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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

MEDICAL DEVICES ADVISORY COMMITTEE

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DEVICE IMPROVEMENTS TO REDUCE UNNECESSARY RADIATION EXPOSURE FROM MEDICAL IMAGING

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March 30, 2010
8:00 a.m.

Holiday Inn Gaithersburg
2 Montgomery Village Avenue
Gaithersburg, MD 20879

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M E E T I N G

(8:00 a.m.)

CDR BOYD: We're going to go ahead and get started. I'd just ask everyone to take their seats.

DR. SHUREN: Good morning, and thank you for participating in today's public meeting.

Last month, FDA announced a collaborative initiate to reduce unnecessary radiation exposure from three types of medical imaging procedures, computed tomography or CAT scan or CT, nuclear medicine studies, and fluoroscopy. These three types of procedures are the greatest contributors to the U.S. population's total radiation exposure from medical imaging. They use much higher radiation doses than projection radiography, which is the imaging of a body part by passing x-rays through it onto a film, such as dental x-rays, chest x-rays, and mammography.

For example, the radiation dose of a single CT scan of the abdomen is roughly equivalent to the dose of 400 chest x-rays. By comparison, the radiation dose of a dental x-ray is roughly half that of a chest x-ray.

CT scans produce cross-sectional images of the body by exposing parts of the body to x-rays from different directions and developing an image using computer software.

In a fluoroscopic procedure, x-rays are used to produce real-

time moving images which can be used to observe the movement of an object or substance through the body.

In a nuclear medicine study, such as a PET scan, a patient is given a small amount of a radioactive isotope by ingestion or injection, and an external detector is used to view it as it moves throughout the body.

CT, fluoroscopy, and nuclear medicine studies can provide healthcare practitioners with important clinical information. 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.

At the same time, like all medical procedures, CT, fluoroscopy, and nuclear medicine studies present risks. These types of exams expose patients to ionizing radiation which may raise a patient's risk, lifetime risk of developing cancer. Accidental exposure to very high amounts of radiation can also cause injuries in the short term such as skin burns and hair loss.

Most Americans will undergo a medical imaging study at least once in their lifetime. We believe that the overwhelming majority of cases, there's an appropriate amount of radiation that's administered. However, the large number of people who receive radiation from medical imaging, and the limitations of some of the existing safeguards and appropriate use criteria, make necessary radiation exposure or unnecessary radiation exposure from medical imaging an important public health problem.

The U.S. population's per capita exposure to radiation has nearly doubled in the past three decades. The rise has been driven by more than a five-fold increase in the per capita exposure to radiation from medical imaging, an increase largely attributable to exposure from CT, nuclear medicine, and interventional fluoroscopy.

While projection radiography, including mammography, makes up roughly 74 percent of the imaging procedure using radiation that are administered annually in the U.S., it contributes only 11 percent of the total yearly exposure to radiation from medical imaging. CT, interventional fluoroscopy, and nuclear medicine studies, on the other hand, represent just 26 percent of the imaging procedures using radiation that are conducted each year but account for 89 percent of the total annual radiation exposure from medical imaging.

Although there is disagreement over the extent of the increasing cancer risks due to radiation exposure from these imaging exams, there is uniform agreement that healthcare decisions made by patients and their practitioners should weigh the medical necessity of a given level of radiation exposure against the risks.

When used appropriately, the medical benefits these exams can provide generally outweigh the risks. However, if proper precautions are not taken, patients can 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 produce a high quality image in a given procedure. Unnecessary radiation exposure may also result from the performance of a particular imaging procedure when it is not medically justified given the patient's signs or symptoms or when an alternative might be preferable, given a patient's lifetime history of radiation exposure.

The goal of FDA's initiative is to support the benefits associated with medical imaging while minimizing the risks. Through a balanced public health approach, we seek to make sure that each patient will get the right imaging exam at the right time with the right radiation dose.

Our actions are based on the principles of optimizing the dose of radiation administered and performing medical imaging that uses ionizing radiation only when justified.

The purpose of this public meeting is to inform FDA about additional safeguards that should be incorporated into device design, assessment, labeling, user training, and quality assurance of CT scanners and fluoroscopes. These safeguards may include warnings in labeling, default settings, installation and maintenance requirements, premarket testing, and postmarket assessment.

Adopting additional safeguards is part of the more comprehensive approach to reducing unnecessary radiation exposure from medical imaging that FDA announced in February.

Over the next two days, you'll hear from healthcare

practitioners, manufacturers, researchers, patients, and FDA scientists who each have their own perspective. As is often the case, these perspectives may not all be in agreement. That's part of the process. This meeting is an opportunity to hear these different perspectives and engage in an open public dialogue on a critically important public health issue. Through respectful dialogue, we can reach better informed conclusions and decisions.

So thank you again for your participation today and tomorrow.

I'd now like to turn the meeting over to Commander Sean Boyd who will talk to you about the logistics for the meeting and also go into a little bit more detail about FDA's initiative.

CDR BOYD: Thank you, Dr. Shuren. Before we begin, I wanted to introduce two individuals from FDA's press office who are here today to serve as points of contact for members of the media in attendance. Peper Long and Dick Thompson, if you could please stand and identify. Thank you. So if you're with the press, please begin with Peper and Dick for us.

As Dr. Shuren said, my name is Sean Boyd, and I'm currently Chief of the Diagnostic Devices Branch within CDRH's Office of Communication, Education and Radiation Programs, and I'm going to be your moderator for the next two days as we walk through FDA's initiative to reduce unnecessary medical imaging exposure.

The format for this discussion will be to hear presentations from the public, followed by round-table discussions on each of these four

topic areas of CT equipment, fluoroscopic equipment, operator training, and quality assurance.

During the open public sessions, each speaker will have five to seven minutes to address one or more of the questions posed in the Federal Register notice that announced this meeting. I will provide each speaker with a one-minute warning by standing up over here. At that time, I'd ask that the next speaker on the program join me up front so that we can keep things moving and make sure that everybody has an opportunity to contribute their views today.

Speakers or anybody is also able to submit written comments to the public docket described in the FR notice.

After the open public presentations, we are not going to have time for questions because of the number of speakers who wanted to address the group today, but if there is time, we will open the forum to questions from the audience.

Following the open public presentations, we'll have a round-table discussion among several subject matter experts. The purpose of the round-table discussions will be to address questions left unanswered by speakers or to further explore specific actions that industry or FDA can take in each of those topic areas, and these sessions will be moderated.

At that time, to allow audience participation, the audience can pose questions to the round-table. You can do this by either using one of the

note cards that was on each of the chairs in providing your question to the registration table out front, or once invited, you can come up to one of the open microphones in the room and pose your question to the round-table.

This meeting is being recorded but not for live broadcast purposes by FDA, but for transcription purposes only, and a transcript of the meeting will be available on FDA's initiative website as well as the regulations.gov website under the Docket FDA-2010-N-0080.

As stated by Dr. Shuren, the intent of this meeting is to inform decisions that will be made by CDRH on how to improve medical imaging technology, specifically CT and fluoroscopic equipment, operator training, and how to improve facility quality assurance programs.

Because FDA's regulatory authority lies with medical device and electronic product safety, basically regulating manufacturers of equipment, activities CDRH plans to pursue directly will be focused on requirements and guidance for our regulated industry, but as you'll see and as you'll hear from several speakers present today, there will be other efforts that CDRH pursues to inform clinical decision making, although this is outside our regulatory oversight role.

Last year, many of you have seen this, that a National Council on Radiation Protection and Measurement Reports showed that over the past three decades, the U.S. population's annual exposure to ionizing radiation nearly doubled and that much of that increase was due to medical imaging

and, in fact, approximately one-half of the U.S. population's annual exposure today is from medical imaging alone.

This report specifically identified CT, interventional fluoroscopy, and nuclear medicine as largest contributors to medical imaging dose, accounting for the majority of that source of exposure. And this report prompted FDA to begin formulating its plan for addressing medical imaging exposure.

Now, while FDA's initiative will address each of these three high-dose medical imaging procedures, the scope of today's public meeting is focused on computed tomography and fluoroscopy equipment alone as the two largest contributors to medical imaging exposure for which CDRH has regulatory oversight.

While nuclear medicine is a large contributor to exposure, we're not addressing this modality primarily because CDRH doesn't have a regulatory role in this area. Nuclear medicine dose is more heavily dependent on the radiopharmaceutical that is delivered to the patient, which would fall under the purview of FDA's Center for Drug Evaluation and Research, and we will be working with them to address issues in this area.

Over time, we expect that actions taken to improve safety of CT and fluoroscopic equipment will spill into other areas of radiographic imaging and diagnostic fluoroscopy equipment and procedures.

So as Dr. Shuren said, FDA announced its initiative in February

of this year with the goal of ensuring that each patient should get the right exam at the right time with the right dose and by promoting principles of dose optimization, to minimize the individual's exposure to radiation for each exam while maintaining image quality and principles of exam justification, to ensure that only medically necessary examinations are performed.

The three main areas of activity described in FDA's initiative are to promote the safe use of medical imaging devices, to support informed clinical decision making, and to increase patient awareness of medical imaging and dose issues. And within each of these areas, FDA plans to pursue specific activities.

For example, we will seek to promote the safe use of devices by establishing safety requirements for CT and fluoroscopic equipment. These may include dose display and recording or reporting features that improve operator awareness of medical imaging dose. They may include access controls that limit operator access or track operator changes to settings or features that affect dose. They may include alerts that notify operators when dose exceeds a diagnostic reference level or a threshold for injury or other established values set by the local facility. They may include optimized default settings that ensure equipment is not delivering unnecessary radiation dose upon installation or upon selection of a default protocol.

And we're also going to talk through training for users on equipment features and controls that affect those to ensure that operators

are aware of those dose saving features and technology that equipment incorporates.

And these are examples of areas where FDA is specifically able to apply its regulatory authority to approve safety of devices.

In other areas, CDRH will partner will other federal agencies or professional organizations to promote safe device use. Under the Medicare Improvements for Patients and Providers Act, the Center for Medicare and Medicaid Services oversees accreditation of standalone medical imaging facilities. Additionally, CMS has established conditions of participation for hospitals and has accompanying interpretative guidelines for Medicare surveyors to define requirements for facilities participating in Medicare.

FDA is working now with CMS in its designated accreditation organizations to support the inclusion of operator training and quality assurance practices in its requirements and guidelines. The work will bridge a gap between where FDA has authority to require that equipment contain certain features and where CMS can exert its authority to ensure that operators and facilities understand and use these features in clinical practice.

FDA is also supportive of efforts to develop diagnostic reference levels for a variety of medical imaging procedures, and we acknowledge that much work has gone into defining reasonable estimates of dose for many procedures as sponsored by the American College of Radiology and the National Council for Radiation Protection, but more work remains to be done.

Where reference levels have not yet been developed on a national level, FDA recommends that user facilities develop their own locally based diagnostic reference levels for use until more broadly recognized levels are available.

It's our hope that efforts to standardize dose metrics and naming conventions for various imaging procedures and technological advances to permit collection and pooling of data would support establishment of local and national dose registries. This information will help facilities benchmark radiation doses relative to a dose delivered by others and could permit analysis and trends over time.

Importantly, this information would fuel evaluation of facility QA practices, not necessarily to spur a reaction that higher doses automatically be reduced without analysis, but to spur or to fuel investigation by a facility that would prompt the question of why more dose was delivered when compared to another facility to ensure that it was justified and, if not, to take corrective action if needed.

Specific activities that FDA is going to pursue in the area of supporting clinical decision making will be to establish record keeping requirements for CT and fluoroscopic devices. This will specifically be to link dose information with patient records that will facilitate tracking of individual imaging history and could support monitoring of patient dose over a long period of time. We would also seek to look to enable equipment to transmit

imaging data to local or national databases in a standardized way as in a DICOM structured report, or we might look to incorporate use of exam ordering systems in clinical decision making to assess whether a specific exam is justified before it's going to be performed. And, again, these are areas where FDA has the ability to establish requirements and guidelines for industry.

Additionally, FDA will support efforts to develop appropriate referral criteria for a variety of medical imaging procedures which might be incorporated into electronic exam ordering systems and to get more to the issue of justifying use of medical radiation.

Finally, FDA will seek to increase patient awareness of dose issues by providing patients with tools to track their personal medical imaging history. This is a near-term goal that we're working on with the American College of Radiology and the Radiological Society of North America and Image Wisely group, where we expect to develop a medical imaging history record similar to what has been available from FDA for the past several years but updated to reflect what is currently developed by the Image Gently group for pediatric imaging, and this history record is intended to fuel patient-provider discussion of medical imaging dose and really serve as an interim solution between now and the time when such information might be captured in an electronic patient's medical record.

I'm going to close with a few slides that describe a future state

and basically ask, can we get to a place in five years where various aspects of the system that defines medical imaging are working in concert to address issues related to equipment safety, operator qualification, and facility quality assurance?

So where a new medical center would be built somewhere in the U.S. and its radiology department is purchasing a new CT system, in order to perform medical imaging exams, it would have to gain accreditation from one of the organizations recently recognized by CMS, and this will occur. Those accreditation criteria would ensure that staff are trained to properly use equipment and its dose reduction features per training programs or guidance provided by manufacturers of the equipment. The facility would routinely review data and assess dose protocols, taking action to ensure exams are justified and the dose is optimized.

Patients and their caregivers would come to this facility equipped with a medical imaging history card and prepared to ask questions about the radiation they're going to receive and why the exam is necessary. Staff will be trained to discuss these risks and benefits of medical imaging procedures, whether alternatives exist, and if not, why not, and answer other patient questions about the exam they're about to receive. The hospital would use an exam ordering system to evaluate appropriateness of the study before it's conducted based on referral criteria established by the facility or other medical professional organizations, and providers will use this

information to confirm that the exam is justified.

Specific imaging protocols in settings would be reviewed in advance. Verification of those settings would be required by the system, and any changes made by staff would be controlled and tracked automatically by the equipment.

The system may also automatically retrieve information from hospital data systems, which contain a local reference level or a larger dose registry in order to verify that settings and dose are within an expected range, and the system would alert users when the dose is outside this range or a range defined by hospital staff or would alert users if the patient recently had another similar medical imaging exam.

During each exam, the system would automatically collect imaging settings and dose data which would be transmitted to the hospital PACS system, a patient's electronic health record, and possibly a national dose registry to support refinement of local diagnostic reference levels, national diagnostic reference levels, and for use in tracking the patient's medical history, individual medical history, and radiation dose.

So with that, let's begin our conversation and get started along this path. That concludes my remarks, and we're to begin the open public session for CT. Dr. Morin is up first.

And just by way of introduction, several questions were proposed in the *FR* notice that were designed to inform FDA on steps that

manufacturers can take to reduce unnecessary radiation exposure through improved product design, enhanced labeling, improved instructions or training for use in facility QA and during this session, we're going to hear from 22 presenters to address equipment features, labeling and/or premarket submission data that might improve CT equipment, and this is for both new devices and those already on the market.

Following the open public session, we'll move into a round-table discussion.

DR. MORIN: Thank you, Commander Boyd, and thank you to the organizers for asking us to present some information about the dose index registry that the American College of Radiology has been involved in.

At the very outset, I think it's very important to kind of set the table here in that the truth is medical physicists do not measure dose. What we do is we measure exposure, and then we calculate a dose estimate. So I would like, if everybody would refer to this as a dose index or a dose reference or something like that because it really isn't the dose, and that's an important thing because patients tend to think, if we give them a number, they can add them up and then they can go to a table or they can look up an article and thereby go and estimate their own personal risks, which is terribly flawed.

So the dose index registry came about because the College was interested in answering a very simple question. What is the average dose

index for a head CT exam in the United States? And the truth is, we don't know.

So the dose index registry is one of many registries that the College has, and it fits into the overall program of quality control so that institutions can thereby have a metric that they can use to see where they are with regard to certain various things, and in our case it's a dose index.

So the registry is going to collect and compare dose index information across multiple facilities. So an individual facility, their quality committee would be able to say our head dose is 5 millisieverts and the average for a head CT is 3 millisieverts, why are we 2 millisieverts high or 2 milligrams, something like that.

The idea here is that this has to be automated so that it can be done for all exams, not just selected exams. So it works like this. The scan data come in. When they go to a workstation and then onto reading, also at this time, the images are also pushed, right now, to a separate PC that has software from the College that extracts dose index information from the header. So this software takes care of automatically extracting both demographic information as well as dose index information.

Right now in the first trial, this was done in a special way with only one vendor. It will move to the IHE profile for the radiation exposure monitoring.

From our previous pilot, we learned several things. One is that

it's not a done deal that every place can implement this kind of thing. We thought that, oh, we've got these wonderful institutions, they've got all kinds of IT people, this is not a big deal. We'll just put up a PC, put software on it, and off we go. Well, that was a little bit optimistic. It didn't really work quite that way.

The other thing we learned is that people don't call things the same things. If we just look at one exam, that is the exam of the pelvis, we had over 40 different names for that, and this comes about because when the RIS is installed, the RIS feeds the modality. If the RIS is installed, the facility can call studies whatever they want to call them, and that's a major problem.

If we take a look at just a little bit of the data, to give you an idea, the other thing is that the issue is, do you want the dose index for an individual scan or do you want the dose index for an exam because clearly some exams have more than one pass with a CT, and therefore that changes what the dose index is going to be because you're scanning the same anatomy. So right now, the Steering Committee is looking at both aspects.

As you can see here from some of the early data for just head CTs, and head CTs should be one of the places where you expect them to be as close as possible, you can see the wide range. We have a huge range here, and this is only with 12 institutions. So we believe that it is very likely that the range is going to be more than one order of magnitude, probably closer to two among all facilities.

However, by facilities participating in the dose index registry, they will know where they are with respect to other places in their region, the country, internationally, and then they can put in methods to address that.

This summer, the pilot will now move onto the REM profile. We're recruiting sites, and we hope to open up the DIR nationwide the beginning of next year. Thanks very much.

(Applause.)

CDR BOYD: Our next speaker is Dr. Jack Ziffer.

DR. ZIFFER: Thank you, and it's a pleasure to be here. My presence is based on my position as president of the Society of Cardiovascular Computed Tomography. I also serve as chairman of a 70-physician radiology department in Miami, Florida.

The Society of Cardiovascular CT is keenly interested in patient care, patient safety, and appropriately providing for our patients a very important technology in their evaluation. The SCCT is a broad-based group of physicians, scientists, technologists, and nurses, of whom 80 percent serve in the arena of cardiology and about 15 percent in radiology and nuclear medicine with the principal missions as defined below, really interested in a patient center and clinical focus, trying to optimize clinical effectiveness of cardiovascular CT through professional education and establishment of standards for quality assurance, those issues with which the FDA is also keenly interested in with this program.

We're specifically going to make efforts at trying to answer questions A6 and A7 during the course of the ensuing six minutes.

A number of years ago, an individual during an interview to become a spokesperson for a federal anti-smoking campaign said the obvious, and obviously didn't intend to say it. Brooks Shields said, "Smoking kills. If you're killed, you've lost a very important part of your life."

With that, why we share concerns with CT and dose, which is obvious for patient safety, there are tremendous concerns that the public has in part that may be unjustified with radiation, specifically radiation from CT, being very different than smoking, smoking having no medical benefit whatsoever, and having to weigh the benefits of CT in terms of disease diagnosis and treatment compared with the potential risks.

The SCCT has been keenly interested in improving the quality of patient care through efforts largely focused, in addition to education and the development of performance guidelines, both for performing CTs and interpreting and reporting them which have been published in the past year.

Our guidelines on cardiac CT and radiation is expected to be published in July 2010 led by Urigh Houseslider, and it will focus on issues of risk which we're all keenly aware recognizing a risk of .00062 per millisievert as our best guess for what the lifetime risk of an induced malignancy may be. Importantly, up-to-date dose estimates are crucial in assessing patient risks. The guidelines will focus on risk reduction but very importantly also what the

benefits of the patient of CT are, with an expectation that when we do a study, it's medically justified and appropriate.

We have to recognize that in the patients we're imaging, done appropriately, the annual risk of mortality may be 10 to 100 times what the lifetime risk is of an induced malignancy. So we're talking about a very dangerous disease state, potentially dangerous, versus a relatively important but low risk from the CT scan itself.

Jim Min published, a number of years ago, what the risks may be, and CT can identify patients with, for example, left main disease where the annual risk of mortality, the annual risk of mortality is 10 percent, and reproduced by Leslie Shaw, comparing CT to coronary angiography, again showing that in the intermediate risk, the annual event of mortality is on the order of 5 percent.

And so in terms of equipment features in A6, should manufacturers incorporate into CT equipment features that ensure that exposure settings and so forth are present, the answer is yes, when done so, that, in fact, those measures as Dr. Amos reported are appropriate and reasonable. They've published guidelines on this, chaired by Gil Raff, recommending that, in fact, in our guidelines that the patient parameters including those type and extent be reported. And so we've anticipated these issues and reported them. Additional guidelines, chaired by Sonny Abbara (ph.), reported that three issues, the scanner should meet or exceed current

standards, radiation dose estimates from coronary CT should be recorded for all patients, not necessarily residing only in the study report, and importantly, periodic review of the site's performance for individual procedures for continuous quality improvement is essential.

That's best exemplified by a study by Gil Raff, a leader within our Society, in a Michigan registry looking at the radiation doses before and after dose reduction strategies, showing a really dramatic process where patients underwent scanning prior to this study with doses ranging from 2 to 45 millisieverts and, after incorporation, marked reductions in doses such that ultimately a large majority of patients were under 50 millisieverts, this before the latest technologies became available, enabling dose reductions with step and shoot.

And, again, maintaining image quality. We could reduce doses, but if image quality wasn't maintained, we would have significant problems.

Very importantly for -- review, tremendous strides by industry at dose reduction have been accomplished in very short years, a 57 percent reduction with prospective triggering, 53 percent reduction with a low -- approach, advanced iterative reconstructions with dose reductions of up to 71 percent, and newer high pitched acquisitions resulting in doses systematically under 1 millisievert.

In terms of the equipment features, should manufacturers incorporate features into CT equipment to facilitate transmission?

The answers to that have to deal with our concerns for issues of risk versus benefit, that doses and outcomes are not necessarily well understood, and importantly, when a patient gets a study, the value of that study needs to be individually assessed based on its benefit and not assessed based on a prior radiation exposure. If a patient will benefit from a cardiac CT, independent of what's happened before, that benefit should be there and outweigh the risks.

So, again, to reiterate, each study should be assessed individually, not based on history.

So in terms of the equipment features, on A7, we think it would be desirable with an institutional database for doses of specific protocols and would like to record that for individual study dose, but have caution about a cumulative dose report for patients in that a specific number, we don't know what to do with. So if a patient has a cumulative history of 100 millisieverts, should they be denied a potentially life-saving subsequent study, and the answer is that test needs to be assessed independently and doses databased.

So with that, thank you very much for your attention.

(Applause.)

CDR BOYD: I'll apologize to every speaker in advance that I need to interrupt, but in order to get through many of these presentations, we do have to honor times so everybody can speak, and then everybody has an opportunity to post their presentations and comments to the public docket

so that they can all be heard.

Our next speaker is Dr. Meltzer.

DR. MELTZER: Thank you. I'm delighted to be here and thank the FDA for putting this open forum together. I am Chair of Radiology at Emory University and Associate Dean for Research in the School of Medicine. I am here today with the Coalition for Imaging and Bioengineering Research. I serve on their Executive Committee and also chair the Associated Academic Council of the Academy of Radiology Research.

The coalition represents approximately 30 academic departments that are prominent in NIH refunded research, 40 patient advocacy groups, and approximately 9 medical device and other relevant industries related to imaging. It was created to advocate for public and private support for research to improve imaging and bioengineering technologies. Such research is a critical component of the broader national priority to improve quality safety and efficiency of healthcare, and we advocate specifically for research that develops and deploys imaging technology and matures its application in a patient-centered and cost-effective approach. Our partnership with patient advocacy groups is particularly critical to ensure that the public good remains at the center of these efforts.

Medical imaging, including CT, has increasingly provided a critical role in mainstream medicine for diagnosis management and treatment

guidance. CT exams, although they only represent 11 percent of the volume of medical imaging, they provide approximately 60 percent of the ionizing radiation exposure to patients.

However, we need to keep in mind that imaging technology has brought us great advantages in patient care in terms of early disease detection, such as mammography that improves survival, advanced diagnostic examinations, such as PET/CT that's used in staging of disease, random MRIs and stroke evaluation, and non-invasive therapeutic procedures that replace more invasive costly and surgical procedures that are associated with enhanced mortality and morbidity.

Yet, there's risk associated with such imaging technologies, which is why we're all here today, particularly those associated with ionizing radiation.

As was mentioned by our host, the Image Gently campaign that's sponsored by the Alliance for Radiation Safety in Pediatric Imaging has been focused specifically on keeping doses low, child-sizing CT protocols, and has been effective but is not focused on adults. We are advocating a greater need to manage and reduce radiation exposure for all patients.

Alliance is advocating a multifaceted approach and focusing on research in particular, the use of ionizing radiation only when medically necessarily, and decision support tools specifically proposed by the American College of Radiology need to be used more on a more widespread basis and

incorporated into electronic medical records and risk tools, legislation to further limit self-referral, opportunities that tend to promote over-utilization of advanced imaging technologies.

We support, as has been discussed, manufacturing requirements for equipment and software that will reduce doses per exam and have greater transparency of doses per patient per protocol. As the last speaker noted, we need to take into consideration the need for the exam in a specific patient, but need to understand what that risk/benefit ratio is and provide fail-safe mechanisms to prevent machine or human error and have more easily auditable tracking of doses.

Informatics approaches are absolutely necessarily to harvest radiation exposure and connect it easily into electronic medical records and into national data registries and provide patients with access to such information.

The research roadmap is central to our mission. We need to have funding available for more studies to optimize image quality and have more information in terms of what we can to do reduce radiation exposure yet still optimize signal and noise characteristics and detection of disease and comparative and effectiveness studies to understand the optimal balance between low radiation techniques and diagnostic capability.

We do a lot in terms of training medical professionals in radiology, but we could do more. Radiologists and nuclear medicine

physicians are training in imaging and radiation physics and must, of course, pass examinations in these areas for board certification. Continued lifelong learning in these areas have been strengthened and could be strengthened more. The onus is on us.

Standardized approaches to benchmarking radiation doses need to be strengthened as well, and accreditation of sites utilizing medical imaging equipment as has been provided by the American College of Radiology, we advocate for this.

There are many aspects of research opportunities. The goal of these are generally to develop federal legislation that would provide funding to be administered through NIH, AHRQ, and the FDA that would finance the required research and development that could lead to improvements in the arenas discussed and to also disseminate best practices that could be adopted in clinical settings, through medical device industries and the national initiatives to adopt electronic health records. Thank you so much.

(Applause.)

CDR BOYD: Thank you. Our next speaker is Dr. Nicholas.

DR. NICHOLAS: Good morning. I'm Julian Nicholas, a medically trained physician, Oxford NIH trained scientist. I'm a full-time gastroenterologist specialized in colorectal cancer screening. I worked full-time as FDA's medical officer in gastroenterology and served as FDA medical expert in colorectal cancer screening devices, including CT, from October

2006 until October 31, 2009.

In order to reduce the risk in CT, we need to know the answer to the following questions. They are: What did FDA know about unnecessary radiation exposure? When did they know it? What did they do about it? Why did they do what they did?

You will learn that more than one year ago, FDA physicians and scientists raised serious safety and effectiveness concerns about patients receiving radiation from CT devices, that these concerns were ignored and then suppressed. You will learn that FDA physicians and scientists who had raised these serious issues on behalf of the public were pressured to change that scientific opinion. Only now, after CT and induced radiation injuries were reported in the press and only now after the risk of radiation from medical devices have become a matter of public concern and only now after recent congressional hearings has CDRH finally recognized that there actually may be a problem.

In March, FDA physicians and scientists warned CDRH of the danger of exposing healthy, asymptomatic people to the high doses of radiation from CT, including the risk of radiation-induced cancer, that there was inadequate safety labeling of CT devices, that there was an absence of sufficient, valid scientific evidence to conclude that the use of CT devices for colorectal cancer is both safe and effective.

In fact, according to the FDA's website at the time, no

manufacturer had ever demonstrated to the FDA that CT is safe and effective for screening for any disease or condition.

On May 12, 2009, FDA physicians and scientists were ridiculed and chastised for raising the bugaboo of radiation. For those of you in the audience who don't know, *Webster's* defines it as an imaginary object of fear. By sheer coincidence, that very afternoon, CMS released its report concerning the use of CT in colorectal cancer screening and reached identical safety and effectiveness conclusions as FDA's own physicians and scientists.

By June, FDA physicians and scientists felt they were being pressured and coerced to change their scientific recommendations. FDA physicians and scientists stood by their scientific recommendations and refused to change them without a valid scientific or medical reason. FDA's chief scientist was informed that CDRH managers and leadership were threatening the integrity of the scientific review process at CDRH and that significant public health and public policy concerns were being ignored and suppressed by CDRH.

In September, nine FDA physicians and scientists met with then CDRH Center Director, Dr. Schultz, at that time, that use of CT for screening was and is a major public health concern due to the radiation dose delivered to otherwise completely healthy asymptomatic patients, that scientific and regulatory review process for medical devices were being distorted by managers who were not following the laws, rules and regulations, that

retaliation could escalate and did escalate into terminating physicians and scientists, unfortunately including myself from their positions.

