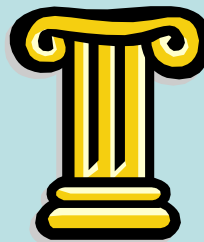


Mission, Function & Organizational Structure of Clinical Engineering Services

Stephen L. Grimes, FACCE
Senior Consultant & Analyst
Strategic Health Care Technology Associates
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Organization's (Hospital's) Mission

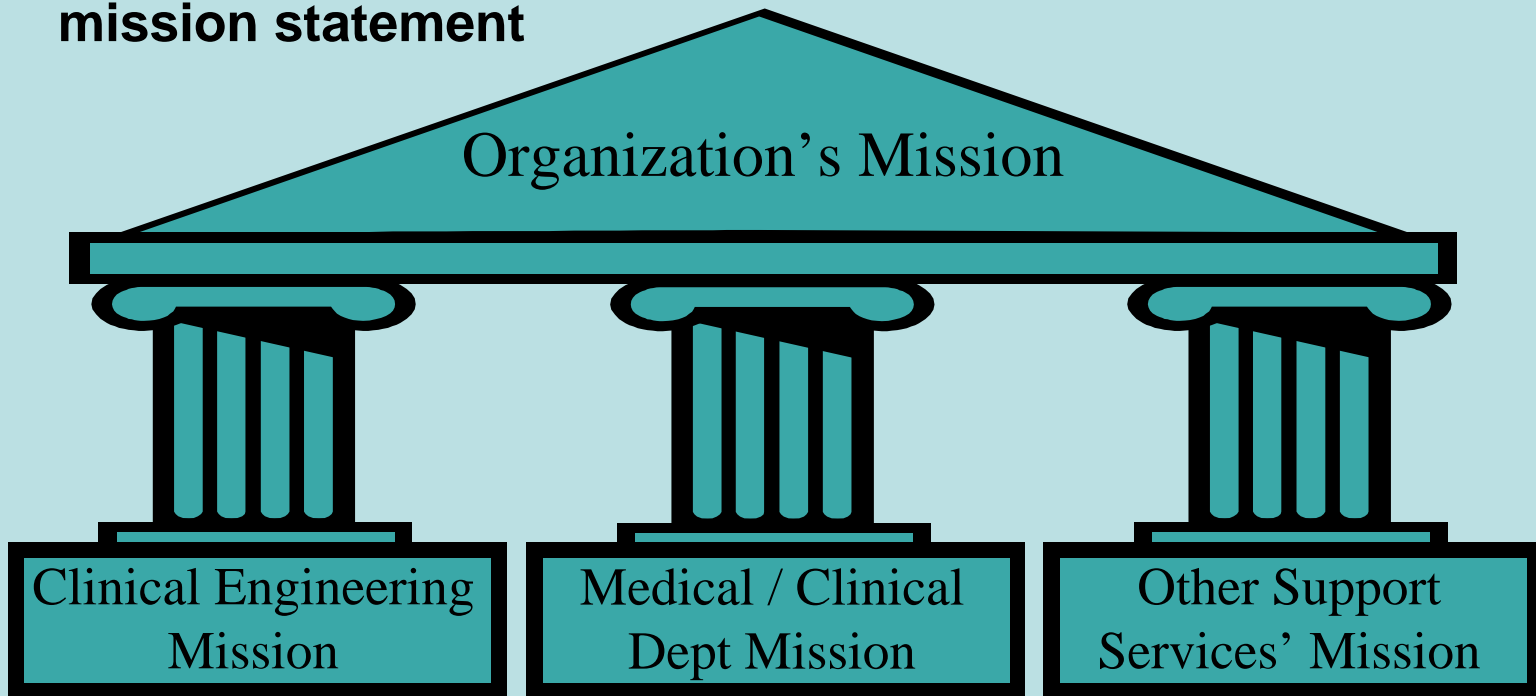
- To improve the health of the communities we serve by delivering a broad range of high quality services with sensitivity to the needs of our patients and their families
 - Hospital's Goal: **To improve the health of the communities we serve**
 - What hospital does: **delivers a broad range of high quality services**
 - How hospital does it: **with sensitivity to the needs of our patients and their families**



Mission

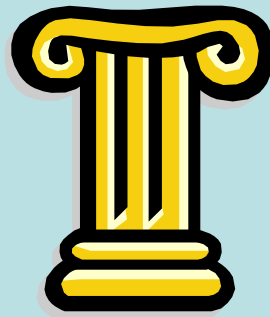


- Program Mission
 - Should be simple
 - Should support & be consistent with organization's mission statement



Healthcare Technology Program Mission

- To support the delivery of healthcare by insuring the availability of safe and effective medical technology in a cooperative effort with other members of the healthcare team
 - Our Goal: **To support delivery of healthcare**
 - What we do: **Provide safe & effective medical technology**
 - How we do it: **In a cooperative effort with other members of the healthcare team**



Mission Statement

- The Office of Engineering Services will apply engineering, technical, and managerial expertise to provide safe, effective, and economical facilities and equipment as needed by University Hospital for patient care, teaching, research, and community service. †

† Slide 10 of Roles of Supervisors & Managers (Miller ~ Peru 2002)

Requirements of a Technology Management Program[†]

- Program to control & monitor equipment performance
 - Routine performance testing
 - Initial inspection
 - Preventive maintenance
 - Repair
 - Action reports on device hazards & recalls

Requirements of a Technology Management Program[†]

- That accurately and consistently computes and monitors total equipment maintenance costs, including:
 - In-house costs
 - Manufacturer costs
 - 3rd party service costs

Requirements of a Technology Management Program[†]

- Involvement in all aspects of equipment acquisition and replacement decisions, development of new services and planning of new construction and major renovations:

Requirements of a Technology Management Program[†]

- Development of training program for all equipment users of patient care equipment and for biomedical technicians

Requirements of a Technology Management Program[†]

- A quality assurance program relating to technology use

Requirements of a Technology Management Program[†]

- Risk management as it relates to technology

Traditional Roles & Responsibilities

- **Technical services**

- Inspection & testing
(functional, safety, performance)
- Calibration
- Preventive maintenance
- Repair



Scheduled Maintenance

Unscheduled Maintenance

- **Technology management services**

- Equipment management program (risk analyses, control elements)
- Evaluation of new technologies prior to acquisition, including life cycle cost analyses
- Service vendor management
- Compliance (government, accrediting standards)
- Education services (equipment users & biomedical equipment technicians)
- Device tracking (hazards & recalls)
- Incident reporting & investigation

Policies & Procedures

- **Policies**

Statements of principles and values that guide organizational activities ...

Effective policies are flexible, coordinated, comprehensive, ethical, and clear

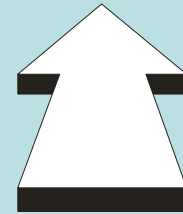
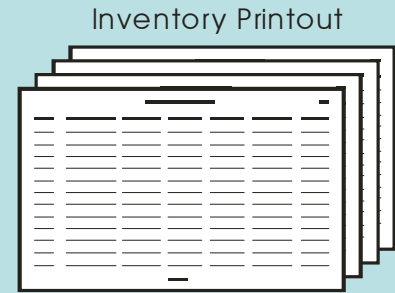
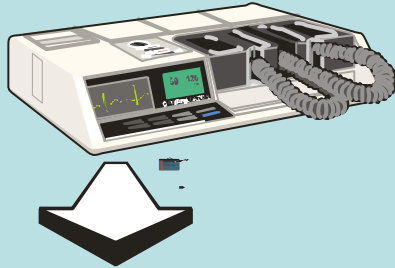
- **Procedures**

Defined courses of established methods used to achieve an objective

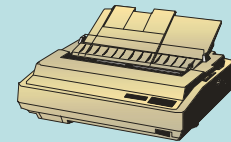
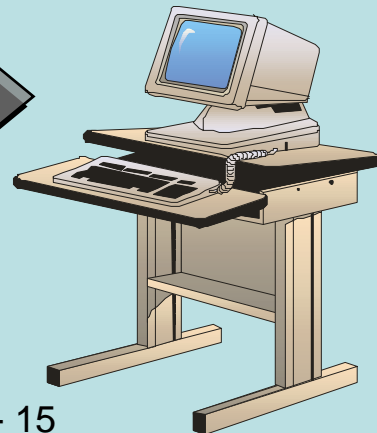
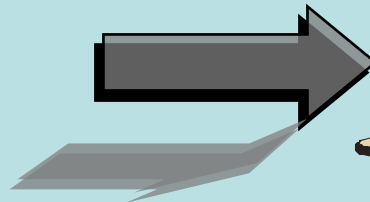
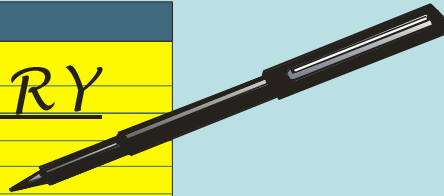
Policies & Procedures

