

2023 CCE Written Exam Review Webinar Series

August 9, 2023, through October 11, 2023

Session #1: Technology Management 1

August 9, 2023

Kim Greenwood, MAsc, P.Eng., FACCE, CCE-CA, FEIC, FCMBES
greenwood@cheo.on.ca

About the host/moderator



Katherine Navarro is a Biomedical Engineer with the VHA Office of Healthcare Technology Management (HTM) where she supports the Biomedical Engineering field in the VA from a national level.

Katherine has been with the VA in the Healthcare Technology Management field for fourteen years. In 2020, Katherine began her new role for the Office of HTM, working virtually from San Antonio.

Katherine served as the chair of the ACCE's Body of Knowledge Committee from 2017 – 2019 as an ACCE Board Member at Large from 2020 – 2022, and as the ACCE Vice President since 2022.

Logistics

- ❖ All attendees have their microphones muted during the presentation.
- ❖ Questions to the faculty must be submitted via the “Q&A” feature in Zoom at any time. They will be addressed at the Q&A portion.
- ❖ If there is any urgent issue, please use the “chat” feature to communicate with the host/moderator.
- ❖ Please remember to complete the webinar evaluation after attending. A link will be provided at the end.



About the faculty

Kim Greenwood, CCE-CA

Kim Greenwood is a Clinical Engineering Consultant at the Children's Hospital of Eastern Ontario (CHEO) in Ottawa, Canada. He was the Director of the CHEO Regional Clinical Engineering Service Program from 1997 to March 2023 and is an Adjunct Professor of Mechanical Engineering at the University of Ottawa. Under his leadership, the CHEO Clinical Engineering Department was selected as the winner of the 2016 International Federation of Medical and Biomedical Engineering (IFMBE)'s outstanding clinical engineering teamwork award.

Kim was the recipient of the 2017 ACCE Advocacy Professional Achievement in Management / Managerial Excellence Award and was made a Fellow of the Engineering Institute of Canada in 2018, a Fellow of the Canadian Medical and Biological Engineering Society in 2020 and the ACCE in 2021. Kim has served as a member with the ACCE Board of Directors since 2018 and is presently President-Elect of the ACCE. Kim holds a Master's degree in Biomedical Engineering from Carleton University.

Learning Objectives

Technology Management 1

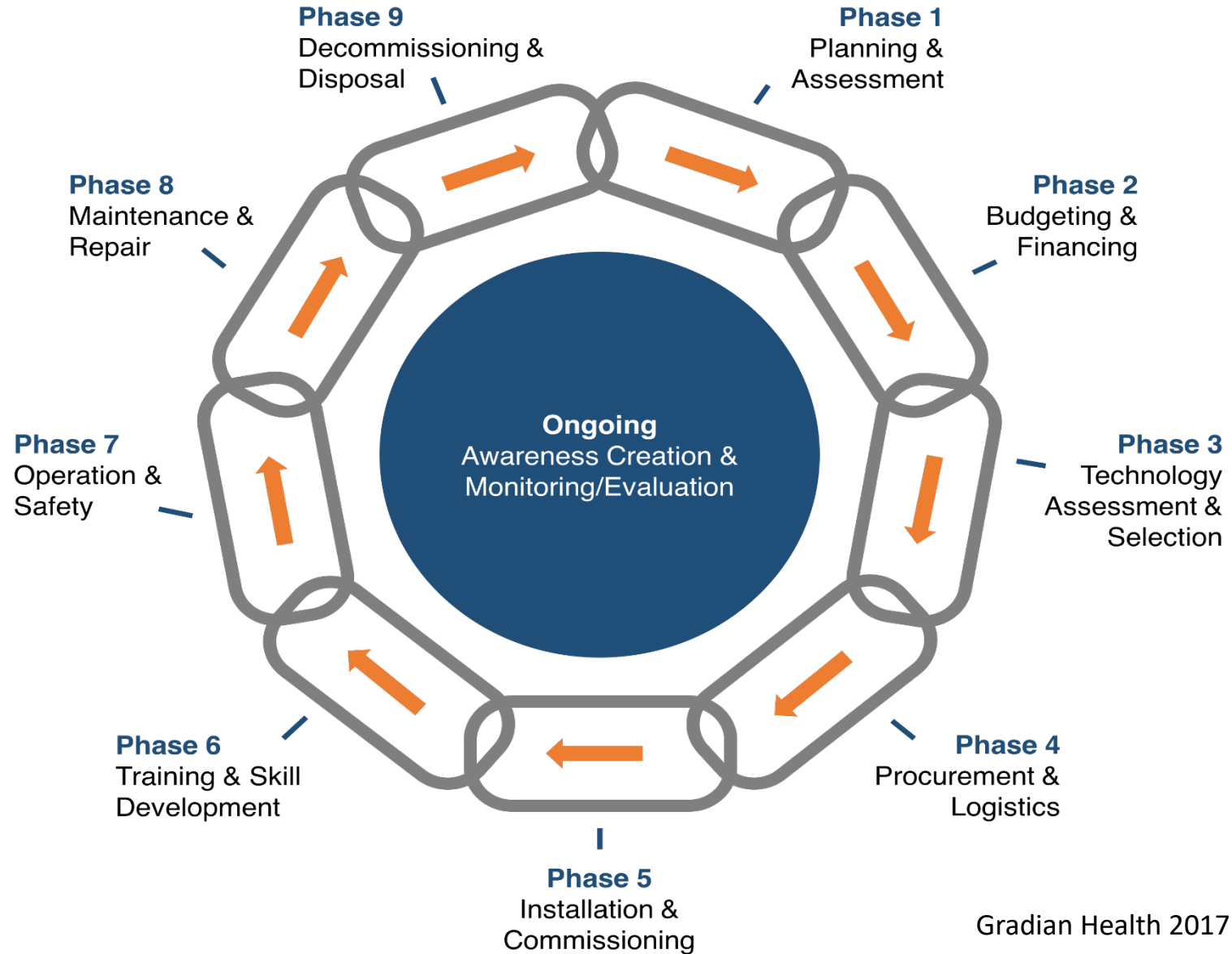
- Healthcare Technology Strategic Planning
- Technology Assessment
- Existing Technology Replacement
- Capital Budgeting
- Technology Acquisition (Product/Vendor Selection)
- Usability/Compatibility Assessment

