

Notes to the Slides

Development of Amendments to the U.S. Radiation-Safety Standard for Diagnostic X-Ray Computed Tomography (CT) Equipment

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Slide 1: Title

This presentation grows out of the collaborative efforts of an FDA group of science, regulation, and economics staff. We're working to facilitate radiation dose reduction through consideration of amendments to the existing CT performance standard. Our motivation is the proposition that the current Federal regulations covering CT—in place since the mid-1980s—have not kept pace with technological developments and with the need to assure the lowest dose for the best image quality practically achievable.

The work group's current thinking and my own personal ideas and analysis presented here do not necessarily reflect any official position of the FDA or its components. Many items in the slides are annotated with superscripted numbers that cite references and notes listed at the end of the presentation. Reference to any products, manufacturers, models of CT systems, or external web sites does not imply FDA endorsement.

Slide 2: Advances and Concerns

The theme of the introductory part of this presentation is the interplay of technology and clinical practice in CT, how the rapid technological and clinical advances of the past few years have increased CT use and have led to public-health concerns. This theme is a basis for background discussion and for updates on the activities CDRH has undertaken to address these concerns since I spoke about them last year.

Slide 3: CT Applications

Computed tomography is a vitally important, beneficial modality whose radiation doses are relatively higher than those of other x-ray exams. The scope of CT applications is broad, and CT is used in many different ways—from diagnosis, to cancer staging, to treatment planning, and more recently for real-time visualization during interventional operations.

Slide 4: Predominant CT Technology

This slide summarizes those physical, geometrical, and mechanical aspects of currently predominant CT technology that bear on individual radiation-dose delivery. Electron-beam CT is not covered here because e-beam CT scanners make up perhaps only 1-2% of approximately 10,000 CT units in the U.S.

The essential feature of x-ray CT irradiation is a thin, fan-shaped x-ray beam that rotates around a patient. In most systems, x-ray detectors are located beyond the patient diametrically opposite the x-ray source, and the beam and detectors rotate together while the detectors register x-rays transmitted through the patient. (In the figure, the x-ray beam is indicated by the red shading, and the detectors are indicated by green.) A single 360° rotation typically takes from one-half to one second, a relatively brief period compared to rotation times of ten years ago. An important point is that while some of the most recent models of scanners now offer different options that enable a system to automatically adjust radiation output higher or lower to account for a patient's circumference, in most systems, the radiological techniques—such as the peak x-ray tube voltage (kVp), the x-ray tube current (mA), the rotation time—need to be set manually by the CT technologist. In an ideal workplace, these settings are based on a technique chart which a facility would develop covering different examination protocols and various sizes of patients.

What's referred to as a single "slice" corresponds to a thickness usually between 1 and 10 mm along the length of a patient, and it yields *one* cross-sectional image per single rotation. Single-slice scanners are distinguished from CT systems that are capable of doing "multi-slice" scanning. Spiral *multi-slice* scanners were introduced only four years ago, and when they operate in multi-slice mode, they produce 2 to 4 cross-sectional images *simultaneously* per rotation. These images correspond to adjacent slices along the length of the patient. Newer spiral scanner models can provide 8 and even 16 slices simultaneously, and in the next few years they will probably replace most of the axial-only models.

In axial CT, the table moves increment-by-increment following each single rotation. Spiral scanning (also called "helical" scanning) refers to table movement at a *constant rate* during *continuous* rotations. (It's called "spiral" or "helical" because the combination of smooth table movement and x-ray source rotation leads to the x-ray field tracing out a helical path around the patient.) The direction along the length of the patient is referred to as the "z-axis," the axis about which the beam and detectors rotate. Typically in a single phase of a CT examination the table movement spans a range covering on the order of 10 to 50 slices along the length of a patient.