1. Equipment Classification System ~ *Criteria for including equipment categories in program*
2. Biomedical equipment inventory management ~ *Process for adding, deleting*
3. Inspection & PM ~ *Determining protocols & frequencies*
4. Obtaining Equipment Service/Repair
5. Incoming inspection of all medical devices & systems ~ *Installation & acceptance testing of all purchased, leased, loaned devices*
6. Storing & Retiring medical equipment
7. Medical Device Tracking ~ *Dealing with hazards and recalls*
8. Education/Training ~ *Regarding proper use, testing & troubleshooting*
9. Evaluating Healthcare Technology Management Program effectiveness
10. Incident reporting & investigation
11. Reporting to Safety Committee

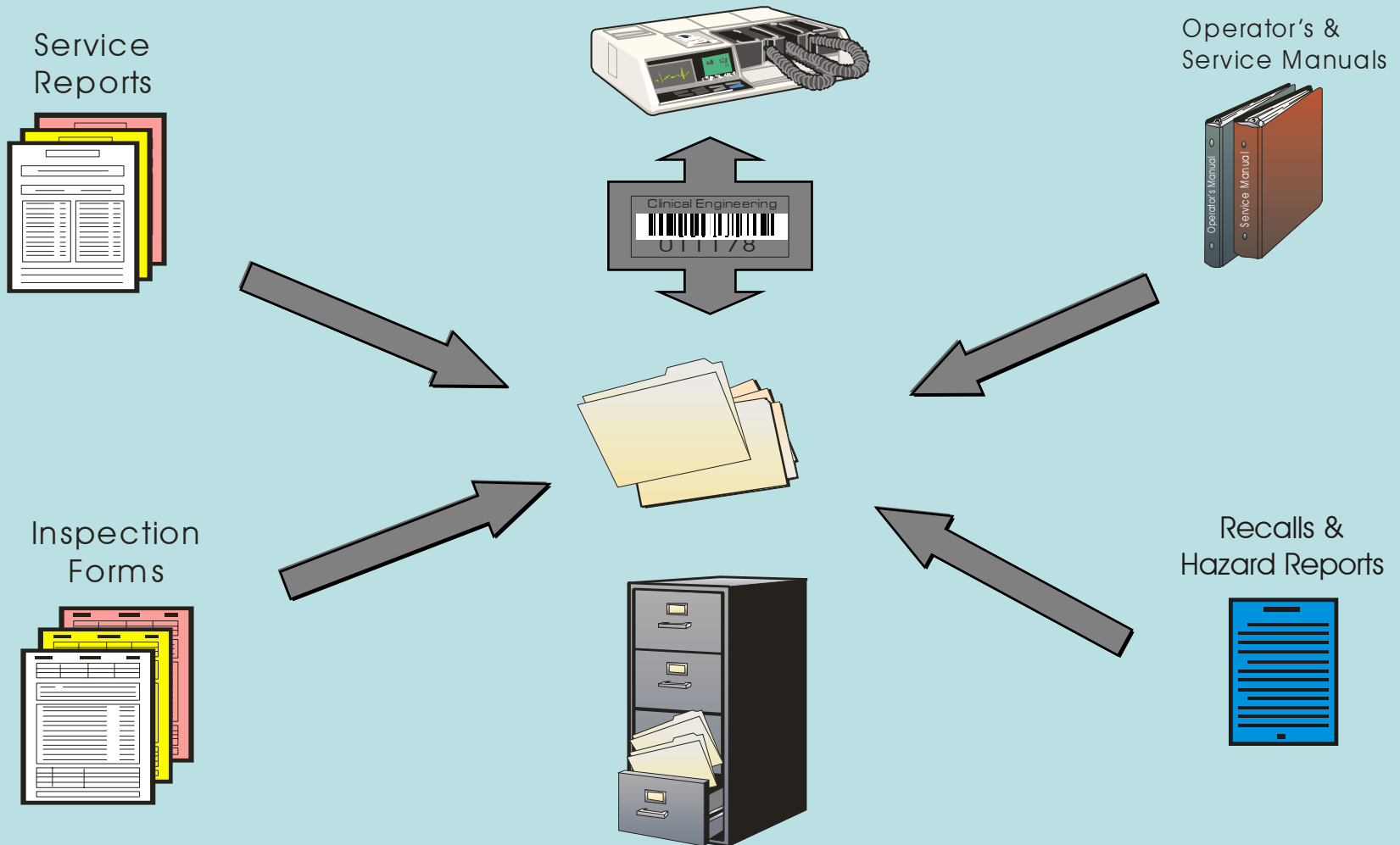
Equipment Inventory



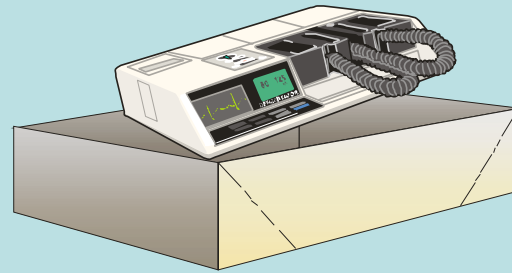
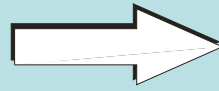
<u>INVENTORY</u>
- ID or Control #
- Description
- Manufacturer
- Model #
- Serial #
- Location/Cost Center
- Acquisition Date/Cost
- Maintenance requirements (frequency/schedule)



Centralized Documentation System

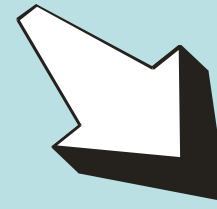
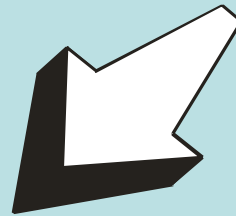


Incoming Inspection of Biomedical Equipment



Purchased,
Leased
Demo or
Loaner
Equipment

Clinical
Engineer



Biomedical Equipment
Technician (BMET)



