ENERGY STAR® Program Requirements Product Specification for Medical Imaging Equipment

Eligibility Criteria Draft 1, Version 1.0

Following is the Draft 1, Version 1.0 ENERGY STAR Product Specification for Medical Imaging Equipment. A product shall meet all of the identified criteria if it is to earn the ENERGY STAR.

Note: EPA received multiple sets of feedback from stakeholders regarding the discussion guide released in November 2022, including numerous letters of support from healthcare professionals across the country. EPA has taken that enthusiasm into account with the development of this Draft 1 proposal. This proposal addresses two areas of concern from end-users: lack of publicly available energy use data and the difficulty of incorporating energy management features into products. EPA looks forward to continuing the discussion with stakeholders as part of this process.

1 DEFINITIONS

A) Product Types:

1) Medical Imaging Equipment: Medical imaging equipment employs technologies, such as radiology and sonography, to create images of the human body. This type of equipment is used to reveal, diagnose, and examine patients for clinical purposes, or to study human anatomy and physiology for the purposes of medical science.

2) Computed Tomography: 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 (CT) scans use X-rays to produce precise cross-sectional images of anatomical structures and spaces within objects.

3) Endoscopy: Use of small camera directly inserted into the body to examine the interior of a hollow organ or cavity in the body.

4) General Radiography (X-ray): 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

   A. Cyberknife: Frameless robotic radiosurgery system composed of (1) a linear accelerator and, (2) a robotic arm that directs the X-ray. The X-ray is used to destroy cancer cells.

   B. Fluoroscope: Device that obtains real time images of internal structures. The fluoroscope employs an X-ray source and a fluorescent screen that go on either side of a patient.

   C. Linear Accelerator: Device that delivers a uniform dose of high energy X-ray to a tumor or other cancerous cells. The X-rays can destroy cancer cells while sparing the normal tissue surrounding a tumor.

5) Magnetic Resonance 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 images.

6) Mammography Equipment: 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.

7) Nuclear Imaging: A patient consumes short-lived isotopes which emit radiation that is 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.

8) Photoacoustic Imaging: A non-ionizing technique that uses low-energy lasers with an infrared wavelength. The wavelength can penetrate deep into the body with sensitive ultrasonic detectors capturing 2D and 3D images from the way the light is absorbed by various tissues.

9) Thermography: A diagnostic technique where an infrared camera is used to capture temperature variations on the surface of the body, revealing sites of abnormal tissue growth below the skin.

10) Ultrasound Imaging/Sonography: Technology that exposes a body part to high-frequency sound waves that are reflected by tissues in the body to produce real-time 2D and 3D images.

B) Operating Modes

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

2) Low power mode: This mode represents the minimum energy consumption state that the user can select according to the user manual. The power consumption is lower than Ready-to-scan and higher than Off mode (e.g., sleep mode, service/evaluation mode).

3) Ready-to-scan mode: 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). This mode does not include potential mechanical movements such as X-ray tube rotor or gantry rotation.

4) Scan mode: 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.

C) Product Family: A group of product models that are (1) made by the same manufacturer, (2) have the same scanning hardware:

1) Configurability Characteristics: Characteristics such as diagnostic computing hardware, variation in traducers and other probe features, and other optional accessories.

2) Aesthetic Characteristics: Characteristics such as external finish, color, and spatial orientation (if applicable).

Note: EPA received feedback that the definitions provided above, largely sourced from the 2014 COCIR medical imaging test method, are outdated. Unfortunately, EPA did not receive any specific feedback or suggestions on ways to update these definitions, so the Agency has retained those definitions for this Draft 1 proposal. The Agency looks forward to further feedback and updates to the definitions, which could be incorporated into a future draft as part of this process.

In addition, EPA notes that some products that are part of the excluded scope do not have definitions. While having definition for excluded products is not always necessary in an ENERGY STAR specification, if there are industry accepted definitions for those products (or any products that are added to this list as part of the specification development process) EPA would be interested in incorporating those into this specification.

Finally, EPA often uses a Product Family definition to group very similar products together, allowing for the testing of one representative model for the purpose of ENERGY STAR certification on behalf of all products in a family, reducing level of effort associated with testing and certification. This definition is different for different products across the program and the Agency has a included a proposed definition that captures the relevant points for this category.

2 SCOPE

2.1 Included Products

2.1.1 A product must meet the definition of a Medical Imaging Equipment in *Section 1* of this document to be eligible for ENERGY STAR certification under this specification. Eligibility under Version 1.0 is limited to Computed Tomography, General Radiography, Magnetic Resonance Imaging, Mammography, Nuclear Imaging and Ultrasound Imaging/Sonography products. Products explicitly excluded from Version 1.0 are identified in *Section 2.2*.

Note: EPA received feedback suggesting that EPA should only focus on one product area in Version 1.0, but this feedback did not specify which product type to focus on nor a full explanation as to why products that are covered by a current industry test method used in Europe should not be addressed by this specification. As such, the Agency believes the proposed requirements are broad enough that in combination with the ENERGY STAR test method can highlight products with effective power management capabilities without negatively impacting patient care for the scope provided in Version 1.0.

2.2 Excluded Products

2.2.1 Products that are covered under other ENERGY STAR product specifications are not eligible for certification under this specification. The list of specifications currently in effect can be found at www.energystar.gov/products.

2.2.2 The following products are not eligible for certification under this specification:

i. Angio Suites;
ii. Bone Densitometers;
iii. C-arms;
iv. Cyberknife
v. Contrast Media Injectors;
vi. Endoscopy;
vii. Line Accelerators
viii. Photoacoustic Imaging;
ix. Thermograph; and
x. Medical imaging products with combined modalities (e.g. PET/CT, SPECT/CT, PET/MRI).

