



MITA[®]
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF **NEMA**[®]

1300 North 17th Street • Suite 900
Arlington, Virginia 22209
Tel: 703.841.3200
Fax: 703.841.3392
www.medicalimaging.org

March 26, 2020

BY ELECTRONIC DELIVERY

Robert Ochs, PhD
Deputy Director for Radiological Health
Center for Devices and Radiological Health
United States Food and Drug Administration

Dear Dr. Ochs,

The Medical Imaging & Technology Alliance (MITA) is writing regarding steps the FDA should take to enable the medical imaging industry to best address the COVID-19 pandemic. Medical imaging and information technologies play a vital role in the global mission critical infrastructure and care pathway of diagnosing and treating COVID-19. The medical imaging manufacturing industry stands ready to meet the increasing demand for our products. In order to meet this demand, we strongly recommend a number of timely steps FDA take. These changes will not impact the safety and efficacy of our devices.

In particular, we believe FDA should:

- Temporarily prioritize review and clearance of medical imaging devices which play a role in the COVID-19 care pathway (e.g. mobile x-ray systems, CT scanners, and portable ultrasound systems used at point of care)
- Leverage Third Party Review recommendations as much as possible for current imaging device submissions
- Expedite issuance of accession numbers for 510(k) cleared products being imported to address the COVID-19 pandemic (e.g. mobile x-ray systems)
- Grant manufacturers greater flexibility for static to mobile conversions for 510(k) cleared medical imaging systems given significant demand and urgent need expected in new temporary emergency hospitals (e.g. greater flexibility in design verification/validation documentation related to the conversion)
- Temporarily grant greater flexibility for use of alternate components and in supplier qualification in order to meet increased demand, similar to recent policies issued regarding ventilators.
- Assess the impact of facility and importation customs inspections on timely delivery of medical imaging devices and potentially postpone inspections until the COVID-19 crisis has abated
- Coordinate with the Department of Homeland Security (DHS) and other government agencies to meet demand for medical imaging devices in severely affected areas and facilitate movement of personnel providing service to these medical devices

We look forward to working with you to address this public health emergency. If you have any questions, please contact Peter Weems, Senior Director, Strategic Operations and Policy, at pweems@medicalimaging.org or 703-841-3238.

Sincerely,

A handwritten signature in black ink, appearing to read "Patrick Hope". The signature is fluid and cursive, with a large initial "P" and a long horizontal stroke at the end.

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.