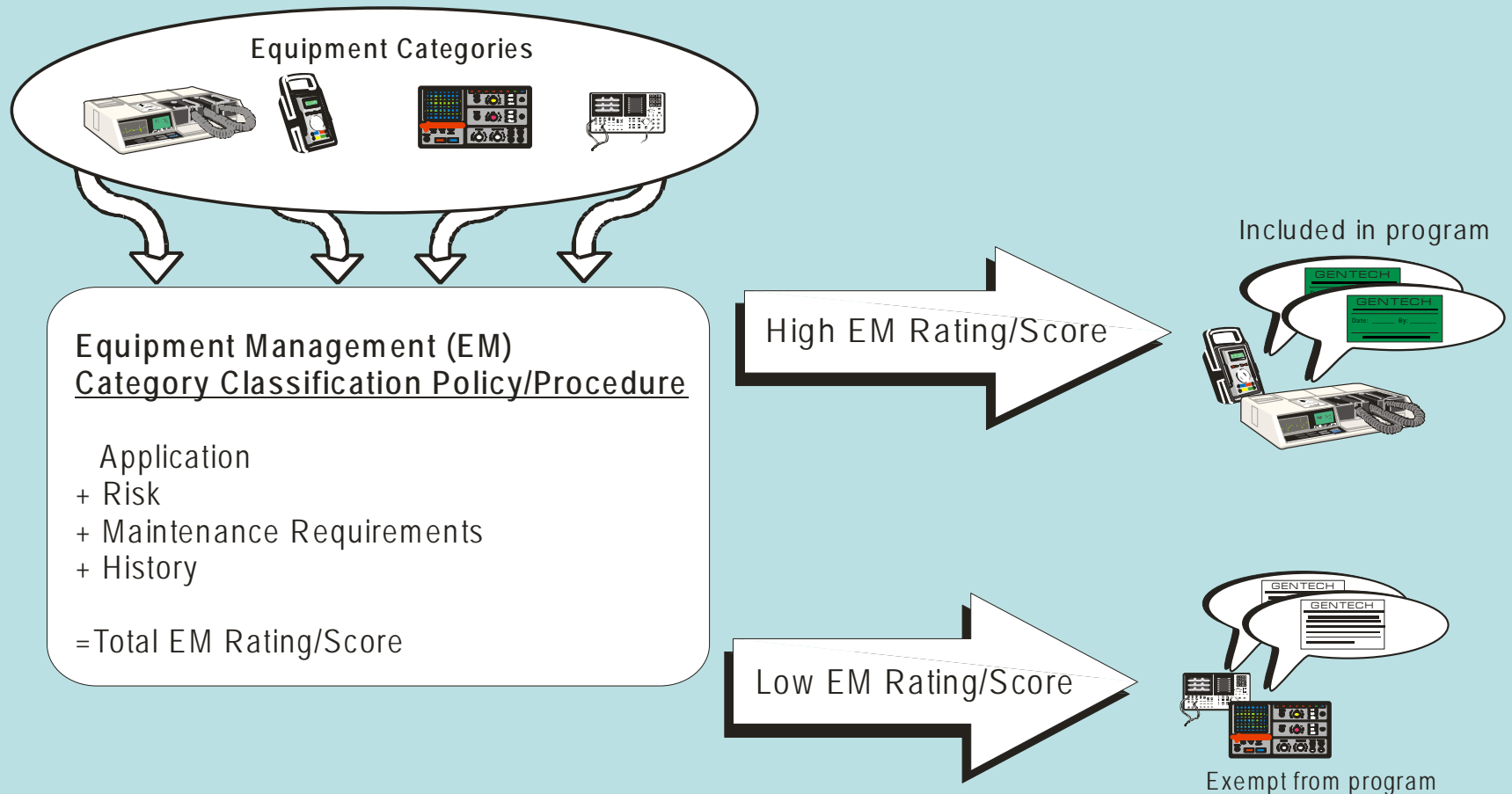
Equipment Inventory
& EM Classification

Centralized Biomedical
Equipment Documentation

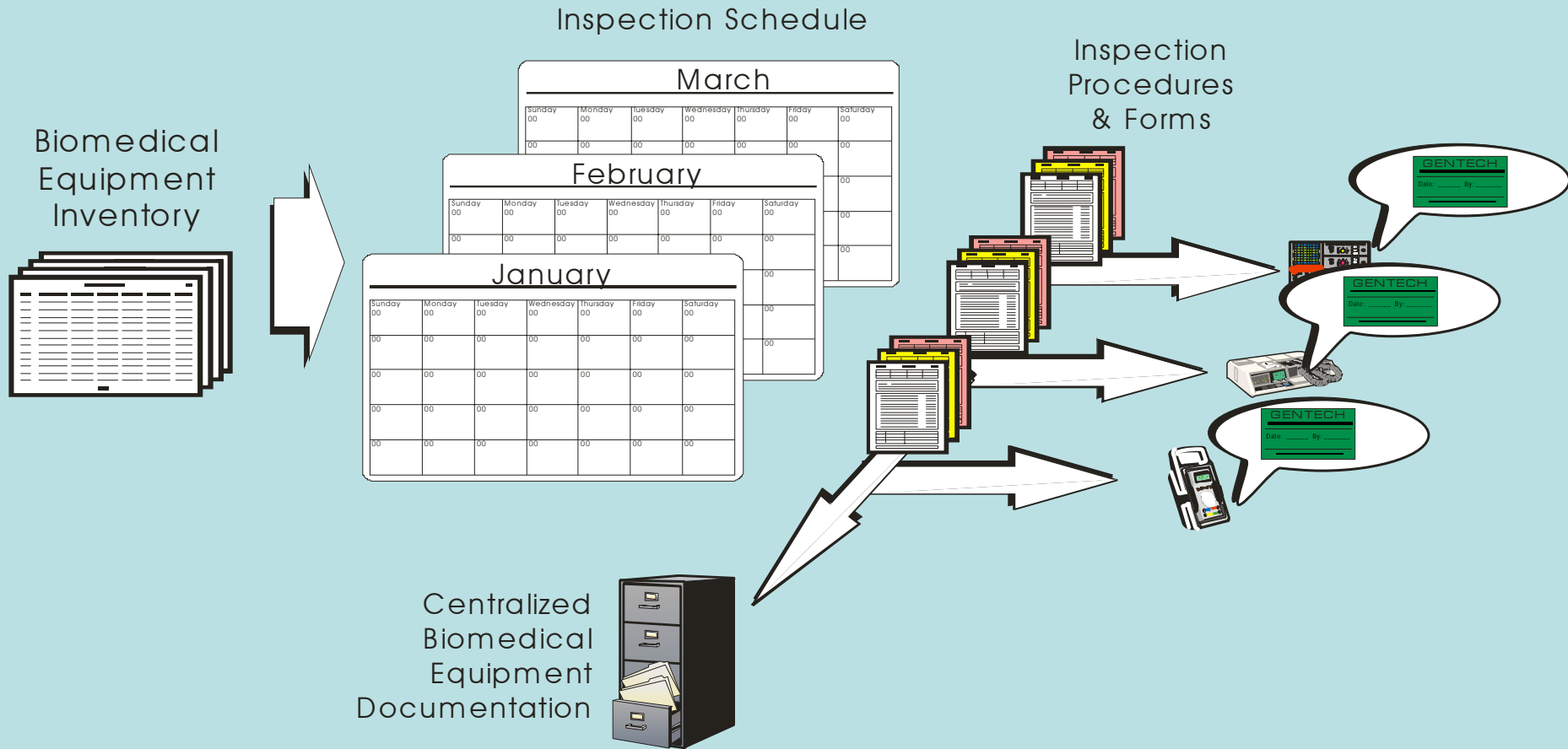


Inspection
Form

Equipment Management Program “Risk-based Classifications”



Biomedical Inspection/PM Program

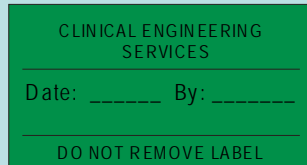


Biomedical Equipment Tagging System

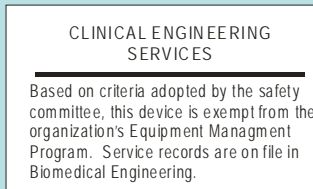
Inventory
Tag



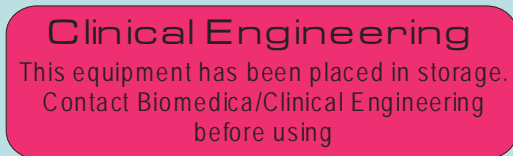
Inspection
Tag



Exempt
Tag



Storage
Tag



NOTICE

This piece of equipment has recently been serviced by a qualified service technician. During the service procedures, settings of the controls, patient circuit components, and other auxillary devices may have been changed. Check the equipment for proper settings prior to clinical use. Remove this label following the preoperational check.

