Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging

February 2010

Center for Devices and Radiological Health

U.S. Food and Drug Administration

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Table of Contents

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] See, for example, the perspective of Obuchowski NA, et al., "Ten Criteria for Effective Screening: Their Application to Multislice CT Screening for Pulmonary and Colorectal Cancers," *American Journal of Roentgenology*, June 2001, Vol. 176, pp. 1357-1362.

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]

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[2] The average effective dose from background radiation is about 3 mSv per year. (Mettler, Jr. FA, et al., "Effective Doses in Radiology and Diagnostic Nuclear Medicine: A Catalog," *Radiology*, July 2008, Vol. 248, No. 1, pp. 254-263.)

[3] National Council on Radiation Protection and Measurements, *NCRP Report No. 160: Ionizing Radiation Exposure of the Population of the United States*, March 3, 2009, pp. 142-146.

[4] Here, the average adult effective doses from CT examinations of the head (2 mSv) and abdomen (8 mSv) are compared to the average adult effective dose from a posteroanterior chest x-ray (0.02 mSv). (Mettler, Jr. FA, et al., July 2008.)

[5] National Council on Radiation Protection and Measurements, *NCRP Report No. 160*, March 2009, pp. 142-146.

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 were performed in the U.S. in 2006, and the authors predict that these figures will continue to grow.[9]

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[6] In Table 1, the average adult effective doses from various study types are compared to the average adult effective dose from a posteroanterior chest x-ray (0.02 mSv). Additional detail is provided below. (Mettler, Jr. FA, et al., July 2008.)

[6a] 0.005 mSv is the average adult effective dose from an intraoral dental x-ray. 0.01 mSv is the average adult effective dose from a panoramic dental x-ray.

[6b] 2 mSv is the average adult effective dose from a CT exam of the head. 16 mSv is the average adult effective dose from a CT coronary angiography exam.

[6c] 0.2 mSv is the average adult effective dose from a lung ventilation exam using ^{99m}Tc-DTPA. 41 mSv is the average adult effective dose from a cardiac stress-rest test using thallium 201 chloride.

[6d] 5 mSv is the average adult effective dose from a head and/or neck angiography exam. 70 mSv is the average adult effective dose from a transjugular intrahepatic portsystemic shunt placement.

[7] In the early 1980's, the U.S. population's per capita exposure to ionizing radiation from all sources was 3.6 mSv. By 2006, that figure had risen to 6.25 mSv. (National Council on Radiation Protection and Measurements, *NCRP Report No. 160*, March 2009, pp. 242-243.)

[8] In the early 1980's, medical imaging accounted for 15% of the U.S. population's per capita exposure to ionizing radiation from all sources (0.54 mSv of 3.6 mSv). In 2006, medical imaging accounted for 48% of the per capita exposure (3 mSv of 6.25 mSv), with CT, nuclear medicine, and interventional fluoroscopy accounting for 24%, 12%, and 7%, respectively. (National Council on Radiation Protection and Measurements, *NCRP Report No. 160*, March 2009, pp. 242-243.)

[9] National Council on Radiation Protection and Measurements, *NCRP Report No. 160*, March 2009, pp. 142-146.

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.

Unnecessary radiation exposure may also result from the performance of a particular medical imaging procedure when it is not medically justified given a patient's signs and symptoms, or when an alternative might be preferable given a patient's lifetime history of radiation exposure.

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

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[10] Brenner DJ and Hall EJ, "Computed Tomography: An Increasing Source of Radiation Exposure," *New England Journal of Medicine*, November 2007, Vol. 357, No. 22, pp. 2277-2284.

[11] Berrington de González A, et al., "Projected Cancer Risks from Computed Tomographic Scans Performed in the United States in 2007," *Archives of Internal Medicine*, December 2009, Vol. 169, No. 22, pp. 2071-2077.

[12] Smith-Bindman R, et al., "Radiation Dose Associated With Common Computed Tomography Examinations and the Associated Lifetime Attributable Risk of Cancer," *Archives of Internal Medicine*, December 2009, Vol. 169, No. 22, pp. 2078-2086.

[13] FDA News Release, "FDA Makes Interim Recommendations to Address Concern of Excess Radiation Exposure during CT Perfusion Imaging," December 7, 2009. Available online at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm193190.htm.

Factors Contributing to Unnecessary Radiation Exposure

Several factors may contribute to unnecessary exposure to radiation in medical imaging exams.

1. Issues Related to Device Use

Concerns have been raised about how imaging facilities administer medical imaging exams that use radiation: wide variations have been observed among radiation doses associated with particular types of medical imaging exams. For example, examining CT studies performed on adult patients within and across several institutions in the San Francisco Bay area, Smith-Bindman et al. report a mean 13-fold variation between the highest and lowest dose for each type of study assessed.[14] This large variability in radiation dose begs for standardization and speaks to the need for better quality assurance.

