

Submitted by: General Electric Healthcare
Name, Position: Katelyn Nye, X-Ray Research Manager
Company: General Electric Healthcare
Address: 3000 N Grandview Blvd. W-702 Waukesha, WI 53188
Phone: (262) 501-0197
Email: katelyn.nye@ge.com
Date of Request: March 7th, 2014
NCCN Guidelines Panel: Lung Cancer Screening

On behalf of General Electric Healthcare, I respectfully request the NCCN Lung Cancer Screening Guideline Panel to review the enclosed data for differentiation between conventional chest x-ray and digital tomosynthesis (an x-ray advanced application) with regards to lung cancer screening recommendations. With the increasing use and adoption of tomosynthesis for thoracic imaging, we think that it is important to clarify the differences in the performance of these imaging techniques, especially in light that the same type of equipment is used in both exams.

Specific Changes: Modify the Risk Assessment footnote 'b' on page LCS-1 within the "NCCN Guidelines Version 1.2014 Lung Cancer Screening" that currently reads "Chest x-ray is not recommended for lung cancer screening" to "Chest x-ray is not recommended for lung cancer screening; however, tomosynthesis has demonstrated superior lung nodule detection sensitivity. At this time, there is insufficient evidence supporting the use of tomosynthesis for lung cancer screening."

FDA Clearance: The VolumeRAD option on the Discovery XR656 fixed x-ray system, originally FDA cleared in 2005 for tomosynthesis imaging, has recently been FDA cleared for the expanded indication of superior lung nodule detection compared to chest x-ray. VolumeRAD is intended for diagnostic imaging of the chest and is indicated for the detection of lung nodules in patients undergoing thoracic imaging. VolumeRAD generates diagnostic images of the chest that aid the radiologist in achieving superior detectability of lung nodules versus posterior-anterior and left lateral views of the chest, at a comparable radiation level. (K132261, Regulation Number: 21 CFR 892.1740).

Rationale: A recent international multicenter clinical trial (publication pending) has demonstrated that VolumeRAD imaging of the chest offers significantly improved detection of small lung nodules and management of patients with lung nodules compared to conventional radiography. This is consistent with the results of numerous studies from other global investigators. Given the large difference between tomosynthesis and conventional chest x-ray for lung nodule detection, for example a 7.5-fold times greater for nodules 4-6 mm, it is important to distinguish between these imaging techniques.

Citations: The following citations are submitted in support of this proposed guideline change. Abstracts to the publications are attached as supplemental material. Copies of these publications were not provided, due to General Electric Healthcare's compliance rules, which restrict any transfer of value to Healthcare Providers, without specific approval. Please contact Katelyn Nye (katelyn.nye@ge.com), if you would like to request a copy of any of the publications provided and she will submit a request for approval, which will track and report a transfer of value to any receiving Healthcare Provider(s).

Båth, M., Svalkvist, A., von Wrangel, A., et. al. (2010). **Effective Dose to Patients from Chest Examinations with Tomosynthesis.** Radiation Protection Dosimetry, 139(1-3), 153-158.

Dobbins III, J. T., McAdams, H. P., Song, J. W., Li, C. M., Godfrey, D. J., et. al. (2008). **Digital Tomosynthesis of the Chest for Lung Nodule Detection: Interim Sensitivity Results From an Ongoing**

NIH-Sponsored Trial. Medical Physics, 35(6), 2554-2557.

Dobbins III, J. T., & McAdams, H. (2009). **Chest Tomosynthesis: Technical Principles and Clinical Update.** European Journal of Radiology, 72, 244-251.

Johnsson, Å. A., Fagman, E., Vikgren, J., et. al. (2012). **Pulmonary Nodule Size Evaluation with Chest Tomosynthesis.** Radiology, 265(1), 273-282.

Johnsson, Å. A., Svalkvist, A., Vikgren, J., et. al. (2010). **A Phantom Study of Nodule Size Evaluation with Chest Tomosynthesis and Computed Tomography.** Radiation Protection Dosimetry, 139(1-3), 140-143.

Johnsson, Å. A., Vikgren, J., Svalkvist, A., et. al. (2010). **Overview of Two Years of Clinical Experience of Chest Tomosynthesis at Sahlgrenska University Hospital.** Radiation Protection Dosimetry, 139(1-3), 124-129.

Kim, S. M., Chung, M. J., Lee, K. S., et. al. (2013). **Digital Tomosynthesis of the Thorax: The Influence of Respiratory Motion Artifacts on Lung Nodule Detection.** Acta Radiologica, 1–6.

Quaia, E., Baratella, E., Cioffi, V., et. al. (2010). **The Value of Digital Tomosynthesis in the Diagnosis of Suspected Pulmonary Lesions on Chest Radiography: Analysis of Diagnostic Accuracy and Confidence.** Academic Radiology, 17, 1267-1274.

Sabol, J. (2009). **A Monte Carlo Estimation of Effective Dose in Chest Tomosynthesis.** Medical Physics, 36, 5480-5487.

Svalkvist, A., Håkansson, M., Ullman, G., & Båth, M. (2010). **Simulation of Lung Nodules in Chest Tomosynthesis.** Radiation Protection Dosimetry, 139(1-3), 130-139.

Svalkvist, A., Mansson, L., Bath, M. (2010). **Monte Carlo Simulations of the Dosimetry of Chest Tomosynthesis.** Radiation Protection Dosimetry, 139(1-3), 144-152.

Terzi, A., Bertolaccini, L., et. al. (2013). **Lung Cancer Detection with Digital Chest Tomosynthesis: Baseline Results from the Observational Study SOS.** Journal of Thoracic Oncology 8(6), 685-692.

Tingberg, A. (2010). **X-Ray Tomosynthesis: A Review of its Use for Breast and Chest Imaging.** Radiation Protection Dosimetry, 139(1-3), 100-107.

Vikgren, J., Zachrisson, S., Svalkvist, A., Johnsson, A., et. al. (2008). **Comparison of Chest Tomosynthesis and Chest Radiography for Detection of Pulmonary Nodules: Human Observer Study of Clinical Cases.** Radiology, 249(3), 1034-1041.

Zachrisson, S., Vikgren, J., Svalkvist, A., Johnsson, A., et. al. (2009). **Effect of Clinical Experience of Chest Tomosynthesis on Detection of Pulmonary Nodules.** Acta Radiologica, 50(8), 884-891.

Sincerely,



Katelyn Nye
X-Ray Research Manager
GE Healthcare