

# Introduction Clinical Engineering & Medical Device Management



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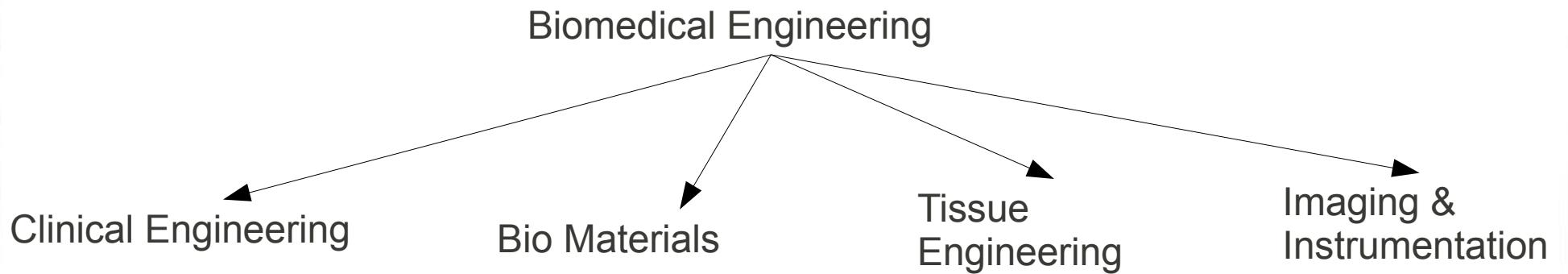
# Developments

- Policies and Standards for the Degree of Bachelor of Science in Electronics and Communications Engineering.
  - Inclusion of Biomedical Engineering Track and Subjects to program page 8
  - Optoelectronics, Bio Instrumentation & Imaging Only
  - <http://www.scribd.com/doc/16849765/Approved-PS-for-ECE>



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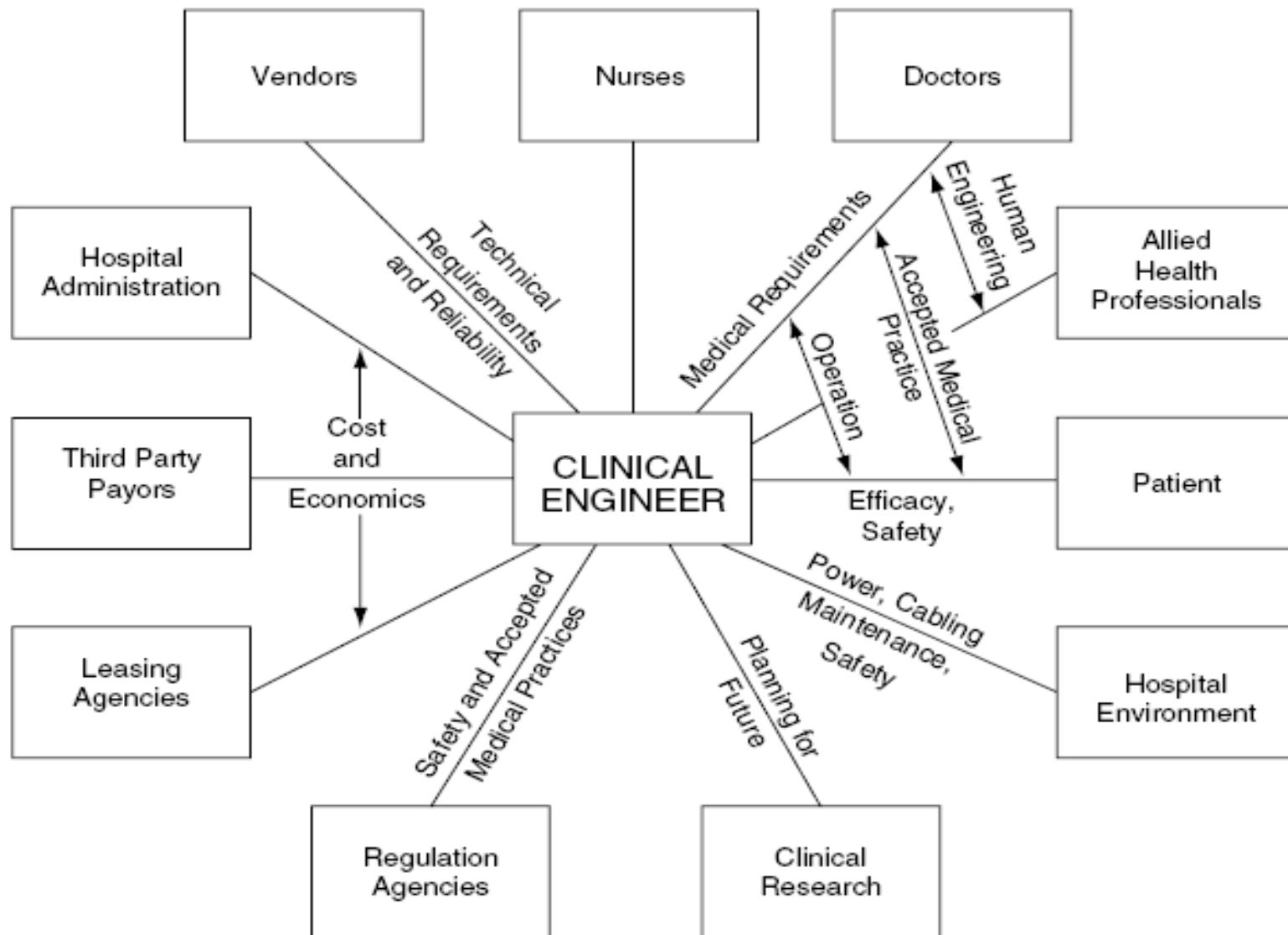
<http://scrapetv.com/News/News%252520Pages/Everyone%252520Else/images-3/emergency-room.jpg>



# Clinical Engineering

- Adapting, maintaining and inspecting medical equipment ensuring safe use and operation
- Education of staff on the use of medical equipment to prevent equipment failure and patient / staff injuries.





Source: Clinical Engineering A View from 7 Countries

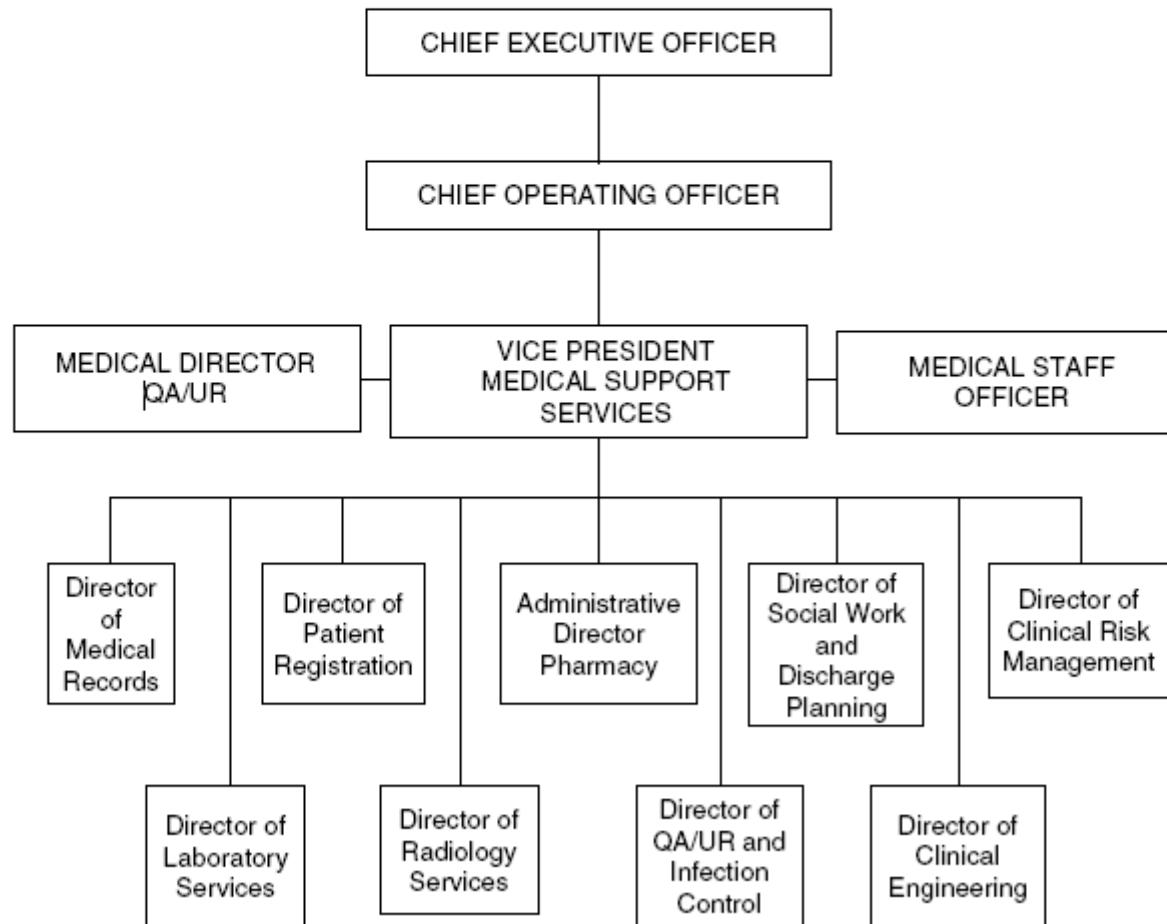
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Source: Clinical Engineering A View from 7 Countries



