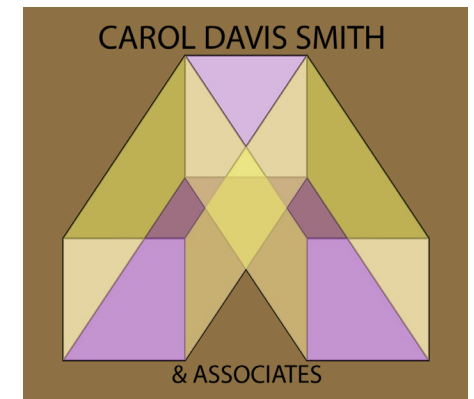


# Understanding the Acquisition Process for Medical Devices

Carol Davis-Smith, CCE FAACE AAMIF  
October 17, 2019



# Why should I care about the acquisition process?

Healthcare organizations today are increasingly mission driven, safety focused, business minded, results oriented, and **cost conscious**.

Clinical equipment planning, acquisition, and sustainability are more **consequential** and **technically complex**.

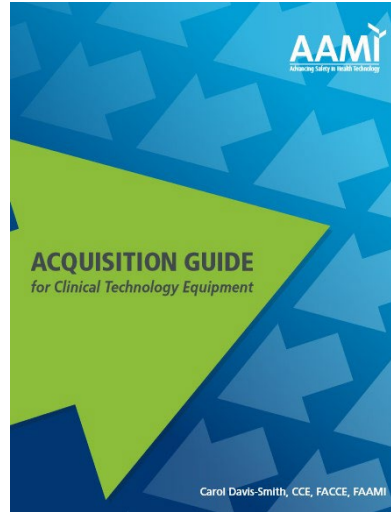
Opportunity to help your organizations make **optimal decisions** that will serve them well throughout the equipment's life cycle.

# Today's Agenda

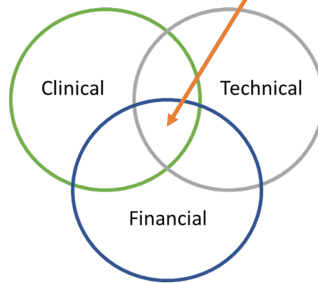
Background – AAMI Guide & Standards

The Acquisition Process

Next Steps for HTM Depts – Leading Practices



Optimal balance between Clinical, Technical, & Financial considerations



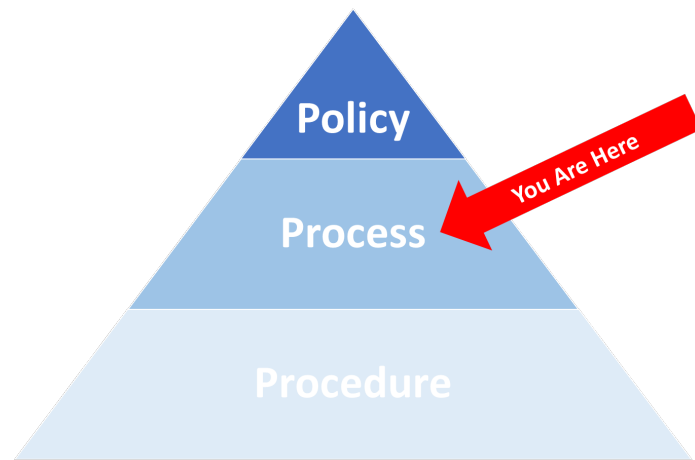
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# Key Points

**Inclusive of all perspectives** to encourage great levels of collaboration - clinicians along with HTM, Facilities, IT, Supply Chain, and Finance professionals

Supports organizational efforts to **acquire** medical devices and systems more **strategically** and effectively

New professionals will find the guide to be a comprehensive introduction to the acquisition process regardless of their position or organizational size



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# What's in the guide?

This guide documents the **process** – not the specific policies or procedural steps – of acquiring clinical technology equipment.

Policies and procedures account for specifics

- Organization strategies & structure (e.g., depts, titles)
- Local regulations & economies

**A process must be universal to serve as a standard.**

The process is applicable to the acquisition of

- a single device
- a fleet of devices
- small or large systems
- new technologies
- replacement devices or systems

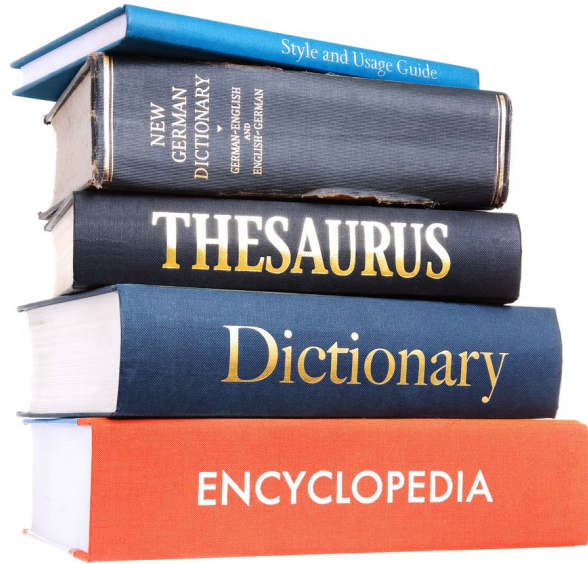


# Regulations & Standards

The guide does not supersede federal, state, or local regulations.

The guide does not supersede your organization's policies and procedures.

Instead, the guide should **complement and supplement** the regulations, policies, and procedures applicable to your organization.

