CLINICAL ENGINEERING

BIOMEDICAL TECHNOLOGY MANAGEMENT

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The Universe of Medical Devices

- More than 500 000 products world-wide classified as Medical Devices
- Medical Devices grouped in more than 15 000 groups – UMDNS, GMDN

- Examples:
  - electric heating pads, wheelchairs, hearing aids
  - breast implants, heart valves, pacemakers
  - x-ray machines, cardiac monitors, ultrasonic machines
  - orthopedic replacement parts, oxygen regulators, laser surgical instruments

Need for Management…

- Wide range of **diverse** and **complex** Medical Devices
- **Problems** arise from their use, concerning reliability and safety, as well as, increased costs of delivering Health Care services

- **Examples:**
  - mechanical failure, electrical failure
  - faulty design, poor manufacturing quality
  - compromised sterility of body implanted materials
  - improper maintenance, user operational error
  - electromagnetic interference among devices

…Need for Management

- Therefore Health Care facilities should ensure that equipment perform as intended by the manufacturer

- and consequently arises the need for establishing of an appropriate program for management of medical technology

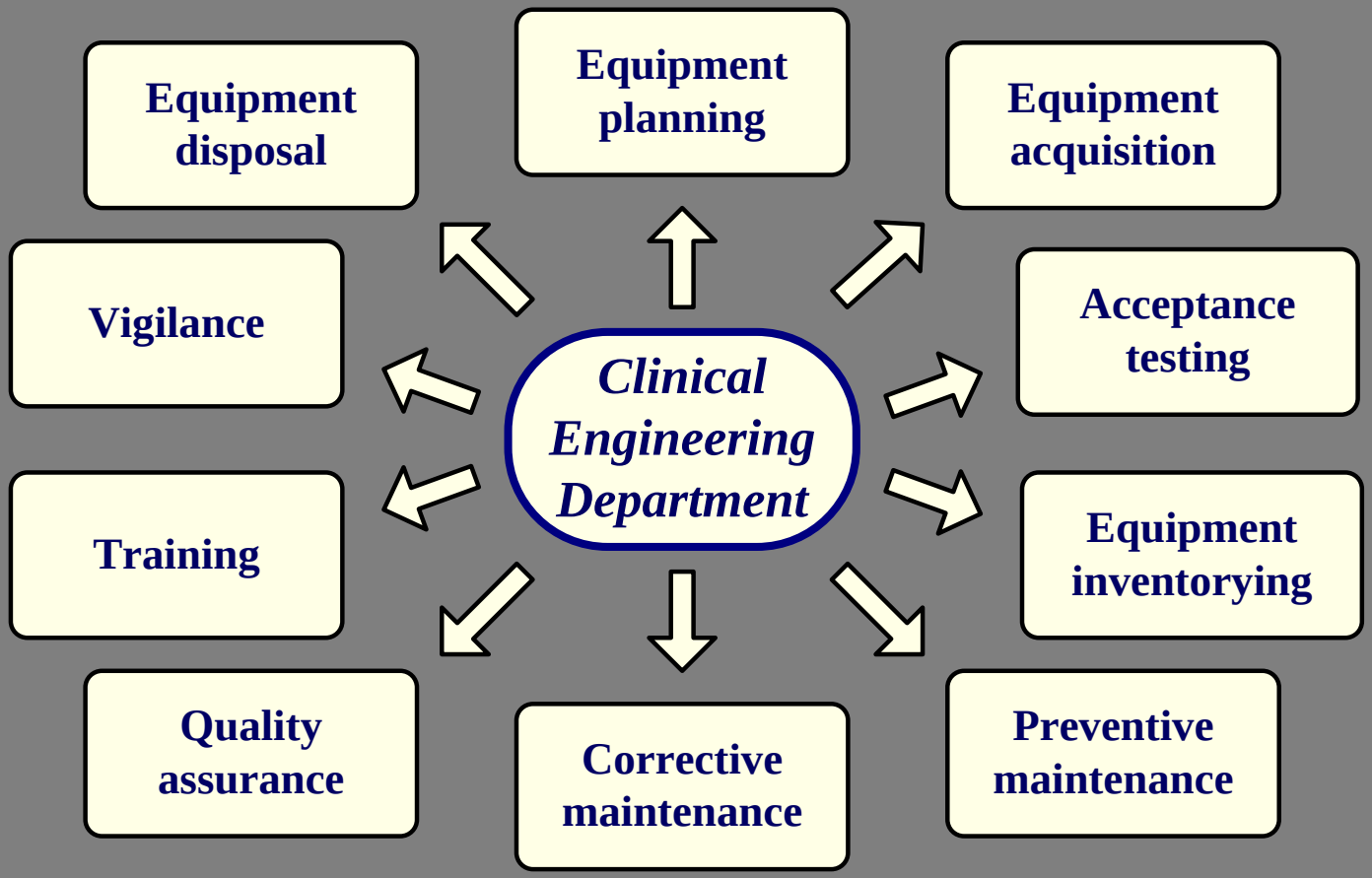
Establishment of CED

- Creation and establishment of
  Clinical Engineering Department (CED)

- Main purpose of organizing a CED:
  - maximum benefit from medical technology
  - assure safe, effective, and cost-efficient use of medical equipment

CED activities

- CED services cover all aspects involved in the life-cycle of medical devices



Need for MEMS

- Management of **extensive** volumes of information and its conversion to **meaningful** values for statistical analysis

- CEDs turn towards **computerization** as the only viable solution
- Use of **software tools**, specifically designed for management of medical technology, used to collect, store, and analyze data
- They are known as **Medical Equipment Management Systems (MEMS)**

PRAXIS – Management of Biomedical Technology

- Biomedical Technology Unit, University of Patras
- Institute of Biomedical Technology - INBIT

- 1st generation – BITMANS 1990 – 1995
- 2nd generation – CLEMANTIS 1995 – 2000
- 3rd generation – PRAXIS 2000 – today
  - mini PRAXIS
  - midi PRAXIS
- 4th generation – WEB PRAXIS 2006 – today

