Accrediting Organization (AO) Verification of Advanced Diagnostic Imaging (ADI) Supplier Compliance with NEMA XR-29-2013 CT Safety Requirements

**Purpose and Applicability:** This policy applies to CMS-approved Advanced Diagnostic Imaging Accrediting Organizations (ADI AOs) that accredit advanced diagnostic imaging (ADI) suppliers providing applicable CT services as defined at §1834(p)(2) of the Social Security Act (the Act).

**Exclusions/Exemptions:** A cone beam CT scanner is exempted from the NEMA XR-29-2013 requirements if the cone beam CT scanner meets one or more of the following criteria:

1. The cone beam CT scanner is not intended for or capable of performing the CT procedures identified as "applicable procedures" in §1834(p)(2) of the Social Security Act;

2. The cone beam CT scanner does not meet the definition of a “CT system” provided in the NEMA XR-29-2013 standards, or;

3. The cone beam CT scanner does not have the physical, mechanical, or technical capability of being upgraded to meet the NEMA XR-29-2013 standards (i.e. – it is not physically possible to upgrade the cone beam CT scanner so that it has all four of the attributes of NEMA XR-29-2013).

**I. Collection of NEMA XR-29-2013 compliance certification documentation from accredited ADI suppliers providing applicable CT services.**

A. Each ADI AO shall require each of its accredited ADI suppliers that provide CT services to provide documentation that indicates whether or not each CT system owned or operated by each accredited ADI supplier is fully NEMA XR-29-2013 compliant.

1. This documentation shall consist of a certificate of NEMA XR-29-2013 compliance for each CT system owned or operated by each ADI supplier accredited by an ADI AO.

2. The certificate of NEMA XR-29-2013 compliance must contain the information specified in section V below.

B. Each ADI AO must collect an initial baseline set of certificates of NEMA XR-29-2013 compliance for each CT system owned or operated by each of its accredited ADI supplier by no later than June 1, 2017.
1. The ADI AOs must obtain an electronic or hard copy of the actual certificate of NEMA XR-29-2013 compliance issued by an approved entity (as described in section IV below) for each CT system owned or operated by each accredited ADI supplier;

2. Attestations of any kind made by an accredited ADI supplier shall not be accepted in lieu of a certificate of NEMA XR-29-2013 compliance which has been issued by approved entities (as described in section IV below);

3. A CT system may not be reported by the ADI AOs to be NEMA XR-29-2013 compliant under any of the following circumstances:
   a. If an ADI supplier cannot provide a certificate of NEMA XR-29-2013 compliance for the CT system;
   b. If the certificate of NEMA XR-29-2013 compliance provided by the ADI supplier was issued by a non-approved entity that did not have the proper regulatory approval to perform a NEMA XR-29-2013 upgrade/modifications to the CT system; or
   c. If the certificate of NEMA XR-29-2013 compliance provided by the ADI supplier does not meet the requirements set forth in section V below.

4. The ADI AOs must maintain an electronic copy of the certificates of NEMA XR-29-2013 compliance collected for each CT system owned or operated by each accredited ADI supplier.

C. On-going ADI AO Monitoring of CT System NEMA XR-29-2013 Compliance

The ADI AOs shall perform additional verification of the NEMA XR-29-2013 compliance status of each CT system owned or operated by their accredited ADI suppliers on an on-going basis.

1. Existing CT systems, for which NEMA XR 29-2013 compliance was previously verified during the initial baseline verification process:
   a. NEMA XR-29-2013 compliance shall be re-verified as part of the periodic accreditation review or reaccreditation process activities.
b. Re-verification of the NEMA XR-29-2013 status of CT systems owned or operated by accredited ADI suppliers (“re-verification process”) shall occur as part of the periodic re-accreditation process, but no less frequently than every 5 years.

2. For any CT systems obtained by existing accredited ADI suppliers, after the date initial NEMA XR-29-2013 baseline verifications were obtained, but prior to re-verification has been performed:
   a. The ADI AO must require that their accredited ADI suppliers notify them if the ADI supplier has obtained any additional CT systems (new, used or recycled) for which NEMA XR-29-2013 compliance verification has not already been obtained.
   b. Upon receipt of notice that an accredited ADI supplier has obtained one or more additional new, used or recycled CT system(s), the ADI AO shall require that the ADI supplier provide initial verification of NEMA XR-29-2013 compliance for these additional CT systems(s) within 30 days.
   c. Thereafter, re-verification of NEMA XR-29-2013 compliance shall be obtained in accordance with the requirements set forth in section I above.

3. For CT systems owned and operated by new ADI suppliers accredited by an ADI AO after the initial NEMA XR-29-2013 baseline verification process has been completed:
   a. When an ADI AO accredits a new ADI supplier, the AO shall require initial verification of the NEMA XR-29-2013 compliance status for all CT systems owned or operated by that ADI supplier.
   b. Thereafter, re-verification of NEMA XR-29-2013 compliance for these CT system(s) shall be performed in accordance with the requirements set forth in section I above.

D. When an ADI supplier takes an existing CT system out of service (for which NEMA XR-29-2013 compliance or non-compliance has previously been verified):

1. The ADI supplier must notify their ADI AO within five days of the permanent discontinuation of use of that CT system;
2. If the CT system removed from service by an ADI supplier was non-NEMA XR-29-2013 compliant, the ADI AO must notify CMS of the discontinuation of the use of that CT system on the ADI AO weekly report submitted the Monday following receipt of notice from the ADI supplier.

II. Reporting of Non-Compliance with NEMA XR-29-2013 Safety Standards to CMS

If an ADI AO identifies that an accredited ADI supplier owns or operates one or more CT systems that are non-compliant with NEMA XR-29-2013 safety standards, this information must be reported to CMS as part of the mandatory ADI AO weekly data report that is submitted via the ADI accreditation e-mailbox every Monday.

A. ADI AOs that accredit ADI suppliers that own or operate more than one non-compliant NEMA XR-29-2013 CT system must report each non-compliant CT system separately.

B. Reporting of each non-compliant NEMA XR-29-2013 CT system shall continue on a weekly basis until compliance is achieved or the system is taken out of service.

C. An ADI AO must report to CMS, the following information about each non-compliant NEMA XR-29-2013 CT system owned or operated by an accredited ADI suppliers:

   1. Name of the ADI supplier that owns or operates the non-compliant NEMA XR-29-2013 CT system;
   2. Address of the ADI supplier;
   3. Location of the non-compliant NEMA XR-29-2013 CT system (if different from above address);
   4. Manufacturer of the non-compliant NEMA XR-29-2013 CT system;
   5. Model name and model number of the non-compliant NEMA XR-29-2013 CT system;
   6. Serial number of the non-compliant NEMA XR-29-2013 CT system;
   7. Date the ADI supplier put the non-compliant NEMA XR-29-2013 CT system into service.

III. Who may prepare certificates of NEMA XR-29-2013 compliance?

A. The CT System Original Equipment Manufacturer (OEM)

   The original manufacturer of the CT system may issue a certificate of NEMA XR-29-2013 compliance which attests to either of the following:

   1. The CT system is fully NEMA XR-29-2013 compliant as manufactured and does not require upgrades or modifications; or
2. The CT system was made fully NEMA XR-29-2013 compliant through installation of manufacturer software upgrades or system modifications.

3. The manufacturer’s certificate of compliance must contain the information stated in section V below.

B. A 3rd party vendor that installs a NEMA XR-29-2013 upgrade

A 3rd party vendor that has obtained the required regulatory approval (i.e. – FDA approval) for the NEMA-XR-29-2013 upgrade or modifications provided, may issue a certificate of NEMA XR-29-2013 compliance.

A certificate of NEMA XR-29-2013 compliance from a 3rd party vendor must contain the following information and attestations:

1. A list of the NEMA XR-29-2013 attributes already present on the CT system prior to installation of the 3rd party vendor upgrade product;

2. A list of the NEMA XR-29-2013 attributes installed on the CT system during the installation of the 3rd party vendor upgrade product;

3. Attestations as to the following facts:
   i. Upon completion of the upgrade installation, the CT system is fully compliant with the NEMA XR-29-2013 safety standards (i.e. – contains the following four required attributes of NEMA XR-29-2013 compliance: 1. Dicom Structured Report; 2. Dose Check; 3. Automatic Exposure Control; 4. Reference Protocols);

   ii. Each of the attributes of NEMA XR-29-2013 installed during the upgrade are fully functional; and

   iii. Upon completion of the upgrade, the CT system is fully operational as a whole.
IV. Certificate of NEMA XR-29-2013 Compliance from the CT System Manufacturer – Required Information¹

A. Certificate number;
B. Date certificate issued;
C. ADI supplier’s name;
D. ADI supplier’s address;
E. CT system manufacturer;
F. CT system model name and model number;
G. CT system serial number;
H. Software revision identifier or other unique identifier (if any);
I. An attestation stating that the CT system is fully NEMA XR-29-2013 compliant and incorporates each of the four required attributes of NEMA XR-29-2013:
   1. DICOM Dose structure reporting;
   2. Automatic Exposure Control;
   3. CT Dose Check; and

V. Certificate of NEMA XR-29-2013 Compliance from 3rd Party Vendor Who Performed NEMA XR-29-2013 Upgrade – Required Information

A. Name of 3rd Party Vendor;
B. Name of 3rd party vendor upgrade product
C. Evidence that this vendor has the required regulatory approvals (i.e. FDA approval) for the upgrade provided;
D. Date certificate issued;
E. Certificate Number (if any)
F. ADI supplier’s name;
G. ADI supplier’s address;

¹ The information required conforms to MITA’s recommended format for a NEMA XR-29-2013 certificate of compliance.
H. CT system manufacturer;
I. CT system model name and model number;
J. CT system serial number;
K. A list of the attributes of NEMA XR-29-2013 already present on the CT system prior to installation of the 3rd party vendor upgrade product;
L. A list of the attributes of NEMA XR-29-2013 installed on the CT system during the installation of the 3rd party vendor upgrade product;
M. Attestations as to the following facts:
   1. Upon completion of the upgrade, the CT system is fully compliant with NEMA XR-29-2013 safety standards (i.e. – contains the four required attributes of NEMA XR-29-2013 compliance;
   2. The attributes of NEMA XR-29-2013 compliance installed during the upgrade are fully functional; and
   3. Upon completion of the upgrade, the CT system is fully operational as a whole.