The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

2019 (Resolution 4)*

ACR-STR PRACTICE PARAMETER FOR THE PERFORMANCE AND REPORTING OF LUNG CANCER SCREENING THORACIC COMPUTED TOMOGRAPHY (CT)

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

PRACTICE PARAMETER

¹ Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This practice parameter has been revised collaboratively by the American College of Radiology (ACR) and the Society of Thoracic Radiology (STR).

Thoracic CT is the only test that has been demonstrated to reduce mortality from lung cancer in high-risk current and former cigarette smokers [1,2]. Screening with CT may have additional health benefits when associated with smoking cessation [3-7]. The optimal performance of thoracic CT for lung cancer screening requires knowledge of normal anatomy, anatomic variants, pathophysiology, and the risks associated with lung cancer screening. In addition, attention to CT technical parameters to achieve lower radiation exposure levels than is characteristic of standard adult thoracic CT examinations is important, particularly because a positive CT screening examination may result in subsequent follow-up examinations that expose screen-positive individuals to additional ionizing radiation, and screening CT may be repeated annually for several decades, depending on when an individual begins screening. This practice parameter outlines the principles for performing high-quality thoracic CT in adults at high risk for lung cancer.

Before participating in screening, individuals should consult with a health care provider about the risks and benefits of lung cancer screening. It is recommended that radiology practices performing lung cancer screening participate in a multidisciplinary approach that includes the specialties of radiology, pulmonary medicine, pathology, thoracic surgery, medical and radiation oncology, and other related health care disciplines.

For current smokers, there should be a mechanism for referral to smoking cessation programs. Educational messaging and materials promoting smoking cessation may be included in program-related patient correspondence.

The primary goal of lung cancer screening CT is to detect abnormalities that may represent lung cancer and may require further diagnostic evaluation. In addition, examinations should be reviewed for other abnormalities in accordance with the <u>ACR-SCBT-MR-SPR Practice Parameter for the Performance of Thoracic Computed Tomography (CT)</u> [8].

II. INDICATIONS AND CONTRAINDICATIONS

Screening thoracic CT is appropriate for asymptomatic individuals at high risk for lung cancer [9]. An individual's risk for lung cancer is primarily determined by:

• Smoking history and age [10-16].

Additional risk factors include the following [17-42]:

- 1. Emphysema and chronic obstructive pulmonary disease
- 2. Interstitial lung disease, such as pulmonary fibrosis
- 3. Occupational and environmental exposures, such as asbestos, arsenic, beryllium, cadmium, chromium, coal smoke, diesel fumes, nickel, silica, and soot
- 4. High levels of radon exposure
- 5. History of cancer, including lung cancer, head and neck cancer, and smoking-related cancers
- 6. Family history of lung cancer
- 7. Extensive secondhand smoke exposure
- 8. Prior thoracic radiation therapy, as may occur for breast cancer and lymphoma

For other thoracic CT techniques beyond the scope of this practice parameter, please refer to the <u>ACR–SCBT-MR–SPR Practice Parameter for the Performance of Thoracic Computed Tomography (CT)</u> [43] and the <u>ACR Practice Parameter for the Performance of High-Resolution Computed Tomography (HRCT) of the Lungs in Adults</u> [44].

There are no absolute contraindications to screening thoracic CT. As with all procedures, the relative benefits and risks of the procedure should be evaluated prior to the performance of thoracic CT. Appropriate precautions should be taken to minimize patient risks, including radiation exposure.

Self-referred individuals are defined as those individuals with no health care provider, who decline having a health care provider, or for whom the health care provider declines responsibility. It is at the discretion of the facility's medical director whether or not to offer screening to the self-referred individual. However, screening facilities that elect to accept self-referred individuals must have procedures for referring them to a qualified health care provider if abnormal findings are present.

For the pregnant or potentially pregnant patient, see the <u>ACR-SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Patients with Ionizing Radiation</u> [45].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT) [46]

IV. SPECIFICATIONS OF THE EXAMINATION [47-50]

A. Prior to the Examination

The written or electronic request for a lung cancer screening CT should provide sufficient information to demonstrate the medical appropriateness of the examination and allow for its proper performance and interpretation. This should include the patient's age, smoking history in pack-years, and should identify the patient as a current smoker or as a former smoker with quit date.