On October 10, for the first time, reports of radiation injuries from across the other side of the country came. They surfaced on the west coast in Los Angeles. Four days later, I was informed that I would not be allowed to continue in my position as a medical officer at FDA. Two days after this, newspaper articles continued to highlight the dangers of the inappropriate use of CT devices. On October 30, two weeks after I was told I was no longer needed, a petition signed by multiple physicians and scientists was sent to the Office of Director on my behalf so that I could continue my work on behalf of the public. The following day, my position as FDA medical officer came to an end.

In November/December, press releases of the dangers of CT continued to surface from around the country. I and others appealed to the highest levels of the FDA to intervene but to no avail. On December 11, 2009, I wrote directly to HHS Secretary Kathleen Sebelius, and FDA Commissioner, Dr. Margaret Hamburg. A redacted copy of this letter will be sent to the official record of these proceedings.

So, what do I tell my kids about what happened? I tell them this: I'll tell them that I'm proud of my record in public service. I did nothing wrong. I tried my best to serve and protect the public. I tell them that when they grow up, it's better to do something for a good reason than to do

nothing for a bad reason, and I remind them of what Robert F. Kennedy told us, "Every time we turn our heads the other way when we see the law flouted, when we tolerate what we know to be wrong, when we close our eyes and ears to the corrupt because we're too busy or too frightened, when we fail to speak up and speak out, we strike a blow against freedom and decency and justice." Thank you.

(Applause.)

CDR BOYD: Dr. Mahesh.

DR. MAHESH: Good morning. Thank you for the opportunity to invite me to give this presentation.

As many of us also participate in various professional societies, my comments here are personal comments. I support indeed the comments supported by the ACR and SCCT in the effort to reduce radiation dose in CT.

What I want to talk today is a few of these items. First of all, we all have to understand the medical benefits of CT scans far outweigh the risks. Currently, there has been a shift from the ongoing slice swath towards dose swath in CT because from past few years, through the multi-detector CT, we have been seeing increased, every technology have been increasing to different number of slices and so forth, but eventually now we are seeing more of these efforts towards radiation dose swath.

One thing which I wanted to mention is like the manufacturers of these CT devices ought to be applauded for their efforts in developing

technologies that have aided in reducing radiation dose.

Also, radiation dose is currently one of the top selling features for CT manufacturers and, in fact, that has come around because it's mainly because of the demand from the users. So we as users, medical physicist, clinicians, and technologists, also have a role in demanding more from the manufacturers to make an effort for reducing dose.

Having said that, many of the recommendations may be similar. Recommendations that are common do recognize the need for further. Because of the time constraint, I'm going to confine my statements to the following questions: number 1, 2, 6, and 7. I'm not going to repeat those questions. It's going to be posted.

Question number 1, related to hardware and software features. Manufacturers should continue to develop features that lower radiation dose without jeopardizing image quality. Warnings should be developed, such as audible or visible warnings during dynamic scans such as CT fluoroscopy or CT perfusions are needed to alert the operators when radiation doses exceed recognizable thresholds. It is very important.

The other thing is such as alerts, these can be alerts. These can be developed by the manufacturers, such as pop-up alerts which alerts or warns or reminds operators when scan parameters are exchanged for a particular CT scan. In a busy clinic and environment, operators are doing all the time the scans, and some of these simple things can be forgotten when

they are doing the scans. So such type of pop-ups or alerts can really make a different in cutting down some of the unnecessary radiation doses.

The second aspect of radiation regarding hardware and software features, CT scans are incomplete sometimes due to scanner problems. Again, most of the time, our operator just restarts or reboots the CT scanners and repeat the scans or complete scans on a different scanner, and I have seen this in a couple of clinical situations.

Therefore, there is a need for a system to track incomplete scans. Like if this has happened in nuclear medicine scenario, the patient is given the wrong dose, it becomes like a misadministration situation.

Similarly in CT also, if there is a missed scan or unaccomplished scan, that has to be chart because currently we don't have that access information. Even though the manufacturers can access such information, manufacturers need to share such information with users, so we as users can perform the -- analysis like what we used to do in the mammography or in x-rays on an annual basis to see further minimized unnecessary radiation dose to patient. This may not be too many, but even few can be reduced by further analysis.

The other aspect regarding hardware and software situations, those modulation techniques, most of us working the field know, are quite applicable to most CT scans across the board. However, it requires special attention during scanning, pediatric CT scans. In such cases, special pop-ups

or warnings should be available. For example, warnings to check if patient disposition at scanner center or check to see if the proper scan techniques are applied, check to see that proper scan regions are selected for scans.

Again, in this world of checklist manifesto books and other things which is getting widespread attention in the other fields, it is also becoming important that we need to have some kind of a checklist or drop-down menu to remind operators during pediatric CT scans that can reduce unnecessary dose to patients.

Regarding question number 2, access controls and audit capabilities. Access controls in general, there should be some access controls provided by the manufacturers which would limit the access to few individuals in the clinic who should be considered as supervisors, such as clinicians or a chief technologist or medical physicist, who are then given the responsibility if they have to make any changes to the protocol and so forth. So that's going to be an important aspect. Now, it's easy to change the protocol or change the settings as you are doing the scans, but that needs to have some type of an access control because that can certainly avoid or at least alert the main users or the main supervisors to see why it's being done and so forth.

Second is in order to enable to track or audit major changes in protocol.

The third, which I would like to see the manufacturers try to

implement, is assigning capabilities. Like in radiation therapy in other units, the technologist or the operator has to sign in for each patient. Similarly, if the manufacturer of the scan develop a software or a methodology so that the operators are required to sign in for each patient exam, that will allow the facility to track patient safety incidence, and also perform analysis on patient performance that can be applied to further enhance operator's training and so forth.

Regarding question number 6 and 7, dose display and recordings, CT dose reports are often not saved automatically with patient images across the board. So currently what happens is operators often have to save or tag those reports along with patient images.

In spite of consistent emphasis in our clinic, we have seen sometime randomly check patient information that a patient dose information is not tagged along. So the system has to be done such that the dose information should be automatically saved with CT images.

Also, currently the dose reports vary across manufacturers. To applaud the manufacturer, all of them, all major CT manufacturers do have some sort of dose reports currently, but they vary across manufacturers. Therefore, there's a need to develop a uniform structure for those reports. Also, ultimately the dose reports should contain dose descriptors that are easy to understand and analyze. If we provide too much information, it goes unused.

Further, the dose reports are to be formatted in such a way it migrates easily across acquisition, the storage, archival, and ultimately to the patient health records.

Finally, the display and recording CT dose descriptors is very critical. What I consider the major dose descriptors are the CT dose index, volume CT dose index, and the dose length product. The minor dose descriptors that can be included in these reports are 2 voltage average to current scan time and so forth.

What I would also like to draw attention is the effective dose should not be listed in those reports because as Dr. Morin mentioned earlier, effective dose is only estimation which can be misinterpreted. So therefore FDA should discourage manufacturers from displaying effective dose estimation since it can be misinterpreted. Thank you.

(Applause.)

CDR BOYD:

MR. JOHNSON: Good morning. I would like to thank the FDA for having us here for obviously an important discussion on the future of radiation exposure management ultimately for our patients, which we all hopefully won't be some day, or if we do, this is probably a very important discussion for us.

As the previous speaker covered, our discussion at the Cleveland Clinic is presented from device enhancements that we would like to

see. We discussed it among the medical physics staff and with clinicians, patients, technologists, what could we do better as manufacturers and users to promotion radiation exposure management?

So the core of my talk will be the scope of utilization of CT at the Cleveland Clinic, current topics of discussion amongst ourselves and proposals for enhancing radiation exposure management.

The Cleveland Clinic currently operates over 50-computed tomography scanners from all major manufacturers across 12 hospitals and 20 regional health facilities. We have facilities in Florida and Nevada.

Reinforcing vendor things we'd like to see, scanners have no conspicuous warning system to alert a technologist that a scan will exceed a reference level of limit before a scan is initiated. The technologist manually records the cases with radiation exposures over reference levels. These measures are reactive, not proactive.

There's currently no routine lockdown access control or mechanism to protect the default CT protocols. Anybody with access to the scanner can modify and save the protocols.

Some manufacturers still use the adult size test tool for pediatric patients dose estimating which significantly underestimates the dose for pediatric patients.

There's little to no automated radiation exposure tracking system for either paper or electronic medical records.

So proposals we'd like to see to enhance radiation exposure management are that all manufacturers should provide radiation exposure management software to do the following: allow for configurable dose limits for specific anatomic regions based on site specific or FDA dose registry, for CTDI bowel and DLP, and provide for warning the operator with visual and/or audible means when the dose is greater than or equal to a reference limit. And also we'd like to see that a scan is prohibited when the dose is greater than a maximum level.

We'd like to see all dose-related information should be recorded into a standard electronic medical record so the PACS and/or electronic medical record can retrieve the patient dose related to the study. Manufacturers should provide routine password access control protection of the scanner protocols and production of x-rays. Manufacturers should use a patient circumference as a guide for all CT scan protocol specifications, and current scanners should be changed to indicate pediatric doses.

The EMR system should be able to pull information related to medical radiation history for the patient, at least from within a given facility or institute.

And as FDA proposed, a national dose registry should be mandated as part of the accreditation requirements.

In summary, CT warns when a reference dose is exceeded, electronic tracking of DLPs over reference limits, protect default CT protocols

from override, require patient circumference as a guide for all CT scan protocol specifications, correct for a pediatric dose phantom, add dose information to the DICOM header, and support radiation exposure dose tracking within the electronic medical record. Thank you for your attention.

(Applause.)

CDR BOYD: Our next speaker is Donald Frush.

DR. FRUSH: I want to thank the FDA for the opportunity to speak here and the audience both for embracing this topic in your engagement in this. Having the seat over here, I want to apologize to those on this side of the audience. I know that you don't have a great view of the screen because I'm probably the baldest guy up here; at least of the top of it you can see okay here.

I'm the voice of pediatrics here, and I'm from Duke, and I'm a member of the Steering Committee for the Alliance for Radiation Safety. I think I speak for the community of care providers for children when talking about CT.

These are the highlights here. We all have a responsibility for dose optimization, and we have to be mindful of that in children. There are unique dose indices as we've heard from several speakers, and we have to collectively accommodate innovation. We can't assume that it's going to be one way today and not build and design a system that will address the changes in innovation.

The FDA mission from the very organization that we're from here says that we have an accountability and responsibility. The FDA has an accountability and responsibility to both the people who use the equipment and to the public they service. From a more general respect, too, I think we, collectively, and it's not just radiologists, but it's physicists, it's technologists, and so on, have a responsibility to understand that dose is a material quantity like a medication that we have to use correctly, and with physicians who give narcotics or chemotherapeutic agents or whatever, have that responsibility for dose. We also have the responsibility for dose in this setting.

So let's look at the responsibility for dose particularly with children, and I want to remind the audience, a lot of what we're talking about today began with this article in *USA Today* in 2001 January, and while the article had some misquotes and so on, it essentially I think stirred up industry, regulatory agencies, radiologists, scientists to attend to these issues in children, and this article was four separate articles in the *American Journal of Radiology*, all dealing with children. So it's sort of the reverse Pied Piper phenomena here where children to a large extent are leading, I think or imaging in children are leading the application of this in the adult population.

Children are scanned frequently. About 10 percent of all the CT examinations we do are on kids. They're obviously more susceptible or more vulnerable to radiation, and there are both public and private issues we're addressing constantly with this, and the public issues, you've heard a great

deal about, two articles in *Archives of Internal Medicine* in December of 2009, continue to focus the attention both in the scientific community but the public response to this, too, but we, and whether you're a physicist or a technologist or a radiologist, are constantly answering questions from parents, from patients as well, and one recent conversation I had with a family, the father of a child who had a head CT scan that he thought possibly was questionable indication, he's worried sick over what's going to happen in 10 or 20 or 30 years with this, and despite reassurances, it still affects on a case-by-case basis patients and their families.

I think everyone here wants to do the right thing. We all collectively want to be able to be sure we optimize scanning so that children aren't exposed to more radiation than they need to be. The question is, how do we go about doing that, and I'll provide some illustrations for that.

First off, some data from a few years ago. We looked at 64-slice scanner, and it's a phantom study. We simply turned the things up as high as we could. What is the maximum dose? And the maximum dose from abdomen CT scan was 120 millisieverts. No warnings. Nothing said. Hey, do you realize you're exceeding 50 millisieverts or whatever? No warnings at all, and I think that's one of the main questions that we need to address are these alerts or warnings. So the dose can be quite high.

If we look at brain perfusion CT, now it's not something that's done in the pediatric population too much, but we find when we're again

using these phantoms, that with some flexibility in dose, that you can deliver up to 50 millisieverts from a single examination. So the doses to an individual patient, the dose index to an individual patient can be quite high in current equipment. And as you've heard, there are unique considerations with children.

Just a little bit of a clarification on one issue of this. If we look at gated cardiac CT examinations, in a five-year-old phantom here, and you can estimate a dose index by taking a dose length product and multiplying by a conversion factor, and this gives you an estimation of dose for that examination.

The conversion factors for a 64-slice gated CT are about .018, but what we found, by measuring organ doses in the phantom and then determining an effective dose, that is working the other direction, that this conversion factor should actually be .045, 2 to 3 times what's published. So when the manufacturer say, oh, you get a gated cardiac CT in this one-year-old child, and the effective dose index is 2 millisieverts or 3 millisieverts, it's probably more like 4 or 6 or 7. So we know that the DLP method, as you've heard, doesn't really apply to the smallest children.

Now, we can look about diagnostic reference levels, and in adults, some things are published say in radiology here, about ranges of CT examinations, but there simply isn't much available in children. Where do we start? We need to develop better DRLs for children, and we're beginning to

do that. Here's an example of head CT examinations where we've looked at the literature and find actually that the youngest ages, the dose is quite variable, up to 8 millisieverts, and it narrows down a little bit at 15 years of age, but these are the beginnings of what we can do to help the manufacturers, help regulatory agencies define what is a high and what is a low here.

Accommodate innovation, for example, what we talk about now in terms of dose tracking as with dose length product or CTDI and that it's problematic especially in children. A number of individuals in this room, I know, are working on individual organ doses for CT examinations and a better calculation of the effective dose, and some of the work that we have done in our lab takes weight or cross-sectional areas so that now a six-year-old child comes on, we have a more specific estimated dose index for that examination than simply using the manufacturer DLP.

So maybe the dose sheet of the future will look like this. Not only are some of the scan parameters displayed, the phantom size, but you'll have estimated organ doses on there, heart dose, lung dose, perhaps an effective dose, conceivably a risk. Now, I don't know that we want to get into that, but these are the kinds of things that we have to talk about in terms of innovation and displaying on a dose record perhaps for the electronic medical record.

New technology surface dose modulation, where the tube

current or the dose is turned off as the beam goes over the anterior part of the chest to reduce breast dose, 120 degree R, well, to maintain image quality in photon flux, that tube current is increased through the back of the patient. Now, while the dose to the breast may be reduced, the dose to the lung, the dose to the bone marrow may actually be increased, and we have to be accountable for these kinds of increases. So you can't simply say I'm using surface dose modulation, and I'll record that. We have to understand and be able to adjust and account for what might be increased doses from this newer technology.

So what are our dose responsibilities? We have to embrace children in these conversations, and the FDA has to be an advocate for these. An advocacy position is very important. It can't be punitive. We know that that's not successful. You can't say I'm going to penalize you if this happens, or you're not going to get a credit if this happens. It is much better to take an approach such as the Image Gently campaign that is an advocacy and an educational campaign of how we can be constructive and productive and do things better.

I would argue that we need to avoid the utilization arm of this. You've heard a little bit about this in the past, utilization, optimization. Utilization is extremely difficult. We can't, even as radiologists, agree when an exam is going to be indicated. How is a regulatory agency or a physicist or a manufacturer going to decide that? I think if we stick to the optimization

thing for improving image quality, and dose optimization is a significant and substantial and sufficient issue to address.

Warnings and alerts and so on must be on these scanners. We do this every day. We get in our car, if we don't put our seatbelt on, there's a warning. If we overheat or our oil is low, there's a warning. If we use our cell phones, and we're out of juice, there's a warning, and yet we can go and do a CT scan and there's no warning at all. It's inconsistent. If we're on the MR scanner, there's a SAR issue that comes up, there's a warning. How can we neglect these things? So they have to be there. It has to be part of routine QC. It has to be configurable, place to place, region to region, institution to institution. You can't simply say A is always A. There has to be some modifications, and they have to be appropriate for children.

We need diagnostic reference levels, whether it's through registries as Rick Morin pointed out or some other method, and start simple. Let's look at tube current. Let's look at kVp. Let's look at multiphase scanning. These are easy things to do, and I would support dose warnings along with the display of the dose and archiving.

And I would take issue with what another speaker said. I think cumulative dose index is extremely important. It's our responsibility. While it may not be used in medical decision making case to case, our patients require this. We have to be able to discuss this with them. So the cumulative dose needs to be there.

That said, nothing is perfect, and it's going to be difficult to align all of these things as we move ahead, but we've got to start, and these are some of the things that I would advocate as a pediatric radiologist in moving forward. Thank you very much.

(Applause.)

CDR BOYD: Our next speaker is Dr. McCollough.

DR. McCOLLOUGH: Thank you. I appreciate the opportunity to be here today. I am speaking on behalf of the AAPM.

In CT, the single most effective way of managing radiation exposure is the use of automatic exposure control. AEC systems adapt the machine output to match the attenuation characteristics of the patient, as the tube goes around the patient and up and down the patient and hence uses the right amount of dose to get the desired image quality.

The system does this by first estimating how big the patient is, how much attenuation is in the beam, and it does this with what's called CT radiograph or a scout. The geometric magnification issue comes into play, and so the scanner is calibrated that the patients at isocenter, it gets the left/right dimension correct, but if the patient is either too high in the scan field or too low, the scanner misinterprets the width of the patient, and hence the dose can be wrong. This can be taken care of easily by using two orthogonal CT radiographs.

Now, the automatic exposure control systems adapt the tube

settings to get a desired level of image quality, but the manner in which the user specifies what image quality they want is done very differently amongst the different manufacturers. Also, these methods are not equally effective across all patient sizes, and the lack of knowledge on how these work I think is the key barrier to the effective deployment of automatic exposure control systems.

I think manufacturers need to be required to clearly describe the algorithms in their FDA filings and readily available white papers. Users should not have to reverse engineer how these things work in order to use them properly, which I seem to be able to make a career out of doing. Figuring these things out and then educating how AEC systems work continues to be the most requested educational topic on CT through the APM.

This is a graph from RSNA exhibit that we did. It's circa 2005. So a lot of the data is outdated, and I'm sure you can't read it on the small screen, but what you have is a hodgepodge of names for pretty much the same physical actions of the scanner. The names can be very confusing. One manufacturer had terms auto MA, smart MA, and smart scan, and I needed to carry a little cheat sheet with me to try to keep straight which ones did what things. I think in order for us to use these appropriately, we need to be more clear in what is going on in the scanner so that it's transparent and users don't just say, oh, I have AEC but they actually know what they're doing and how to use it.

Now, these systems were innovative responses to concerns about dose, and we do not want to get in the way of innovation, but users do need the information about what the systems are doing so the technology is not a black box, and the manufacturer jargon needs to be replaced with generic descriptions of what is happening.

I would also really like to see systems give us ALARA tools. The technique charts that we need to build for our scanners have to take into account some little secrets in system efficiency including different kV's. It's a very complex relationship between the detector combination, the slice width, the KV on exactly what noise, what image quality you get for certain settings, and it's not always the linear relationship one might expect, and so it takes thousands of measurements sometimes to reverse engineer these things. It needs to be clarified up front.

kV should be adapted into automatic exposure control systems now. We recently published a paper giving a paradigm for how to do this because when you reduce kV, you can either reduce dose in small patients or improve the image quality. So the knowledge is there. Let's get it onto the scanners.

There are also many types of noise reduction algorithms that preserve the sharp edge detail, and these are widely available in the image processing community. Let's see them on the scanners.

And, finally, noise insertion tools which let you use a clinical

dataset with a known pathology and insert noise, such that you're simulating a lower dose scan, are very helpful tools for doing ALARA research, meaning the adenoids, you get lots of low dose levels, and then you have the radiologist review them and see at what dose level they finally compromise diagnostic accuracy. The manufacturers have some of these tools, or if you have a research group, we can build these, but they're not widely available, and I think they should be.

Finally, we need meaningful dose information. Now, the CTDIvol is an example of a standardized measure of scanner output, and if you use the same size phantom, it's monotonic. Radiation output goes up, the CTDIvol goes up. But that tells us what the scanner is doing. It doesn't necessarily tell us what's happening within the patient. So we need to move from CTDIvol into also providing information on the mean dose and the surface dose for a range of patient sizes. To do this, you need to know what size the patient is, but if you've done the two view CT radiographs, you have that knowledge. Once we know these values, they need to go into structured DICOM reports so that we can get them to databases, and as Dr. Morin mentioned, the exam type and clinical indication needs to be part of that database. Otherwise, you're comparing apples and oranges in terms of types of exams when you try to set up your diagnostic reference levels.

We also support the user configurable alerts and warnings that have been mentioned. Certainly diagnostic reference levels can be used for

the stochastic limits, abdomen CTs, diagnostic reference level 25 milligray. We can have skin injury thresholds for the perfusion type exams, but in all these, patient size has to be taken into account.

This is a set of eight phantoms. They simulate, they're tissue equivalent torsos, and we go from newborn up to a large adult and got all their dimensions, and what we did was take this data and say, well, how big would an infant torso be, and if we did an abdomen scan, how long would that scan be. We asked that same question all the way up to the large adult, and then we put the abdomen phantom next to other phantoms. In this case, here's our newborn, and this would be our adult so that we have all of the scattering material, and we measure dose. Real dose according to the AAPM new TG 111 protocol. So this isn't a dose index. And what we find is that the mean dose as a function of patient size is very predictable. There's an exponential relationship, and so if you know what the scanner is giving out, you can predict the mean dose to any size object. Same for surface dose.

So from a standardized scanner output, we can reliably report mean dose, mean surface dose for any patient size, and I think this is where we need to go.

We can also estimate organ doses, and my colleague, Dr. McNitt-Gray, will talk about this, that you can actually move to organ doses across different patients, sizes which would then eventually, and this is just a spreadsheet example of what we do for research subject, is you figure

out the organ doses from any type of exam. It could be nuclear medicine, fluoro, CT, and then you can add organ doses together to appropriately track patient information. Thank you.

(Applause.)

CDR BOYD: Our next speaker is Dr. Sodickson.

DR. SODICKSON: Thank you. I'm very pleased to be able to join this forum today. I'll be speaking from my background primarily as a clinical radiologist, specifically in the area of emergency radiology, and in this setting, I oversee our CT operations for our very busy emergency department scanner at Brigham and Women's Hospital. I'm involved in CT protocol optimization and in some degree of technologist oversight and clinical training in our work environment.

But I'm also involved in informatics research in longitudinal dose tracking efforts and radiation risk assessment efforts to integrate radiation risk assessment into decision support tools at the point of care when CT scans are ordered by our referring physicians.

I'm going to discuss a variety of the questions posed in the Federal Register announcement.

The first, hardware/software features that are needed, I would argue that the scanner count is always, of course, the right place to minimize dose per exam. We have a variety of excellent dose reduction tools available to us from the manufacturers, and really we're in the nice position of this now

being a point of competition between the CT manufacturers and the market differentiator that they use in promoting their scanner sales, but to some degree, we need to go further and somehow need to decouple some of the availability of these low dose technologies from the financial sales incentives, and we need to figure out ways to get better penetration of these technologies to the older scanner models that remain in standard use.

We definitely need access controls and audit capabilities on our scanners. As has been mentioned, our CT scanners are some of the few hospital devices that currently don't require a login, and really anyone can step up to these machines and can modify protocols, can even save these as standard protocols on the scanners, and this creates the potential to propagate what would have been an isolated medical effort to a large number of patients, as we've seen in some of the recent high publicity events. So we need better accountability on our scanners, and one way to do this is with access controls. We need required logins to limit access to appropriate personnel only, and we need to limit permissions to save protocol changes only to those medical physicists, technologists, radiologists who have been selected at their given site.

Audit capabilities, of course, are required for accountability as well. For every scan that's performed, we need to log the tech performing that case and any changes that they've made from the baseline approved protocol. We need to log any warnings or alerts that that technologist has

dismissed so that we can provide appropriate feedback and accountability if any issues arise, and these logs I would argue ought to reside both in the DICOM header so that they're linked to the actual exam itself, but also need to be exportable to separate databases for broader oversight of the operations of the scanner.

Separate from this sort of scan specific log capability, we need scanner specific logs to track all protocol changes, both the changes that were made and the user that made the changes.

Warnings, alerts, lockouts have been touched on already, but I agree with what's been said, that we ought to have warnings and alert messages if diagnostic reference levels are exceeded. We should in these circumstances allow tech overrides for special cases that require a higher dose scan, but again these overrides need to be logged so that we can feedback in inappropriate cases.

And I would argue as well, just like the SAR limits in MRI, we need hard lockouts for extremely high technique settings that should never be appropriate in any clinical circumstance, and this would prevent the tech from proceeding without first modifying the CT technique.

For any of these to work, we obviously need expert consensus on what diagnostic reference levels to use, and most importantly, these diagnostic reference levels need to be adjusted for patient size because if we pick only a fixed diagnostic reference level for all of our patients, we'll end up

severely overdosing our small patients and underdosing our large patients.

Default CT protocols, I think scanners do need to contain best practice dose optimized protocols for the majority of our clinical needs. Just to give some perspective, in our emergency room, probably over 90 percent of our scans derive from 10 or less CT protocols, but because of the multitude of combinations of these exams and a number of niche exams for specific applications, we end up with anywhere between 50 and several hundred protocols on any of our CT scanners, but we at least need to get some dose optimized protocols for the bread and butter work that we do as starting points for further protocol building.

To do this, we need good academic and industrial collaborations to ensure that we're balancing image quality with radiation dose for the particular clinical task at hand, and this would likely require a collection of expert panels of users for every machine in use because the technologies available on all of these machines do vary.

Parameter and dose display and recording, this has been discussed already, but I'll add my cent as well, that CTDIvol and DLP are currently displayed on the console and for the latest generation of scanners can be saved to PACS but only as a screen capture image. And this allows you to go in one scan at a time and review what's been done, but this is not at all a scalable solution for any sort of rigorous quality control efforts. So the immediate need that we could do today is instead of screen capture sent to

these same parameters, likely as a DICOM SR element into PACS and into the electronic medical record or other external databases. And this is absolutely a requirement for any real effort to continuous quality control.

In the future state, as has already been discussed, CTDIvol and DLP are only x-ray output metrics. They do not adequately reflect patient dose, and the K factors that are commonly used to convert dose length product into an effective dose estimate really do not incorporate the large effect, the large influence of patient size in these dose values, and so we need further methodology development to provide better size corrected dose estimates, and you'll hear more from Dr. McNitt-Gray next on this as well.

I would argue that there are some changes that need to be made to all installed devices that are still actively used that have service contracts with the manufacturers. Every scanner out there ought to have some baseline dose optimized protocols making best advantage of the existing technology on that machine.

Also, anything that's done to improve our standardized dose reporting, both to PACS and to the electronic medical record, needs to be extended to all scanners in use. This isn't something that can be tied to a fee or that can be tied to buying the latest and greatest scanner. This really needs to be a uniform requirement for all scanners in use.

Exam appropriateness criteria, I would argue that the scanner console is absolutely the wrong place to do any sort of utilization control

either with appropriateness criteria or decision support tools, and while I believe very strongly, and my research interest is actually in providing better integration of appropriateness criteria and radiation risk assessments into exam ordering, this needs to come from the clinical realm, and once the patient's at the scanner, it's far too late to make any impact whatsoever in utilization. And so while the CT manufacturers need to provide us the tools to do good imaging, they don't have the clinical expertise to govern decisions about when we should use those tools.

Finally, to the remainder of the questions on the *Register*, my answer is no to all of these. CT scanners are a multifunctional tool used for a large number of exams in patients, and any of these suggestions would add a tremendous amount of busy work but wouldn't actually improve clinical practice. I think for those questions, the relative clinical expertise needs to come from the medical community, and these issues are best addressed with continuous quality control in the clinical realm if we meet the requirements of having sufficient monitoring tools with database capture of scanner output and ultimately hopefully more accurate patient dosimetry metrics. Thank you.

(Applause.)

CDR BOYD: Dr. McNitt-Gray is up next.

DR. McNITT-GRAY: Thank you, and good morning. I'm a faculty member at UCLA in the Department of Radiology and researcher. I'm the

principal investigator on a grant funded by NIBIB which is up for competitive renewal, collaborating with Dr. McCollough and Dr. Cody at MD Anderson. And I wanted to talk about things that we want to record and indicate on the scanner and in the patient record.

I'm going to go through this a little bit and talk about CTDIvol and DLP but also appreciate that we need information about patient sizes that you've heard from several of the speakers. And also while I don't think we can do this tomorrow, but I want to give an argument for a pathway to organ dose, which is really the building block for a lot of stochastic risk estimates such as effective dose, whether you believe in that or not, BERA 7 risk estimates, but organ dose is really the building block and a key component to this, and also peak dose. We think there's ways to estimate that for deterministic effects.