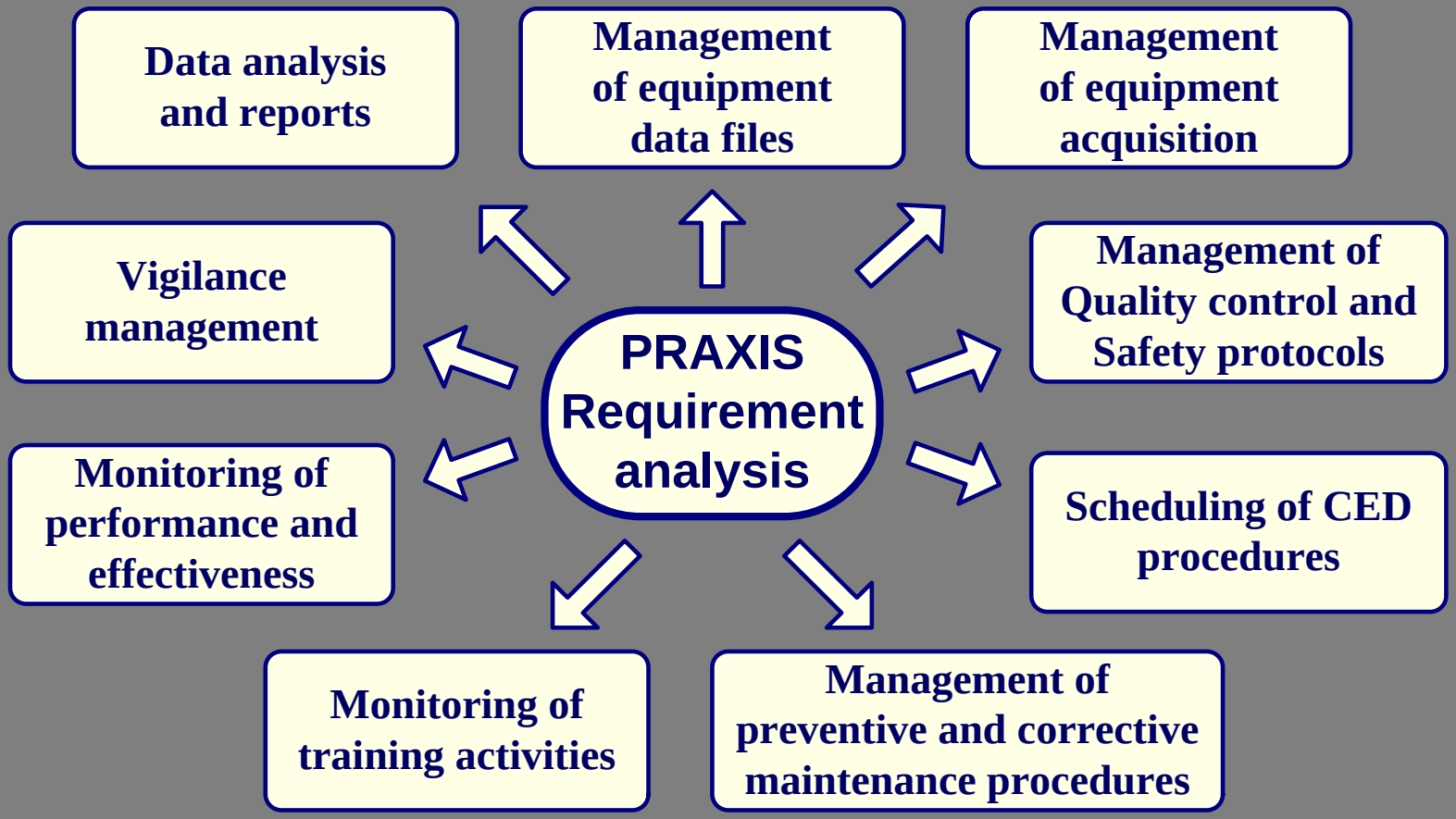
PRAXIS – Development

3 phases

- Requirement analysis
- Design
- Implementation

PRAXIS