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# Clinical Engineering Functions

- 1) Technology management
- 2) Risk management
- 3) Technology assessment
- 4) Facilities design and project management
- 5) Quality assurance
- 6) Staff Training



# Clinical Engineering

| OHS                     | Facilities |
|-------------------------|------------|
| Allied Medical Sciences |            |
| Biology                 |            |
| Engineering Sciences    |            |
| Physics                 | Chemistry  |

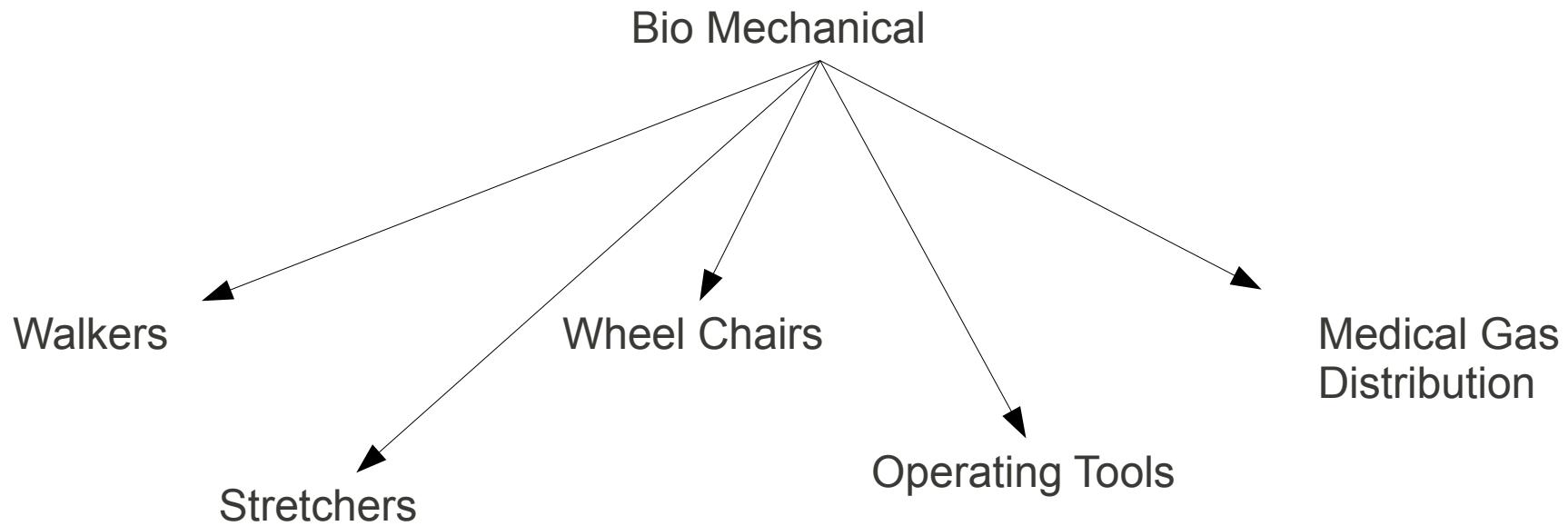


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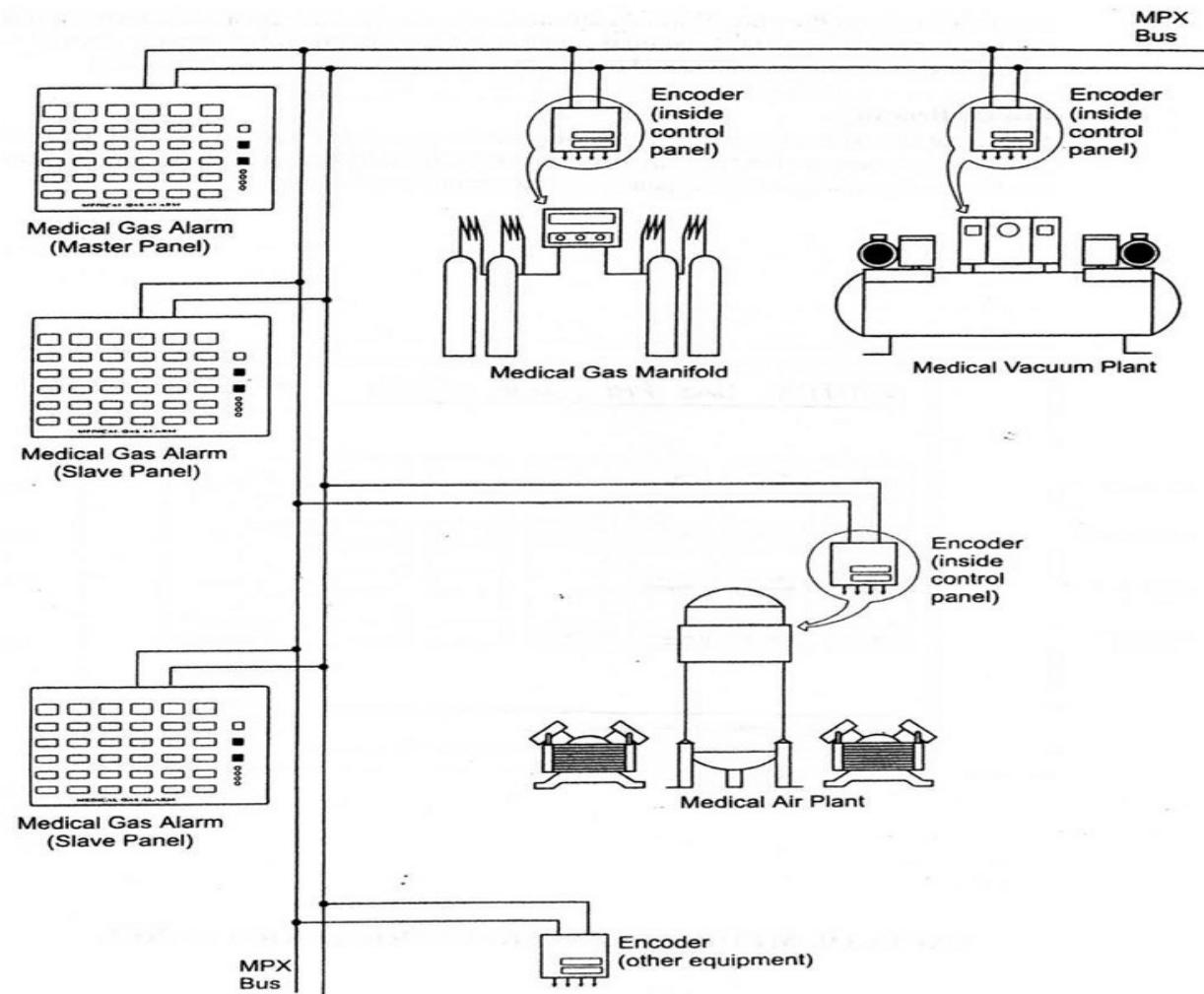
# BioMedical Equipment Categories