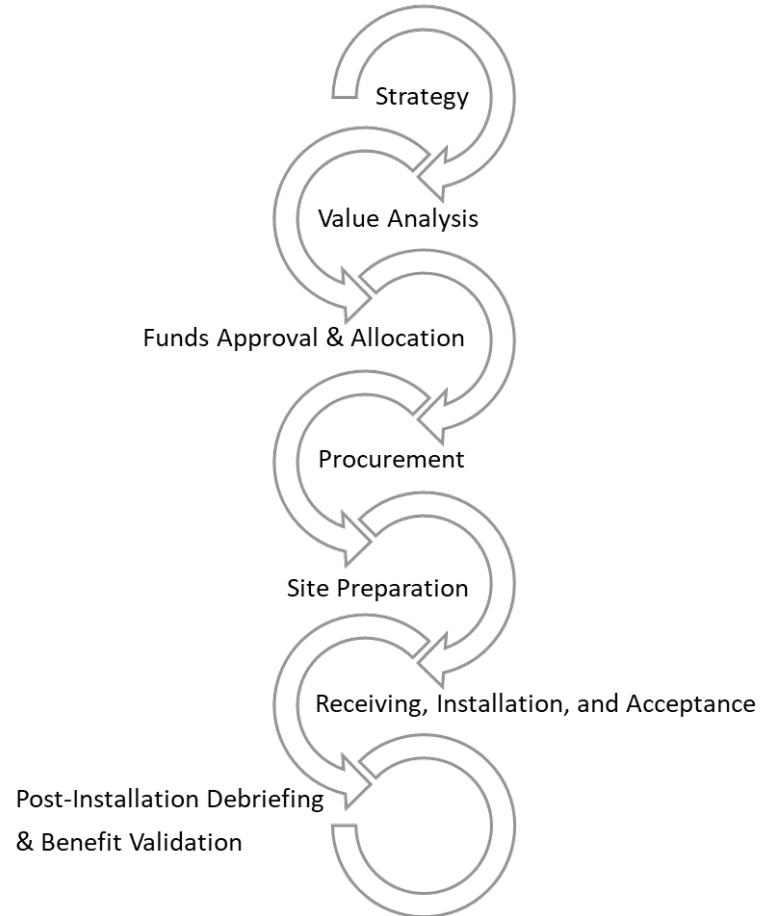


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# Definitions

# References

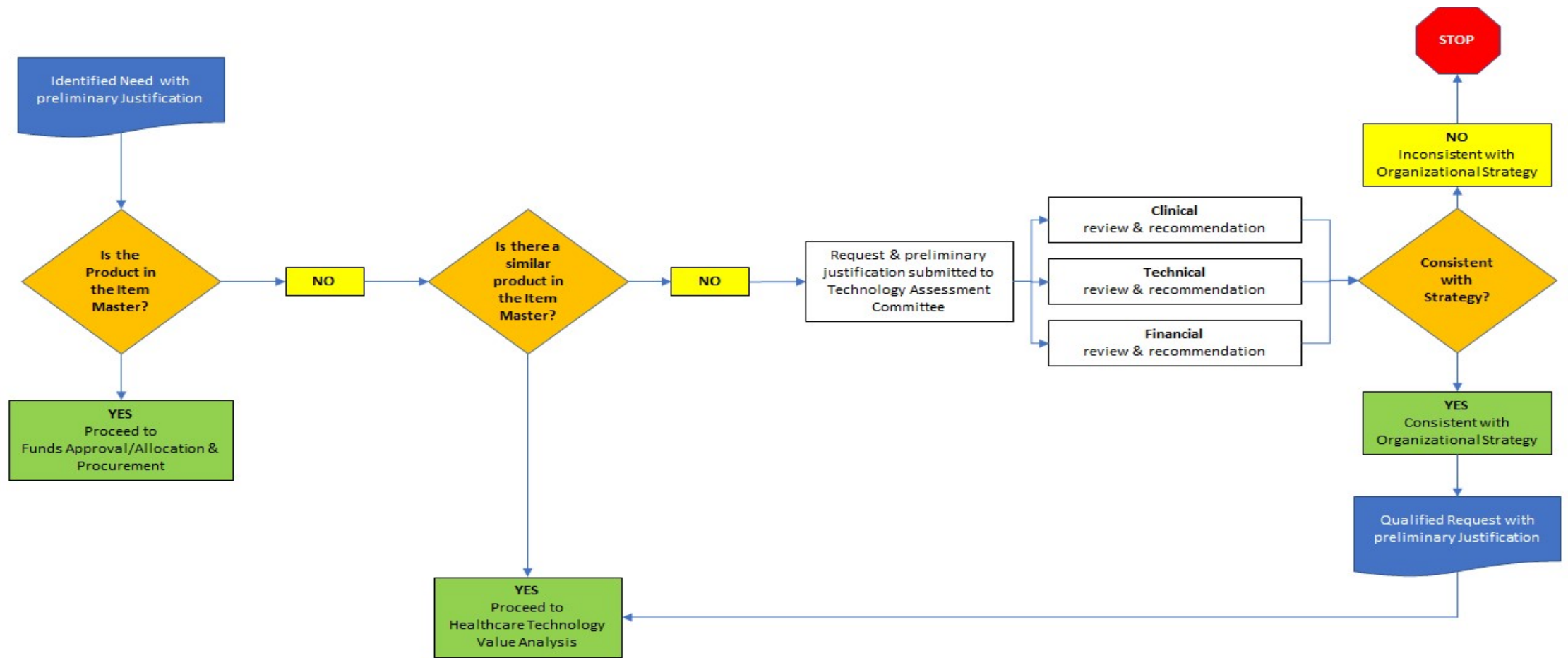
# Additional Resources



# The Process

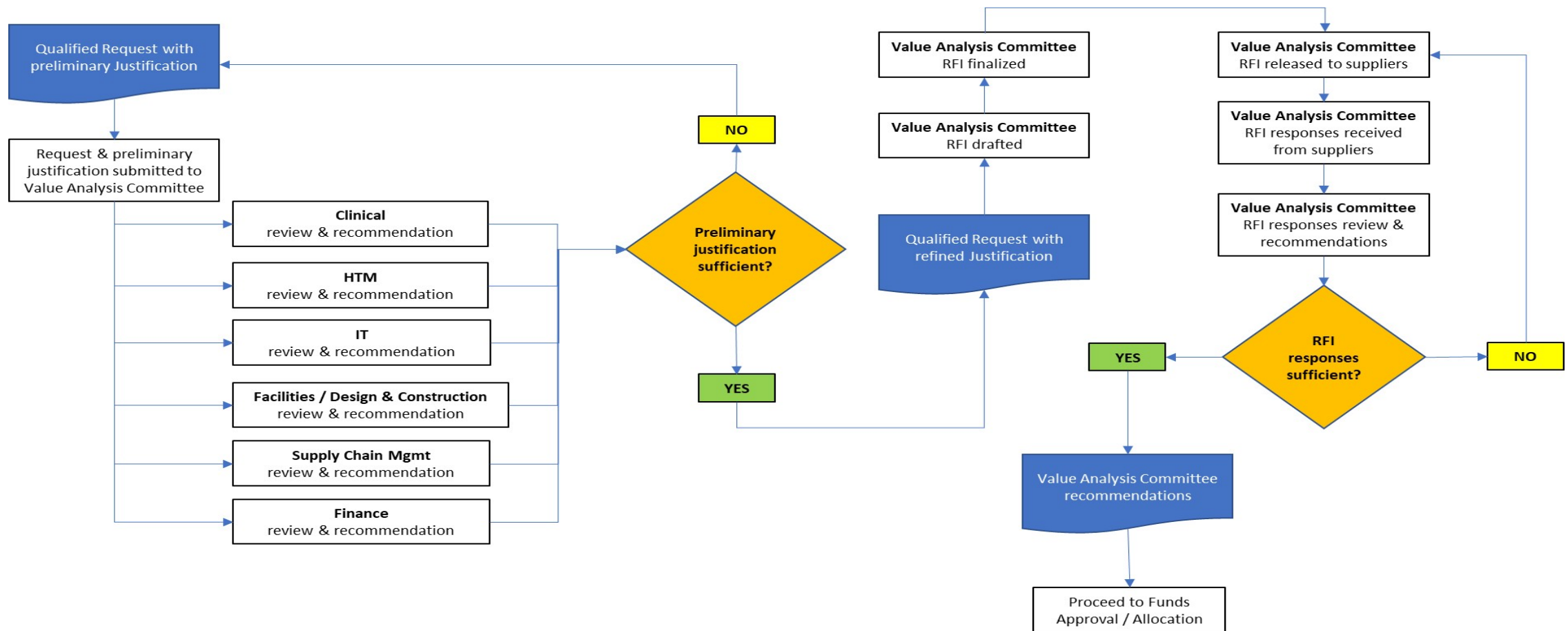
When each of the phases is executed in a consistent, standardized manner, the probability of excellent outcomes greater.

When any of the phases or steps within any required phase are omitted, operational and clinical outcomes may be compromised.



