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May 6, 2024

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

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

CC: john.clinger@icf.com

Re: ENERGY STAR Medical Imaging Equipment Draft 2 Specification Comments

Dear Mr. Fogle:

As the premier trade association representing the manufacturers of medical imaging equipment and focused ultrasound devices, AdvaMed Medical Imaging Equipment Division (formerly the Medical Imaging and Technology Alliance) is writing with comments to the U.S. Environmental Protection Agency's (EPA) ENERGY STAR Medical Imaging Equipment Draft 2 Specification.

AdvaMed Medical Imaging would like to reiterate our support for the collaborative work that has been done to prepare for the Draft 2 Specification. We believe that working collaboratively will yield a more successful result for all stakeholders.

AdvaMed Medical Imaging supports the EPA's modality-by-modality approach for Version 1.0 ENERGY STAR for Medical Imaging Equipment and limiting Version 1.0 to MRI. We believe that this phased approach will provide learnings that can be carried over into subsequent modalities.

Below are the areas that AdvaMed Medical Imaging would like to provide comments on:

Refurbished or Remanufactured Systems

Although not explicitly included in the specification, it is AdvaMed Medical Imaging's understanding from previous correspondences with EPA that refurbished or remanufactured systems are not in scope of ENERGY STAR unless explicitly mentioned. We would like confirmation in the record that refurbished or remanufactured systems are not included in this specification. Inclusion of refurbished or remanufactured would adversely impact the availability of life-saving

equipment as well as cause an increase in other environmental aspects such as material use and energy use associated with the collection and use of those materials.

Definitions

AdvaMed Medical Imaging would like to propose the following updates under Definitions for Product Types (1.A.):

2) Computed Tomography (CT): We would like to clarify that the CTs in scope are medical imaging equipment. We propose the following edit to the definition:

Medical imaging technology that creates a computer-generated 3D image from a large series of two-dimensional X-ray images taken around a single axis of rotation. Computed Tomography scans use X-rays to produce precise cross-sectional images of anatomical structures and spaces within objects.

3) Endoscopy: AdvaMed Medical Imaging proposes the addition of "optical" to the definition to clarify the equipment in scope.

Use of small **optical** camera directly inserted into the body to examine the interior of a hollow organ or cavity in the body.

4) General Radiography (X-ray): AdvaMed Medical Imaging proposes the following definition for x-ray to further clarify the scope and types of general radiography medical equipment. The recommendation also removes references to Cyberknfe and Linear accelerators which are not general radiography equipment.

Draft 2 Specification	AdvaMed Medical Imaging Proposal
An X-ray image is produced when a small amount of ionizing radiation passes through the body. The ability of X-rays to penetrate tissues and bones varies according to the tissue's composition and mass. Examples of devices using general radiography include a cyberknife, fluoroscope, and linear accelerator	Medical imaging technology that encompasses various imaging modalities such as X-ray machines, fluoroscopy, and digital radiography systems. These devices utilize X-rays to produce images of the body's internal structures. In traditional X-ray machines, a tube emits X-rays through the body, and a detector captures the transmitted radiation, creating a medical image.

4.A. Fluoroscope: We would like to update the definition of fluoroscope to remove reference to a fluorescent screen which is no longer in use. We propose the following edit to the definition:

Device that obtains real time images of internal structures. The fluoroscope employs an X-ray source and a fluorescent ~~screen~~ **image receptor** that go**es** on either side of a patient.

5) Magnetic Resonance Imaging (MRI): AdvaMed Medical Imaging would like to clarify that the MRIs in scope are medical imaging equipment, and that the technology is not limited to 2D images. We propose the following edits to the definition:

Medical imaging technology used to obtain highly refined images of the body's interior. It employs magnets that polarize and excite hydrogen nuclei in water molecules within tissues and creates ~~2D~~ **medical** images.

AdvaMed Medical Imaging determined that there is an additional specialized category of MRI, Permanent Magnet MRI, that we are proposing to add to the specification.

Permanent Magnet MRI: MRI system that uses permanent magnets to generate the magnetic field instead of a superconductive magnet, typically in the range of 0.2 to 0.5 Tesla.

6) Mammography Equipment: AdvaMed Medical Imaging would like to clarify that the mammography equipment in scope is medical imaging equipment and updates the technical definition based on current and anticipated technology. We propose the following edits:

Medical imaging equipment that uses ~~low-dose~~ X-rays to examine the human breast ~~for tumors and cysts~~. ~~Mammography equipment can be either analog, projecting low dose X-rays on film, or digital, converting X-rays into electrical signals that produce digital images.~~ **Mammography equipment uses a digital x-ray image receptor to measure the quantity of x-rays passing through the breast to generate medical images.**

7) Nuclear Imaging: AdvaMed Medical Imaging proposes an update to the definition to better clarify the technology.