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# Medical Gas Distribution



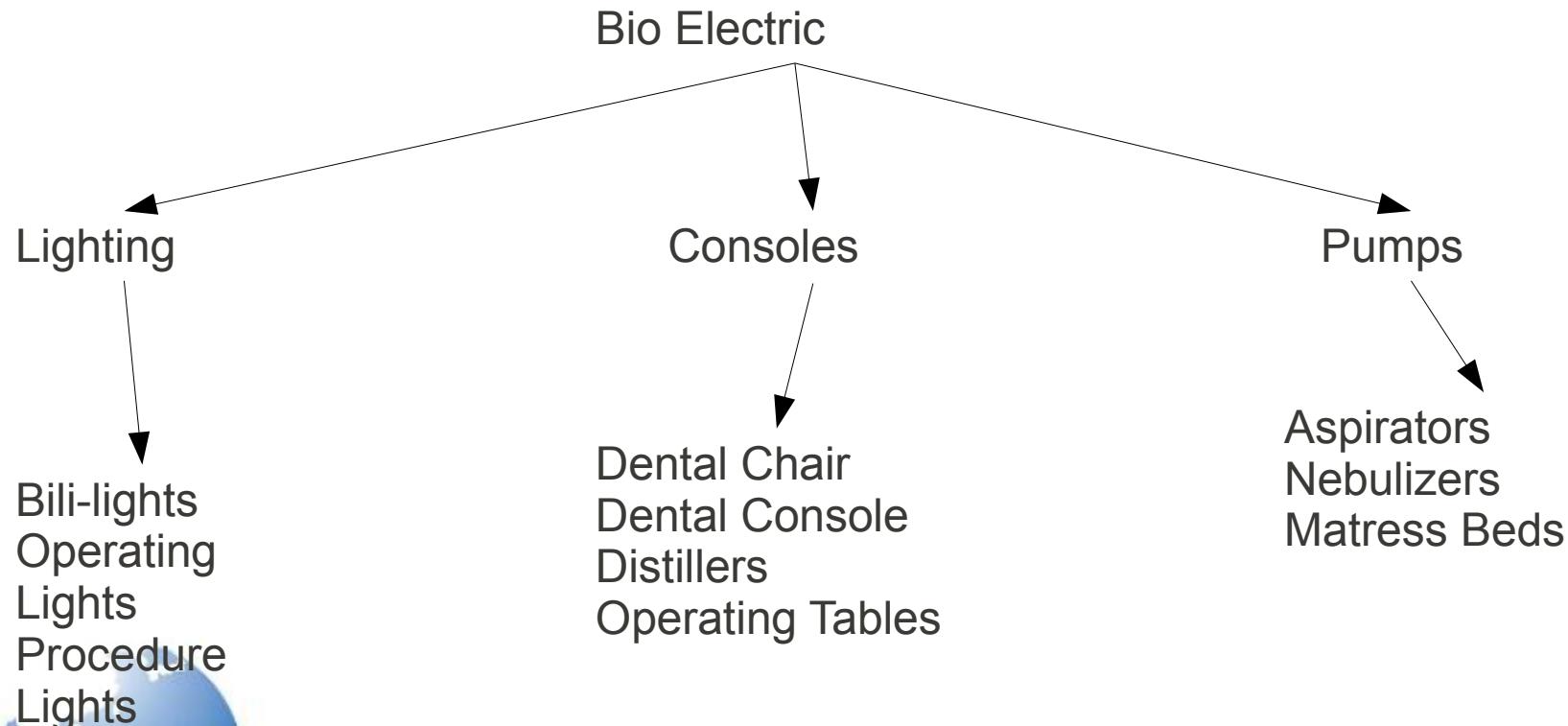
Medical Gas Plant Alarm Panel Wiring Example



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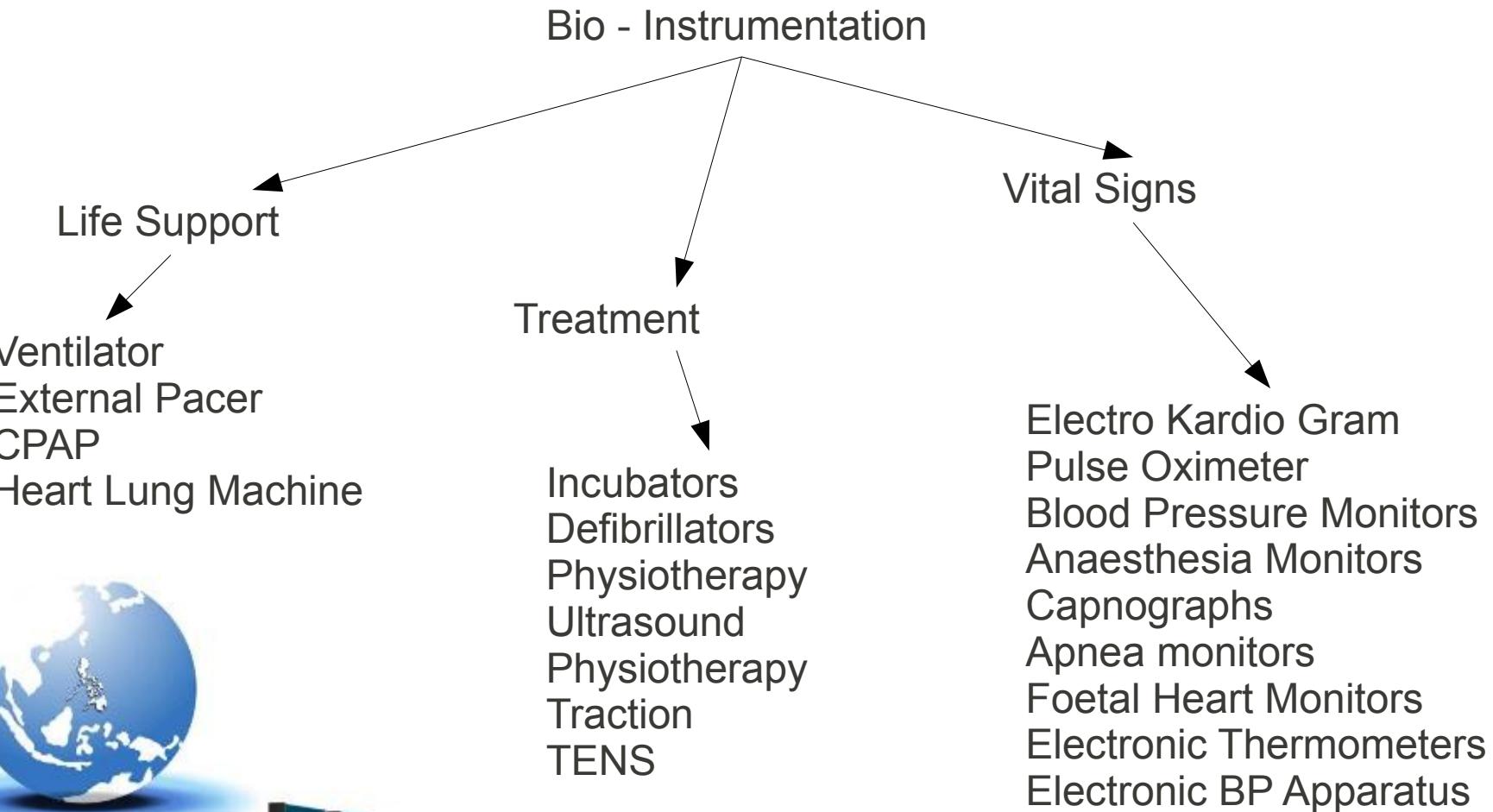
# BioMedical Equipment Categories



