

# **Health Technology Management in the Republic of Moldova. Accomplishments and Perspectives.**

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**Victor Sontea**

**Technical University of Moldova**

**Reinhold Werlein**

**Swiss Tropical and Public Health Institute**

**Claudio Zaugg**

**Swiss Tropical and Public Health Institute**

# The HTM Importance

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- ..... without functioning facilities, medical equipment, and medicines, it does not matter if the knowledge, skills and staff levels are high. The delivery of services will still be poor.

WHO (World Health Organization), World Health Report 2000

- Good management of medical technology can reduce total investment and reduce the running costs of equipment.

# HTM - Volume

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- ❑ > 6 000 distinct device groups
- ❑ > 1 000 000 brands and models
- ❑ > 15 000 manufacturers on the world market
- ❑ large number of local manufacturers
- ❑ \$250 billion market world-wide
- ❑ \$50 - \$200 annual per capita spending in EU
- ❑ development time 1 - 3 years
- ❑ obsolete, off-market 5 - 7 years

# HTM – Facts

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## Causes of defects and accidents with medical equipment (rule of thumb)

- 10% Technical defects
- 30% Inadequate strategy of maintenance
- 60% User mistakes

## □ 80/20 (70/30) (Pareto rule):

- A correct implementation of health technology management allows 80% of problems to be solved within 20% of the resources.

# Ongoing and Related Projects

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## **Moldovan-Swiss Projects:**

Modernizing the Moldovan Perinatology System,  
(PERINAT) Phase II & III

Implementing Agency: Swiss Tropical and Public Health  
Institute (SwissTPH)

Project leader: Professor Petru Stratulat

Regionalization of the Paediatric Emergency and  
Intensive Care Services in Moldova (REPEMOL)

Implementing Agency: Centre for Health Policies and Services,  
Bucharest, Romania (CPPS)

Project leader: Dr. Silvia Morgoci

# Partners

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## **Beneficiary**

- ❑ Ministry of Healthcare of the Republic of Moldova

## **Funding Agency**

- ❑ Swiss Agency for Development and Cooperation (SDC)

## **Partners**

- ❑ Association of Perinatal Medicine, Moldova
- ❑ Technical University of Moldova
- ❑ Biomedical Engineering Society from Moldova.

# Situation in the Republic of Moldova

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- ❑ Lack of coherent Policies for Health Technology Management.
- ❑ Acute shortage of Health Technology Specialists  
(diagnosis, maintenance, inspection, of biomedical devices especially for imported modern technology)

# Situation in the Republic of Moldova

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- ❑ Insufficient availability of technical competence on all the levels in all hospitals, but if present they are underused
- ❑ Poor or non existent Management of Health Technology (planning, acquisition, maintenance of medical equipment)



# Situation in the Republic of Moldova

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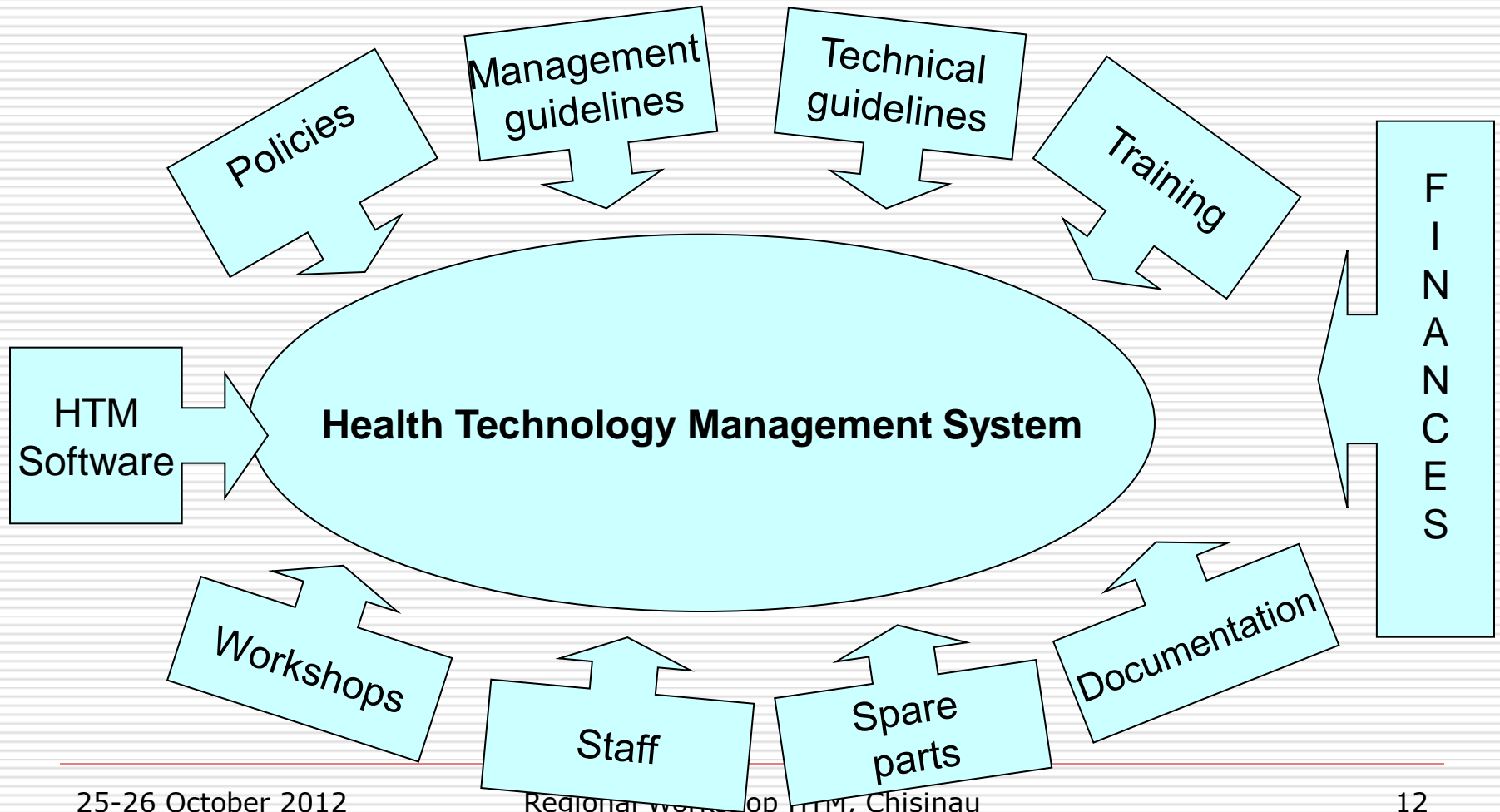
- ❑ Absence of systematic continuous training for technical service personnel (planning, maintenance, marketing and commissioning )
- ❑ Insufficient user training to assure effective operation of complex medical equipment
- ❑ Services offered by providers of medical devices are expensive and often delayed.