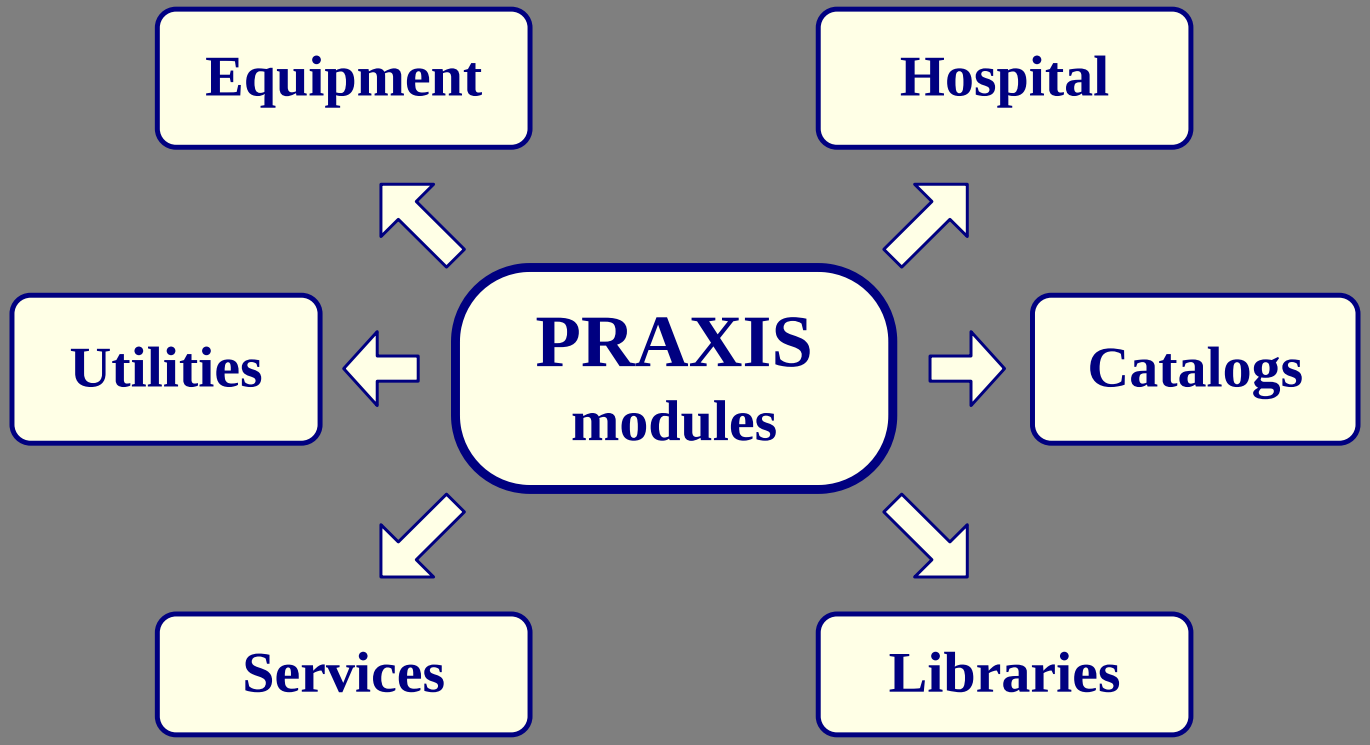
- PRAXIS cover basic equipment control, as well as, all advanced technology management activities of CED.