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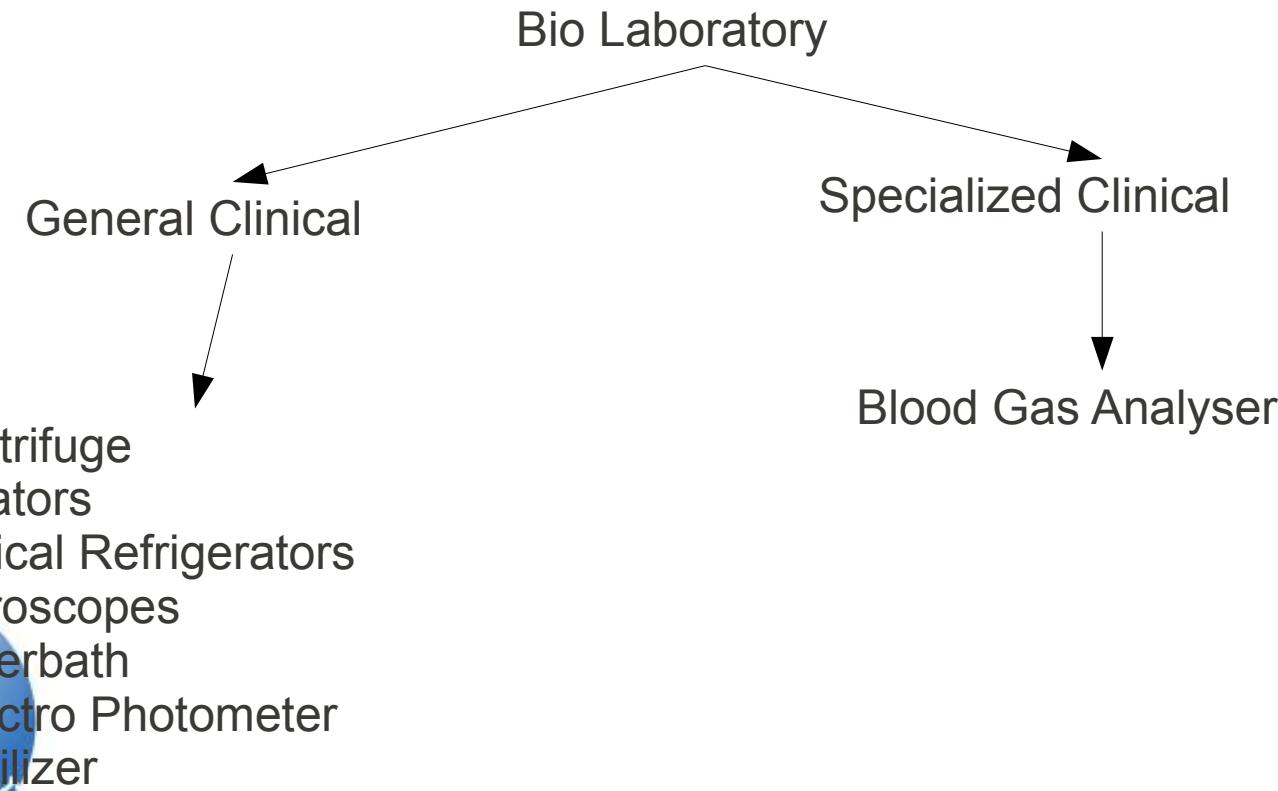
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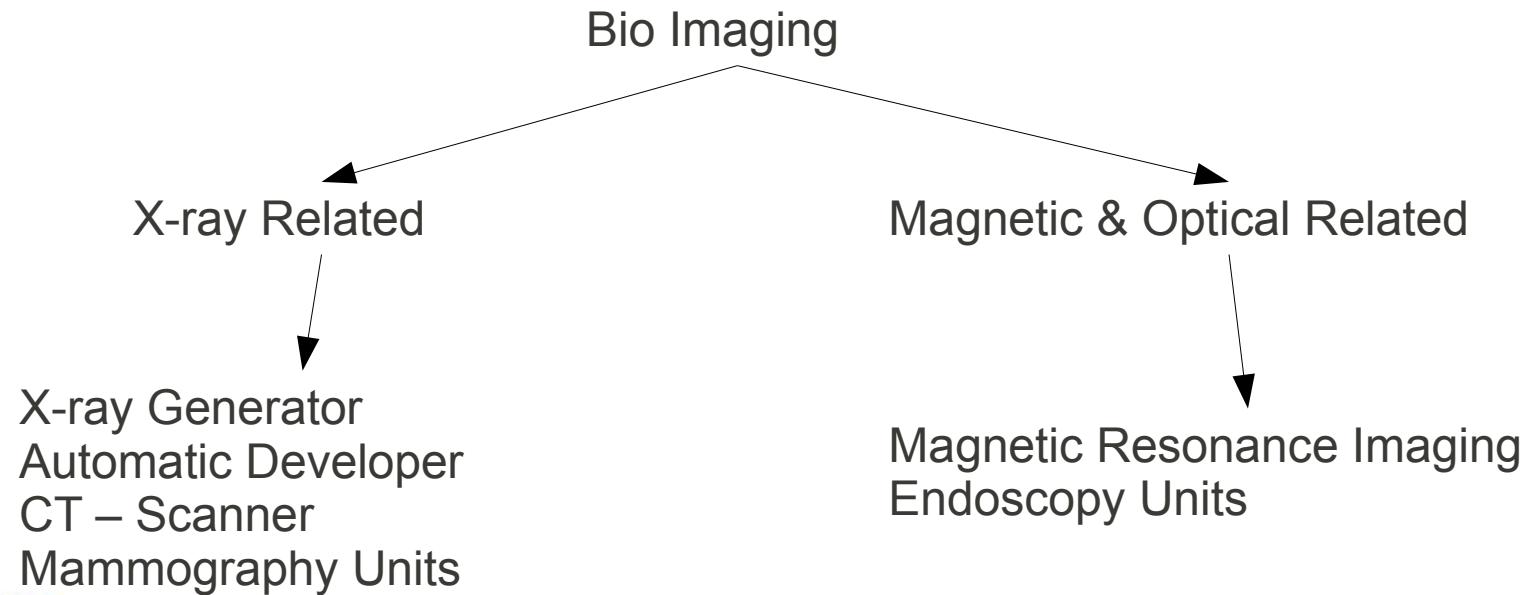


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# BioMedical Equipment Categories



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# Developments

- Department of Health & Philhealth Accreditation
  - Philhealth Bench Book Guidelines
    - Section 6.2.3.x.1
      - Equipment is serviced only by core people trained in the maintenance of that equipment.
      - Registers and records of equipment and related maintenance are kept.
    - Why Phil Health Accreditation?
  - DOH Hospital Accrediation Guidelines
    - Calls for Biomedical Equipment Engineer or Technician for every Secondary & Tertiary Hospitals



# Developments

- Mercury Free Hospitals in PH
  - Elimination of Mercury based measuring instruments in the patient care area.



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# What we learn from university?

## Operation & Design



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The fundamentals will always be the same the case and safety features just improves.