# Objectives to improve HTM

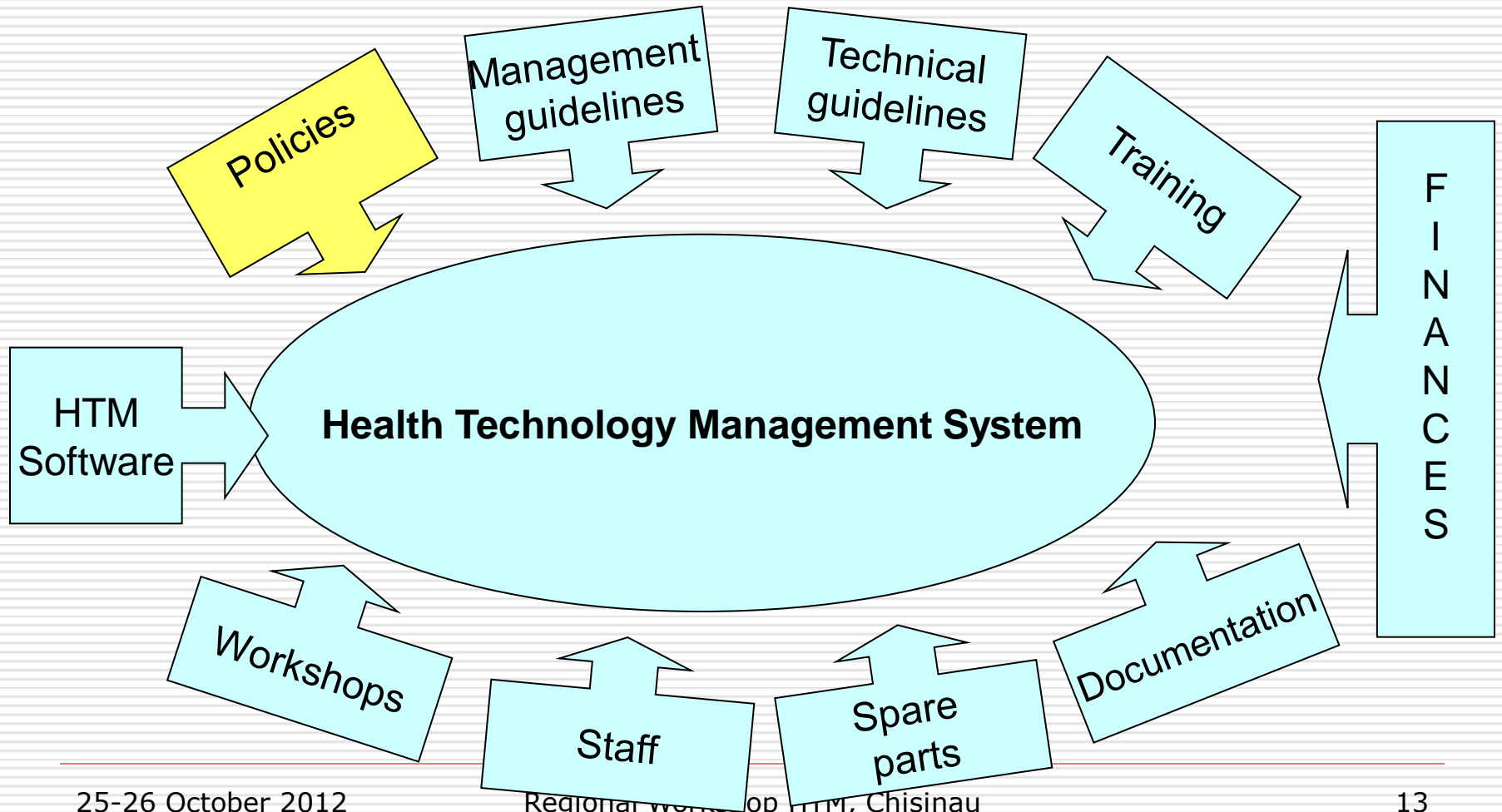
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- ❑ assuring the availability of adequate and affordable medical equipment for health services
- ❑ increasing the life span of medical equipment through effective maintenance
- ❑ reducing inappropriate use of modern technology
- ❑ reducing cost for maintenance and premature replacement of medical equipment
- ❑ providing relevant equipment data for informed decision making

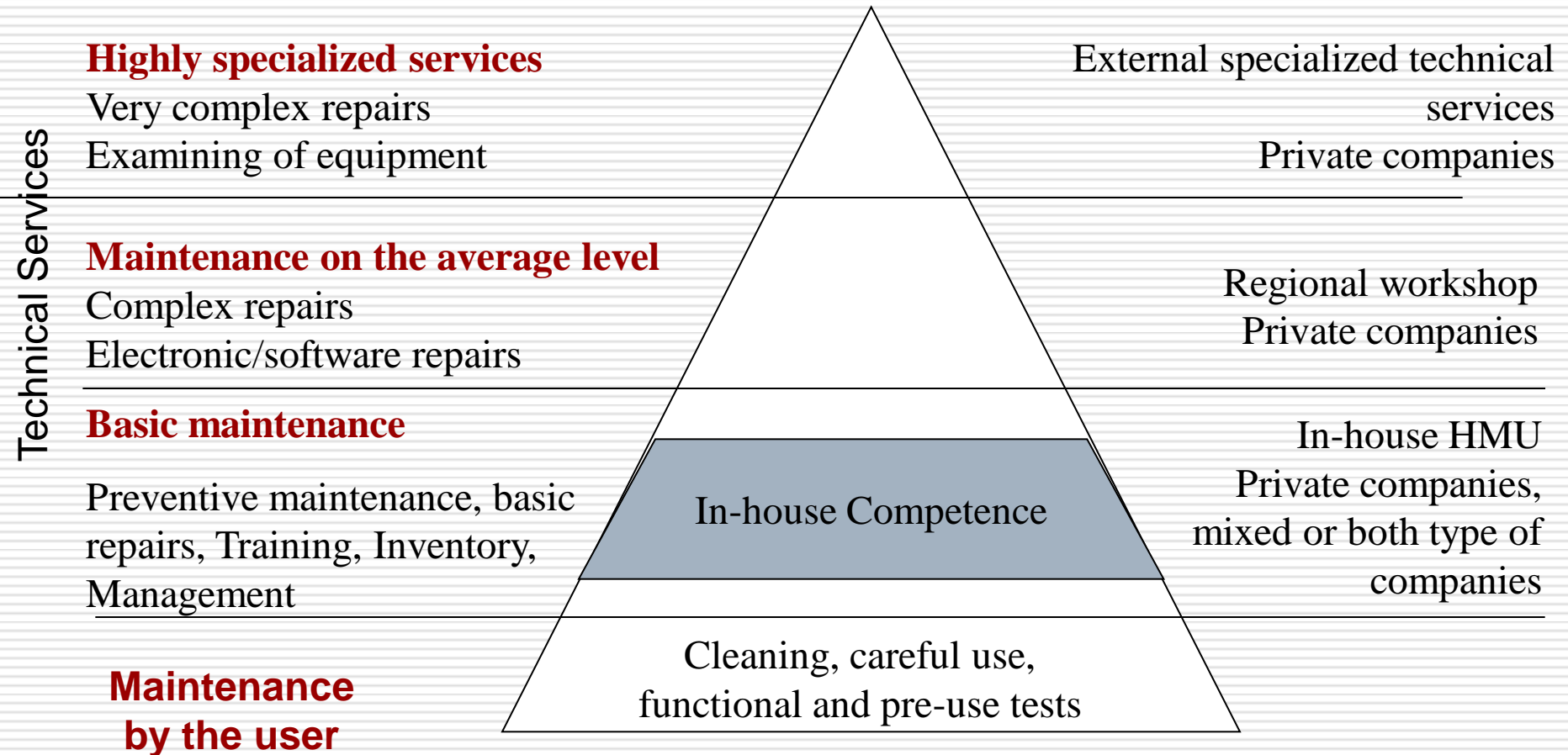
# System Components



# System Components



# HTM – Maintenance Policy – The Reference System



# Sensitisation for HTM

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- establishing a working group on HTM
- conduction sensitisation meetings in MOH and Hospitals
- Foundation of Biomedical Engineering Society from Moldova

# Order of MOH

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- Order of MOH No 661 of 27.09.2010 on implementation of HTM in Pilot Hospitals
  - approval of Forms and Documentation
  - implement electronic Inventory system
  - identify responsible person
  - identify supervisors

# Policies, Regulations,

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- ❑ Decree of the Government of the Republic of Moldova no. 96, from January 26, 2007  
"Regarding the establishment for market placement terms and usage of medical devices"
- ❑ Regulation regarding the establishment of market placement terms and usage of medical devices in the Republic of Moldova.
- ❑ Law no. 92, from April 26, 2012 Biomedical devices

