

The American College of Radiology

NEMA XR-29 (MITA Smart Dose) Standard: Frequently Asked Questions

(Revised: February 28, 2017; updated questions in red)

*The Protecting Access to Medicare Act (PAMA) signed into law in April 2014 was the last “patch” of the SGR and included many implications for imaging providers. Among these are requirements that health care providers comply with the National Electrical Manufacturers Association (NEMA) XR-29 Standard Attributes on CT Equipment Related to Dose Optimization and Management, also known as MITA Smart Dose. During the summer of 2015, the Centers for Medicare and Medicaid Services (CMS) issued Medicare Physician Fee Schedule (MPFS) and the Hospital Outpatient Prospective Payment System (HOPPS) proposed rules for public comment outlining how the law will be implemented. The ACR, as well as other professional organizations, submitted detailed comments for their consideration. The final rule was published at the end of October 2015. **This law went into effect on January 1, 2016. Be sure you know what is expected and take action to avoid cuts to your reimbursements.***

The following Frequently Asked Questions contain information from the law, the federal regulations and CMS (current as of the date noted above) on meeting this new requirement and does not constitute ACR “guidance.” Please note that CMS is currently finalizing its processes for implementing the XR-29 requirements so some information provided herein may be subject to change.

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General

1. Q. What is XR-29?

- A. The NEMA XR-29 standard ([MITA Smart Dose](#)) specifies four attributes of CT scanners that “contribute to or help perform optimization and or management of doses of ionizing radiation while still enabling the system to deliver the diagnostic image quality needed by the physician.” CT scanners meeting the XR-29 Standard have the following:
- DICOM-compliant radiation dose structured reporting. See [NEMA XR 29-2013](#) (Standard Attributes on CT Equipment Related to Dose Optimization and Management) and <http://dicom.nema.org/>.
 - Dose check features. See [NEMA XR 25-2010](#) (Computed Tomography Dose Check).
 - Automatic exposure control. See [NEMA XR-28-2013](#) (Supplemental Requirements for User Information and System Function Related to Dose in CT).

- Reference adult and pediatric protocols. See [NEMA XR-28-2013](#) (Supplemental Requirements for User Information and System Function Related to Dose in CT).
2. **Q. What is the law that calls for compliance with XR-29?**
 - A. [Protecting Access to Medicare Act \(PAMA\) of 2014](#)
 3. **Q. What is the final CMS rule regarding XR-29?**
 - A. CMS requires the following:

“Beginning January 1, 2016, hospitals and suppliers will be required to report the modifier “CT” on claims for CT scans described by any of the CPT® codes identified in this section (and any successor codes) that are furnished on non-NEMA Standard XR-29-2013-compliant CT scanners. The use of this modifier will result in the applicable payment reduction for the CT service, as specified under section 1834(p) of the Act.”

Search on “XR-29” in the CMS document below to find the relevant rule and their response to public comments:

 - Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 Medicare Physician Fee Schedule (<https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-28005.pdf>)
 4. **Q. What were the ACR comments to CMS regarding XR-29 in the proposed CMS rules?**
 - A. Search on “XR-29” in the following ACR letters to find the relevant comments on the CMS proposed rules:
 - [ACR comments on 2016 Medicare Physician Fee Schedule](#)
 - [ACR comments on Hospital Outpatient Prospective Payment System](#)
 5. **Q. I have questions regarding CMS’s requirements for CT scanner compliance with XR-29 and reimbursement. How do I contact CMS?**
 - A. See the CMS FAQs included in their [April 8, 2016 memo](#) to State Survey Agency directors. You may also contact CMS at ADIAccreditation@cms.hhs.gov.

Applicability and Reimbursement

1. **Q. What are the penalties for non-compliance with XR-29?**
 - A. **Effective January 1, 2017, CT equipment not in compliance with all four attributes of the XR-29 Standard will be subject to a 15 percent per scan technical component reduction.** (This is an increase from the 5 percent per scan reduction that was in place on January 1, 2016.)
2. **Q. Where does the law apply?**
 - A. This penalty applies only to the **technical component** [and the technical component of the global fee] on diagnostic CT procedures billed in **imaging centers, physician offices and hospital outpatient settings**. If a facility bills for both inpatient and outpatient CT scans on the same scanner, the reduction applies only to those scans billed as Medicare outpatient procedures. The policy does not affect scans billed under the hospital inpatient setting (including those at **critical access hospitals**).

3. Q. To what procedures does this law apply?

A. This penalty applies only to the **technical component** and the technical component of the global fee of the following diagnostic CT procedure CPT[®] codes:

- 70450–70498
- 71250–71275
- 72125–72133
- 72191–72194
- 73200–73206
- 73700–73706
- 74150–74178
- 74261–74263
- 75571–75574
- Any succeeding codes

These are diagnostic CT procedures that include head/brain, abdomen, pelvis, upper extremity, lower extremity, etc. CMS will maintain a list of codes subject to the “CT” modifier in the web supporting files for the annual rule.

4. Q. Does the law apply to interventional radiology procedures on the CT scanner?

A. No, the law does not apply to interventional radiology procedures performed on the CT scanner.

5. Q. Does the law apply to CT simulation for radiation therapy?

A. No, the law does not apply to CT simulation for radiation therapy.

6. Q. Does the law apply to PET/CT procedures?

A. No, the law does not apply to PET/CT procedures. However, if the PET/CT scanner is used for **diagnostic CT studies and includes any of the CPT[®] codes listed above**, the law does apply.

7. Q. How will imaging facilities be expected to document to CMS that their CT scanners do or do not comply with XR-29?

A. CMS created the modifier “CT” (computed tomography services furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) XR-29-2013 standard) to assist practices in identifying noncompliant equipment. The rule specifies that:

*“Beginning January 1, 2016, hospitals and suppliers will be required to **report the modifier “CT”** on claims for CT scans described by any of the CPT[®] codes identified in this section (and any successor codes) that are furnished on **non-NEMA Standard XR-29-2013-compliant CT scanners**. The use of this modifier will result in the applicable payment reduction for the CT service.”* See [MLN Matters MM9250](#) for the official information from CMS.

8. Q. How do you add the CT modifier to the technical component for noncompliant CT scanners when the facility bills globally?

- A. Append the “CT” modifier to the global charge to designate the procedure was performed on equipment that is noncompliant with the NEMA standard. Medicare Administrative Contractors will make the payment adjustment only to the technical component of the global charge.

According to [CMS Transmittal #3402](#):

*“Effective for claims with dates of service January 1, 2016, through December 31, 2016, a 5 percent reduction applies to the technical component (and the technical component of the global fee) of the MPFS amount when the CT modifier is billed with the procedure codes...**For a global procedure billed with modifier CT, contractors shall reduce the global fee schedule amount by an amount equal to 5 percent of the fee schedule amount for the TC only code.**”*

*“Effective for claims with dates of service on or **after January 1, 2017, a 15 percent reduction** applies to the technical component (and the technical component of the global fee) of the MPFS amount when the CT modifier is billed with the procedure codes...**For a global procedure billed with modifier CT, contractors shall reduce the global fee schedule amount by an amount equal to 15 percent of the fee schedule amount for the TC only code.**”*

9. Q. What if our facility or practice equipment is not XR-29 compliant and we do not report modifier “CT?”

- A. If modifier “CT” is not appropriately assigned on the claim form to designate a procedure performed on equipment not in compliance with XR-29, Medicare will pay the full allowed amount. Once Medicare identifies an overpayment has been made, **the overpayment amount becomes a debt owed to the Federal government.** [Civil monetary penalties](#) may apply if you know of an overpayment and do not properly report and return it.

The ACR highly encourages all practices with CT equipment to check their equipment for compliance and update equipment as necessary to become compliant. If noncompliant XR-29 equipment is used, ensure modifier “CT” is assigned to indicate to CMS the procedure was not consistent with the NEMA XR-29 CT equipment standard.

10. Q. Our facility has two different CT scanners: one is compliant and one is not upgradable to become compliant. Will reimbursement for all CT scans performed at the facility be reduced or just those specifically performed on the non-compliant scanner?

- A. Reimbursement will only be reduced for applicable CT examinations performed on the noncompliant CT scanner that are designated by modifier “CT.” In order to ensure that only procedures performed on noncompliant units will be marked for reduction, facilities will need to modify their internal procedures so that the correct modifier is submitted for noncompliant machines. In order to receive full reimbursement for all applicable CT exams performed, **all** CT scanners within a facility will need to comply with XR-29.

11. Q. If a hospital bills for both outpatient and inpatient CT scans done on a scanner located in the hospital, would the hospital be penalized for both outpatient and inpatient procedures performed on the noncompliant equipment?

- A. When a hospital bills for both outpatient and inpatient CT scans performed on a scanner located in a hospital, the payment reduction would apply only to those scans billed as

outpatient examinations with modifier “CT,” regardless of the exact physical location of the CT scanner.

12. Q. If a noncompliant CT scanner is replaced in March 2017 with a new, XR-29-compliant scanner, will the facility only receive a 15 percent per scan reduction in reimbursement from January to March 2017?

A. Yes. Reimbursement will be reduced by 15 percent per scan for all applicable CT examinations performed on the noncompliant CT scanner from January to March 2017. The facility should receive full reimbursement for applicable CT examinations performed on the new, XR-29-compliant CT scanner after March 2017.

13. Q. Can the patient be held responsible for the reduction in payment by Medicare?

A. No, the Medicare beneficiary is not liable for the payment reduction applied to procedures performed on noncompliant CT equipment.

14. Q. Does the XR-29 penalty affect reimbursement for patients on state Medicaid programs?

A. No. XR-29 only applies to Medicare.

15. Q. Does ACR know how non-Medicare insurances (e.g., HMOs, PPOs, Medicare Replacement Plans, and commercial) will treat CT scans that are noncompliant with XR-29? Are they planning on following Medicare’s lead and lowering reimbursement rates?

A. At this time, we are not aware of any commercial plans that are following the XR-29 Medicare mandate. The ACR’s Managed Care Network will monitor this and provide information on our website should this change.

16. Q. How will noncompliance with XR-29 standards be verified?

A. According to the Medicare Claims Processing Manual, Chapter 12 – Physician/Nonphysician Practitioners, (issue 1-6-16) 20.4.7:

“The statutory provision requires that information be provided and attested to by a supplier and a hospital outpatient department that indicates whether an applicable CT service was furnished that was not consistent with the NEMA CT equipment standard...The statutory provision also provides that such information shall be verified, as appropriate, as part of the periodic accreditation of suppliers under SSA section 1834(e) and hospitals under SSA section 1865(a).” (See [CMS Transmittal #3402](#), section 20.4.7.)

17. Q. Our facility is accredited in CT with the ACR. How will ACR verify that our CT scanners do or do not comply with the XR-29 standards?

A. The statutory provision for XR-29 provides that “such information shall be verified, as appropriate, as part of the periodic accreditation of suppliers under SSA section 1834(e) and hospitals under SSA section 1865(a).” (See [CMS Transmittal #3402](#), section 20.4.7.) **The ACR is currently asking its accredited facilities to provide a copy of each CT unit’s Certificate of NEMA XR-29 Compliance so we can verify compliance with XR-29.** Going forward, the ACR will request copies of Certificates of NEMA XR-29 Compliance for each unit as part of the routine accreditation application and renewal process.

CMS is currently finalizing procedures for accrediting organizations to monitor and report CT system compliance with XR-29. Consequently, the ACR's current process for verification may change in the near future. The ACR intends to update these FAQs after the CMS procedures are publicly available.

18. Q. Must our CT scanner meet the XR-29 standards in order to achieve accreditation with the ACR?

- A. No. The ACR does not require that your CT scanner meet the XR-29 standards in order to achieve accreditation. (See the [CT Accreditation Program Requirements](#) for complete information on achieving accreditation with the ACR.)

Certificates of NEMA XR-29 Compliance

1. Q. Are there requirements for an acceptable Certificate of NEMA XR-29 Compliance?

- A. Yes. CMS has informed accreditation organizations of the following:

- Certificates of NEMA XR-29 Compliance from the **CT system manufacturer are acceptable.**
- Certificates of NEMA XR-29 Compliance from **3rd party vendors are acceptable if:**
 1. The 3rd party vendor has obtained the required **FDA 510(K) pre-market clearance** for their upgrade product; **and**
 2. The 3rd party vendor upgrade product has been **approved by CMS.**

Currently, the only FDA & CMS approved 3rd party vendor NEMA XR-29 upgrade product is the Medic Vision SafeCT-29. However, CMS will make an announcement if any additional 3rd party vendor NEMA XR-29 upgrade products receive the FDA 510(k) pre-market clearance and are approved by CMS.

If you have further questions, please contact CMS at ADIAccreditation@cms.hhs.gov.

2. Q. Our independent CT service provider has installed an upgrade so that our CT scanner is now compliant with all XR-29 required features. They provided us with a Certificate of NEMA XR-29 Compliance on their letterhead for our scanner. Is this certificate acceptable?

- A. No, accrediting organizations are not allowed to accept such certificates to document compliance with XR-29. See question #1 for CMS's instructions on acceptable Certificates of NEMA XR-29 Compliance.

3. Q. We purchased a refurbished CT scanner. The reseller (not the original equipment manufacturer) has upgraded this scanner to be compliant with XR-29 and provided us with a Certificate of NEMA XR-29 Compliance on their letterhead. Is this certificate acceptable?

A. No, accrediting organizations are not allowed to accept such a certificate to document compliance with XR-29 because it was prepared by the re-seller of the CT system, not the CT system manufacturer or 3rd party vendor with FDA 510(k) clearance for their NEMA XR-29 upgrade.

The CMS has informed us that there are several possible ways you may be able to obtain a valid manufacturer's Certificate of NEMA XR-29 Compliance. You could:

- Contact the original owner of the CT system and request a copy of the original manufacturer's Certificate of NEMA XR-29 Compliance (if any exists), or
- Contact the CT system manufacturer and request that they provide you with a Certificate of NEMA XR-29 Compliance that had been issued to the original owner (if one was issued), or
- Contact the CT system manufacturer and request that they provide you with a new Certificate of NEMA XR-29 Compliance.

See question #1 for CMS's instructions on acceptable Certificates of NEMA XR-29 Compliance.

Equipment Compliance and Features

1. Q. How can I determine if my CT scanner is compliant with XR-29?

A. To determine if your CT equipment complies with the NEMA XR-29 standard, please contact your CT scanner's manufacturer. You should also visit your manufacturer's XR-29 Vendor Certification Web Portal on the [MITA Smart Dose](#) website to download verification of compliance.

2. Q. Our CT scanner meets some but not all of the four XR-29 provisions. Must our scanner meet all of the XR-29 provisions in order to obtain full reimbursement?

A. Yes, your scanner must meet all of the following XR-29 provisions in order to obtain full reimbursement.

- DICOM-compliant radiation dose structured reporting.
- Dose check features.
- Automatic exposure control.
- Reference adult and pediatric protocols.

In addition, you must have a Certificate of NEMA XR-29 Compliance from the **CT scanner manufacturer** or an **"FDA & CMS approved 3rd party vendor"** to verify compliance upon request by CMS or your accrediting organization. See the Certificates of NEMA XR-29 Compliance section.

3. **Q. Our CT scanner manufacturer has informed us that they are unable to upgrade our scanner so that it is compliant with XR-29. May we modify our CT scanner with a commercial 3rd party solution to meet XR-29 compliance?**
- A. Yes. However, to qualify for full reimbursement, this upgrade must be performed by an **“FDA & CMS approved 3rd party vendor”**. See the Certificates of NEMA XR-29 Compliance section.
4. **Q. Does XR-29 require that the facility use any or all of the XR-29 features (e.g., dose check, automatic exposure control, reference adult and pediatric protocols, etc.) available in the XR-29-compliant CT scanner?**
- A. No. XR-29 only requires that the CT equipment used for applicable examinations **be compliant with XR-29**. The law does not require facilities to use these features. However, ACR recommends that XR-29 dose optimization features be used as clinically appropriate to optimize radiation dose to the patient.
5. **Q. Does XR-29 require that the radiation dose from the examination be documented in the patient’s final report?**
- A. No. XR-29 **does not** require facilities to document radiation dose in the patient’s final report.
6. **Q. What agency do we submit the dose report to? Does the report have to come straight from our scanner to a computer?**
- A. There is no requirement to submit a dose report to any agency.
7. **Q. Do we have to have dose monitoring software to keep a cumulative log of each patient’s DLP (dose-length product) and CTDI (computed tomography dose index) to meet the CMS requirements?**
- A. No. XR-29 does not require dose monitoring software or keeping “a cumulative log of each patient’s DLP and CTDI.” Furthermore, the ACR does not recommend adding up DLP and CTDI_{vol} for individual patients since these numbers are not patient dose but rather dose indices to plastic phantoms that probably don’t mimic the size of the patient that is being examined. Adding up such numbers is especially meaningless if the exams were done on different body regions of the patient.
8. **Q. How can I learn more about the XR-29 features of my CT equipment?**
- A. Contact your manufacturer’s representative or applications specialist for details and training on your CT scanner’s XR-29 features.
9. **Q. How can I better understand XR-29’s DICOM-compliant radiation dose structured reporting feature?**
- A. See [“The DICOM Radiation Dose Structured Report: What It Is and What It Is Not”](#) in the Journal of the American College of Radiology.

10. Q. How can I better understand XR-29's Dose Check feature?

- A. XR-29's Dose Check feature provides notifications and alerts so that radiologic technologists and physicians are aware of potentially high radiation doses during CT examinations. It is important that staff be aware of the proper use and limitations of these notifications and alerts. The AAPM-ACR-ASRT-MITA FDA Working Group Standardization of CT Nomenclature and Protocols have developed a set of **free**, general and manufacturer-specific educational slides that cover key points to ensure successful implementation of these features. Visit the [AAPM CT Scan Protocol](#) website and click on the "CT Dose-Check" tab to view these slides and obtain for more useful information.