Draft 2 Specification	AdvaMed Medical Imaging Proposal
A patient consumes short-lived isotopes which emit radiation that is	Medical imaging equipment that creates medical images of the

measured, commonly with the use of a gamma camera. Scintigraphy, single proton emission computed tomography (SPECT), and positron emission tomography (PET) are types of nuclear imaging technologies. Scintigraphy produces 2D images, while SPECT and PET technologies produce 3D images	distribution of gamma-ray emitting radioactive materials that have been introduced into the body. The technology uses a detector that measures the intensity and spatial distribution of the gamma rays that exit the body. Scintigraphy, single proton emission computed tomography (SPECT), and positron emission tomography (PET) are examples of nuclear imaging technologies.

We would also propose updates under Definitions for Operating Modes and Periods (1.B.):

1) Off mode: The system is shut down with ac mains off, according to the user manual. The system consumes no energy.

Note: certain modalities cannot be switched off

For MRI, this definition is not needed and AdvaMed Medical Imaging recommends removing this definition from Version 1.0 to avoid confusion. If not removed, AdvaMed Medical Imaging recommends adding a statement clarifying that this mode does not apply to MRI.

3) Power save mode: AdvaMed Medical Imaging proposes this update to the definition. MRIs, excluding permanent magnet MRIs, have automatic functionality. It cannot be assumed that automatic functionality would be appropriate for permanent magnet MRIs or other modalities while providing safe and reliable operation:

This mode applies to operating hours and is automatically **or manually** activated ~~by the product~~ in its ~~as shipped~~ **as handed over** state to consume less energy than Ready-to-scan mode while maintaining the ability for the product to quickly re-enter Ready-to-scan mode.

4) Ready-to-scan mode: AdvaMed Medical Imaging proposes an update to clarify that there are no energy savings functions engaged during ready to scan mode. We also do not think that the definition needs to explicitly exclude potential mechanical movements.

This mode represents the state of the system between individual scans, where no scan has been prescribed (e.g., during patient handling, data archiving, examination planning, or contrast agent injection) **and without**

any energy savings functions engaged. ~~This mode does not include potential mechanical movements such as X-ray tube rotor or gantry rotation.~~

5) Scan mode: AdvaMed Medical Imaging proposes the following update as we do not think that the definition needs to explicitly exclude potential mechanical movements.

The system is actively scanning the patient to generate images. The computing system interprets the data and generates the image. ~~This mode also includes any potential mechanical movements such as X-ray tube rotor or gantry rotation.~~

Addition of Separate ENERGY STAR Criteria for Permanent Magnet MR

After the initial data collection was completed, there was data that was collected by AdvaMed Medical Imaging on permanent magnet MR. They are an MRI system that uses permanent magnets to generate the magnetic field instead of a superconductive magnet, normally in the range of 0.2 to 0.5 Tesla.

AdvaMed Medical Imaging recommends including permanent magnet MRs in ENERGY STAR as a separate category. Based on data obtained, we propose that the ENERGY STAR criteria for permanent magnet MRIs be set as a 40% reduction from ready-to-scan to power save mode and a 40% reduction from ready-to-scan to low power mode. We recommend that the criteria allow for manual or automated functionality as not all permanent magnet MRs have automatic functionality.

Important considerations for permanent magnet MRIs include that: they have a very low energy consumption per unit on the order of 1 kW; there are a small number of devices being sold in the United States; and the equipment has no automated functionality between power modes.

Automatic Power Management Feature v. Version 1.0 Scope

In prior communications with EPA, AdvaMed Imaging advised and provided data that the automatic product power management feature may not be feasible for all modalities. The scope of ENERGY STAR Version 1.0 for Medical Imaging Equipment is MRIs.

Therefore, we recommend clarifying that Section 3.2. is limited to MRIs. AdvaMed Imaging therefore recommends the following slightly adjusted text (bolded and underlined):

3.2.1 Automatic Product Power Management: To certify for ENERGY STAR, ~~a Medical Imaging Equipment~~ **an MRI** product…

We recommend clarifying that Section 3.2.2 is limited to MRIs. In addition, we recommend clarifying that the energy savings percentages apply to the reduction from the ready to scan mode. AdvaMed Medical Imaging therefore recommends the following slightly adjusted text (bolded and underlined):

> 3.2.2 Manual Product Power Management: To certify for ENERGY STAR, ~~a Medical Imaging Equipment~~ **an MRI** product must be able to be powered down manually by the end-user to a low power mode during non-operating hours. The maximum amount of energy this mode shall consume is defined as a percentage less than the energy used in **ready-to-scan** mode with no power management enabled, as stated in Table 2 below:

Power Save v. Low Power Modes

In we believe the text needs to be clearer to indicate that the automatic power management function applies to the power save mode and that ready to scan mode is a mode with no power management enabled.