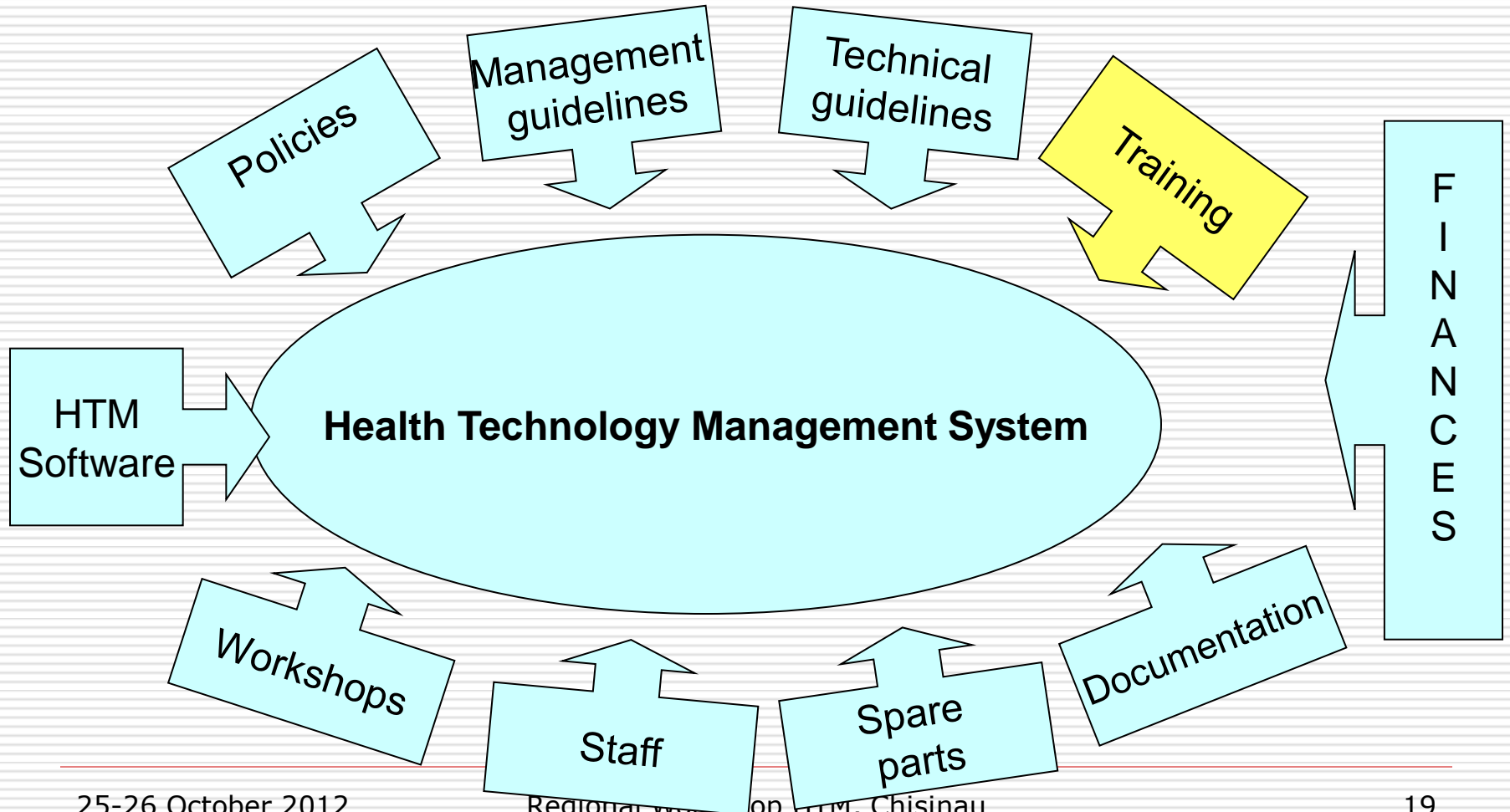


# Implementation of Norms in Medical Technology Management

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- European standards (international)
  - Active Implantable Medical Devices (AIMDD) . [Directive 90/385/EEC - OJ L189/ 20.7.90](#)
  - Medical Devices Directive (MDD). [Directive 93/42/EEC - OJ 169/ 12.7.93.](#)
  - In Vitro Diagnostic Directive (IVDD). [Directive 98/79/EC - OJ331/ 7.12.98](#)
- Rational norms
- Local norms.

# System Components



# Education Biomedical Engineering

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## Technical University of Moldova

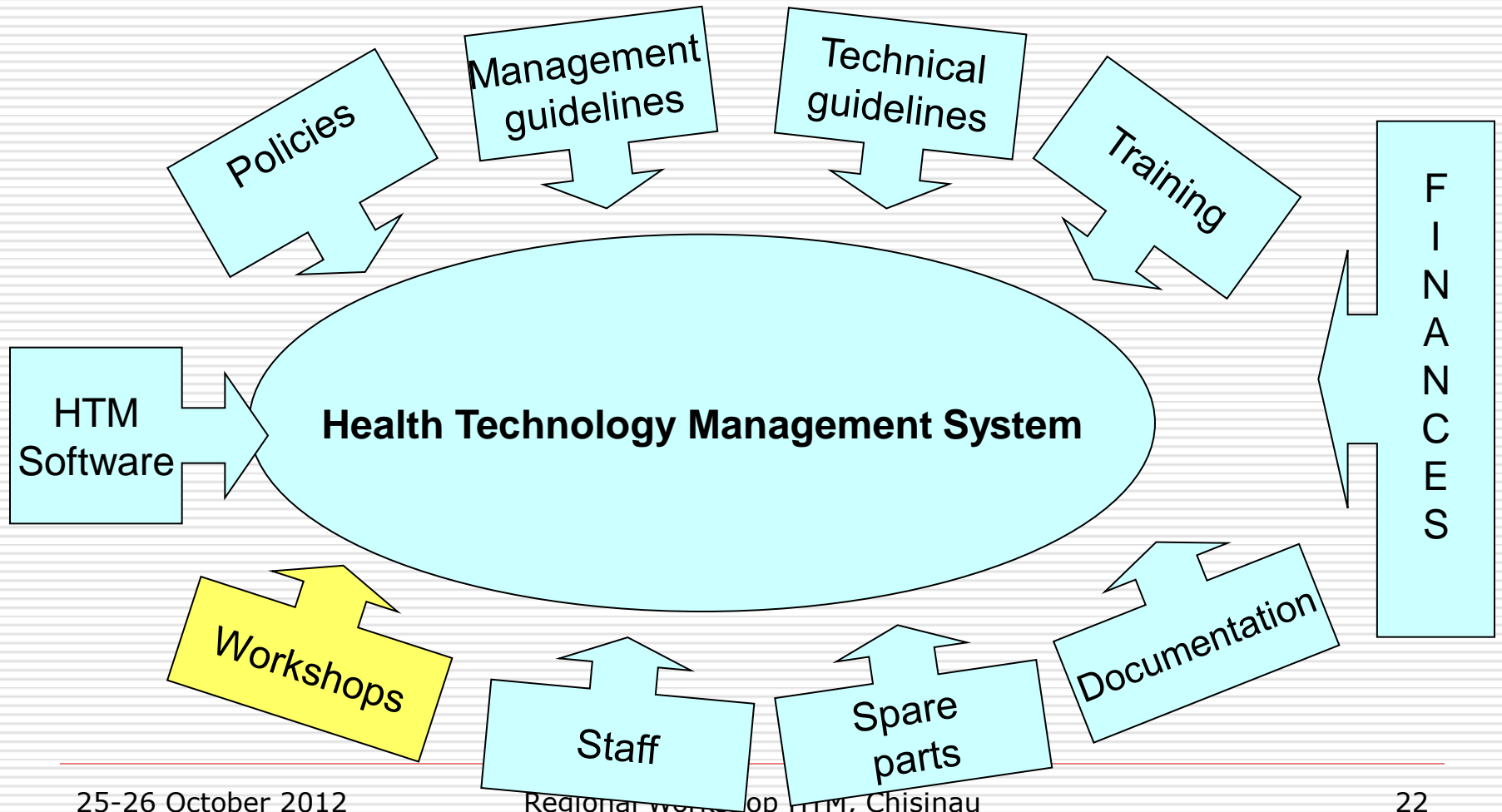
- Biomedical Engineering Systems - 4 years of license studies
- Biomedical Engineering - MA studies 1.5 years

# Specific Training

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- ❑ Training courses for users for priority equipment
- ❑ development and introduction of brief user instructions
- ❑ training on the job
- ❑ specific training session for maintenance engineers and technicians

