

TERMS AND CONDITIONS FOR MEDICAL EQUIPMENT

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Patient safety, life cycle costs, and even the ability to use and maintain the device; these and more can be significantly improved by early efforts to learn as much as possible about the unit and the vendor's commitments to our success.

We provide a comprehensive list of issues for you to consider as you develop your Terms and Conditions. A primary goal is to establish (or maintain) good communication and cooperation with current and potential vendors, and to set the stage for negotiations. The earlier and more complete the communications, the more likely a win-win result: the more likely that the device will fit your needs (including safety, efficacy and support), and be obtained at the most reasonable price.

There are two lists in this section. The Clinical Engineering Terms and Conditions Word® document is formatted to enable your organization to include it as routine "boiler plate" in Requests for Information (RFI), Requests for Proposal (RFP) or Requests for Quotation (RFQ). You may want to use all, or only some of these, and format it to meet your standards. Feel free to edit it to meet your needs. We disclaim any implication that this represents legal advice, and encourage you to obtain a review by your legal as well as purchasing professionals.

The second document, a questionnaire, provides early indication of the user's special needs as well as assists in maintaining coordination on clinical evaluation, facility/environmental requirements, user training and installation.

Medical Equipment Purchasing User Requirements

The questionnaire is ready to use. It offers a set of standard questions you can edit to meet your needs, with specific contact information for you to personalize (shown in red). A standard questionnaire, like this one, can help avoid costly and time consuming problems such as receiving a new piece of equipment and finding that doorways are too small, utilities not readily available, or the OR ceiling is too low. Safety and efficacy, as well as user satisfaction often depend upon the way a new device is introduced. Defining needs and desires for clinical evaluation, and initial and follow up training can make a big difference in patient care, user satisfaction and clinical engineering workload.

Clinical Engineering Terms and Conditions

This extensive list of issues will help identify issues you want to address. You can select specific paragraphs for individual purchases, or use it as a generic attachment when first contacting potential suppliers. As noted above, we recommend sharing this with suppliers at the first appropriate time. We have found that transactions are smoother and more cost effective when the vendor receives a full list of requirements at the earliest possible date. These Terms and Conditions, after all, are part of the negotiations, and compromises are often required.

Starting early allows maximum time for negotiating support such as training, extended warranties, and price. It minimizes the likelihood of settling for a purchase agreement that does not provide all

possible benefits, such as assurance of manufacturer technical support, equal priority for repairs with organizations that have maintenance contracts, and assurance of parts availability. Early communication allows you to establish or build good communications with potential vendors and leaves time to calculate the cost/benefit aspects of the various maintenance alternatives.

There are times when it is helpful to have the vendor/manufacturer's staff install and/or conduct incoming inspection (e.g., when receiving 300 infusion pumps). This and other "special circumstance" requests are included even if they are used infrequently.

Specific contact information to personalize is in red type.

A Word About Evaluating Equipment Prior to Purchase

Clinical engineering staff can make a significant contribution to patient safety, and to their own operating efficiencies and effectiveness through pre-purchase evaluations as well as through communications using the Terms and Conditions and other tools.

Demonstrations are useful. Clinical evaluations are essential – when purchasing critical equipment and equipment where human factors can make the difference in patient safety and user satisfaction. The optimum is an integrated clinical and technical evaluation, with both clinical engineering staff and users participating and communicating. Obviously, clinical engineering staff provides expertise on technical specifications, maintainability, reliability, upgrade/update potential, compatibility with other equipment and related issues. Just as important, they have a lot to offer in the evaluation of human factors, operational aspects and environmental issues. Human factors, difficulties using a device in the busy and often stress filled environment, and training are major contributors to adverse patient events. For clinical engineering, these lead to Use Error, Cannot Duplicate or Abuse diagnoses. For the organization, this may mean the psychological and financial burdens of a patient injury, shorter equipment lifetimes, or even equipment that is not used to its full potential or not used at all.

However rigorous your involvement, JCAHO's Element of Performance for Standard EC.6.10 reads "The hospital identifies and implements a process(es) for selecting and acquiring medical equipment." You may consider using a variation of Failure Modes and Effects Analysis (FMEA) or other process to include proactive risk management during the selection phase for critical equipment. This implies assembling stakeholders, identifying the potential issues, and prioritizing them based on severity and probability of occurrence. Including proactive analysis of the potential risks can raise your visibility, increase your contributions, and save money by providing improved selection, introduction and use of the equipment. This process can become a documented part of the patient safety and risk management programs, integrated with the Medical Equipment Management Plan.