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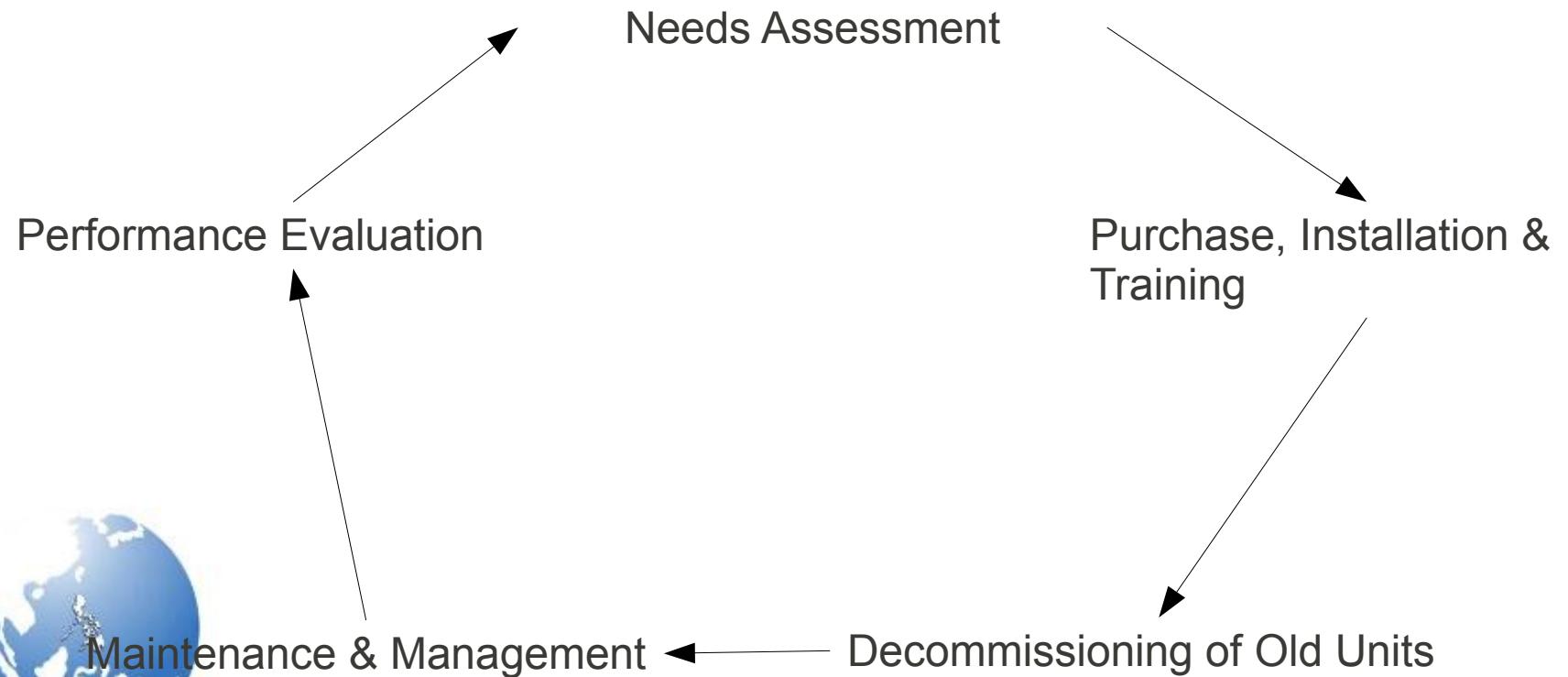
# What is really needed by hospitals?

## Currently Maintenance and Management of Units



# Medical Equipment Management

## AS/NZS 3551



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# Needs Assessment

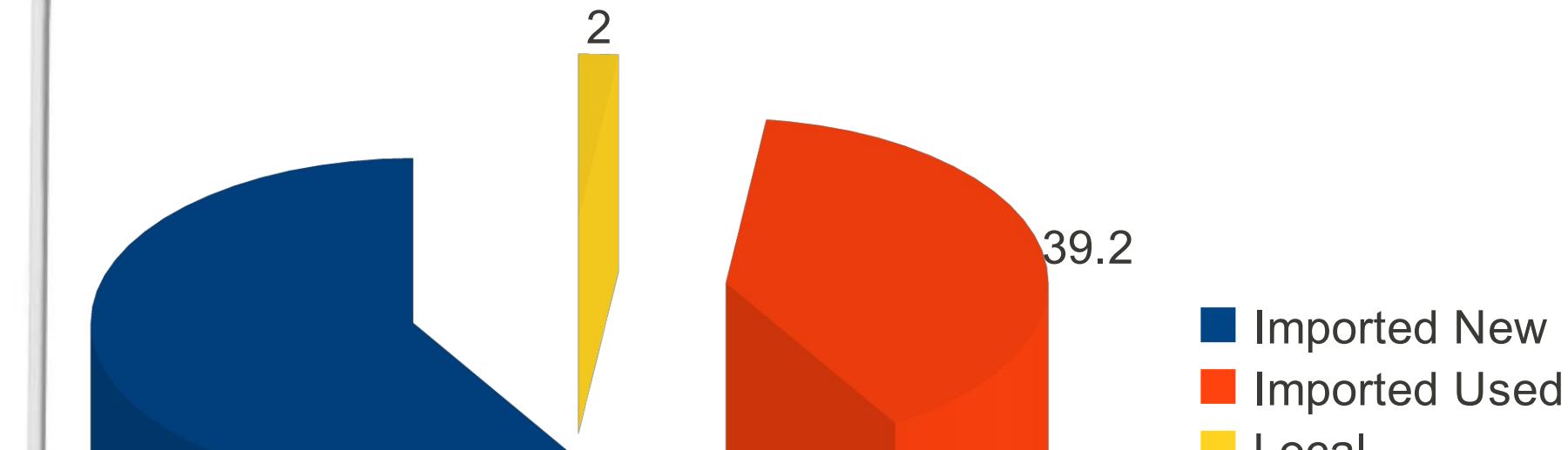
- What do we need?
  - What is possible to operate in our current facilities?
- What are the specifications?
  - Do we need newer facilities?
- Is there enough money to purchase this equipment?



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# Nature of Medical Equipment in PH



- [http://www.ita.doc.gov/td/health/PreOwnedMedEquip\\_FINAL\\_060506.pdf](http://www.ita.doc.gov/td/health/PreOwnedMedEquip_FINAL_060506.pdf)

# Current Industry Concerns

- Regulation Nature of Used Equipment
  - Government does not impose any restriction on used medical equipment except thatthese should be comparable in safety with new equipment.
  - Refurbishers of used equipment must obtain a clearance from the original equipment manufacturer and must conform to good manufacturing practices.
  - Refurbishers are also not allowed to distribute commercially, any device that has not been produced in conformity with such requirement.
    - Source: Report from CS Post (via E-Mail), 1 July 2002
    - Medical Device Regulatory Requirements for the Philippines, July 1, 2002



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# Purchase, Installation & Training

- Inspection of materials
- Oversee installation of equipment
  - Learning to assemble & disassemble units
- Training
  - Staff training
    - Operation of Units & Basic Housekeeping
  - Technical Training
    - Testing
    - Basic Maintenance Procedures
    - Modular or component replacement procedures

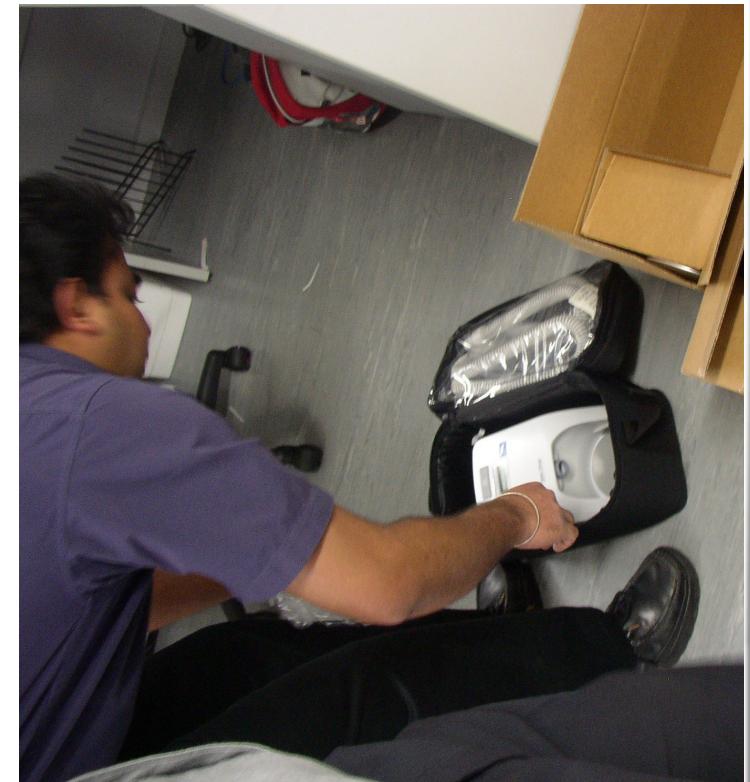


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# Acceptance

- All plugs or sockets are provided for the connection of associated parts.
- Check that access for operator maintenance, such as filters, adjustments, and liquid containers does not expose live parts.
- Check that liquid levels in tanks, gearboxes or similar are satisfactory and there are no leakage or spillage from containers pipes, hoses, or couplings.