B. Examination

A typical lung cancer screening CT of the thorax must be performed with multidetector helical (spiral) technique in a single breath-hold. The study must include axial images from the lung apices to the costophrenic sulci acquired and viewed at 2.5-mm slice thickness or smaller, with reconstruction intervals equal to or less than the slice thickness. The examination may be acquired and reconstructed at 1.0-mm slice thickness or smaller, and reconstruction intervals to allow for better characterization of small lung nodules [51]. Maximum intensity projection (MIP) reconstruction is a technique that may be useful to increase the sensitivity for lung nodule detection [52-56]. Multiplanar reconstruction (MPR) may be useful to further characterize nodules, particularly nodules located along the pleural surfaces (also known as perifissural nodules) [57-59].

Scans should be obtained in a suspended state of full inspiration whenever possible. Scans must be obtained through the entire lungs, from apices to bases, and the field of view must be optimized for each patient to include the entire transverse and anteroposterior diameter of the lungs.

The examination is conducted without the use of intravenous contrast medium.

Although many of the operations of a CT scanner are automated, a number of technical parameters remain operator dependent and may significantly affect the diagnostic quality of the CT examination. Wherever possible, scanning protocols should be preprogrammed and saved on the CT scanner console to reduce the operator input required. It is necessary for the supervising physician to acquire familiarity with the following:

- 1. Radiation exposure factors (including milliamperes, peak kilovoltage, gantry rotation time)
- 2. Detector configuration (including detector rows, width of each detector row, configurations allowed, etc)
- 3. Slice thickness and interval
- 4. Field of view and matrix size (eg, 512)
- 5. Window and level settings
- 6. Reconstruction algorithms
- 7. Reformatted images (MPR, curvilinear, MaxIP, and MinIP)
- 8. Advanced dose reduction techniques such as automatic exposure control and iterative reconstruction methods, if available

Optimization of the CT examination requires communication between the supervising physician, medical physicist, and radiologic technologist to develop and monitor appropriate CT protocols based on the clinical indications and associated risks. The technique should be set to yield a dose index volume (CTDI_{vol}) of 3 mGy or less for a standard-sized patient. It should be reduced for smaller-sized patients and increased for larger-sized patients [47-49,60-68].

The protocol should be developed with attention to the organ system of interest, in this case primarily the lungs, for the specific purpose of lung cancer screening. Techniques should result in diagnostic quality images with the lowest possible patient radiation exposure. For each study, the protocol should specify:

- 1. Use of volumetric acquisition
- 2. Collimation, table increment, and pitch as appropriate
- 3. Peak kilovoltage and milliamperes appropriate to body habitus
- 4. Superior and inferior extent of the area of interest to be imaged
- 5. Reconstructed image thickness and spacing (interval)
- 6. Reconstruction algorithm and level and window settings
- 7. Field of view and matrix size
- 8. Image reformatting

Examples of lung cancer screening protocols for several specific CT scanner manufacturers and models are available [69]. They should not be used for other manufacturers or models without careful review and adjustment with the assistance of a qualified medical physicist. The lung cancer screening protocol should be reviewed at regular intervals or with a change in screening equipment.

V. INTERPRETATION AND REPORTING

Anatomically appropriate window and level settings should be used to view all of the anatomy within the obtained CT coverage, including the lung parenchyma, mediastinum, chest wall, bones, lower neck, and upper abdomen within the scanned field of view.

Lung nodules and focal lung lesions should be reported with respect to anatomic location (lung lobe, segment) and series/image number to facilitate comparison to both prior and subsequent thoracic CT examinations. Nodules should be described with respect to size, attenuation (soft tissue, type of calcification, fat), opacity (solid, ground glass [also known as nonsolid], and part-solid, containing both solid and ground-glass components), and margins (eg, smooth, lobulated, spiculated) [70-76]. Comparison with prior imaging studies is an important part of nodule evaluation. Specific reference should be made to change, or lack thereof, from prior examinations when serial examinations are reviewed. If previous imaging studies, particularly thoracic CT examinations, are needed to determine the significance of positive findings, an attempt should be made to obtain and compare with the images directly and not rely on prior reports alone. When comparing changes in nodule size, opacity, and contour, efforts should be made to compare the oldest scans available in addition to the most recent prior scan to assess for changes over time, including subtle changes. Volumetric analysis or volume measurement of nodules may be incorporated into the report.

The use of computer-assisted nodule detection and volumetric assessment of nodule size and growth by computer workstation analysis can be valuable adjuncts to the evaluation.

