

The Q-Net™ Monthly

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Reader Feedback

In response to last month's issue of this newsletter, an outsourcing company asked that differences between refurbishing and reprocessing instruments be further clarified.

Outsourcing can be divided into 3 distinct services: (1) refurbishing opened but *unused* disposable items; (2) reprocessing *used* disposable items; and (3) reprocessing *used* reusable items. Because reusing disposable items is controversial and could pose a safety risk to the patient, some outsourcing companies may only reprocess reusable items.

'Q-Net 97'



'Q-Net-97,' a bound collection of all of 1997's newsletters, is now available. Order your copy today for \$9.95 (includes S&H).

What is 'Q-Net'?

Q-Net is a technology-assessment network of questions and answers. Its newsletter is *The Q-Net™ Monthly*.

Q-Net's main goal is to encourage the infection control and endoscopy communities to not only ask good questions but to also demand succinct and well referenced responses.

Q-Net addresses the needs of both the health care provider whose goal is to provide the best care possible, and the patient who deserves affordable quality health care.

Outsourcing II

~ PART 1 OF THIS DISCUSSION WAS PRESENTED IN LAST MONTH'S ISSUE ~

Several factors may influence a hospital's decision to "outsource" its instruments to a third-party company for decontamination and sterilization. Advertised claims that outsourcing reduces costs without jeopardizing patient safety have attracted the public's attention.

As the number of outsourcing companies increases, the need to establish and standardize comprehensive safety and performance criteria, designed to protect the patient, cannot be overstated.

A company that refurbishes or reprocesses disposable devices may be considered a manufacturer, since the company has, in effect, re-labeled the devices (for more than one use). As a manufacturer, the company may be subject to regulation by the Food and Drug Administration. (In spite of their instrument reprocessing activities, hospitals are not considered to be medical device manufacturers.)

✓ *The FDA currently regulates companies whose activities could alter the safety or performance specifications of a medical device. The FDA may soon expand its regulatory oversight to also include companies, such as instrument repair companies, whose activities do not necessarily alter the device's intended use.*

Before reusing a disposable device, several safety and performance criteria must be satisfied. For example, data must be available showing that the device: (1) can be thoroughly cleaned and sterilized, and (2) will perform safely and effectively during reuse.

But few hospitals have the resources to perform the rigorous safety and performance tests necessary to acquire these data. Nor can hospitals be expected to always satisfy industry standards for sterilization (i.e., a sterility assurance level of 10^{-6}), as the FDA requires of the original manufacturers of disposable devices.

Most outsourcing companies, however, have performed these onerous and expensive tests and have also validated and documented the effectiveness of their cleaning and sterilization processes. Because their activities could alter the safety or performance specifications of medical devices, outsourcing companies are expected (but not necessarily required) to register with the FDA.

Whereas the reuse of disposable items is not recommended, some disposable items, such as coronary angioplasty catheters, have been reported to be safely and effectively reused (Browne KF, et al. J Am Coll Cardiol 1997 Dec;30(7):1735-1740).

In addition to reducing costs, outsourcing offers several potential benefits:

✓ Hospitals with increasing reprocessing responsibilities, although limited space, may find outsourcing a convenient alternative to costly renovations or

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moving;

✓ Rather than purchasing expensive instrument sets that they rarely use, hospitals may find that leasing them from a third-party company is more practical and cost-effective; and

✓ Hospitals can reduce, if not eliminate, their use of ethylene oxide (EtO) gas by outsourcing their heat-sensitive instruments to companies equipped with EtO gas and other low-temperature instrument reprocessors.

While outsourcing has several potential benefits, few (if any) published studies have evaluated its effect on the quality of patient care. Nor have reports been published that compare the reliability of outsourcing companies to reprocessing departments in hospitals. The paucity of data to support (or refute) the merits of outsourcing warrants a cautious approach.

Determining whether outsourcing will benefit your hospital is not a simple task. Asking outsourcing companies the following questions may facilitate the process:

- 1 *Is the company registered with the FDA? Has the company ever received a warning letter from the FDA? Does the company comply with Current Good Manufacturing Practice (cGMP) Quality System regulation? Is the company ISO 9001 certified?*
- 2 *How often does the company audit its procedures to ensure compliance with cGMP regulation?*
- 3 *What types of instruments does the company have experience refurbishing and reprocessing? What is the turn-around time? Does the company reprocess used, reusable instruments? What about used, disposable instruments? Does the company lease instrument sets?*
- 4 *Will the company indemnify the hospital of all claims were a patient injured due to device failure or inadequate reprocessing? Is the company's liability policy clear and concise? What are the policy's exemptions?*
- 5 *What types of instruments are (and which are not) covered by the company's liability policy?*
- 6 *Does the company offer a warranty? If yes, does it cover instruments that break or are damaged during cleaning, sterilization, or shipping and handling?*
- 7 *Has the company validated each of its safety and performance tests? Is the quality of each instrument tested before it is returned to the hospital?*
- 8 *Has the company validated and documented the effectiveness of its cleaning and sterilization procedures?*
- 9 *Are the company's cleaning and sterilization processes in agreement with the instruments' operator's manuals?*

10 *Are all of the company's testing protocols and data available for the hospital's review?*

11 *Is the sterility assurance level (SAL) of the company's sterilization processes 10⁻⁶?*

12 *Does the company steam sterilize all instruments not damaged by heat, pressure and moisture? If not, why not? (Refer to SGNA and AORN guidelines, e.g., "Recommended Practices VII." AORN J Oct 1993; 58 (4):789-795.)*

13 *How often are biological indicators (BIs) used to monitor the company's sterilization processes?*

14 *Does the company quarantine its processed instruments until the sterilizer's BI is determined to be negative? What does the company do if the BI is positive? Does the company maintain accurate instrument tracking records?*

15 *Does the company have a list of hospitals using its services? What are the experiences of these and neighboring hospitals that have used the company's services?*

At the end of last year a colleague and friend of ours retired from public service at the Centers for Disease Control and Prevention. His dedication to patient safety will be deeply missed. Indeed, to try to fill his shoes would be an exercise in Sisyphean futility. Happy trails to you, Mr. Walter Bond.

☞ An article written by this newsletter's author will be published in this March's *AORN Journal*. It discusses instrument design and cross-infection. Two other articles, also written by this newsletter's author, are scheduled for publication in *The American Journal of Infection Control*.

Thank you for your interest in this newsletter. *I have addressed each issue to the best of my ability. Respectfully, the Publisher: Lawrence F. Muscarella, PhD.* Please direct all correspondence to:

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