Okay. I'm going to talk briefly, just a little background about what we're doing in our research group, the Monte Carlo simulation. What we do is we basically do four major things here. We model the scanner in tremendous detail. We look at things like spectrum and filtration. We look at patients in quite a bit of detail. We've used these vocalized anatomic models that identify radiosensitive organs. We simulate a CT scan where we actually move a source around the patient and do simulations about the transport of photons through the patient, looking at photoelectric and all those details, and then we can do things like, we can actually tally the radiation dose in a

radiosensitive organ, and that allows us to do things like this. This is an article we published a couple of years ago. I hope you can see some of that, where we've estimated the radiation dose to different organs from a thoracic scan, and we've done this on a normalized basis in terms of organ dose per mAS, and we've done this for different patients of different sizes. So we can look at the effects of different size on radiation dose to patients. I'll come back to that in a minute.

With CTDIvol and dose length product, you've heard about this a lot this morning already, it's currently reported on the scanner though it is not required to be reported in the United States. It is dose to one of two phantoms, either 16 or 32 centimeters. It is not dosed to a specific patient. I'm going to walk you through an example in a second, and it does not tell you whether the scan was done correctly or as low as reasonably achievable, at least not without other information about patient size. It may be used, as I'll show a little bit later, as an index to organ dose. I'll show you that in a few minutes.

Okay. Let me walk you through a couple of scenarios here about what CTDI can and can't do. Let's say we have a site where there's no adjustment for patient size. We have a small patient on the left, big patient on the right, and they get the exact same techniques. The CTDIvol will be reported for those two patients as the same. It's the dose to a phantom, and the values will be identical. They are listed as 20 milligray.

Okay. In the second scenario, where a site does adjust the techniques for the two patients and gives half the mAs for the one patient, the smaller patient, and keeps the mAs the same for the larger patient, the CTDIvol for the smaller patient shows up as half the CTDIvol of the larger patient. Okay. Is that what really happened to the patient?

Now, CTDIvol now has changed, but do the doses to the different patient sizes adjust appropriately? Did that CTDIvol really reflect what happened to the patient?

Well, we know not only from our own work but other groups' work that for the same technical factors, the smaller patient will absorb dose. We've seen this back in 2001 with the articles that Don Frush and others published, okay. But what that means here is that scenario 1 where CTDI was the same, the smaller patient's dose is really higher, okay. So CTDI did not reflect that. In scenario 2, where mAs was adjusted, the CTDI now is smaller, but the patient's dose is closer to equivalent between those two. Okay. So CTDI has its limits, and it does not tell you anything without information about patient size.

Okay. This is what really happened to patient dose. In our simulation work, where we looked at these different models of lots of different sizes, going all the way down from a baby 7 weeks old to a 5-year-old child, up to several adult males and females, you can see here, see that, but anyway, there's a factor of 2 different for the same technical factors, a

factor of 2 difference in the dose between just across these patient sizes, and these are not tremendously obese patients.

All right. So CTDIvol is not patient dose by itself. It really can be misleading. If it's going to be recorded, it should be recorded with a couple of things. I don't know if you can read this either. Description of the phantom size. It should be clear whether it is the 16 or 32 centimeter phantom. Description of patient size, some metric, lateral width, perimeter, weight, some metric of patient size, and preferably a description of anatomic region. We would want to know whether the head was scanned, abdomen, chest, et cetera.

But what is it that we really want to know? Is CTDI what we really want to know, and I would argue that what we really want to know is an organ dose or a peak dose. CTDIvol may provide a path to get us there. We're not there yet, but may provide us a path.

Now, this is a work that our research group presented at RSNA a year and a half ago. The article has just been accepted into *Medical Physics*, and we ask a simple question. How does organ dose vary across scanners of different manufacturers when using as comparable techniques as we could, same likeness of scanner, 64 row scanners, same technical factors, nominal technical factors, same kVp, mAs, be in collimation as close as we could get, and using one of our model patients as a reference, and we did the same scan all the way through.

And what you see here, I don't know if you can see this, but I'll point it out anyway, that if you look at these different organs, these are organs in the columns, and the dose is normalized here to mAs on the Y axis, you see about a factor of 2 difference between scanners, same nominal settings, 120 kVp, whatever the mAs is, same pitch, everything's nominal, the same, but the dose can vary by a factor of 2 between scanners, and that's from organ to organ pretty consistent.

However, if you do the following, it turns out the CTDI also varies by about a factor of two. So if you normalized that out, organ dose divided by the CTDI volume, these values start to come together, and you get coefficients that are approximately constant across scanner. So we think this is a pathway to get something that's scanner independent in terms of organ dose. And by the way, the values there, you can't see them, but this is the dose divided by the 32 centimeter phantom. This value is about 2 right there. So CTDI not only is not the right value for dose, even the normalized value says the dose is actually about twice what's reported on the scanner.

All right. What about patient size? How does organ dose change with patient size? Again, we went back to our simulations. We went back to looking across different patient sizes, again all the way from a small child to a large adult, and what we see is this, similar to results Dr. McCollough presented a few minutes ago. A very nice, smooth variation with patient size. We use perimeter here, and these are all organs. Each of

these icons is for a different organ, but you can see these very nicely, smoothing, varying functions, okay. So now we think we can get to organ dose that's reasonably scanner independent, and as long as we have information about patient size, we think we could make a good estimate. This is from an abdomen scan here. We have other areas to pursue.

Okay. What about peak dose? Does CTDIvol indicate peak dose? Okay. It's a weighted average of measurements made at the periphery and center. It's designed to reflect dose from a series of scans, when there is table incrementation between them. It's not patient dose, not even skin dose, and it typically overestimates skin dose. And by the way, the dose metric proposed in AAPM Task Group 111 will do a better job of this, but it's still not going to make an adjustment for patient size.

So let me show you some highlights of some results that we did, again, back to our simulations, where we simulated a head scan, and we did a couple of different locations, one through the lens of the eye and others where it was away from the lens of the eye, and what we found was at different techniques, we saw how many rotations at how many mAs you would have to give to get 2 gray to the lens of the eye and what the CTDIvol value would have been at that level, at that technique, and it typically overpredicted by about 50 to 70 percent, and that's if you're scanning right through the lens of the eye, and if you're not at the lens of the eye, then the dose to the lens of the eye is significantly less. And if you're looking at skin

dose, okay, then the CTDIvol also generally overpredicts by at least 30 percent.

Okay. The summary is what should we record now? Something that we can do right now, we can record technical factors. We can record CTDIvol and DLP, and there's been lots of discussion about that. There is a DICOM structure report that is coming about. I hope we'll have more discussion about the rate at which it's implemented because some of these things have been available for about four or five years but are not implemented yet. But we like CTDIvol and DLP phantom-sized, used for that CTDIvol calculation, some information about patient size and anatomic region, and in the future, the AMP task group 111 dose value could be recorded, as well as potentially organ dose and information about peak dose or skin dose, that would be informative as well. Thank you.

(Applause.)

CDR BOYD: Dr. Robert Zeman is up next.

DR. ZEMAN: Thank you very much. I'd really like to express my thanks to the FDA for hosting this session and helping us focus our shared responsibilities on reducing radiation exposure.

My name is Bob Zeman. I'm the Chief of Radiology over at GW and was the former chair of the ACR CT accreditation program, and I'm speaking on behalf of myself as a radiologist in the trenches who does clinical work.

I'd like to jump right into some of the questions or comments. Some of this will be redundant with what you heard earlier speakers mention.

Question number 2, should we be able to identify users who can change protocols or have audit controls in place? Of course, we should. Again, it's ironic that so many of our CTs don't require any kind of password protection like other devices require. We've been able to lock down and control MR protocols for years, but again in CT, we haven't been that aggressive, and I think we need to do that obviously for the future. It's too easy to override protocols and to change subtle things. I've seen pitch, for example, be changed a number of times with its resultant alteration in dose index. So again this is something I think we need to do.

Should we incorporate reference levels into the devices? Well, as you've heard from everybody, obviously reference levels represent a dose distribution of the most frequently used doses. They should be provided as guidance, I believe, to sites but not as absolute restrictions because one size really doesn't fit all. So I think if we want to create some absolute limits with warnings, that would be acceptable, but they shouldn't be the reference values. The reference values should be provided as guidance only.

Should we incorporate referral criteria to check appropriateness of the exam? Again, sort of as Dr. Sodickson suggests, I think that this is better done on the order entry end or on the referral end of creating that order. It could be done an institutional or a practice-based

electronic medical record. So while this can be very useful, the radiologist really can't be the gatekeeper at the time the examination is being performed and the patient is already on the scanner table. Obviously we need to continue to educate the clinical refers about appropriateness criteria, create some expert systems and tools for decision support, and really implement those over time, but the scanner is really not the place to do that.

At GW, we've created some critical pathways in our systems. This is a screen shot from our emergency department order entry system where we have not only critical pathway, but we have it linked to specific referring symptoms as well as the specific exams that may go with those symptoms, and this has created a lot of uniformity of the ordering process for us and has been very good, but these kinds of division support tools are going to be very valuable in the future.

Another question that was asked was whether the manufacturer should incorporate features to ensure that exposure settings, imaging protocols, and metrics of body dose and peak skin dose are displayed, and again, my comments are similar to what you've heard earlier for CT, that obviously the parameters should be reported and are reported as part of the DICOM header. The dose estimates, and ultimately this may take different forms, but the dose estimates need to be reported in the DICOM header as a structured report that can be exported to databases like you heard from Dr. Morin earlier like the ACR NRDR database. So we need that and also the

ability to export it to medical records, but also I would argue that we need two other things. We need these screen shots also because it makes it so accessible and easily available to the radiologists and the referring physicians to see without having to go looking into the DICOM header. So I think it is important to have it there. When we burn CDs, they may not be diagnostic quality images, but again having that data readily available for the patient and the referring physician is very useful.

And, again, the information regarding dose estimate needs to be prospectively available, and available and updated in realtime when we're planning the study so we can effectively protocol the examination.

One of my pet peeves is my three-year-old PET/CT that doesn't really give me adequate dose estimate information. After the scout views, it gives me an estimate of the first initial series that we're going to do after that scout view, but not of the subsequent series. So we're sort of left to manually estimate the dose on the individual exams as opposed to having the device give us that information.

The reason I bring this up is because we've just got to make sure that we don't abandon legacy devices. There's a lot of scanners out there that are relatively recent scanners but where we need this information because we really do rely on it.

And I want to mention sort of specifically about how we rely on the information in terms of these dose indices. We presented at RSNA,

Dr. McCollough and others involved in the accreditation effort, some of the evolution of the dose index measurements that we took in the early years of the program, and you can see from this slide that for an adult abdomen, the number of exams, they were over the proposed recommended reference values that we had in place at that time, diminished over time because people really became educated about using these dose index values, they became very familiar with them, and this ultimately led to us actually lowering the reference value that we implemented in 2007 based on the earlier years of the program, but radiologists became very familiar with using these kinds of estimates.

Contrary to that, I think it's important to realize that looking at just the scan parameters, the mA and the kV and those sorts of settings, it's very difficult for radiologists to determine the dose of an exam or to predict the dose. We do use that information. It's important to us, but again when we looked at 518 exams that were part of the ACR database and looked at what clinical experts thought about the dose index measurement as compared to just having the scan parameters, they woefully underestimated the dose index measurements based on if they only had the mA and the kV to make those kinds of predictions. We were only 21.2 percent sensitive in predicting which exams had a dose estimate that exceeded the reference values that we were using at that time.

So, again, it's important that we have the actual dose estimate

numbers, for better or for worse, and obviously over time, those metrics are going to become more and more refined, but do we really need the CTDIvol or the DLP displayed? Well, I think absolutely we do. It's crucial for us. We need the dose estimate data displayed not only so we can plan specific exams, but we can learn for the future in planning our future protocols that we're going to apply to larger numbers of patients. These estimates may be refined over time; they may become more organ based. There's a lot of things that will happen, and we'll need to educate people and adjust to those changes, but for now we need these displayed because just the scan parameters alone is not enough for our radiologists and ultimately our technologists to plan the exams. Thank you.

(Applause.)

CDR BOYD: Our next speaker is Thomas Priselac.

MR. PRISELAC: Good morning, everyone. My name is Tom Priselac. I'm president and CEO of the Cedar-Sinai Medical Center in Los Angeles. Cedar-Sinai is a 958-bed academic medical center that's nationally recognized for the quality of our care and the medical research that we conduct.

I want to thank the FDA for the opportunity to share Cedar-Sinai's perspective on the critically important issue of radiation equipment safety and provide some concrete recommendations to improve patient safety. I think the themes of what I'll address have been mentioned by many

this morning already.

As the first medical center to communicate with the FDA about problems with higher than anticipated radiation doses in brain perfusion CT scans, an issue that has since been identified in CT scanners and other hospitals around the nation, Cedar-Sinai has examined this issue very closely. Our goal is to be certain that we're reviewing all aspects of the care system involved so that everything possible is done to assure that the situation doesn't occur again at Cedar-Sinai, at other hospitals that had similar problems, or at any hospital.

In any aspect of healthcare, assuring patient safety requires a combination of effective hospital processes with adequately designed equipment and technology.

Our examination of the issues led to several improvements in our own internal processes which have since been implemented. More relevant to today's meeting, however, we also identified issues in the equipment design that we believe are important to help prevent this type of situation from occurring again. We present this information to maximize patient safety by highlighting for the FDA and equipment manufacturers key safety issues that should be addressed.

In my remarks, I'd like to follow up on our letter to the FDA last November that was specific to the scanners involved at Cedar-Sinai. The comments today concern changes and improvements that we would

recommend not just for those machines but generally in the safety design of CT and other ionizing radiation equipment. As these machines have become more powerful and complex over the past several years, we believe it's even more crucial that the FDA require manufacturers to implement additional safety features that cut across all uses of their equipment and render the equipment safe from hidden dangers and other potential hazards.

Let me begin with the observation that advances in radiation technology, as others have said, have without question positively changed the face of medicine in important ways. Because of this technology, physicians can diagnose and address conditions in ways not imaginable a few years ago, making an important difference in the health of patients. It's for these reasons that we continue to advocate for necessary changes in CT equipment to ensure patient safety.

We believe the companies responsible for creating this evolving technology should also be responsible for addressing unreasonable or unguarded safety risks. The equipment manufacturers have a responsibility to design out as may of the potential hazards as possible and incorporate into their technology design the necessary safety measures to address the technology hazards.

What should those design features be? I'd like to offer four. First, machines should be designed to be incapable of delivering a hazardous dose in an ordinary operating activity. Radiation producing equipment like CT

scanners incorporate sophisticated computer programs that estimate the dose to be delivered during a scan. Before any operator presses the start button, the machine is capable of estimating the anticipated dose parameter based on the settings of the machine, taking into account the intensity of the x-ray beam, the positioning of the patient, the duration of the scan, and the anatomical region being examined. When a machine is designed to serve a diagnostic purpose, it should not be capable of delivering doses that are far beyond the acceptable outer limits of the intended diagnostic scan. We recommend that manufacturers design machines safely so that this potential hazard is eliminated at the outset whenever possible. The manufacturer can build this design limitation into every protocol for every scan that the machine is capable of conducting.

Second, if a machine must be designed to be capable of delivering a hazardous dose in an ordinary operating activity, it should have safety functions such as an interlock or forced function that blocks the excessive dose from being delivered unless there is a specific override by the user. Guarding or interlocking mechanisms are a basic safety feature in industrial equipment. Complex medical equipment like CT scans should incorporate at least these same type of safety features.

Third, machines that for some reason can't be guarded from delivering excessive dose must at least incorporate very clear visual and audible warnings to the operator that the machine setting are such that an

excessive dose will be delivered. Warnings must be distinguishable signals that alert the user to an unsafe condition, such as color signals, pop-up warnings, audible signals, or other means intended to unmistakably alert the user that the machine's conditions are such that an inappropriate dose will result.

The most important safety design features are the three I've just mentioned as each of them would prevent excessive dose.

In addition, there's been much discussion recently about the desirability of tracking and trending dose levels. For that purpose, CT and other radiation producing equipment should include an audit function that ensures automatic storage and easily retrievable records of dose information and other relevant scan parameters. Periodic review of such records would be a useful tool to triple check the scan activity on the machine remains within acceptable dose parameters, to permit speedy identification of any irregularities, and to promote continued evaluation of the optimal uses of radiation medicine.

These recommendations for safety features are consistent with but amplify the existing guidelines issued by the FDA in its quality system regulation 21 C.F.R. Part 820. Those guidelines provide that where needed and feasible, hazards should be designed out of the devices or reduced or prevented or reduced by interlocks, warning signs, explicit instructions, alarms, et cetera.

The safety features Cedar-Sinai recommends provide concrete requirements for radiation equipment to address hazards that have not been adequately addressed under the existing guidelines. We believe that the FDA can and should require manufacturers to implement these basic safety principles, design, guard, warn, and audit, into their technologies as a condition of marketing the equipment. These requirements should be universal so that no matter what manufacturer model, what user interface, what software version or update or what design features, basic safety of the patient is always ensured.

We believe that mandating these specific safety features in radiation equipment is consistent with the FDA's purpose and function to promote safe medical equipment and require manufacturers to meet basic standards that are fully within their capability to achieve. We look forward to further contributing to the discussion so that the safety features I have described can be implemented by manufacturers at the earliest possible time. Thank you very much.

(Applause.)

CDR BOYD: Dr. Robert Smith is our next speaker.

DR. SMITH: Thank you for the opportunity to speak here this morning. My name is Robert Smith. I just want to read a short disclaimer before I start my talk. I am currently a medical officer at the FDA. I was a practicing radiologist for many years. I'm also a lawyer. I work in my capacity

as a physician for the FDA. I work at the Center for Devices and Radiological Health. However, I'm not speaking today in an official capacity for CDRH or FDA. My comments today are my own and do not represent the views of CDRH or FDA.

What about CT technology? CT has clearly revolutionalized the practice of medicine and patient care, and I'm a very strong proponent of CT, but for clinical indications where its use has been shown to be safe and effective. It is a technology that has been misused by physicians, both radiologists and non-radiologists. Many non-radiologists use it in place of physical exam and history and order a CT instead. And radiologists have to make sure that before they do an exam, that it's actually indicated appropriate and necessary, and I don't think we do a very good job of that.

There have been incredible technological advances over the last 10 to 15 years, and I applaud the manufacturers and researchers who have vastly improved this technology and have allowed a reduction in dose of CT. Unfortunately, those technological advances have not been used to reduce the dose in CT but instead have been used to do such things as obtain very thin sections which require a higher dose which is often unnecessary, and I conducted technical and clinical research for many years. I do have numerous publications in this area, in the use of CT for patient diagnosis and care. As many of my colleagues know, I did pioneer the use of unenhanced CT, for the diagnosis and management of patients with acute flank pain, and for that

specific indication, the benefits of CT clearly far outweigh the risks compared to alternative methods, and it provides a clinically significant impact on diagnosis, management, and patient care.

And as I said, while CT has revolutionalized the practice of medicine, as we've talked about today, it also provides the highest dose of any imaging procedure. These are well recognized by the FDA. The FDA's own website discusses the increased lifetime risk of cancer due to radiation exposure. As many speakers have talked about today, these concerns are greater for children than adults, but they're also very concerning for adults who have multiple CT scans over the course of the years.

Radiation from CT obviously has no benefit but does pose a significant risk when misused. So, again, one of the main points I want to emphasize is if CT is to be used for any particular clinical indication, there must be a clinically significant benefit that outweighs the risks. And when performing a CT, physicians, and that's the person who orders the test, as well as the radiologist who's going to perform the test, we have to always weigh the risks versus the benefits of alternative methods.

For patients with symptoms of disease, the benefits typically outweigh the risks. For patients with no symptoms of disease, for example, population screening, the risks frequently will not outweigh the benefits compared to alternatives, or at least there's no data to show that. An example of that is when you use CT for population screening for colorectal

cancer versus optical colonoscopy, and there are many other applications where people have used CT to screen for disease in healthy asymptomatic patients, and that can be very dangerous.

As stated on the FDA website, which I noted prior to a recent update on March 26, 2010, and as far as I know, this statement is still correct, at this time, the FDA knows of no data demonstrating that any CT system is effective for screening, i.e., examining individuals without symptoms for any disease or condition.

CT scanners have been cleared or approved by FDA for general purpose use throughout the body, essentially to produce cross-sectional images for diagnosis in patients with symptoms. FDA does not regulate the practice of medicine. There's a statute about that, but it also has a disclaimer in it when the practice of medicine is involved in a legitimate physician-patient relationship. This is really referring to off-label use. Once a device is cleared or approved by FDA for one use, physicians are free to use it for another use in the context of a legitimate physician-patient relationship.

On the other hand, if a manufacturer wants to market a CT device for a specific clinical indication, then that manufacturer has to provide to the FDA valid scientific evidence to show the device is safe and effective for that specific clinical indication.

What causes unnecessary radiation exposure from CT? We've heard a lot of things talked about today, and I agree with many of the points.

I just want to touch on a couple that I think the FDA can do something about.

The first one, perhaps not, unnecessary use of CT exams. That's largely driven by physicians, both radiologists and non-radiologists. Repeat CT exams, same thing. Unindicated use of CT. This is where I think the FDA can play a big role, and the way I define an unindicated use is performing a CT for an indication for which there has not been a demonstration of safety and effectiveness. And the final one which again has been touched on today, necessary CT exams that use more than the necessary dose.

So what can FDA do to reduce unnecessary radiation exposure from CT? The biggest thing we can do, I believe, is FDA can force that manufacturers provide valid scientific evidence to demonstrate safety and effectiveness for the specific clinical indications for which they seek clearance or approval of their CT device.

What about necessary CT exams that use more than the necessary dose? We have to assure that manufacturers use software controls, many of which have already been talked about, at a minimum should calculate and prominently display the dose and, depending on the circumstances, should limit the radiation exposure or lock out the scanner from operating when the exposure levels exceed some predefined thresholds, and that includes both before the exam or possibly during the exam. As was pointed out by another speaker, even MRI exams which don't use ionizing radiation, since they came on the market back in the 1980s, have had

software features to prevent exposing patients to high levels of RF energy which can only essentially heat the body, and if you can do that with MRI scanners, it doesn't make any sense not to do something with ionizing radiation.

What else can FDA do to reduce unnecessary radiation exposure from CT, and this probably the most important slide of my talk.

FDA must have safeguards in place to prevent obstruction of science. Science must not be ignored, suppressed, or distorted as that endangers the public. FDA must follow the laws, rules, and regulations. Otherwise, the public is at risk. And, finally, FDA leadership must protect physicians and scientists so that they can simply do their job serving and protecting the public. Therefore, FDA must have a zero tolerance for harassment, discrimination, and retaliation and hold accountable those who have engaged in such activities.

And, finally, I'd like to say that I greatly admire the courage and integrity of Dr. Julian Nicholas who came here today to share his experience with you, and I hope that the Agency has and will learn something from that experience. Thank you very much.

(Applause.)

CDR BOYD: Our next speaker is Dr. Michael Pentecost.

DR. PENTECOST: I want to thank the FDA for the opportunity to speak here today. I'm an academic interventional radiologist and currently a

senior medical officer in National Imaging Associates, which is a subsidiary of Magellan Health, a benefits management company. We're publicly traded. I'm an officer in the company and a stockholder. We have revenues of about $3 billion, and we're listed on the NASDAQ as a publicly traded company.

You may not know much about radiology benefits management, but I want to bring you up to date as a potential partner in this effort to reduce unnecessary utilization. At NIA, we have about 19 million patients that we oversee. We have about 40 health plans that we manage. There are about 90 million patients in the United States that are managed by radiology benefits management companies, and let me just leave you with one function of these companies that I think may interest you greatly and talk about some of the advantages and disadvantages of this.

That product is an accumulator function where we keep, as people have talked about a medical imaging history, based on claims data of all of our 19 million members. What that is, is every time you have a CT of the chest, Column A goes, the millisieverts is accepted as the dosage for that. Column B is the number of CTs of the chest or abdomen or pelvis that you've had over your lifetime, over a given annual dose. The product of those is your cumulative dose, and we use those to influence appropriate utilization in a real-time basis.

Let me explain a little bit about what that means. When you're scheduled for an outpatient CT of the chest, a nuclear study, procedures like

this, you go through one of two mechanisms to have those authorized. You call up our call center and they know, based on your history, your cumulative history, whether or not you're approaching the 50 millisievert Nuclear Regulatory Commission annual limit for that. If you are approaching that, then you are offered, your ordering physician, is offered the opportunity to have what we call a peer-to-peer consultation and discuss whether or not that imaging examination is necessary or not.

About 48 percent of our patients come into the system through this mechanism. About 52 percent come in through a web-based system where the referring physician goes through a series of questions and they're authorized or not, but the same workflow happens. If they're approaching the 50 millisieverts annual limit, the ordering physician is recommended or is offered a peer-to-peer consultation about whether or not the appropriateness of this is indicated or not.

This works today. There are 90 million patients that are being managed this way now. So a lot of what we've talked about today is physics, the actual accurate dosage. We're talking about a way to actually influence appropriate utilization and appropriateness that again works in virtually a huge number of patients already in this country.

We would urge you to see this function as a partner. We're strongly in support of question 5, that appropriateness is an important attribute of reduction in radiation dosage. It's more than physics. It's a

complex business, decision support, controversial process, but there is extensive experience in it in the United States. Again, it's used by 94 percent of America's health insurers, over 90 million patients, about 10 million patient in Medicare advantage plans, and a growing number of people in Medicaid. So we would welcome the role as a partner, using these mechanisms that we've already outlined in guaranteeing or increasing the appropriateness of utilization of imaging procedures. Thanks very much.

(Applause.)

CDR BOYD: Dr. Mark Hiatt.

DR. HIATT: Good morning. My name is Mark Hiatt. I'm a medical doctor. Specifically, I'm a diagnostic radiologist, the type of physician who oversees the performance of radiology tests such as CT and interprets them. I see from the agenda that a lot of you come from far away, and to get here, I came from Houston, Texas, and my capable assistant booked the flight, and so she successfully obviously got me here, but let's suppose instead that she had erroneously booked a flight to the state of Washington. Now, that would have been much to my surprise and dismay when I landed to see the Space Needle instead of the Washington Monument.

Now, what I'd like to ask you is, what is the appropriate way to correct that misstep? Would it be at the point of her booking the flight, at the point of my being at the gate and being surprised to my dismay, or at the point of possibly during the flight or at landing? Well, I submit to you

obviously that the best point is at the point of booking to make that change.

I agree with many previous speakers that the benefits of radiology of tests far exceed the risks. That is, would you rather reduce the radiation to zero and have no image, or would you like to perform the appropriate CT to yield helpful images to assist the surgeon who suspects appendicitis.

Now, with my example, double checking at the point of booking obviously is better than at the point of boarding, but both are preferable to the point of flying or landing. Likewise, as some other speakers have mentioned, when a CT is ordered at the physician's office, that is the best time to check its appropriateness, but double checking just before the CT is performed at an imaging facility may serve as a desirable double check.

Now, let me tell you about who your fellow traveler is on this journey to promote quality in imaging. I serve as the chief medical officer for a company called HealthHelp. We're a leading specialty benefits management company operating in the same space as the company of the distinguished Dr. Pentecost who preceded me just before this.

My company assures appropriate utilization so that patients may receive the right tests and treatments at the right times. HealthHelp has expertise and experience in using appropriateness criteria to help guide healthcare providers in getting the right procedures for their patients, thereby sparing them the unnecessary radiation, inconvenience, and cost of

unnecessary or inappropriate exams.

I'd like to share HealthHelp's experience in using appropriateness criteria as the FDA considers device improvements to reduce unnecessary radiation. HealthHelp uses exam referral criteria to check the appropriateness of an exam at the point of ordering, but this experience may apply to the point of performing the test as well, perhaps incorporated into the devices that perform the exams. I again suggest, though, that the optimal place to check the appropriateness or necessity of a test may be at the point of ordering more so than at the point of performance.

You see, at the point of performing, there's greater opportunity to guide the ordering provider. It's easier to change a flight plan before the plane takes off rather than in mid-flight. For example, let's suppose the surgeon I mentioned, in evaluating a patient with abdominal pain, for some reason orders a MRI of the head as opposed to the desired CT of the abdomen. This MRI may likely be as useful as having no image at all, just as I have no slide here behind me. It's utterly useless. It would be ideal for some consultant to suggest a preferred alternative at the point of that physician making up his mind as to what test to order as opposed to later when the patient presents at the imaging facility. Use of HealthHelp's criteria would pick up on the mismatch between the patient's pain and the ordered test so that a procedure more suited to advancing down the path to a proper diagnosis may be pursued by the clinician at the point of ordering. Catching

the discrepancy later at the point of performance may delay the necessary readjustment on the part of the clinician and thus be comparatively suboptimal.

First point of ordering, then point of performance. In my mind, that is the optimal prioritization. We may all agree that some filter is needed, ideally at the point of ordering, but possibly also at the point of performance as a desirable redundancy to assure that no inappropriate, potentially harmful test slips through.

To illustrate success in ensuring appropriateness at the point of ordering, I'd like to share the experience of one of our clients, Humana, which is one of the nation's largest health insurance plans, that oversees the specialty and radiology benefits of millions of Americans. And we've been partnering with Humana for some years. In fact, Humana's laudable concern has existed for more than half a decade, and to Humana's credit, this foresight has proven prescient as numerous recent studies and stories have sounded the alarm about the deleterious effects of radiation.