The features of fast, multi-slice spiral CT have enabled scanning of large volumes of patient anatomy, three-dimensional rendering of images, angiography, single-breath-hold imaging and visualization of small lung nodules. The bottom line is that these advances in CT technology have been rapidly adopted into clinical practice and have led to an explosive growth in the number of applications, to a capability of examining patients quickly, and to a high rate of use.

Slide 5: Public Health Concerns & Responses

The items on the left-hand side of this slide underscore some public-health concerns ensuing from the growth in use of CT. The right-hand side lists the preliminary responses of CDRH in addressing these concerns. First, we are faced with the problem of determining the scope of radiological exposure from CT—how many CT examinations are going on annually, and just how large are the doses from what particular exams? CDRH provided the principal technical direction for a survey conducted through the Nationwide Evaluation of X-Ray Trends program administered by the Conference of Radiation Control Program Directors. Between April 2000 and July 2001 State inspectors surveyed examination doses and workloads in 263 CT facilities randomly selected in 39 States to provide the first national understanding of the magnitude of collective dose from CT since the first CT survey in 1990. A related project is the ongoing development of a handbook of patient doses associated with approximately 50 of the most common CT examinations. Such a handbook would foster risk communication between medical staff and patients, and it would enable medical physicists and radiologists to evaluate patient tissue doses and effective dose for their facility's CT systems and adjust their protocols as needed to reduce doses.

In February 2001 the *American Journal of Roentgenology* published a series of papers describing the potential risk associated with inappropriate equipment settings and scanning techniques in CT examinations of children. A great deal of publicity resulted from these studies, and our concerns were voiced at the last meeting of TEPRSSC. Following the advice of TEPRSSC, last November CDRH issued a Public Health Notification to radiologists, radiation health professionals, risk managers, and hospital administrators alerting facilities to the problem and providing practical advice on how to reduce risk associated with CT dose in pediatric and small adult patients.

Since that time there has been burgeoning popularization of a group of applications commonly referred to as CT "screening" of self-referred individuals who are asymptomatic of any particular disease. Among these applications are included "whole-body" examinations, examinations of the lungs for cancer, and "calcium-scoring" of the heart as a purported indicator of potential heart disease. Right now CT screening makes up only a tiny fraction of the number of CT procedures performed annually in the U.S. Our main concerns are the risks associated with false positive results and with radiation dose. False positive results could needlessly lead to follow-up tests or procedures that might be invasive—associated with surgical risks of anesthesia, bleeding, infection, scarring—or entail additional radiological exams. Radiation doses in diagnostic CT are among the highest of those of all x-ray modalities, and screening CT doses are significantly large even when "low-dose" protocols might be applied.

There are no scientific studies demonstrating that whole-body CT screening of asymptomatic people is efficacious. Were it a useful screening test, it would be able to detect particular diseases early enough to be managed, treated, or cured and advantageously spare a person at least some of the detriment associated with serious illness or premature death. At this time any such presumed benefit of whole-body CT

screening is in fact *uncertain*, and the benefit may not be great enough to offset the potential harms such screening could cause.

FDA has recently posted a web page about CT screening. The page provides information about our concerns, contains brief explanations of computed tomography, radiation risks, radiation quantities and units, the regulatory status of CT, and includes links to related resources. It is hoped that an objective presentation from a government institution whose fundamental mission is to protect public health will clarify the natures of the risks and presumed benefits in a way that persuades people to carefully consider these aspects of CT screening before deciding whether or not to have such exams.

Finally, we are aware of the small but growing use of what's called "CT fluoroscopy" or "dynamic CT" to visually guide interventional procedures involving biopsy, drainage, and device placement. "CT fluoroscopy" refers to the capability of a CT system to update images in nearly real time as the x-ray field and detectors rotate multiple times around a patient at a fixed z position, that is, without table movement. Recent reports cite mean values of entrance skin dose of approximately 100 to 400 mGy, below the threshold for skin injury. Several years ago a small CDRH group drafted guidance for reviewers and manufacturers of CT systems capable of CT fluoroscopy, but the move to formal adoption of final guidance has been on hold in view of the relatively small probability for skin injury in the most common procedures and also since preliminary findings of the 2000 CT survey indicated that only 5% of the most frequently used CT units in facilities have the capability of doing CT fluoroscopy.