PRAXIS

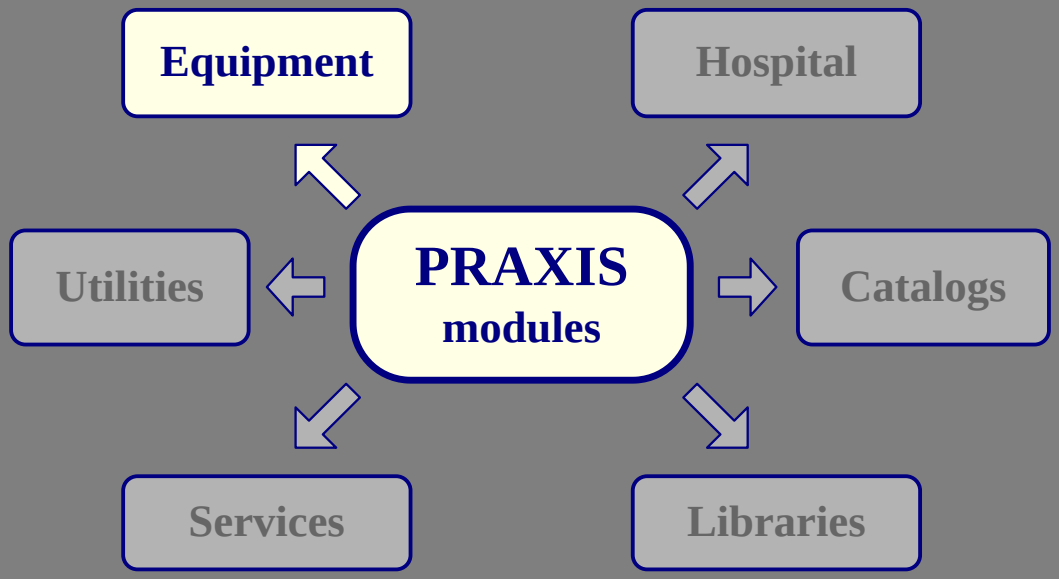
- support overall management of medical equipment in healthcare

