

ASNC IMAGING GUIDELINES FOR NUCLEAR CARDIOLOGY PROCEDURES

Introduction of New Technology for Clinical Use

The following imaging guideline is intended to provide an appropriate means of assessing new equipment function in conjunction with nuclear cardiology imaging. Because imaging systems can vary considerably with the optimal manner in which to perform specific tests, this document should be used as a guideline only and is not intended to replace the recommendations by manufacturers of specific models of imaging equipment.

For established technology, instrumentation metrics and quality assurance protocols in the ASNC Imaging Guidelines are documented based upon published literature and clinical use. For example, for ASNC guidelines, no additional standards or testing should be required for Single-Photon Emission Computed Tomography (SPECT) imaging based on conventional, collimated scintillation camera equipment, e.g., Anger camera technology, using filtered backprojection reconstruction or iterative reconstruction. For established technology, the specific parameters of the quality assurance protocols and the frequency of use should be defined by the manufacturer.

NEW TECHNOLOGY—STANDARDS FOR SPECT IMAGE ACQUISITION AND PROCESSING

In order to provide minimum standards for new technologies so that they can be used clinically, we recommend the following minimum acceptable values for image acquisition and processing. These values are intended to define an output of image quality that would be comparable to existing SPECT image quality acquired and processed using a collimated scintillation camera.

Using an approved SPECT performance phantom (e.g., Data Spectrum Deluxe Phantom) that can be imaged within the sampled field of view of the system, the standard minimum acceptable values for SPECT image acquisition and processing for new technology are:

1. *Detector field uniformity*

	Standard	Preferred
Integral uniformity	6%	4%
Differential uniformity	5%	3%

2. *Reconstructed resolution*

Cold rods of diameter greater than or equal to 11.1 mm should be resolved.

3. *Reconstructed uniformity*

The uniform section of the cylinder should not have ring artifacts in more than one slice. Uniformity within the cylinder should be less or equal to twenty percent (20%).

4. *Reconstructed contrast*

Spheres with diameter 19.1 mm or greater should be clearly visualized. Contrast in the 31.8 mm sphere should be greater than sixty-five percent (65%).

5. *Cardiac count density*

For SPECT imaging, manufactures have various means of making acceptable count rate/count density information available to the user. It is expected that any new technology would have an U.S. Food and Drug Administration (FDA) 510 K Approval (including reporting of both phantom and patient images), in which count density information is specified.

Although for new, innovative detector systems different values may be used for image count rates, they must be comparable to preferred count rates for SPECT using an Anger camera. Metrics should be defined and tested using a SPECT cardiac phantom.

For new software methods specifically designed for reduced acquisition times and/or lower count density images, cardiac count density should be in accordance with that specified in or implicit to the method's 510 K FDA approval. For example, if a technology has been approved for half-time SPECT acquisition, cardiac count density should be half the preferred count density for full-time SPECT using a collimated scintillation camera. Metrics should be defined and tested using a SPECT cardiac phantom.

Disclaimer

This Imaging Guideline on the Introduction of New Technology for Clinical Use has been prepared from publicly available information and is intended for the personal use of ASNC members. The purpose of this guideline is to provide objective information and analysis on a timely basis. This guideline is not intended to be prescriptive or definitive as to appropriate medical practice or minimal standards of care for patients. In addition, the new technology standards discussed

in this guideline may not be appropriate for all practice settings or for all patients. ASNC members should carefully consider the positive and negative aspects of existing technology before deciding whether to adopt any new technology referenced in this document. ASNC expressly disclaims any liability for reliance upon this guideline. As new clinical data are published related to new technology, the ASNC imaging guidelines will be updated.