DATE: _____ BY: _____

Clinical Engineering

Operator
Warning
Tag

DEFECTIVE

Do Not Use

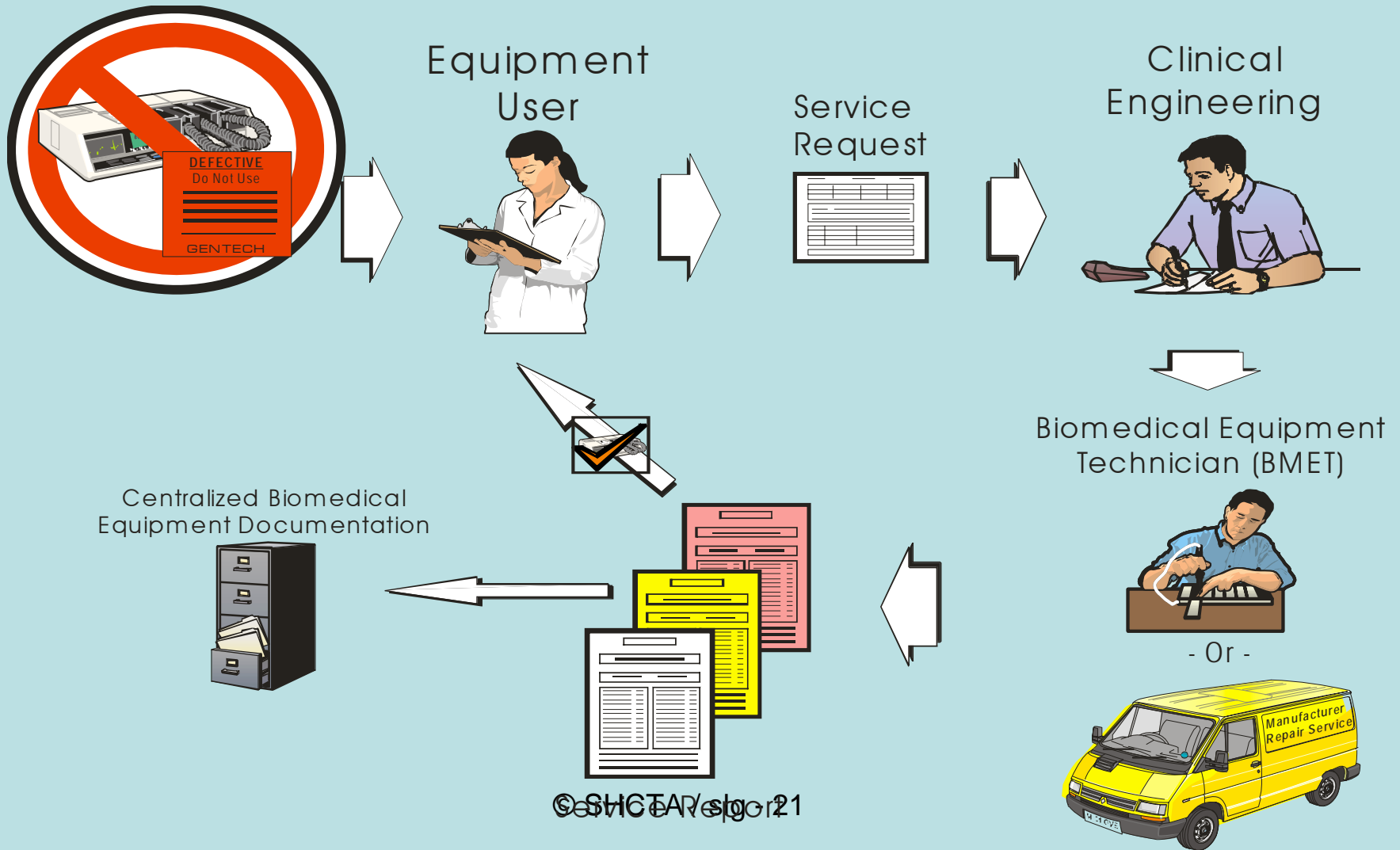
Comments: _____

DATE: _____ BY: _____

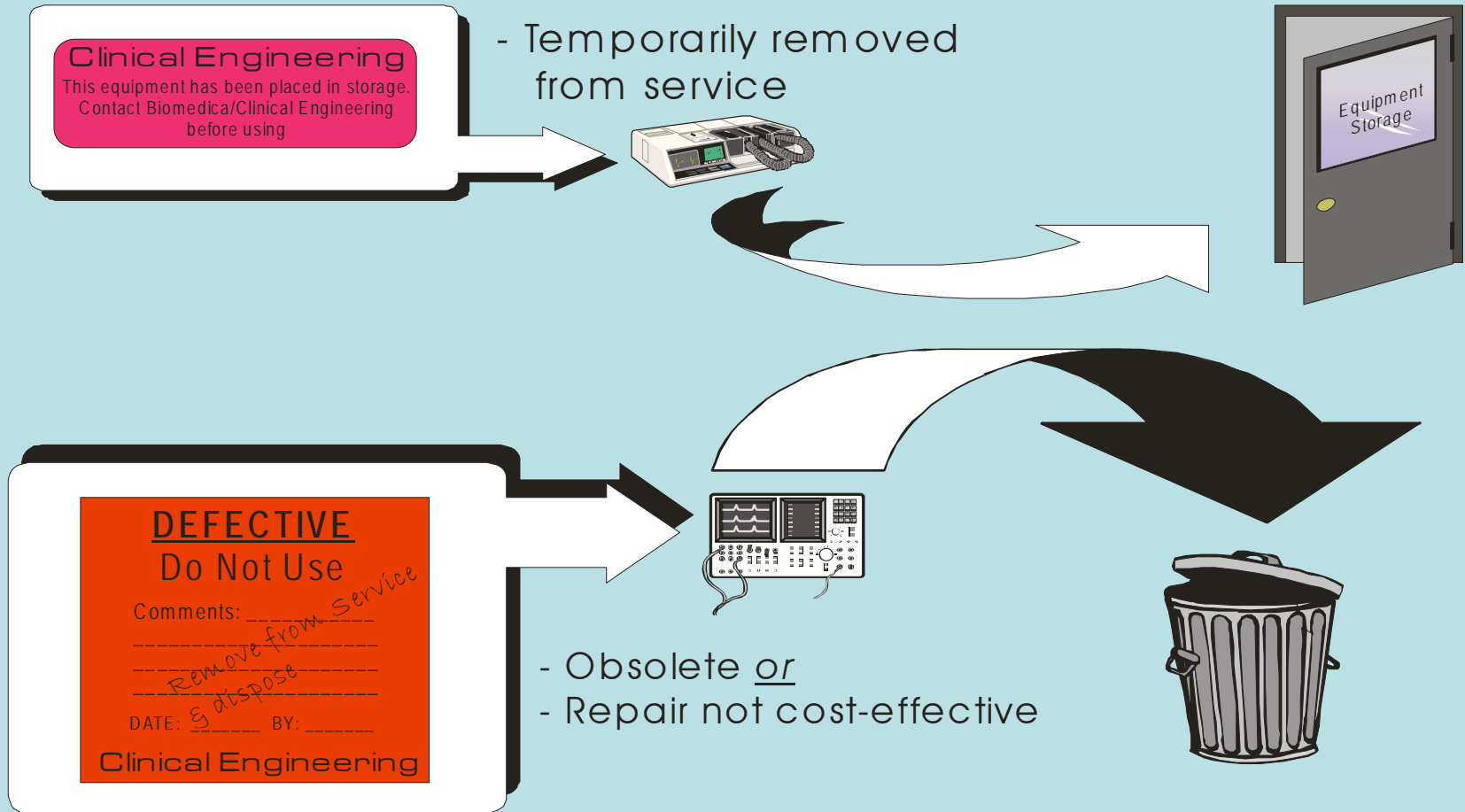
Clinical Engineering

Red
(Remove
from Service)
Tag

Biomedical Equipment Service/Repair

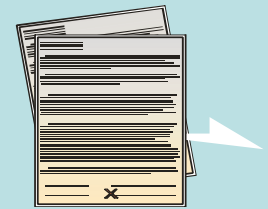


Biomedical Equipment Storage/Retirement



Acquisition of Biomedical Equipment

1. Assess Need ~ Determine Specifications
2. Compare available manufacturers & models. Assess ease of use, ease of maintenance, operating & life cycle costs
3. Make selection & prepare purchase order with specifications including operator & service manuals, user & service training, warranty, etc.
4. Acceptance/payment conditional on passing incoming technical inspection, inclusion of manuals, provision of user & service training, adequate warranty



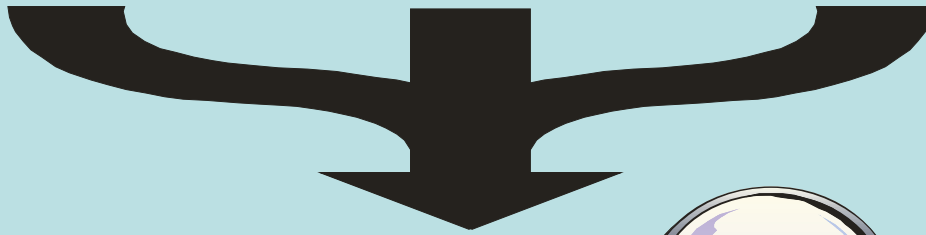
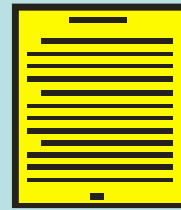
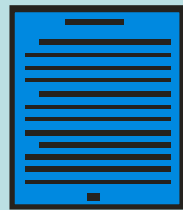
Equipment Hazard/Recall Program

Manufacturer
Recalls & Alerts

FDA Enforcement
Reports

ECRI/Health
Devices Alerts

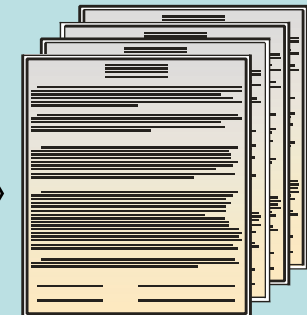
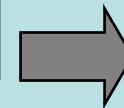
Centralized Biomedical
Equipment Documentation



Clinical Engineer



Biomedical
Equipment
Inventory

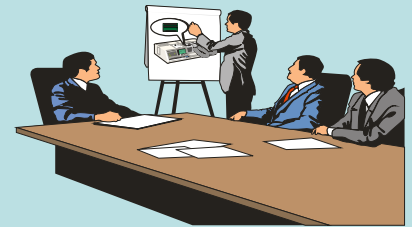


Action Reports



Equipment Program Education

- Clinical Staff
 - Basic operation & proper use
 - Basic Troubleshooting
 - Potential hazards
 - Equipment management (dealing with obtaining equipment service, equipment related incidents)
- Clinical engineering staff
 - Professional (mission, ethics, conduct)
 - Codes & standards
 - Technical (troubleshooting & use of equipment)
 - Clinical equipment operation & inspection procedures
 - Policies, procedures & documentation



Equipment Related Incident Investigation

1. Minimize further injury to patients & personnel
2. Minimize any damage to equipment & facilities
3. Impound all equipment, supplies, disposables, wrappers, etc.
4. Identify witnesses
5. Notify Risk manager, clinical engineering
6. Complete incident report
7. Notify authorities



Equipment Management Program Benchmarking

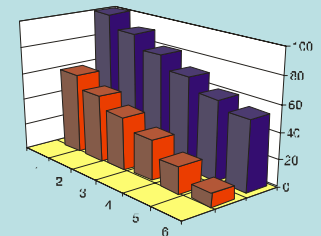
- **Safety Committee**

How to measure program performance & effectiveness?