Slide 6: Current Federal CT Equipment Standards

The baseline of radiation protection with respect to CT *equipment* is prescribed by the Federal government through performance standards established under the Radiation Control for Health and Safety Act. The regulations in place now date back approximately 20 years. These rules apply to manufacturers of CT equipment, not to the facilities that *use* the equipment. The basic mandate is *documentary*: Manufacturers must provide users with specified *documentation* of dose values for CT systems under typical operating conditions. Because this mandate predates special or new modalities such as electron-beam, multi-slice, spiral, fluoroscopic, or cone-beam CT, the doses manufacturers report don't necessarily pertain to those modes of operation. There is no regulatory ceiling on patient dose, and there are few major equipment requirements particular to CT per se.

Slide 7: FDA CTDI

The current FDA standard for CT dose documentation is represented by the computed tomography dose index, abbreviated "CTDI." CTDI incorporates a number of the physical aspects associated with the geometry and irradiation conditions of computed tomography. These aspects include a rotating fan-shaped beam, collimation of the primary radiation to a thin slice along the z-axis (the axis of rotation), broad scattering of the primary radiation by the material it passes through, and scattered-radiation contributions to the dose that are *cumulative* with multiple rotations.

CTDI is an *index* of dose, a *descriptor* or *indicator* of the magnitude of dose associated with the radiation output of a specific CT model. It is *not* a measure of patient dose on a *person-by-person* basis. CTDI is a representation of dose which is *standardized* for specific reference materials and reference-procedure conditions. It's measured in a cylindrical phantom made of nearly solid acrylic, with diameter either 16 cm to correspond to the adult head or 32 cm to the adult body. The figure in the center of the slide depicts a cylindrical phantom, and to the left is a face view of the phantom within the fan beam indicated by the red shading. The x-ray source is at the apex on the bottom, and the x-ray detectors are indicated by the green shading at the top. In a single scan, the fan beam and detectors rotate as an ensemble once around the central axis represented in the figure on the left by the origin of the x-y coordinate system. This central axis of rotation is the z axis.

Even though the CT radiation intended for image formation is collimated within a relatively thin section along the z axis, much radiation actually scatters throughout the phantom (or patient). In the center figure, the red shading corresponds to the primary radiation passing through the phantom to the detectors, and the dark blue-green shading represents the scattered radiation. So the dose is actually *distributed*, not localized exclusively to the narrow region collimated. The figure on the right is called the dose "profile," and it represents the distribution of dose along the z axis for a single slice. The abscissa corresponds to position along the z-axis, where 0 mm is at the center, and the ordinate is the dose in units of *rad*. For single-slice scanners, the z-axis collimation of the system defines the slice thickness, designated "T," and in this example T is 13 mm. One sees that although most of the primary radiation is contained within the 13-mm-wide central zone of the phantom, the scattered radiation extends *far beyond* the central zone, to more than 100 mm on either side. Furthermore, when there are multiple scans extending over a range along the patient length, as there are in most CT exams, at any one location along the z axis, the scattered radiation from these other scans cumulatively *adds* to the dose.

FDA therefore defined the dose index CTDI to be proportional to an integral which includes the dose contributions from scattered as well as primary radiation over a range of the dose profile extending from negative seven to positive seven times the slice thickness T. In the example depicted, for a slice thickness of 13 mm, the range of integration is from -91 mm to +91 mm, covering practically all of the dose contributions, and the CTDI here is 0.82 rad. An advantage of defining a dose index this way is that mathematically CTDI is identical to the *average dose* in the central plane of 14 contiguous axial scans. In other words, the integral appropriately accounts for the dose contributions of adjacent, nearby slices, each with its own single-slice profile. So one can think of CTDI as the dose associated with a reference procedure: It is the average central-plane dose for a 14-slice exam, a reasonable representation of how exams were done 20 years ago.