Practitioners who use medical imaging equipment may not have adequate information or a comprehensive understanding of radiation dose and associated quality assurance processes to provide for quality, consistency, and radiation safety in medical imaging exams. For example, while new CT and fluoroscopic devices include displays of dose metrics, some lack other safeguards, such as default parameter settings that optimize radiation dose or alerts when the radiation dose in a given exam exceeds a particular reference level or range. Because current methods of measuring radiation dose are largely based on adult-sized models, providing meaningful, real-time dose metrics for pediatric procedures can be particularly challenging. FDA is engaged in efforts to improve and establish standards for pediatric dose calculations.

Norms for patient radiation dose are referred to as "diagnostic reference levels" or "dose reference values," and they generally correspond to the 75th or 80th percentile points of the distributions of measured dose values for particular imaging procedures.[15] Diagnostic reference levels are benchmarks to which a facility's practice may be compared in a radiation-protection quality assurance program: when the diagnostic reference level is exceeded in any particular examination, the facility may investigate to see if it is possible to reduce exposure without adversely affecting image quality.

Groups including the American College of Radiology (ACR), the American Association of Physicists in Medicine (AAPM), and NCRP have undertaken work to establish nationally recognized diagnostic reference levels for many imaging procedures, and FDA has been an active participant in these efforts.[16] However, equipment safety features alerting operators and

[14] Smith-Bindman, et al., December 2009.

[15] Diagnostic reference levels were introduced in the UK (NRPB/RCR, "Patient Dose Reduction in Diagnostic Radiology," *Doc. NRPB*, 1990, Vol. 1, No. 3, pp. 1-46) and were included in the recommendations of the International Commission on Radiological Protection (*Radiological Protection and Safety in Medicine*, ICRP Publication 73*, Annals of the ICRP*, 1996, Vol. 26, No. 2). Following the European Council Directive 97/43/Euratom (*Official Journal of the European Communities*, July 9, 1997, No. L 180, pp. 22-27), diagnostic reference levels have been broadly adopted in Europe. See, for example, the following references and citations therein: Roda AR, Lopes MC, and Fausto AM, "Diagnostic Reference Levels in Computer Tomography at IPOCFG, EPE," World Congress on Medical Physics and Biomedical Engineering, September 7 - 12, 2009, Munich, Germany, *IFMBE Proceedings*, Vol. 25/III, Olaf Dössel and Wolfgang C. Schlegel (Eds.), Springer 2009, pp. 26-29; Treier R, et al., "Diagnostic Reference Levels in Computed Tomography in Switzerland," *ibid*., pp. 146-149.

[16] Diagnostic reference levels recommended by ACR are available online at http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/med_phys/reference_levels.aspx. Reference values recommended by AAPM are published in Gray JE, et al., "Reference Values for Diagnostic Radiology: Application and Impact," *Radiology*, May 2005, Vol. 235, No. 2, pp. 354-358. Information about NCRP's

interpreting physicians to doses that exceed diagnostic reference levels or that exceed peak skin-dose[17] thresholds for radiation-induced skin injury are not yet standardized. Furthermore, there are many medical imaging procedures, particularly for pediatric patients, for which diagnostic reference levels have not yet been established. Without diagnostic reference levels, it is difficult for practitioners to assess whether the radiation dose used during a given study falls within a reasonable range.

Even when equipment safeguards are in place, users may not have received adequate training in the proper use of these features and the importance of optimizing radiation dose. Additionally, imaging facilities may not have adequate quality assurance practices in place, such as regular evaluation of their study protocols and equipment.

Some steps have been taken to address these issues. Through its Image Gently and Step Lightly campaigns, the Alliance for Radiation Safety in Pediatric Imaging has developed educational materials for pediatricians, radiologists, radiologic technicians, and parents to encourage careful use of CT and interventional fluoroscopy with children.[18] These campaigns are designed to increase awareness of ways to reduce radiation dose in pediatric imaging procedures. ACR and the Radiological Society of North America (RSNA) are currently developing an Image Wisely campaign, which will apply the same principles to the adult patient population.

2. Issues Related to Clinical Decision Making

Concerns have also been raised that physicians may lack important information that could inform their decisions in ordering medical imaging exams that use radiation.

Ordering physicians may not have access to patients' medical imaging or radiation dose history. Due to insufficient information, physicians may unnecessarily order imaging procedures that have already been conducted. Additionally, standardized dose structured reporting, while technically available in new CT systems and fluoroscopes used in interventional procedures, is still in its infancy; dose reports are not generally linked by facilities either to the image files or to patient medical records. If a physician had a record of the radiation dose to which a patient has been exposed in previous medical imaging procedures, such information might influence his or her decision to order a particular type of exam.