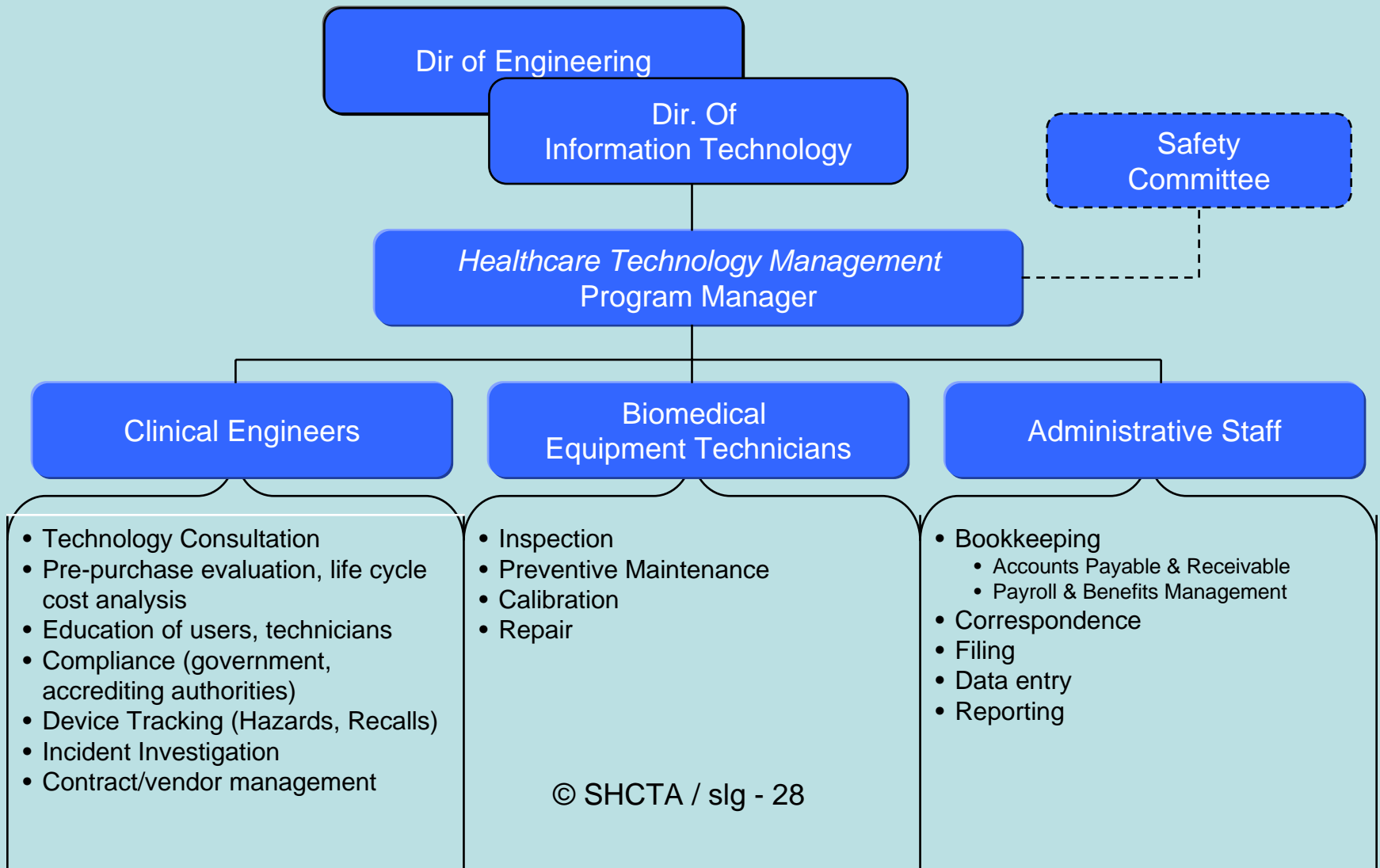
- **Establish Goal & Compare with Actual**

For example:

- User related equipment problems
- Scheduled vs Actual inspections
- Percent of inspections with problems found



Typical Organization Chart Healthcare Technology Program



Organizational Reporting

- Reports directly to
 - Director of Engineering (a “*traditional*” approach)
 - Director of Information Technology (the “*trend*”)
 - Other (e.g., Administrator of Support Services)
- Also reports indirectly to
 - Safety Committee (interdisciplinary group responsible for hospital safety ... including technology management elements)

Safety Committee

- **Purpose**

To bring members of the healthcare team together in an non-adversarial environment to:

- ◆ identify issues affecting patient & staff safety and formulate an effective approach toward the resolution of those issues
- ◆ reviews and approves elements of technology management program that impact on safety of patients & staff

- **Membership must be interdisciplinary to be effective**

Typically includes representatives of

- administration
- nursing/clinical staffs
- personnel
- engineering
- risk management
- medical staff
- education
- purchasing
- security
- clinical engineering

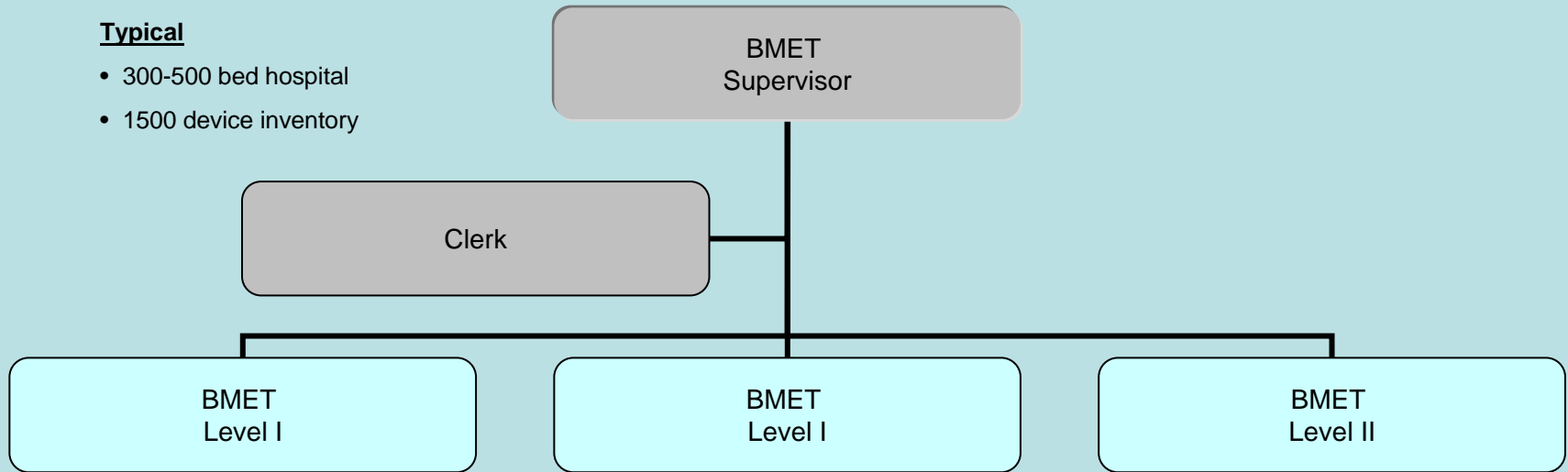
Staff Qualifications

- **Biomedical Equipment Technicians (BMET)**
 - Associate Degree in Technology (AA) or higher, Military or Manufacturer Training
 - Certified Biomedical Equipment Technician (CBET)
 - Specialties: General Biomedical, Laboratory, Medical Imaging
 - Rankings: Level I, II, III ... higher level reflects more experience, education and/or specialization
- **Clinical Engineers (CE)**
 - Bachelor or Masters of Science Degree in Engineering
 - Certified Clinical Engineer (CCE)
- **Manager**
 - Clinical Engineer
 - Master's in Business Administration ... or business education

Organization Chart for Small Clinical Engineering Program

Typical

- 300-500 bed hospital
- 1500 device inventory

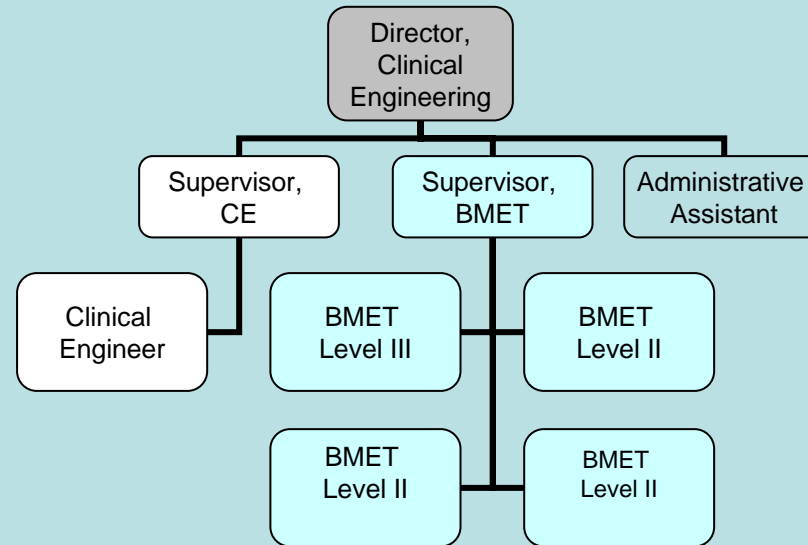


- ✓ Capable of providing basic service on majority of general biomedical devices
- ✓ 3rd parties provide most sophisticated technical services
- ✓ 3rd party provides clinical engineering consultation & related services