From today's perspective, there are several problems with the regulatory definition of CTDI. CTDI is simply not defined for spiral CT scanning, which is how most body

exams are done currently. (For spiral scanning the irradiation geometry and dose profile are different than these figures depict.) Also, spiral scanning or no, the regulatory definition of CTDI does not account for CT procedures where the slices are *not adjacent*, that is, where slices may be separated by gaps or where they may overlap.

Over the years medical physicists have introduced a number of non-regulatory variants of CTDI that have been adopted into practice and to some extent by manufacturers. For example, it is much easier to measure CTDI with a fixed-length, 100-mm long ionization chamber rather than integrate a dose profile determined through thermoluminescent dosimetry. “CTDI₁₀₀” refers to the practice of using a 100-mm long ionization chamber either in the center hole of a phantom or in any of its peripheral holes to measure a value of CTDI integrated from -50 mm to +50 mm irrespective of the slice thickness T. Although the ionization chamber is contained entirely within the acrylic phantom, CTDI₁₀₀ usually refers to dose to *air*, not dose to acrylic as in the FDA definition. A variant of CTDI₁₀₀ is what is called the “weighted” CTDI, abbreviated “CTDI_w,” and it is based on a combination of values of CTDI₁₀₀ measured in the center hole and in the peripheral holes. This combination approximates the CTDI₁₀₀ average over the entire central plane of the phantom. Another variant, the “volume” CTDI is being introduced in an amendment to the current international manufacturers’ consensus standard covering the radiation safety of CT equipment. The bottom line here can be broken into two parts: First, variant quantities of CTDI that are either more easily determined, or of broader generality, or of more utility, have by and large replaced the FDA definition of CTDI for most practical purposes. Second, as a result of this proliferation of non-standardized terms, there is confusion amongst CT system users about precise definitions of CTDI values, especially for values displayed by some CT systems.

Slide 8: Amendments Being Considered, Technical Features to Reduce Dose

Possible amendments to the current radiation-safety performance standard would *require* particular technical features for CT equipment. Although requiring such features through a mandatory standard applicable to all new CT systems conceivably guarantees the largest and most systematic dose reduction on a population-wide basis, there are a number of associated issues that demand careful thought before we undertake such change. We seek your comments, ideas, and questions on any aspect of what is being suggested. The initial focus of the work group effort is on three possible features—display and recording of standardized dose indices, automatic control of x-ray exposure according to individual patient thickness, and x-ray field-size limitation for multi-slice systems.

Slide 9: Dose-Index Standardization, Display, Recording

This amendment would require each new CT system to provide users with options to display and record one or more dose indices for every patient’s examination. The dose indices and related terminology would be standardized through formal definition in the regulations.

This amendment would enable an aspect of facility quality assurance that today is feasible only with extra effort or through features available on just some newer scanner models. The basis of this quality assurance is the use of what are called “reference dose values” as norms to which individual examination doses could be compared. If reference values are exceeded, facilities could follow up anomalies by looking at possible problems to see if exposures could be reduced without compromising image quality. A reference dose value corresponds to the 75th percentile of the distribution of measured dose values for particular radiological procedures. Reference values may be generated based on a facility’s own records of dose distributions for various CT exams or based on regional or national dose distributions.

The concept of reference dose values, also called “reference levels,” was introduced in the United Kingdom about 10 years ago and is being adopted throughout Western Europe. It is being introduced into the U.S. by the American College of Radiology with the aid of a task group of the American Association of Physicists in Medicine. For example, the ACR requires facility audits of dose values for comparison to reference levels in its new CT accreditation program. There is no question about the technical feasibility of simpler versions of such displays because they already are available on some of the newer CT models, albeit with ambiguous definitions. We assume that the systematic use of dose-index display or recording in a facility audit program could reduce patient CT dose on average on the order of 15%. This projection is based on the range of dose reduction observed between 1985 and 1995 in the United Kingdom for modalities *other* than CT, in a period before particular indices of patient CT dose were introduced.