In some cases, ordering physicians may lack or be unaware of recommended criteria to guide their decisions about whether or not a particular imaging procedure is medically efficacious. As a result, they may order imaging procedures without sufficient justification and unnecessarily expose patients to radiation. Various professional organizations, including ACR and the American College of Cardiology (ACC), have developed and are working to disseminate imaging referral criteria, called "appropriateness criteria" or "appropriate use criteria," associated

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efforts to develop diagnostic reference levels is available online at http://www.ncrponline.org/Current_Prog/SC_4-3.html.

[17] See, for example, Miller DL, et al., "Radiation Doses in Interventional Radiology Procedures: The RAD-IR Study Part II: Skin Dose," *Journal of Vascular Interventional Radiology*, August 2003, Vol. 14, No. 8, pp. 977-990; and Marx MV, "The Radiation Dose in Interventional Radiology Study: Knowledge Brings Responsibility," *ibid*., pp. 947-951.

[18] More information about the Image Gently and Step Lightly campaigns is available online at http://www.pedrad.org/associations/5364/ig/.

with a number of medical conditions.[19] However, criteria for appropriate ordering of medical imaging exams have not yet been broadly adopted by the practicing medical community.

Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging

FDA is launching a collaborative *Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging*, with a focus on the types of imaging procedures that are associated with the highest radiation doses: CT, fluoroscopy, and nuclear medicine.

Through this initiative, FDA will take steps — directly and in collaboration with others — to mitigate the factors contributing to unnecessary radiation exposure from these three medical imaging modalities. The goal of these efforts is to support the benefits associated with medical imaging while minimizing the risks. Because some of the contributing factors described above fall outside of FDA's purview, we are also recommending complementary actions for other groups to take, which will support and be supported by our work. FDA will collaborate with our partners and others to monitor and assess the impact of these efforts.

1. Promote Safe Use of Medical Imaging Devices

FDA oversight of medical devices extends throughout the total product life cycle, from development through use. FDA will take the following actions to support the safe use of medical imaging equipment.

1.1. Establish requirements for manufacturers of CT and fluoroscopic devices to incorporate additional safeguards into equipment design, labeling, and user training.

FDA will issue targeted requirements for manufacturers of CT and fluoroscopic devices to incorporate important additional safeguards into the design of these machines, develop safer technologies, and provide additional training to support safe use by practitioners. As a first step, FDA intends to hold a public meeting on March 30 and 31, 2010, to solicit input on what requirements to establish. FDA may require, for example, that CT and fluoroscopic devices display, record, and report radiation dose, and alert users when the dose exceeds a diagnostic reference level, a peak skin-dose threshold for injury, or some other established value. FDA may also require that manufacturers provide additional data in their premarket submissions to support specific clinical uses, and incorporate that information into product labeling and training to enhance safe use of these devices.

1.2. Partner with the Centers for Medicare and Medicaid Services (CMS) to incorporate key quality assurance practices into accreditation and participation criteria for imaging facilities and hospitals.

Under the Medicare Improvements for Patients and Providers Act (MIPPA),[20] CMS oversees accreditation of stand-alone medical imaging facilities.[21] Additionally, CMS has established

[19] ACR's Appropriateness Criteria® are available online at http://www.acr.org/SecondaryMainMenuCategories/quality_safety/app_criteria.aspx. ACC's Appropriate Use Criteria (AUC) are available online at http://www.acc.org/qualityandscience/clinical/auc.htm.

[20] Medicare Improvements for Patients and Providers Act of 2008. P. L. 110-275. 15 July 2008. 122 Stat. 2494.

[21] 42 C.F.R. 414.68.

conditions of participation for hospitals and accompanying interpretive guidelines for Medicare surveyors.[22]

FDA is working with CMS and its designated accreditation organizations to support the inclusion of key quality assurance practices in MIPPA accreditation criteria for stand-alone imaging facilities. FDA and CMS are also exploring options to enhance the existing interpretive guidelines for hospitals related to their radiologic and nuclear medicine services. FDA traditionally builds quality assurance instructions into product-specific labeling and training in order to promote safe use. Collaborating with CMS will help improve quality assurance at user facilities and further support safe use of medical imaging equipment.

1.3. Recommend that the healthcare professional community, in collaboration with FDA, continue efforts to develop diagnostic reference levels for CT, fluoroscopy, and nuclear medicine procedures locally and also through a national radiation dose registry.

Building on the efforts of various professional organizations, such as ACR and NCRP, FDA recommends that healthcare professional organizations continue to develop nationally recognized diagnostic reference levels for medical imaging procedures that use radiation, including pediatric procedures. FDA will increase our participation in these efforts. For example, we will collaborate with others to develop tools for collecting more meaningful radiation dose data from user facilities, in order to support the establishment of more accurate diagnostic reference levels. These levels will support quality assurance and the safe use of medical imaging devices by helping practitioners assess whether the radiation dose used during a given exam is reasonable.

