**Radiology Compliance Branch**
RADIATION PROTECTION SECTION

Division of Health Service Regulation ● N.C. Department of Health and Human Services

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

**The uses of Cone Beam CT, Veterinary CT, CT Simulation and CT attenuation correction are exempt from the requirements of this Rule and should reference the "Medical Inspection Checklist," found at https://radiation.ncdhhs.gov/Xray/documents/medicalinspcklist.pdf.**
**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 CTDIvol 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
  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