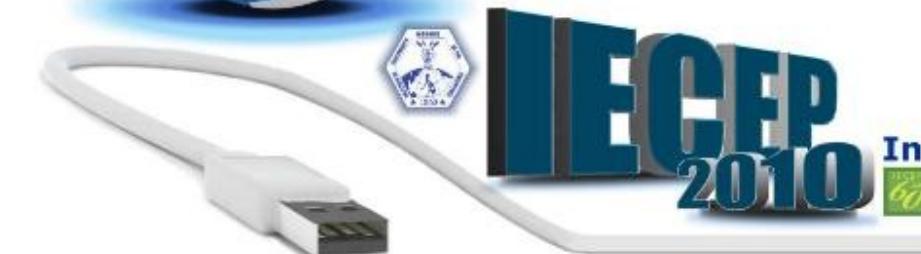
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# Acceptance

- Check that the following markings are visible and legible:
  - Name or Trade Mark of Manufacturer
  - Supply Voltage and Frequency and Current and Power Ratings
  - Class Markings (For Class II Equipment Double Square)
  - Type and rating of all operator replaceable fuses.
  - The voltage of any power supply outlet sockets fitted to the enclosure of the equipment.



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# Acceptance

- Equipment Markings Continued.
  - Markings / Labels
    - Special purpose or controlled power supply outlets fitted to the equipment indicating their special function.
  - Function indicated on all operator controls and indicators.
  - Warnings on equipment with potentially hazardous outputs.
  - Marking to confirm that the equipment and any applied parts are consistent with the type and classification marked as such or with the symbols shown.



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# Acceptance

- Markings to indicate if applied parts are protected against the output of defibrillator.

|          |  |   |
|----------|--|---|
| CLASS I  |  | PROTECTIVE EARTH                                    |
| CLASS II |  | DOUBLE INSULATION                                   |
| CLASS IP |  | INTERNAL POWER SUPPLY                               |
| TYPE B   |  | NON-ISOLATED APPLIED PART                           |
| TYPE BF  |  | ISOLATED APPLIED PART                               |
| TYPE CF  |  | ISOLATED APPLIED PART<br>DIRECT CARDIAC APPLICATION |
| TYPE F   |  | FIXED DEVICE  |
| TYPE T   |  | TRANSPORTABLE DEVICE                                |



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# Acceptance

- Permanently Installed Equipment
  - Check that any covers or panels which can be removed without using a tool do not expose live parts to personal contact.
  - Check the correctness and security of the equipment mounting.
  - Check that any environment requirements are complied with. Example Exhaust Extraction for surgical LASERs.
  - Check cables on moving parts are secured so that they are not caught in the gear drive mechanisms.



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# Acceptance

- Suspended Masses

Units with motorized drives shall be checked for their behaviour in the event of power failure.



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# Acceptance

- Electrical Safety Tests
  - Protective Earthing Test
  - Insulation Resistance Test
  - Earth Leakage Current Test
  - Applied Part Current Test
  - Mains Contact Current Test



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# Acceptance

- Essential Safety and Performance Parameter Test
  - Confirmation that the device is performing accurately, reliably, and within manufacturer's specifications.
    - This includes function, alarms or protective device.



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# Acceptance

- Formal Acceptance Procedures
  - Identification of Equipment
    - Marking of devices to indicate it has been tested, when the next due for testing. and the organization carrying out the test.
  - Addition of the device to the equipment database



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# Decommissioning

- Dispose
  - Sell to manufacturer
  - Destroy & sell to scrap yard
- Store
  - Spare Parts Source
  - Back up Unit in case of new equipment failure



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# Management

- Planning Preventive Maintenance Periods
- Creation of Recording Tools or Systems
- Evaluation of Maintenance Period and Procedure

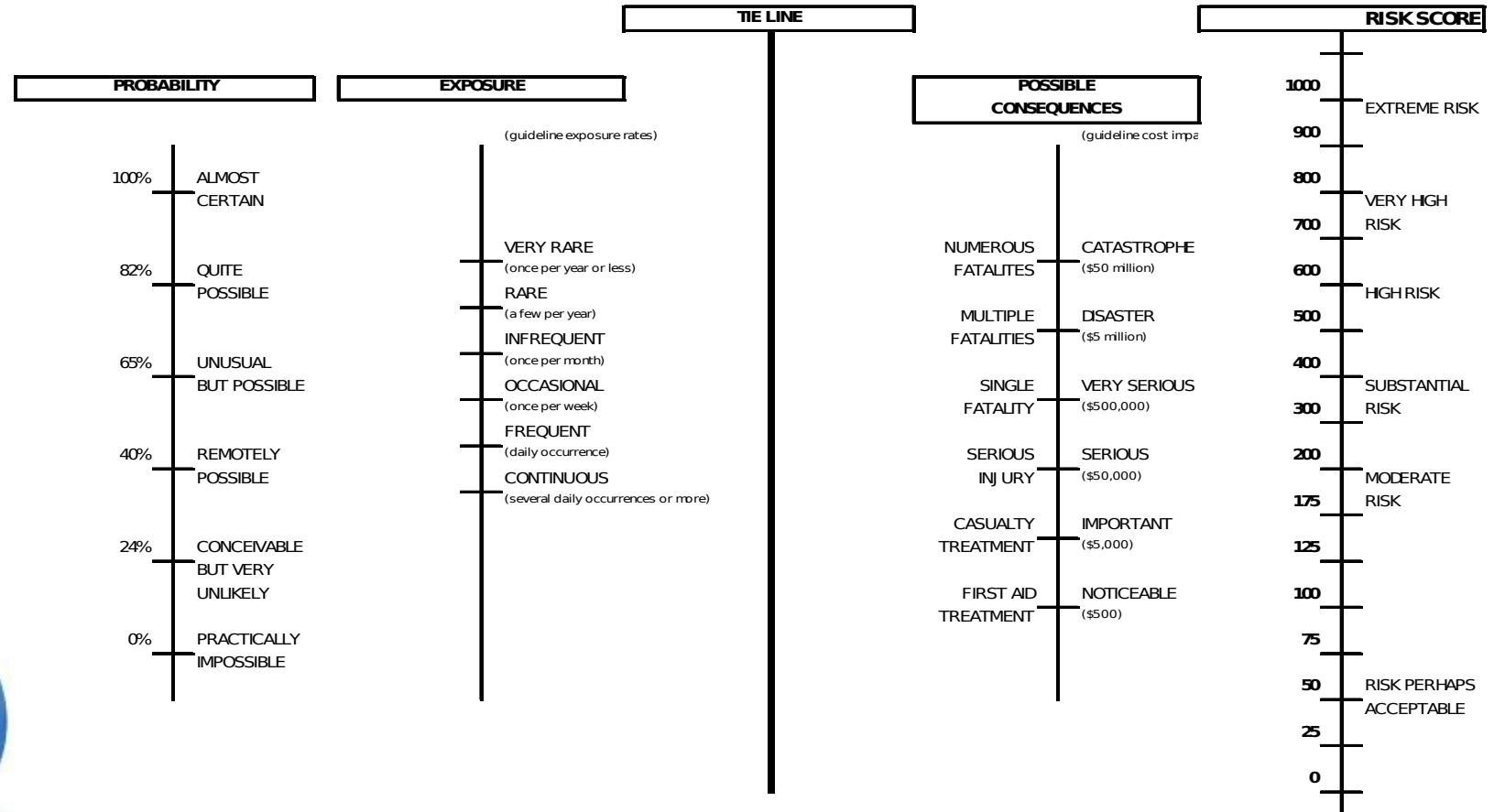


# Maintenance

- Preventive Maintenance
  - 80% of equipment breakdown occurs as a pattern of wear and tear that can be resolved by periodic monitoring of equipment performance.
    - Testing & Evaluation
    - Parts Replacement



