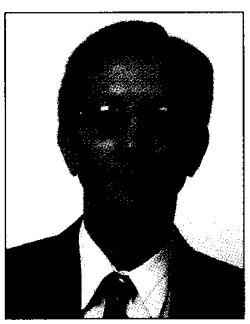
By Binseng Wang

# How would you like to be regulated?

By the time you read this column, the FDA may already have published a proposed regulation on medical-device maintenance and repair services performed by healthcare organizations (HCOs) and independent service organizations (ISOs). In July 1995, FDA proposed to include both these groups in its new Current Good Manufacturing Practices. But last October the agency reversed itself, stating it would exclude them. At the same time it has "elected to address application of the CGMP requirements to persons who perform servicing and refurbishing functions outside the control of the original manufacturer." There will be an opportunity for public comment on this proposal rule later this year. I hope you will carefully read the proposed rules and use the opportunity to comment wisely. FDA has demonstrated its willingness to change its position — albeit sometimes only a little — when it receives well-grounded comments.

It seems clear that FDA is going to regulate service even if it does not have the data to prove there is a need. FDA alleges that the medical-device reporting (MDR) database does not contain sufficient information regarding service history. However, ECRI performed a word search on the same database and concluded that the number of problems attributed to service is negligible. I do not understand why FDA wants HCOs and ISOs to spend time and energy to "solving" a problem no one is sure exists, at a time when resources are scarce and everyone is trying to contain costs. The healthcare industry should not passively accept FDA regulation of service based on the argument that improperly serviced medical devices can be a threat to public health. Otherwise, physicians and other healthcare professionals may eventually be fending off similar regulation.



On the other hand, regulation of service as part of manufacturing practices is, in my view, an important component of the quality system principle that underlines CGMP. Through feedback from service data, OEMs can improve the design and manufacturing of their products. Many forward-looking OEMs have been doing this for years to keep a competitive edge. OEMs who consider this requirement an additional regulatory burden do not understand the principles of TQM/CQI, and ultimately, will be driven out of business by their own myopic views.

In principle, FDA has two basic choices in writing the new regulation for service. It could adopt the prescriptive style of the old GMP or the quality-system approach used in CGMP. I believe it will be the latter. This is good news for in-house teams and ISOs that have already embraced ISO 9002. For the rest — who probably are following JCAHO standards — it will be a costly and painful exercise. For their own long-term survival it would be better for them to follow a regulation similar to TQM/CQI or ISO 9002. However, unlike prescriptive rules, a quality system is difficult to interpret. An enormous number of policies and procedures have to be generated. This is especially challenging for organizations with only a few technicians. I hope FDA will be sensible enough to give small ISOs plenty of time and perhaps a few exemptions. Otherwise smaller organizations will be driven out of business. Let us not forget that the only reason that ISOs and in-house service departments exist is because no OEM can provide timely and cost-effective service to all devices at all user locations. To drive ISOs and in-house service departments out of business will not improve public safety, quite the opposite. It would add to healthcare costs and be a disservice to the nation.

The regulation will ultimately benefit medical-device owners the most. They will know that whomever they choose (OEMs or ISOs) for service will have to comply with the same set of rules. However, it will take many years for all service providers to achieve the same level of quality. Initially, the regulation — just like ISO 9002 registration — will only guarantee that the vendor has set up proper policies, processes and procedures for correctly performing maintenance and repairs in a timely manner. It does not guarantee good service. It only ensures that problems will be corrected and the quality will improve with time. Like ISO 9001 for OEMs, those who have registration do not necessarily have good products, while those who do not have registration may have excellent products.

The lesson derived from the July 1995 CGMP proposal suggests that HCOs and ISOs must read — carefully — the new service regulation proposal. The 1995 CGMP proposal contained requirements that severely restricted their competitiveness and raised their liability risks. For example, the apparently innocent requirement, "a copy of all service reports shall be forwarded to the original manufacturer" actually provided the OEMs with confidential market information. Equally disturbing, information on ISO service schedules and parts replacement can be used by competing OEMs and plaintiff attorneys as evidence of "violations" of OEM recommendations. Currently these practices are explicitly allowed by JCAHO standards and covered by the service provider's liability insurance.

A benefit that ISOs may realize from the regulation is the reduction of liability insurance premiums. Knowing that ISOs are tightly regulated and must set up detailed policies and procedures, insurance companies are likely to reduce their rates. While onerous to implement and keep, comprehensive paperwork tends to reduce the opportunities that plaintiff attorneys have in proving negligence against ISOs.

So clean off your magnifying glasses and uncap your highlighting pens. After thoroughly reading the new regulation, fire up your word processor and express your thoughts. The old days of carefree brainstorming are gone — welcome to the new world of regulated industry. HTM

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