AdvaMed Medical Imaging therefore recommends the following slightly adjusted text (bolded and underlined):

- 3.2.1 Automatic Product Power Management: To certify for ENERGY STAR, **an MRI** product must be able to power down automatically to a ~~low power~~ **power save** mode within 30 minutes upon reentering ready-to-scan mode after a scan during operating hours. The maximum amount of energy this mode shall consume is defined as a percentage less than the energy used in ~~this~~ **ready-to-scan** mode with no power management enabled, as stated in Table 1 below:
- The title for Table 1 should be changed from low power mode to **power save mode** to be consistent with the definitions.
- We propose to update the titles of Tables 1 and 2 to clarify that the energy savings percentages apply to the reduction from the ready to scan mode.
    - Table 1: Required Power Down Percentage in POWER SAVE MODE, as compared to ready to scan mode, for Automatic Power Management
    - Table 2: Required Power Down Percentage in Low Power Mode, as compared to ready to scan mode, for Manual Power Management

Data Reporting Requirements

AdvaMed Medical Imaging proposes updates to the Data Reporting Requirements section (4.1) to:

- Clarify that the data is for representative system configurations as it is not practical to list every applicable system configuration.

4.1.iv. **representative** system configuration(s);

- Clarify that the energy reduction is from the ready-to-scan mode to either low power or power save modes.

4.1.v. reduction in energy consumption ~~in~~ **from ready-to-scan to** low power **and power save** modes as a percentage as determined from testing;

Number of Units Required for Testing

AdvaMed Medical Imaging proposes the following updates to 5.2.1. to accurately present the purpose of representative models for the purposes of testing:

5.2.1.i. For certification of an individual product configuration, the ~~unique~~ configuration that is ~~intended to be marketed and labeled as ENERGY STAR is considered the Representative Model.~~ **used as the basis for ENERGY STAR testing shall be considered the Representative Model. All configurations to be marketed and labeled as Energy Star shall meet the ENERGY STAR criteria.**

5.2.1.ii. For certification of a product family, the product defined by the ~~partner~~ **manufacturer** as the ~~base~~ **representative** configuration ~~within the family shall be considered the Representative Model~~.

Time Period to Enable Functions

AdvaMed Medical Imaging would like to reiterate from our previous letter that MRIs as well as many other medical imaging equipment may be part of an extensive project set-up and not based on a generic or "out-of-the-box" solution. Medical imaging devices such as MRI (and CT, NI, large x-rays) are installed, tested, verified, and configured at the customer site. For shipment and transportation reasons (e.g. intermediate cooling in logistic processes for MRI) energy saving options might be disabled and enabled during customer installation and prior to handover.

Therefore, we recommend changes to the following sections in the Draft Specification:

1.B.3. Power Save Mode:

This mode applies to operating hours and is automatically activated by the product in its ~~as-shipped state~~ **handover condition** to consume less energy than Ready-to-scan mode while maintaining the ability for the product to quickly re-enter Ready-to-scan mode.

3.2.4 Power Management Availability and Reporting:

To certify for ENERGY STAR, all power management techniques listed above must be enabled ~~as-shipped and both automatic and manual power management features~~ **prior to handing over to the customer and** must be detailed in the certification submission. This requirement applies to power management features in the medical imaging equipment itself, as well as supporting computers and displays that can be configured by the installer or end-user.

And in the Draft Test Method:

5.A. ~~As-shipped~~ **At Handover** Condition: Products shall be tested in their ~~"as-shipped"~~ **"handover condition"** configuration that is specified by the manufacturer, which includes~~ both hardware configuration and system settings,~~ **hardware and software** configurations unless otherwise specified in this test method.

Please note that the recommendation above clarifies that software can influence the energy usage of an MRI device. Hardware and software configurations apply to the device parts and the system.

6.1.D. Verify that the UUT is configured in its ~~as-shipped~~ **handover** condition configuration.