# System Components

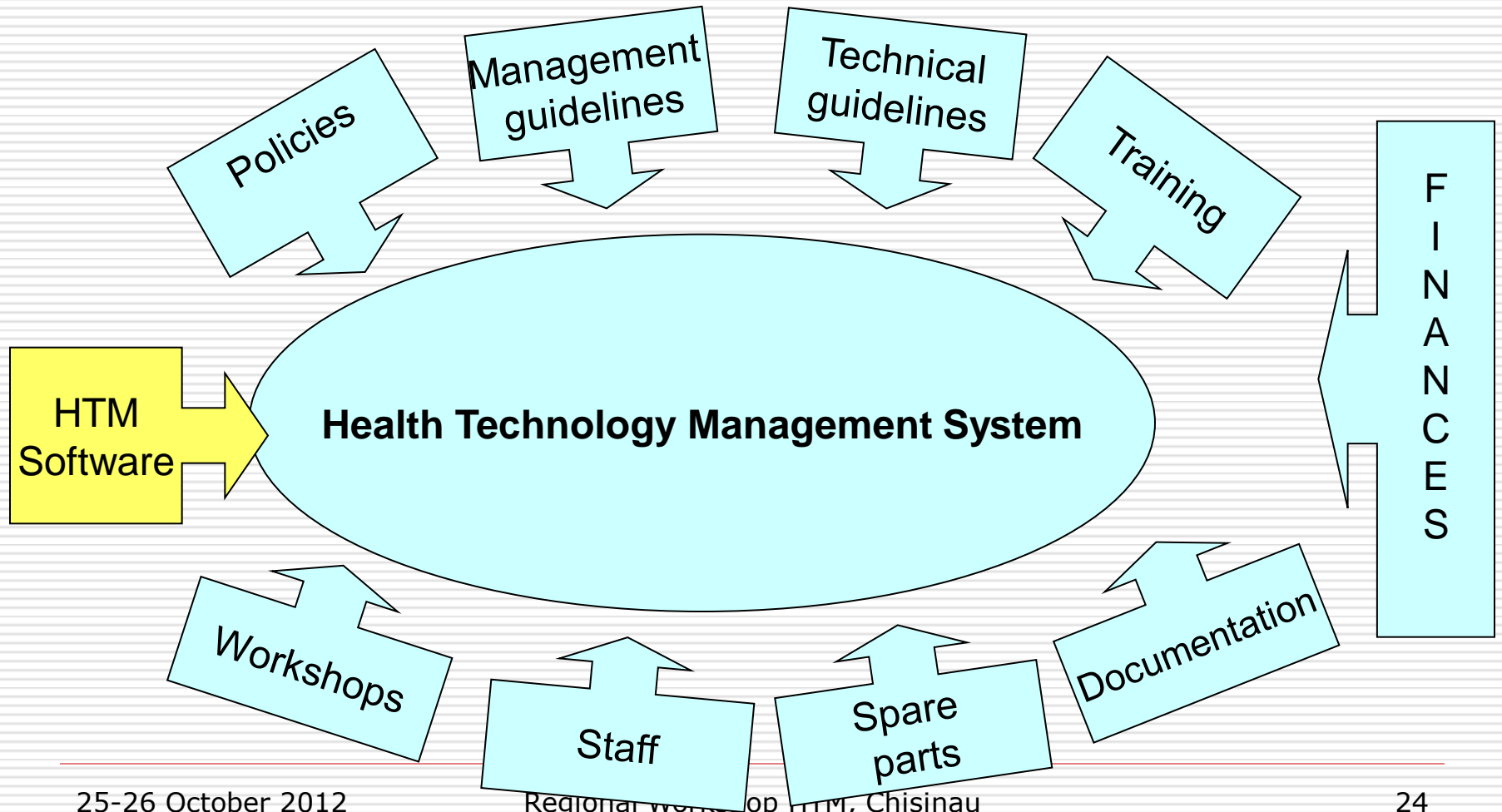


# HTM Workshops

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- Creation of HTM Workshops in 5 Pilot Hospitals
- provision of tools and test equipment
- all workshops are manned by a biomedical engineer

# System Components



# HTM Software

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- ❑ Introducing an open Source software (openMEDIS) for Inventory of medical devices
- ❑ Training of staff to use software
- ❑ taking inventories in all pilot hospitals
- ❑ more than 5000 pieces of equipment registered



# Adapting and Developing Electronic Register of Medical Devices Open MEDIS

open MEDIS
Acasa Dispozitive Contacte Angajati Repoarte Configurare Unele Iesire

Open MEDIS - registru electronic a dispozitivelor medical.



**Swiss TPH**  
Swiss Tropical and Public Health Institute  
Schweizerisches Tropen- und Public Health-Institut  
Institut Tropical et de Santé Publique Suisse

**Ultimile noutati**

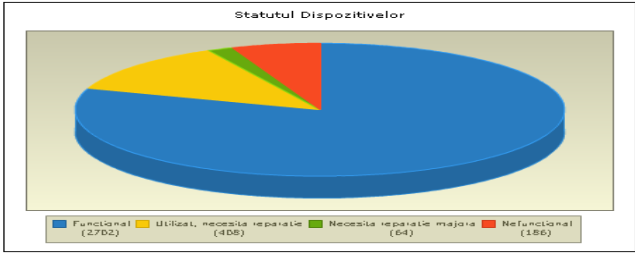
22.12.2010 - openMEDIS actualizare. Principalele schimbări: Tabloul de bord care prezintă date numai de facilitate proprie (pentru utilizatori) și procesului de economisire a activelor este mai rapid

09.13.2010 - A fost adaugata o noua pagina "Fisa Sumarului Inventarului" sumarizarea datelor. Verifica in "Repoarte" sau fa click aici: [Fisa sumarului](#)

**Prezentare generala**

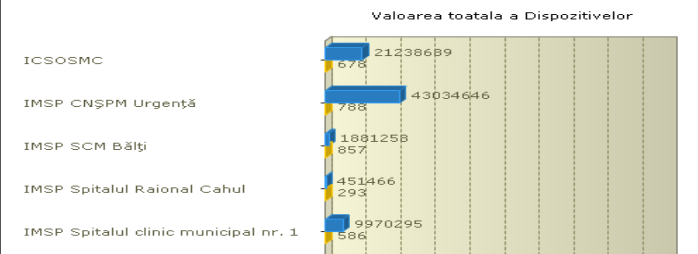
Astazi: duminică, martie 27, 2011  
 Utilizatorul curent: sontea  
 Spital: all in database  
 Baza de date activa: openmedis\_ro  
 Versiunea bazei de date: 2010-10-13 17:08:24  
 Dispozitivele in baza de date: 3360  
 Versiunea Software: Beta Version 1.22

**Statutul Dispozitivelor**



Statut	Numar
Fuctional	2702
Utilizat, necesita reparatie	408
Necesita reparatie majora	64
Nefunctional	186

**Statutul Financiar**

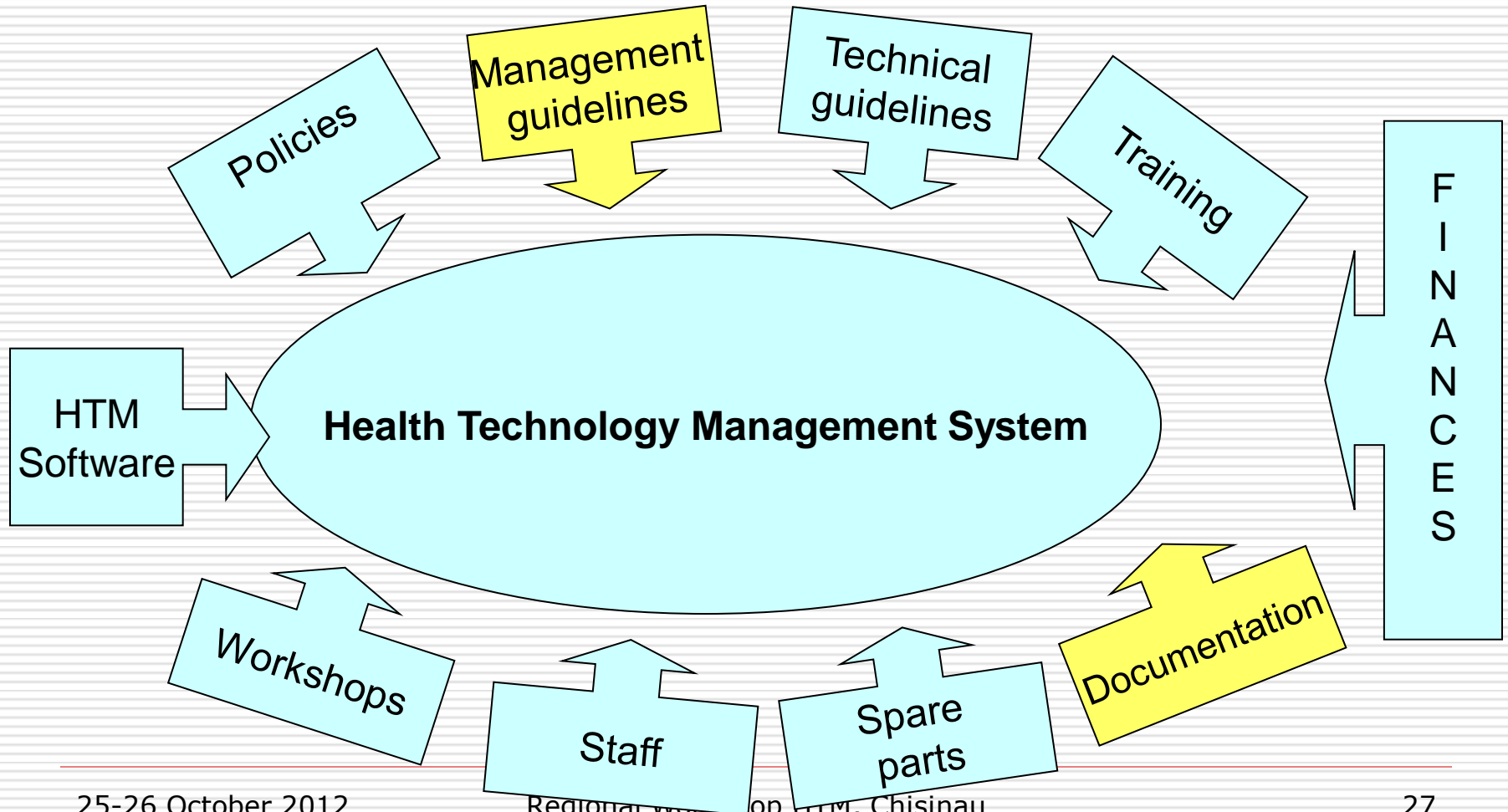


Spital	Valoarea totala a Dispozitivelor
ICSOSMC	21238689
IMSP CNŞPM Urgență	43034646
IMSP SCM Bălți	1881258
IMSP Spitalul Raional Cahul	451466
IMSP Spitalul clinic municipal nr. 1	9970295