6 modules, 44 main forms, 75 main tables



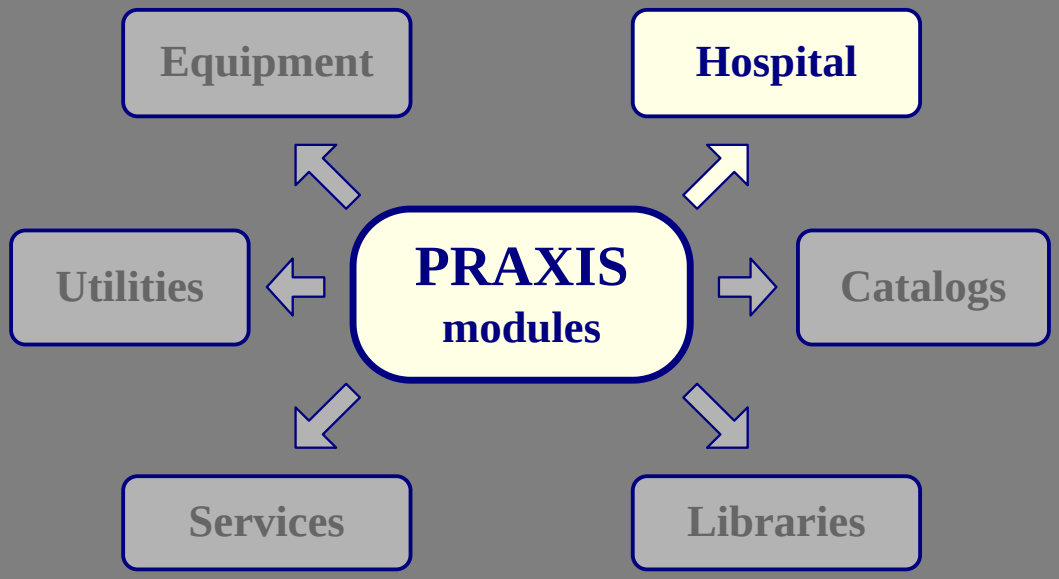
PRAXIS – Equipment

- Equipment inventory
- Device groups
- Device types



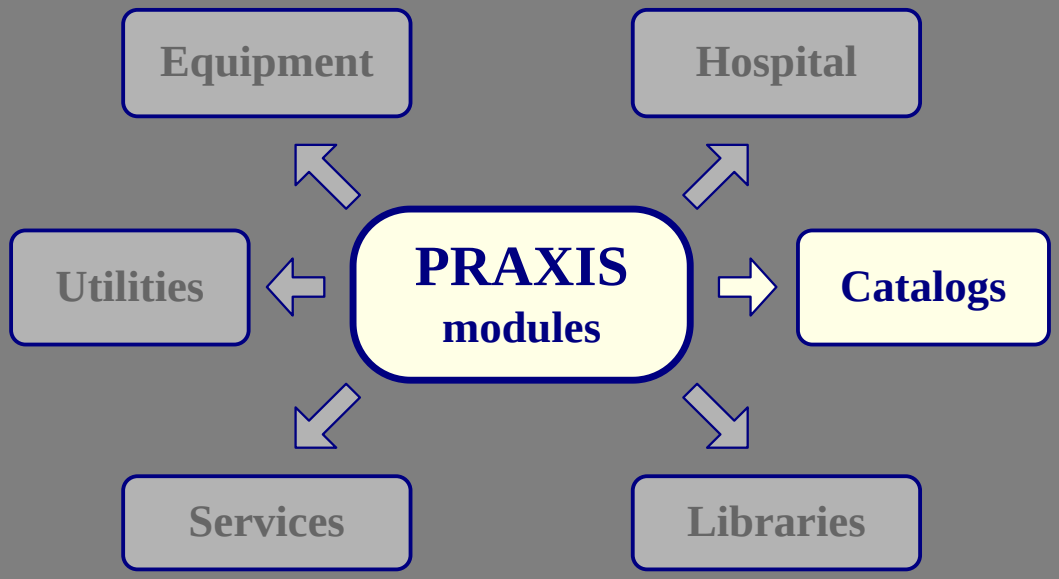
PRAXIS – Hospital

- Hospital profile
