MITA®
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA®

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VIA ELECTRONIC DELIVERY

William H. Maisel, M.D., M.P.H.
Director, Office of Device Evaluation
Acting Director, Office of Compliance
Deputy Director for Science and Chief Scientist
Center for Devices and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Maisel,

As part of our ongoing efforts to promote safety and quality in medical device servicing, we are writing to make you aware that on May 19, 2020, a firm known as iFixit populated its website with numerous proprietary service manuals and other documentation for regulated medical devices, including devices manufactured by MITA Member companies. This documentation is now openly accessible to the public and may be used by unregulated entities.

We are concerned that uncontrolled use of documentation—whether current or out of date—by entities that are not required to have appropriate processes and controls in place could lead to improper servicing of a medical device, and possibly cause patient safety or device performance issues.

Adequate performance of medical device servicing activities is not dependent only on possession of certain materials. Knowledge of and compliance with FDA regulatory requirements is essential to performance of these activities in a way that results in the safe and effective operation of the medical device.

Operating within a quality management system is essential to performing servicing activities in a manner that consistently results in the safe and effective operation of the medical device. A quality system is necessary to ensure that medical devices consistently meet applicable requirements and specifications. Safe and effective servicing is not merely acquisition of certain documentation or materials—it is the implementation of and adherence to a set of policies, practices, and procedures which consistently return the device to a state of safe and effective operation.

We request that FDA take immediate action to implement consistent quality, safety, and regulatory requirements for everyone who services a medical device, including requiring all servicers to register with the FDA, file Medical Device Reports (MDRs), and implement a quality management system.

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If you have any questions, please contact Peter Weems, Senior Director, Strategic Operations and Policy, at pweems@medicalimaging.org or 703-841-3238.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.