Slide 10: Promising Indices of Patient Dose

There are several prospective indices of patient dose that could be displayed and recorded for the purpose of dose audits. For the two indices described in this slide, equivalent quantities are recommended in quality criteria guidelines published by the European Commission, although not quite with the same nomenclature as used here. In the first amendment to the second edition of the International Electrotechnical Commission safety standard for CT equipment, the “volume” computed tomography dose index is introduced. It is based essentially on the weighted CTDI, which is a weighted sum of $CTDI_{100}$ measured in the central and peripheral holes of an acrylic phantom. For axial scanning the denominator in the expression for volume CTDI is $\Delta z/nT$, the ratio of the table increment per rotation to the total thickness of tomographic sections imaged. In axial scanning the volume CTDI is essentially what’s known as the “multiple scan average dose,” abbreviated “MSAD.” “Pitch” is the analogous denominator for spiral scanning. The important point here is that these denominators account for modifications to the weighted dose index arising from possible gaps between multiple scans or their possible overlap for examination protocols that may differ according to the particular exam being performed. This accounting makes the volume CTDI more sensitive to differing examination protocols than either $CTDI_w$ alone, or $CTDI_{100}$ alone, or the FDA regulatory CTDI.

Another possible index for dose-display and recording is called the “dose-length

product,” and it may hold more promise than the volume CTDI. Dose-length product is simply the product of the volume CTDI and the length of the irradiated volume. Here is its chief advantage: Because the length of the irradiated volume depends on the region of the body being studied, different examinations will be associated more uniquely with characteristic values of dose-length product than with values of volume CTDI. This result is evident from the table on the left, which compares values of volume CTDI to those of dose-length product. The dose-length product values are relatively sensitive to differences in exams, whereas for the kinds of exams listed, volume CTDI is practically constant between 30 and 35 mGy. The implication is that facility audits of dose-length product could be exquisitely sensitive to anomalously large doses for each different kind of examination; each kind of examination could be associated with its own unique distribution of dose-length product values. Another point in favor of the use of dose-length product is that it is approximately proportional to the total energy imparted and is therefore a better indicator of radiation risk than is the volume CTDI. Using anatomy-specific coefficients derived from computer simulations, one can estimate effective dose from the dose-length product, and effective dose is the closest indicator we have for overall radiation detriment. It is my understanding that one manufacturer already displays values for effective dose on newer CT models in Europe.

Slide 11: Automatic Exposure Control

Of the three technical areas that we are considering, probably the largest dose reduction—at least for thinner patients—would be brought about by requiring every newly manufactured CT system to provide the capability of automatically adjusting the amounts of x-ray emissions to those needed to image particular patient anatomy. In other words, as the x-ray beam probes a thinner portion of the anatomy, which would not require as much radiation as a thicker portion would in order to reach the detectors, the CT system would *automatically reduce* the average tube current, or voltage, or some combination of radiological variables to *spare* that thinner part unnecessary dose. And, conversely, when the beam encounters thicker anatomy, the CT system would automatically *increase* the tube output to levels needed for adequate visualization. An automatic exposure control system offers a technical answer to facilities where for practical or clinical reasons it is not the practice to change manual techniques on a patient-by-patient basis let alone readjust techniques within a single patient exam. With an AEC system in place, the presumption is that pediatric and thinner adult patients would receive lower doses than thicker patients.