- Departments, Places
- Personnel
- System users, user groups



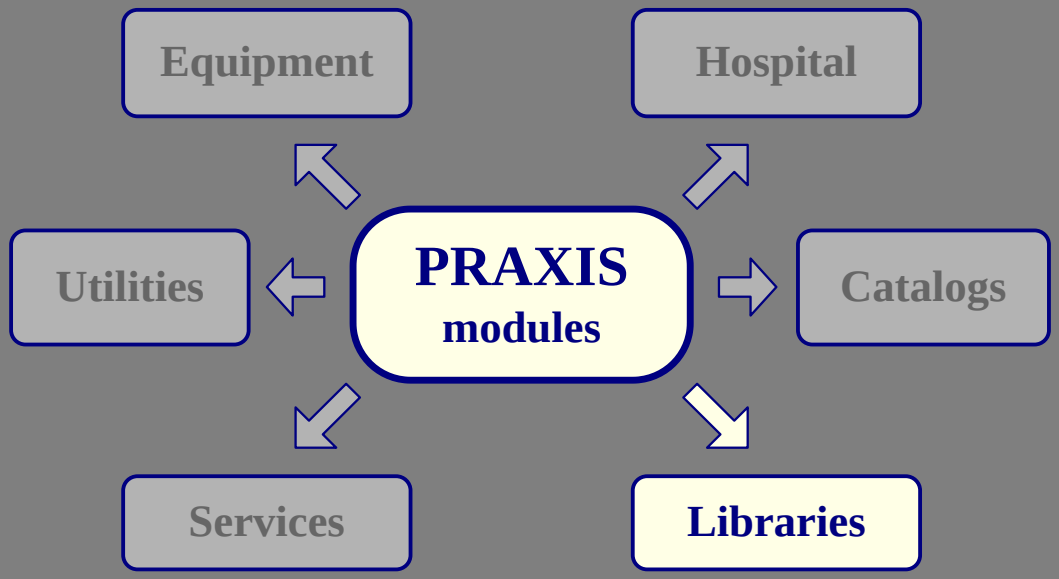
PRAXIS – Catalogs

- Manufacturers, Suppliers, Organizations
- Failure types
- PM cancellation and modification causes
- Repair suspension causes