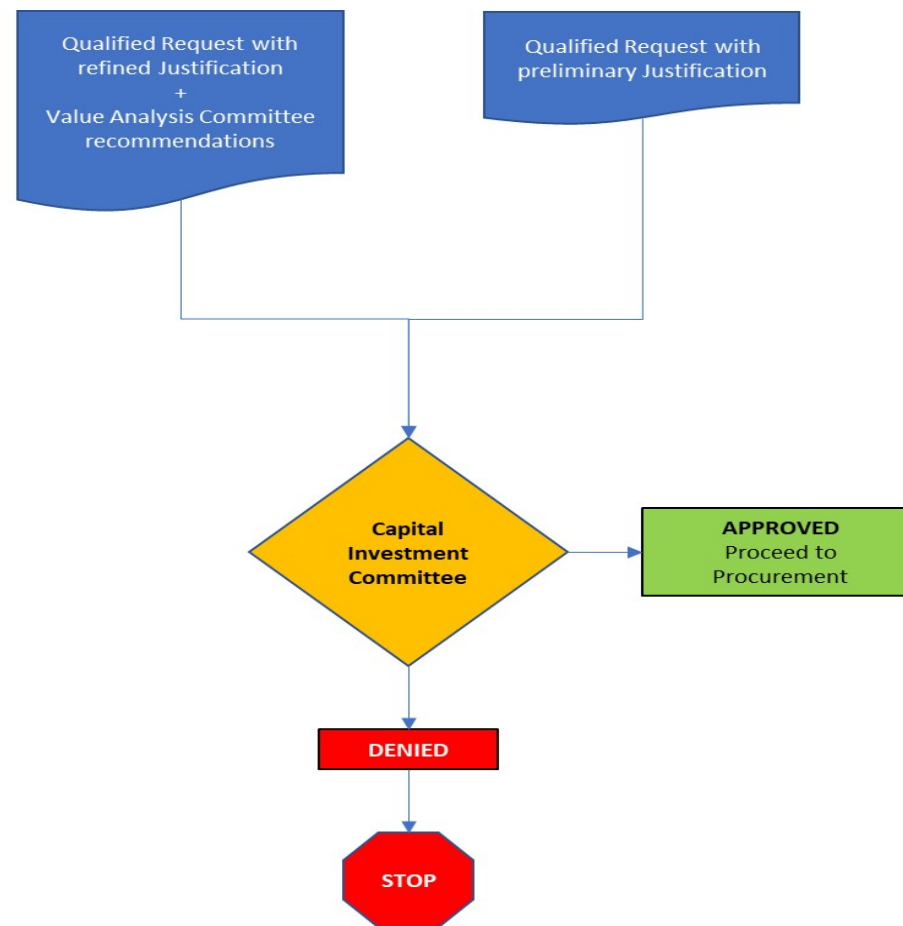
## Strategy

Define the **functional requirements** that will meet the specific clinical, technical, and financial needs of your organization. Be brand agnostic with your strategy—don't cut and paste performance specifications from suppliers.



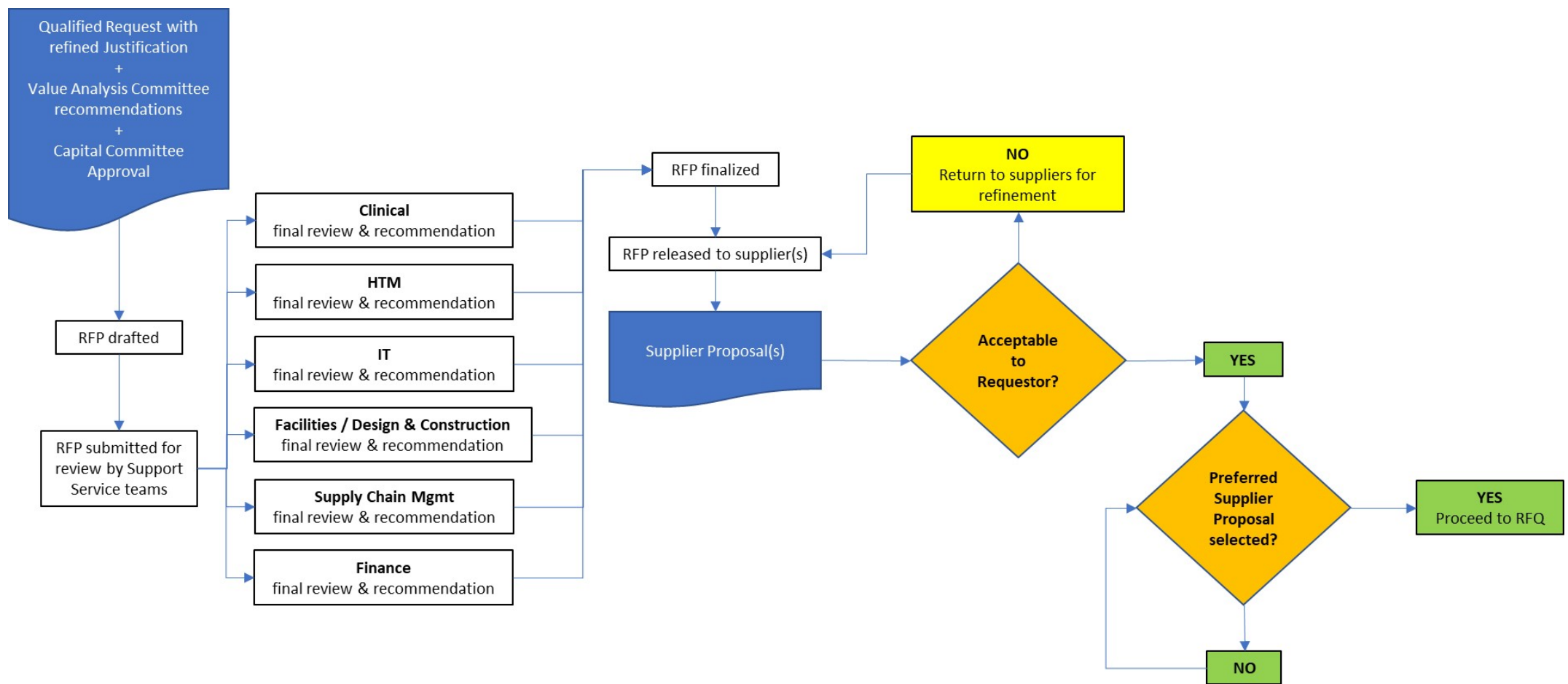
## Value Analysis

Due diligence up front can save a lot of time and money. Be a smart prospective buyer. Put all your **requirements** on the table, from **manuals, training, services, and support** to total cost of ownership and “deal breakers.” Do not rely on boilerplate language.



