

OUTSOURCING: BE SURE YOU'RE GETTING YOUR MONEY'S WORTH

BINSENG WANG

At the beginning of this year I shared with you my opinion — admittedly highly biased — as to why outsourcing biomedical services was not saving you much money. Now I would like to revisit outsourcing from the quality assurance and regulatory compliance vantage point.

Most healthcare organizations that outsource or are contemplating outsourcing their biomedical services only want their equipment inspected periodically and repaired when needed. Most outsourcing companies are happy to comply with this request. What many administrators do not realize is that this is not enough to make the organization compliant with JCAHO standards or federal regulations. Listed below are some of the components of the

mandated by the FDA. Although most of the upgrade work is performed by the OEM, technical expertise is often required to identify and inspect the units being recalled, coordinate the upgrade, and perform incoming inspection on upgraded equipment before putting it back into clinical use;

d) *"Monitoring and reporting incidents in which a medical device is connected to the death, serious injury or serious illness of any individual."* Again, this is also mandated by the FDA in compliance with the Safe Medical Devices Act of 1990 (SMDA '90). Recent FDA regulation actually requires the reporting of user errors, which can only be determined after a thorough evaluation of the equipment and its environment;

e) *"Establishing a medical equipment orientation and education program."* This

protective equipment when handling potentially contaminated equipment.

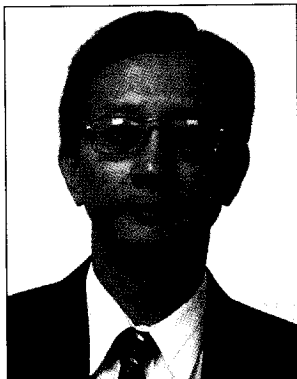
h) *OSHA regulation on chemical hazards:* Similarly, healthcare organizations are responsible for verifying that the contract personnel have been properly trained and are protected against hazardous chemicals and have available the corresponding material safety data sheets (MSDS);

i) *Medical device tracking:* This regulation was mandated by SMDA '90 and issued by FDA. Although it is mostly applicable to implantable devices, some critical equipment used outside of the hospital (i.e., homecare) must be tracked to the level of individual patients. This includes apnea monitors, ventilators, infusion pumps and defibrillators (including those used in ambulances). Service personnel can assist in the tracking of these devices, as well as making sure that they are included in the inventory and periodic inspection schedules.

The above duties may not seem valuable or critical until the organization is reported by a JCAHO inspector or involved in litigation. Many outsourcing companies ignore these duties because they are time-consuming tasks that also require highly qualified staff (often clinical engineers rather than BMETs). It is much easier and more economical to perform repairs and inspections. Some even only perform electrical safety tests on equipment whose safety and performance is essentially determined by mechanical or pneumatic components. A few "creative" outsourcing organizations have offered their customers equipment management programs duplicated from other hospitals. This "cookie-cutter" approach often backfires because the recipient has a different organizational structure and skill set, making the implementation very difficult, if not impossible.

Hospital administrators should not settle for the lowest bidder. I hope the pendulum of technology management will not go too far before it swings back toward a more reasonable center position for these organizations.

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equipment management program required by JCAHO but often neglected by outsourcing companies.

a) *"Selecting and acquiring medical equipment."* All new purchases must be preceded by evaluation and discussion among the clinical users and clinical engineering staff;

b) *"Establishing criteria for identifying, evaluating, and taking inventory of medical equipment to be included in the management program before the equipment is used."* Although all equipment can be included in the inventory, it is advantageous to use risk-based criteria to avoid frequent inspection of low-risk and low-usage devices. The inventory must be kept up-to-date, which can be a challenging task for large or multi-facility organizations;

c) *"Monitoring and acting on equipment hazard notices and recalls."* This is also

program must include user training for operation, safety procedures, emergency procedures, management problem reporting, and access to services. In addition, the personnel servicing medical equipment must have available records of their training and competency; and

f) *Test equipment calibration:* Although not explicitly stated in JCAHO standards, periodic inspection and calibration of the test and measurement equipment used for inspecting medical equipment is just as important as the work performed.

Beside JCAHO requirements, the following federal regulations (similar regulations often exist in each state) must be observed:

g) *OSHA regulation on bloodborne pathogens:* Healthcare organizations can be held liable if the employees of an outsourcing company are not properly trained or are not wearing personal pro-