Organization Chart for Medium Clinical Engineering Program

Typical

- 500-700 bed hospital
- 2000 device inventory

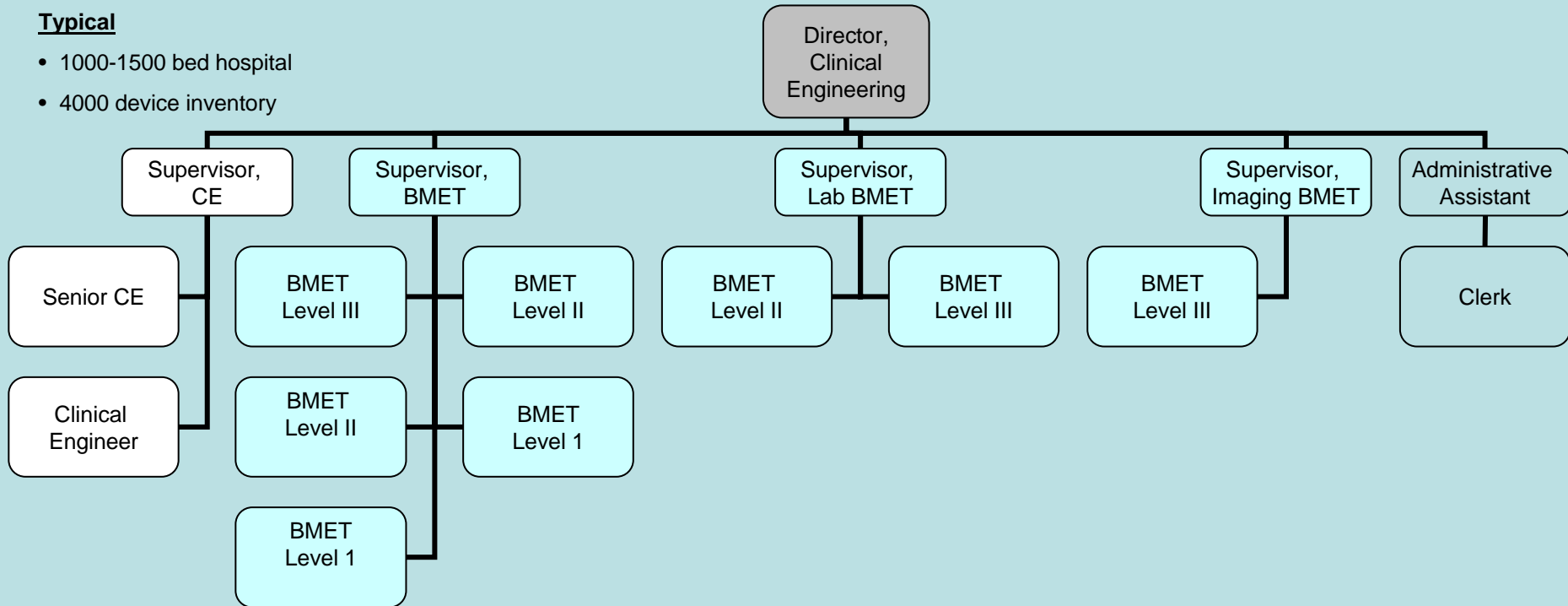


- ✓ Capable of providing basic to mid-level services on all but most sophisticated medical devices (e.g., lab, imaging) in inventory
- ✓ Capable of providing basic clinical engineering services
- ✓ 3rd party provides most sophisticated technical services (e.g., lab, imaging)
- ✓ 3rd party provides high-level clinical engineer services

Organization Chart for Large Clinical Engineering Program

Typical

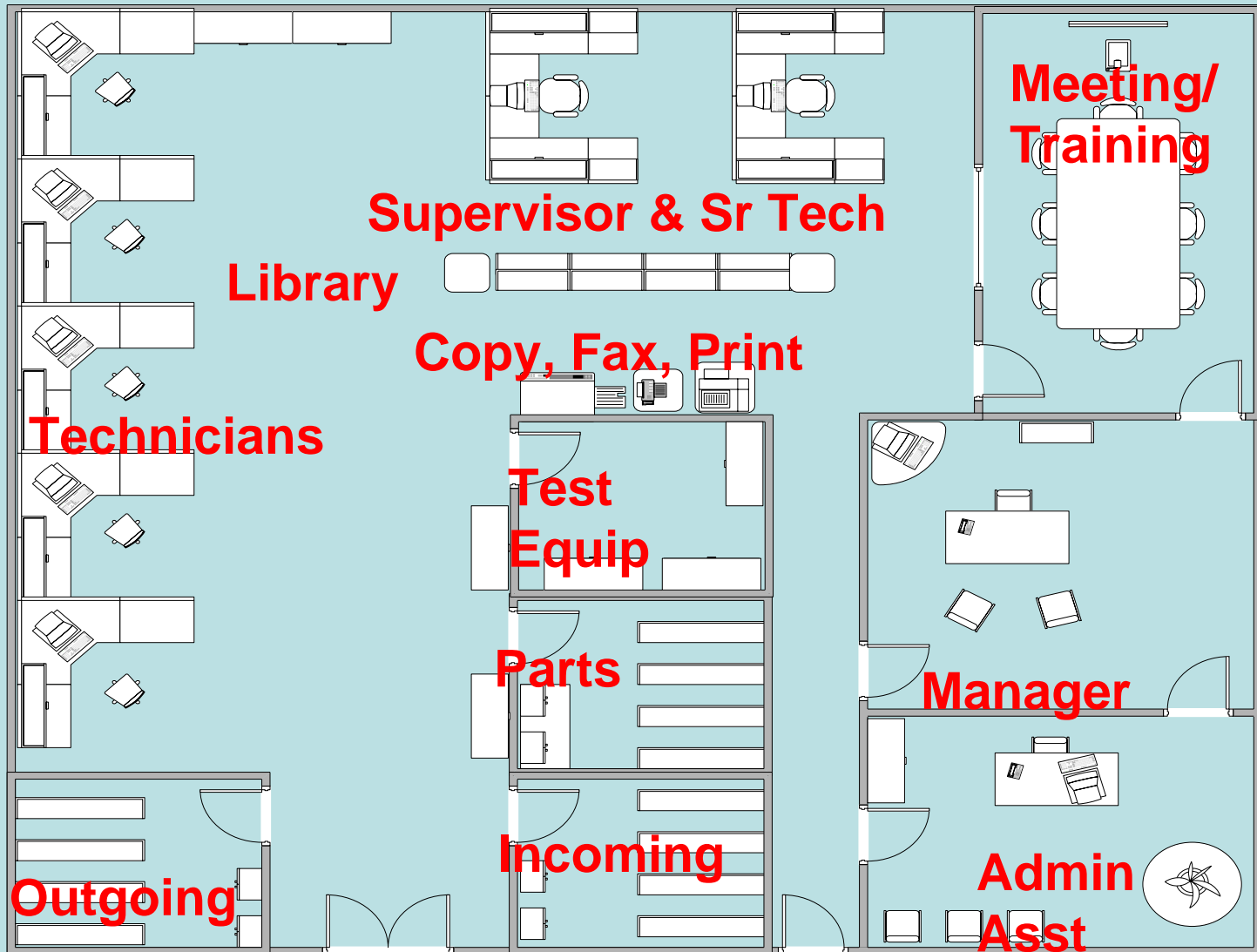
- 1000-1500 bed hospital
- 4000 device inventory



- ✓ Capable of providing basic to high-level services on almost all medical devices on inventory (including imaging, lab)
- ✓ Capable of providing basic to high-level clinical engineering services
- ✓ 3rd party provides sophisticated technical services on few devices
- ✓ 3rd party provides audit of clinical engineer services

Clinical Engineering Center

2,200 Sq Ft



Equipment & Other Resources

- Test & Repair equipment
 - Oscilloscope
 - Digital multimeter
 - Electronic thermometer
 - Electronic pressure/vacuum gauge
 - Spirometer
 - Flowmeters
 - ECG analyzer
 - Defibrillator analyzer
 - Electrosurgical unit analyzer
 - Gas analyzer
 - Electrical safety analyzer
 - Pacemaker analyzer
 - Hand tools
- Office equipment
 - Computers, printers
 - Photocopiers,
 - Facsimile
- Library
 - reference books
 - equipment manuals,
 - reference guides,
 - subscriptions to journals, services
- Office furnishings
 - Workbenches
 - Desks
 - Chairs
 - Stools
 - Tables
 - File cabinets
 - Shelving units
 - Storage cabinets

