverse event reporting (AER) system for medical devices is important. Adverse event reports can also be seen as deviations in business and as such an input to improvement.

An adverse event with a medical device is an accident and/or an incident that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, users or other persons and involves the use of a medical device.

Adverse incidents in medical devices may arise due to:

- shortcomings in the design or manufacture of the device itself,
- inadequate instructions for use,
- inadequate servicing and maintenance,
- locally initiated modifications or adjustments,
- inappropriate user practices (which may in turn result from inadequate training),
- inappropriate management procedures,
- the environment in which a device is used or stored, or
- selection of the incorrect device for the purpose.

Conditions of use may also give rise to adverse incidents:

- environmental conditions (e.g. electromagnetic interference),
- location (e.g. devices designed for hospitals may not be suitable for use in the community or ambulances).

What to Report

Incidents and accidents when medical devices and its accessories are used as well as observations when such situations could have occurred must be reported in order to learn from failures and mistakes. All medical devices will sooner or later break down, but when safety for patients, users and third person is directly influenced it must be reported. All CE-marked devices has an intended use stated in accompanying documents, and have user instructions telling how it shall be operated. Also mistakes in the usage of devices must be reported so user instructions and/or training can be improved.

How to Report

Everyone employed in medical care (public as well as private) has a responsibility to report to nearest boss. He/she shall take notice of what has happened and announce it to the person in charge of medical safety at the institution. A written report must be developed. The report shall then be sent to the Medical Devices Management Sector (MDMS) in the MoH for further analysis. It must be sent from the medical care provider within four weeks after the observation.

MDMS has designed a model for reporting of adverse events process of the report. A sample report form is attached to this document (refer annex 6). Based on this each medical care provider, public and private, shall set the local procedure on how to report incidents and accidents with medical devices.

All devices and its accessories that have been involved in an incident/accident shall be taken out of use, isolated and stored in a safe and protected place. Everything must be left as they were at the moment of the accident/incident in order to facilitate future investigations.

Registration of Reports in MDMS

The health care provider sends the report to MDMS for further handling. At MDMS the report must be identified and filed. Immediately a receipt for a received report shall be sent to the

reporter. Incoming reports shall be copied and sent to members of an advisory board. If deemed necessary, MDMS shall organise a complementary investigation. When all necessary material is collected to perform a good analysis of the cause of event, MDMS shall inform the medical service provider that the medical device can be repaired and taken into use again.

Advisory Board

In order to analyse the reports professionally and view the incident/accident from different perspectives a multi-professional advisory board shall be assigned to strengthen the competence of MDMS. Such a board shall have representatives such as medical doctors from different specialties, nurses, clinical engineers, specialist in laws for medical services, representatives from patient organisations and suppliers of medical devices.

The board shall meet regularly and discuss all incidents/accidents reported and arrive at conclusions and recommendations on each case. The terms of reference for the Advisory Board are described in section 4.2 of this document.

Feed back to the Health Care Provider

Following analysis of the cause of the incident/accident and a discussion by the advisory board on how to mitigate the risk in a repeat situation the medical service provider shall immediately be informed of the result. Further, documents shall be produced and presented based on the adverse event reports in order to improve safety in the use of medical devices in the country. It can be alerts if necessary, findings or just statistics from the reports. Such documents shall be anonymous and published in Albania for all medical service providers.

European Union Vigilance Reports

EU has organised a mandatory system of reporting failures with medical devices to help the manufacturers to monitor patient safety. It is called the Vigilance System. MDMS must

inform any given manufacturer if and when her/his device has failed to function properly and exposed a risk to the patient.

Annex 6.2 Terms of Reference for an Advisory Board in the Adverse Event Reporting System

Introduction and Background

Adequate feedback is very important in an adverse event reporting system. Therefore all reported incidents/accidents must be scrutinised by a competent team, the Advisory Board, before a comment is made. Some incidents/accidents must be analysed deeper to find the cause of failure and suggest suitable corrective action. The Advisory Board is a competent unit and can therefore be of great help.

Mission of the Advisory Board

To create a positive and blame-free culture in the health care sector of Albania and promote willingness to report adverse events in order to improve the safety and use of medical devices in health care.

Tasks of the Advisory Board

- Study reports, analyse them and find underlying cause of failure. (Ask 5 why)
- Comment the reports and suggest improvements to get safer use of medical devices.
- Issue information based on findings from the reports.
- Develop methods and procedures to improve the 'Adverse Event Reporting' system and promote the reporting.

Selection of the board members shall be based on:

- Professional competence.
- Structure and proactive attitude to work.
- Acceptance of fast feedback.
- Presence at meetings. Meeting frequency will change over time depending on number of incoming reports.