Healthcare Technology Strategic Planning

Healthcare Technology Strategic Planning is the method of determining a health entity's healthcare technology requirements and prioritizing these needs in unison with the strategic goals of the organization while keeping within imposed corporate resource (financial, human, technical) realities.

- A comprehensive healthcare technology strategic plan has four fundamental steps.
- These fundamental steps include needs assessment, technology benchmarking assessment, technology trends review and prioritization of requests.
- These plans typically are mapped out over multi year cycles (3 to 5 years) either on fixed or rolling schedules (updated annually).

Health Technology Management Lifecycle



Gradian Health 2017

Why do we need a Strategic Plan for Healthcare Technology?

- The global medical technology growth rate is growing at a steady average rate of 5.3% from 2018 to 2022. This growth rate is expected to grow even further during the next decade.
- Many of the new medical technology innovations discovered over the last decade are now producing tangible results such as Artificial Intelligence (AI), Robotic Surgery, Genomic Editing, Wearable Medical Technology, Regenerative Medicine and Therapy and Advanced Neurostimulation, just to name a few.
- To keep healthcare costs in check there will continue to be a big movement to home healthcare in the coming years.
- To keep your organization up to date with healthcare technology and operating effectively a Strategic Plan for Healthcare Technology has never been more important than it is presently.

Assess and Document Current State of Healthcare Technology

- The first step in the development of the plan is to assess the existing entity's technology base and resource needs. This step involves reviewing current technology resources and cataloguing all major equipment's condition, age, capabilities, and service history.
- Reviewing the service history and problem reports are essential to understanding whether the device represents a potential hazard or is costing more to maintain than it would to replace.
- This step should also include a utilization review, by matching technology capacity with current and projected procedural volumes.
- Key clinical, technical, and administrative staff should be interviewed to understand the strategic, clinical, and technical needs from all perspectives.

Benchmarking of Organizational Technology Base

- It is important to compare the existing technology base in your organization against that of other institutions, especially local competitors.
- This is done so your organization can remain competitive and provide high-quality patient care.
- Review the local, state and national healthcare technology data where it is available.
- This work can identify gaps in technology and risks from continuing to use outdated technology.

Clinical and Technology Trend Review

- Review current clinical and technology trends. Consider new and emerging technologies that may make existing technology obsolete.
- Consider changes in clinical standards of care that affect technology selection.
- Review clinical and technical publications related to efficacy and cost-effectiveness of new and emerging technologies.

Request Prioritization and Plan Development

- After your inventory data is collected and validated then prioritize all needs for replacement and new technology based on established, rational criteria.
- Using the information gathered in the first three steps provides data for a ranking matrix, which reflects the relative overall importance to the organization.
- There is no ideal ranking available but there are a number of reasonably effective ranking matrices that have been developed ten to twenty years. These ranking systems are documented in many publications.
- Best suggestion is to test a few popular examples and adapt a few into a model that works best for your organization. Strategic, clinical, risk-management, and fiscal factors identified in the planning process should be included.

Justification and Impact Criteria*

Please select the applicable Criteria that support this Request, and rate the Impact by selecting from the drop-down menu option to the left of each item. Please use the space provided below the Criteria to expand on the justification for this Request.

High Impact ▾

Legal/patients/staff safety and risk management:

The request is a legislated requirement. The request is essential to address a patient and/or staff safety issue, without which safety would be knowingly compromised. The request should be based on unsafe conditions reports in the clinical literature, manufacturer information, safety alerts, radiation-protection concerns, safety/security/accessibility standards and recall information.

Not Applicable ▾

Technological and/or Material Obsolescence; Age of Equipment, Physical Condition and Reliability:

The request is essential to the operations of the service. The equipment is currently in place and working but should be replaced based on factors such as life duration, reliability and the level of support provided internally or externally. Changes or advances in a technology may make the current system clinically obsolete.

High Impact ▾

Impact on Productivity & Service Delivery:

The request will address an acknowledged service gap and have tangible and quantifiable impact on the quality and volume of services (reduced waiting list) as perceived by our clientele and by the staff (increased functionality and throughput). Requests submitted must demonstrate improvements in efficiency by reducing operating costs and increasing productivity.

High Impact ▾

Impact on Patient Experience or Local Area Priority:

The request will improve patient experience in the hospital, and reduce hospital stay, or bring positive impact for the local area.