For procedures for which such norms have not yet been developed on a national level, FDA recommends that each user facility, to the extent feasible, develop its own locally-based diagnostic reference levels, for use until more broadly recognized levels are available.

A radiation dose registry is a collection of de-identified patient radiation dose data from individual medical imaging exams. By pooling dose data across imaging facilities nationwide, a national radiation dose registry[23] will help support the development of diagnostic reference levels where they do not yet exist, and allow for broad validation of those levels that have been developed to date.

Such a registry will also help facilities benchmark their radiation doses relative to those of others, and could be a key source of information about trends in doses over time.[24] Raff, Chinnaiyan, Share, et al. recently used a statewide dose registry for cardiac CT angiography in Michigan to measure the effectiveness of implementing selected dose-reduction best practices.[25]

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[22] 42 C.F.R. 482.

[23] A single national dose registry could be established for multiple types of imaging procedures, or separate registries could be established for different types of procedures. Although the term "registry" is used here in the singular, FDA supports either approach.

[24] ACR is working to establish a Dose Index Registry for various imaging modalities, to allow for comparisons across participating facilities. ACR recently conducted a dose index registry pilot project for CT exams. More information is available online at http://www.acr.org/SecondaryMainMenuCategories/quality_safety/NRDR.aspx.

[25] Raff GL, Chinnaiyan KM, Share DA, et al., "Radiation Dose From Cardiac Computed Tomography Before and After Implementation of Radiation Dose-Reduction Techniques," *Journal of the American Medical Association*, June 2009, Vol. 301, No. 22, pp. 2340-2348.

2. Support Informed Clinical Decision Making

FDA does not oversee the practice of medicine; however, there are direct and indirect actions FDA can take to provide healthcare professionals with tools that would inform their decisions with respect to medical imaging.

2.1. Establish requirements for manufacturers of CT and fluoroscopic devices to record radiation dose information for use in patient medical records or a radiation dose registry.

FDA will issue targeted requirements for manufacturers of CT and fluoroscopic devices to incorporate equipment features that will provide clinicians with more information to guide their decision making. As a first step, FDA intends to hold a public meeting on March 30 and 31, 2010, to solicit input from our external constituencies about what requirements to establish. FDA may require, for example, that CT and fluoroscopic devices be capable of specific functions, such as capturing the radiation dose value from each exam and linking it with the study image to facilitate the storage of dose information in a patient's paper or electronic medical record. FDA may also require that devices be capable of automatically recording radiation dose information in a standardized Digital Imaging and Communications in Medicine (DICOM) structured report, and transmitting this information to a patient's electronic medical record or a dose registry. Such steps will provide ordering physicians with more comprehensive information about a patient's imaging and radiation dose history, to support their decisions about the most appropriate clinical course of action for each patient.

2.2. Recommend that the healthcare professional community continue to develop and adopt criteria for appropriate use of CT, fluoroscopy, and nuclear medicine procedures, or other procedures that use these techniques.

Building on the efforts of various professional organizations, including ACR and ACC, FDA recommends that the healthcare professional community continue to develop and adopt appropriate use criteria for CT, fluoroscopy, and nuclear medicine procedures. Electronic decision support tools for ordering imaging procedures could incorporate these criteria to improve quality and consistency in clinical decision making.

3. Increase Patient Awareness

As the efforts described above proceed, FDA recognizes the importance of empowering patients with information and tools to help them and their physicians manage their exposure to radiation from medical imaging in the short term, even before longer-term changes take effect.

3.1. Provide patients with tools to track their personal medical imaging history.

FDA is collaborating with the ACR and RSNA joint task force currently coordinating Image Wisely, to develop and disseminate a patient medical imaging record card.[26] FDA will make this card available on our website. While ultimately the best way of tracking a patient's history of radiation exposure will be to incorporate it into that patient's paper or electronic medical record, a personal record card will give patients and their caregivers a means, in the short term, of

[26] The new medical imaging record card will be an updated and enhanced version of FDA's pre-existing x-ray record card, which is currently available online at http://www.fda.gov/downloads/Radiation-EmittingProducts/ResourcesforYouRadiationEmittingProducts/Consumers/UCM142630.pdf.

tracking their own medical imaging histories and sharing this information with their physicians. This will help facilitate critical discussions between patients and providers about the best available clinical options.

Conclusion

Medical imaging has many important clinical uses and can provide significant benefits. However, CT, fluoroscopy, and nuclear medicine imaging procedures also present risks. A balanced public health approach seeks to support the benefits of medical imaging while reducing the risks. FDA, others in the Federal government, and the healthcare professional community all have a role to play in such an approach. Through the *Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging*, FDA and our partners will work to measurably reduce unnecessary exposure of patients to radiation in CT, fluoroscopy, and nuclear medicine imaging exams.