SOAPBOX

By Binseng Wang

ISO 9000 is a Better Alternative for Servicers and Remarketers

In December 1997, the Food and Drug Administration (FDA) published an Advance Notice of Proposed Rulemaking (ANPR) to announce the intention of regulating the service, refurbishing and remarketing of medical equipment. Since then, numerous meetings and discussions were held with the participation of manufacturers, healthcare organizations, servicers, remarketers and professional organizations. Based on this feedback, the FDA drafted a "guidance document" that requires the servicers and remarketers to identify themselves and their relationship with the device, and provide the date of service or remarketing. In addition, this "guidance document" also "encourages" the creation of voluntary standards that will require the servicers and remarketers to provide disclosure regarding the types of services performed, the condition of the equipment after service and a mechanism (registry) to record complaints.

Opponents inside the FDA are, however, holding up the publication of this "guidance document" because they feel the proposal is not strong enough. Now that the reprocessors of devices labeled for single use, including the hospitals, are being required to register with the FDA and follow the applicable portions of the Quality System regulation, some FDA officials believe the manufacturers and other "hardliners" are likely to demand the same from the servicers and remarketers. So, unfortunately, *no news is not good news.*

In reality, the proposed labeling requirement is very wide in scope. It applies to all who service equipment that they do not own and to those who sell or donate any equipment, even if no service was performed. In other words, this regulation would cover all manufacturers, independent service organizations (ISOs), shared services and numerous in-house clinical engineering departments that perform inspection, repairs and preventive maintenance on healthcare equipment. In addition, all companies that buy and sell used equipment and healthcare and non-profit organizations that sell or donate excess or obsolete inventory are also covered by this new regulation. The total number of organizations that will have to comply with the new rule is estimated to be 20-35,000.

Instead of waiting for the impasse to be resolved, I think the industry should unite behind an alternative that is likely to be acceptable to all within the FDA. The best alternative, I believe, is ISO 9000 registration.

First, this is a well-established, worldwide-recognized standard.

Second, this is the same standard to which almost all major manufacturers comply, so it will be difficult for them to reject this proposal.

Third, and most important, ISO 9000 registration offers independence and flexibility that no other alternative can claim. There are numerous registrars and consultants who are totally independent of the various interested parties, yet they all have a vested interest for the candidate organization to succeed in the initial registration and retain its status. This is much better than having to deal with a single organization that may not be very sensitive to the needs of the servicers and remarketers.

Finally, the FDA has already harmonized its Quality System regulation with ISO 9000, and even JCAHO has decided to integrate ISO 9000 into its own standards for healthcare organizations, so the likelihood of its acceptance is high.

The main drawback of ISO 9000 registration so far has been the associated costs. The total cost of training, consulting and registration can add up to $35,000. Fortunately, some relief is now available. Many states are offering financial assistance through their small business agencies. Also, a number of experienced clinical engineers and medical device specialists are being certified by the Registrar Accreditation Board (RAB) making qualified professionals more readily available. It is now possible for a small company to be registered within nine months and spend as little as $10,000! So instead of waiting for another ANPR, let us unite behind ISO 9000 and present it as a concrete alternative to the FDA.

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