High Impact ▾

New Technology, Best-Practice:

The request is considered as an advance to the standard of care where there is sufficient evidence showing that it will provide safer and less invasive and/or more effective provision of patient care. The request is required for the development and leadership in an area of service. The addition is based on factors such as service continuity and/or technology that will complement, expand and /or improve the existing services provided. The request is required to follow Best-practice guidelines

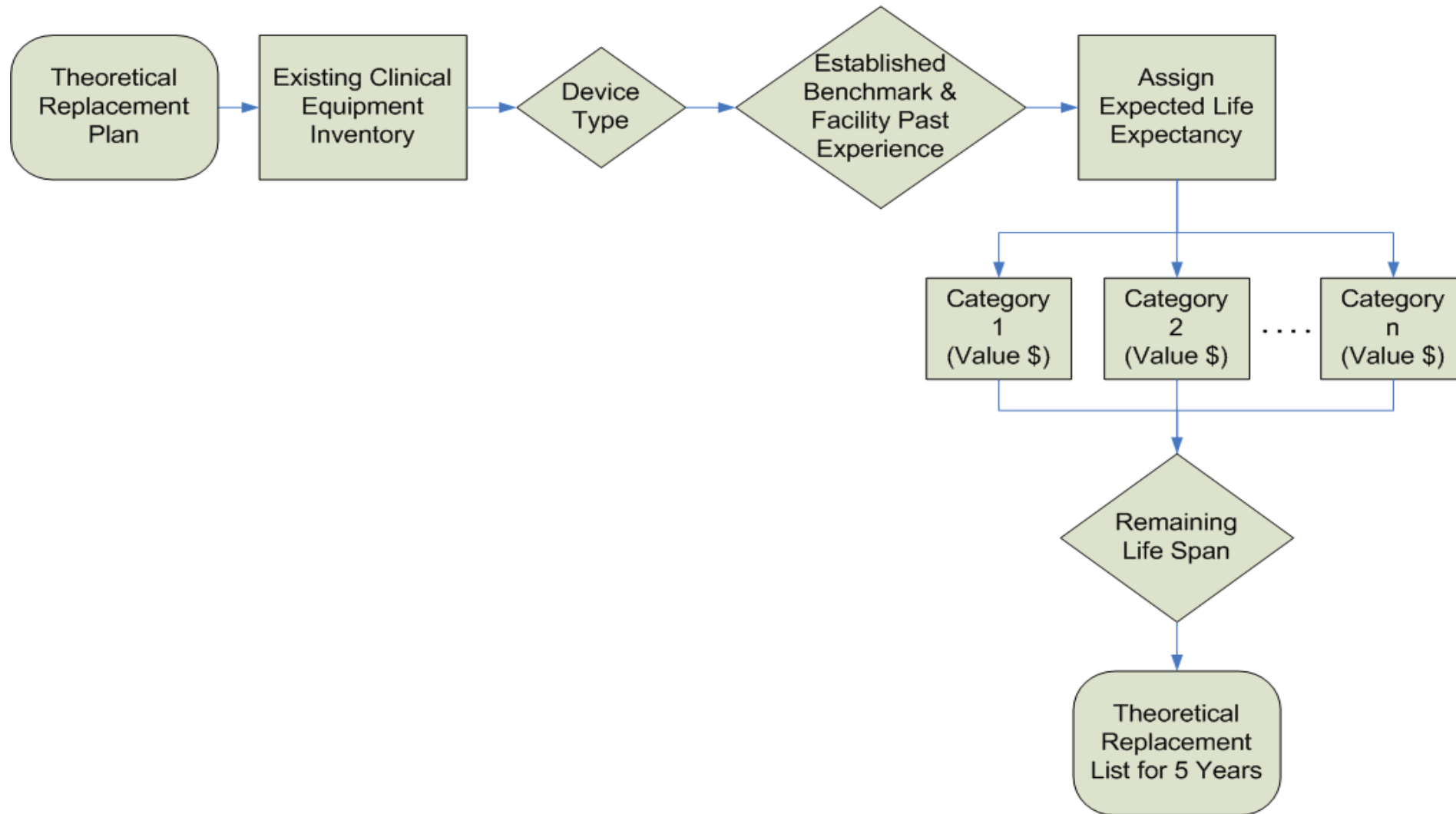
Example of a Typical Ranked List

No.	Project Category	Item requested	Project Cost	Score
6	Nursing	Large Volume Infusion Pump (Remainder)	\$ 350,000.00	100
7	Critical Care	Neonatal transport incubator (Unit 1)	\$ 250,000.00	100
8	Perioperative Services	Water System for Instrument Processing	\$ 60,000.00	100
9	Perioperative Services	Cart washer in CSS	\$ 370,000.00	100
39	Diagnostic Imaging	CT Scanner (Low Dose) Part 1	\$1,500,000.00	97
42	Fleet	4 West Beds (20 Beds)	\$ 105,000.00	92
43	Diagnostic Imaging	MRI Compatible Patient Monitor	\$ 100,000.00	92
44	Diagnostic Imaging	MRI Workstation (Syngo Via)	\$ 200,740.00	91
51	Emergency	End tidal module	\$ 10,400.00	85
52	Critical Care	Portable Transilluminator	\$ 5,995.00	83
53	Ambulatory Care	Siemens Upgrade - Snesis XP	\$ 24,000.00	83
54	Critical Care	Non-invasive ventilator (Bipap Vision)	\$ 30,000.00	84
55	Ambulatory Care	Ultrasound Unit	\$ 124,000.00	85
56	Laboratories	Water Purification System	\$ 45,000.00	86
57	Emergency	Slit lamp and chair	\$ 22,000.00	87
58	Critical Care	End tidal module	\$ 26,000.00	88

Request Prioritization and Plan Development

- Consistency with the overall institutional strategic direction; costs of ownership and operation over the device's expected lifespan, as well as up-front capital costs; construction costs, reimbursement conditions and overall relevance to the provision of high-quality patient care are part of the analysis.
- A well-developed strategic technology plan which is in sync with the corporate strategic plan can result in long term savings, transforming technology spending into future organizational effectiveness.
- This plan aids the annual corporate capital request decision making process.

