

Ensure Patient Safety Through Accountable Medical Device Servicing

It's Simple: The FDA Should Hold All Servicers to the Same Quality, Safety, and Regulatory Standards

Medical imaging devices are complex pieces of capital equipment, some of which emit radiation. Patients and providers depend on the safe and effective operation of these devices. If the equipment is improperly serviced, it could put technicians and patients at risk for serious injury or result in poor image quality, leading to a delayed or missed diagnosis or repeated imaging procedures. This could increase healthcare costs. Patients deserve to know that medical device servicers did not cut corners and accept responsibility for quality and safety outcomes of their work.

Increasing accountability and transparency of the third-party service industry is an important step to ensuring the safe and effective operation of all devices.

Medical device service activities performed by the original equipment manufacturer (OEM) are regulated by the Food and Drug Administration (FDA). These companies and their servicers meet rigorous quality, safety, and regulatory requirements, including proper training, adverse event reporting, and registration.

In contrast, very little is currently known about unregulated third-party medical device servicing businesses. Non-manufacturer, third-party servicer businesses do not even have to register with the FDA, and they are not held to any quality, safety, and regulatory requirements. In May 2018, the FDA estimated that “total number of firms performing medical device servicing in the U.S. is between 16,520 and 20,830,” but said the “precise number of entities that perform servicing of medical devices in the U.S. is not known.”

Why do third-party medical device servicers refuse to make themselves known to the FDA?

Why do they resist adoption of quality controls and remain unwilling to report deaths, serious injuries, or major malfunctions?

Without proper oversight, there is an increased risk for serious patient safety and device performance issues. Independent servicing businesses need to accept responsibility for ensuring the return of medical devices to safe and effective operation by adopting appropriate quality systems and investing in the development or adoption of valid servicing protocols, tools, and training.

Our Solution

We support policy reforms that would protect patient safety by requiring third-party servicers (not hospital clinical engineering staff), to also meet the basic requirements that OEMs are currently meeting, including:

- **Registration:** All servicers of medical devices should be required to register with the FDA.
- **Quality Management System:** All servicers of medical devices should be required to adopt and maintain a quality management system that ensures devices are returned to safe and effective condition.
- **Reporting of Adverse Events:** All servicers should be required to report adverse events to the FDA when they encounter death, serious injury, or device malfunction.