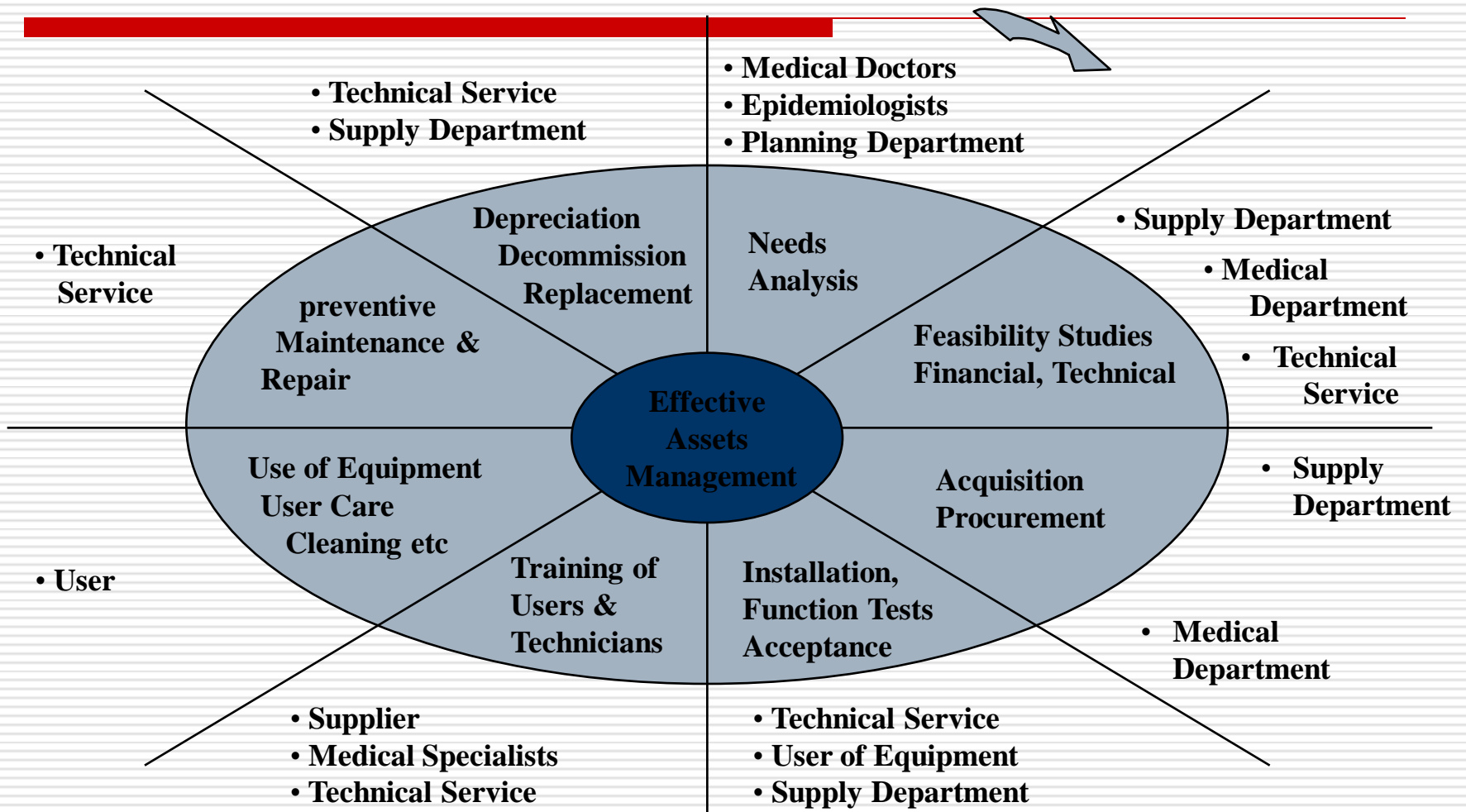
**Agenda**

Data Expirării Garanției			
Numele generic a dispozitivelor	Furnizorul	Department	Localizarea
<b>aprilie 1, 2011</b>			
<a href="#">Fetal Puls Detector</a>	SRL SOGNO	Obstetricală nr.2	IMSP Spitalul clinic municipal nr. 1
<a href="#">Fetal Puls Detector</a>	SRL SOGNO	Obstetricală nr.1	IMSP Spitalul clinic municipal nr. 1
<a href="#">Fetal Puls Detector</a>	SRL SOGNO	Obstetricală nr.1	IMSP Spitalul clinic municipal nr. 1
<b>aprilie 20, 2011</b>			
<a href="#">Defibrilator</a>	Nespecificat	Department necunoscut	IMSP SCM Bălți
<b>mai 1, 2011</b>			
<a href="#">Incubatoare pentru sugari</a>	Grant Elvetia	Reanimare nou/născuților nr.1	IMSP Spitalul clinic municipal nr. 1
<a href="#">Incubatoare pentru sugari</a>	Grant Elvetia	Reanimare nou/născuților nr.1	IMSP Spitalul clinic municipal nr. 1

# System Components



# Technology Management Cycle



# Management Procedures and Documentation

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- Development of a set of documents on the Medical Technology Management
  - Medical device usage logbook
  - Maintenance request, jobcard
  - Medical device history file
  - Maintenance report
  - Annual maintenance planning
  - Annual plan for required consumables
  - Maintenance protocols specific to the medical unit

## Fisa de deservire

Numărul lucrării:

Este completata de utilizator:

IMPS ICSDOSM si C	Sectia
Nume utilizator:	Nr. de telefon:
Dispozitiv:	Număr de inventariere:
Descrierea defecțiunii:	
Data ,ora cererii:	

Recepționat de către:	Inginer responsabil:
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 Este completata de inginer

Descrierea defecțiunii		
Cauza defecțiunii:		
Vechi si stricat	Greșeala mecanica	Greșeala utilizator
Greșeala electrica	Greșeala electronica	Abuz
Sursa slaba de electricitate	Sursa de apa/gaz slaba	Instalare de calitate proasta

# Maintenance Report

Numele spitalului: ICSDOSM si C

## Raport de mentenanța

Spitalul:	Inginer/tehnici respons.:
Perioada de raportare:	Data:                      Semnătura:

Raport de activitate pentru dispozitivelor  
medicale

Analiza activității

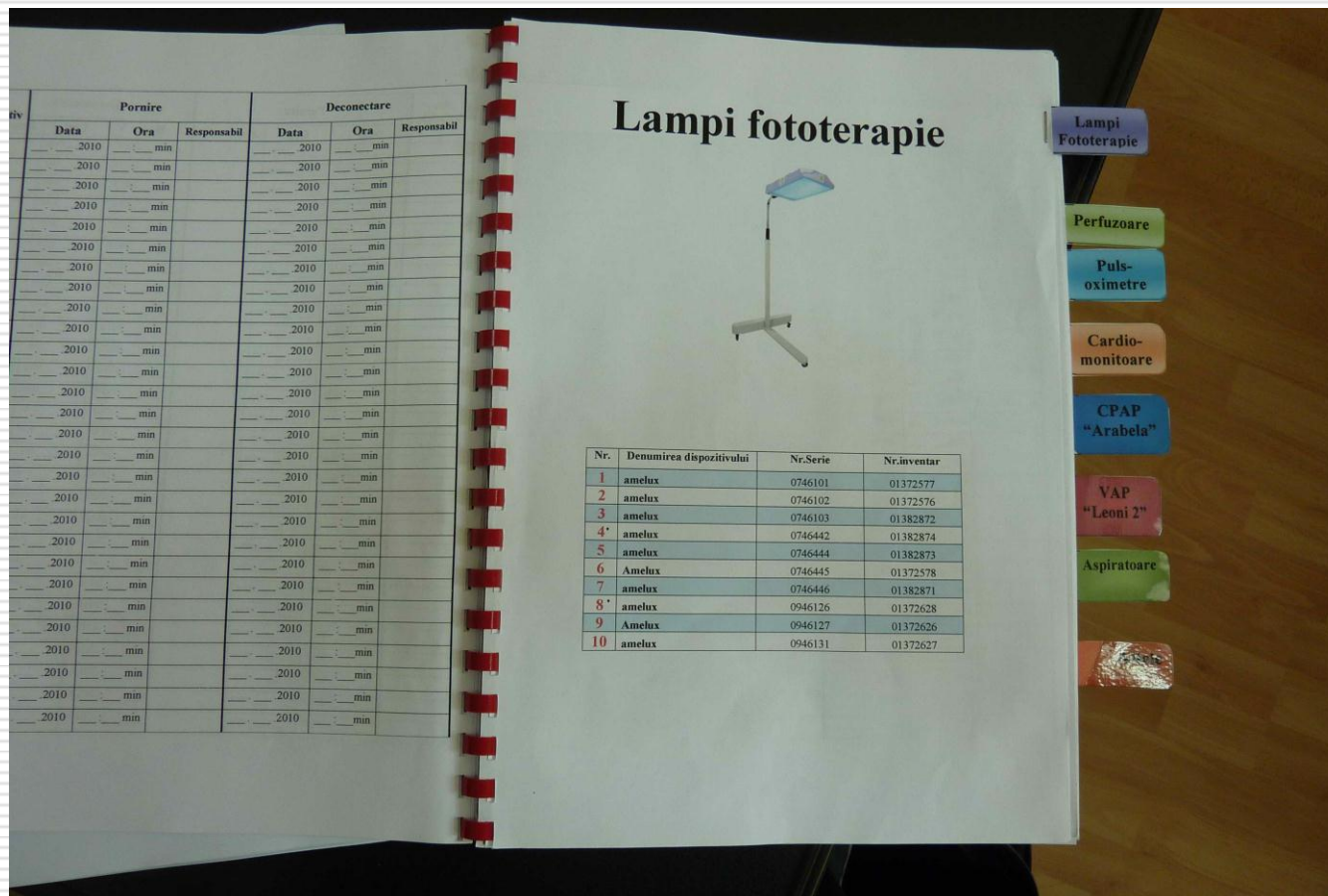
	Număr	Timp
Lucrări de reparare		
Nr. de MPP		
Alte, ex instalații		
Servicii ale companiilor		

	Număr	Timp
Mecanica		
Electromecanica		
Electronica		
Total		

Analiza timpului lucrului efectuat in perioada (timpul echipamentului nedisponibil pentru  
utilizare)

	> 1 ora	1<x<5	5< x < 1 zi	1zi<x<sap	Sapt<x<oluna	> o luna
Lucrări de reparare (Nr.)						
MPP						
Alte, ex. instalări						
Total lucrări						
Cereri către companii						

# Register for use of equipment



# Management Procedures and Documentation

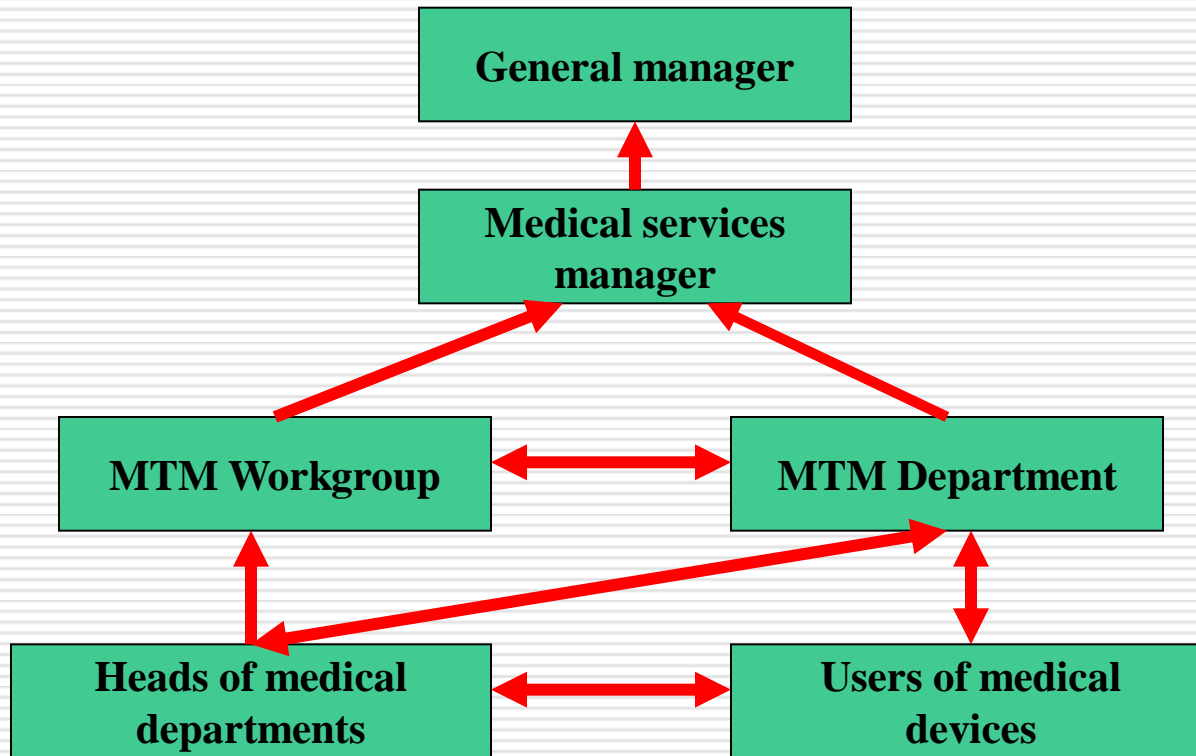
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- Development of the concept of organization and structure functioning of the HTM
- Developing the concept of management of consumable items and spare parts
- Creation of an record register register of technical and user manuals and technical development of digital library
- Developing a glossary for the Medical Technology Management



# HTM Organizing Structure

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# HTM Evaluation, order 661

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- Total medical departments - 198
- Total devices in departments - 3669.

Implementation of documentation system:

Call Log - 114 departments (58%)

Maintenance File/equipment - 2302 (63%)

Electronic Register - 3360(91,5%)

Medical Device Usage Log - 1252 (34,5%)

# The evaluation results

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- ❑ **Questioned persons:** chiefs of section-25, doctors-23, superior medical assistants-23, medical assistants -81.
- ❑ **The necessity to implement HTM:** very necessary – 57%, Necessary – 35%, not necessary – 3%, Can not appreciate – 5%
- ❑ **The necessity to implement the Journal of Guard:** very necessary – 64%, Necessary – 35%, not necessary – 1%, can not appreciate – 0%
- ❑ **The necessity to implement the quickly user guide:** very necessary – 67%, necessary – 30%, not necessary – 0%, can not appreciate – 3%
- ❑ **The necessity to implement the maintenance sheet of medical devices:** very necessary – 33%, necessary – 44%, not necessary – 0%, can not appreciate – 23%