Since the beginning of our collaboration with Humana, Humana members have been spared the unnecessary radiation from CT and nuclear medicine procedures to the equivalent of millions and millions of chest x-rays. The success of this collaboration may be attributed to three keys, which the FDA may choose to consider in any approach that it employs to use appropriateness criteria to reduce unnecessary radiation.

First, the appropriateness criteria must make sense, achieved by relying on the guidelines of professional societies, the latest literature, and expert opinion. Good rules lead to good results.

Second, the means of implementing these criteria must make sense. Achieved through peer-to-peer collaborative consultation, not coercive edict. For example, HealthHelp enlists expert physicians, namely board certified subspecialist radiologists from leading academic institutions, to consult with ordering providers about the best tests for their patients. Good rules work when they're wisely applied.

Number three, the means of perpetually improving the process must make sense, achieved by common sense incorporation of valuable feedback from providers and consultants as well as continual consideration of the latest literature and guidelines. Good rules wisely implemented must be appropriately updated to reflect evolving technology.

HealthHelp has found these three keys invaluable in formulating and implementing evidence-based appropriateness criteria to enhance physician knowledge and reduce unnecessary radiation. Reducing radiation by limiting unnecessary radiation can save lives, and I think it's a real credit to the FDA that it's concerned about this very important endeavor, and I pledge HealthHelp's continued support and even partnership as we promote this quality in imaging. Thank you.

(Applause.)

CDR BOYD: Our next speaker is Dr. Eric Bailey.

DR. BAILEY: Thank you very much. I'm probably the first of many of the only few CT manufacturers on the planet to present. My background, primarily I was trained as an engineer, particularly by the military, and my first indoctrination into x-ray physics and radiation safety was as a officer in charge of two underground nuclear tests, and so I can tell you that I've always had radiation safety very much on my mind. I've been around and worked around in my whole professional life around radiation, in some cases very dangerous amounts of radiation. So it's always been a concern, but when I left the Air Force, I went to work for Analogic Corporation and became the vice president of CT engineering and in the middle '90s engineered the first multi-slice CT.

Listening to some of the speeches earlier today, it sounds like maybe I created something evil. In fact, many of you that traveled here today, your baggages were inspected for explosives by my device that I engineered there, but it also allowed the first full-body CT examinations on the planet. Beyond that, I've been part and parcel of designing for many of the other manufacturers, in complete or whole, other medical scanners.

But in 2004, I founded a company called NeuroLogica where I designed the first whole head only portable CT scanner, and I'm going to tell you a little bit about why I did that later on before, but we're involved in some specific spec scanners and are in part releasing a body product similar

to that.

I'm involved very heavily in medicine. As you can see, I'm part of many neuroscience boards, hospital boards, et cetera.

Let me tell you my personal experience which affects all of my decision making. I lost my only brother, and really my only near and dear relative, coming from a small abusive family, in a remote accident in the mountains of New Hampshire, a traumatic brain injury, very similar to Natasha Richardson who was dramatized in the press. She was only less than probably about an hour away, her injury. Same injury, brought to a hospital, mid-nineties, upper New Hampshire, no CT scanner, can't see the bleed in his head that could have been fixed, and he passed away, and I lost a great deal of myself in that process.

It's sort of ironic, the guy that pioneered the use of multi-slice CT lost his brother in this way, but it's made me make a lifelong career now fighting against stroke and traumatic brain injury, which are the number three and four causes of death and the number one and two causes of long-term disability in this country where CT is essential. It is almost our only and our first and only diagnostic tool in this golden hour with these traumas, and we need to be careful that whereas we're trying to prevent some other injuries and other things of CT, we don't want to throw the baby out with the bath water here.

So let's talk about risk versus benefit. As far as I can see, it's

one of the most highest benefit to risk pieces of medical devices that are out there on the plant, probably safer than doing a needle biopsy on somebody. It's involved in almost every disease and organ system and process. It is routinely lifesaving and life extending, albeit that it's also now being used for stuff that isn't life threatening and things, and that ought to be looked at pretty strongly.

There's sort of two types of risks that we've been -- and a lot of the other speakers have been mingling together here, and that's the accidental overexposure of something extremely high that nobody should have ever programmed, and then the second risk which is just long-term effect to cumulative small doses annually, which up to this point we've seen as entirely anecdotal, meaning there's nothing from even me as a CT provider, data to go on for me to program a number in my machine to set as that limit.

But then, thirdly, we're all concerned with the effects of radiation on pediatrics. We know that children are more susceptible to many different kinds of drugs, including radiation is one, and that's almost a separate subject.

As far as my opinions of what we manufacturers should do, can do, in fact, many of the features that some are being called into logging in, putting dose reports, explaining the dose on the screen before the person presses the button, all of these features we programmed into our scanner four years ago and have been on the market. We did so because having a

portable scanner, we were sort of on the forefront here of being questioned about bringing radiation out into different places of the hospital, like the operating rooms, ICUs, things like this. So, in fact, I chose to put an upper dose limit onto the machines. So on our machine, if you do a CT brain perfusion scan, you're limited. You're grade out, if a tech tries to plug in protocols that are greater than 30 rad, it's just grade out, but I chose that limit, and really that's my opinion, and it would be better if it were a collective opinion of the medical societies, the physics societies, that we could all agree on what that limit should be but, you know, and some people were saying I was taking a risk in doing that. So, what if there was a patient that really needed 40 rads and my machine now couldn't allow them to have 40 rads? So there's a two-edged sword here that we're dealing with.

The next thing I want to make a point of, I've heard some of the most prominent physicists and people in this industry get up here and talk and many others, and I've heard millisieverts, milligrays, rads, REMs, röntgens, et cetera. And members of the press are probably sort of, you know, rolling their eyes as many people do when I talk about radiation. And I've heard of ways that we ought to even complicate it more. Let's go to more different factors, let's come up with new mathematical equations, when instead what we're talking about to members of the public is we want to sort of dummy this stuff down. If you want to actually have people be aware of what kind of radiation, we need to start presenting it in terms that the

average Joe Public can understand.

I propose something as simple as equivalent airline units. We all probably flew here on an airplane or received a certain amount of radiation in flying here. Maybe that's something that we could all sort of, you know, mutually agree upon, but there's many other ones. I'm open to whatever those are but, you know, we present, again we were the first to present these kinds of dose informations to technicians and everything, but I do see a lot of them roll their eyes when they see it, and they don't know what it is.

But lastly on our machines, I had envisioned that I might create the standard brain protocol in the world, first put out the machine that had only one brain protocol, quickly found out that many institutions, different doctors, different clinical scenarios wanted variability up and down. So our machine, like all the other manufacturers, has to allow the hospital, the particular physicians and everything, to allow them to program their protocols, to administer what dose they think is the right dose.

I'm proposing that another thing that manufacturers could do, and I would do on our next machine here, is make it such that a physician or a physicist were the approver of those protocols. It probably shouldn't be a technician.

Regulatory proposals, I do propose that CT detector technologies -- and there are some people attempting to make CT-like devices

out of 2D x-ray detectors and everything. That's kind of dangerous here. They don't have the efficiency of CT detectors, but also I'm proposing that the regulatory bodies that be in this room do some long-term scientific studies on cumulative effects that we could really scientifically link this amount of dose and that we can find out what these thresholds are and that manufacturers like me who are trying to do the right thing, want to do the right thing, can program those right numbers into our machine. We don't know those numbers yet, and to run off and just start throwing numbers in there is a piece of danger because the limbo game that we're playing here is we're trying to go as low as we can, but the other side of the limbo here is that your CT picture of your child or brother, mother, wife, et cetera, is going to be too noisy for the physician to find out what could potentially be lifesaving wrong with your body. So it's a dangerous effect. Do you want your CT exam to be just fractionally above that diagnostic level? So I think it takes all of the particularly medical professional societies, physics societies, et cetera, to get together here and to really to figure that out.

We, the manufacturers, I'll speak for myself, but knowing the other folks as well that are going to follow me, we're ready to sit down at that table and get this stuff in. Thank you.

(Applause.)

CDR BOYD: Dr. Charles Shaughnessy will speak next.

DR. SHAUGHNESSY: Thank you. I'd like to thank Dr. Bailey first

for taking the point position as the first manufacturer to speak. I think you all have to realize how difficult that was for all of us.

In this presentation, I would like to ask you all to consider the dose question from a different perspective, that is, in a unique perspective, that is, from a small manufacturer of hardware subsystems for CT. We're not a full manufacturer. We don't build them and install them in hospitals, but we build components that are in just about every CT scanner out there.

Specifically, I would like to address the issue of cost of adding dose features into CT scanners. This is something that is of great importance to us. The question is why is cost so important?

Well, fundamentally, the cost of goods is what is limiting the availability of CT expanding to new markets. We find that there is currently renewed market interest in 16-slice CT, especially for rural hospitals, but based on circa 2002 designs, they're way too expensive. Why is that?

Well, the original 16-slice scanners were designed for the premium segment back in 2002. The primary mission then was second generation cardiac imaging. Customers were demanding the Swiss Army knife feature set. That is, they wanted the CT scanner to do absolutely everything and do it well, and there was high demand for the latest model. This all drives cost, and that's why the original scanners were selling for $2 million apiece.

Well, we can't expect to sell 16-slice scanners now to small regional hospitals for those kind of prices. So reducing the cost of goods of

16-slice CT to meet the value segment target is extremely challenging. Our target and what the target of a lot of the manufacturers is right now is to build these things for significantly less than $100,000, which, as you can see, is very challenging.

Our approach is what we call the value CT concept, and it is as follows. We want to minimize the feature set that goes into the CT scanner. We want to review every component, keeping only those which add to core functionality, that is strip off all the bells, the whistles, the added features which really don't add core value but do drive up costs. And, finally, we want to consider that no cost savings is actually too small to consider. It's all about tradeoffs.

For value CT, the dose strategy has to take cost into account. Now, we all want to do the right thing. We all adhere to the ALARA doctrine as low as reasonably achievable, but what I would pose to you is this: What is a reasonable interpretation of the term reasonable?

We suggest that the CT hardware manufacturer shall do the following. Well, manage the overall dose efficiency rollout. That is, what is the bottom line dose that you get after you roll in all your special dose features?

Second, produce the balance design. That is, you don't want to have any wild dose efficiency outliers that you're going to try and compensate with your one magic feature. You want all of the dose features that you've

incorporated to do a pretty good job.

And, finally, consider the impact of dose features on the cost of goods. This is what's going to allow us to build these low-cost CT scanners.

Now, in the next slides, what I'm going to do is evaluate the effectiveness of some specific dose management technologies versus the cost to actually implement.

The first one that you've heard a lot about today so far is dose modulation. It's also been referred to as automatic exposure control, a very popular feature, extremely effective. In its simplest form, what goes on is this: There's a relatively slow modulation of the x-ray tube current or power or dose, maybe up to two cycles per gantry revolution, that will modulate the dose up to 80 percent of its full scale range. Now, it's a very complicated feature, but surprisingly it doesn't have a very big cost impact, the reason being that a high quality CT generator, and if you look in the figure up there of my CT gantry, it's one of the components on there that we manufacture is a generator, but high quality CT generators need to control the dose accurately anyway. So modulating it up and down doesn't really add a lot of cost.

The dose savings can be very high. You've heard up to 50 percent. More conservatively, maybe 10 to 30 percent, something like that, is reasonable, depending upon how you implement this feature and what anatomy is being exposed.

Now, the system and software impact, however, is significant.

This is something you have to take into account. There would be several man-years of design effort just in getting this to work, but the upside to this is that these are non-recurrent expenses. The cost is spread over many units. We do the design once, and then we reap the benefit when we sell 1,000 of these systems.

Finally, the software can actually be phased in if the control hooks are in place during the design phase. That is, if we design our hardware right, we can then continually upgrade the software later and add additional modulation functionality.

So dose modulation is definitely something that should be included in even the lowest cost CT scanners.

Next, a very common one that you may have heard a little bit about earlier is something called focal spot tracking, which is used from way back in the early days of multi-slice CT to reduce dose. Now, what it does is it uses what's called a dynamic pre-patient collimator which matches the x-ray beam to the detector so that there's not much radiation spilling over the edges of the detector. This has been highly effective for narrow detector lengths, but unfortunately we haven't used these narrow detector lengths significantly since the 4-slice days, back in around the year 2000.

Now, in my bar graph here, that's the first column, the one indicating 5 millimeters of axial coverage, what you can see there is a 25 percent efficiency improvement is what that should be, and what that is, is an

improvement over if you didn't do tracking. So, for a narrow coverage, you get a very significant dose improvement.

Now, we should go to more modern scanners, the 10 and the 15 and the 20 millimeter apertures being represented by 16-slice scanners, you can see the improvement falls to well below 10 percent. You're in the 5 percent range, and the superwide coverage scanners that you get today, your 64's and 128's and 256's, vanishingly small improvement. It's not even worth doing tracking anymore.

But what I would argue is that for a fixed aperture, 16-slice detectors, some 15 millimeters in coverage, focal spot tracking really doesn't add significant dose reduction, and it's not really worth the expense anymore, almost heresy in this community to suggest removing a dose feature, but I think we can spend the money better on other dose features.

The next one, again something that's been around for a long time but I'd like to analyze, selectable shaped filters. First, the basic one-size fits all shaped filter, which was originally brought into CT many years ago, reduces the surface dose up to 50 percent, no moving parts, very inexpensive, very reliable, a good bang for the buck. What you see in the middle there is an actual shaped filter. It's made of graphite.

Now, the next improvement is that you use a selectable filter, for head and small body and pediatric anatomy. This is better, 15 to 20 percent improvement. I'm all in favor of reducing dose in the smaller bodies,

in the pediatrics, not a very big cost increment. Again, this is something we should definitely do in CT.

Gantry tilt is one that is not traditionally called a dose feature, but it is commonly used in every CT scanner. It adds about $5,000 to the cost. I propose eliminating it. There are better ways to reduce dose to the eyes, namely tilting head supports, dose modulation, and eye shields.

One that you've also heard briefly about before is digital image filtration. Shouldn't have saved this until last. It's an extremely big bang for the buck and also brand new, 40 to 50 percent dose reduction, and it's only software, and it's modular, too. It can go at the end of the image chain. After we've done reconstruction, we can add this in as an additional feature and reduce dose by up 50 percent.

So, in conclusion, there are a few dose features that we strongly advocate for a low-cost system and others that I think probably have outlived their usefulness. But we recommend that each CT vendor be given the opportunity to do the same kind of a tradeoff and reach their own conclusions but end up with the same low-dose targets in the end. I thank you for your attention.

(Applause.)

CDR BOYD: Our next speaker is Michael Harsh.

MR. HARSH: Good morning. Let me just start by introducing myself today. I'm Mike Harsh, vice president and chief technology officer for

GE Healthcare and speaking on behalf of GE Healthcare today.

You know, at GE Healthcare and at GE's Global Research Center, I have over 30 years of design, research, and engineering experience in medical imaging, medical instrumentation, scanning, everything from x-ray, CT, MR, ultrasound, PET, nuclear as well as physiological monitoring systems. I'm also a member of the American Institute for Medical and Biological Engineering College of Fellows, and I'm just pleased to be here representing GE's position today.

Now, GE Healthcare is committed to the principle of ALARA, compliance to regulations, conformance to applicable standards, advancement of dose reducing technology, and standardization as a key enabler in our effort to deliver clinical value and patient safety. GE Healthcare CT devices are designed, manufactured, and certified to 21 C.F.R., IEC, and other applicable requirements and standards intended to control exposures and minimize dose.

GE Healthcare already manufactures hardware and software features to aid users in reducing unnecessary exposure to ionizing radiation during each imaging exam.

Now, for over two decades, GE Healthcare has invested in technology for dose reduction technology while improving image quality. Examples here include dose efficient detection where we really drive high detector quantum efficiency, x-ray field filtration so that we optimize the

x-ray spectrum to the detector that we have, dose display and advanced image reconstruction algorithms, not just filters, but reconstruction algorithms that model the physics and the optics of the CT system so that we can demonstrate up to a 50 percent dose reduction while maintaining overall image quality.

In addition, GE Healthcare CT systems provide provisions for pediatric, small patients to help users to right size dose. Examples include tailored pediatric protocols and filters, power limitations on system output for pediatric field of view, and a dedicated pediatric and small patient chapter in our operator's manual.

Now, I'd like to further address the additional questions provided by the FDA for this meeting.

With regard to the second question specific to access controls and audit capabilities, GE Healthcare CT devices currently provide the ability for users to control system access for modifications to scan protocols and identify the operator during an examination. These are optional features provided to all user facilities. In the interest of usability and patient safety, GE Healthcare believes manufacturers should continue to develop enhanced protocol management tools that improve authorization and audit capabilities specific to protocol creation, editing, and content changes. However, it's important to maintain the system's ability to be used in any emergency situation.

Now, question 6 addresses the information that is displayed and recorded for system users. Here, GE Healthcare incorporates features to ensure that exposure settings, imaging protocols, and dose metrics are displayed to the equipment operator and recorded for physician review. GE Healthcare CT equipment displays the information required by regulators in international standards.

Now, on many recent developed products, GE Healthcare CT goes beyond these requirements with respect to dose information for the user. This information includes exposure settings, imaging protocols, defined dose metrics such as a dose efficiency, volume CT dose index, phantom type, and dose length product both projected and accumulated. This information is recorded for review by the physician and transmitted with the patient's exam information.

Metrics such as effective body dose and peak skin dose have not been fully standardized and therefore have not been incorporated into device design. Adoption of a dose metric by a standard body such as IEC is needed. Once standardized, GE Healthcare would incorporate new dose metrics such as effective body dose and peak skin dose into future designs.

Regarding question 7, GE Healthcare is incorporating features into equipment that facilitate transmission of technique parameters, including imaging protocols and dose metrics, to a patient's imaging record per DICOM and the DICOM dose SR standard.

Now, DICOM dose SR is a standard report format for dose reporting. It contains specific information for the exam and is managed by the DICOM standards committee. Now, this enhancement allows electronic review, audit, and transmission capability of dose parameters.

Now, GE Healthcare has introduced dose SR in new product development starting in 2008, and we will continue to do so going forward.

In addition, GE Healthcare supports the standardization DICOM dose SR format with image archiving devices as well as other IT solutions as display, storage requirements, customer needs, and industry standards evolve.

Now, to address the third question posed by the FDA, GE believes that manufacturers should incorporate warnings, alerts into equipment that would inform users and require confirmation or possibly procedure modification during an imaging session in which the patient could be exposed to intentionally high levels of radiation. With respect to medical practice, manufacturers should not define preset lockouts or overrides.

Currently, GE Healthcare CT devices provide information, alerts, and warnings, such as dose display and single location scan warnings, in according with applicable standards.

Now, our industry is committed to implementing the dose check feature. This feature is intended to alert the user when a CT scan exceeds a diagnostic reference level or other reference level that has been

medically established and entered by the facility. A dose check feature would allow facilities to provide an overall system limit based on medical determination of what constitutes an inappropriately high level, to password protect and additional prominent alerts. The feature would enable a facility to provide tighter controls and enhance the ability to monitor patient exposure levels.

It is important to note that diagnostic reference levels are not universally defined and are based on medical practice. GE Healthcare supports the advancement of a CT dose registry for further development of diagnostic reference levels.

With regard to FDA questions 9 and 10 and premarket submissions, GE Healthcare is working with MITA and other industry organizations to provide comments to the FDA to further define premarket submission content.

So, in closing, GE Healthcare is committed to the principle of ALARA, compliance to regulations, conformance to all the applicable standards, the advancements of dose reducing technology as we've demonstrated through the last several decades, and we see standardization as a key enabler in our efforts to deliver clinical value and patient safety.

GE Healthcare thanks you for allowing us the opportunity to provide our comments to the FDA's questions. Thanks.

(Applause.)

CDR BOYD: We do have a change in the order of the speakers remaining. Mark Olszewski is going to be next.

MR. OLSZEWSKI: Good morning. Firstly, I'd like to say that Philips Healthcare through our dose biased philosophy is committed to researching, developing, and deploying tools and product features that enable the reduction of dose along with the optimization of image quality in support of the ALARA principle in every way possible.

That being said, today I am here representing MITA, the Medical Imaging Technology Alliance, a manufacturers association, and we will be presenting four talks to close out the session here and will begin with the review of CT dose reduction technology that has been introduced over the past 15 years as well as since the inception of CT. My colleagues, Christianne Leidecker and Rich Mather, will present recent applications of technologies to the establishment of diagnostic reference levels and associated content, as well as the aforementioned MITA dose check feature and initiative and the associated standardization effort that is currently ongoing to support that.

So to begin, you know, manufacturers as a whole have devoted incredible effort throughout the past 15 years in particular in parallel to the rapid acceleration and maturation of CT technology associated with the increasing slices, if you will, or the multi-detector, multi-slice CT evolution. These dose reduction features take place throughout the entire optical imaging chain of the CT scanner as well as in the reconstruction and analysis

software associated with CT imaging.

If one were to synopsize or make a synopsis of these features, it would be that we control the quantity and the quality as well as the spatial or temporal or time placement of dose at the appropriate level necessary for the diagnostic imaging task at hand. In addition, we've recently all made significant improvements in reconstruction and imaging processing technology to improve further reductions of dose through an indirect method.

And I'll give a couple of examples of each of these steps of progress in the next slides, although many of these have been mentioned in the prior talks. So I won't dwell and make you wait for lunch much longer.

Firstly, we are all committed to optimizing the quantity of dose necessary for a particular image quality through the implementation of features such as automatic exposure control, also known as automatic current selection that adapts our tube current to the patient size at hand. An example of this is shown in the picture here where we set an upper bound of the current that is selected based on the patient size and then modulate the dose in both the longitudinal access as well as the angular position based on the intensity or density of the organ or tissue being imaged at that time. If one were to think about doing this in a manual fashion on a slice-by-slice basis along the Z location of the body, this would be incredibly burdensome if not impossible, and it really speaks to the technological developments that have occurred. Dr. McCollough also pointed out that this is perhaps one of the

single, most important things that can be done to reduce dose across imaging areas.

In addition to these exposure controls and modulation techniques, we have in the cardiac arena various ECG-based tube current modulations both in retrospective and prospective imaging of different flavors that have led to substantial reductions in dose in those applications.

In addition to the quanta of radiation that is deployed, Dr. Shaughnessy pointed out the benefits of matching the bowtie filters to patient size or clinical application and the effect that those matched filters have on reducing skin dose while optimizing the distribution of photons or photon flex across the body to optimize image quality. Here you see three examples where you have a relatively -- the example is meant to show a medium-sized object, and perhaps a heart in a small child, that would have been imaged with perhaps a small wedge where you would have or a small bowtie filter, depending on what you call them, where your dose distribution across the body is non-uniform leading to perhaps a degraded image quality at the periphery. Although it's not a high skin dose, it is perhaps an underexposure, if you will, of the region of interest that would lead to degradation of image quality. In the center you see a uniform green distribution after rotation. For those of you who are wondering what the colors represent, the center row here shows a single projection from a single direction of the x-ray beam to a cylindrical or circular object as represented

here, and the bottom shows you the accumulation of that dose as the tube rotates around the circular object, which is probably right behind my belt for half of the room at least. If you want to see it later, we can look at it on the laptop.

And what you would see, if you were able to see here, would be a small circle that has a uniform green color across it representing both a sufficient photon flux for image quality across that object while not exceeding the skin dose necessary to acquire that image quality, and on the right you would see that with using a larger bowtie filter, you would get an increased skin dose for or an increased dose outside of the region of interest in that image.

Next, there's the idea of dynamic collimation, something that has been highlighted in at least two, if not more, recent publications. These dynamic collimators that is available on some of the manufacturers' equipment allow you to block the end effects in helical acquisitions. This is a dose that is unnecessary with respect to image reconstruction but could lead to irradiation if dynamic collimation was not used. This particular feature becomes of increasing importance as detector coverage increases with modern multi-detector, multi-slice CT scanners and helps to mitigate, if not reduce, the dose in these newer generations of scanners below that of their predecessor equipment.

Similar, you saw this in Dr. Shaughnessy's presentation, the

x-ray being a tracking concept that continues to keep the x-ray beam focused on the detector and avoid, as he said, the spillage of photons over the edges of the detector into the space that does not contribute to image formation.

Another feature that is implicit in the evolution of CT scanners from generation to generation, as detector coverage increases, is the dose efficiency or the geometric efficiency of those individual detector elements. This is related to the penumbra effect for those of you who have heard about that or know about that, is relative to the percentage of photons that are actually captured on the detector rather than falling between the gaps on those detectors and, as detectors get larger, the geometric efficiency of the detector increases, and another point, in addition to the dynamic collimation that helps to combat the sometimes misperception that increased detector coverage automatically equals an increase in exposure to the patient.

Next, all vendors at this point have some form of prospectively triggered or prospectively easily triggered cardiac acquisition, whether that be a prospective axial acquisition or a prospectively triggered high pitched helical acquisition, all of which have been introduced under various trade names by various manufacturers, and these prospective techniques here is an example of the prospective axial acquisition in practice, have been shown through clinical research to provide substantial dose reductions for given clinical indications. Dr. Ziffer referred to the population-based savings, I believe, in his presentation this morning, with individual savings being also

quite high for a given exam.

Lastly, I think part of the aforementioned competitiveness aspect, you've all seen and heard of reductions of dose due to advanced reconstruction techniques or advanced image processing techniques being introduced by various manufacturers over the past few years, and all of these techniques have led to substantial reductions in patient exposure while maintaining or in some cases even improving image quality beyond those that were possible in traditional image reconstruction or image processing techniques.

Lastly, as a closing summary, each of us as MITA manufacturers do display our dose indices, as specified in international standards, before, during, and after the scan, on the operator console as shown here in one example, in close proximity to the scan enable or go button, depending on which you may call that on individual scanners. Those dose indices are displayed in conjunction with the scan parameters as well as the confirmation dialogue.

Lastly, after the scan, the doses are displayed on the operator console, saved as screen captures, and at least as a screen capture in everyone's software, and lastly as Christianne will talk, each of us is introducing the DICOM structured report in forthcoming software releases to augment these other methods of display for reporting, and those dose indices, scan techniques, and phantom types are captured for each respective

scan and for the entire exam as noted.

With that, I thank you for your time.

(Applause.)

CDR BOYD: Our next speaker will be Christianne Leidecker.

MS. LEIDECKER: Good morning. Thank you for the opportunity to speak here. To briefly introduce myself, I'm a physicist working in the computed tomography department at Siemens Healthcare, but I am here speaking on behalf also of all manufacturers in the MITA, the Medical Imaging Technology Alliance.

We've heard a lot about technologies available to reduce dose and also heard about the importance of diagnostic reference levels, and what I want to do is go a little bit more into detail about what diagnostic reference levels are, how they come about, and how they can be used.

So physicians are expected to choose the appropriate methods for diagnosis and treatment, and as a consequence of this, there typically are no upper limits for the medical use of ionizing radiation.

In its publication on radiological protection and safety medicine, the ICRP has emphasized the importance of two principles, namely the justification and optimization of the use of medical ionizing radiation, and these two principles do reflect the currently only accepted principle in the use of radiation, namely the ALARA principle. And going further, the ICRP recommends the establishment of diagnostic reference levels and at the same

time also notes that upper limits are not a suitable tool to manage radiation protection in medical use.

So what is a diagnostic reference level? It is a measurable unit to identify situations in which radiation exposure is unusually high. This means, and is reflected in the ICRP publication, that it has to be implemented as an easily measurable unit for typically frequent diagnostic procedures and also for generally available technology.

It also means as a consequence that DRLs need to be checked and updated periodically, and there need to be processes in place to track these levels, to track situations where they are consistently and significantly exceeded and, of course, to have processes in place to start appropriate measures in eliminating these consistent and significant increases if possible.

How can we obtain diagnostic reference levels? This is the tricky and then very excruciatingly complicated part. Namely, they need to be derived from surveys or have the currently existing DRLs in various countries over the world have been derived from surveys, and these typically also take into account previously published values. These surveys for the currently existing levels have been carried out by non-profit organizations, and typically a DRL then is defined as the 75th percentile of the dose values obtained within the survey. And I've already talked about the need that these DRLs need to be reviewed and updated to reflect changes in technology and in clinical practice.

And this already brings us to the very important tool of (a) how to obtain these diagnostic reference levels and how to monitor and update them. So this means that we need tools in place to record, collect, and analyze these levels, and in order to do so, manufacturers have introduced, together with our organizations, a new tool as part of the IHE. There is a new profile, the so-called radiation exposure monitoring profile, and these profiles are directly based on DICOM dose reports. It regulates the creation, collection, distribution, and processing of DICOM dose reports, and it defines the integration of the systems that are reporting the dose and systems that are receiving, storing, and analyzing these reports, applies to all modalities, PACS, workstations, scanners, and, of course, can then be used to facilitate compliance, for example, with ACR guidelines.

So to illustrate this, we have various modalities that create not only images but also dose reports. These dose reports, based on these DICOM structured reports, are then archived and can be used subsequently for NLSs and can be also, for example, sent to national registries to facilitate such surveys to create and monitor diagnostic reference levels.

The DICOM dose reports currently for x-ray and CTs including all modalities and the various parameters that are introduced and included in these dose reports are typically the already parameters in place, although they are currently under review and new parameters might be optionally added.

