Medical Imaging & Technology Alliance (MITA) CT Group

FAQs for Users of ACR's CT Quality Control Manual

Q. Can the ACR QC manual replace the vendor recommended QC program?

A. No, the vendor's quality control program is carefully crafted with the specific design of the hardware and software in mind and should be followed. Service and manufacturer personnel are trained according to these manufacturer procedures and are best able to assist you using these vendor QC tests. In addition, failure to maintain the system using the QC protocols, procedures, and frequencies recommended by the manufacturer may result in voiding of warranties and may be in violation of your purchase or service agreement. The ACR QC manual can be used as a supplement to manufacturer QC for troubleshooting purposes but should not be used to determine if the machine is within its operating specifications.

Q. How do the vendors establish their QC program?

A. Manufacturer QC programs are based on the FDA-recognized international consensus standards IEC 61223-3-5 and 61223-2-6 for Acceptance and Constancy testing. IEC standards are developed as an international collaborative effort between manufacturers, regulators, and academic scientists.

Q. What if a scanner does not pass a specification recommended by the ACR in their QC manual or a specification that the medical physicist designed?

A. First, repeat the test to confirm the result. Next, consult the vendor's Technical Manual. If the same type of test is provided in the vendor's technical manual run the test as specified by the vendor and apply the vendor's specification. If the vendor's specification is passing and the clinical images do not have a clinically significant image quality issue, corrective action is likely not needed. If the vendor-provided test result is outside the vendor's specification, or there is believed to be a clinically significant degradation of image quality the images used for diagnosis, your Service engineer should be contacted. If the vendor does not provide specifications for a particular test, then the ACR or medical physicist's test result should be benchmarked and monitored over time. Please note additional testing outside of the vendor specifications may not be supported by the manufacturer.

Q. My machine passes all the vendor specifications, but when I apply my clinical protocol to the ACR phantom I get a failing result. What could be the problem?

A. Some elements of a clinical protocol, such as the reconstruction algorithm, may make assumptions that apply to human anatomy but may cause distortion in phantom images. For example, beam hardening or scatter corrections may perform differently in phantoms than in patient and distort CT numbers or lead to artifacts. The hardness of the x-ray beam can also vary among scanner models,

shifting CT numbers relative to non-vendor specifications. In addition, specifications that involve adaptive aspects of clinical protocols, such as iterative reconstruction or size-specific calibration files, can depend on precise interaction of phantom, test object, and protocol.

Q. For pediatric bodies, my system produces CTDI values using the 32cm phantom. The ACR instructions use the 16cm phantom. Can you clarify this difference?

A. The manufacturer reports dose according the most recent IEC standard (60601-2-44 v 3.1), which states the 32cm should be used for all body CTDI values. It is our understanding the ACR will update their instructions to reflect this update in the future.

Q. The ACR QC Manual beam width test contains a note stating: "It has been the experience of the ACR CTAP Physics Subcommittee that most scanners can be calibrated to meet these tighter standards." Is this the case?

A. No. Service engineers are unable to alter manufacturer specifications and, in fact, for each installation must attest on FDA form 2579 that the assembled components were installed according to manufacturer specifications.

Q. Can you clarify the scope of "Acceptance testing"?

A. Acceptance testing encompasses testing carried out after new equipment has been installed, or major modifications have been made to existing equipment, in order to verify compliance with contractual specifications. This testing should be conducted using the phantom, procedures, and specifications specified in the purchase contract.