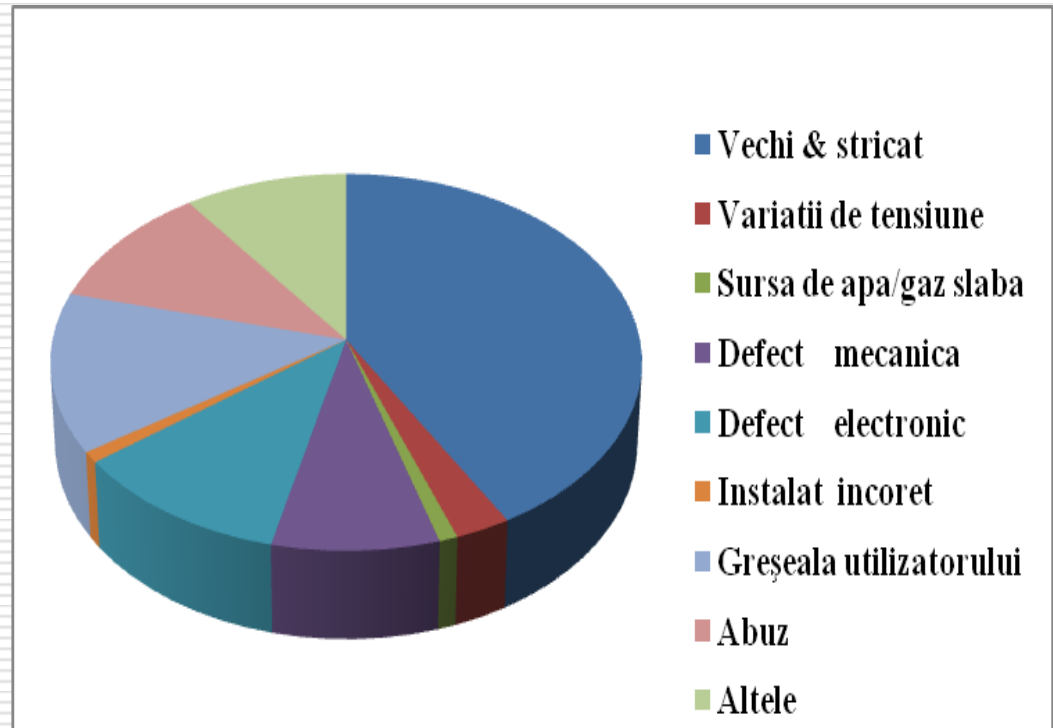
# The evaluation results

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- ❑ **The changes that occurred after implementation the HTM:** very good – 48%, good – 42%, satisfactory – 7%, Not changed – 3%
- ❑ **The need training for users:** very necessary – 55%, Necessary – 44%, Not necessary – 0%, Can not appreciate – 1%
- ❑ **The role of bioengineers in the work of the your institution:** very big – 91%, big – 9%, small – 0%, Can not appreciate – 0%
- ❑ **The comparing the quality of local medical device to foreign firms:** better – 88%, at the same level – 12%, unsatisfactory – 0%
- ❑ **The need of department (workshop) servicing of medical devices in your institution:** very necessary – 87%, Necessary – 13%, not necessary – 0%, Can not appreciate – 0%

# Analysis of the Failure Causes

	Number
Old & damaged	46
Voltage variations	3
Poor source of water/gas	1
Mechanical defect	9
Electronic defect	12
Incorrectly installed	1
User mistake	15
Abuse	12
Other	11
<b>Total</b>	<b>110</b>