Testing Scope

AdvaMed Medical Imaging believes that test methods may need to be different depending on modality and therefore the scope of the Version 1.0 Test Method should be limited to MRIs. Based on this comment, we make the following edits to the Draft Test Method:

Reorder Applicability (2.) to flip the sentence order:

At this time, the specification, and this test method, only covers magnetic resonance imaging (MRI) equipment. The proposed test method…

Testing Criteria Clarification

Version 1.0 for MRIs has different criteria than other ENERGY STAR product categories. The criteria is based on the percentage reduction of energy use from ready to scan to power save or low power modes. This may be confused with the term "energy efficiency." Based on this comment, we propose the following edits to Applicability (2.) in the Test Method:

2. APPLICABILITY: …The proposed test method shall be used to determine the ~~energy efficiency~~ **percentage reduction of energy use from ready to scan to power save or low power modes** of all products under the ENERGY STAR Product Specification for Medical Imaging Equipment.

Accurate Determination of Ready-to-Scan Energy Use

It is important to accurately determine the power consumption during the ready to scan mode without the application of any energy saving functions. Therefore, this requires all energy saving functions to be disabled when testing during the ready to scan mode.

AdvaMed Medical Imaging proposes the following recommendations to Power Management (E.) in the Test Method:

E.1. When testing power consumption during the ready to scan mode, all power management and/or power saving features shall be disabled.

E.2. When testing power consumption during the power save or low power modes, applicable power management and/or power management features shall be enabled.

UPS During Testing

AdvaMed Medical Imaging recommends clarifying 6.1.C.1. in the test method applies only to external uninterruptible power supplies (UPS) because internal UPSs would be considered part of the UUT.

1) No **external** uninterruptible power supply (UPS) units shall be connected between the power meter and the UUT;

Test Procedures

Since ENERGY STAR criteria for medical imaging equipment is based on energy reductions during non-scanning activities, a test requirement to verify scanning functionality is not needed. AdvaMed Medical Imaging therefore recommends deleting this testing step.

There is no reason to specify the number of minutes in the test method; what is important is to verify that the device has achieved the desired mode before conducting the test for that mode. AdvaMed Medical Imaging recommends removing references to specific time and instead specifying that the equipment reach the appropriate state.

Based on the comments above, AdvaMed Medical Imaging makes the following recommendations for edits to sections 6.2, 6.3, and 6.4 in the test method:

6.2 Ready-to-scan Mode Testing

A) Ensure that the power meter is on and functioning.

~~B) Prescribe a patient and execute any scan to ensure that the UUT is functioning.~~

B) Select the ready-to-scan mode.

C) ~~After the scan completes, wait 5 minutes,~~ **After the system is in ready-to-scan mode,** ~~and then~~ record the average power draw (rate of energy consumption), for a period of 12 minutes.

D) Record this value, in kW

6.3 Power Save Mode Testing

A) Ensure that the power meter is on and functioning.

~~B) Prescribe a patient and execute any scan to ensure that the UUT is functioning.~~

B) Select the power save mode.

C) ~~After the scan completes,~~ **After the system is in power save mode**, ~~wait 30 minutes, and then~~ record the average power draw (rate of energy consumption), for a period of 12 minutes.

D) Record this value, in kW.

In addition to the comments above, For Low Power Mode Testing (6.4), we are unsure of the rationale in 6.4.D., and recommend it be removed. It is our understanding that any variability would be averaged out in the test across the testing period of 12 minutes.

6.4. Low Power Mode Testing

A) Ensure that the power meter is on and functioning.

B) Select the Low-power mode ~~as specified in the user manual~~.

C) ~~Wait to ensure that all applicable system elements of the UUT have adapted to this mode.~~ **After the system is in low power mode, record the average power draw (rate of energy consumption), for a period of 12 minutes.**

~~D) Measure the average power draw (rate of energy consumption), for a period of at least 10 minutes. If the system has a variable power usage in this mode, the measurement duration shall be amended to one complete power usage cycle, which shall be taken to be the cycle from minimum to maximum usage.~~

~~E)~~ **D)** Record this value, in kW.

Excluded Products

AdvaMed Medical Imaging would suggest removing contrast injectors from Excluded Products (2.2.2.) as they are not imaging equipment.

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In conclusion, AdvaMed Medical Imaging reiterates its support of the EPA's goals of energy efficiency in medical imaging equipment and will continue to be an engaged partner for the EPA as ENERGY STAR for Medical Imaging Equipment progresses.

If you have any questions, please feel free to contact me at afrederick@advamed.org.

Sincerely,

Adrienne Frederick
Senior Manager, Health Policy & State Government Affairs
AdvaMed Medical Imaging Division

AdvaMed Medical Imaging Division represents the manufacturers of medical imaging equipment and focused ultrasound devices. Our members have introduced innovative medical imaging technologies to the market, and they play an essential role in our nation's health care infrastructure and the care pathways of screening, staging, evaluating, managing, and effectively treating patients with cancer, heart disease, neurological degeneration, COVID-19, and numerous other medical conditions.