Technology Replacement Plan Development



Strategic Technology Planning

- Prioritizes clinical needs against availability of resources (financial, space, human).
- Helps better schedule the staging of major capital projects including fleet replacements.
- Encourages the effective design of the annual capital budget process.
- Leads to system wide improvement of the reliability of medical devices which translates into increased capacity and a safer patient environment.

Definition of Technology Assessment

- Health Technology Assessment (HTA) is the systematic evaluation of properties, effects or other impacts of health technology.
- The main purpose of HTA is to inform policymaking for technology in health care, where policymaking is used in the broad sense to include decisions made at, e.g., the individual or patient level, the level of the health care provider or institution, or at the regional, national and international levels.
- HTA may address the direct and intended consequences of technologies as well as their indirect and unintended consequences. HTA is conducted by interdisciplinary groups using explicit analytical frameworks, drawing from a variety of methods.

National Library of Medicine: <https://www.nlm.nih.gov/nichsr/hta101/ta10104.html> (2022)

Technology Assessment

- Continued advances in medical technology have had a substantial impact the daily operations of all healthcare organizations.
- More complex and highly integrated medical devices necessitate a well-structured technology assessment process as part of the overall equipment planning for the hospital.
- This activity includes a multidisciplinary team of stakeholders with the necessary knowledge and expertise to address the needs of patients, users and support teams when selecting a safe and effective technology that will also provide an optimum ROI (Return on Investment) for the hospital.
- Clinical Engineers are charged with the task of analyzing the hospital's existing technology base during the overall technology planning process.

Technology Assessment

- Requests for technology assessment are generated either on an adhoc basis throughout the course of the year but requests often peaks during the period of the annual call for clinical capital in many facilities.
- Each year clinical departments work closely with the Clinical Engineering department to submit their capital requests based on age of equipment, estimated useful life, condition, reliability, safety compliance with standards and best practices, and other criteria such as patient or staff experience.
- The capital request is submitted to corporate capital priorities team. Members from this team and Clinical Engineers review the requests and evaluate the condition of the existing technologies, paying close attention to continued applicability, remaining useful life, operability and usability, current needs, cost of support/maintenance and more.
- This team is composed of a multidisciplinary task force of Clinicians, Finance, Procurement, Executive Office, Clinical Engineering, Information Services and Facilities Management.

Resources for Technology Assessment

- Clinical Engineers make use of various tools during the technology assessment process including:
 - National conferences and medical technology exhibits (i.e.. HTAi, RSNA, ACCE, AAMI)
 - Database services, directories, university libraries, ECRI, AAMI publications, FDA, NIH (US) publications, CADTH (Canada) and networking with other professionals in hospitals and industry just for starters.
- These tools and resources are essential to Clinical Engineers as they move forward with evaluating and recommending new technologies.
- After the initial research is completed, the Clinical Engineer would bring their findings back the team to allow them to collectively assess the need, impact, cost and benefits of the proposed replacement technology against the current standard.

Technology Assessment Decision Making Process

- All the stakeholders have different responsibilities in the decision-making process.
- The Clinical Engineer evaluates the proposed equipment, reviews its application in a clinical environment by working with Nursing, Physicians and other healthcare professionals and performs the necessary technical evaluations
- Then validates its regulatory compliance ensuring that the device's FDA or other agencies approval matches with the intended clinical application and is not being used incorrectly (off label).
- Hospital legal counsel may need to get involved at this juncture to assist in the evaluation process.
- Finally, the cost of parts, maintenance, reimbursement, service contracts, consumables where applicable, and other related financial criteria are reviewed with Purchasing and Finance. Facilities and Information Services may also need to provide input on the feasibility and timing of implementation of the proposed solutions.

Closing the Loop on the Technology Assessment

- The results from equipment evaluation are scored and presented to the hospital's value analysis or medical technology assessment or product evaluation committee or equivalent.
- Only **IF** the equipment successfully passes the technical evaluation and achieves a high score will it receive full approval from the committee and then proceed with clinical trial.
- The Clinical Engineer subsequently sets up the desired clinical trial and designs appropriate evaluation tools to gather feedback from the users. If the clinical trial is successful, the results along with the results from the technical and financial evaluations will be presented to the hospital administration.
- This activity will then close the loop on the full assessment on the desired technology that is safe, effective, efficacious and cost effective for the hospital.

Role of the Clinical Engineer in the Assessment Process

- Initiating, managing and planning the evaluation process.
- Coordinating the process and test protocols.
- Overseeing the technical evaluation and testing.
- Bringing the stakeholders together to come to consensus on the conclusions from the evaluation.
- Summarizing the recommendations in a summary report and submitting for final executive approval.

Technology Replacement

- In an ideal world your facility Clinical Engineering's Computerized Maintenance Management System (CMMS) reduces the need to make snap decisions during a crisis situation.
- Steers the decision-making process away from subjective or hearsay influences (“this equipment is ten years old and has never worked properly”).
- Prioritizes end of life / end of support devices with a systematic methodology.
- Although this is theoretical plan it can be tied to your corporate strategic or capital plans.
- You can use a consistent numerical ranking system in all three instances which encourages buy in from the clinical staff and executive team.