Note: EPA received feedback supportive of the scope exclusions proposed in the discussion guide, but also included that Cyberknife and Line Accelerators should be placed on this list as they are not truly medical imaging equipment products. In addition, stakeholders requested that combined modality products be excluded from scope due to their complexity. EPA's proposal accepts these recommendations. EPA notes that products may be added to the scope in the future if there is further interest and the test method is viable for these new product types. Such scope expansion would occur through an amendment process, which would be a subsequent open and transparent process.

3 CERTIFICATION CRITERIA

3.1 Significant Digits and Rounding

3.1.1 All calculations shall be carried out with directly measured (unrounded) values.

3.1.2 Unless otherwise specified, compliance with specification limits shall be evaluated using directly measured or calculated values without any benefit from rounding.

3.1.3 Directly measured or calculated values that are submitted for reporting on the ENERGY STAR website shall be rounded to the nearest significant digit as expressed in the corresponding specification limit.

3.2 Power Management Requirements

3.2.1 Product Power Management: To certify for ENERGY STAR, a Medical Imaging Equipment product must include a power management feature that powers the unit down automatically to a low power mode within 30 minutes upon reentering ready-to-scan mode after a scan. This low power mode shall consume no more than 80% of the energy used in ready-to-scan mode. Products are encouraged but not required to enter any lower power modes available (e.g., sleep mode) that consume progressively less energy upon product inactivity lasting longer than 1 hour if applicable.

3.2.2 Computing Power Management: To certify for ENERGY STAR, any computing products sold with the Medical Imaging Equipment product to process images and/or perform data entry must enter a low power or sleep mode within 30 minutes of inactivity.

3.2.3 Display Power Management: To certify for ENERGY STAR, any external displays sold with the Medical Imaging Equipment product to view diagnostic results must enter a low power or sleep mode within 30 minutes of inactivity.

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 must be detailed in the certification submission. This requirement applies to power management features in the Medical Imaging Product itself, as well as supporting computers and displays that can be configured by the installer or end-user.

3.2.5 Report the following to aid purchasers in the appropriate usage of power management.

i. Provide either physical or electronic documentation which explains how power management is engaged, disengaged, and adjusted for the specific product in question.

ii. Provide the web link on the partner's website that shows information on the power management features of their product.

Note: EPA received feedback stating that power management to lower power modes is complicated and not appropriate in all operating conditions for all product types. EPA is proposing that power management to low power modes is enabled as shipped, understanding that some customers may disable these features at initial installation/configuration for their given workload, particularly when considering products with high use throughout the day and night. With that said, EPA expects this mode to be available and for partners to educate their customers on how to configure and/or interact with these modes. Further, EPA encourages partners to highlight the energy benefits of power management to lower power modes to customers. The Agency is intent on making power management an opt-out feature rather than an opt-in feature, and to ensure power management operates without negatively impacting performance. Currently, opt-in is the status quo for power management, creating customer confusion and significantly limiting the savings delivered by the feature.

EPA is also proposing conservative power management requirements for any computer or display products that are sold with Medical Imaging Equipment product to align with existing ENERGY STAR power management requirements for those product types. EPA understands that some of this hardware may be custom built and ENERGY STAR criteria may not be appliable.

4 STANDARD INFORMATION REPORTING REQUIREMENTS

4.1 Data Reporting Requirements

4.1.1 The following data will be displayed on the ENERGY STAR Web site through the product finder tool:

i. model name and number, identifying SKU and/or configuration ID;

ii. system type;

iii. system characteristics (form factor, scan specifications, power specifications, etc.);

iv. system configuration(s);

v. energy consumption data from testing;

vi. enabled power saving features (e.g., power management); and

vii. for product family certifications, a list of certified configurations with certified SKUs or configuration IDs.

4.1.2 EPA may periodically revise this list, as necessary.

5 TESTING

5.1 Test Methods

5.1.1 When testing Medical Imaging Equipment products, the test methods identified in Table 1 shall be used to determine ENERGY STAR certification.

Table 1: Test Method for ENERGY STAR Certification

Product Type or Component	Test Method
All	ENERGY STAR Draft Test Method for Medical Imaging Equipment (Rev. May 2023)

5.2 Number of Units Required for Testing

5.2.1 Representative Models shall be selected for testing per the following requirements:

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.

ii. For certification of a product family, the product with the highest energy use within the family shall be considered the Representative Model.

5.2.2 All product configurations within a product family that is submitted for certification must meet ENERGY STAR requirements, including products for which data is not reported.

Note: Partner must ensure that all configurations certified as ENERGY STAR continue to meet the certification criteria through subsequent firmware, software, or other changes to the certified product.

6 EFFECTIVE DATE

6.1.1 Effective Date: This ENERGY STAR Medical Imaging Equipment specification shall take effect on **TBD**. To certify for ENERGY STAR, a product model shall meet the ENERGY STAR specification in effect on its date of manufacture. The date of manufacture is specific to each unit and is the date on which a unit is considered to be completely assembled.

6.1.2 Future Specification Revisions: EPA reserves the right to change this specification should technological and/or market changes affect its usefulness to consumers, industry, or the environment. In keeping with current policy, revisions to the specification are arrived at through stakeholder discussions. In the event of a specification revision, please note that the ENERGY STAR certification is not automatically granted for the life of a product model.

Note: As presented in the Discussion Document, EPA continues to work towards a goal of having a completed Version 1.0 specification by the end of 2023 and having certification available at that time.

7 CONSIDERATIONS FOR FUTURE REVISIONS

7.1 TBD