Structure of the Advisory Board

The Advisory Board needs a working group to prepare cases and initiate investigations, analyses and to prepare reports. They shall be MDMS employees as part of the Ministry of Health with competence in the fields of clinical engineering, law and medicine. One of the members of the Advisory Board will chair the working group. All other members of the Advisory Board shall be senior and be well recognized representatives of their special field of competence. The work shall be considered to be honorary with minor financial compensation of costs incurred. Competences needed in the Advisory Board:

- Medical Doctor with specialty in intensive care.
- Medical Doctor with specialty in diagnostics.
- Medical Doctor with specialty in internal medicine.
- Medical Doctor with specialty in surgery.
- Nurse from intensive care or surgery.
- Nurse from primary health care.
- Clinical Engineer from a hospital.
- Representative of the medical device suppliers
- Representative of a patients' organisation.

Responsibilities

The Advisory Board members must prepare cases and execute necessary investigations. It is a MDMS responsibility to staff this work group. Members of the Advisory Board must accept to read, form opinions and comment on the cases. They must be present and discuss cases at the Advisory Board meetings. The Advisory Board gives advice to MDMS which will take legal action if found necessary. A classification system shall be developed by the advisory board in order to be able to follow the trend of adverse events and cause of those events over time. The classification system shall comprise information on the category, cause and severity of the event as well as recommended action.

Process of Work

MDMS shall prepare cases and preliminary investigations for

plenum discussions with the Advisory Board. MDMS shall send relevant material including a preliminary report to members. Meetings shall be documented in protocols.

Each case must be commented upon and accepted/closed by the Advisory Board. Special emphasis shall be put on the underlying cause of failure. The discussion shall concern:

- The quality of the report and investigation.
- What was the underlying cause of failure?
- Decisions on suitable corrective action.
- Formulation of advice on the content of feedback information to the reporting organisation, if applicable.
- Decisions on classification of the events for statistical purposes.

MDMS shall contact the reporting clinic/unit with recommendations based on advice from the Advisory Board. Reporting of adverse events shall be considered a process of learning from mistakes.

To be completed by the user	F DOCUMENTATION			
	Was the instruction manual present?		<input type="checkbox"/> YES	<input type="checkbox"/> NO
	Was the instruction manual read and understood (including		<input type="checkbox"/> YES	<input type="checkbox"/> NO
	Was the staff trained enough?		<input type="checkbox"/> YES	<input type="checkbox"/> NO
	G CONSEQUENCE:			
	G1 DESCRIPTION OF PATIENT INJURY			
G2 DESCRIPTION OF STAFF INJURY				
G3 OTHERS				
H STAFF INVOLVED (Will be anonymous in following report)				
a) Doctor				
Name:		Position	Dep.:	Phone:
Responsibility/task at event:				
b) Nurse				
Name:		Position	Dep.:	Phone:
Responsibility/task at event:				
c) Other person present or contact person:				
Name:		Position	Dep.:	Phone:
I REPORTER				
Hospital:				
Name:		Position	Dep.:	Phone:
Date of reporting 200		-	-	

If necessary continue on a separate sheet of paper.

Signature of reporter if sent by mail: _____

This report shall be forwarded to the hospital medical director via the head of clinic.

To be completed by hospital management

J HOSPITAL IDENTIFICATION NO.
K ADDITIONAL COMMENTS
L SUGGESTION FOR IMPROVEMENT TO PREVENT A REPEATED EVENT
M PRELIMINARY INVESTIGATION
An investigation on the cause of event is performed, and reported in a separate document: Yes No
N NEED OF DEVICE
It is important to restore the device for immediate use. (The device shall be stored in a secure place in order to
O VIGILANCE
The manufacturer is informed about the event: Yes No
P MANAGEMENT REPORTER
Hospital: Name: Position Phone:
Date of reporting 200 - -
O THIS REPORT SHALL BE SENT TO THE MDMS MoH
Ministry of Health E- Ruga PHONE FAX:

Annex 7

In-house manufactured products

Box Annex 7. Roadmap to design and commission in-house products

- Define intended use
- Decide Medical Device Directive (MDD) risk class
- Decide which essential requirements are valid and must be tested
- Set up a technical file including
 - Scientific documents
 - Specification of components
 - Drawings and other documents
- Test the device according to relevant standards and essential requirements
- Perform risk analysis
- Describe how to mitigate found risks
- Set up and perform a clinical trial if necessary.
- Mark the device with a unique number for traceability
- Store documentation in a safe place
- For detailed explanation refer to MDD.