# Risk Calculator



<http://www.safetyrisk.com.au/2010/03/14/electronic-risk-score-calculator-nomogram/>



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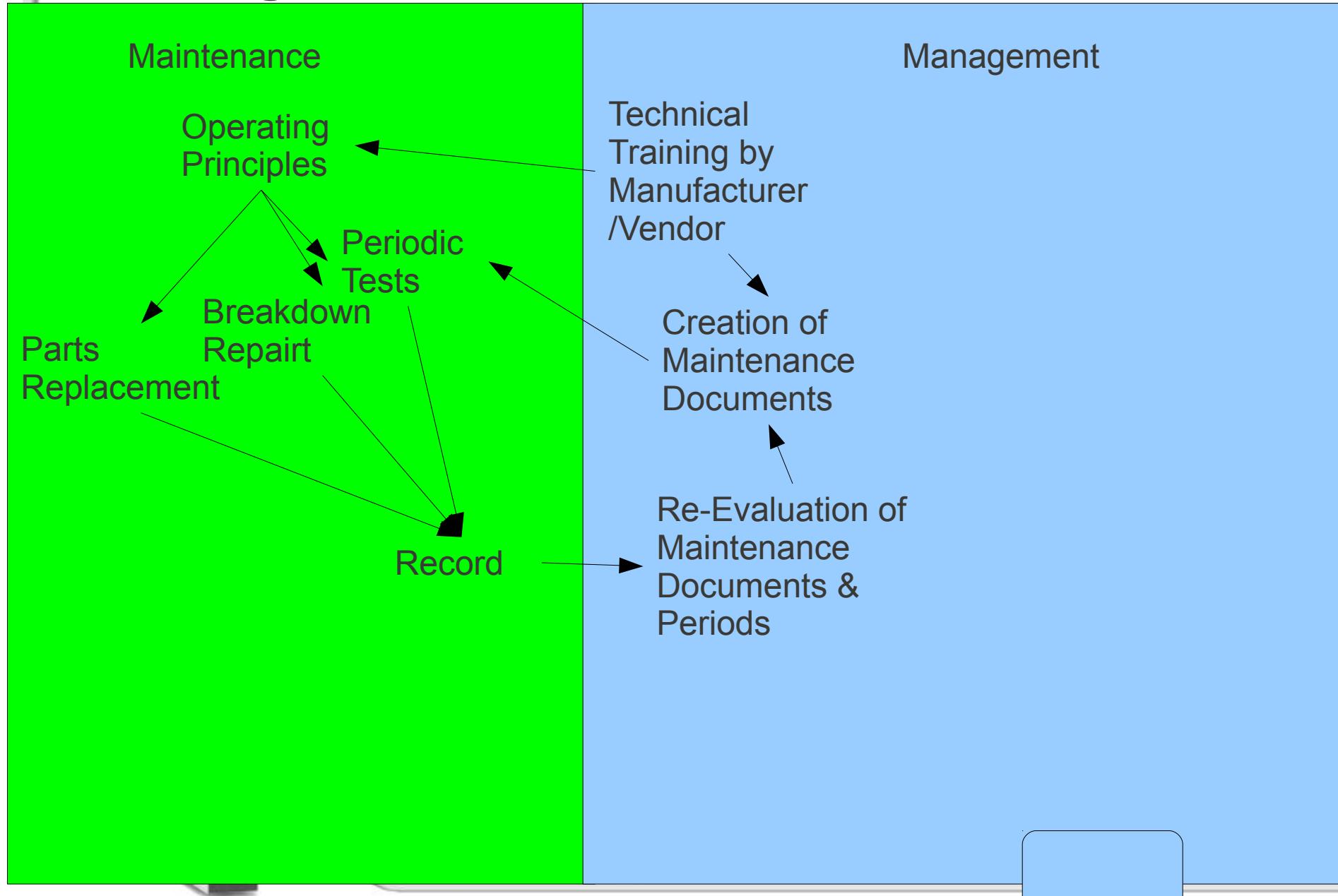
# Tool to Determine Maintenance Periods



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# Management of Devices & Facilities



# Performance Evaluation

- Did it last its predicted lifespan?
  - Is it long enough to obtain a reasonable return of investment?
- Did it breakdown often?
  - What broke down often and why?
  - Did the manufacturer or vendor provide adequate support?
- Did it have the same output specifications thru its life?
  - Did any staff complain about its operation or cause any minor or major problems?



