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April 12, 2018

The Honorable William Botzow II
Vermont State House
115 State Street
Montpelier, VT 05633

The Honorable Michael Marcotte
Vermont State House
115 State Street
Montpelier, VT 05633

Re: S.180: Draft No. 4.1, 3-20-2018

Dear Chairman Botzow and Vice Chair Marcotte:

The Medical Imaging & Technology Alliance (MITA) is the leading trade association representing the manufacturers of medical imaging equipment and radiopharmaceuticals. If the intent of S.180 is for a task force to study "right to repair" principles and their application to consumer electronics, MITA believes it is inappropriate to include medical devices within the scope of the task force's work. Medical devices are a fundamentally different and unique class of products which, if repaired improperly or incorrectly, can result in serious and even fatal consequences for patients and operators.

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MITA members are the manufacturers of sophisticated and highly regulated diagnostic imaging devices and technology, such as computed tomography (CT), magnetic resonance (MRI), X-ray, positron emission technology (PET) and ultrasound systems. Medical devices are only able to be used under the order of a physician by trained and credentialed operators and are not intended to be replaced every 1-2 years as is the case of consumer electronics. In fact, medical devices can be routinely used for more than 10 years before replacement if effectively serviced and maintained by skilled and qualified providers.

In correspondence sent to the Senate Committee on Economic Development, Housing and General Affairs on January 24, 2018, MITA expressed opposition to requiring original equipment manufacturers (OEMs) of medical devices to provide diagnostic and repair information to unregulated repair providers and owners of digital electronic products. Currently, servicing activities are only regulated by the Food and Drug Administration (FDA) when performed by the OEM. Service activities performed by non-OEM entities do not have the same oversight or transparency and are not held to the same quality, safety, and regulatory requirements. Unfortunately, Section 2 (d) of the current version of S.180 neglects to identify operator and patient safety as an issue of review and concern by the Right to Repair Task Force as they develop a written report on their findings and recommendations for legislative action. Patients have the most at stake if the device fails to perform in a safe and effective manner due to

improper and/or unregulated servicing activity. The same is true for device operators. If medical devices are to be included in the focus of the Task Force should S. 180 be enacted, then MITA recommends the following language be included to specifically address this topic:

- **Sec. 2 (d) (#) issues relating to patient and operator safety**

Findings Section 1(4) of the proposed amendment to S. 180 asserts that the knowledge and tools to repair and refurbish consumer electronic products should be distributed as "widely and freely" as the products themselves. As stated in our letter sent on January 24th, medical device manufacturers invest significant resources into the manufacture and design of their products and also invest heavily in the development of servicing tools, training and protocol. These proprietary resources are not necessary for the successful servicing of devices. In many cases, one manufacturer may service another manufacturer's device, doing so based on their own know-how and reverse engineering efforts. Many non-OEM services are also already making this kind of investment and innovation. MITA believes that independent service providers need to accept the responsibility of ensuring the return of the device to safe and effective operation and can do so by adopting appropriate quality systems and developing their own servicing protocols, tools, and trainings. Providing diagnostic and repair information to unregulated repair providers negates the significant investments in innovation, safety and repair that manufacturers have dedicated to create safe and effective medical devices. Additionally, Section 1 (4) seems to conflict with the Task Force's review and consideration of issues regarding consequences or impacts for intellectual property and trade secrets in Section 2 (d) (4). MITA recommends that Section 1 (4) is stricken from S. 180.

Findings Section 1(2) states that manufacturers may limit access to information or parts to correct defects to only customers who are under warranty and not for older models and that consumers are often left with few options other than to buy new products. MITA's goal is to ensure that performance of servicing activities always results in the safe and effective operation of medical devices. Medical imaging device servicing requires the highest level of technical and procedural training. This training needs to be regularly updated to reflect knowledge of the latest products, including software and hardware, and a deep understanding of and adherence to current best practices. Operating within a quality system ensures that devices consistently meet applicable requirements and specifications. MITA believes that servicing and maintenance activities are dependent on more that possession repair materials and information. Suitable training, adherence to a quality system, and compliance with regulatory requirements set by the FDA are essential to proper device servicing. High quality servicing and maintenance actually allows devices to continue to function safely and effectively for a longer period of time. Unfortunately, in today's unregulated environment, these activities are not always performed correctly, resulting in dangerous or ineffective devices that may fail or be unusable earlier than anticipated.

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Since S.180 was first introduced on January 3, 2018, the Vermont Legislature has heard concerns from many stakeholders regarding the negative implications of "right to repair" requirements. Given the overwhelming concern, MITA is pleased that the Committee recognizes the need to

devote further time and resources to understand this issue and solicit the testimony and participation of relevant stakeholders rather than hastily enact requirements that threaten privacy, security, and safety. MITA maintains the position that it is inappropriate to include medical devices in the scope of such requirements as this unique class of products, if repaired without the proper training and knowledge, can result in serious and even fatal consequences for patients and operators.

Should Vermont enact the amended version of S.180 and establish the Right to Repair Task Force and include a review of medical devices in its scope, MITA is willing to participate, as appropriate, as a representative of the medical device industry. Additionally, some of the concerns and perspectives of medical device OEMs are different than testimony previously submitted by non-OEMs about medical devices, and as such, MITA would appreciate the opportunity to elaborate further in future conversations facilitated by the Task Force. If you have any questions, please contact Cassandra Ricci at 703-841-3228 or by email at cricci@medicalimaging.org.

Sincerely,

Patrick Hope
Executive Director, MITA

Cc: Senator Christopher Pearson
Representative Jean O'Sullivan, Ranking Member
Representative Robert Frenier
Representative Matthew Hill
Representative Charles Kimbell
Representative Patricia McCoy
Representative Linda K. Myers
Representative Amy Sheldon
Representative Valerie A. Stuart
Representative Linda Joy Sullivan