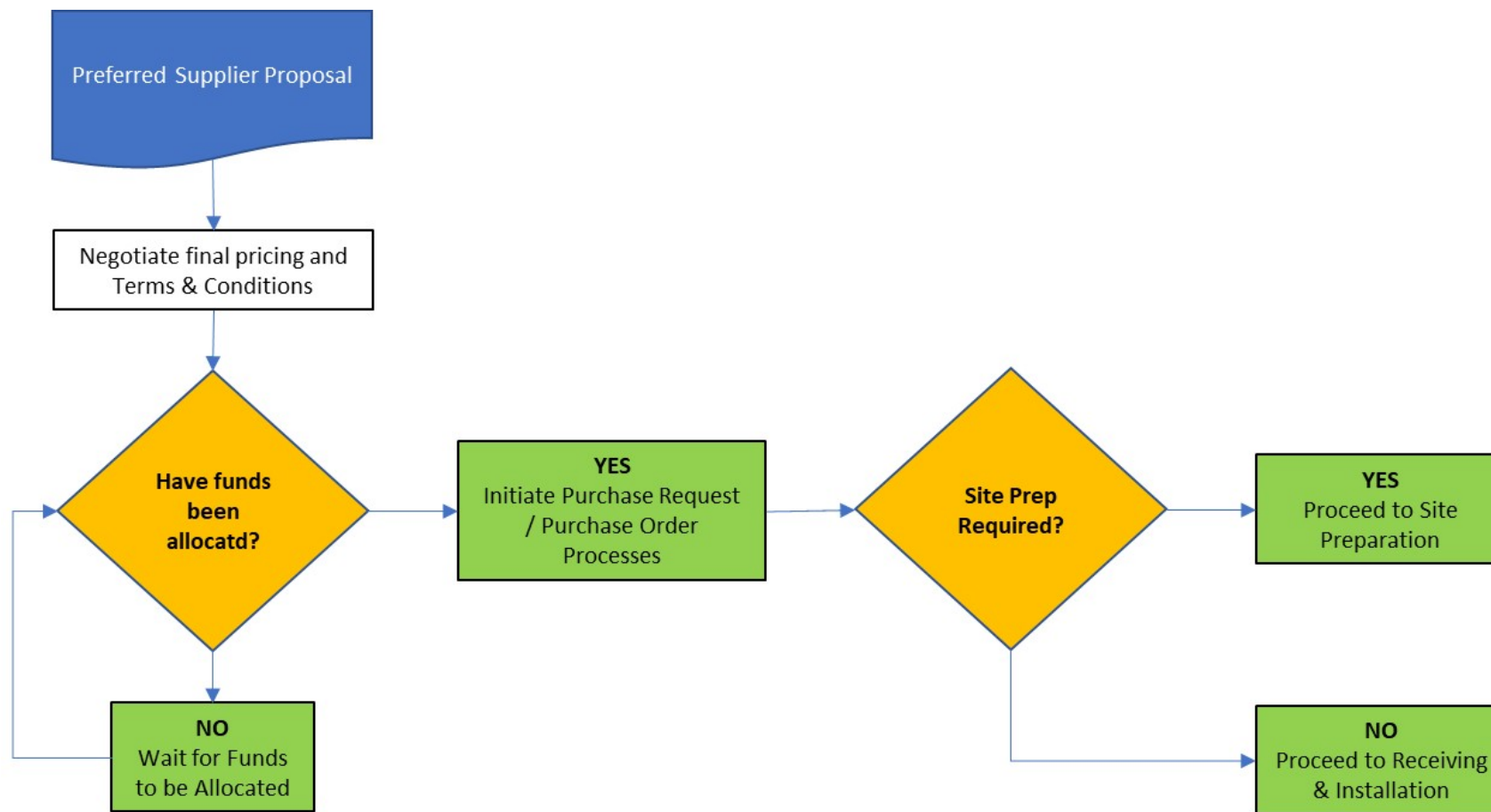
## Funds Approval & Allocation

Don't fall into the trap of conflating funds approval and allocation. In many organizations, these are **separate financial processes**. Funds approval does not necessarily mean funds will be allocated.



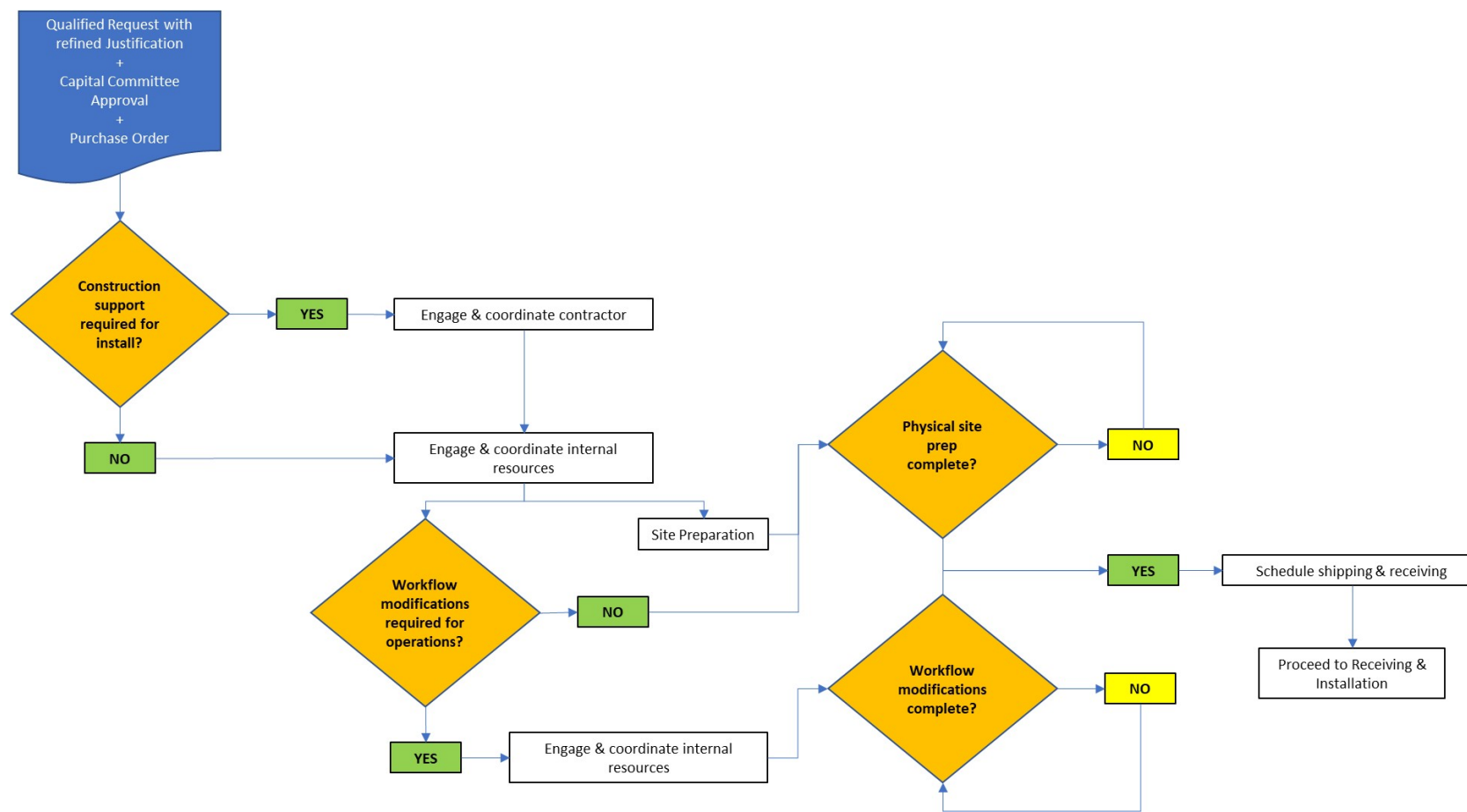
## Procurement (RFI/RFP)

