TECHNICAL SERVICES PROGRAM
CLINICAL EQUIPMENT ACQUISITION PROCESS

____ Clinical and Facility Requirements:
Probe the current and expected applications, and compare with current medical practice. The purchase should not only meet the current need, but be practical for 7-10 years. Facilities Management needs to have specific input into required changes to the facility or limitations to specific options.

____ Hospital Budgetary Planning:
Plan for the acquisition of the equipment based on clinical and financial need, and staffing considerations. Be prepared to justify the acquisition against other needed capital items.

____ Request For Proposals (RFP):
After selecting 3 to 5 vendors through basic product and manufacturer information, complete and accurate specifications and terms are published to protect the interests of the hospital and to provide a basis of comparison. These are the basis for standardized proposals by the vendors.

____ Review of Quotations:
The bids are reviewed by a committee responsible for the purchase to determine specification compliance. Manufacturers literature, including sales, technical, and corporate report, are reviewed by the committee. The vendors are evaluated for quality product, quality service, and customer satisfaction. Choose two or three vendors for further consideration. Quotes should be reviewed by TSP/MDBI to make sure that the best deal is secured.

____ Service Planning and Performance Testing:
Make arrangements for safety testing, preventive maintenance, and service training and parts over the life of the equipment. Negotiate for parts availability and training for hospital/TSP service training to support the equipment.

____ Order Equipment:
The order for the selected item is to be made using all of the conditions and stipulations set forth by the committee. Site, utilities, delivery, training and installation issues are to be resolved before the order is made.

____ Acceptance Testing and Installation:
All items are to be tested in accordance with current standards and bid specifications prior to their use. Careful planning with the vendor may be required to ensure that installation is low-key, and does not interrupt the orderly care of patients.

____ Operator Education:
Educate all users of the equipment fully prior to placing the equipment in service. Videotapes, written material, and make other training aids available based on the specifications for purchase. Determine what the measurements should be for continued staff performance measurement.

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TSP Medical Equipment Acquisition Guideline

This guideline is provided as a tool for hospital personnel to program the acquisition process of any medical equipment. Not all steps may be applicable to every acquisition, however, each step should be evaluated for its utility in the specific case.

___ Appropriate vendors have been identified through departmental recommendation, outside sources, and TSP recommendation.
   ___ has the device been on the market at least one year?
   ___ how many identical units are in service in New England?
   ___ is there a service technician located within 100 miles of the hospital?
   ___ number of years that the company has been in business?

___ The vendor certifies that the equipment is FDA approved for the intended application, and is UL or CSA listed, and meets applicable Electric Code, CGA standards and NFPA Standards.
   ___ has this device competed FDA approval process for the application?
   ___ will the vendor meet all NFPA 99 requirements for medical equipment?

___ Demonstrator equipment has been tested since last clinical usage for safety and proper performance. Written certification by the vendor may be accepted in lieu of on-site hospital testing in some cases.
   (demo and loaner equipment should be checked and managed)
   ___ has the vendor provided equipment with time enough for testing of the equipment?
   ___ has the vendor provided adequate user education prior to the clinical trail?
   ___ if the device cannot be tested by the hospital, will the vendor certify that the device is safe for use before the trial?

___ A delivery schedule is provided with the quotation. Delivery is FOB hospital, paid for by the vendor.
   ___ will the device be shipped to the facility at the expense of the vendor?

___ All items on quotation are itemized and individually priced. Discounts are listed.
   (bundled items make changes to specifications difficult)
   ___ has a detailed quote been provided for this equipment (as shown)
   ___ if the product to be purchase differs from the demonstrator unit, is the vendor explaining how the delivered device will differ from the demo?
   ___ are end dates of discounts clearly provided in writing?
All items are fully supported with in-stock parts, and service will be available for at least 5 years from the date of installation. Critical parts are available on 24 hour overnight basis (it will be no good to you if is not supported)

are parts available?

User references have been obtained and checked.
(regional references of like size and application)
has the vendor provided a list of regional customers and contact numbers for calling?

The warranty has been evaluated. Basic warranty should include all parts, labor, and travel. (term of warranty can be negotiable and no less than 1 year)

has a copy of the warranty been provided?

does the warranty cover all parts and labor for at least 12 months from the date of first use?

does the warranty include a loaner for the facility to use?

are their conditions for warranty extension if the product is unavailable during the warranty period?

have service contract quotes been provided for full and partial service for years 2-5?