Technology Replacement

- The technology replacement report although theoretical should cover all of the medical devices within a facility including fleet devices. All of the devices within a facility that provide the same purpose (e.g. vital signs monitors, stretchers, ultrasound machines are a few examples).
- These key replacements should be planned over a 1 to 3 year cycle depending on resource availability.
- Key resource is the American Hospital Association “Estimated Useful Lives of Depreciable Hospital Assets” 2018
- see <https://ebooks.aha.org/15tjdqn/>

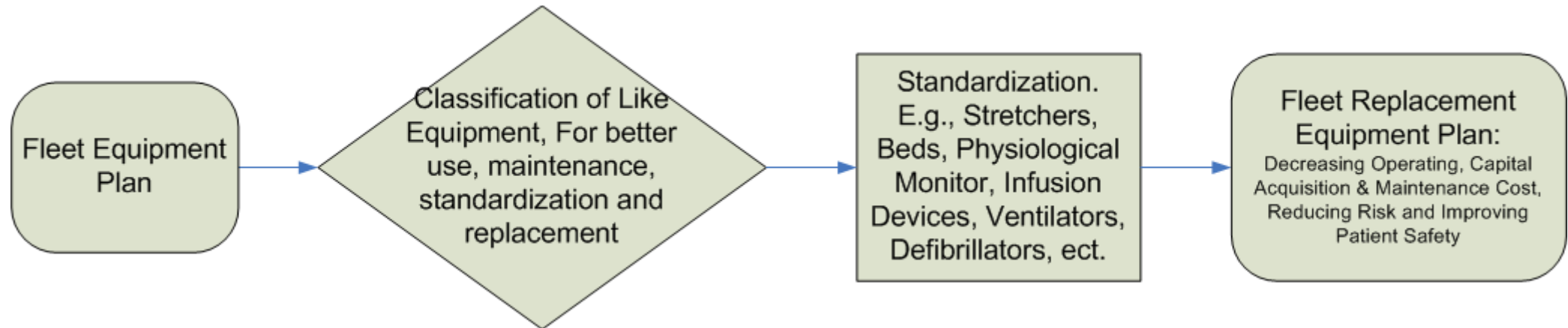


Technology Replacement

Fleet Management

- Fleets are a group of assets that are standardized throughout your healthcare facility
- These assets may be used by one department or may have multiple users and maybe interchanged between departments (e.g. infusion pumps)
- The minimum number of assets that should be grouped as a fleet is 5.
- Most fleet equipment are high volume, lower cost equipment.
- Standardization helps to reduce human factor variabilities, reduce consumable cost.
- Using the fleet management concept better manages the replacement of large inventories of like devices.
- Standards are set through a replacement process and then implemented over a few years as the budget allows.

Fleet Equipment Replacement



Technology Replacement

- Limited capital equipment contingency budgets are usually limited to between 5 to 10 percent of the overall capital budget.
- Technology replacement reporting data can be key in taking the pressure off of meager capital contingency budgets.
- Important to the decision-making process is the CMMS.
- If key data is captured within each equipment inventory record including details of previous safety recalls, incident reports, all maintenance and repair costs, reliability issues and age over the entire lifespan of a device then it greatly simplifies the process.

Technology Replacement

Maintenance Factors

- Service support (End of Support) has passed or nearing its end of term.
- Service contracts are not available, replacement parts are getting scarce, inhouse staff, may no longer be available than are familiar with the service of this device.
- Test jigs or calibration equipment or software no longer available.
- Device operating system is no longer supported.
- End of Life. Support will no longer be provided by the original manufacturer.
- Maintenance costs are in the range to 25 to 50 percent of the replacement cost.
- Reliable issues are routinely coming to light.

Technology Replacement

Other Impacting Factors:

- Age (date of manufacture or installation)
- Recommended Life Expectancy
- Recalls (FDA or Manufacturer) some cannot be resolved.
- Device removed from market.
- Incident reports

Technology Replacement

Other Factors:

- Standardization within facility
- Strategic Plan directional change.
- Changes in standard of care within the facility
- Cost advantages with newer technology. Cost of ownership is less.
- Clinical preference to use newer technology. (Improved Useability)

Technology Replacement

High Priority Replacements

- Unresolved Safety Concerns, No Parts or Support, Regulatory

Medium Priority Replacements

- Increased Revenue Potential, Documented Reliability Concerns, Below Standard of Care

Low Priority Replacements

- Undocumented Reports of User Problems, Age of Device, Newer Technology Available

Technology Replacement

- Technology replacements need to be factored into the capital plan.
- Single item replacement should have the buy in of the specific end user department.
- Fleet item replacements should be championed by Clinical Engineering with the support of key departments (Nursing, Information Services, Surgery, etc.)
- Ranking criteria must be flexible enough to prioritize safety and obsolescence issues ahead of new technology.
- This decision-making process goes beyond the annual capital cycle. It is an ongoing process that is required to resolve issues as they arise during the course of the year to make repair - replace decisions.

