

**GUIDELINE FOR THE EVALUATION OF
COMPUTED TOMOGRAPHIC X-RAY UNITS**



**WASTE MANAGEMENT
& RADIATION CONTROL**

GUIDELINE FOR THE EVALUATION OF COMPUTED TOMOGRAPHIC X-RAY UNITS

Inspection Program Objective

The overall objective of the Division x-ray inspection program is to reduce the likelihood that individuals will be exposed to unnecessary radiation. In the case of registrants using x-ray equipment in the healing arts, patient exposure is of concern and proper equipment performance is essential. Registrants are required to demonstrate that the equipment satisfies the appropriate regulatory standards for calibration and performance.

Purpose of Guideline

The intent and purpose of this document is to provide users of computed tomographic (CT) x-ray units guidelines for the documentation necessary to demonstrate to the Director that the x-ray equipment satisfies the regulatory standards under clinical use conditions.

X-ray Equipment Performance and Calibration

The registrant is to document that the following requirements are met:

- 1) X-ray exposures greater than 0.5 seconds can be terminated by the operator at any time.
- 2) Visual indication of x-ray production at the gantry and control panel after x-ray production is initiated and if applicable, whether the shutter is open or closed.
- 3) Technique factors, tomographic section thickness, and scan increment are indicated prior to the initiation of a scan or series of scans.
- 4) In the event of equipment failure affecting data collection, x-ray exposure automatically terminates by either de-energizing the x-ray source or intercepting the x-ray beam with a shutter mechanism (through either a back-up timer or devices which monitor equipment). A visual signal is indicated when the x-ray exposure is terminated in this manner.
- 5) Emergency buttons or switches are clearly labeled as to their function.
- 6) Means is provided to permit visual determination of a reference plane which can be offset from the location of the tomographic plane. If a light source device is used to meet this requirement, the light source should provide illumination at levels sufficient to permit visual determination of the location of the tomographic plane or reference plane. The total error in the indicated plane or reference plane should not exceed 5 millimeters.

Quality Assurance Procedures

Quality assurance procedures for the CT x-ray system shall be developed and implemented by the registrant. The Quality assurance procedures shall be written and include, but are not limited to the following: specifications of tests that are to be performed, including instructions to be employed in the performance of those tests; and specifications of the frequency at which test are to be performed, the acceptable tolerance for each parameter measured, and actions to be taken if tolerances are exceeded. The parameters measured to satisfy this rule shall include, but are not limited to kVp, mA, and reproducibility of dose appropriate to the type of CT procedures performed. Records of tests shall be maintained for three years for inspection.

Dose Calibration

Radiation measurements shall be performed annually and after change or replacement of components which could cause a change in the radiation output. The calibration of the radiation measuring instrument shall be traceable to a national standard and shall be calibrated at intervals not to exceed two years. Measurement shall be specified in terms of the multiple scan average dose, using phantoms and technique factors appropriate to the type of CT procedures performed. If either or both pediatric and adult CT procedures are performed clinically, measurements shall be specified in terms of multiple scan average dose using technique factors appropriate to pediatric or adult CT procedures.