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July 7, 2023

Mr. Ryan Fogle
EPA Manager
ENERGY STAR for Medical Imaging Equipment

VIA Email: medicalimaging@energystar.gov and fogle.ryan@epa.gov

Re: ENERGY STAR Medical Imaging Equipment Draft 1 Specification Comments

Dear Mr. Fogle:

As the premier trade association representing the manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound devices, the Medical Imaging & Technology Alliance (MITA) is writing in response to the U.S. Environmental Protection Agency's (EPA) ENERGY STAR Medical Imaging Equipment Draft 1 Specification. Given the short timeframe and the Agency's no decision on our letter dated June 27, 2023, requesting a 120-day extension, MITA's comments are limited in the details of this response. We continue to believe more time is necessary to properly assess the full impact of the Draft.

MITA would like to reiterate our desire to work collaboratively with the EPA. We believe that acting collaboratively will yield a more successful result for all stakeholders. MITA is not disagreeing with ENERGY STAR applying to medical imaging equipment, however, we believe that the current EPA proposal could cause problems with its implementation. To that end, MITA would welcome the opportunity to convene a workshop with stakeholders such as the EPA, the U.S. Food and Drug Administration (FDA), and the U.S. Department of Energy (DOE) to review the details of the proposed specification with the intent of moving the process forward to a successful implementation.

Below are the areas that MITA would like to provide comments on:

Operating Modes

MITA would like to address the definitions of operating modes and request additional clarification from the EPA, in the form of graphical presentations by modality. For example, Magnetic Resonance (MR) machines cannot be in an "off" mode as power is required to cool the magnets.

We believe that the operating mode definitions and ENERGY STAR criteria should be modality-specific as medical imaging equipment is varying and complex. For example, an ultrasound machine can be turned completely off and brought back to a "ready to scan" mode with a lesser impact to patient care, while an MR machine cannot be turned completely "off" and would take time to be brought to a "ready to scan" mode, with that time potentially impacting patient care.

When appropriate, MITA recommends adding a "power save," "hibernate," or "sleep" operating mode that has the following definition: "This is a mode that is activated by the system during operation time

(during "ready-to-scan") after a certain period of time that the system is not used. The power consumption is lower than ready-to-scan and higher than the "low power" mode."

Settings

MITA believes that ENERGY STAR should not apply to equipment that is used in emergency departments or other acute care settings where a timely diagnosis vastly impacts patient outcomes. In the case of severe trauma or other acute events, time is of utmost importance to diagnosis, treatment, and management of the patient's condition.

The ENERGY STAR specification would be more fitting in an ambulatory care or a setting with set hours where the equipment could be turned off or put into a "low power" mode, especially in the case of MR when the facility is closed or not seeing patients. These settings can better manage and accommodate the time that equipment needs to reach a "ready to scan" mode from an "off" or "low power" state and can schedule patient care accordingly.

In addition, EPA, in its specification, is specifying that the "low power" mode start after equipment is not used for 30 minutes. We are concerned that this approach may potentially cause delays in medical care. In addition, for devices used in a sterile environment, there is the risk of contamination if the user must interact with the system after the sterile environment is established. There is a concern that if the user does not fully understand the implications of changing settings that it could cause a risk for the patient.

Placing a medical imaging device into a "low power" mode during normal business hours should remain a manual decision up to the applicable technologist, since the technologist will best understand one's operational schedule and the implications. A possible solution could be to introduce an intermediate "power save" mode to the ENERGY STAR criteria that allows for rapid change to "ready to scan" mode in addition to "low power" mode when feasible and appropriate. We note that most of the projected energy savings will come during non-operational overnight hours.

In the stakeholder webinar on June 14, EPA representatives stated that these functions can be created with an "opt-out" approach to alleviate manufacturer concerns for medical device readiness. MITA members are concerned that an "opt-out" approach requires detailed knowledge of the systems and ramifications and are not comfortable with this approach. The assumption cannot be made that all users will have such detailed knowledge.

Additional Stakeholders

MITA strongly believes that the FDA must be included as a stakeholder in the development of this specification, as medical imaging equipment is highly regulated by the FDA, including when in an "off" or "non-scanning" state. We are very concerned about the unintended consequences of this specification on patients, health care providers, and manufacturers. To this end, MITA has begun to engage the FDA on this issue and recommends the EPA include them in the process.

Voluntary Nature

It has been reiterated many times that ENERGY STAR is a voluntary specification and manufacturers are not required to comply with it. However, there is federal criteria that, in Section 104 of the Energy Policy Act of 2005, requires agencies to purchase ENERGY STAR-qualified or Federal Energy Management Program (FEMP)-designated products when procuring energy-consuming products. The requirement applies to products and equipment purchased through any agency procurement action, and exceptions are allowed only if the head of an agency finds in writing that a qualified product is not cost-effective over

the life of the product or is not reasonably available meeting the agency's functional requirements. See Federal Procurement Policies for ENERGY STAR Certified Products | ENERGY STAR. Please note that the US government is a large customer of medical imaging equipment.

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In conclusion, MITA supports the EPA's goals of energy efficiency in medical imaging equipment. Those goals must be balanced, however, against our goals to ensure the safety and optimal performance of our equipment that protects patients and health care providers.

Without the EPA's approval of our requested extension to the comment period, MITA requests a broad stakeholder workshop that includes the EPA, DOE, FDA, and other stakeholders to allow for collaboration and the opportunity to provide more detailed comments in the development of ENERGY STAR criteria for medical imaging devices. We feel that this collaboration will result in practical energy savings and a quicker implementation of the ENERGY STAR criteria for medical imaging devices. In addition, MITA would like to receive the data and methodology that was used to develop the draft specification.

If you have any questions, please contact Adrienne Frederick, Manager, State Government Relations at 703.841.3240 or afrederick@medicalimaging.org.

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.