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February 3, 2023

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

VIA Email: medicalimaging@energystar.gov

Re: U.S. Environmental Protection Agency's (EPA) ENERGY STAR Medical Imaging Equipment Discussion Guide

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 Discussion Guide issued November 2022. We appreciate the EPA working with industry and narrowing its ENERGY STAR focus in the Discussion Guide to "ready to scan mode and an automated power down to an energy saving low power state when it has not been in use for an extended time."

MITA recognizes the importance of the EPA's long-running, successful ENERGY STAR program and its success in reducing energy consumption in consumer products. ENERGY STAR has proven to be an effective tool to promote the use of energy efficient consumer-focused products, and we commend the Agency on its mission to seek even further reductions with an easy-to-understand labeling system. While we support efforts to bring certain medical imaging equipment into this successful program, medical imaging equipment are complex, and each modality has unique qualities that are less suited for energy efficiency than others. Therefore, we urge the Agency to move cautiously and deliberately as it begins the process while considering the industry's current efforts on energy efficiency and labeling for energy-efficient design and procurement.

We appreciate recent discussions with the Agency, and we look forward to continuing to work with the Agency as it takes initial steps to develop ENERGY STAR labeling for certain medical imaging equipment.

Below are our responses to EPA's questions for discussion:

Proposed Scope
1. Are there products listed within the included scope that should not be included in the scope of Version 1.0, and if so, why?

We believe the initial product types listed in the Discussion Guide are too broad to begin Version 1.0 ENERGY STAR. MITA recommends the EPA start with just a single modality with fewer components and a minimal risk of patient harm before expanding its scope to more medical imaging equipment. There are several factors and variables to consider, and we believe the most prudent approach would be to start with one modality before expanding to a broader scope of medical imaging products.

2. Are there products either listed out of scope or not listed at all that should be considered in scope, and if so, why?

MITA believes the EPA should start with one modality for Version 1.0 ENERGY STAR. Further, as a general matter, the EPA should exclude the following products as being out of scope:

- Interventional products, such as:
    - Angio Suites
    - Bone Densitometers
    - C-arms
    - Contrast Media Injectors
    - Endoscopy
    - Photoacoustic Imaging
    - Thermography
- Cyberknife is not an imaging device. It is a radiosurgery equipment that uses Cobal-60 sources for gamma-ray delivery
- Liner accelerators or LINACS are radiotherapy devices
- Combined modalities, i.e., PET/CT, SPECT/CT, PET/MRI

3. As part of its previous work on the test method, EPA defined many of these products. However, EPA seeks stakeholder feedback on if this set of definitions is acceptable or if there is a separate set of definitions used and accepted by industry.

MITA believes the definitions created under the 2014 test method are outdated. All stakeholders need to fully understand the functions and capabilities of the modalities, as well as recognition of the differences in provider settings, before assessing the different modes and the likelihood it will lead to energy efficiencies. MITA, along with our European counterpart, COCIR, would like to work with the EPA on updating the definitions.

Ready to Scan and Auto-Power Down Mode

4. Which of the product types proposed for inclusion in this specification possess auto-power down functionality?

5. If auto-power down functionality is present, is it enabled by default when the unit is shipped and/or configured for customers on-site?

MITA is answering questions #4 and #5 together. Many medical imaging equipment products have auto-power down mode functionality and capability. The extent of its use is based on the health care provider's need and feature use is linked with clinical diagnosis being performed, patient condition, and the position of the device in a workflow with other modalities. In some cases, the default to auto-power down mode is not be an appropriate out of the box feature for medical imaging equipment based on the customer's needs, however, auto-power down mode is configured through on-site training.

6. What challenges, if any, complicate the use of auto-power down or lower power modes in the product types proposed for inclusion?

The type of modality, the location, and frequency of use of medical imaging equipment can complicate the use of auto-power down or lower power modes. For example, emergency care settings such as an Emergency Room utilize medical imaging equipment 24/7 and the device must be ready to scan at all times. Certain modalities, such as CT, take time to power up and need to be always in ready mode; making it impossible for the device to be switched off between scans. Other devices, such as MRI, also need to be always on to avoid quenching, which has broad patient and safety implications.

Unlike consumer products, medical imaging equipment is made up of highly complex systems and many electronic components. Those components are turned on or off based on the specific use-case, workflow, and examination, in combination or on its own. Each component has a unique up and down time to provide the best clinical result at each point in the patient workflow. These factors complicate the use of standardized auto-power down or low power modes for two reasons: 1) standardized modes may not translate successfully into customer and patient needs and workflows and 2) customers may not have the full picture of how these standardized modes fit into patient needs and workflows if manufacturers design to the standardization rather than customer use cases.

7. Are there any other non-active/scan energy requirements besides focusing on ready to scan and low-power modes that EPA should consider in a Version 1.0 specification to help highlight best energy practices and/or new energy features present in these products?

No, not at this time but we look forward to working with the EPA in the future to promote the existing COCIR Self-Regulatory Initiative initiated in collaboration with the EU Commission.

That initiative encompasses environmental purchase criteria as well as other environmental topics like circular economy and substances of concern.

Potential Savings Impact

8. Can stakeholders share measured product energy data, ideally measured using the ENERGY STAR draft method or the COCIR test method to help EPA better understand energy usage both ready to scan and low power modes for the different product types proposed to be in-scope for Version 1.0?

All available data have been published in the COCIR SRI "Annual Status Report" and in the "Guidance to energy savings" for each modality. However, the COCIR use-case scenarios needs revalidation for power down mode and in need of further testing. The potential for energy savings depends on the modality and the frequency the facility is using the equipment and the COCIR data should be revalidated with these particular use-case scenarios. MITA proposes work together with COCIR to revalidate use-case scenarios for power down mode.

9. Are there specific technologies and/or functionalities that EPA should highlight that drive lower energy use during non-active state operation of these various product types?

Not currently but we need further discussion.

Testing Considerations

10. Are there any recent or upcoming updates to the COCIR test method that EPA and DOE should consider making for possible adjustments to the current ENERGY STAR draft test method?

See response to #8

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Again, we share the Agency's goal to achieve energy efficiency in medical imaging equipment. We appreciate the Agency narrowing the ENERGY STAR focus to ready to scan mode and an automated power down and believe as an initial step Version 1.0 should start with one modality.

We look forward to working with the Agency and COCIR to update the definitions and revalidate the use-case scenarios to better determine the costs and benefits of ENERGY STAR in medical imaging equipment.

If you have any questions, please contact me at phope@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.