ENERGY STAR® Program Requirements
Product Specification for
Medical Imaging Equipment

Eligibility Criteria
Draft 2, Version 1.0

Following is the Draft 2, 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.

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 (CT): 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: 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. 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.

Note: EPA has removed the X-ray sub definitions for Cyberknife and Linear Accelerator previously proposed in Draft 1 as their industry accepted definitions do not currently meet the ENERGY STAR definition of Medical Imaging Equipment.

5) Magnetic Resonance Imaging (MRI): 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.

   A. Low Helium Magnetic Resonance Imaging: MRI systems that have an enclosed helium circuit using 100 liters or less of helium.

   B. Ultra-High Field Magnetic Resonance Imaging: MRI systems with a nominal magnetic field strength of 7 or more Tesla. These systems have high resolution capabilities of ultra-high field.

Note: EPA received stakeholder feedback providing definitions and supporting data to justify the recognition of two subtypes of MRI systems, low helium and ultra-high field. After reviewing the information, EPA agrees that these products are sufficiently different fundamentally that they warrant special consideration and is proposing the definitions above to differentiate them from regular MRIs.

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 and Periods:

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 applies to non-operating hours. It is manually or automatically activated by the user and 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.

3) Power save mode: This mode applies to operating hours and is automatically activated by the product in its as-shipped 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: 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.

5) 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.

6) Non-operating Hours: Daily times/hours outside of operating hours as defined by end users.

7) Operating Hours: Daily times/hours that a business provides for pre-scheduled and walk-in appointments, including emergency care, where the use of medical imaging equipment can be expected.

Note: EPA received stakeholder feedback suggesting the need to define operating and non-operating hours to better categorize and address products with automatic vs. manual power management functionality at different times of the day. EPA is proposing to adopt the suggested definitions above and welcomes feedback on whether any further clarity on these definitions is needed.

As a result of these new operating period definitions, EPA has also clarified that low power mode applies to non-operating hours and that the new power save mode is applicable to operating hours to avoid confusion between the different types of low power modes available in the product during different operating conditions.

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).

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 Magnetic Resonance Imaging. Products explicitly excluded from Version 1.0 are identified in *Section 2.2*.

Note: After several meetings with industry, EPA now agrees that more data is needed to successfully address additional modalities in this specification accounting for all complexities and their potential impact on user experience and patient health. As such, EPA is focusing on MRI products in the Version 1.0 specification, where sufficient data is available to set requirements that both EPA and stakeholders feel can encourage improvement in products without creating any unintended consequences on patient care or product availability. EPA will continue to work with stakeholders to cover more modalities over the coming months to cover more modalities as additional data allows. These will be added to scope either through specification amendments or full a full revision.

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. Ultrasound Imaging/Sonography;

ii. Computed Tomography;

iii. General Radiography;

iv. Mammography:

v. Nuclear Imaging;

vi. Angio Suites;

vii. Bone Densitometers;

viii. C-arms;

ix. Contrast Media Injectors;

x. Endoscopy;

xi. Photoacoustic Imaging;

xii. Thermograph; and

xiii. Medical imaging products with combined modalities (e.g. PET/CT, SPECT/CT, PET/MRI).

Note: EPA has moved Ultrasound, CTs, X-rays, mammography, and nuclear imaging to the scope exclusion list for the time being in Version 1.0, with the intent of adding them to scope in future specification amendments and/or revisions.

In addition, EPA has removed the previous references of Cyberknife and Linear Accelerators as they do not meet the current ENERGY STAR Medical Imaging Equipment definition.

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 Automatic Product Power Management: To certify for ENERGY STAR, a Medical Imaging Equipment product must be able to power down automatically to a low power 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 with no power management enabled, as stated in Table 1 below:

Table 1: Required Power Down Percentage in Low Power Mode for Automatic Power Management

Product Type	Operating Hours
MRI	10%
Low Helium MRI	7%

3.2.2 Manual Product Power Management: To certify for ENERGY STAR, a Medical Imaging Equipment 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 with no power management enabled, as stated in Table 2 below:

Table 2: Required Power Down Percentage in Low Power Mode for Manual Power Management

Product Type	Non-Operating Hours
MRI	25%
Low Helium MRI	16%

3.2.3 Additional Low Power Modes: Products are encouraged but not required to enter any lower power modes available (e.g., sleep mode) upon product inactivity lasting longer than 1 hour if applicable.

Note: After considerable discussion with industry and a review of new data on product power management behavior in both operating and non-operating hours, EPA is proposing to revise the product power management levels to create requirements for both operating hour types. Furthermore, in discussions with stakeholders, EPA found that there is the ability to automate and incorporate as-shipped power management during operating hours. For non-operating hours, EPA found that setting up power management manually retains the best balance of energy efficiency and patient care. EPA believes that these requirements set a foundation to work with stakeholders to continue to improve the energy profile of their products in the future.

In addition, EPA received feedback that the custom nature of much of the computer and display equipment does not lend itself to the previously proposed component level power management requirements in Draft 1, particularly since their energy use is a very small fraction of the product's overall energy use. EPA is proposing to focus on the power management of the overall product only in Draft 2, which does include periphery components including computers and displays at an aggregate product level.

3.2.4 Power Management Availability and Reporting: To certify for ENERGY STAR, all automatic power management techniques listed above must be enabled as-shipped and both automatic and manual power management features 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.

Note: EPA has clarified above that only automatic power management is required to be enabled as-shipped for ENERGY STAR certification.

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. reduction in energy consumption in low power modes as a percentage as determined from testing;

Note: The EPA is aware of stakeholder interest in obtaining better data on how much energy their medical imaging products are consuming. However, EPA is also aware that the energy profile of medical imaging equipment is complex and variable. As such, EPA plans to share the percent reduction in energy use for the operating and non-operating power modes on the certified product list and product finder tools.

In addition, EPA is assessing if certain tools provided by COCIR would be applicable for assessing more accurate energy consumption estimates for the particular product purchased or considered for purchase by end-users. EPA will provide further information after this assessment has been completed. If considered applicable, the Agency would provide this information on the ENERGY STAR website for end-users to use.

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 3 shall be used to determine ENERGY STAR certification.

Table 3: Test Method for ENERGY STAR Certification

Product Type or Component	Test Method
All	ENERGY STAR Draft Test Method for Medical Imaging Equipment (Rev. April 2024)

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 defined by the partner as the base configuration within the family shall be considered the Representative Model.

Note: After discussion with stakeholders, EPA has revised the Representative Model to align with what manufacturers typically define as their base configuration for a product model line.

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: EPA continues to work towards a goal of having a completed Version 1.0 specification by the summer of 2024. The Agency is aware of interest in completing the test method in advance of releasing the specification to allow stakeholders the ability to begin testing their products and having product ready to be certified when the specification is released.

7 CONSIDERATIONS FOR FUTURE REVISIONS

7.1 EPA intends to work with partners to expand the scope of this specification through future amendments and full specification revisions as needed to include Ultrasound, CTs, General Radiology Equipment, Mammography Equipment and Nuclear Imaging as supporting data allows.