As a practical example, the ACR provides diagnostic reference levels for selected examinations, in this case, for head and body examinations for adults and for the abdominal examinations of pediatric patients, and also these values have been reviewed and updated, and such an update reflecting clinical practice can go in both directions. You can either increase the value if necessary, if this is reflected in clinical practice, or the value can decrease if this is reflected in clinical practice. So the monitoring and updating of diagnostic reference levels is equally important.

In summary, diagnostic reference levels are a powerful tool to decrease the average dose exposure and to create dose awareness. However, they should not be used as an upper limit because the appropriate dose for an individual exam depends not only on technical parameters but also such features as patient size, patient cooperation, and last but not least, the decision of the performer and the radiologist.

So more important than obeying these diagnostic reference levels themselves is to have a process that forces physicians to constantly consider the dose levels that they are applying, document when those reference levels are consistently and significantly exceeded, but diagnostic reference levels are not mandatory constraints when the diagnostic need justifies a higher level.

And I want to end by recognizing that we do need the tools to establish and to monitor those diagnostic reference levels, and my colleague,

Rich Mather, will be going into more detail of how we can do that, and last but not least, to state that diagnostic reference levels only work well in combination with well-trained clinical staff who make conscious and educated decisions when using ionizing radiation. Thank you very much.

(Applause.)

CDR BOYD: Our next speaker will be Rich Mather.

MR. MATHER: Thank you very much. First, I'd like to thank the FDA for organizing this, and I'd like to thank you all for some patience and interest in this wonderful topic, and there's been a great series of talks from across the board, and I'm very happy for that. And I'd also like to thank my colleagues, Mark and Christianne, for putting these together with me as we talk through some things the manufacturers have done.

I'm from Toshiba Medical. I'm a medical physicist there, and just at the outset, Toshiba is committed to ALARA as we've heard from across the board, and Mark and Christianne have shown some of the things that we've done along the way to continually reduce and optimize dose so that we can do the best things for our patients, which is ultimately our goal.

So, first of all, I'd like to go through, we've heard several things about dose check, looking at pop-up warnings and other things, and I'd like to talk a little bit about what MITA is doing as a manufacturer group to standardize and realize these dose check features.

First of all, CT scans, optimized CT scans for that matter, involve

multiple different scan techniques that go in, and they really must be customized for the individual patient because you have patients of different size, different densities, different clinical needs, and so each exam really requires the technologists to integrate the scanner protocol with the patient that's actually on the table at the time, optimizing that protocol. However, given the complexity of all the different values that have to be maintained and modified to get the right dose for the right patient, it's just a reality that errors can occur. And so we need to do our best to prevent those errors at the point of scanning so that again we can provide safety for our patients.

So the goals of this MITA dose check initiative are, first of all, to promote dose awareness so that each site can know what the doses are that they are giving to their individual patients, to help avoid excessive radiation events should they occur, and to assist with site QA, and we've talked about the gathering of clinical data so that we can create DRLs.

MITA is finalizing this standard, and manufacturers are working together so that we can have uniform implementation, we can get it quickly and get it to as many scanners as possible in the shortest period of time so that there is not confusion because we really see this as a feature that goes to caring for the patients, less than a competitive feature between the manufacturers.

So there's two levels that we have looked into creating these alert messages for, and first of all, we'll talk about the reference level, and

this could be a diagnostic reference level or site reference level, and the check in the protocol is based on this reference level.

To define per scan series, for example, the head without contrast, and it's really defined per clinical site because depending on the site, depending on their mix of patient population, they might have slightly different needs as far as what that recommended value is. And what this feature would do is that if the scan that's programmed by the operator at the time exceeds the level, it would pop up an alert message, and that alert message would require the user to confirm that, yes, indeed this is what I want to do or go back and change the scan parameters to get it back under that reference level set by the site. But it would also record an audit trail so that we can go back and do QA processes at the site and really facilitate that, that would record the exceeded level, the reference level, the actual level that was there, and, of course, the date and time of the exam and other parameters that would give some context to the event.

The second level of checking would be this sort of upper level of check. This would be trying to prevent those excessive radiation levels that, of course, we want to stop whenever possible. So the slight difference here is it would track for the entire patient exam, from the time the patient comes in, is on the table, it would look at the cumulated dose, or dose index, at any given location on that patient because you could have multiple exams over the same area, and those can add up to a dose that would exceed an upper

limit, and we want to make sure that we catch those as well. They would be defined, as I said, at the study level, for maybe adult versus a pediatric or a head versus an abdomen looking at the individual area to be scanned.

Again, if this value is exceeded, it would pop up a different message, probably a little more stern, that would caution that the upper level of dose has been exceeded, and it would require the user to either confirm and put in their name if they wanted to go on or to again go back, reduce the technique and do a more appropriate value, and again, this would carry an audit trail with it with the level that they put in, the reference level that was exceeded, date and time and operator name and other parameters.

As the standard is being finalized, we're also having a lockout capability. This would be configurable, but that would prevent the execution of the scan were that upper level to be exceeded and really only applies to the upper level, not to the diagnostic or the reference level, but this would have to be a user configurable feature. As Christianne just pointed out, the ICRP notes that upper levels are, in the medical context, not necessarily the best way to perform radiation protection as they could be obstructing valid medical care, and you certainly wouldn't want to be in an emergency situation and not be able to perform a lifesaving exam, but it would give good context to the procedure.

So just a couple of quick examples on how this might work. For example, a pediatric exam, young patient is referred to an abdominal exam,

and the typical technique chart calls for a 30 mAs. The operator accidentally hits two zeros as they type it in, and they get 300 mAs. They didn't notice perhaps, they weren't watching carefully, and the scanner would then compare that value as they hit confirm to the reference level value that's been saved for that protocol and alert that the value was too high, higher than it expected, and the operator would then have the opportunity to go back, correct the mAs, and proceed to scan normally with the appropriate dose for that patient.

Similarly, for the upper level, multiphase scan might be the situation. A patient referred to a perfusion scan, for example, and the 2 voltage got changed for various reason from 80 to 140 kV, which might result into a cumulative dose for the body part for that patient's study that would exceed some upper limit, for example, 1 gray. Then the user would be notified that that limit is exceeded. Depending on the configuration of the scanner, they might be locked out or just really go ahead and change those technique factors and proceed with the protocol as appropriately planned.

So, in summary, MITA is really committed as a manufacturing group to standardizing and implementing this dose check feature. Just in recap, to promote dose awareness, avoid those excessive radiation events and assist with site QA, but as has been stated many times already here today, we need the help of physician groups, physicist groups, and the entire medical community to get appropriate diagnostic reference levels and

appropriate upper levels so that we can all agree on good values to maintain there.

And then, finally, work with the IEC to get this to be an international standard, and then MITA's congressional commitment, we're committed to getting this feature out within the next year or so. And I thank you for your time.

(Applause.)

CDR BOYD: Our last speaker of the morning will be Stephen Vastagh.

MR. VASTAGH: Thank you very much. I am MITA staff member, industry director for the x-ray section of the CT group.

The previous MITA speakers have described and illustrated the numerous innovations implemented in the past and currently being developed that contributed to reduced patient dose in CT imaging. The MITA CT manufacturers continue to innovate. In fact, dose reduction has become one of the primary areas of competition among the manufacturers. This resulted in the rapid introduction of new dose reduction features that have been accepted and integrated into clinical practice. This behavior is in the best interest of all stakeholders, especially patients.

Dose reduction features have a long history of safe and effective introduction and use. However, in order to deliver the benefits, these features both developed and under development must reach the

patients. In order to reach patients, new features must be cleared by the FDA.

We remain concerned that additional clinical data requests from FDA in the clearance process or other new burdens will delay these essential innovations from entering to the market and reaching the patients. More specifically, we argue that for the purpose of clearing dose reduction features, phantom images are sufficient and appropriate indications of system performance.

In phantom testing, CTDI is measured which is rigorously defined by the international CT safety standard. Phantom analysis is the standard and accepted practice in the international CT community to demonstrate dose reduction claims. Dose reduction is demonstrated by showing that the defined image quality parameter is maintained in phantom scans at the lower CTDI. Hence, this is a performance capability of the system and is best demonstrated by bench data.

Using defined engineering tests to demonstrate this capability provides for a scientifically reproducible and accurate method and enables cross-scanner apples-to-apples comparisons without subjectivity. We urge the FDA to use such reproducible bench test data for clearing dose reduction features.

CT systems are designed and totally tested in accordance with stringent FDA quality system regulations, performance standards, and

international safety standards. Manufacturers must also have a robust complaint handling process that monitors performance of these systems while in use. Adverse events must be taken as appropriate. FDA performs routine facility inspections to verify compliance to these requirements.

In conclusion, manufacturers are committed to providing products that enable clinicians to provide their patients the best care possible. We are constantly striving to innovate and improve technology to further this goal. Thank you very much.

(Applause.)

CDR BOYD: All right. Thank you for your attention. That concludes our open public session this morning. We are going to break for the next 15 minutes until 11:33.

Round-table participants please come up to the podium for some instructions. If you have any questions you would like to pose to the round-table, you may write them on a note card and give them to the registration desk out front. Otherwise, you can hold them for the open discussion during the round-table.

(Off the record.)

(On the record.)

CDR BOYD: If the round-table could meet us up front so we can get started.

(Pause.)

CDR BOYD: We're going to get started again.

The purpose of our round-table discussion is to hear some more from round-table participants and the audience about how we can specifically improve CT equipment or how industry can improve CT equipment. So I'd ask that any questions that you'd like to pose be specifically directed to that subject area. If you have a question on fluoro or on training or QA, the appropriate time to raise that issue will be at this afternoon's session or tomorrow.

So we have the next hour or so to discuss issues relevant to how we can improve CT equipment to reduce medical imaging exposure or optimize and justify medical imaging exposure in exams. And we did receive some questions on note cards.

The first question that I wanted to raise for discussion among round-table participants was related to the installed base of equipment. We heard a lot about things that can be done or could be incorporated in future equipment or some things that may be already incorporated into existing equipment, but there is an issue that's already out there. Can the round-table comment on the importance of getting to the installed base so that it has dose reduction features in technologies and how to go about doing that? Any volunteers to begin?

MR. JAECKLE: Yeah, I'm John Jaeckle. I work for GE Healthcare and also represent MITA. I'm the chair of the MITA CT Group. So MITA, as

part of the dose check feature that you saw Rich talk about, and our commitment is already made to congressional testimony for a dose check and DICOM SR, do include an IB, installed base provision. So by next year, starting next year, we'll be putting dose check and DICOM SR on installed base products. The complete scope of that is not yet defined but definitely includes a robust IB plan.

And as far as like the dose-reduction feature, going back, I would also say -- manufacturers, I think most manufacturers, not all manufacturers, do have programs where they typically develop new dose-reduction programs like on premium line product for initial introduction but then have methodologies where they take them back onto legacy products or other platforms. So I think that's already kind of a standard practice.

MR. MATHER: Right now, certainly, the development of those dose reduction features naturally go to the new manufacturing as you're building those up, but then you always have a plan in place to, you know, backfill those into the existing product as the software allows.

CDR BOYD: So will those be license fees or how is that going to work?

MR. JAECKLE: I probably can't speak to all manufacturers, but I would expect dose check and DICOM SR, there will not be a charge.

CDR BOYD: Are there other questions on that subject from the --

UNIDENTIFIED SPEAKER: Can you just address the dose-reduction feature? So it's fabulous that the standard report won't be a charge, but how about the dose-reduction algorithms that are now developed and potentially could be applied to the 10,000 CT machines that are already out there?

MR. JAECKLE: That's a little bit more difficult of a question, and I know that some of the features that have been around for a while, like automatic exposure controls, you know, are going back, and they do get updated and, you know, subsequent soft releases. The more premium features probably still have a commercial life into them. So I'm not at liberty to say what the plan might be. Rich.

MR. MATHER: Yeah, I mean it's really on a case-by-case basis. Sometimes these include hardware and other developments that, you know, in the end cost, and so obviously we want to get as much out there as possible, but at the same time, you know, the development of those comes because we have engineering resource and things like that. So absolutely we need to get those out, and we get them out as reasonably as possible.

DR. SHAUGHNESSY: If I can add, even recon features or algorithms are not necessarily free just for a download, only because they may require special hardware. You know, you can't always port a new algorithm to the existing hardware. If it does require additional compute power in the field, then it's really hard.

MS. WILSON: I'd like to applaud the manufacturers for doing everything that they've done so far to help reduce our radiation dose, but at this particular time, we all know what's happened to reduced dose especially in the pediatric population, and in the adult population as well, is there has been a union of the physicians and the technologists who have actually done this at this particular time. So the education and training of the operator, the technologist, is essential and will remain essential no matter what you do to the equipment.

MR. MATHER: I think you bring up a great point that, you know, we're a team, the entire manufacturer, physician, physicist, technologist, training, it's a group that we can all work together, and we all have things to bring to the table to bring this down, bring the dose down. We can build scanners with technology, but we need the help of the users to feed us ideas for that technology and to use it in an appropriate way.

CDR BOYD: One comment I heard kind of made me differentiate between or at least raise the issue of software versus hardware. It would appear on the surface that it might be easier to incorporate software changes or upgrades that might capture or facilitate some of these dose capturing algorithms or other features into the equipment. Can you comment on that?

DR. SHAUGHNESSY: Yeah, in fact, that's been done in the past. I know in early 4-slice, at least one system that I'm very familiar with, went

out the door with no focal spot tracking, although the hardware was fully enabled for it. The feature then came later in a software release. So if the manufacturer is thinking well in advance and thinking of what features he wants to add down the road, they can be enabled with software at a very low cost.

MS. LEIDECKER: I'd like to add that while we try to anticipate future developments and then try to anticipate the necessary hardware to even introduce or implement software, this may be possible maybe one, two, three years down the road, but certainly not very much longer. So there might be software which simply does not run on older hardware, and then the easy applicable case of rolling back software to the installed base might not work. So I think it's a case-by-case decision. It's not as easy to say hardware won't work, software will work. It will be case dependent.

MR. JAECKLE: I'd agree with that, that the software platforms do change over time. Same with some aspects of the operating systems. So just because it's software doesn't mean it's easy to go back.

DR. MORIN: But while we're talking about things in the future and going back, there are steps that could be taken right now today at every place doing CT if they would just view this in the same way as they do other imaging arenas where somebody is responsible. In mammography, you have to have a mammographer that is responsible, and you've got a chief tech and a medical physicist involved. You could do the same exact thing right now by

educating the users of this technology in that they need to be more aware, they need to have a culture of dose responsibility and dose optimization. They need to have a time-out before they start a scan to make sure that the protocol, that what they've just loaded is consistent with what was intended with that particular protocol, and those are education steps that our professional societies could take and, in fact, AAPM is having a summit on this at the end of next month.

MS. WILSON: And while the AMP is doing a good job as well, the basic training for the technologists comes through another arena, and the ASRT is very involved in education and training and, of course, the ARRT in its certification and registration process. So, yes, that could be done, and I think there are steps being made in that particular direction. So to facilitate, that those who are performing these particular examinations are very qualified to do so.

CDR BOYD: Other comments?

MR. JAECKLE: Yeah. I'd also like to add like systems for many years have been showing some of the dose metrics that have been talked about, too. So as an interim procedure, those are available for review. So, you know, institutions could institute some sort of albeit more manual process to educate the users, you know, here's where you look up here and this is the values we want to use at our institution. So the displays are there already for that on many, many installed base systems going back because I

think the IC standard came in like in 2001 that first required the dose display. So systems since then would have that.

DR. SMITH-BINDMAN: Is it possible, through MITA, given that you have implemented these systems on quite a lot of scanners, to, until we get good at collecting those data and looking at them locally, for you to help create some diagnostic reference levels based on those data that are collected already at the level of the machine and store it in the PACS, albeit not usually accessible by the user but a little more accessible by the PACS and CT manufacturers?

MR. JAECKLE: I think MITA would believe that the creation of the diagnostic reference is really more of a clinical-medical decision. We are more than happy and are fully behind having the systems able to have those values inputted and then checked against, but I'm not sure MITA's the right vehicle to create the reference values, although we can have features such as DICOM SR or other DICOM components that can help collect the information.

DR. SMITH-BINDMAN: I was really talking about the existing data that we have today until these data become available a year from now as a quick way to generate some of these data.

MR. CLUNIE: Well, certainly in the PACS, if you have stored the screen shots that contain the dose information that several vendors have been producing for some years now, there's no reason you can't go through that data, do optical character recognition and extract say the total DLP for

the exam. So that information is mineable, and there are tools available to extract that. But it's no substitute for the greater detail that's present in the DICOM structured report. You wouldn't want it to become a sort of de facto alternative that delayed the introduction of the structured report, which is something that people fear. If you remove incentives from vendors because there's a work-around that works in practice, then the industry's adoption of the standards is somewhat undermined.

MS. LEIDECKER: I would also like to comment to the assumption that it's easier accessible to us. It's actually not. So we don't store patient or exam specific data on the scanner. While we do deliver and save this data, be it as an image or as a structured DICOM report, we don't store it on the scanner. It's not easier accessible for us.

DR. SMITH-BINDMAN: So correct me if I'm mistaken, but my understanding is that the data are collected within the Philips PAC system that collects the data within the CT PAC system. The data are not readily available, but they're in the system for all the exams that are done in whichever information is stored within the DICOM header. So if the DICOM header contains all the information from the standard dose report, it's available. If it's not, whatever features are, and there's some features that are in all of them, that those data are available.

MS. LEIDECKER: Well, the data are available on the PACS system, but not necessarily on the CT scanners, and if the PACS system is from

another vendor, there is no easier access other than the user has.

MR. CLUNIE: And I think the important point is that it's not accessible to the vendor. It's accessible to the site. So the vendor can't really troll through the information in the PACS because they don't have the patient identity information in the PACS. It's the site's job to use the information in the PACS with tools perhaps provided by the vendor to extract it, but the vendor can't really extract the dose reference values for you from your own PACS on a global scale anyway. Does that make sense?

DR. SMITH-BINDMAN: Quite honestly, no, it doesn't make sense. So we are currently working with Philips who are helping us extract these data on a very large number of studies through the PACS that we don't have ability as the end user to extract the data. So I fully appreciate you can look at the data that are printed on the sheet. I've done that, and it's extremely time intensive.

MR. CLUNIE: Right, but that's not my point. My point is the vendor can't do it alone. The site has to use the vendor's assistance to do the job. So in other words, the vendor doesn't have access to the information without the site's cooperation and compliance. That's really my point.

The other thing is that the data that's not included in header attributes may be in a screen shot. That information can be extracted just like I can scan in a piece of paper and the Post Office sends it to the right place, we have the tools to extract the information from the images retrospectively,

and that can be mined, and as far as I know, that's not being done on a regular basis right now.

MS. WILSON: May I ask if anyone is working on a means of taking the dose received per procedure of every patient and logging and keeping track of their lifetime cumulated dose from these procedures? I don't know if anyone believes that's important. I think it's important for future research to see in actuality what does happen to individuals after repetitive exposures over their lifetime.

MR. CLUNIE: Perhaps I could answer that purely from an informatics perspective, what's possible as to what's desirable. Certainly any dose information that's tracked, whether it be what's delivered by the machine or some affected dose or surrogate for risk of some kind, if it's provided by the machine or if it's quantified by the physicist at the site or some tool at the site, then there's no real conceptual barrier to that becoming part of the patient's longitudinal medical record, which then begs the question, how many patients in this country have a longitudinal medical record at all in the first place that spans any boundary beyond one enterprise or one institution that follows them for their life. So to me, this is a problem that really should be in the hands of the Office of the National Coordinator. You know, the meaningful use criteria, for example, do not require longitudinal capture of radiation dose information, but they could, and maybe this is the time to raise that question.

DR. MORIN: There are several institutions that have their own internal projects on this. I'm aware of Dr. Jim Duncan is here someplace, and at WASH Univ, they're doing that. We're doing it at our institution as well.

I would caution though that just taking the dose index and beginning to add them up to come up with one number is a very dangerous, perhaps reckless thing to do because of the fact that we don't yet have the organ doses that Dr. McNitt-Gray talked about. If he could just get going a little bit faster and get this into the machines, we'd be very happy about that, and I'm happy to add up organ doses, but adding up things like depth measurements and things like that, you don't even know if the same anatomy has been fluoroscoped, is somewhat difficult.

However, just knowing the number of exams that a patient has is probably a worthwhile thing to be tracking so that a medical decision could be made. If this is the 27th time you've done a chest, abdomen, and pelvis on this patient, do you really need that 28th scan or not? Or could you do it with a different modality? And I think that those decisions would be very useful, but Dave's quite right. You can do it within your institution because you don't have HIPAA problems, number one, and then secondly, if you have an institution that has a lot of return visits, then this becomes plausible, but if you have patients that are moving around from place to place, there are many, many patients that they couldn't tell you even if they were x-rayed seven years ago. They won't remember. So I think it's very difficult to go

ahead with this in multi-institutional settings, but definitely individual institutions can begin to look at this, and once again it's a culture shift, that we would then begin to be asking the question, how many studies have been done using ionizing radiation on this particular patient, and do we want to do another one?

MR. MATHER: And not just how many but what body part and what the exam was, and I think that starts to go back to the need for more universal naming of scan convention for the scan type so that we can start to compare those things in a reasonable way.

MR. CLUNIE: Actually, since you mentioned that, on behalf of MITA, maybe we could put you on the spot in the sense that, for the last 20 years or so, CT equipment has not provided a place in the screen to enter the body part as a separate item. It has not made use of the many codes for anatomical regions that are available both in numerous lexicons and also in the DICOM standard for some 10 years or so. The protocols are pre-prescribed and could populate such field automatically for the user if necessary. Ideally this information, including the procedure that was being performed, would come from radiology information system through the work list rather than have to be entered in the console, but even having a place to enter it on the console would be a good thing. So as you guys commit to produce structured reports, both for your new product development and also your installed base retrofit, I would make a plea that you also include at the

very least coded anatomical information in the way that's described by the DICOM standard. It has been for a decade.

If I could actually make another point, too, the cross-institutional handling of dose, if we burn the dose reports onto the CDs that we routinely carry around between facilities, then they could be reimported just as the standard of care now has become to reimport the outside exams into the PACS for prior comparison, et cetera, et cetera. So there's no reason that the dose information can't be burned on the CD and imported to try to temporarily at least alleviate this issue of not having a complete history.

CDR BOYD: I do want to take some time to field some questions that were provided by the audience. There was one question regarding image quality, noting that several comments were made to state that maintaining image quality is very important, and the question, what is an objective definition of image quality and how that might be incorporated with what we're trying to accomplish.

I guess maybe discuss the balance of maintaining image quality with dose reduction as a panel for the next few minutes.

MR. MATHER: I think you can start off that discussion by saying that there's no dose that's worse than a wasted dose. And so if your image quality isn't up to at least a minimum diagnostic level, that is far worse than if it were slightly above that diagnostic level. That said, we always strive for the minimum image quality necessary for a diagnostic exam, but we have to be

careful that that image quality is maintained to a level where the diagnostic task can be accomplished, and otherwise you're wasting your dose and that's a problem.

DR. FRUSH: I will say as a radiologist that there won't be any specific level that you can determine that will satisfy all physicians who look at those scans. That said, we're fat right now and we have been for decades. In terms of the overdosing of patients, and we're nowhere near the threshold of sub-diagnostic levels. We are I think as a country in excess, and so it's a little bit of a moot point that perhaps we'll reconvene in 5 or 10 years when we get close to that point and answer that specific question, but I would venture to say and have said this before, that if most people turned down their tube current by 30 percent across the board, there may be a few grumbles in the clinical realm, but people would be able to read those scans just as well as what doses they're using now and continues to be an excess of use.

DR. SMITH-BINDMAN: I think to just put a practical number on what Don says, if you look at routine scans, a routine head, a routine abdomen, those doses we typically use here, if we look at the ACR numbers were about twice as high as the numbers they use in the UK and most of Europe. For very similar, very basic exams, the doses are twice as high. That's not the outlier doses. We have much, much higher extremes of doses, but the typical average doses are substantially higher, more than twofold higher

in the U.S., and it's not clear that there's any data that suggests we're doing any better by our patients in terms of detecting disease in any way.

DR. McNITT-GRAY: Just as a quick scientific process, to answer your question, I think specific objective measures, what is quality and what isn't quality, is really tough to achieve, and that's going to vary not only based what the organ is but what the clinical context is. So a dose that's necessary to detect a 1 millimeter renal calculus would be potentially very, very different than somebody with a follow-up for a huge hepatic mass.

And so as a specific, though, example of how dose can be qualitatively measured, I would refer to Gil Raff's Michigan registry study where blinded reads of coronary CTAs were carried out and the diagnostic quality in terms of was it adequate or not to confidently determine a diagnosis was assessed, and showing that with significant dose reduction strategies, there was no decrease whatsoever in image quality. And so I think it's going to be a qualitative assessment that there obviously is some threshold we could get to where it's just noise, and when that's encountered, all but occasionally, it's a high risk of wasted radiation which is the worst thing we could do.

MR. JAECKLE: I would like to address that also from a manufacturing standpoint. As new features are developed, so how do you assess IQ in a phantom, to say, is this feature doing what we intended it to do? There's a variety of IQ tests done, a whole bunch of different phantoms.

I think you have to tailor the test to the specific feature and the specific, you know, diagnostic intent of that feature to look at. However, there are proposals now at IEC for some enhanced image quality testing that we've done, such as noise power spectrum. I think we'd all be in favor of going and looking at those as enhancement to the process, maybe some standardization around that. So I think there are areas that we would all be willing to move towards for more IQ analysis in phantoms.

DR. FRUSH: And if I could just make a plea here, too, a lot of what we've talked about obviously from a technical component, manufacturing component, requires some investment, sometimes for free and sometimes there's material required. These things that we're discussing with image quality and scan review are extremely resource dependent, extremely, and if you talk about the clinical realm where these things meet, they have to be tested in the community practice, in academic centers. You're talking about technologists, radiologists, and medical physicists being invested in this. The academic mission does not support this kind of work. Community practice does not support this kind of work. Everyone here agrees that it has to be done. Everyone here agrees that it has to be done. It's going to cost money, and the issue is where does that money come from? And it's tough to find those resources. The expertise is here. The expertise is here to be able to answer those questions.

So if the FDA were going to provide some funding, say for

individuals to look at the quality, I think that would be well received, and it doesn't have to be this organization per se, but understand these are extremely consuming things that we're asked to do and extremely important that aren't supported by the everyday working environment of people. So it's more complicated than this is where we need to go and these are the people who are going to do it. It's not going to happen without some additional support there.

DR. CHAKRABARTI: I have a question following up Dr. Frush and John. This is also raised by one of the manufacturer in MITA, the -- that we have, as an agency, we do like to see the reduction in dose, and as a physicist, I believe that some of the features that the manufacturer provide, phantom image and some image quality metric as far as spectrum -- can do, but I like to hear from some of you that the image quality evaluation. Are we talking about some clinical evaluation is necessary when a manufacturer says that dose is reduced by such and such, 40 percent, and the image quality remains same? Because we are very concerned. If the dose is reduced at the same time image is reduced, they repeat scan, at the end of the day, you probably will deliver more dose. So is some non-clinical tests with some phantom images sufficient to look at the quality of the images in the previous algorithm versus the next algorithm which reduces the dose, and just comparison of those non-clinical images and non-clinical metrics will be sufficient or not?

DR. FRUSH: Well, I think what you ask is your answer there,

and as Dr. Ziffer said, it's a marriage between the technical evaluation of those measurable image quality parameters that we're all familiar with, but it has to be rolled out into the clinical environment, and it has to be tested in academic centers and in community practices or it simply won't be received, and if something's built there and not used, then it's not a useful technology.

DR. MORIN: I think one thing over the years that we've always done is when the scanner is installed, it comes with previously preloaded protocols. We typically then begin ratcheting down the mA until the radiologist in that area now complains that the images are getting too noisy, and that's how we set what technique we're going to use, but it is very intensive actually. But this is a regular read and things like that. So it's not that it can't be done in the community practice, but someone has to own this. Someone has to step up and take responsibility to say this is what we're going to do, but every practice is different, and I can tell you, in our practice, I don't think it's any secret, there are some of our physicians that are very noise sensitive and others that are noise, we don't really care that much, we "read through it." And I don't think that's ever going to go away. I think you have to involve the human in this because ultimately it is the human that's going to be making a decision about whether that is a nodule or is not a nodule, and there are various thresholds for detectability. They're not identical, and that's why I'm off -- I mean I'm a physicist. So I'm all for line paraphantoms and MTFs, and I even have a very clever way that I like to measure the MTF. Well,

Ron Drogy (ph.) and I did.

So, yeah, I'm all for those quantitative parameters, but they don't necessarily reflect that particular practice. So somehow, once again, I think it's a culture shift that when things come out of the box, you don't necessarily just use all those protocols blindly without questioning.

MR. JAECKLE: If I may, I think want to clarify Kish's question here. I believe it was from the standpoint of obtaining premarket clearance on the system. So, you know, what is the right path to go down? Is it a rigorous phantom study before the product is then released, or is it a phantom study plus some level of clinical evaluation before FDA, you know, that FDA could review to grant a clearance. I think historically it has been relied upon to do that in phantoms, and then the manufacturers would go out to a few sites pre-release to have the clinical community, you know, review that, is it working right. I'm not aware of that, in any dose reduction features that we have, that that has ever run into a problem. So if I could just maybe ask the clinicians here, given that's what the concept of it is, you know, what is the appropriate level needed for FDA to grant a clearance? You know, has what we've been doing in the past been sufficient? Does it need to be enhanced?