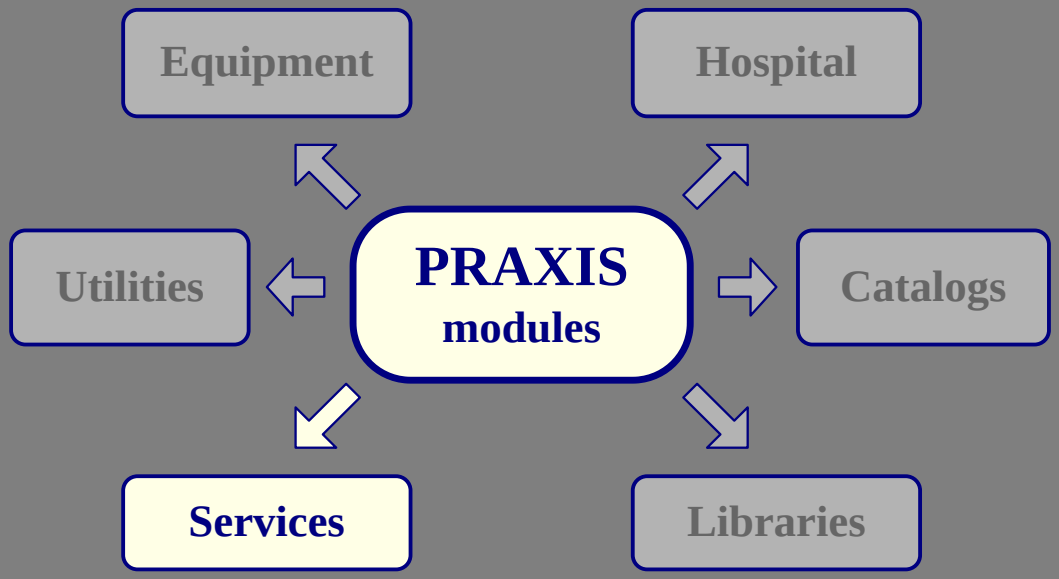
PRAXIS – Libraries

- Specifications
- Protocol measurements
- Inspection protocols
- Books, manuals



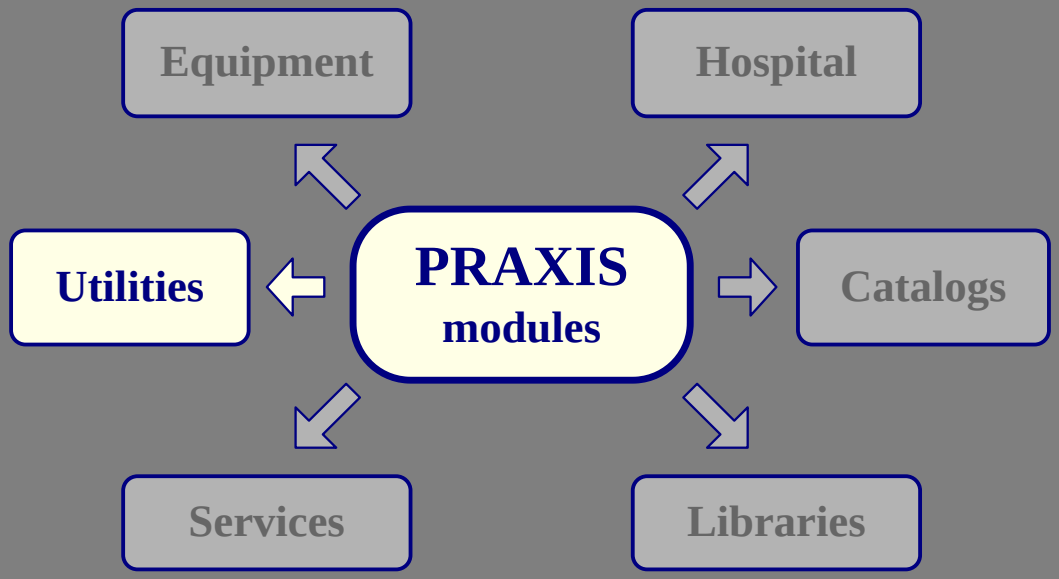
PRAXIS – Services

- Acquisition of medical equipment
- Periodic inspections and Repairs section
- Training
- Vigilance



PRAXIS – Utilities

- Calendar – Scheduler
- Reports, Quality indicators
- Export data
- Navigation tree, Toolkit



http://www.web-praxis.gr/demo//index.php?controller=dashboard&lang=en

QUALITY INDICATORS

General Discussion

- Support comprehensive medical equipment inventory of the Healthcare facility
- Assist in decision making concerning replacement of old technology and acquisition of new medical equipment
- Schedule and follow up of preventive and corrective maintenance activities
- Evaluate CED and equipment performance by means of quality indicators
- Provide vigilance information on safety related issues, such as potential alerts and adverse incidents

Perspectives

- Continuous improvement of the services provided based on evaluation feedback
- Implementation of new applications, addressing new management tasks

Quality Indicators - introduction

- Clinical Engineering Departments in their practice use quality indicators, in order to evaluate their performance and improve the management of medical equipment.

- Since resources are limited and not everything can be measured, certain selection criteria must be implemented when establishing a quality indicator.