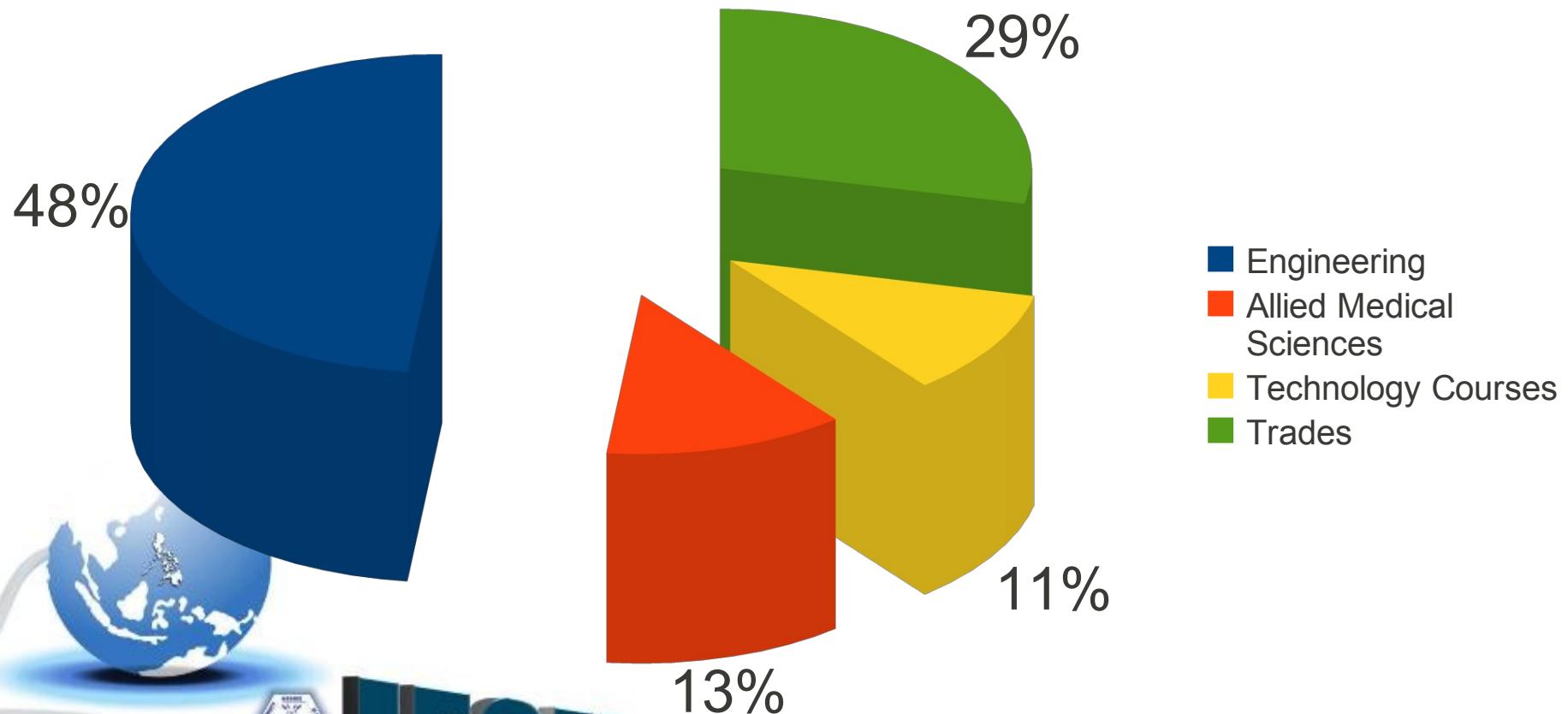
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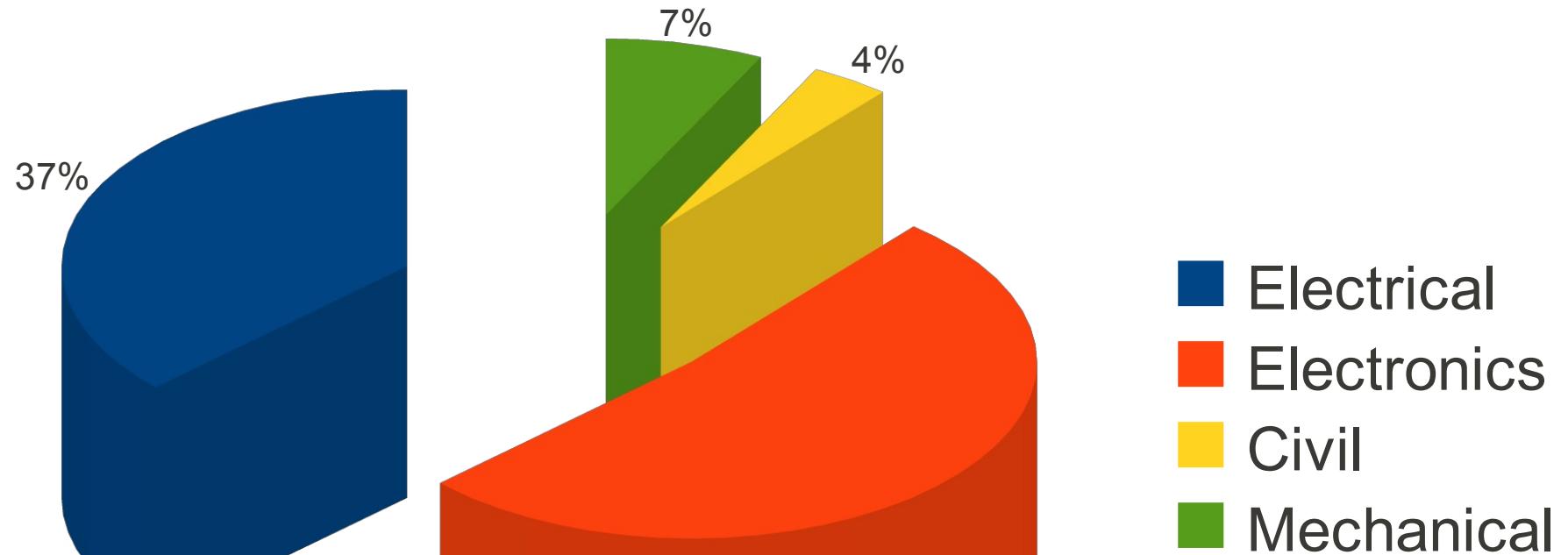


# Biomedical Staffing Based on Modular Enrollment Statistics



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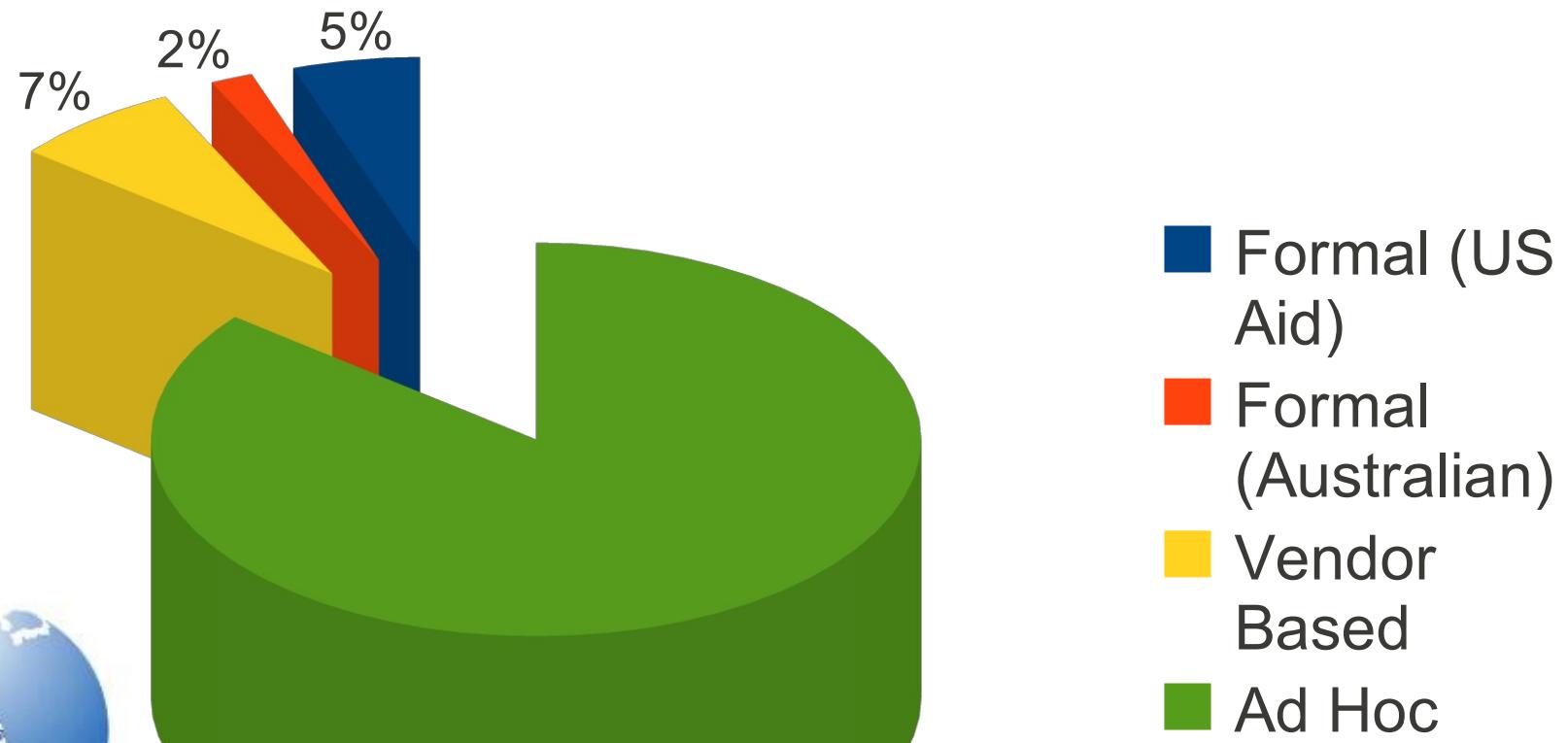
# Distribution of Engineering Fields



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# Biomedical Education prior to Enrollment



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# Experiences in the Field

- Nature of Work at Hospital Settings
  - Work Flow can be different in hospitals
    - Orderly Maintenance may sometimes be difficult due to high patient use of equipment
  - Access to Technical Manuals & Material Support from Manufacturers
  - Cost of Medical Test Equipment



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# Experience in the Field

- There are institutions across the world that are aware of the conditions for developing countries
  - EWH – Provides Test Equipment and Training
  - US Aid – Provides Training and Technical Support to students
  - Australian Aid – Provides Materials for Training of Technicians.



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# What to Learn More?

- Devices and Procedures Visit
  - <http://www.ewh.org/>
  - <http://www.ebme.co.uk/forums/ubbthreads.php/ubb/cfrm>



Thank you for Listening  
Any Questions?



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