The Connecticut Society of Radiologic Technologists

Affiliated with the American Society of Radiologic Technologists

Public Health Committee,

There is a public hearing February 23 2011 on HBO 5639. AN ACT CONCERNING THE LICENSING OF NUCLEAR MEDICINE TECHNOLOGISTS. This proposed legislation is long overdue. The citizens of Connecticut deserve the best medical treatment, by the most qualified individuals. Although there is no explanation at this time in the proposed legislation, the Connecticut Society of Radiologic Technologists hopes that only those persons performing Nuclear Medicine procedures will have been properly trained, and certified by the American Registry of Radiologic Technologists (ARRT) or from the Nuclear Medicine Technology Certification Board (NMTCB).

The CSRT also strongly believes that this legislation should not allow Nuclear Medicine Technologists the ability to perform the CT (computed tomography) part of the PET/CT exam without further training in CT. The PET/CT exam is called fusion imaging, which take two different modalities (Radiology and Nuclear Medicine) and merges them together. Radiographers operate stand alone CT units, while Nuclear Medicine Technologists operate PET Scanners. A Radiographer would not be able to become a Nuclear Medicine Technologist without further training, nor should a Nuclear Medicine Technologist operate a CT machine without the appropriate training. The American Registry of Radiologic Technologists offers Nuclear Medicine Technologists the opportunity to become certified in CT. The CSRT strongly encourage the Public Health Committee to recommend any certified Nuclear Medicine Technologist also have the certification in CT from the ARRT, if they are performing a PET/CT exam.

Below is an excerpt from the FDA's "White Paper: Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging" This and more information on Radiation Safety can be found at the FDA's web site ***www.fda.gov***

"Executive Summary

Like all medical procedures, computed tomography (CT), fluoroscopy, and nuclear medicine imaging exams present both benefits and risks. These types of imaging procedures have led to improvements in the diagnosis and treatment of numerous medical conditions. At the same time, these types of exams expose patients to ionizing radiation (hereinafter "radiation"), which may elevate a person's lifetime risk of developing cancer. A balanced public health approach seeks to support the benefits of these medical imaging exams while minimizing the risks.

Managing the risks of computed tomography (CT), fluoroscopy, and nuclear medicine imaging procedures depends on two principles of radiation protection: appropriate *justification* for ordering and performing each procedure, and careful *optimization* of the radiation dose used during each procedure. These types of imaging exams should be conducted only when medically justified. When such exams are conducted, patients should be exposed to an optimal radiation dose – no more or less than what is necessary to produce a high-quality image. In other words, each patient should get the right imaging exam, at the right time, with the right radiation dose.

FDA can advance this goal by using our regulatory authority judiciously while also collaborating with the healthcare professional community.

This document announces the launch of a cooperative *Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging*. Through this initiative, FDA and our partners will take steps to:

1. Promote safe use of medical imaging devices;
2. Support informed clinical decision making; and
3. Increase patient awareness.

By coordinating these efforts, we can optimize patient exposure to radiation from certain types of medical imaging exams, and thereby reduce related risks while maximizing the benefits of these studies.

Background

Medical imaging procedures, which are used to view different areas inside the human body, can provide physicians with important clinical information. Imaging exams can allow for noninvasive diagnosis of disease and monitoring of therapy, and can support medical and surgical treatment planning. For many diseases, early detection, more effective diagnosis, and improved monitoring of therapy through the use of imaging exams may contribute to reduced morbidity, additional treatment options, and increased life expectancy.[1] Image-guided techniques are also commonly used in a variety of procedures, such as putting in place catheters or stents, or removing blood clots or other blockages.

1. Types of Medical Imaging Procedures

There are many types - or modalities - of medical imaging procedures, each of which uses different technologies and techniques. Ultrasound imaging (also called sonography) uses high-frequency sound waves to view soft tissues, such as muscles and internal organs. Magnetic resonance imaging (MRI) uses radio waves and magnetic fields to produce images.

Unlike ultrasound and MRI, projection radiography (commonly called standard x-ray), CT, fluoroscopy, and nuclear medicine procedures all use ionizing radiation to generate images of the body. Ionizing radiation is a form of radiation that has enough energy to potentially cause damage to DNA. Individuals are exposed to some background level of naturally occurring ionizing radiation every day.[2]

These different imaging procedures use different amounts of ionizing radiation. Projection radiography procedures, which include chest x-rays and mammography, use relatively low amounts of radiation. (See Table 1, below, for the typical radiation doses from dental x-rays, chest x-rays, and mammography exams.) In these exams, a device passes x-rays through a patient's body to produce one to a handful of two-dimensional pictures — called radiographs — of a particular area of the body. While projection radiography, including mammography, makes

up roughly 74% of the imaging procedures using radiation that are conducted annually in the U.S., it contributes only 11% of the total yearly exposure to radiation from medical imaging.[3]

During a CT scan (also called a CAT scan) a rotating source passes x-rays through a patient's body to produce several cross-sectional images of a particular area. These two-dimensional images can also be digitally combined to produce a single three-dimensional image. In a fluoroscopic procedure, a device passes x-rays through a patient's body for a brief length of time to capture a real-time moving image, which can be used to observe the movement of an object or substance in the body. During a nuclear medicine procedure, such as a positron emission tomography (PET) scan, a patient is given a small amount of a radioactive substance, called a radiopharmaceutical or radiotracer. A detector outside the body is then used to view an image of the radioactive material as it moves through the body.