Quality Indicators - introduction

- An indicator must be an **objective, quantitative measurement** of an outcome or process that relates to performance quality

- It must be objective in the sense that the **same measurement** can be obtained by **different observers**

Quality Indicators - classification

- **Monitoring internal operations – provide an objective, accurate measurement of the different services provided in the CED**
- **Monitoring process for quality improvement – an additional step is required. Expectations (threshold values) must be quantified**
- **Indicators for external comparisons – benchmarks. Great care must be taken when comparing services provided by CED in different hospitals, otherwise, the results may be misleading or misinterpreted.**

Quality Indicators - Categories

- Inventory and equipment acquisition
- Preventive maintenance
- Corrective maintenance
- Training
- Productivity
- Effectiveness and efficiency
- Cost–effectiveness

Inventory, Equipment acquisition

- total equipment acquisition cost
- equipment service cost
- service cost to acquisition cost ratio
- percent of new purchased devices
- percent of disposed (withdrawn) devices
- percent increase of inventory

- number of new equipment inspections
- man-hours spent on acceptance testing

Preventive maintenance

- PM compliance indicator - ratio between the number of MD inspected, according to the schedule and the total number of MD
- number of the PM inspections completed is monitored for each item and individual
- PM costs
- number of medical devices failed during PM
- Percentage ratio of the PM inspections successfully completed for given time
- Reasons leading to not accomplishing PM inspection at a time or at all

Corrective maintenance

- the number of work orders for given time
- downtime of a MD
- repair turnaround time of a MD
- average time per repair for a specific equipment type or model
- number of repeated repairs
- response time of the CED
- response time of the outside vendor
- Repair costs

Training

- rate of equipment out of service due to operation error
- repair calls due to user or operator error

Productivity

- Productivity measurement is related to all facets of the CED management responsibilities
- One way to be measured is the percentage ratio of overtime hours over available hours
- repaired turnaround time over the total downtime of the equipment

- man-hours spent on PM activities
- man-hours spent on Repair activities

Effectiveness and Efficiency

- Effectiveness is related to the proper maintenance and availability of the medical equipment for use. It is influenced by all the services provided by CED
- Efficiency is related to the ability of the equipment to function properly without wasting of time and resources. The focus is on money related issues and profit obtained from the equipment

- Difficult to be evaluated - no direct way to measure them

Cost - effectiveness

- ratio of the total cost for PM + CM to the total acquisition cost of the medical equipment, can be used for external comparison among CEDs in different hospitals
- labor cost per hour
- labor cost per repair
- equipment maintenance cost per bed supported

- strict definitions must be applied, when used for inter - departmental comparisons.

Quality Indicators - examples

Indicator

- **Equipment age**

Description

- **The age of a device from its manufacturing to date**

Limits

- **up to 15 years**

Quality Indicators - examples

Indicator

- **Completed to Scheduled periodic inspections Ratio**

Description

- **The ratio of completed periodic inspections to the scheduled ones for a given time period**

Limits

- **80% - 100%**

Quality Indicators - examples

Indicator

- **Periodic inspections leading to Repairs**

Description

- **The ratio of periodic inspections revealing the non-compliance of a device to the specifications and the standards of operation and safety, to all periodic inspections performed**

Limits

- **4% - 0%**

Quality Indicators - examples

Indicator

- **Number of repeated Repairs**

Description

- **The number of repairs for a specific device in a given period of time**

Limits

- **up to 3 repairs in 3 months**

Quality Indicators - examples

Indicator

- **CED repair Response time**

Description

- **The time between the announcement of a failure and the commencement of the repair by the Clinical Engineering Department**

Limits

- **up to 4 hours**

Quality Indicators - examples

Indicator

- **Third Party repair Response time**

Description

- **The time between the call to a third party and the commencement of the repair**

Limits

- **up to 1 day**

Quality Indicators - examples

Indicator

- **Downtime**

Description

- **The period of time during which the operation of a device is interrupted for a repair to be performed**

Limits

- **up to 1 week**

Quality Indicators - examples

Indicator

- **Periodic Inspections to Acquisition Cost Ratio**

Description

- **The total cost of periodic inspections to the total cost of acquiring a medical device**

Limits

- **1% - 4%**

Quality Indicators - examples

Indicator

- **Maintenance to Acquisition Cost Ratio**

Description

- **The ratio of maintenance cost of a MD to the acquisition cost of that device. Maintenance includes periodic inspections, preventive maintenance and repairs regardless the party performing these jobs**

Limits

- **3% - 7%**