For the management of screen-detected lung nodules, standard guidelines should be followed within a practice or screening program [77-80] and should be included in the radiology report. Although a guideline about interpretation and follow-up may be useful as an attachment to the report, the interpreting radiologist should make recommendations for the appropriate management and follow-up specific to the individual patient whose CT is under review.

Screening results should be reported using a structured reporting system for lesion assessment, imaging-pathologic correlation, quality improvement, and medical outcomes auditing. Reporting and management recommendations of incidental findings are also important for lung cancer screening [81].

Review of the entire examination for other potentially significant findings should be performed and reported in accordance with the <u>ACR-SCBT-MR-SPR Practice Parameter for the Performance of Thoracic Computed Tomography (CT)</u> [43]. In addition, the report should include the presence or absence of coronary artery calcification and, if present, the degree of coronary artery calcification (eg, mild, moderate, severe) [82-84].

VI. DOCUMENTATION AND COMMUNICATION OF RESULTS

Reporting should be in accordance with the <u>ACR Practice Parameter for Communication of Diagnostic Imaging Findings</u> [85].

A structured reporting system facilitates data management, patient care, and quality assurance activities. Such a system should include the adherence of radiologist recommendations to screening guidelines, patient tracking and storage of findings in a structured database, automatic generation of results-specific findings, triage of risk categories within the screened population, and appropriate referral of the small number of patients with suspicious findings who require multidisciplinary team management.

Imaging providers may wish to establish infrastructure in the form of a relational database application that facilitates and helps manage patient intake, scheduling, and follow-up.

Lung Cancer Screening Registry:

Studies performed for lung cancer screening under the Medicare program should also be reported to a CMS (Centers for Medicare and Medicaid Services) registry to meet quality reporting requirements. Data from the quarterly reports of the facility can be used for improving the lung cancer screening program. https://www.acr.org/Practice-Management-Quality-Informatics/Registries/Lung-Cancer-Screening-Registry.

VII. EQUIPMENT SPECIFICATIONS

To achieve acceptable clinical CT scans of the thorax for lung cancer screening, a CT scanner should meet the current <u>ACR-SCBT-MR-SPR Practice Parameter for the Performance of Thoracic Computed Tomography (CT)</u> [43] and meet or exceed the following capabilities:

- 1. Gantry rotation times: 0.75 seconds or less
- 2. Slice thickness: 2.5 mm or less (1.0 mm or less is preferred)
- 3. Detector rows: 16 or more detector rows are preferred

The CT scanner and/or the viewing platform should be capable of generating MIP and MPR images.

VIII. EQUIPMENT QUALITY CONTROL

The quality control program for CT equipment should be designed to minimize patient, personnel, and public radiation risks and to optimize the diagnostic quality of the examination. The program should be supervised by a medical physicist and follow the <u>ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment</u> [86].

IX. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, non-physician radiology providers, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel who work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, application of dose constraints and limits) and the principles of proper management of radiation dose to patients

(justification, optimization including the use of dose reference levels). https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1775_web.pdf

Nationally developed guidelines, such as the <u>ACR's Appropriateness Criteria</u>®, should be used to help choose the most appropriate imaging procedures to prevent unnecessary radiation exposure.

Facilities should have and adhere to policies and procedures that require ionizing radiation examination protocols (radiography, fluoroscopy, interventional radiology, CT) to vary according to diagnostic requirements and patient body habitus to optimize the relationship between appropriate radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used, except when inappropriate for a specific exam. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org). These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be periodically measured by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Monitoring or regular review of dose indices from patient imaging should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry and relevant publications relying on its data, applicable ACR Practice Parameters, NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends; 2006, 2009, amended 2013, revised 2023 (Res. 2d).

A medical physicist and radiologist together should verify that any dose reduction devices or utilities maintain acceptable image quality while actually reducing radiation dose.

X. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

A rigorous quality assurance and medical outcomes audit program should be established at screening sites to document that performance and interpretation is of the highest possible quality. This is central to patient safety because of the potential morbidity and mortality associated with false-positive workups and biopsies. Methodology should be in place to evaluate the appropriateness of screening referrals.

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

It is recommended that a lung cancer CT screening program have a documented policy for collecting outcomes data, such as positive and negative screen rates, the rate of clinically significant incidental extrapulmonary findings, and false-positive finding rates.

For specific issues regarding CT quality control, see the <u>ACR Practice Parameter for Performing and Interpreting</u> Diagnostic Computed Tomography (CT) [87].

Equipment performance monitoring should be in accordance with the <u>ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment [88].</u>

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