DR. MORIN: Well, if you really wanted the answer to that quantitatively, a contrast detailed dose experiment would answer that question, but once again, there are different observers that will be more or

less sensitive to low contrast objects.

I think that the only thing that you can rely upon now if you want quantitative measures are line paraphantoms and maybe DQE and things like that, and the vendors can certainly measure that in the factors, but unless you involve the observing community, you really are not -- it's two separate issues.

DR. SMITH-BINDMAN: Dr. Morin, to go a little further, understandably doctors have different ideas about what the perfect CT looks like and their comfort level, but we know that their level of understanding radiation risk and dose is very, very small. So they're really making decisions with only half of the information, how pretty can we get this picture to be, without understanding that it might come at a cost. And I'm wondering, and I know this wasn't the question, but if there's a role for the manufacturers to get more active when they're setting up the preloaded protocols to work with sites like yours, to figure out how to make those preloaded settings as low as possible. So a facility would have to increase the dose as opposed to working so hard, because I mean what Don pointed out is it's incredibly time intensive, and individual facilities simply can't do it. So at least if the existing protocols that come on the machines were installed to really minimize dose to the degree possible as opposed to maximize the beauty of the images, could that actually lead to substantial dose reductions without the kind of physician input needed or that you've done?

DR. MORIN: Well, if you did it the other way around and just lowered the mA for that protocol, then the first 10 or 12 patients that are being done might, in fact, have non-diagnosable, non-interpretable studies. So you would waste the radiation entirely for those. So whether you come from protocols that are beautiful and then need to be ratcheted down or start with low ones and ratchet them up, either way, you're getting the same thing, and either way, you're still going to need dedication of that facility to take a look at that and say, yeah, I'm committed to this process, and while I think that most people would agree with your statements regarding the practice of CT in the U.S., that's certainly not the case across the globe. There are other places where they are very radiation sensitive.

DR. ZIFFER: As a follow-up to the specific question, I think though with regard to the FDA and what body of evidence is needed to proceed, I wonder whether it's easy to apply one size fits all based on what the potential dose saving regimen is, and I would contrast two different arenas. One is advanced reconstruction algorithms that seem to me potentially are valuable with phantoms and with quantitative measures of noise and so forth, to show that you have comparable image quality, and there are other ones that are much more clinical, and since it's my field, I use that. I'm sure there are others. There's prospective ECG triggering which has to do with a whole host of issues that can you slow the heart rate, how regular it is and so forth, where evaluating that as a dose read extra regimen

probably requires a clinical comparison between a group of patients that had that and a group of patients that don't, not easily done in the phantom.

What would be difficult, it seems to me, would be having some type of quantitative measures for image quality. Let's go back to advanced reconstruction algorithms for a moment. It would require us clinically to evaluate renal stones, liver masses, adenopathy, and so forth, each prospectively clinically on whether it's valid or not because there are issues of if you can maintain resolution and in large part you're okay. They're resolution issues and ought to be able to proceed in a static environment.

MS. WILSON: The problem I see with some of this is the fact that one size does not fit all. There are differences in patients, the size, the condition, and all of those particular things that have to be taken under consideration. So the operator is still involved to make a determination whether or not this should be changed due to this patient's body habitus or their illness or what have you, then also knowing what their radiologist or other interpreting physician wants, and they vary. You can't even say one size fits all at the same institutions because doctor such and such wants this and doctor such and such wants this. So that's really very difficult, and still a lot is left up to the operator's ability to critically think through the patient as one separate patient. Every patient is different.

DR. ZIFFER: Just as a follow-up to the one size fits all, I think this is an arena, though, where the professional societies can fill a very

important void in terms of guidelines and standards for what appropriate doses are, and rather than start too low and failing and too high and wasting dose, come up with as best we can for a typical institution of what's appropriate. There may be regions of the country where obesity is much more common. There may be regions where obesity isn't. We need to modify that, but all in all, it seems to me this is one arena where the practice of medicine could be closer to recommended dosage, for example, for penicillin in patients.

DR. FRUSH: Well, to continue with the one size fits all, I think really what we're dealing with here is nobody's wearing any clothes, and what we've got is manufacturers to an extent giving us some threads and a needle and some dye and saying dress your patient, and the threads are getting more complicated and the needles are bent and sometimes, you know, difficult to work and who knows what color. So we're not even to the point yet where we have that one size, and it's the educational component that a number of people have talked about, which I think is this afternoon, but it's help in scanning. It's really designing the equipment when it's so complicated that if you make a mistake, something there is going to say, wait a minute, this is not normal, and we're not even there yet. That's fundamentally what we have to do. So there's that component, and there's the educational component because we can talk all day about, you know, certain disease processes and resolution, and we'll never cover everything. It is so complex in terms of

quality and so on, but I think we have to step back and say, what are we here to address that's fundamentally making it harder to make a mistake? That's what it is. We're making errors, and how do we reduce errors?

By making the system less complex, that's the Institute of Medicine report, that's the fundamental statement of that report, is complex systems provide for mistakes.

So how do we make the system less complex? We teach people how to use it. That's this afternoon, and we provide safeguards, checklists like in the aviation industry where you enter these things in, and it comes up and says, yes, go on, yes, go on, yes, go on. Do you want to complete this scan? And you do that, and then the tracking and archiving issues are a little bit separate from that, but I think really that's what we're here to do.

CDR BOYD: I want to get to another question that was posed by the audience, and if there is anybody that has a question, you can stand up and approach the mic and ask it.

Related to establishing diagnostic reference levels, it might help provide the guidance that we're talking about right now. Can the group comment on collaborating or collaborations with private health insurance groups as presented earlier by a couple of our speakers that have already been collecting information on patients and dose they've received and talk about how that might be used or best incorporated into equipment? Are there areas where that could yield fruit?

MS. LEIDECKER: I would strongly advocate for that. We need cooperation and working together to establish these diagnostic reference levels because one alone probably cannot do it from having the resources to collect the data, getting the information, what to collect, and how to collect it. This would be something that the manufacturers certainly support, and we have done so in the past for events or countries where these reference levels do already exist, and last but not least, providing the tools to do so, and there's also something that we're already actively doing, namely implementing those structured reports. But, yes, it will be cooperation of many stakeholders.

DR. FRUSH: Even if it's something as simple as the type of CT examination as Dr. Smith-Bindman has done and is doing and exploring with some health management organizations currently, those data are out there. It's just getting to them, and again it comes back to the fundamental issue and conversations that her research group has had, is, yeah, everybody thinks this is a great idea, but who's going to pay for it? Again, it comes down to money. So I'd appreciate your comments on that, Rebecca.

DR. SMITH-BINDMAN: There are several things. I can appreciate the manufacturers think this is the user's responsibility, and I in some ways agree, that it is the user's responsibility, but on a practical level, the manufacturers through their packs, parts, I understand they're separate companies, but you have the same name at the top, it says GE, it says Philips,

it says Siemens, have access to huge amounts of diagnostic reference data now, and I think those data are accessible and would do an enormous amount to make us aware at how high the doses are and how much better we can do. The fatness that you're talking about in our dose are actually a major obesity epidemic that we can bring down quickly, and the first thing to do that is to look at the dose data, and while I see it's not the manufacturers' responsibility, they have the capacity to do this. And so I think if you can help us as researchers collect those data and make them available, on a practical level, that would have an enormous impact very quickly.

On a separate level, I think we need to start having the responsibility at the institutional level, of someone who is going to take responsibility, as Dr. Morin has pointed out, for these data, and I'm working with some other people to put forward a quality metric that would just start by allowing facilities to keep track of very simple dose information. And so I think if we go both of those approaches, we could come up with diagnostic reference data in a month's time, but we would need cooperation to do it.

MR. CLUNIE: I think also we're talking about apples and oranges in that the health benefits management companies and the third party payers have information about the type of procedure and how many of them are performed, which may help you make decisions about an individual patient. If you're looking for dose information, about a particular procedure, they don't have that information because they don't have the dose record. To

establish a dose reference level requires that information; hence, it needs to be done within institutions or within say the ACR dose registry, but the health benefit management company at the present time isn't receiving the dose reports for argument's sake.

DR. MORIN: I'd point out that our experience with the dose index registry has definitely showed that the lack of harmonization of what people call exams is a major, major issue. We're hoping to reconcile this by using RadLex in a retrospective sense to be able to group these together at least for some major classifications of CT examinations.

I also think that one of the problems with reference levels, no matter where they have been established, is that they've been samples basically of the scanning that's been done in phantoms or in some cases on patients, but one of the things that we felt was very important about the dose index registry is that all scans from that institution would go into the registry. So we would get a much better idea of the variation that occurs across the board, and that certainly is the case with our pilot in CRDR, and it was true in our initial pilot with CT as well.

So I think the setting reference levels, you do have to know something about the state of practice because you can set a reference level, but that doesn't mean that people will end up following that all the time.

MR. CLUNIE: If I can just follow up on that all scans question, one of the comments that came up this morning in several presentations was

the matter of automatic and reliable transfer of the dose information. If you require a tech to manually push the dose SR, you're going to miss scans. It's not going to happen. So I think when MITA gets together with its vendor members to decide how to implement this feature and what to commit to, it's important to commit to automated and reliable and confirmed transmission of the dose information to whoever is the designated actor for receiving it.

CDR BOYD: Why don't we field a question from the audience, and please introduce yourself so our transcribers are able to identify you.

DR. McNITT-GRAY: Okay. I'm Mike McNitt-Gray from UCLA. I was inspired by Dr. Frush's comment a minute ago about keeping things simple, and one of the issues I'd like to put to the panel is, within a certain manufacturer, there are certain terms that are used, and across manufacturers, other terms are used, and I appreciate the need to innovate and differentiate and marketing strategies, but is there a solution that we can use to come up with a universal language here so that when our technologists are faced with moving one day from one scanner and scanning on another scanner from a different manufacturer on the next day, that they can translate between things like mA, mAs, effective mAs, or the tube current modulation information, which is a noise index on one scanner, a quality reference mAs on another, and it's very complex and can be very confusing. I appreciate these are very well-intended concepts, but can be very confusing to our operations.

And by the way, most of that information is not recorded directly in at least the tube current modulation, not in the DICOM header. So if you went back and saw a scan that you didn't like, it's actually hard to replicate the operator's information, what they were seeing at the operator's console when that occurred.

CDR BOYD: And the only thing I was going to add would be to comment on what you perceive is FDA's role in requiring more standardization of those types of things.

DR. MORIN: Well, I'm not a manufacturer, but I can say, this is the kind of thing that the AAPM should get a hold of and begin to standardize some of this terminology. Mike's absolutely correct. The technologist that is very well versed on one vendor's equipment may have to go someplace else to another location, and that could be a disaster at that place because they don't realize what parameter they're changing when they change that, and standardization of these terms really would be a very, very useful thing, and I think that we should look to our professional societies to do this, much like the AAPM's task group has done the same thing with regard to dose indices for CR and DR, where all the vendors had their own different indices, but they've now come up with a particular quantity that is calculated the same way by everybody.

MR. MATHER: And I agree that in conjunction with the societies and the users, probably the ASRT and other interested groups, the

standardization then has to go through MITA and finally through the IEC because you can't have, you know, different standards within the U.S. versus the rest of world, but I agree that ease of use is definitely key while obviously giving some ability to compete because that's what drives innovation and whatever, but yeah.

MS. WILSON: And it's really hard to keep up with terminology from vendor to vendor, and when you're teaching potential technologists or practicing CT technologists, you have to say on the GE scanner, this is the term used, Siemens uses this, and what have you. So it's been known for a long time, we need some standardization of terminology across the manufacturers.

CDR BOYD: Thank you. We've got about five minutes left, and I'm going to allow some more questions. So, sir.

MR. MALIK: I'm Paul Malik (ph.), but I'm representing the public, okay. So far what I've heard here is the vendors, the users, but there is no input from the average public person. For example, on November 26th, I got my CAT scan. It was over 1,000 milligram, and I used to work in the nuclear field, and I never got that in 20 years. So I know there is someplace the dose is not quantified or accounted for. What I recommend, some input from the public person who goes into the machine and gets the dose as to how much dose he's going to get. If he knows or she knows that he got 1,000 milligram or 500 milligram, let him know it. That's my question. Let the

public become more educated.

DR. MORIN: I think the only thing that I would be concerned about is what if we had a situation, this really did occur by the way, where mother and young child, a five year old, are in a motor vehicle accident. Child for some reason hits the head on the windshield, comes into the ED, presents with possible subdural hematoma. Mother won't allow the scan to occur because she's worried about the generation of a cancer 20, 30 years down the road. If that particular case, if we hadn't had a resident around to talk to the mother, and if the patient had left and ended up having a life-threatening event, how would that mother feel the rest of her life? So given a number, a number by itself, it needs to be put in context of what is the benefit likely to be derived from that study. I think both things are important, and we need to express both.

The last thing that I would want would be, particularly in a ped situation, if there's a life-threatening situation, we can use tools to either determine or eliminate disease or trauma, and I think the issue we have to consider is what is the benefit to that particular patient.

MR. MALIK: In my case, they took a CAT scan. It was never used. Never used.

DR. SMITH-BINDMAN: Dr. Morin, the case you highlighted is obviously compelling, but we would also cringe away if that child had a brain perfusion scan in that setting and had the dose of 30 rads that we hear is the

max of this one system, and that happens as well. And so we need to find the balance, and I'm not sure keeping that information from the patient and making the decisions as the physicians is the only way to move forward, and it might be having families involved in decision making. In this case, you had a resident who said, look, your child needs this scan more than the concern of the risk, and I think we've gone to the degree of imaging so much that we need to step back a little bit, and part of that stepping back means there will be situations where the resident has to convince the parents that, in fact, it's worthwhile.

DR. MORIN: I would certainly agree that if the patient presents to the ED, didn't see any physicians at all, and immediately had a head to toe CT scan, that that wouldn't be indicated. I mean, I think that what's important here is that, and in the situation that I was addressing, is that it's not just the number. It's that we need to have a healthcare professional explaining to that person what the likely benefit is and what the likely risk is, and I think that those two have to go hand-in-hand. We can't ignore the one.

DR. FRUSH: It's really about accountability, and for us, us as technologists or physicists or a physician, to be ignorant, to say, well, I don't know what the dose is or I'm not prepared to discuss the risk or it's not displayed or I don't know how many CTs you've had at this institution even though you've been coming here for 10 years, is unacceptable and that's the education part of this.

So in answer to your question there, whether you're provided that information or not could be on an institution-by-institution basis, but those decisions have to be made within the input of all the imaging experts, and everyone has to be able to, from the technologists all the way through to the other imaging experts, to be able to answer those questions that a patient has at the time they're there, and maybe your level of discussion is quite different than somebody else who doesn't want to know much about the dose, but we're not even to that level yet where everyone can provide that information because we don't have dose tracking, dose recording, cumulative dose, and we don't have good display of doses on the scanners, and we don't know what it means. That's why we need to move ahead here.

CDR BOYD: And I think we could talk more about user training and how to communicate --

DR. FRUSH: Absolutely.

CDR BOYD: -- benefit versus risk to patients in tomorrow's session.

We've got four more questions, and we're at time right now. So we'll allow the four questions and about three minutes of discussion of each so that we can get through everybody.

DR. McCOLLOUGH: This is Cynthia McCollough. I'm at the Mayo Clinic, Rochester. I wanted to follow up on the discussion of diagnostic reference levels. We do have a tremendous amount of data. I had two

summers of summer interns mining all that data, and what is essential that I think is missing from this conversation is that we need to bin that data by patient size. The definition of a diagnostic reference level is a distribution of doses for a given task on a given patient size, a standard individual.

The use of the effective dose coefficients that people are using quite frequently right now is from a very skinny phantom, not the American public, and so the CTDIvol, if you double it to take appropriate measures to address the image quality for even a large patient, not an obese patient, one might think, ah, the effective dose just doubled because my CTDIvol doubled. If you actually do the Monte Carlo work, actually the effective dose only went up about 20 to 30 percent because the patient somewhat self-shields their internal sensitive organs.

And so as we go forward, I'd like the committee or the panel to discuss, do you foresee a sort of diagnostic reference level proliferation that we have for newborns and one year olds and five year olds and all these patient sizes or a model where the community knows fairly well the physics, tell you how to dial up and down across patient sizes so that if we stick with the diagnostic reference level for the standard size and people appropriately right size the dose, then we by de facto get the right diagnostic reference level at different sizes.

The former version, lots of diagnostic reference levels, is I think probably the more pragmatic people that may want to go grab the data and

bin it, but then we're going to have a whole lot of numbers and a whole lot of exams to keep track of. So I would welcome comments on that quandary.

MS. LEIDECKER: I would like to start by saying that I do think that these values need to be to some degree size adjusted. So in practice this would, for example, mean that you would have separate values for pediatric and adult patients. But also that diagnostic reference levels are not to be used as upper limits. So the main purpose of these, as defined by the ICRP, is to detect a significant and constant increase of dose at a certain facility or in a certain group of patients. So I would say that the problem is not whether or not a diagnostic reference value is exceeded. It's whether or not it's justifiable that it is exceeded, and because diagnostic reference levels are not set in stone but should be reviewed and monitored periodically, we can account, for example, differences in patient size if this is consistent, but I do agree that we need to do some review of these values, and they're not set in stone when once established.

DR. McCOLLOUGH: What I'm really worried about, Christianne, is these pop-up warnings that say you're above a diagnostic reference level. I've been doing clinical CT for 20 years. The techs will eventually start ignoring pop-up levels because they complicate life, and they will adjust the default protocol so that we don't get that anymore. That's exactly what happened in the ACR program. Reference level was 60, everybody just dialed down to get 60, and then the large patients will suffer.

MS. LEIDECKER: I completely agree, but this is exactly the point that we need to make very clear, that it is allowed to exceed those diagnostic reference levels, at least this is the definition of this particular quantity, the reference level, and we need to do that on occasion, it's allowed to be exceeded but we need to justify it. But I see, I completely agree that there is a certain caveat in having these kind of warnings.

DR. McCOLLOUGH: So you think we need multiple diagnostic reference levels across sizes.

MS. LEIDECKER: Or at least education and information how to use diagnostic reference levels or how to adjust them, yes.

DR. MORIN: As always, my colleague asks very interesting questions. We struggle with this quite a bit in the dose index registry. What we would love to see is that the EMR would feed the RIS with the body mass index or some other appropriate measure that we could then use to be able to bin these together, and maybe we could get Dr. Dicom over there to put a tag in, in the next release of DICOM so that we could then begin to coerce the EMR vendors to include that kind of information and it would get into the image header.

MR. CLUNIE: Yeah, I was already working on that in my mind, but we should also capture the size information that the vendor captures from the scouts because right now we're not capturing that, and that's free information that we're wasting.

CDR BOYD: Thank you. Dr. Mahesh.

DR. MAHESH: Mahesh from Johns Hopkins. I have a general question. First of all, we've been talking a lot about the dose registry. I know multiple professional societies are doing this dose registry, but at the same time, the question is to the FDA directly, there is a need for a national dose registry because professional societies are developing as a pilot and they're starting. However, in order interchange the data sometime into more user friendly, it has to be more of a national kind of dose registry where the information is more standardized and more readily available and so forth. So I just want to ask the FDA to comment on this and also comment from the panel about this need for a more national registry rather than the same efforts done in multiple societies. Everybody's doing the same effort but multiple ways rather than reinforce all the efforts for the same point. Especially in the time of lack of financial support, all the time effort, we need to look into consolidating these efforts so that everybody can go into the same pot.

Adding onto the same point is when the patient asks about the dose, right now I agree with Dr. Morin's comment that unless we provide some perspective, which very -- kind of wrong, it can mislead, however, the public are coming to the clinics sometime when they can Google radiation doses in CT, they get million webpages, and out of it, only probably 10 percent are accurate and 90 percent are misleading, and patients are coming

with information in those websites which tells a CT of a barium swallow study should be only with 3 radiograph, and here comes the center where the physician decides to do 7 radiograph, and immediately the patient is totally concerned. So we have to have a balance between what information we provide; otherwise, public gets information somewhere. It can all be wrong. So two comments, dose registry comment and the national consolidation. Second is balancing the act of information about the patient risk to the public.

CDR BOYD: Regarding FDA, I mean we agree that there ought to be a national dose registry that collects information on dose metrics and patient information on a national level, an anonymized thing. I mean we haven't made a decision that this is something that FDA should retain or house on its own because of our regulatory oversight roles that we have, and we understand that participation in such a national registry and getting to facilities using such data to improve their own internal quality assurance practices at making decisions that would impact the practice of medicine is outside of our regulatory oversight role. So we haven't made a decision on who that should be to retain that, but we agree that it's necessary, and we're here today to hear that.

DR. MAHESH: Just adding to that comment, probably in the month of February, FDA had a meeting about the device issues. Well, the AAPM has, American Association of Physicists in Medicine, has provided information telling like they're proposing to start a technology assessment

institute, which is an independent body which will house all the experts to provide this information. So FDA should look into that type more.

DR. FRUSH: If I can address those real briefly. First, I can't speak for CRDR and fluoroscopy, but I don't know of any professional radiologic organization that has a registry particularly established like the ACR. I think it's actually very unusual, and maybe we can talk afterwards, from a professional society standpoint, and I think it's critical that we have that information. With respect to the patient access to it, we'll never stop that. I shop for a car. You know, I go to the Internet, and the information I may get may be totally foolish to the auto makers who are having a similar conference somewhere else talking about me. So we're never going to fix that. What we have to do is be prepared as the end user to reeducate that person and be able to answer their questions, which we don't do very well right now and the college, and you're involved in this, is currently working on quite a text of questions and answers directed to patients, physicians, and radiologists that will get at these issues themselves, and whether they go up on the radiologyinfo.org or ARC site, that will be very helpful.

MR. BANASIAK: My name is Gene Banasiak, and I'm with Clinical Microsystems. For the past 16 years, we've been monitoring dose to patients for angio studies, cardiac EPs, but not CT, and currently we've done a lot of work with the DICOM SR for those modalities. What are the parameters or the fields that are reported for the DICOM CT structure, and if they are

standardized, where can they be found?

MR. CLUNIE: I guess I should answer that. The DICOM standards, it's available on the web. There is Part 16, which contains all that information. You and I should probably talk offline, and I can point you directly to what you're interested in.

MR. BANASIAK: And, currently, what percentage of the installed base CT scanners have this DICOM structure?

MR. CLUNIE: About 0.001 percent. Let's put it this way. I oversee about 10,000 exams a month for CT in my clinical trials practice, and I've surveyed the last three year's results, and I had one, one single exam, that contained a dose report from one vendor.

MR. BANASIAK: That's what, you know, from a standpoint, it seems like the DICOM SR for angio, cardiology, and it's information that's going to be, you know, throughout, it's going to be information that everybody's going to use. It's going to be industry standard just like a DAP meter is. It's an industry standard now. So going forward, you're going to have a standard set of parameters that we can talk about that we can implement now?

MR. CLUNIE: Absolutely, and MITA's made the commitment. It's being tested on a regular basis at the IG Connectathons at which time there's generally about half a dozen vendor participants testing this. So as the MITA folks have noted, this is coming, and they have made a commitment

to retrofit some proportion of the install base, which is something that the FDA and MITA are going to have to negotiate I guess.

MR. BANASIAK: What percent of the installed base?

MR. CLUNIE: You're asking the wrong person.

CDR BOYD: Okay. Our last question.

MR. VASTAGH: How critical is harmonization of the names, the nomenclature for the examination, for the success of the structured report, comparable data from different sources? You mentioned RadLex, and a couple of times this was mentioned as a problem. How do we move forward to solve it?

DR. MORIN: We actually have the steering committee for the dose index registry has got the assistance of folks from the RSNA who have done this retrospectively, and so we're optimistic that this will be utilized. The other things that we've looked at over the years have been CPT codes and other procedural codes and that kind of thing. The trouble is that people map these in very, very different ways. So we would be happier if, in fact, all of the RISs at least in forward production mandated the use of RadLex. That would certainly be a step in the right direction, and I suspect some day that will come about, but the overall environment in the U.S. is that people like to do their own thing, and so this level of discipline is very difficult to enforce, but in terms of getting the results out and having them be meaningful, it is extremely important that you all call the same thing the same thing because if

we don't do that, then we will have a tremendous bias in the data on the back end.

MR. CLUNIE: But there's no need to wait for RadLex procedures and RIS, and RIS are outside the scope of the FDA because they're not medical devices for some strange reason, but the anatomy can be done now. The anatomy can be coded now by the manufacturers from the protocols without waiting for the RIS, without waiting for RadLex, without waiting for any changes to any standard because the standards already exist. I think that's the first step and the most important step.

DR. MORIN: The other thing is that even though you know the body part, it is important to know how many times that body part was examined during one examination. Did you have a triphasic pancreas study or did you do an exploratory urogram with four phases or two phases and that kind of thing? So those issues -- but you're absolutely right, Dave. I mean that would be a real step forward.

DR. SMITH-BINDMAN: I'm not sure that that information is quite as crucial as we like to think. If the purpose of the diagnostic reference levels is mostly to allow an institution to know how they're doing, and if their diagnostic reference levels for the abdomen are four-fold higher than they should be, that suggests they're either scanning a really long area or doing a lot of quad phase exams, and it's unlikely that one institution needs to do all of their exams as quad phase exams. They probably learn a lot about that.

Now, there are examples when there might be an institution that only does liver transplants and they might need to, but it would be an exception, but I think in general, the anatomic area would get us 90 percent of the way where we need to be.

MR. CLUNIE: And don't forget that as radiologists with the PACS, we also have the images. So we can use the images to retrospectively ascertain how many times the same region was covered, if you could separate the reconstructions that are multiple and all that kind of stuff, and that's also one thing that is missing and the vendors should commit to, and that's the incorporation of the unique identifier for the irradiation event. It's a feature of the DICOM SR, but if it's not in the images, you can't correlate the images with the SR. So when you implement the DICOM SR, you also have to put irradiation event UID into the images. Sorry to get into the technical details.

DR. SMITH-BINDMAN: That's technical, but it's actually incredibly difficult for someone who's not a radiologist to tell an irradiating event from not an irradiating event, and even for radiologists, it's not that straightforward. So it's probably trivial for you and really hard for us when we're looking after the fact.

CDR BOYD: Well, with that, I want to thank everybody for their attention this morning and thank your round-table participants for engaging in discussion.

(Applause.)

CDR BOYD: You have earned your lunch today. We're going to break for one hour. Be back at 1:47 by my watch, and we'll resume at 1:50. Thank you.

(Whereupon, at 12:47 p.m., a luncheon recess was taken.)

AFTERNOON SESSION

(1:49 p.m.)

CDR BOYD: I'd like to get started in a minute here. Just as a reminder for speakers from this morning, if you weren't present earlier, that you have five to seven minutes to make your remarks. I'll send up when you've got about one minute left, and if you could wrap up at that time so we can get through the 19 speakers that we have this afternoon, I would appreciate that.

This afternoon's topic is fluoroscopic equipment, and again we're going to address the same set of questions that were posed in the Federal Register notice but relative to fluoroscopic equipment, and as stated in our earlier presentation, we're focused initially on interventional fluoroscopy, and again we have 19 presenters in this afternoon session to address either equipment features, labeling, and/or premarket submission data that might improve equipment for purposes of reducing, optimizing, and justifying medical imaging exposure.

Our first speaker this afternoon is Dr. Goldstein.

DR. GOLDSTEIN: Thank you, Commander Boyd. It's an honor to be able to present on behalf of the Society for Cardiac Angiography and Intervention, to talk about the importance of our field of interventional cardiology and the patients we take care of, and also the healthcare personnel involved in taking care of these patients, because as I'll make in my

points, not only are we focused first and foremost on the safety and clinical outcomes for our patients, but also healthcare workers who are in the same environment getting exposed to radiation and also some of the physical burdens of working in the cath labs and their complications.

And the mission statement of the Society of Cardiac Angiography is to promote excellence in invasive and interventional cardiovascular medicine through education and representation and the advancement of quality standards to enhance patient care, and that is our first and foremost goal.

I just want to disclose a conflict of interest. I'm trying to make the cath lab a better place to work. So I do have a conflict of interest with some designs that I hope ultimately will make it a safer place to work in the cath lab.

Cardiology has changed. Early on, we used to diagnostic caths where we'd come in and put in some hemodynamic catheters and measure pressures, take a few pictures, and that was it, but with the advent of interventional procedures, we've seen a dramatic change, and that's helped people. Far fewer people are suffering from heart disease, and those who do suffer it are dying less, particularly with heart attacks and other forms. We're now treating all kinds, not only coronary disease, but valve and other problems, in the periphery and structural heart disease, neurovascular. It's really been an incredible 30-year evolution, and as we've improved the ability

to diagnose and treat patients, we've changed the environment of the cath lab. The typical operator who used to do maybe 2 cases a day now does sometimes 7, 8, 9, 10 cases a day. Those are much more complex cases. They require more fluoro time. They're much more complex, require all kinds of imaging, both fluoroscopic and non-fluoroscopic imaging, and therefore radiation exposure has increased both to the patients and also to the operators and healthcare personnel.