Documentation including all available user training materials, service and operators manuals, parts lists and schematics has been provided with the delivered equipment.
(do not let this be dropped from the final spec's)
will 2 copies of service manuals be provided with each device?

has a service manual (print and CD) be provided for the evaluation?

does the service literature include a parts list and schematics?

Operator training for all shifts has been provided prior to acceptance and clinical use. This has been coordinated with the hospital inservice educator. (JCAHO requirement. Document this well)

was a qualified trainer made available to train staff for the clinical trial?

was the training adequate to instruct staff on basic use, care, and troubleshooting of the product?

could the trainer answer all questions from staff regarding the use of the device?
Formal service training for a person designated by the hospital has been agreed to by the vendor. This training should cover all service and maintenance. (Do not buy into service contracts without evaluation of alternatives)

Is service training available for this device from the vendor/manufacturer?

Are there any parts restrictions associated with training status or service contracts?

Is the service training cost itemized in the quotation?

Are there discounts for service contracts if the facility does "first look" troubleshooting?

How long will parts be available after the device is no longer produced?

Will software upgrades be available for free?

Will the facility be notified of new software releases whether under contract or not?

Completion of payment has been made after successful usage of the installed equipment. (The facility loses most leverage when item is paid for)

What are the terms of the acquisition?

Will the final payment of >10% be acceptable upon successful clinical use of the device?

Departmental staff have identified critical specifications, and at least three desired vendors as part of the request.

Have users and clinicians discussed and outlined the needed and desired characteristics of the device (or application)?

Have performance specifications been discussed and identified (list all types of clinical usage possible and what levels of operation will be acceptable)

Have vendors been identified for evaluation?

A Request for Proposal has been issued to desired vendors. (For new, complex, or large systems)

Did the vendor follow instructions?

Are all components itemized?

Does the quote meet the desired clinical requirements of the facility?

Was the quote returned by the date/time specified?

The quotation meets all hospital terms and conditions.

Will the vendor honor all hospital or other terms and conditions of the acquisition?
A TSP engineering evaluation has been performed on the proposed products. Reliability, Serviceability, Safety, Clinical Efficacy, and Ease of Operation have been assessed.

Did TSP provide an evaluation?

Was this a vendor for which TSP had information?

Was the number of FDA reported events excessive?

Is the pricing in line with ECRI/TSP estimates?

Could TSP service this device once the warranty is over?

Would TSP require additional training to service this device?

Arrangements have been made for discounted replacement of the equipment if the vendor makes the equipment obsolete within three years through a new product introduction.

Will the vendor provide updated equipment at a reduced cost if the equipment now purchased is made obsolete within 3 years?

The vendor has agreed to provide software revisions, corrections, and updates that affect the present operational functions of the equipment for the life of the equipment free of charge.

Will the vendor provide free software upgrades over the life of the equipment?

The vendor has evaluated the site and commits that the equipment will operate on available hospital power, and that space, access, cooling, heating, and shielding required has been included in the quotation or has provided specific written exceptions.

If installation is required, has the vendor certified that the location is appropriate and that all utilities changes are identified?

Has the vendor evaluated the power and certified that the product will work on available power?

Has the vendor provided an installation guide to the facility?

An evaluation of the adequacy and cost of service options has been made by the materials manager. This includes warranty, service contract, TSP time and materials, and CAPP.

A quote on a service contract for years 2-5+ has been provided

All special test equipment and software to maintain the device (factory service) is listed with an associated cost.
CLINICAL TRIAL FEEDBACK FORM

Device
Vendor
User
Department
Date

Rating System: A=superb, B=very good, C=average, D=poor, F=very poor. Include commentary under each question or on reverse.

_____ The device was easy to set up for clinical use.
_____ The directions for setup were easy to follow.
_____ The controls were easy to see and understand.
_____ The displays were easy to see and understand.
_____ Clinical settings guidance information was provided in the literature or on the device.
_____ The device was easy to operate for the user and support personnel.
_____ Audio signals were easy to hear and understand.
_____ The device integrates well into the layout of the clinical area.
_____ The device is easy to clean and store for future use.
_____ The disposables provided with the device were easy to open and use.
_____ The device did not interfere with other devices in use in the clinical area.
_____ The operator literature provides adequate information on clinical use, troubleshooting, leaning, and service.
_____ Consumable products related to the device were easy to use and were clearly labeled with expiration dates and/or usage instructions.

General Commentary: