COMPUTED TOMOGRAPHY INSPECTION CHECKLIST
10A NCAC 15 .0611 Computed Tomography (CT) X-Ray Systems
New Requirements as of 10-1-17

Registrants that are required to comply with the .0611 Rule can be found in [%0611 (a)]
Definitions can be found in [%0611 (b)]

Required for Inspection

☐ All applicable items on the general Medical Inspection Checklist
☐ Systems required to meet requirements of 21 CFR 1020.33 [%0611 (c)]
☐ Aural communication capabilities [%0611 (c)]
☐ Operator training documentation [%0611 (d)]
☐ System performance evaluations and documentation of [%0611 (e)]
  • Performed by CT Qualified Expert (CT QE), or under general supervision of, and
    performed within 30 days of installation and at least every 14 months. [%0611 (e)]
  • Performance evaluation standards and tolerances met [%0611 (e)]
  • Performance evaluation to include specific requirements [%0611 (e)]
  • Output performed with an appropriately calibrated dosimetry system [%0611 (e)]
  • Performance evaluation is to be maintained for inspection by the Agency. [%0611 (e)]
☐ Routine quality control (QC) program and documentation of [%0611 (f)]
  • Development and/or approval of by CTQE [%0611 (f)]
  • Program requirements [%0611 (f)]
  • Routine QC documented and records retained for 14 months [%0611 (f)]
☐ Operating requirements [%0611 (g)]
  • Required information to be accessible to operators [%0611 (g)]

Recommended to Include in Written Safety Procedures

☐ Initiating any changes in CT protocols
☐ Permanently recording patient doses
☐ Radiologist and dose committee review of CTDI_{vol} in potentially high dose CT procedures
☐ Facility identification of CTDI_{vol} in excess of recommended levels
  (E.g. facility alert level in place and/or dose tracking in place)
☐ Reporting adverse events associated with CT overexposure
  (E.g. reporting requirements to the FDA) MedWatch How To Report Serious Problems to FDA
☐ Calibration and maintenance records [21CFR1020.30 ]
☐ Protocol manual that includes the technical factors and the maximum dose
  (Projected CTDI_{vol} values or equivalent for each type of study performed)
Additional Recommended Items

*FDA, CRCPD, The Joint Commission, AAPM, and ACR recommended practices.*

- Annual Physics Reports Performance Monitoring of Diagnostic CT Equipment
  - 2012 ACR Technical Standard of Diagnostic Medical Physics Performance Monitoring of CT Equipment
- Facility accreditation documentation, if applicable
  - CMS Advanced Diagnostic Imaging Accreditation.
- CT Dose Management Committee established 
  - CRCPD CT Dose Management Trifold
- Patient Safety Program established (TJC Facilities)
  - Education and radiation dose in imaging departments
  - The Joint Commission Sentinel Event Alert
- Protocols password protected or software modifications in place
- “Notification” and/or “alert” values in place on scanners
- NEMA XR 25 CT Dose-Check Standard
  - AAPM Recommendation Notification and Alert Levels Statement
- Facility participates in the ACR Dose Index Registry
  - ACR Dose Index Registry
- Additional guidance:
  - FDA Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging
  - Image Gently; “Think A Head Campaign”
  - Image Wisely