Be comprehensive and specific in your RFP. Ask for everything you want. The details become the basis of the contract. **Document all requirements, terms, and conditions.**



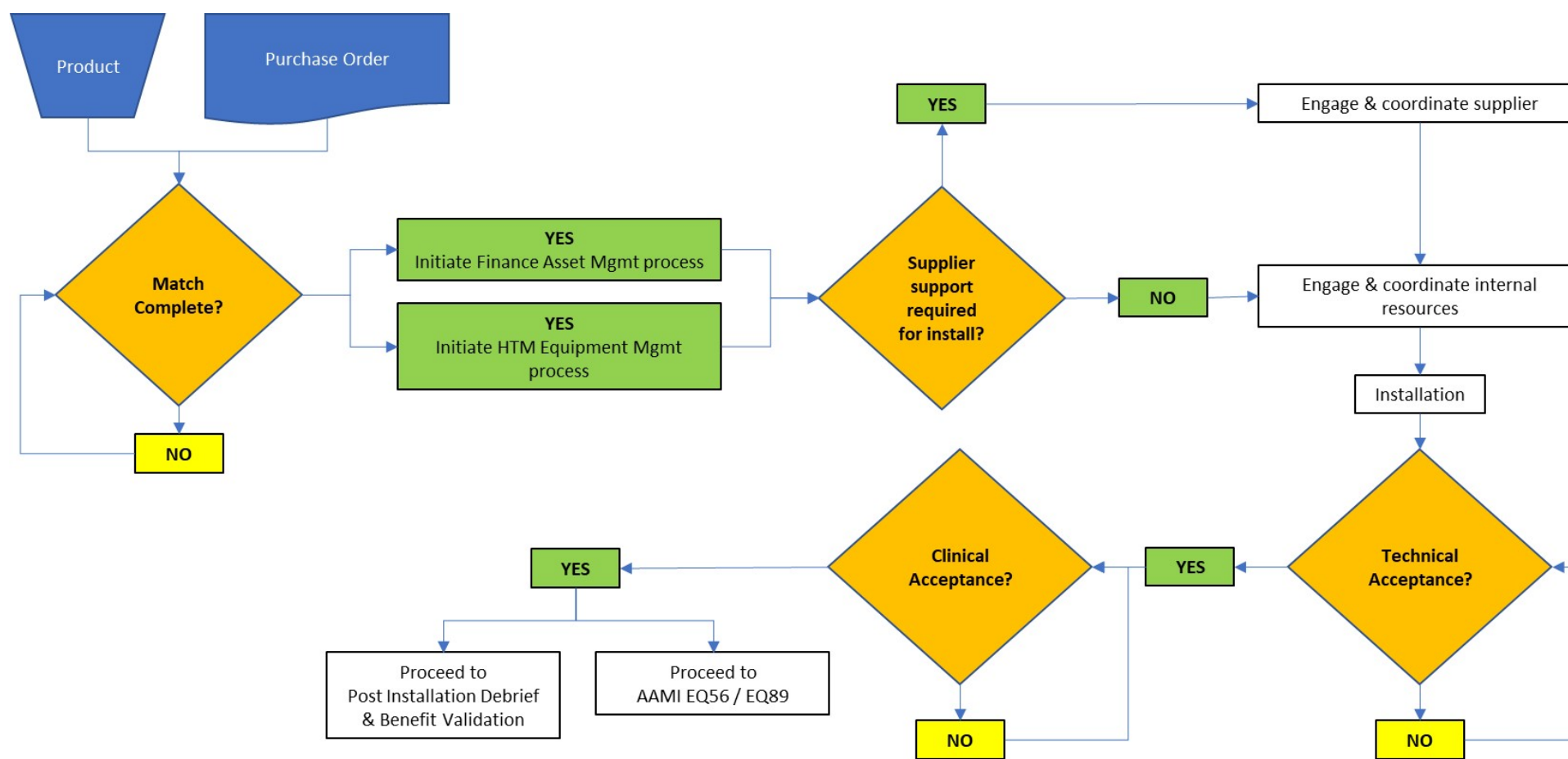
Procurement (RFQ/Requisition)

**Maintain consistency with your RFP.** Document all requirements, products, services, terms, and conditions within the contract and purchase agreement.