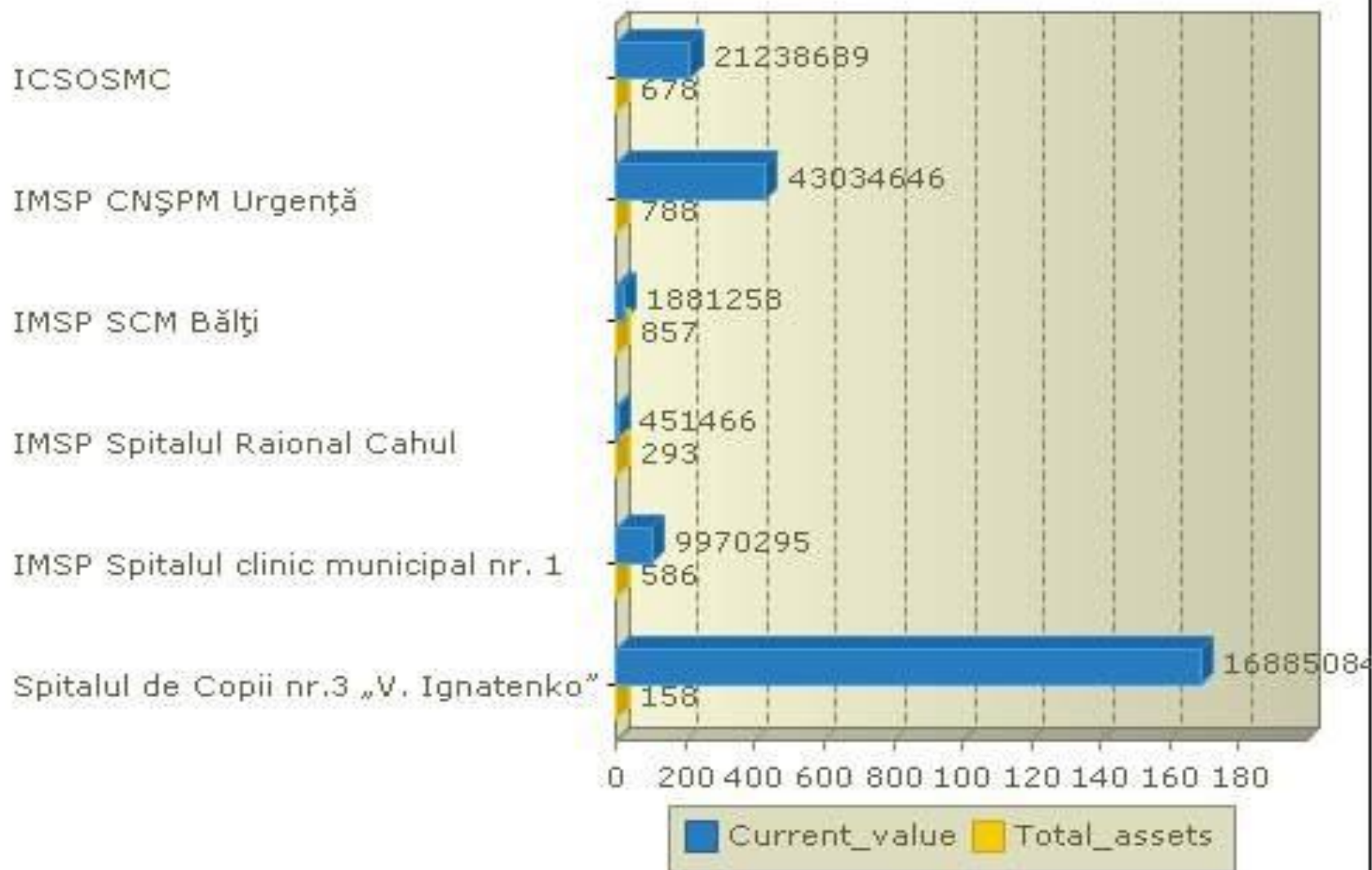
# Repair time per case

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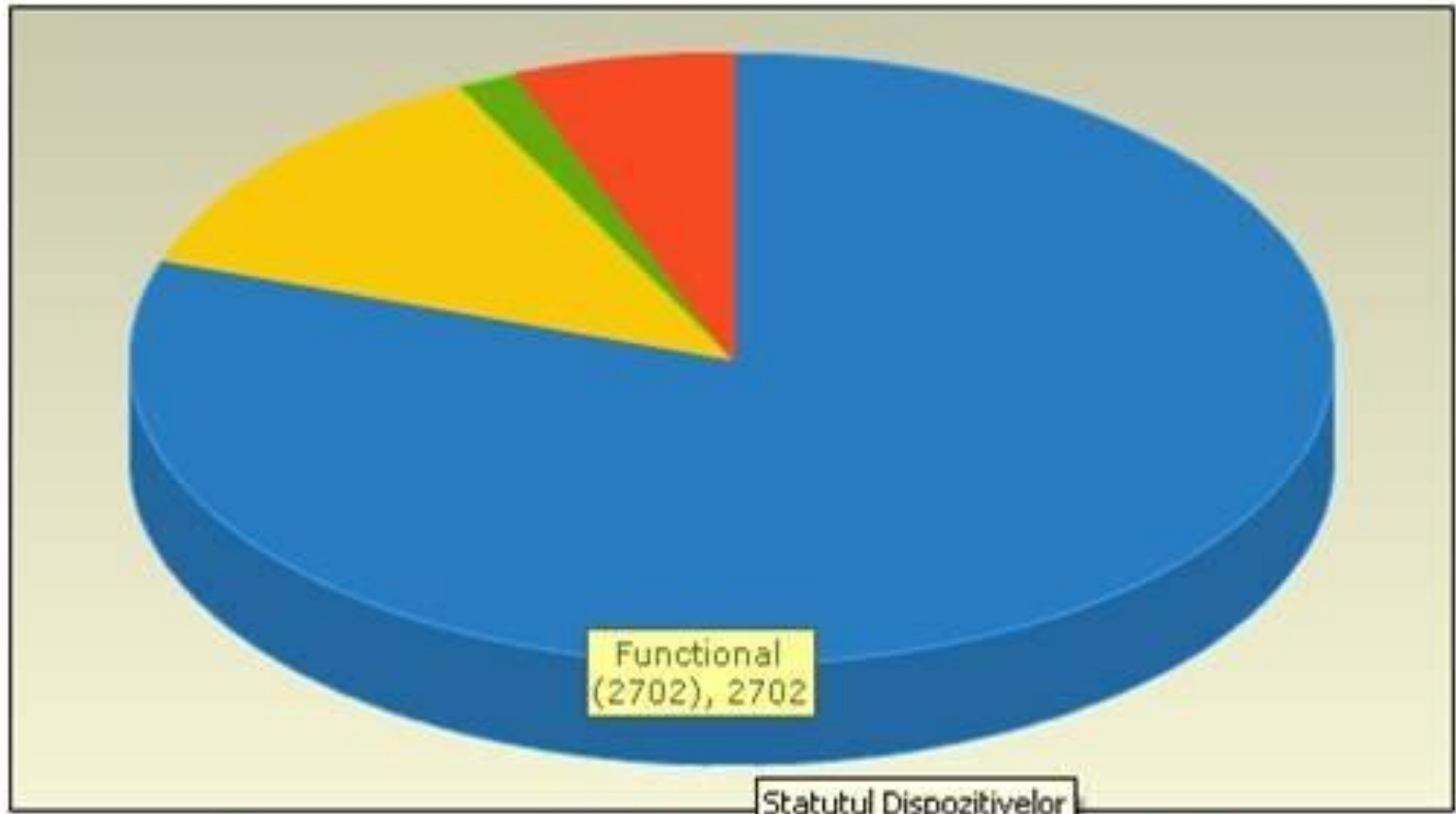
	< 1 hr	1 hr to 5 hrs	5 hrs to 1 day	1day to 1week	1 week to 1 month	> one month
Total repair activities	67	46	4	1	-	-
PM done	4	17	-	-	-	-
other	-	5	1	-	-	-
<b>Total activities</b>	<b>71</b>	<b>68</b>	<b>5</b>	<b>1</b>	-	-

# Financial Status

## Total device value



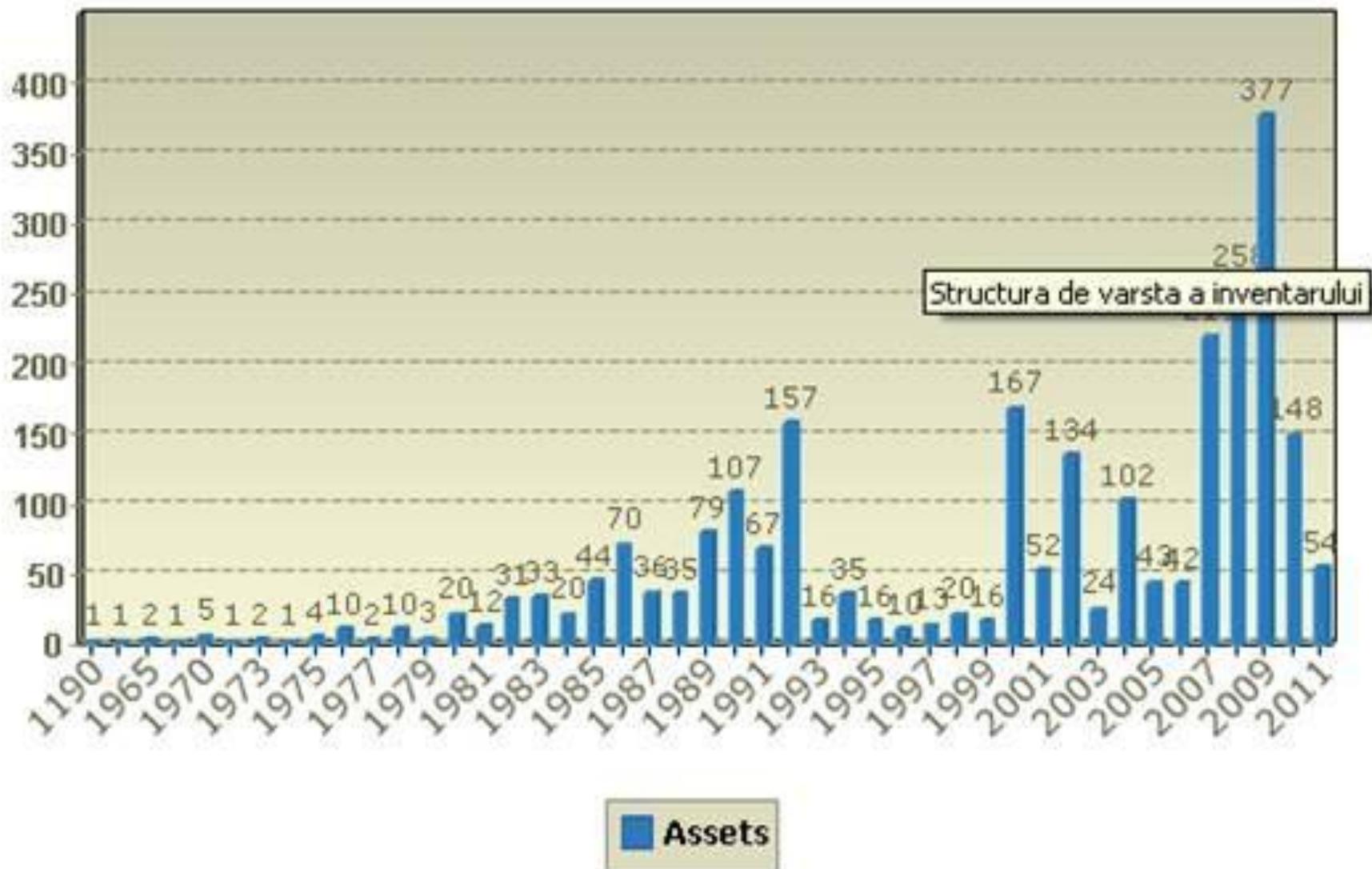
# Device Status



■ Functional (2702) ■ Utilizat, necesita reparat (408) ■ Necesita reparatie major (64) ■ Nefunctional (186)



# Inventory Age Structure



# Expected Results

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- Medical facilities can provide a complete service not impaired by non-functional technologies
  
- The equipment is used correctly, maintained properly and safe to use
  
- adequate and timely information to hospital management on
  - Functional status of the equipment
  - Performance of maintenance services
  - Practice and skills of staff involved in use of equipment.

# Expected Results

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- ❑ Reduce costs of maintaining medical devices, through adequate and timely inhouse services
- ❑ Quality improvement through written procedures and good practice for medical staff
- ❑ Optimal use of expensive medical devices through qualified and trained staff reducing user errors and thus maintenance cost.

# Recommendations

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- Development of appropriate policies adequate to the EU rules regarding deployment of management activities in medical technologies domain, standards in the field.
- Inclusion of the biomedical engineers and technicians in the staff list of medical professions of the MOH
- Promoting the profession of biomedical engineering in the national health system

# Recommendations, cont.

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- Creating in Hospitals Medical Technology Departments in charge of all matters relating to management and administration of health technologies.  
(At the first stage, on the level of republican institutions, municipal and district (groups of districts)).
- Define the required number of bioengineering and clinical engineer posts.  
(Recommandation:  
Europe: 1 engineering staff to 4-5 medical staff  
Molodva: 1 engineering staff to 6-8 medical staff).

# Recommendations, cont.

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- ❑ strengthen the inhouse maintenance workshops to provide rapid services and reduce maintenance cost
- ❑ Enhance the electronic inventory system to a complete information system “Management and administration of Medical Technologies“.
- ❑ Upgrade the Pilot-Center "Medical Technology Management" from the Mother and Child Healthcare Institute to a reference workshop for testing of medical technologies, verification and maintenance of medical devices and continuous training.

# Feasibility Study - Financial

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**“Iceberg”- Effect in  
Medical Technology**

**Purchase cost**

The diagram illustrates the 'iceberg' effect in medical technology. A blue mountain-like shape represents the total cost, with the portion above a wavy black line (the water surface) labeled 'Purchase cost'. The much larger portion of the mountain is submerged in a light blue area representing hidden costs, which are not visible to the consumer.

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**The need for technology management services should deserve the same recognition as the need for the pharmaceutical services in a health care facility..**

World Bank  
An Overview of Medical Device Policy and Regulation,  
February 2007



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Thank you for your attention