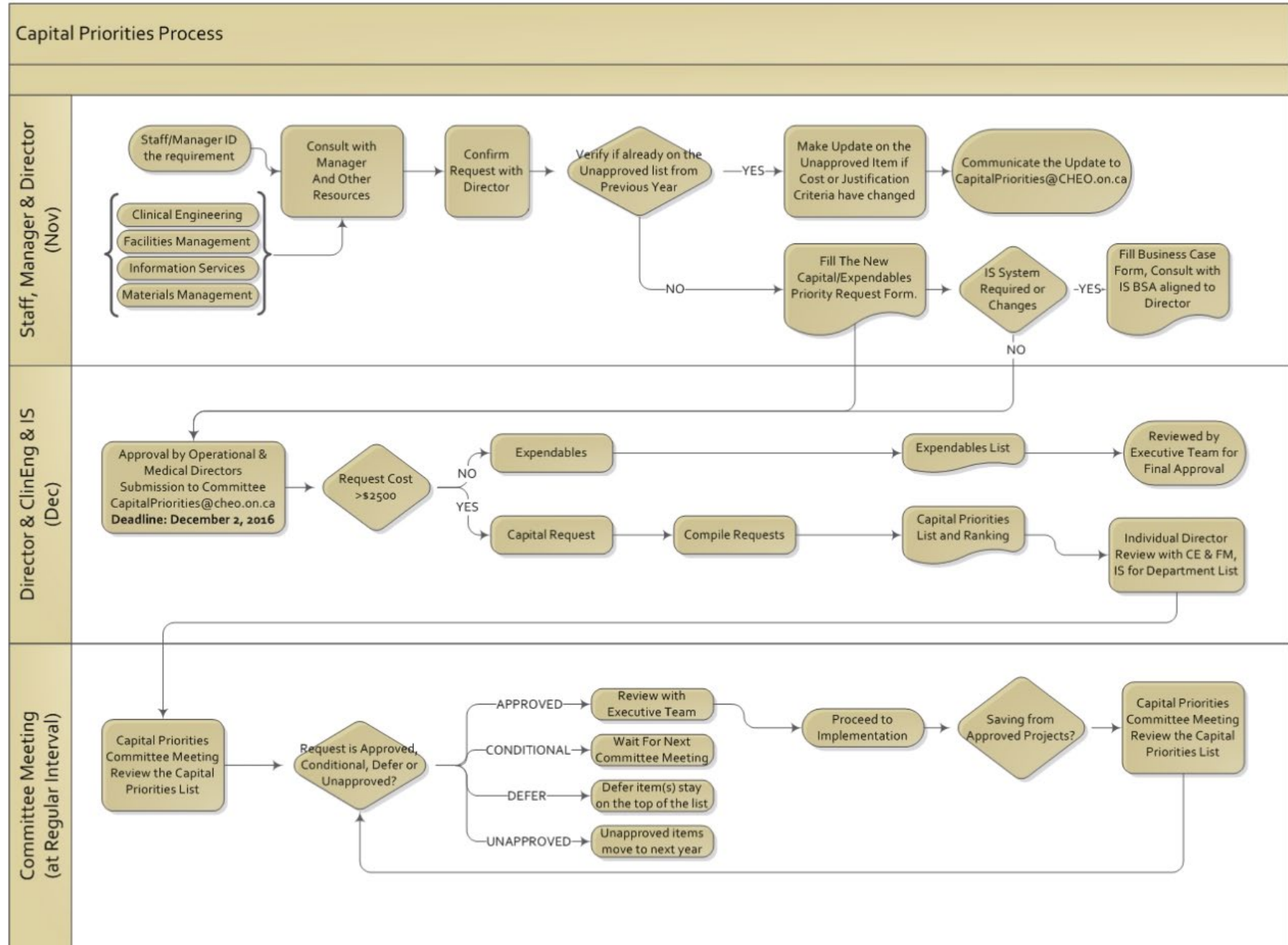
Capital Budgeting

- The capital budgeting process is developing a plan for major purchases over the course of the upcoming fiscal year. It can involve equipment, facility renovations or upgrades or information technology upgrades.
- The term capital purchase refers to the purchase threshold at which a facility has designated to expense the purchase cost of a device over the estimated useful life of the equipment as opposed to an immediate financial transaction as occurs with minor equipment.
- This threshold value is either determined by the facility or its supervising authority and will vary between organizations.
- Most facilities have working group that leads the annual capital priorities process. It is usually led by the Chief Financial Officer and Chief of the Medical Staff.

Capital Budgeting

- The capital priorities committee membership usually is comprised of individuals from the Executive Office, Finance, Procurement, Corporate Planning Office, Medical and Administrative Program leads, Clinical Engineering, Facilities Management and Information Services.
- An annual call for requests is made usually several months before the start of the fiscal year.
- All of the capital requests are ranked by a scoring tool and then considered by the capital priorities committee and working subgroups.
- The Committee will eventually come to a consensus on which capital projects to recommend the Executive Team & the Board of Directors based on the available capital budget for the upcoming fiscal year.
- Once the annual capital budget is approved the working teams for each capital group can begin planning their approach for their projects.

Example Capital Priorities Process:



Technology Acquisition Process

- Once the capital budget is approved the work really begins on the acquisition of this new medical device(s).
- Clinical Engineers review whether the desired product is a standardized product in the hospital or perhaps a new technology or application that has not been evaluated by the Clinical Engineering previously.
- If there is no standardized product then Clinical Engineering will develop a detailed specification for this product with input from the appropriate clinical staff (specific nursing and physician leads, Medical Device Reprocessing, Information Services, Facilities, Procurement and others as required.

Technology Acquisition Process

- Once the device basic technical requirements are drafted, a market survey is conducted to determine what products are available on the market using available research tools (Internet, ECRI, manufacturer websites). This step may include sending out a Request for Information proposal out to market to gain more insight into this device.
- Procurement processes for medical devices, equipment and technologies may include a competitive process such as a Request for Information (RFI), Request for Quote (RFQ), Request for Pre-Qualification (RFPQ), Single or Sole Sourcing and Request for Proposal (RFP). . The process needs to be carried out in an open, fair and transparent and must meet the legal guidelines for procurement.

Technology Acquisition Process

A determination first must be made by the committee on whether to lease, outright purchase or use a consumable agreement to acquire the device in question. Some front analysis must be done by the team.

Options should be evaluated from several vendors. Questions include:

- What is the ongoing operating cost?
- What is the ongoing maintenance cost?
- Will more BMET labour be required to support this product?
- Will ongoing operational savings be realized with the conversion to a new product?

Technology Acquisition Team

In the United States the Joint Commission requires that formal processes be established for selecting and acquiring medical equipment and completing incoming inspection of all newly acquired medical equipment

- EC 2.04.01 : The hospital solicits input from individuals who operate and service equipment when it selects and acquires medical equipment.
- EC 02.04.03 ; Before initial use of medical equipment on the medical equipment inventory, the hospital performs safety, operational and functional checks for both high risk and non-high risk medical equipment.