Logistic Models for Service Delivery

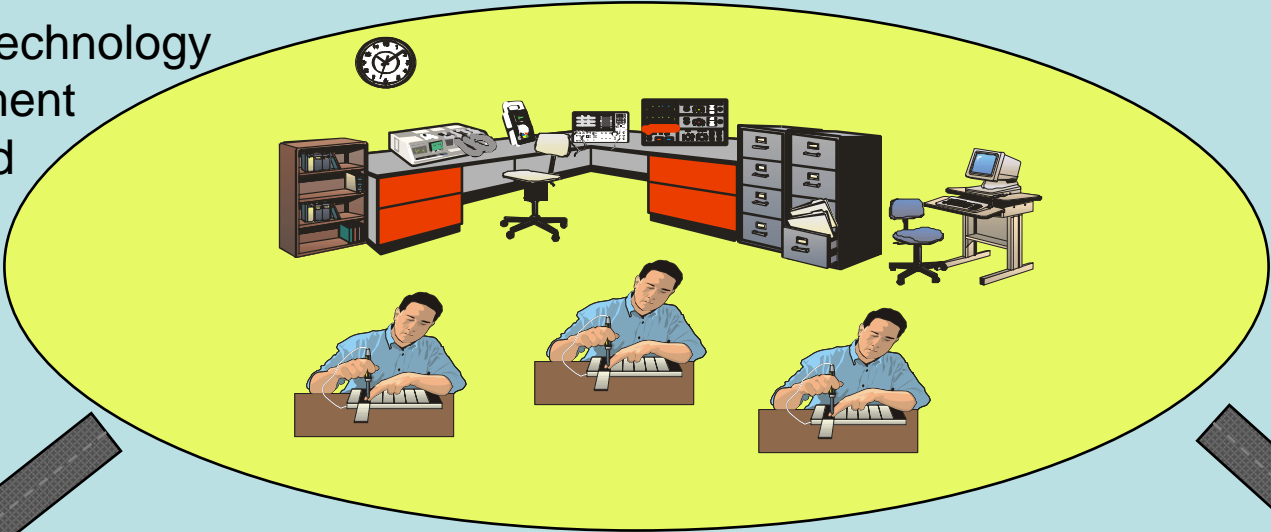
- **Service Delivery Models**
 - Centralized (dispatch or depot)
 - less duplication, easier management
 - Distributed
 - Better response time (therefore less downtime)
 - Generally less efficient use of resources (more costly)
- **Issues affecting decision on which model is best for situation**
 - Nature (method) & quality of communications
 - Geography of service area (i.e., travel distances)
 - Nature (method) & quality of transportation available
 - Response time necessary

Mixed Approach toward Service Delivery

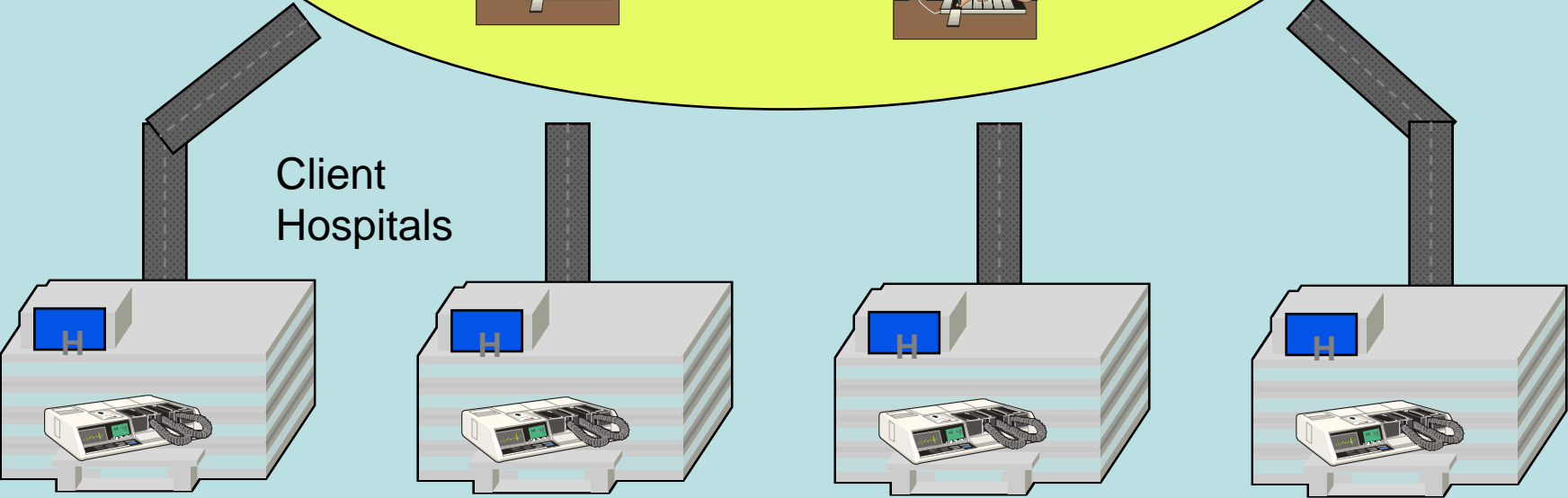
- Use resident or *in-house* services for “basics”
- Use centralized or *ISO* services for more technically specialized needs