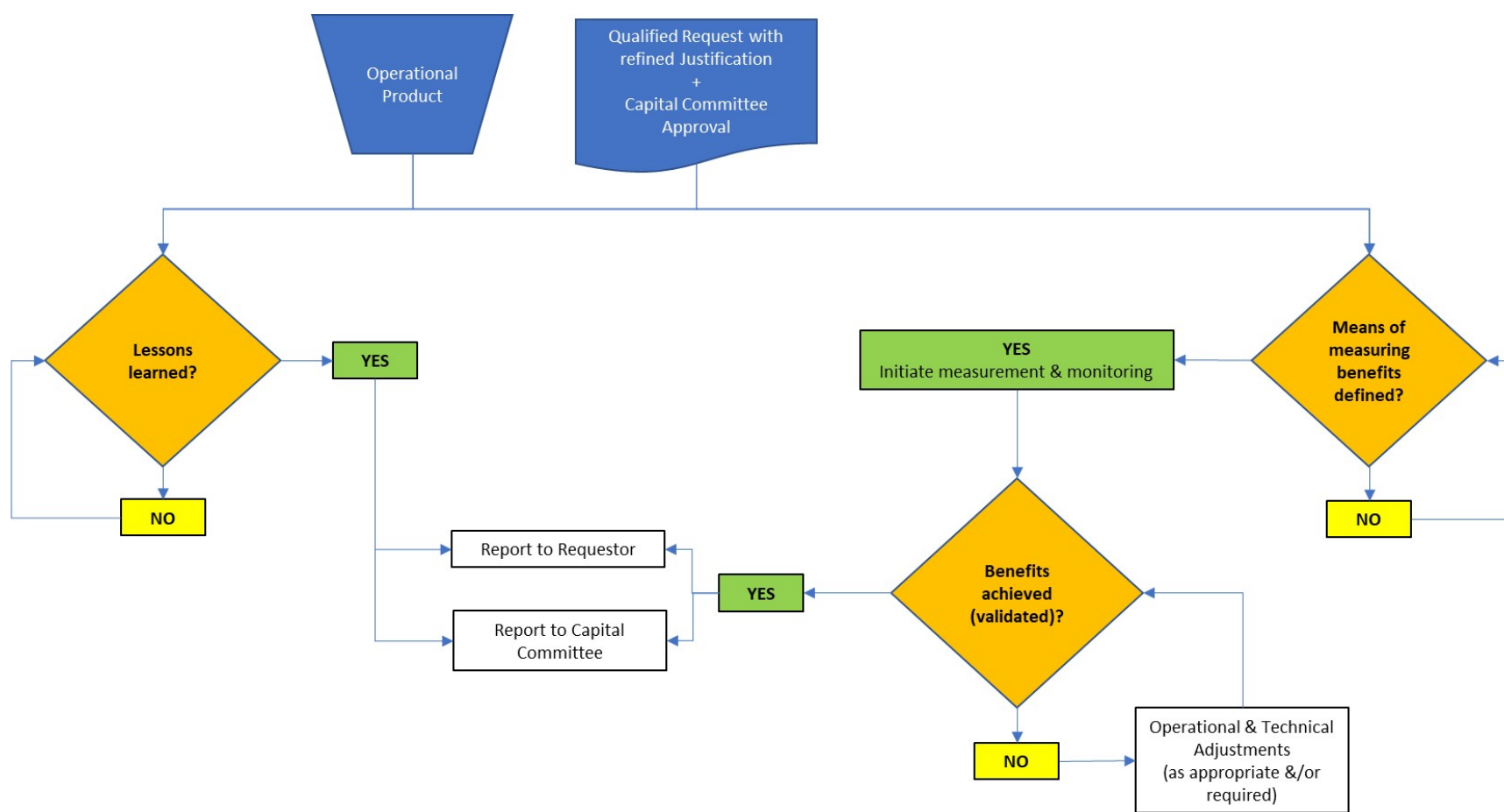
## Site Preparation

Coordinate closely with **all internal and external stakeholders** who will be involved with, or impacted by, site preparation activities.



## Receiving, Installation, & Acceptance

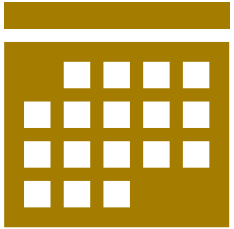
**Be willing to reject a delivery** on the receiving ramp if it does not meet the requirements, terms, and conditions of your contract or does not include everything you agreed to with your supplier. Establish, manage, and reinforce expectations for supplier relationships with clinicians, HTM and IT professionals, and others who are impacted by the clinical technology equipment during this phase of acquisition.



## Post-Installation Debriefing & Benefit Validation

**Capture lessons learned**—positive and negative—in a “safe space” free from blame and judgments. Turn this feedback into a plan for continuous improvement. Determine how well the clinical technology equipment has achieved the identified **mission need and justification** for acquisition.