In Canada, Accreditation Canada has similar requirements within its Leadership Requirements under the Medical Devices and Equipment section

- 9.4 There is a formal and open process for selecting and buying medical devices and equipment, and for selecting qualified suppliers.
- 9.7 Plans or processes for maintaining, upgrading, and replacing medical devices and equipment are followed.

Technology Acquisition Team

Often ad-hoc teams developed from a formal committee most often directed by Finance. These individuals are asked to work an acquisition team for a specific project.

Membership will include some or all of the individuals listed:

- Finance
- Procurement
- Clinical Users (Nursing, Medical staff, Pharmacy)
- Program lead responsible
- Clinical Engineering
- Facilities
- Information Services

Technology Acquisition

- Will IS interface work be required for this new device and what are the resource implications?
- Will facility renovations be required what are the resource implications?
- Will this purchase be in line with hospital strategic and capital plans?
- Are there implications with disposables, pharmaceuticals or regents?
- There should be a committee consensus decision on the acquisition approach
- Most importantly the committee consensus decision must meet the needs of all our patients?

Technology Acquisition Resource Material

- ECRI
- MD Buyline
- KLAS Reports
- CADTH Assessment Reports (Canada)
- Professional Conferences (RSNA, ACC, etc.)
- Group Purchasing Organization (GPO)
- Your colleagues

Request for Information (RFI)

- Often used at the start of an acquisition process to collect written information (specifications, manuals, user lists etc.) about the capabilities of various suppliers. Normally it follows a standardized format that can be used for comparative purposes.
- Normally an RFI is used to gather information to help make a decision on what steps to take next in the procurement process.
- RFIs are not intended to be a final stage purchase document therefore it is seldom is the final stage of acquisition.

Request for Quotation (RFQ)

- RFQ is a business process in which a company or public entity requests a quote from a supplier for the purchase of specific products or services.
- RFQs normally include the specifications of the items/services received to make sure vendors are bidding on the same item/service (apples for apples). A good rule thumb in this situation, the more detailed the specifications, the more accurate the quote will be and its comparability to the other vendor's responses.
- Another reason for providing adequate detail in your RFQ document is that these specifications could be used as legal binding documentation for the vendors in a formal agreement.

Request for Proposals (RFP)

- Effective RFPs typically reflect the strategy and short/long-term business objectives, providing detailed insight upon which suppliers will be able to offer an acceptable submission.
- Informs suppliers that an organization is looking to a commodity or service and encourages them to make their best effort.
- Requires the company to specify what it proposes to purchase. If the requirements analysis has been prepared properly, it can be incorporated quite easily into the Request document.
- Alerts suppliers that the selection process is competitive.

Request for Proposals (RFP)

- Allows for wide distribution and response.
- Ensures that suppliers respond factually to the identified requirements.
- Is generally expected to follow a structured evaluation and selection procedure, so that an organization can demonstrate impartiality - a crucial factor in public sector procurements.
- Always keep in mind that the RFP and the successful vendor response will form a substantial portion of the final purchasing agreement and is therefore a legal agreement. Spend as much time as necessary to fine tune this document.

RFP Typical Composition

Sections of an RFP:

- General Information
- Mandatory Requirements
- Technical Requirements
- Power Requirements & Battery
- Alarm, System & Event Logs
- Integration with the Electronic Medical Record (EMR)
- Accessories
- BME Requirements
- Material Properties, Cleaning
- Documentation requirements
- Training
- Implementation

RFP Typical Composition

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Source: https://procurement.novascotia.ca/pt_files/tenders/IWK-2019-C010-RFP.pdf

RFP Evaluation Process

- The evaluation team will review the responses and score the individual sections.
- At this point vendors maybe shortlisted to 2 or 3 vendors for evaluation.
- An inhouse evaluation maybe conducted or with larger equipment the evaluators may go on site visits. This evaluation will be then scored.
- Inhouse evaluations are normally conducted in a simulation lab settings but in specific some cases the equipment is placed into active use during evaluation.
- User references are checked and scored.
- The summary scoring is reviewed by the evaluation team and consensus decision is agreed upon.
- Next step is to negotiate with the preferred Vendor. If negotiation is a success then on to purchase of the equipment.
- Important to remember three words:

Confidentiality, Fairness and Transparency

Sole and Single Source Acquisitions (Non-Competitive Procurement)

- **Sole Source** is the use of a non-competitive procurement process to acquire goods or services where only one supplier is able to meet the requirements of a procurement. Often custom designed and constructed items.
- **Single Source** is the use of a non-competitive procurement process to acquire goods or services from a specific supplier even though there may be more than one supplier capable of delivering the same goods or services. This method is used when urgency necessitates this approach such as a catastrophic failure or damage to a piece of equipment or serious recall issue.

Standardization

Advantages of Standardization

- Better pricing on long term capital agreements.
- Operational savings with service support costs, consumables pricing, service and clinical training.
- On-going in-house service support is more streamlined.
- Straightforward ongoing clinical training programs.
- Improved Patient Safety – Decreases the likelihood of clinical user errors.

Disadvantages of Standardization

- Noncompetitive prices on upgrades.
- Becoming comfortable with one vendor and failing to keep abreast with current developments.

Review of the Quotation

All quotations should be requested formal format from the supplier on their corporate letterhead and be authorized by the company's signing authority.

- Name, title, and signature of company's authorized agent
- Your facility name.
- Date of Quote and Expiration Date.
- A complete itemized listing of all quoted components with current catalog numbers.
- Total purchase price with tax breakout.
- Payment terms.
- Delivery and Freight Costs.
- Installation costs, timing and responsibilities.
- Discount.
- Quotation Reference Numbers.
- All training/ education to be provided (with associated costs).

