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IS YOUR CT SMART DOSE COMPLIANT?

The National Electrical Manufacturers Association (NEMA) XR 29-2013 (Standard Attributes on CT Equipment Related to Dose Optimization and Management) also known as the Medical Imaging & Technology (MITA) Smart Dose Standard identifies four key attributes of CT systems that are designed to help clinicians with dose optimization and management in order to maintain the standard of care established by professional societies and regulatory agencies, such as the American College of Radiology (ACR), The Joint Commission, and others. Subsequent to MITA's publication of the Smart Dose Standard, the Federal Protecting Access to Medicare Act of 2014 became law. Under this law, Centers for Medicare & Medicate Services (CMS) will pay less for certain diagnostic CT scans performed on equipment in a physician's office or hospital outpatient setting that does not meet all four attributes of the Smart Dose Standard. The purpose of this document is to clarify with CT users and hospital administrative staff how to determine whether their CT equipment conforms to the Smart Dose Standard and outlines important considerations for assessing system modifications marketed to obtain Smart Dose Standard conformance.

How is compliance determined?

Under the law, healthcare providers will be required to report when a CT service is performed using equipment that is not compliant with the Smart Dose Standard. We believe that at minimum, healthcare providers will be required to provide documentation from the manufacturer of their CT system identifying whether or not their system meets the four attributes. CT manufacturers (OEMs) have committed to provide a certification, based on their knowledge of individual system configurations, when the four required attributes have been integrated on a particular piece of equipment. These attributes are described below along with specific considerations in determining compliance.

The CT DICOM Radiation Dose Structured report (RDSR) enables capturing of both pre- and post-exam dose information in a standardized electronic format that can be included in the patient record. It is also the key to being able to monitor and track doses for establishment of diagnostic reference levels as well as facility dose management and quality assurance.[1]

DICOM RDSR is available on new model CT Scanners. Prior to the industry adoption of RDSR, many CT systems stored an image containing a screen capture of a dose report, listing $CTDI_{vol}$ and DLP values for each CT series. The reports contained much less information than the RDSR, and the values could not be directly processed. Commercial and open source software attempts to perform optical character recognition and text parsing, but this is only capable of partially populating an RDSR, and does not achieve compliance.

The CT Dose Check notifies and alerts the operating personnel, prior to starting a scan that the estimated dose index is above a value defined and set by the practice or healthcare organization. To accommodate different operational and medical decisions at the health provider level, this Dose Check attribute does not define or require specific notification values, only the capability to select and define them within the equipment.[2]

Dose Check is incorporated into the firmware of a CT system by the manufacturer and dose related notification and alert messages must appear on the operating console of the CT scanner prior to starting a scan in order for the system to be compliant. To continue scanning, a compliant system must prompt the user to enter their name, diagnostic reason for exceeding the predetermined threshold, reconfirm the chosen protocol, and in some cases provide a password before proceeding to the scan. An accessory or external software application not integrated into the firmware of the CT system cannot meet the Dose Check requirements.

Automatic Exposure Control (AEC) is an operational mode that tailors a CT system's radiation output to the specific body regions and parts being imaged in order to manage the radiation delivered to obtain the desired level of diagnostic quality. Its controls are displayed on the operating console.

AEC is incorporated into newer CT machines as a as part of the system design and firmware, relying on patient specific parameters obtained during the scan setup process and/or continuously during the scan to modulate the X-Ray tube output. If you are not familiar with this attribute on your system, check your equipment guide and other labelling. If you're still unsure, contact the service line for the applicable manufacturer.

Pediatric and Adult Reference Protocols A protocol is a set of scanning parameters (such as scan type(s): kV, mA, collimation, rotation speed, reconstruction algorithm, etc.) established to accomplish a particular clinical task (such as capturing an image of the abdomen). Protocols that are pre-loaded on a CT system that may be selected at the operator's discretion are called reference protocols. Manufacturers develop reference protocols through detailed knowledge of the system's specific performance characteristics and input from clinical collaborators.