We see the goals of procedures requiring radiation as a balance. First and foremost is the diagnosis and therapy for patients, and it has to be balanced against any kind of risk, including radiation exposure, and those risks must be thoughtfully discussed with the patient and the family, and the physician is the key, has responsibility for discussing the risks and benefits and monitoring the risks and benefits for every procedure, including those that are involved with radiation exposure, and we, the Society of Cardiac Angiography, are committed to that. And we have position statements on radiation safety. We've put a particular focus, more recently in the past few years, on those procedures with the highest exposure rates of radiation to the patient, including complex procedures where we try to open up what are called chronic total occlusions which take many hours, in some cases, structural heart disease where we now work novel procedures to fix valves with catheters; it can take many hours and a lot of fluoroscopy time as well as other interventions. We also focus increasing awareness on those

patients who are at highest risk from getting any radiation, such as pediatric cases and women. We are intensely involved with training minimized patient exposure and adhering to the policies of reporting and monitoring in patients with high exposure.

We have also been involved as one of the founding groups, along with the Society of Interventional Radiology, the Heart Rhythm Society, Neurointerventional Radiology, and Association of Physicists in Medicine, forming the multispecialty occupational health group that has looked at the risks to operator in the cath lab. I spent 35 years in the cath lab.

My second conflict of interest is I had lumbar disc surgery eight weeks ago today, and that is a complication of being not 25 years old anymore and also working in the cath lab, and we wrote this important paper that says, if I can quote it, "X-ray exposure and the physical demands predispose the interventionalist to distinct occupational health hazards. These hazards accumulate over time. They've been known for years. The physical stresses inherent in this career choice appear to be associated with predilection to orthopedic injuries attributable in greater part to the cumulative adverse effects of wearing leaded aprons."

Working in the cath lab for 30 to 35 years is asking for trouble, and the cath lab environment in which we work, you walk in, and you wear these heavy leaded aprons, wear your thyroid shield, you're bent over the table and you're working for 8, 10, 12 hours a day, and your arms are still

getting radiated and your brain's still getting radiated and your legs are still getting radiated, and you've got this heavy lead on, and if you've never worn it, you have no concept of what it's like to wear that 8 to 10 hours a day for 30 to 35 years. And so it's not surprising as we published in our surveys of our Society that if you look at the prevalence of orthopedic injuries, spine problems, 60 percent of folks at my stage in their career have had a major C spine or L spine problem, a third have hip, knee, and ankle problems, and we're very concerned, and there will be some personal testimonies coming in, and the data that we're looking at is a society regarding cancer issues.

So radiation is a big issue. I don't need to tell this crowd that the NCRP has already defined that there is no threshold below which no harmful effects can occur. You're all familiar with the concept I think of ALARA, which is the present standard for all radiation safety, which is as low as reasonably achievable.

My third conflict of interest is I have a son who is a second year medical student who's thinking of going into interventional cardiology, and he's thinking do I want to spend 35 years getting radiated and wearing lead and ending up with an orthopedic problem when I'm 65.

And so we ought to be able to work together to come up with a safer environment, not just for the doctors but also for the nurses and the other technicians who work beside us, all of whom are at risk for these different kinds of problems.

So as we wrote in the paper published by the Multispecialty Occupational Health Group of which the SCAI is a part, we published in our journals a year ago, interventional physicians and the professional societies working together with industry should strive toward the ultimate zero radiation exposure work environment that would eliminate the need for personal protective apparel and prevent orthopedic and ergonomic consequences.

And, finally, the SCAI's efforts to promote radiation safety for patients and healthcare personnel, some of the specific things we do, we spent 15 percent of the interventional cardiology board exam, devoted to radiation related issues, and obviously to pass the boards, you've got to be trained, and our training requirements include significant radiation education. The SCAI is an active member of the NCRP and also one of the founding members of this Multispecialty Occupational Health Group looking to gain more insight as to what happens to people who work in cath labs for 30 years and how we can make it a safer place. Thank you.

(Applause.)

CDR BOYD: Keith Strauss is our next speaker.

MR. STRAUSS: Thank you. It's a pleasure to be with you here today. I'm the Director of Radiology, Physics and Engineering at Children's Hospital in Boston. I'm speaking to you today on behalf of Image Gently.

This is who we care for in pediatric hospitals and this, of course,

is the focus of the Image Gently campaign. What is Image Gently? Well, I think most of you know that it's an education and awareness advocacy campaign. We're trying to improve radiation protection for children worldwide. Fifty-two different healthcare organizations representing about 700,000 people in the medical care field have signed up to be a part of that effort.

One of the main themes of the effort is we really need to appropriately size the patient and do the right thing with respect to our equipment.

I want to make a few quick comments about pediatric imaging. I want to talk a little bit about the hardware of interventional equipment and general fluoroscopic equipment. I'm sorry I didn't get the memo that I was only supposed to talk about interventional equipment. I want to speak about configuration issues for children, and then I want to conclude by recommending an expanded required functional check for pediatric fluoroscopes.

What is pediatric imaging? I always chuckle when people come into our hospital and say, oh, I didn't realize you did more than babies. Yes, we image everybody from neonates to 21 years old, even if they're 300 pounds. I also chuckle at people that come to the conclusion after thinking about it for a while that any improvement to an imaging device that improves pediatric imaging probably also is going to improve the adult imaging on that

machine.

Another thing that people that don't work in pediatrics sometimes forget is that patient age is a poor index of patient size. This is some data that will be published in the *AJR* in a couple of months, and what this illustrates for instance is that a large three year old exceeds the size of a small teenager. And pediatric technologists kind of have calibrated brains that take care of that, but in adult institutions that do children, occasionally the technologists may not be as cognizant of that.

Pediatric imaging, yes, is all about size. These images show the standard CTDI phantoms and newborn phantoms for the head and thorax in adult-sized phantoms. I'm not trying to promote any phantoms here. I'm just trying to give you a concept of the difference in size between the newborn and the adult patient.

This is just a scale drawing of the different ages of patients. I remind you that in fluoroscopy, it's 70 kVp. The half valuator of tissue is about 3 centimeters. That, of course, means that every time we add 3 centimeters of tissue, we need to double our technique. Some people kind of don't think about that a lot, and I think, oh, well, we now have a 20 centimeter patient instead of a 10 centimeter patient, I probably need to double the technique, and that, of course, is not true. It's driven by the half valuators here, and from this table, you can conclude that in the PA projection from a neonate to a large adult, you need a dynamic range of 512 if the kVp is

fixed. Now, of course, the kVp isn't, but if we were to do that, in the lateral projection you'd need a dynamic range of 16,000.

The point I'm trying to make, of course, is that pediatric equipment needs to be optimized for children.

It's all about size and elevated risk. Hall published this figure a couple of years ago, and whether you like numbers or figures, these two publications agreed with one another, and again it illustrates to us that children are about three times more sensitive to radiation in the first decade of life than the average adult. Maybe there's debate whether or not the percent per sievert is 5 percent, but I think there's some common agreement that kids are more radiosensitive.

What about the hardware for fluoroscopic equipment? I just want to list the kinds of things that you need to consider. You need to have a removable grid. Certainly in this day and age, you shouldn't be purchasing equipment without variable rate pulse fluoroscopy if you're going to do children. You need adjustable added filtration ideally with atomic numbers greater than 29. It's great to have a triple focal spot x-ray tube especially if you're in the cath lab to match up the load of the x-ray tube with the size of the -- or the focal spot with the size of the patient.

There's one manufacturer out there interestingly enough that actually moves their x-ray tube with respect to the tabletop in a standard tilting fluoroscopic table. They did it for other reasons, but because the SSD

changes from 50 to 64 centimeters, that alone can be used to reduce the patient air kerma rate by a factor of 40 percent. All these things tend to add up.

Once I've got equipment with the right hardware, what do I do with respect to configuring that unit that's different than adults? Well, I need a unique kV. I need a unique tube current. I need reduced pulse with which to freeze motion. I need appropriate variable pulse rates. In a lot of cases, in children you need a higher pulse rate, especially if you're doing cardiac work. I needed added filters with appropriate thickness, and in general, with kids, I can use thicker filters than with adults. Again, I need a proper focal spot size. I need a grid that's removable, and I need appropriate image processing.

So all these things have to do with configuration, and basically if you pull the machine out of the box and you try to use it, it won't usually do well with children and will do perfectly well with adults.

Once you set up that configuration, you also need to worry about the exposure to the image receptor. You need a prior air kerma rate there, and the baseline kerma value that you select at tableside is important. Again, the filter that the machine chooses is important. How does the exposure rate to the image rate receptor change as a function of the field of view, and how does it change as a function of the pulse rate? All those things need to be optimized for children.

Now, here's an example of what happens if you don't optimize

these things. I took this data a number of years ago on a brand new cath lab. It was a perfectly good cath lab, and when I simulated a newborn child, instead of fluoro seeking 70 kV in the automatic brightness mode, it sought 45 kV, and as a result of that, the patient exposure or dose per frame was 2 microgray instead of .4. It was increased by a factor of 5.

The same was true for the cine acquisition. Now, obviously there was no improvement in image quality here, just because I reduced the kV from 70 to 45, but my patients were paying a dose penalty with that equipment out of the box of a factor of 4 to 5. That's why we need to do better configuration for kids.

This is just an example of a VCUG study that we did in our institution. We optimized the equipment for children, and basically we reduced the air kerma skin entrance rate to the patient by a factor of 7 to 10 with zero loss of image quality. There's a lot you can do to reduce dose.

So as a result of this, with respect to fluoroscopes, I'd like to make the recommendation that if someone intends to use a piece of imaging equipment for pediatric fluoroscopy, they should make sure that when they purchase that unit, they purchase the appropriate hardware, and once they have that hardware, they need to configure it to provide good image quality with appropriately managed radiation dose to the pediatric patient.

This is something that the manufacturers I believe need to roll up their sleeves and help the end users identify, and we need to work

together and develop pediatric modes.

But I think even more importantly, we all know that physicists on a periodic basis go around and we check fluoroscopes for adults. Nobody would advocate using 20 R per minute instead of 10 R per minute for an adult, but nobody is concerned if on a newborn I use 1 M or 1 R per minute instead of a half when a half is perfectly fine. Nobody's checking it. So I'd like to advocate that that's something that the FDA think about incorporating in the future.

So dose rate limits for adults during fluoroscopy exist. Optimization of hardware and configuration for pediatric patients today is not required, and there really are no good pediatric reference values. We need to establish those, and we need to establish them and get them incorporated.

So, in conclusion, let's all work together and remember to Step Lightly and Image Gently.

(Applause.)

CDR BOYD: Dr. Nicholas had to leave for the day. So our next speaker will be Dr. Duncan.

DR. DUNCAN: Thank you. So it's a real honor to be here and to talk about how to improve safety during fluoroscopy.

I'd like to say that fluoroscopy is dynamic. We're trying to collect data in the midst of a procedure to make decisions, and that you're trying to balance, that you have a cycle that leads to increased dose, the idea

of more data, better decisions, better results, that clearly drives more dose, but it's counterbalanced by what should be in the back of all our minds when we're stepping on the peddle is that there's tissue damage, and whether it takes months or years to accumulate, you're going to have delayed complications and that clearly we need to dynamically balance within the midst of these procedures the risk/benefit ratio.

And when assessing system performance, this is a model that we sort of proposed is that when you look at the probability of a desired result and you measure it against how much data, how many photons do I actually have to use to get that desired result, I sort of compare this to trying to drive my car with my eyes closed. I can drive my car, but I probably won't get to work, and I'll probably run over somebody if I try to drive with my eyes closed. I could probably do some of these procedures without fluoro. The chance that it works out is very, very small, but clearly you get to a point where you saturate. So as we increase the dose, the probability increases, and then when you reach the top, you're saturating this curve. More fluoro, more time, doesn't improve the probability of a desired result. And so we really need to have systems that stop us from collecting data when there's enough information to make some valid decisions, and really we want to design systems that study the past to improve the future.

So I like to take lessons from other fields, lessons from aviation. Aviation had an unacceptably high accident rate in the late fifties. They

decided that they had to do something, and I have to congratulate them that they continue to keep working on this problem, and they've dramatically decreased the risks, and a big part of it was flight data recorders. They became mandatory in 1958, and voice recorders became mandatory in 1966. And as a consequence of that, we've seen a dramatic decrease. We thought, well, why don't we put something like that in our pediatric interventional lab.

So we put together a pediatric procedure data recorder where we have inputs, information from the fluoroscopic as well as cameras and microphones in the room. They go to a data capture device, and I can look at a video output or I can take the data from that, and here's a timeline of radiation use, and when I look at the video recordings from this, I often think that it's not me that's in the recording, it's my evil twin brother. Okay. I wouldn't be putting my hand in the beam. I wouldn't be the one that isn't collimating and isn't optimizing the fluoro use. It's got to be somebody else that looks a lot like me.

And then when looking at how we've used radiation in the midst of this exam, we've graphed out here as a timeline with the amount of radiation used as a function of time, and it's a dose metric being used as a function of time, and it accumulates during the exam, and when I go back and I look at this recording, I can convince myself that my evil twin brother convinced me that I had to do this step when in retrospect it was two-thirds of the dose and really didn't contribute to the outcome for this child.

And so when we look at performance curves, we see a couple of very interesting things. One is that we clearly see a difference in operators, and if we're going to put together dose reference limits, we're going to have to start thinking about the difference in operators, as a novice or as an expert, because there's clearly differences in performance. When we looked at VCUG performance, we saw that the attendants when they're functioning function dramatically different from fellows who are in the last six months of their training. They're shifting the curve as it goes back and forth.

And clearly Lorene Therew (ph.) would tell us that learning is a logarithmic function of experience and clearly emphasizes the importance of feedback, and we need better feedback because there's a large benefit from small changes, and this is the FDA's data from a long time ago that said, what would be the benefit 10 years after a 15 percent dose reduction? Fifteen percent is like falling off a log, okay. It's something that you can do really with very little intervention, and they estimated it based on exam frequency, dose per exam, the excess mortality of cancer, and the years of life remaining, and what they came up with is the conclusion that it's common procedures, susceptible populations. It's upper GIs in kids. We'd like to focus on the high-end exams, they're exciting, they're interesting, but it's really the simple things, small improvements and simple things can go a long way. And so I fully support Image Gently and the Step Lightly campaign.

So what other lessons from aviation can we learn? There's a

new program. It's actually not that new. It's called flight operational quality assurance. Their goal is they continue to say can they make aviation safer? Just because planes aren't crashing doesn't mean there still aren't problems, and so it's a voluntary program with the FAA pilots and airlines. They take de-identified data off the flight data recorders in airplanes, examine it within the airline and the pilots union, and then take some of that data and send it to the FAA so that the FAA can monitor a national trend and say, you know, where are the vulnerabilities that we need to address in the future.

So we clearly need to do something. I mean the plan's out there. We can follow it. It's really you study what you do in your patient procedures, you capture some data, and it needs to be linked to a trigger tool. So the trigger tool tells you to go back, that there's something out of the ordinary, you need to investigate this further. You do a deeper dive into the data, do a detailed analysis, and you come up with what's known as a model of the system. What is it that we understand about this particular procedure or the sequence of events that we could leverage to improve the future performance, and that would be the process changes that we'd say, well, those are ways we could improve, and you ought to test those changes, hopefully in a simulation lab, and then you implement them, and clearly what you need to do is to go back and say how did that implementation change patient procedures because it's not necessary to change. Survival's not mandatory.

So, in summary, we cannot improve things that we cannot measure, and we cannot measure anything with absolute certainty. We can measure dose metrics, but what we don't know is dose and the risk that we're imparting on our patients, and although all these measurements are flawed, they're still far superior to using emotion to drive decisions. Flight data recorders became mandatory in aviation. System-based approaches clearly have a future in medicine. Don Berwick has just been named as the appointee for CMS. He helped the Institute of Medicine write it's To Err is Human report, and so I would think that procedure data recorders will lead to safer imaging if we start thinking about how to implement them, and really much of what we're doing now is talking about how are we going to implement these process and improvement strategies. Thank you.

(Applause.)

CDR BOYD: Our next speaker is Dr. Brateman.

DR. BRATEMAN: Thank you. I'm Libby Brateman. I'm a medical physicist at the University of Florida, and I am not representing anybody other than myself. These are the questions that I'm going to try to answer in the seven minutes that I have allotted. The slides I'll post on the website. I have way too many, but it's all stuff that since you asked I feel like I have to say.

First of all, I've become involved recently in looking at peak skin doses and in particular for biplane angiography procedures in the head, neuroangiography. And in terms of looking at where the beams overlap, I

have this head phantom, and you can see that there's a significant portion of the head that is getting an overlapping dose, and according to our interventionalists, when lesions are superficial, that there's no way to collimate that out, and so if we're going to be posting the entrance air kerma, it should be the sum of all those things for the operator to be aware of that.

And also from mobile C-arm fluoroscopes, we are limited in space particularly in the operating room, and in order to keep to a minimum source of skin distance, we need to sometimes take a spacer out, and then for the next patient, the spacer might not have been put in place. So if we had an alert when the spacer was missing, at the start of an exam, that we could reduce the risk for the next patient.

Also when we have beams coming in, not from underneath the table, then we have, with abdomens being wider in the lateral dimension or any oblate dimension, then when the patient is larger than where the reference point is for the entrance air kerma, then if we don't have what the source of skin distance is, then we can't really find an estimate of the peak skin dose for patients. So for some patients, this is an issue as we try to deal with Joint Commission standards.

So one of the things that we could do about that is if we have a ruler from the tube head like we use in radiography, we could potentially measure the source to skin distance, and even though during a procedure, the tables move around, then once the system is calibrated to a patient, then it

could track where the skin is with respect to a table moving around.

And in Florida, they've gotten so concerned about the peak entrance skin dose being so high, they've created some regulations that really don't work for us to try to keep patients outside of the high dose rate levels. So one of the things that could happen is that if we were at a distance that was sufficiently close to the skin that it was more than the maximum dose rate for normal fluoroscopy, then there could be an alert, as we use for high level control, to identify for the user that they're in this high level radiation exposure rate range.

One of my graduate students made some measurements on one of our pieces of equipment with respect to table height, and you can see that there's a dose rate change that's greater than a factor of two by where the source of skin distance is but based on the table height with the x-ray beam coming in from below the patient.

And so in terms of our first speaker, when a procedure is long, the operator tends to move the table around particularly during long procedures because they get uncomfortable, and people like me who are very short, we have the table closer to the floor or closer to the x-ray tube focal spot to begin with, and so patient doses are higher, and as one of my colleagues says, why should the patient dose depend on the height of the operator of the equipment?

Okay. So as the table height is varied in the middle of a study,

then also the distance to the imaging assembly, the source to image receptor distance also changes, and the operator is probably not going to be paying a lot of attention, at least in my experience of the way things happen, because they're working on the clinical case, and so again there's another factor that's going to be impacting the patient radiation dose because of the operator's comfort, not for anything related to the patient's needs.

So this is in a biplane unit with the head phantom that you saw sitting at the isocenter, and you can see that even without changing the table height, just moving the imaging assembly up and down, that we can get a dose rate change that's close to a factor of two from that.

So you've already seen this slide from Dr. Goldstein.

And so I thought, well, you know, maybe we need to do something in addition to looking at patient dose, and maybe at the same time do something about operator dose, and the other piece of this is that in a biplane unit, then the lateral C-arm also needs to be able go up and down which one of our rooms does, but one of ours doesn't, even though they're both pretty new rooms.

So thinking completely out of the box, let's just redesign equipment and remove the impact of the operator height and the comfort and so we can do a couple of things. We can make a height adjustable platform for the operator to sit or stand on, and then instead of moving the table, then we could move the operator, and it would move up and down, and

also for some people who would rather sit or some who would rather stand or be supported by a little stool behind them, then this could be something that can move up or down as well, and the shield, the front of it with transparent protection for the part they need to see through, and that would shield their heads and their upper bodies and their lower bodies all at one time, and people could work through there, and maybe with using robotics and new viewing technology that would show on some glasses or something, instead of having to try to look at a display, maybe this could really change the way interventional procedures are done.

Like I said, I'm not representing anybody else but just my thoughts about what we might be able to do to save patient dose.

So then if we did that, then we could start a procedure that was at the maximum table height, and then with the imaging assembly as close to the patient as possible, then we would only have the entrance air kerma rate depending only on the patient thickness, and so then if we had a ruler from the imaging assembly to where the beam enters the patient, then we could calibrate that part of the system. And so if anything moved around when the SID became really large, there could be an alert on that as well.

So the real thing that the eyes of medical physicists have to deal with is, if I want to know the peak skin dose, I need to know where the skin is, and since I don't have information of where the table height is, I don't know where the beam is entering the patient, whether it's coming from below

the patient or on the side of the patient, and so what I need is the distance to the skin, and in particular one of our biplane rooms has the lateral tube on one side of the head and the other on the other side of the head. So it would be really useful to know whether the beam is entering the right side or the left side of the patient, particularly when patients come for repeated exams, and sometimes they're getting the beam from the right side and some of them from the left side.

And our newest units give us the entrance air kerma as well as the kerma area product, which is very nice because then we can get an effective field size.

So to know the peak skin dose, we need to be able to look at repeated studies, and so we need to be able to relate the values and the locations of the beam among devices for different rooms, and in biplane studies, then we need to know about beam overlap, whether there was beam overlap, where it was, and what part of the total came from beam overlap.

(Applause.)

CDR BOYD: Our next speaker is Dr. Stephen Balter.

DR. BALTER: Thank you for giving the opportunity. I'm speaking in behalf of the NCRP and the Society for Interventional Radiology, which pretty much has things in common but not totally. Where there's difference in opinions, I'll show you this on the slides. We do expect that each organization will submit separate written responses.

Fluoroscopy is not CT. In CT, as you saw this morning, the dose is pretty much determined by the selection of the specific protocol; that is, if you put the same phantom of the beam, push the same button, you'll always get the same dose.

Fluoroscopy, the best you can do is determine dose rate. The total dose during procedures varies considerably due to clinical factors, patient's condition as well as height and weight, the operator ability, details of the equipment. The operator is the key to this.

The equipment is very multipurpose. Several of my rooms actually have three distinct personalities. They can be used for cardiac electrophysiology, very low dose per image, very low frame rates, coronary interventions, typically 15 frame a second fluoroscopy, 15 frame a second cine dose rates are about a factor 5 to 10 higher on an average, and you get to some of the interventional radiology procedures, particularly the neurointerventions which use DSA where the frame rates are fairly low but the dose per frame is two orders of magnitude above the fluoro dose per frame.

Many of the questions in the FDA announcement have already been addressed by NCRP, by SIR, and both of these organizations have relied a lot on some IEC standards that are already in existence. We've heard some of them this morning. I'll repeat them.

We've just finished the review of a NCRP report on

fluoroscopically guided interventions. There are 33 recommendations in the report, justification of the exams, scientific overview of various bits of biology and physics, issues of patient safety, issues of staff safety, issues of training, credentialing and privileges for the operators and other people. The public comments literally closed yesterday, and we're eagerly awaiting to see what people have to say to us.

The Society for Interventional Radiology has been rather active. In 2004, there was a statement that required dose reporting in the medical record for all interventional procedures. Last year, there was a report on patient safety jointly with the Cardio and Intravascular [sic] Radiological Society of Europe. This year, there's been a companion paper on staff safety. Presently SIR is developing a module on physician training in radiation. It's in beta testing. This includes a laboratory of about a half day with practical measurements as well as didactics.

IEC has two key documents relative to today. The first is 60601-2-43, which describes equipment for fluoroscopically guided interventions. It gives a long list of safety features for interventional fluoroscopes. The second edition is currently out for vote. It's expected this year. It has some incremental advances. The FDA has actually picked up some of the 2000 IEC document into its 2005 performance standards.

The second document is the IEC PAS publicly available specification from 2007, which is the radiation dose structured report. This is

the same general idea of the CT one. There's a DICOM object uncoupled from the image header. This means these reports can be generated even if there's procedure that have no images. The images are discarded. It's generally applicable to projection radiography.

In former times, the FDA was very active in IEC activities. This has sort of tapered off in the last few years. We would encourage the FDA to get back into a more active role in IEC.

Here's some responses to specific questions. Hardware and software for interventional fluoroscopes, it's easy. Everything that's in the 2-43 document for any fluoroscope that's used for intervention. For other fluoroscopes, many of these features are practicable. As I've mentioned, they've already done this in 2005 for last image hold and dose monitoring. Pediatric adaptations are important as discussed by Keith Strauss. Also there's a need for a physics mode for better testing. As these systems become sealed, it's harder and harder to do the physics work in a very substantial way.

One of the problems we see is dose reduction components are often quoted as optional extras. Interventional radiologists feel that everything needed to meet any manufacturer's claim of dose reduction or improved image quality without increased dose should be supplied as part of the standard system. You shouldn't have to pay extra for safety.

Regarding the next question, access control, system access by

users is certainly important, knowing who's using the machine. System configuration is limited by the service vendor, various passwords and passkeys, and there's a limit to what institutions can do. Access control and audits for any permanent changes, tracking what people do during individual procedures, to find out what they really did. When the physicists do QA, that should be tracked as well because this is important to establish the QA was done and was done without damaging the equipment.

Warning, alerts, and lockouts. There's much in the current FDA regulations and the IEC 2-43 document, dose displays, dose area product, fluoro time, the whole sequence of things are in there.

Routine safety information is presented. We'd like to see more. The biggest problem is improving the visibility of these. Some models of equipment, you get the feeling they put it in the smallest way that is legally acceptable. The new IEC standard will correct this and have minimum legibility requirements.

Lockouts on this equipment we think are dangerous to the patient. You don't want a buzzer to go off 90 percent of the way through the procedure and the radiation to stop.

There are default imaging protocols. The maximum fluoroscopic dose rate is regulated, and you've heard this. This has been done for about 30 years. There's no regulation on acquisition modes. In fact, there's no dose reportings, I'll say in a minute, on even reporting what these

things can deliver. The net result is the total dose doing an interventional procedure is at the discretion of the operator. One of the goals of dose displays is to provide feedback to the operator, how much radiation has actually been used.

Available displays, the dose at the reference point, the kerma area product, the fluoroscopy time. At present, there is no commercially available way of mapping peak skin dose. We think that this will come in the next few years. I'm looking forward to it.

The radiation dose structured report, again this is a separate DICOM object that includes the dose data even without images. It's constructed in a way that can stream realtime to allow third parties to develop dose mapping solutions.

The electronic dosimetry question, the radiation dose structured report will meet this. Early deployment actually starts late next year. The second edition of the 2-43 document will make this mandatory for all interventional fluoroscopes.

Policies are needed to maximize the deployment of this reporting and install equipment. I was very happy to hear the MITA intention to deploy this in CT equipment back into the install base this morning. I hope they're planning to do the same for interventional equipment.

IEC gives data in the user manual. Dose rate measurements are available. We think there's a need for increased reporting of maximum cine

and DSA rates. We need better outputs to do digital image quality.

New fluoroscopes should conform install base. We'd like to get it built up as much as possible.

How to get the people to pay attention, better instructions to the operators. Ultimately this is the responsibility under the present rules of the professional organizations, state health departments. Thank you.

(Applause.)

CDR BOYD: Our next speaker is Paul Johnson.

MR. JOHNSON: First of all, I'd like to say thank you to the FDA for giving us this opportunity. Very excellent talks from the previous speakers, very good points.

Our talk today from the Cleveland Clinic perspective was an open discussion with our clinicians and staff, what would help them do their job more efficiently and manage radiation exposure?

I'm a board certified diagnostic imaging physicist and a health physicist. So I have perspective on both sides. The safety part is very important to the workers. So it's a whole big picture of radiation exposure management. So giving that perspective, I'll go through a little bit about the scope of utilization of fluoroscopic equipment at the Cleveland Clinic, some of our topics we had with the interventionalists and staff, and then proposals to manufacturers to possibly enhance the safety features that are already present.

The Cleveland Clinic system operates approximately 165 fluoroscopy units across 12 hospitals and 20 regional health facilities. The Clinic operates approximately 65 interventional cardiovascular labs performing state of the art, minimally invasive endovascular procedures. We've come a long way in the procedures that are being performed for our patients, and ultimately, that's what we're doing. So these are really some of the most impressive type of procedures that can be done to repair critical pathology.

The equipment in use represents a broad range of clinical use at the clinic and represents all major manufacturers. The operators are privileged on the basis of vetted formal education, post-graduate training, and on-site radiation safety training. The equipment and operators are continuously monitored for radiation output and exposure compliance.

At the Cleveland Clinic, we're lucky enough to have some of the most state-of-the-art equipment out there for doing these procedures, and the equipment records cumulative doses per case in the DICOM file format. The cumulative dose per case is recorded in the formal physician report of the procedure, but the regional dose or organ-specific dose is not recorded. So, regionally, we don't know where the exposure occurred.

Current warning systems for contemporary units presently occur at regular timed intervals of fluoroscopy exposure time. The warnings are not triggered in the unit when the radiation exposure exceeds a reference

level, and flexibility of exposures may be warranted on the basis of presenting clinical problem or body habitus. So that's an important part for a clinician has to have the flexibility to do his job because you don't know what you're going to run up against sometimes. That's pretty much a given.

So as one of the speakers prior to me coming up here indicated, you don't want to have a stop on the procedure. You want to have informed information getting to the clinician.