Usability and Compatibility Evaluation

- Health Technology Assessment (HTA) must be performed before purchasing a device and also continuously after the device is deployed.
- The main reason for performing HTA is to identify the device with the best performance, when compared to alternatives.
- It is a decision-making process, where a decision is made whether to procure a new technology or not, based on its efficiency, efficacy, workflow compatibility and best value for money.

Source: Cravern, M.P., 2006. Routes and requirements for realizing pervasive medical devices (Chapter 9). In: Bardram, J.E., Mihailidis, A., Wan, D. (Eds.), Pervasive Computing in Healthcare. CRC Press, Taylor & Francis Group. ISBN 084933621X

Clinical User Survey

Evaluation form is completed by the clinical users and feedback is obtained on:

- Ergonomics (Ease of use, ease of transport etc.)
- User interface/Features
- Entering Patient Demographics
- Alarms
- Transducers and other accessories
- Complexity of using the equipment
- Compatibility to current workflow etc.

Purchasing Medical Devices-Pre-purchase Evaluation/Assessment

- Collecting necessary documentation and information to evaluate the purchase including manufacturer's instructions for use (IFU) and licensing information
- Confirming that the device meets the regulatory licensing requirements
- Checking with other facilities who are using the model
- Confirming that the device meets minimum requirements and necessary resources are in place:
 - Technical requirements
 - IT requirements
 - Installation and Facility modification requirements (Electrical, ceiling mount etc.)
 - Compatibility if used in conjunction with other equipment
 - Clinical user training and Biomed training
 - Reprocessing requirements
- Setting up a trial of the equipment and obtaining evaluation results and feedback from the clinical users

Source: "Purchasing Medical Devices – Pre-purchase Criteria for End-Users", Alberta Health Services, 2019

Purchasing Decision & Agreement

Don't forget the following before signing off:

- Service training availability, cost of additional training course in upcoming years and training facility location.
- Service training course you staff receive should be the same as the one the vendor service techs receive.
- Are specialized test equipment and jigs required?
- Diagnostic software cost, availability and licensing requirements.
- Technical support line.
- Vendor service considerations call back time & on-site response time.
- Time & materials rate (standard, OT, travel).
- Service Contract Options - PM frequency, uptime guarantees, coverage, exclusions.

Purchasing Decision & Agreement

- Full service and operator's manuals (electronic copies or lifetime web access).
- Software update agreements for life of equipment.
- Parts and support availability guarantee.
- Loaner unit availability.
- Service reports availability (mandatory).
- Warranty and options.
- Specific environmental requirements (temperature, humidity, electrical, cooling requirements)

Purchasing Decision & Agreement

Don't forget the following:

- Service Training Availability
 - Cost, Location (On-Site Is Best)
 - Same As Vendor Provides Its Reps
 - Hospital's Choice Of Individual
- Specialized Test Equipment
 - Cost, availability, training requirements
- Diagnostic Software
 - Cost, Availability, Training Requirements, Licensing
- Technical Support Line
- Vendor Service Considerations
- Call Back Time & On-Site Response

Purchasing Decision & Agreement

Don't forget the following:

- Time & Materials Rate
 - (Standard, OT, travel)
- Service Technician Qualifications
- Service Contract
 - Pm time, uptime guarantees, coverage
- Documentation - 2 Copies
 - Operation Manuals, Video Tapes
 - Service Manuals
 - Theory Of Operation
 - Pm & Troubleshooting
 - Detailed Schematics
 - Parts Lists

Purchasing Decision & Agreement

Don't forget the following:

- Software Updates For Life Of Equipment
- Parts Available For The Life Of The Equipment
 - Ship Critical Parts Within ? Days
 - Exchange Policy
- Service Reports Provided By Manufacturer's Service Rep.
- Warranty (Detailed)
- Environmental Requirements Satisfied
 - Temp, Humidity, Electrical, Etc.

Negotiations

You may negotiate the following:

- **Price** -- Equipment and service contract pricing (Usually 3 to 5 years for equipment pricing, service 5 to 10 years)
- **Upgrades** -- Negotiate at no charge for a given period of time or negotiate a discount for the life of the equipment for both hardware and software.
- **Installation** -- Initial equipment installation and turnkey construction.
- **Service** -- Response time; replacement parts consignments and pricing agreements, support agreements.
- **Training** -- Clinical staff and BMET. Initial and follow-up sessions.
- **Previews** of new products/enhancements.
- **Warranty** start date, term and exclusions.

Technology Implementation

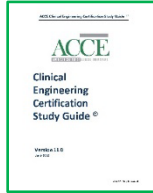
- Agree on a delivery date.
- Complete construction if required.
- Installation or deployment terms. Testing of equipment.
- Training
- Acceptance Approval.

Acceptance Testing

- During Incoming Inspection check that the order is complete, the device is deemed to meet to the manufacturer's specifications and all required documentation (manuals, test jigs, etc.) are included.
- In some cases, the vendor must complete commissioning of the equipment.
- The electrical and radiation safety is validated.
- Staff user training is completed.
- Final payment depends on the terms of the agreement. Sometimes immediate, after first use and after 30 days of use.

Session #1: Technology Management I References

1. ACCE Certification Study Guide Version # 12, June 2023.



2. American Hospital Association [“Estimated Useful Lives of Depreciable Hospital Assets”](#) 2018

3. Clinical Engineering Handbook



4. [The Joint Commission](#)
5. [HTA 101 – Introduction to Health Technology Assessment – NIH](#)
6. [Health Technology Management, Open University](#)



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