Centralized Model for Service Delivery

Central Technology
Management
Office and
Service
Center



Client
Hospitals

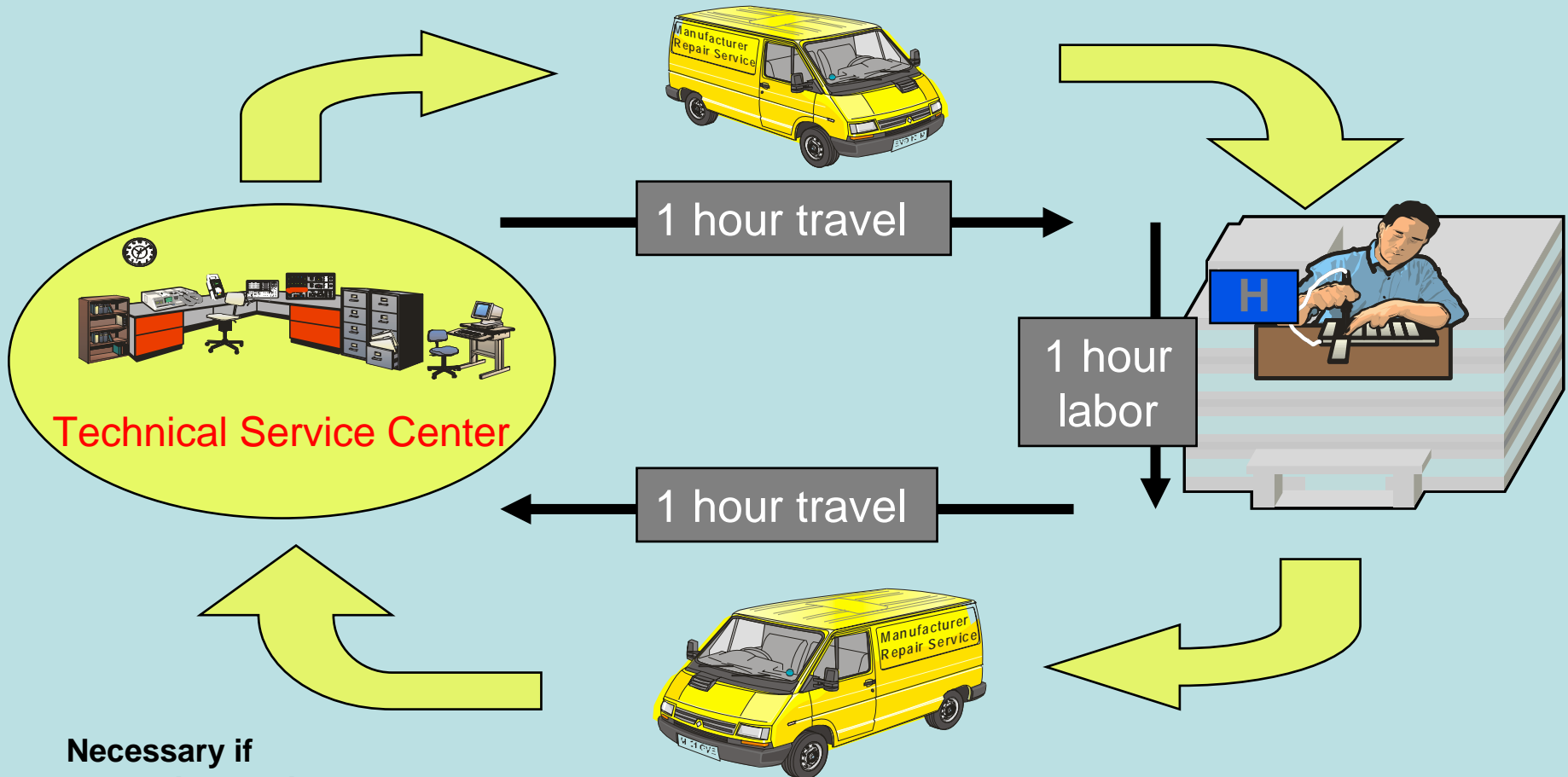


Central Dispatch Model for Service Delivery

In this scenario

Cost = 3 hours labor

Downtime = 3 hours



Necessary if

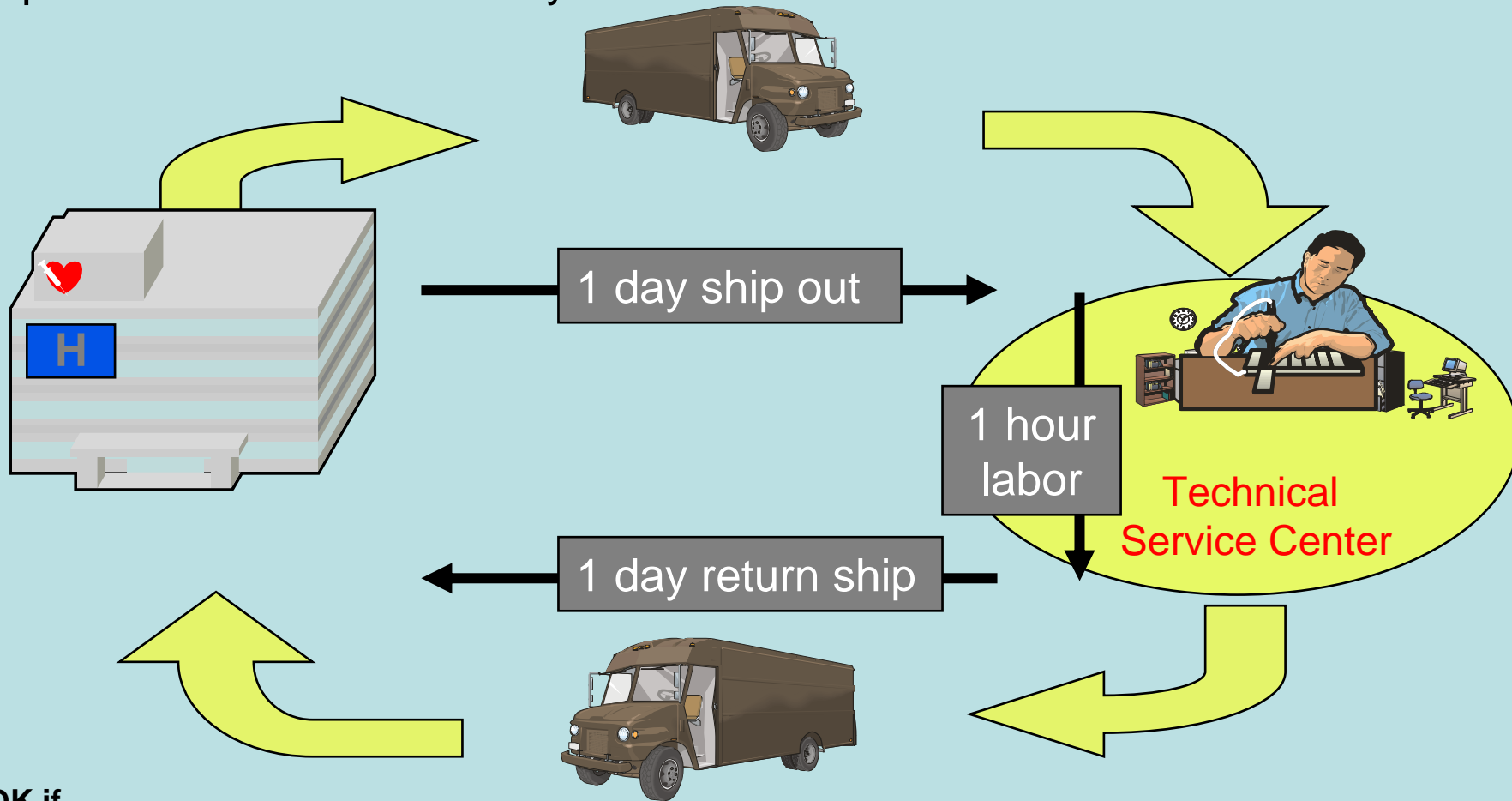
- equipment is not portable
- speed to restore is critical

Central Depot Model for Service Delivery

In this scenario:

Cost = 1 hour labor plus shipping

Equipment Downtime = 2-3 days



OK if

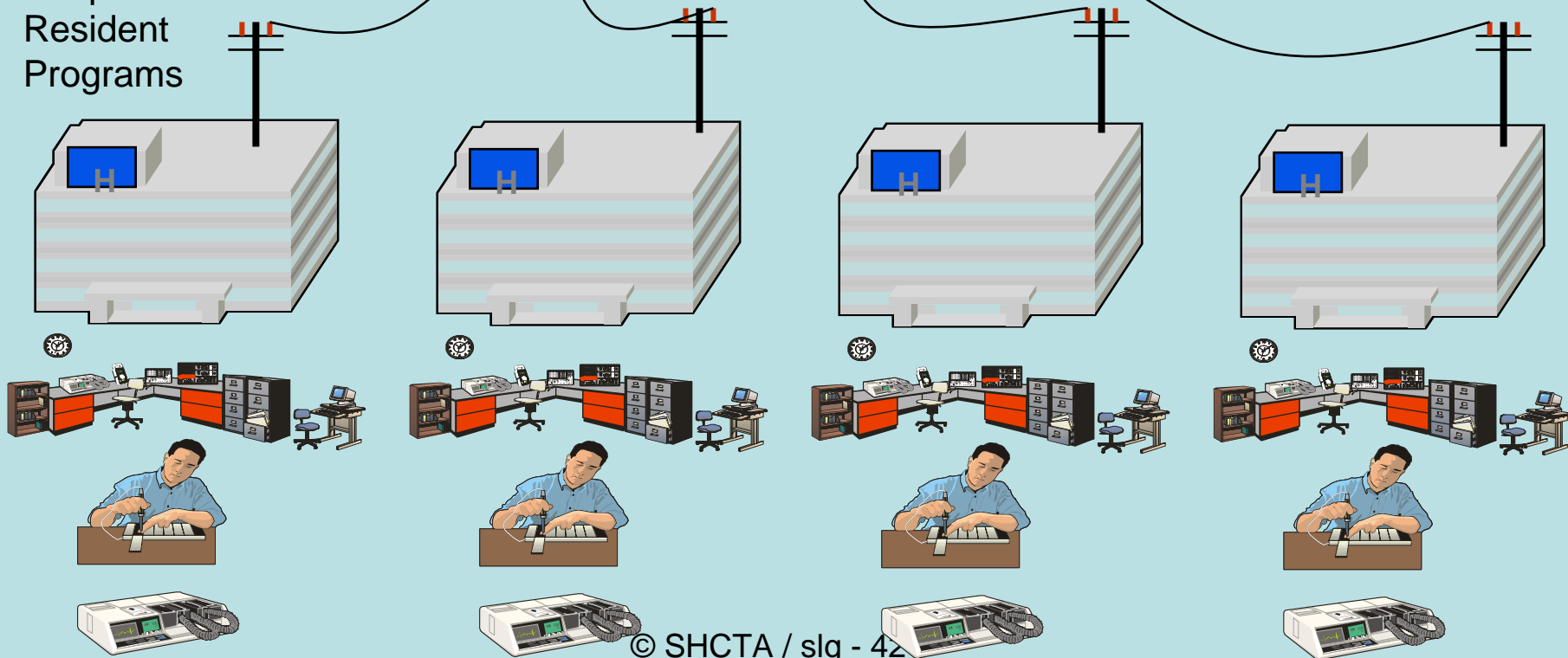
- there is redundant capacity &
- equipment is portable

Distributed (Resident) Model for Service Delivery

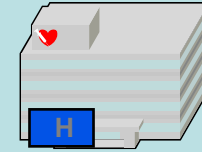
Central Office
for Technology
Management



Hospital-based
Resident
Programs



Centralized



		Technician Schedule				
Location	Beds	Mon	Tues	Wed	Thu	Fri
Hospital #1	500	2	2	3	2	3
Hospital #2	350	1	2	1	2	2
Hospital #3	200	1	1	1	1	1
Hospital #4	170	1	1	1	1	
Hospital #5	150	1		1		1
Hospital #6	100		1		1	
Hospital #7	50	1				
Depot		2	2	2	2	2
Total	1530	9	9	9	9	9

Important that clients can rely on a firm schedule ...
there will be fewer “emergencies”

Advantages/Disadvantages of Sourcing Options

- **In-house (e.g., hospital owned & based)**
 - Less expensive in organizations with larger workload
 - Hospital can exercise more control over process
- **Independent Service Organization (ISO)**
 - Less expensive in organizations with smaller workloads
 - Usually a more efficient use of resources
 - Shared resources with other clients (program development, management, specialized technical expertise & equipment)
Access to resources (specialized expertise, equipment) that couldn't be afforded on own

Questions?

Thank You!

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