Because CT, fluoroscopy, and nuclear medicine procedures involve repeated or extended exposure to radiation, these types of exams are associated with a higher radiation dose than projection radiography. For example, the adult effective dose from a CT exam of the head is equivalent to the adult effective dose from roughly 100 chest x-rays. The adult effective dose from a CT exam of the abdomen is roughly equivalent to the adult effective dose from roughly 400 chest x-rays.[4] (See Table 1, below, for the range of doses from various CT, fluoroscopy, and nuclear medicine procedures.) While CT, interventional fluoroscopy, and nuclear medicine studies make up only approximately 26% of the imaging procedures using radiation that are conducted annually in the U.S., they contribute 89% of the total yearly exposure to radiation from medical imaging.[5]

Table 1. Radiation Doses from Various Types of Medical Imaging Procedures[6]

Type of Procedure	Average Adult Effective Dose (mSv)	Estimated Dose Equivalent (No. of Chest X-rays)
Dental X-ray	0.005-0.01[6a]	0.25-0.5
Chest X-ray	0.02	1
Mammography	0.4	20
CT	2-16[6b]	100-800
Nuclear Medicine	0.2-41[6c]	10-2050
Interventional Fluoroscopy	5-70[6d]	250-3500

2. Concerns about Radiation Exposure

According to a March 2009 report by the National Council on Radiation Protection and Measurements (NCRP), the U.S. population's total exposure to ionizing radiation has nearly doubled over the past two decades.[7] This rise is largely attributable to increased exposure from CT, nuclear medicine, and interventional fluoroscopy.[8]NCRP estimates that 67 million CT scans, 18 million nuclear medicine procedures, and 17 million interventional fluoroscopy procedures,

and 18 million nuclear medicine procedures were performed in the U.S. in 2006, and the authors predict that these figures will continue to grow.[9]Concerns have been raised about the risks associated with patients' exposure to radiation from medical imaging. Because ionizing radiation can cause damage to DNA, exposure can increase a person's lifetime risk of developing cancer. Although the risk to an individual from a single exam may not itself be large, millions of exams are performed each year, making radiation exposure from medical imaging an important public health issue.[10]Berrington de González et al. estimate that approximately 29,000 future cancers could be related to CT scans performed in the U.S. in 2007.[11]Smith-Bindman et al. estimate that 1 in 270 women and 1 in 600 men who undergo CT coronary angiography at age 40 will develop cancer from that CT scan; the risks for 20-year-olds are estimated to be roughly twice as large, and those for 60-year-olds are estimated to be roughly half as large.[12] Although experts may disagree on the extent of the risk of cancer from medical imaging, there is uniform agreement that care should be taken to weigh the medical necessity of a given level of radiation exposure against the risks.

Accidental exposure to very high doses of radiation can also cause injuries in the short term, such as burns and hair loss. Direct exposure of the eyes to such doses can increase the risk of developing cataracts. FDA is currently investigating several recent incidents of acute overexposure to radiation from CT brain perfusion scans.[13] In each of these cases, patients were exposed to a much higher dose of radiation than is typical for such scans.

3. Unnecessary Radiation Exposure

Because CT, fluoroscopy, and nuclear medicine require the use of radiation, some level of radiation exposure is inherent in these types of procedures. Nevertheless, when these procedures are conducted appropriately, the medical benefits they can provide generally outweigh the risks.

However, if proper precautions are not taken, patients may be exposed to radiation without clinical need or benefit. Unnecessary radiation exposure may result from the use of a radiation dose above what is optimal to meet the clinical need in a given procedure. To a point, using a higher radiation dose can produce a higher-resolution image. If the dose is too low, the quality of the resulting image may be poor, and, as a result, a physician may not be able to make an accurate clinical determination. An optimal radiation dose is one that is as low as reasonably achievable while maintaining sufficient image quality to meet the clinical need.

There is broad agreement that steps should be taken to reduce unnecessary exposure to radiation."

The Connecticut Society supports all legislation that will reduce radiation risks to the citizens of Connecticut. The licensure of Nuclear Medicine Technologists would be in the right directions.

Respectfully Submitted

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