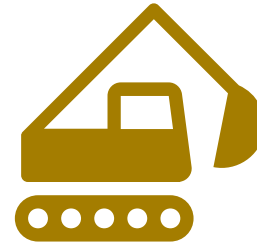
# Leading Practice



## **Annual capital planning**

5-year equipment forecast that informs the annual capital budgeting process

Immediate reaction to an emergent (crisis) situation



## **Construction project equipment planning**

10-year equipment plan that informs the facilities master planning process

Reaction to an emergent (crisis) situation within the last year of a construction project



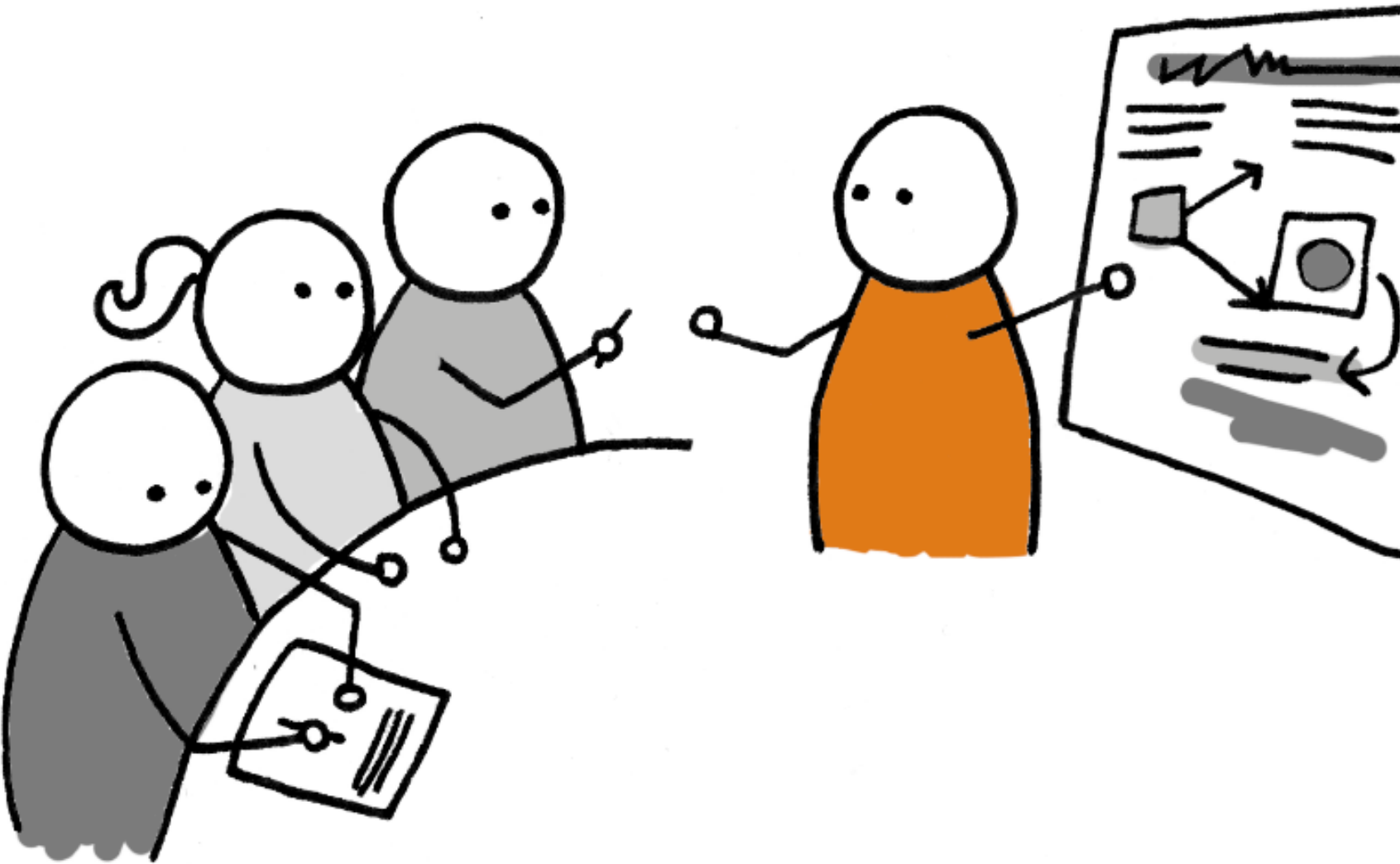
# Leading Practices

Identify a **Project Manager** who has the knowledge, responsibility, and authority to shepherd the request through the acquisition process from beginning to end.



# Leading Practices

**Executive management** must act as an advocate of the overarching acquisition process rather than an advocate of any participant in the process.



# Leading Practices

**Training all participants** in the acquisition process is a leading practice.

In the absence of orientation and training in the formal process, participants all too often default to “the way we’ve always done it.”



# Leading Practices

Before releasing the RFI or RFP, require each **supplier** to identify their **primary point of contact**.

This ensures that the “right” person is in the lead for the supplier and has the authority to engage all necessary subject matter expertise within the supplier organization.



# Leading Practices

Review the **technical service documentation** and tools in detail as part of the supplier proposal and during final negotiations.



Questions?



# Carol Davis-Smith & Associates, LLC

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Carol Davis-Smith & Associates, LLC provides a consultative bridge between technical, clinical, and strategic perspectives in healthcare through our passion for excellence, creativity, and integrity.

[Carol@CDSAssoc.com](mailto:Carol@CDSAssoc.com)

<http://cdsassoc.com/>