A number of different approaches for modulating x-ray tube output are available on newer scanner models, and these approaches span a range of technical complexity. For example, at one end of the range are systems that offer *recommendations* of specified technique settings for tube current-time product and tube potential that the user may choose to apply. Such recommendations are not automatic adjustments per se, but they are based on anterior-posterior and lateral scan projection radiograph data. Scan projection radiographs are the scout views obtained prior to regular CT scanning. At the other end of the range of approaches to AEC is truly automated, continuously updated tube-current modulation in three dimensions based on measurements of x-ray attenuation

at the corresponding angles of the previous rotation. In between these two extremes are several other algorithms offering, for example, automated tube-current modulation axially for various image qualities that may be selected by a user.

The figures in the slide depict how emissions would vary according to patient sizes in three dimensions. On the left is a cross section of the torso in the x-y plane, and the thickness or thinness of each red arrow corresponds to the relatively greater or lesser amount of radiation needed for reconstructing an image as the x-ray tube rotates around the z axis. Not only is there tube-current modulation for the x and y dimensions, there is also modulation corresponding to changes in average anatomical thickness along the z axis—as the table moves. The graph on the right shows how the tube current is reduced or increased by this *additional* current-normalization factor that accounts for the average anatomical thickness which the fan-beam slice encounters along the length of the patient. For example, the x-ray output would be relatively small when the patient's neck is passing through the fan beam, but increases rapidly when the shoulders are in the beam and decreases as the beam probes the lungs. Calculations and measurements suggest that use of a sophisticated automatic exposure control system could reduce patient dose by approximately 30% compared to systems where the techniques are set manually.

Slide 12: Concern—"Over-beaming" in Multi-slice CT

We are concerned that a number of different multi-slice CT models produce images with a technologically inefficient application of radiation. This inefficient technology has been dubbed "over-beaming." The two figures represent a comparison of the spatial distributions of radiation incident along the length of a patient. The figure on the left depicts the distribution for a single-slice CT scanner, whereas the one on the right corresponds to that of a multi-slice scanner. The CT system represented on the left produces one image associated with a single slice, while the model on the right can produce four images simultaneously, each associated with a thinner slice. In each figure the gradient in area and intensity of shading from dark red to light pink is a representation of the falloff in radiation exposure from the central umbra of the collimated x-ray field to the peripheral penumbra. On the left, a single detector (indicated by the green rectangle) captures essentially the entire radiation distribution. On the right, however, the system of four detectors captures only the radiation of the umbra region.

The *total* width of the tomographic section imaged—5 mm in this example—for the slice associated with the one image produced on the left is *equal* to the sum of the widths of the *four* 1.25-mm wide slices respectively associated with the four images produced on the right. In other words, in either figure the amount of visual information that can be used for image reconstruction is approximately the same, and, in fact, in the case of the multi-slice CT system, a user could *elect* to trade off the resolution offered by four adjacent 1.25-mm wide slices for a single 5-mm wide slice with relatively less image noise than in each of the thinner-slice images.

Here's the important point in this comparison: Although the amount of radiation applied to *construct one image* with the single-slice scanner or to construct a *set of images* with

the multi-slice system is the *same* for each configuration, for the multi-slice CT system the radiation distribution is much wider than that of the single-slice system. Why? Multi-slice CT imaging requires that radiation incident on the patient be consistently distributed across *each* of the separate areas subtended by the detectors. Such consistency can be achieved by opening up the z-collimation of the source radiation so that only the most spatially uniform region of the x-ray field—the umbra—is subtended by the detectors, and the spatially varying penumbral regions are excluded. Furthermore, since the x-ray focal spot tends to wander around spatially, multi-slice models *broaden* the umbra by opening the collimation *even more* to compensate for x-ray source excursions. In the example depicted by these figures, the width of the z-collimation for the multi-slice system is 15 mm versus 5 mm for the single-slice system. The problem of consistent spatial irradiation is not encountered in single-slice systems because the single detector is longer than the extent of the incident radiation, and it simply integrates the whole distribution incident. However, multi-slice systems are not efficient users of radiation in this sense: All of the radiation that falls beyond the spatial extent of the detectors is *not* used by the detectors for image construction, but it is nevertheless incident on the patient, and it contributes to the dose.