Reference protocols may be in the format defined in NEMA XR 28-2013, explained within section 2.4 and appendix C and found in the system's user manuals. The XR 28 standard is free for electronic download. If you are unsure whether your system meets the reference protocols attribute, contact the service line for the applicable manufacturer.

Carefully evaluate upgrades of non-compliant equipment:

A decision to upgrade non-compliant CT equipment should take into consideration many factors such as the complexity of your equipment, your clinical usage, and ultimately the cost/benefit of upgrading.

To understand Smart Dose upgrades, consider how the four attributes are integrated into the CT equipment. As described above, many of the required features are integral to the system design/firmware and a third party software tool or bolt-on accessory likely will not achieve compliance. Additionally, you should consider whether the level of invasive integration into the OEM system and software required to incorporate these features would void any OEM warranty and/or require the third party vendor to obtain and maintain their own regulatory registration to design and perform such modifications.

Please see Appendix A for a guide to evaluate upgrades for achieving Smart Dose compliance and ask the vendor to supply a certification that the specific CT system meets all four of the attributes to be Smart Dose compliant.

References

1. The CT Dose details of an RDSR are described in DICOM PS 3.16-2011 as TID 10011, 10012, 10013, 10014, and TID 10015. The details of the study and patient to which the RDSR applies are referenced in DICOM PS 3.3-2011 in Section A.35.8 and are similar to most other DICOM objects.
2. CT Dose Check is defined in NEMA XR 25-2010 the Computed Tomography Dose Check standard and incorporated in IEC 60601-2-44, Ed. 3.1, paragraph 203.107 "Safety measures against excessive x-radiation".
3. AEC is defined in IEC 60601-2-44 Ed. 3.1, paragraph 203.106 "Control of RADIATION output" for AEC. Additionally, NEMA XR 28-2013 *Supplemental Requirements for User Information and System Function Related to Dose in CT* contains a general explanation of AEC functionality that may be present on a CT system.

Appendix A: Independent Vendor Evaluation Guide:

Vendors may offer modifications or solutions about dose management including some that claim will make your CT equipment compliant with the Smart Dose Standard. We suggest you approach the decision to purchase a solution with caution and consider the following factors:

1. Does the vendor provide a certification that the four required attributes have been integrated on a particular piece of equipment?
2. Assess the upgrade solution as it relates to each of the four attributes. Ask the vendor for detailed information on how their product meets each attribute.
    a. Are invasive modifications to the CT system required?
    b. Will an invasive modification be designed and performed by a vendor who is regulatory registered to do so.
    c. **DICOM SR:** Is a *complete* DICOM Structured Report generated (not just $CTDI_{vol}$ & DLP)?
    d. **Dose Check:** Do alerts and notifications appear *on the operating console* of the CT scanner *prior to starting a scan*? Does the system prompt the user to enter their name, diagnostic reason for exceeding the predetermined threshold, reconfirm the chosen protocol, and in some cases provide a password *before proceeding to the scan*?
    e. **AEC:** Does the system use patient-specific parameters obtained during the scan setup process and/or continuously during the scan to modulate the X-Ray tube output? If not, can this feature be implemented without invasive modifications to the system?
    f. **Reference Protocols:** Are reference protocols pre-loaded *onto the CT system* and developed with detailed knowledge of the system's specific performance characteristics and input from clinical collaborators?
3. If invasive modifications are required, will this modification void the OEM warranty?
4. Smart Dose Standard compliance requires these four, and only these four, attributes. There are no substitutes (e.g. iterative reconstruction) for any one or all of them that can make your equipment compliant or render any one or more of these four attributes unnecessary.
5. Review the vendor product information and specifications.
    a. Do you understand clearly how the product effectively upgrades your system to meet each of the four attributes?
    b. Does this meet your understanding of how your system operates?
    c. Does it sound possible and technically accurate?
    d. Does the vendor's response confuse you by referring to various other features not specifically related to the Smart Dose Standard?