Slide 13: X-Ray-Field Size Limitation

To mitigate the inefficient use of radiation in multi-slice computed tomography, we suggest consideration of an x-ray-field-size limitation. Such an amendment would require that all new CT systems be capable of automatically limiting field sizes to those no larger than needed to construct multi-slice images.

Several technical approaches to enable such limitation have been patented, and one in fact has been implemented. The approach implemented uses some of the x-ray detectors lying beyond those capturing the clinically useful signal to track the wandering of the penumbral regions of the x-ray field and feed back instructions to motor-driven collimator cams to readjust their positions. Tracking and updated instructions are done in real time to maintain the narrowest needed umbra incident on the detectors. This system is represented by the figure on the left. The x-ray field borders demarcated by dashed lines are set by the collimator cams—also indicated with dashes—for an initial position of the x-ray source so that the umbra is subtended by the clinical-signal detectors. As the x-ray source wanders to the right, other detectors (not depicted here) pick-up the movement of the penumbra and instruct the collimator cams to re-adjust their positions to those indicated by the solid lines. The result is that the umbra remains subtended by the clinical-signal detectors. Had the collimation position remained unchanged, there would have been an inconsistent spatial distribution of the x-ray radiation across the clinical-signal detectors.

The chart on the right represents two multi-slice dose profiles measured in a head phantom on the same CT system. For the same 5-mm wide imaging-sensitivity profile, the dose profile in black is obtained when there is no tracking and collimation-update system, whereas the dose profile in fuchsia is obtained when the tracking-update system is activated. It is evident that the non-tracking dose profile is approximately 50% wider

than the tracking profile. All of the radiation represented by the difference between the two profiles would correspond to radiation which is absorbed by a patient but *not* used to construct images. Data suggest that the kind of x-ray-field size limitation enabled by tracking and collimation adjustment could reduce dose in multi-slice CT systems on the order of 30%.

Slide 14: Projected Benefits Introduction

I will present quantitative projections of benefits that could result from the relative amounts of dose reduction associated with the possible implementation of amendments to the Federal radiation-safety standard in each of the technical areas just described. The principal benefit would be a population-wide *reduction* in morbidity and mortality associated with avoidance of cancers produced by CT radiation.

Slide 15: Annual CT Dose, U.S.

Projections are based on preliminary estimates of the current annual CT dose in the United States derived from the 2000-2001 *NEXT* survey. The survey results indicate that the total number of CT exams annually is approximately 58 million, where 79% of all exams are comprised of scanning in 6 anatomical regions or combinations of regions—brain, abdomen-pelvis, chest, abdomen, chest-abdomen-pelvis, and pelvis alone. Approximately 29% of all CT units in the U.S. can do multi-slice spiral scanning, a remarkably large percentage since this technology was introduced to the market in 1998. The effective dose average for the 6 exam regions is approximately 6.2 millisievert, and the product of this average and the number of exams corresponds to a collective annual dose of approximately 360,000 person-sievert per year.

Slide 16: Projected Benefits—collective dose, cancer mortality, pecuniary savings

If *all* CT equipment were to include the technical features just proposed for consideration as mandatory standards, then, based on the relative dose reductions and the collective dose attributable to CT, one can estimate an annual collective dose savings of 193,000 person-sieverts per year—54,000 for dose-index display and recording in a quality-assurance program, 108,000 for automatic exposure control, and 31,000 for x-ray-field size limitation. All of these values are uncertain, and they're based on a number of assumptions detailed in the slides, references, and notes.

For an annual collective dose savings of 193,000 person-sieverts, on the order of 8,700 radiation-induced cancer mortalities are projected to be avoided per year beginning 20 years after each annual collective exposure. The yellow shading is intended to highlight the uncertainty in this projection which is based on an extrapolation to the CT-dose region of a mortality risk estimate derived from larger-dose epidemiological data. Other methods of extrapolation could yield higher or lower estimates of the number of radiation-induced cancer deaths, and it is even possible that the estimated dose savings would not result in any avoidance of cancer death at all. In the United States in the year 2000, the annual number of deaths linked to cancer from all causes not specifically

associated with radiation is approximately 550,000 [Minino and Smith 2001].

There would also be a significant benefit in the pecuniary savings associated with societal willingness to pay to avoid mortality risk. Economists have estimated that society is willing to pay on the order of \$5 million per premature mortality that it perceives might be avoided.

Slide 17: Amendments? Initial Steps

Will there be amendments to the CT radiation-safety standard? Here are the initial steps in this process: We've come up with a framework for analysis that will lead to what is called a "concept paper" for amendments, which will be the basis for CDRH decisions on how to proceed.

Slide 18: Framework of Analysis

This slide represents a framework for analyzing prospective technical areas with respect to issues that need to be addressed in decisions on how to proceed. In the block on the right, the region shaded in green lists the technical areas summarized in this presentation, and the region shaded in pink lists areas where we have an interest that is deferred for the time being. The yellow-shaded block on the left lists some general categories of issues—technical feasibility, impact on clinical aspects such as efficacy and frequency of utilization, harmonization with international consensus standards, CDRH resources required to develop test methods and to incorporate the administration of new rules in a compliance program. The arrows indicate that in principle each of these issues can be applied as a basis of assessment to each technical area under consideration.

We would like to hear your thoughts about *any* of these issues. Although the equipment features that I've discussed today may all be technically feasible, there remain a number of particular questions outstanding. Here are a few examples: First, for the purpose of display or recording in a quality-assurance program, not only would we have to select a representative index of patient dose, we would need to specify whether the dose index could be based on average values determined by manufacturers for all models of scanners or whether it must be specific to the particular unit be used in a facility. Should the dose index displayed or recorded be based on real-time measurements made during actual patient examinations? How would the index represent values in an automatic exposure control mode? Parameters based on CTDI may not be good candidates to represent skin dose, particularly for CT fluoroscopy. What is a good index for skin dose? What impact might a dose-index recording capability have on practice and use? Would there be any inhibitions fostered by the possibility of associating recorded values with patient medical records?

Second, with respect to automatic exposure control, in addition to specifying what kind of technological approach is best, perhaps the key question is how to define the optimal amounts of radiation needed by the detectors for particular imaging tasks. These amounts would effectively set the points of detection equilibrium driving the modulation of

emissions from the x-ray source according to patient anatomy thickness. Should standards be set to optimize detection? Who should set the equilibrium points and how would that be done? By manufacturers? By radiologists? By FDA? Philip Judy, a prominent medical physicist, has posed a related question [Judy 2001]: If automatic exposure control reduces dose to thinner patients, would it on average increase dose to thicker patients? The answer is not obvious.

Third, a primary challenge in developing an amendment for x-ray-field-size limitation or for automatic exposure control and most likely other areas as well would be how to prescribe performance standards—not a design standards—forward-looking enough to transcend limitations that might be present in current technological approaches.

Slide 19: Conclusion

In conclusion, an FDA work group has identified several areas for possible development of mandatory CT-equipment radiation-safety performance standards. The initial focus is on technically feasible features that would reduce patient dose—dose-index standardization, display, and recording, automatic exposure control, and x-ray-field size limitation. Were these features implemented on all CT systems, the projected collective dose savings in the United States would be approximately 193,000 person-sievert yearly. The work group has established a framework of issues for analysis that would be detailed in a regulatory concept paper for decisions on how to proceed. In the development process we need input from industry, professional and other stakeholder groups, the Conference of Radiation Control Program Directors and States, as well as TEPRSSC. Our timeline for the initial stage of this process is the completion of a concept paper by the end of this year for CDRH review and decision making and a follow-up briefing for TEPRSSC next year.

References cited in these notes

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