Manufacturers should provide for limited access password control to establish and log base protocols, and that's important, not to get too technical, but setting pulse modes and that, and I as a physicist, I can come in there and do my annual checks, change different pulse settings and that, and if it doesn't go back to a predetermined setting, you may find out later in the case, for pediatrics especially, I'm sensitive to children myself, but for any of us, adult size patients. So we should have some kind of protection on the base protocols.

There's currently no universal radiation exposure tracking system to inform the ordering clinician or interventional clinician about the history of medical radiation exposure for the patient and/or body part. Because there is a radiation effect that lingers a while with these long dose procedures, it would be a good thing to know for the ordering clinician and/or interventionalist to know that.

Our proposals would be that manufacturers should provide

radiation exposure management software to do the following: provide for configurable reference levels for specific anatomic region based on site specific or an FDA dose registry for kerma. These wouldn't be stop levels, but they would provide the operator warning with realtime, graphical feedback when radiation exposures or doses are going to exceed a reference level.

Manufacturers should provide limited access control mechanisms for creation of routine fluoroscopy exposure protocols, and manufacturers should provide a limited access control mechanism for enabling x-ray production in current, if possible, and future fluoroscopy units. When these machines are left on, and I get the test over my lunch break or everybody else's lunch break, there's an enable button or disable for radiation generation. Anybody with access to that area can turn it on. So there should be some kind of passcode, once you disable it, to re-enable x-rays.

Consolidated exposure dose reporting for stochastic, which if any of you were here this morning, that's a long way off I think, but the deterministic effects should be recorded within the EMR. Systems able to mine the data related to medical radiation exposure history should be provided. Ideally, this would provide same reference levels for specific anatomic regions as applied imaging modalities.

So, in summary, I'd like to see that we provide for a configurable anatomic reference exposure level, and probably one of the most important applications we would like to see would be to provide

realtime graphical warnings when reference exposure levels are exceeded, provided limited access control mechanisms for creation of routine exposure protocols, password protect x-ray production, and support radiation exposure dose tracking within the EMR. Thank you.

(Applause.)

CDR BOYD: Our next speaker is Phil Rausch.

MR. RAUCH: Good afternoon. I'm happy to represent the AAPM to give a physicist's perspective of some of the issues, especially with the equipment in interventional radiology.

So if we're going to have an impact on dose and interventional radiology, we need to change our thinking. So a new paradigm would require that when we start a study protocol, that we actually have it optimized for a particular study, the clinical procedure, and also for a particular patient size, and these might be as simple as pediatric, adult, and morbidly obese, or they might be broken down into smaller categories.

We need to select a kV and a filtration so as to optimize the ratio of the image contrast and noise squared and then divide that by the patient entrance. So we optimize that ratio, and then we're basically getting the best image for the dose that we do deliver. It has been shown in the literature that this ratio is actually independent of the detector dose. So then we can now modify the detector dose and optimize that for the particular clinical needs, and those might change depending upon the experience of the

radiologist and the particular study.

And then we can provide the operator with options for adjusting the detector exposure or maybe even pixel binning so that we can change the examination and change the dose for the particular parts. There may be parts where you need a good higher or lower noise level. Others, maybe you can tolerate more noise.

And then for pulse fluoroscopy, we need to automatically adjust the detector input dose per frame according to the affrictive seal, and I don't have time to get into that, but those that are in intervention will know exactly what I mean.

Now, study protocol, so we need documentation that clearly defines the design of a given study protocol and specifies precisely what procedure and patient type are intended to be imaged with that protocol. This is not currently available. In fact, generally there's just categories like cardiac, head, abdomen, ablation. So it takes a medical physicist to come in with a dosimeter, and actually you take some different phantoms and determine what the doses are, and when they do that, then they can compare those with reference levels, in this case the horizontal line is a Michigan reference level for fluoroscopy, and we find that for the most part, as long as we're under a lower SID, in this case, the data was at 92, we're pretty much under the reference levels for most of the procedures, but we do see some spikes. And so when we examine what was the nature of those spikes, we

find that those were specific modes that were pulse fluoroscopy at 15 pulses per second and 10 pulses per second, and then when we look at that for the 30 pulse per second in the same category, it turns out those are higher. So the operator who has gone to the fluoroscopy training class, and all of them have, and they hear the words pulse fluoroscopy and they hear the words low dose rate or low pulse rate fluoroscopy to a lower dose, they may tend to want to choose those 10 pulse per second or 15 pulse per second and, in fact, they're going to wind up with much higher doses.

And this particular vendor automatically removed some of the spectral filtration, in fact, a majority of it, as soon as the SID is above 97 SID, and that's regardless of the patient size.

Also a medical physicist needs to come in and actually look at it for different thicknesses. So in doing that, we've got a whole bunch of study protocols, and these are actually generator operating curves that are listed on the right side, and we take a particular one that has low doses for the 4 inches and 6 inches of acrylic. So we might say, as Keith alluded, that we want to try to optimize for pediatric the dose, and this is not image quality yet. We want to make sure the image quality is appropriate, but for dose purposes, that protocol tends to give us really low doses for these two attenuator thicknesses, but we can't assume that that protocol is also going to give us low doses for adults. For the 8 inches and 10 inches, these actually give approximately the highest dose levels.

So is this true? We have a lot of flat panel imagers now out in the market. Flat panel imagers lower dose when compared with x-ray imagers insofar as for the same study protocol and patient type. So answer this for yourself based upon what you know, what you've measured, or what you've seen in the literature.

For the most part, the vendors say the reality is that the flat panel detectors, the DQE drops precipitously as you approach the fluoroscopic levels that you would normally use with an image intensifier. So around 1 micro or 8 to .8 nanogray, you would still use that for an image intensifier in many fluoro situations, maybe double that for angio, but you can't do that with a flat panel. In fact, you need about anywhere from two to maybe four times that value at the detector.

So why are vendors making that claim, and why is some of the literature saying that? Well, it turns out along with the flat panel, they introduced the spectral filtrations up to as much as a millimeter of copper, and that is really what is lowering the dose, not the use of the flat panel detector itself. We need to understand these things.

Now, dose obviously is important for keeping the noise down, but maybe there's other things we can do to lower the perception of noise. So there's been some work done in terms of image processing to remove the effects of noise, but we have to remember, we can't ignore the detail that might be present, and we also can't impact the temporal fidelity of the study.

What about pixel binning? It's already used with the large format interventional angio machines. In the largest format, they do at least a 2 by 2 pixel bin. Some of them actually do larger than that, and that improves the contrast to noise and actually allows about a 50 percent lowering of the dose to the detector. But can this be used as a means of lowering the dose rate, for instance, for morbidly obese patients, that is a user selectable binning mode, 2 by 2, 3 by 3, maybe more, for really any field of view, not just the largest format.

You will get a loss of resolution, but contrast to noise trumps resolution, and this is actually intended to be a dynamic because fluoroscopy is dynamic and any single frame of fluoroscopy is going to be more noisy, but clearly what we're seeing is that these wires are really more readily seen even with the 200 micron pixel pitch detector because of the better contrast to noise.

Dose reporting, FDA requires accumulated air kerma value, but it's not required to be saved. So it may actually be automatically deleted after the study is closed. We have one cardiovascular system two years old that does exactly that.

Dose archiving is not currently required. So it is mostly nonexistent. A wide variation of reported information is provided by vendors, and there is a need to be able to export a dose report to a retrievable document so that you can actually start accumulating data. You must provide

sufficient information to reconstruct the exposure conditions because sometimes you take the air kerma value, now you want to know what the skin dose was. Dose reporting and archiving must be mandatory in order to distribute the development costs and lower costs to the individual users. Otherwise, nobody's going to buy it.

Now, here's a dose report that actually has quite a bit of information, but still there's glitches. If you look at the top, there was 18 frames for this particular DSA run, but there was no dose reporting. That's actually just a glitch in the system. The runs are numbered, but what happened to run 12 and 18? It looks like maybe they're missing. In reality, they were fluoro loops that were saved, and the fluoro is not individually reported, only accumulated.

But what is reported is the study protocol type, the name, in other words, the run time, the frame rate, the image plane that was used, the generator settings, the spectral filtration, the field of view, the cap, the air kerma, and the beam angulations. All of these are provided, almost enough to reproduce the dose if you want to make a measurement, but you have to have a few more pieces of information, but what you do get is the accumulated cap and the accumulated air kerma, and these are valuable. These are not the skin dose, however. The accumulated cap and the accumulated air kerma are actually given for fluoroscopy separately, and then the total fluoroscopy plus all of the acquisition runs as a total. So you have to

subtract the fluoroscopy to get the acquisition total.

This also gives the ability to annotate. So the doctors can actually put in the contrast that was utilized for the study.

This report, however, is the exception, not the rule. Okay. The reported air kerma is not the patient's skin dose. So if, in fact, there's going to be this national registry for dose, air kerma is not dose. It's not dose to skin. It's actually dose to air. The report tracks air kerma to a reference point in space, and that may not be the actual location of the skin. It does not account for back scatter. It does not account for table and mattress attenuation and does not account for changes in the radiated skin as the C-arm is angulated.

Missing from the dose report, the source to table distance. Now, Libby said maybe we need a ruler, maybe it should just be automatic. Tell us where the table is, and we know the patient's on the table. What about the lateral plane? Well, if we get the source to the center of the table, then we can measure the patient before the study and adjust for that.

Presence or absence of grid is not reported. Accounting for the table mattress attenuation, which I am surprised, I actually heard this from Steve, and I had to make my own measurements, but between 24 percent and 40 percent of the beam is attenuated, mostly by the mattress.

Pulse setting, this is a label issue. I have machines that actually have the continuos fluoro, and then they have a "pulse mode." Now, again

we teach in our classes, use pulse fluoroscopy. So they see the fluoroscopy is continuous, then they see pulse, and they start engaging that, and it turns out that particular setting is not pulse fluoroscopy at all. It's pulsed acquisition at a higher dose.

I thank you for your time, and I look forward to the rest of the talks.

(Applause.)

CDR BOYD: Our next speaker is Dr. Michael Pentecost.

DR. PENTECOST: Still no slides.

CDR BOYD: Still no slides.

DR. PENTECOST: It's nice to see everybody again this afternoon. Once again, I'm from Magellan Health, National Imaging Associates, a radiology benefits management firm where I'm a senior medical officer.

I had the great pleasure in 1996 of being the president of the Society of Interventional Radiology, and in that capacity, one of my most interesting exchanges was with the Food and Drug Administration because, as many of you know, in that era was the first recognition of skin burns from interventional devices, and as the leader of organized interventional radiology, I had to deal with some very frank exchanges, to say the least, with the FDA. But that was a long time ago.

Today, what I want to talk about is to give our vote of support

to issue number 7, answer number 7, which is basically about a seamless transfer of radiation dose information into the electronic medical record, electronic health record, whatever databases you're using, and to emphasize that radiation, be it diagnostic imaging or interventional, is pretty much the same to the patient, and I want to make sure that we're not falling into the trap of maybe balkanizing this information, thinking that what's important to me or to us as interventional radiologists may not be important in diagnostic imaging and vice versa.

As I mentioned earlier today, we have an accumulator function in the 19 million patients that we oversee the practice of radiology in, and that accumulates average dose per advanced imaging procedure, myocardial perfusion, CT, et cetera. That's Column A. However many number of scans you have is Column B, and the product, of course, is the two of those together, and we use those in realtime, 450,000 times a month, to fashion what we think is appropriate utilization of imaging studies, and in our accumulator function, we can store the data from interventional procedures. It is just as important to a patient that we have the information that you're generating from these dose reports from interventional procedures so that we can make informed decision making about diagnostic imaging also. You probably didn't know, I didn't know, until last August that the number one cause of diagnostic radiation in the United States is myocardial perfusion nuclear medicine studies, about 21 percent of the radiation. That, too,

because of the different specialization of cardiology and radiology, could fall victim to this balkanization or separation. We're accumulating this information in the medical record, whatever the source, with the expectation that it will inform intelligent decision making, and I hope you will support it, I hope the FDA will support making sure that everybody who touches that medical record who is interested in irradiation, regardless of the source of it, will have fast and quick access to this information. Thanks a lot.

(Applause.)

CDR BOYD: And Dr. Hiatt.

DR. HIATT: Good afternoon. I'd like to thank all the speakers thus far. You know, I've really enjoyed hearing these excellent insights. They've really newly invigorated me in our common pursuit to provide the best care for patients, for American patients across the nation.

My name is Mark Hiatt. I'm a radiologist, and I'm also chief medical officer for a company called HealthHelp. HealthHelp is a specialty benefits management company. We oversee proper utilization such that patients across the nation get the right tests at the right time such that their exposure to unnecessary radiation is limited.

I thank the FDA in particular for this chance to share my company's experience in using appropriateness criteria, which the FDA may wish to consider or incorporate as an effective means to limit radiation, and this I believe is really low lying fruit.

What I'll do is cover two aspects in the next six hours, I mean six minutes, because there's really a lot of material here to cover. But just briefly, first, I'll share with you the need for criteria, and second, I'll discuss how to use such criteria.

First, with respect to the need for criteria, HealthHelp has found that often in radiology, paradoxically less is more, that is by getting the test right the first time, you spare the whole rigmarole of going through an abundance of various unnecessary, not as optimal tests along the way towards definitive diagnosis, and what you do by getting the test right the first time is you attain an answer more quickly, the right answer, sparing the patient the unnecessary sidesteps of being subjected to inappropriate tests. Less is more.

I'd like to describe some of these undesirable sidesteps. Of course, there is the major misstep of being exposed to radiation that you didn't even need to be exposed to because the test was utterly unnecessary or inappropriate. Other trip-ups include the inconvenience of patients having to schedule time away from work, or away from family and friends, to get that procedure. The cascade of unnecessary interventions that ensue, the false/positive results and the test that was even unnecessary in the first place, and then to add insult to injury, there's the sidestep or the misstep of then having to pay the copayment for that test which wasn't even indicated. Criteria are needed as a safety net to catch the fishy requests for

inappropriate or unnecessary exams.

Now, second, I'd like to cover some of the key essential factors which are needed to achieve success in implementing these criteria. There are three keys which we have found to be essential in developing and implementing needed criteria. These keys arise from HealthHelp's collaboration with one of our major clients, Humana, which, of course, is one of the nation's largest health insurance plans covering the supplemental and health benefits for millions of Americans across the nation.

Humana's laudable concern for radiation exposure began really half a decade ago, and what I'm sharing with you is that result of years of collaboration in which we spared patients the equivalent of millions and millions of chest x-rays by reducing the number of unnecessary CT and nuclear medicine studies.

Now, the success of the stepping lightly along the straight and narrow path of appropriate imaging utilization without stumbling or stomping too heavily upon that fluoroscopy pedal may be attributed to three keys, which I touched kind of briefly this morning, but what applies to CT may also be said for fluoroscopy.

Number one, the appropriateness criteria used has to make sense, achieved by relying on the guidelines of professional organizations such as the American College of Radiology, of course, on the latest medical literature as well as on expert opinion. If you have good rules that make

sense, you'll have good results.

Key number two, the means of implementing these criteria must make sense, achieved through wide-scale buy-in from those who are participants. I can only account or recount to you our experience, and this is probably much harder to achieve than key number one. The way we try to achieve buy-in is employing peer-to-peer consultations using subspecialist radiologists from academic institutions with a high level of credibility to consult with the ordering providers to really give them the guidance they need and that they can trust in. For example, we use neuroradiologists to converse with neurosurgeons, and to me this is really intuitive. It makes sense. It's not really brain surgery. We're able to make the process work because there's that buy-in. So good rules work best when they're wisely implemented.

And, finally, I'd like to leave you, well ahead of the six hours, the third factor, and that is the means of perpetually improving the process must make sense, achieved by commonsense incorporation of valuable feedback from the participants, both the providers and the consultants, as well as continual consideration of the latest literature and guidelines, and I'm sure you all will agree that radiology is an incredibly dynamic discipline. So much is happening. It's such a fast pace that there needs to be this continual updating. At HealthHelp, we do this quarterly. This may be an obstacle to the FDA's implementation of any type of appropriateness criteria as these things

will have to be updated, of course, on a regular basis. Good rules wisely implemented must be appropriately updated in a timely manner to reflect evolving technology. And this is, as I said, a grand task for the FDA to consider as it considers using appropriateness criteria.

HealthHelp has found that these three keys are invaluable in implementing evidence-based appropriateness criteria to reduce unnecessary radiation from unnecessary tests.

Reducing radiation by limiting unnecessary and inappropriate studies can save lives, and I appreciate this opportunity to share with you some of these insights. Thank you.

(Applause.)

CDR BOYD: Dr. David Lewis is our next speaker. Dr. Lewis must not be here.

Next on the agenda will be Dr. David Gauntt.

DR. GAUNTT: I'd like to thank the FDA for this opportunity to speak on anti-scatter grids in dose reduction. I'm a medical physicist working at X-Ray Imaging Innovations with Dr. Gary Barnes, and I'm an adjunct professor at UAB Hospital in Birmingham, Alabama.

First, I wanted to do a little bit of rad physics 101. This is a schematic diagram of a typical fluoroscopy system. As you all know, radiation from the x-ray tube passes through the exam table that passes through the patient to produce an image that's read by the image detector.

There are three interactions that can occur anytime radiation passes through the patient. First of all, you'll get the primary information. It's transmitted straight from the x-ray tube through the patient and interacts with the image detector. And then, of course, you'll get the absorbed radiation that will stop in the patient and cast a shadow on the image detector, and it's the difference between these processes that gives you the clinical image. Then there, of course, is a third process, scattered radiation which radiation can scatter off the patient into a new direction. This radiation will produce a diffuse fog on the image that will tend to reduce the image quality.

It's widely known that the effective scatter in the image can be profound. This radiographic image was taken with no effort to reduce the scatter in the image. Under the spinal column, as much as 90 percent of the radiation striking the image detector may be scattered radiation and not have any clinical value.

The image of the same patient, on the right, was taken at the same patient dose but with most of the scatter removed from the x-ray beam. The visualization of subtle structures, especially around the spinal column, is vastly improved when scatter is removed.

But why is scatter important in a discussion of radiation dose? The answer is noise. These are stationary radiographic images taken at a much higher dose level than you get with a typical fluoroscopic frame. They

are therefore a lot less noisy than fluoroscopic images.

I simulated the look of a high dose fluoroscopic image by adding some noise. Now, we'll start to add increasing amounts of noise, simulating the effect of reducing the radiation dose. First we drop the dose per frame by a factor of 2, and then another factor of 2. Now, drop the dose in both of these images to 25 percent of that original fluoro dose value. All the details of the heart and the spine have disappeared in the high scatter image but remain visible in the low scatter image.

When the operator, whether a radiologist or cardiologist, is presented with the image on the left, he'll be forced to increase the radiation dose rate in order to see any details. In other words, with high scatter images, the operator is forced to choose between increasing the x-ray dose rate to the patient to improve image quality or accept lower quality images that may lengthen the time to perform a procedure. Either approach will result in an increased radiation dose to the patient.

This effect is best demonstrated with these images. The low dose image on the right is clearly noisier than the full dose image on the left, but because of the higher contrast due to better scatter control, structures around the heart and the spinal column are much more visible.

For 70 years, the most widely used technique to reduce scatter has been the anti-scatter grid. The device can be thought of as a set of venetian blinds made of lead separated by spacers made of aluminum or

carbon fiber. Primary x-rays traveling straight from the tube through the patient will pass through the anti-scatter grid at the right angle to be able to pass through and contribute to the image.

Scattered radiation, however, hits the anti-scatter grid at the wrong angle to pass through and is absorbed and is thus removed from the image. This is not a perfect process. With any real grid, some of the primary radiation is absorbed and some of the scattered radiation will get through.

This brings us to what I call the perfect storm of scatter. It's well known there's been an epidemic of obesity in the United States. X-ray beams passing through obese patients have more scatter with less contrast than thinner patients. Similarly, less primary radiation is transmitted through the heavier patients. We get higher noise in the image.

We're also seeing increasing use of high resolution digital detectors which are wonderful devices, but they are more sensitive to scattered radiation than image intensifiers. And also if you use an old style grid with these detectors, the -- of visible and cast shadows on the detector. So we are using finer grids that do a poorer job of removing scatter.

So with x-ray beams containing increased scatter and increased noise, and anti-scatter grids are doing a poorer job of removing the scatter, radiologists are forced to use higher and higher radiation doses in order to see image structures. We therefore need better grids in order to produce acceptable images at lower dose rates.

What precisely do I mean by a better grid? This would not be a physics talk without at least one equation, and here it is. In 1977, Dr. Robert Wagner of the BRH, the predecessor to the CDRH, developed a quantity to evaluate the dose efficiency of anti-scatter grids. This quantity, the DQE, compares the radiation dose required to achieve a given image quality using a given grid for a given patient. The radiation dose would get the same image quality on the same patient using an ideal grid, that is a grid that passes no scatter but passes all the primary radiation.

The grid DQE is a measure of dose efficiency. If you double the grid DQE, you can cut the dose by half and get the same image quality.

In X-Ray Innovations, we've used a Monte Carlo model to calculate DQEs or grids commonly used in fluoroscopy and compared them to the grid DQE for an ideal grid on the right and for no grid at all on the left. It was done from models of a fairly trim adult and for a medium weight adult. The results are remarkable. The dose efficiencies of these commonly used grids are approximately 25 percent for a medium adult and lower for an obese adult. It would be lower for an obese adult. These are significant improvements over the DQE when no grid is used, but as you can compare this to an ideal grid, there is a large room for improvement.

We believe it should be possible to develop innovative grid designs that can double the dose efficiency from medium to large patients to allow operators to lower the x-ray dose rate by a factor of 2 without loss of

image quality or give the operator better images of the same dose rate, allowing them to finish the procedures in less time. Either approach results in lower radiation dose to the patient.

In summary, I'd like to reiterate that poor control of scatter using existing grids forces the operator to increase dose to the patient during exams. The dose efficiency of current grids is only about 25 percent, and a factor of 2 improvement in dose efficiency of the grid would allow a significant reduction in fluoroscopic x-ray dose, and according to our research, it may be possible to build practical grids that do this and would give possibly even better than a factor of 2 improvement in obese patients. Thank you for your attention.

(Applause.)

CDR BOYD: Our next speaker is Andrew Fay.

MR. FAY: Thanks to the FDA and for the opportunity to speak today regarding x-ray detector considerations for reducing unnecessary radiation exposure from medical imaging.

My name is Andrew Fay. I'm with Thales, and we manufacture x-ray detectors. Since 1960, we have delivered to our customers more than, actually it's closer to 200,000 x-ray image intensifiers, and since the advent of the flat panel, we have delivered about 24,000 detectors.

So today I'm just going to touch on some of the criteria that's important when you talk about the component selection when low dose is

your ultimate goal. I'm going to go into the typical x-ray detector technology. I'll talk about detector quantum efficiency, scintillators, modulation transfer function, and noise equivalent dose. Some of this I'm sure is a refresher to you and going back to your training days, but I think it's well worth spending five minutes today.

So these are the two typical electrated detector technologies on the left, the x-ray image intensifier, and the right, the x-ray flat panel detector. As you can see, they both use a scintillator layer; both in this case are using a cesium iodide scintillator. The scintillator converts the x-ray photon to light photons. Those are converted through a photocathode from light photons to electrons. In the case of the x-ray image intensifier, the electrons are focused onto an output window, which is a phosphor coated glass similar to your cathode ray tube at home, and the electrons are exciting the phosphor. They emit light and are focused through a lens onto a digital capture device, which in this case is typically a CCD camera. Those cameras are typically 1 K by 1 K resolution with 12-bit depth.

On the flat panel side, you have the scintillator as well converting onto a photodiode, onto a glass TFT substrate, and then the signal is read out through the integrated circuits.

Both these technologies, which we've been working with, similarly optimize, will require careful consideration for all the components in the digital conversion chain.

So I tried to take a sort of visual approach to things here, looking at DQE or detective quantum efficiency. The higher the DQE detector will result in a better signal to noise at the same dose level, or it will require a less dose for an equivalent signal to noise ratio. So as you can see on the left here is a detector of 5 percent DQE, in the middle 40 percent, and on the right 70 percent. All other things being equal, you can see the benefit here. It might be a little on these projectors, but there's a clear benefit to the increased DQE, as you can imagine.

So the detector design factors to obtain this high DQE, they have to have a high absorption of the x-rays, and that's achieved through scintillator technology and your choice of scintillator. The high conversion rate of the x-rays into electrons, and that's done through a combination of the scintillator and your TFT flat panel detector, and thirdly, you need to have a low electronic readout noise so that you're not introducing any additional noise into the image, and that's achieved through high design drivers and readout electronics.

This is a graph of several different brands of detectors done by an independent study, but you can see that even when you look across the board, there's a great variation in the DQE performance of detectors. So this is really something that should be considered as you look for low dose performance.

If we look now to the scintillators, which is a key component to

the DQE, on the left is the image intensifier. As I mentioned, the image intensifier utilizes the cesium iodide needles passing through an aluminum window. The one x-ray photon produces 1,000 photons of light out of the cesium iodide, and then it is focused, passes through the photocathode, becoming 400 electrons and hitting the phosphor stimulating plate output window, producing 400,000 light photons available to your CCD camera. Of course, some of that is lost in the optics and so forth.

If you look at the scintillators for the flat panel detectors, these are just a couple of them. There are many in development, but there's cesium iodide, Gadox, and there's also the so-called direct conversion selenium detectors, each with various steps in the process.

If we just look, for example, at the Gadox detector or Gadox scintillator versus cesium iodide detector, the Gadox scintillator is a pressed powered type of scintillator, and you can see that the x-rays excite these scintillator in many directions, whereas the cesium iodide will focus the output directly onto your output electronics.

So in most cases, the Gadox scintillator can require up to two times or three times the dose for the same image quality as a cesium iodide detector. Gadox is generally not used in fluoroscopic systems. However, it is used in many digital radiography systems.

We look at modulation transfer function. Again, trying to give a visual here, the spatial modulation transfer function is kind of a measurement

of your spatial resolution, and that is achieved through the complete MTF of your x-ray conversion layer, not just your scintillator but how your scintillator is coupled to your photodiodes and the sandwich makeup of your detector. It's also a function of the pixel size. So as you can see, as we move from left to right, again the improvement in MTF has a dramatic impact on the image quality.

Noise equivalent dose, this is an important measurement. It gives the dose. It is the dose giving a quantum noise equivalent to the electronic noise. So this is really -- you have the two noises competing in a flat panel detector, one being the quantum noise and the other being the electronic noise. This measurement or this technique of measurement is good to show you the amount of noise that your detector will introduce at low dose. The image quality, the images at doses below the noise equivalent dose will be limited by the detector electronic noise while the image, quality of images at doses above the NED will be eliminated by the -- quantum noise. NED is one of the figures of merit of the detector, but it is not the only one, and one should also look at actual signal to noise and contrast to noise provided by a given detector at a dose equal to the NED in order to compare real performance of images at low dose.

So, in conclusion, what we can say is that the x-ray image intensifier and the flat panel detector have similar performance across typical dose ranges of fluoroscopy. X-ray flat panel detectors have distinct

advantages in anatomical coverage and reduced distortions. We can also say noise equivalent dose is a technique that is important in measuring and comparing detectors for your low dose performance, and careful scintillator selection is the critical important first step to ensure low dose detectability of x-ray systems. Cesium iodide allows for the reduction of dose by a factor of 2 to 3 in this area over Gadox. Thank you.

(Applause.)

CDR BOYD: Our next speaker is Edward Solomon.

MR. SOLOMON: Good afternoon. I'm Ed Solomon. I'm the chief technical officer of NovaRay Medical, and I will be describing a new x-ray source and detector that we have developed specifically for low dose fluoroscopy. I will also be presenting independent test results obtained by Dr. Mike Speidel at the University of Wisconsin-Madison.

This is the first production system incorporating the new source and detector on a standard looking C-arm. It will be installed at the end of the year. The results that I will be presenting today were obtained on an earlier prototype.

We call the new technology inverse geometry. Instead of a point x-ray source and a large area detector, the inverse geometry system has a large area scanning x-ray source and a small area detector. From each location on the x-ray source, a narrow beam of x-rays is produced that passes through the patient and is received on the smaller area detector array. As the

x-ray source scans in two dimensions, we collect a series of small field of view overlapping images that we combine electronically to produce the full field of view image. The source scans the entire field of view in a 30th of a second, and we reconstruct the full image in realtime with low latency.

The scanning x-ray source operates in a similar way to a cathode ray tube TV. An electron beam in vacuum is steered from the outside using electromagnets. The transmission target is stationary, and the electron beam is positioned sequentially behind each collimator hole. The fixed collimator allows only those x-ray photons that are headed towards the detector to emerge. Heat is removed by a cooling liquid that flows directly behind the target.

Here is a photo and specifications of the scanning x-ray source. It operates at typical diagnostic energies, 70 to 120 kVp. It has a 23 by 23 centimeter scan area that gives the system the same field of view as a typical cardiac system with a 20 by 20 centimeter flat panel detector.

The direct conversion detector uses a cadmium telluride tile flip-chip bonded to a custom IC. The detector operates in photon counting mode. When a single x-ray photon is absorbed in the cadmium telluride material, approximately 10,000 electron-hole pairs are generated. A bias field across the tile drives the electrons towards the individual charge amplifiers on the integrated circuit, and the packet of charge is registered as a single photon.

Because the bias field prevents the electrons from spreading or blurring, the cadmium telluride material has been made 2 millimeters thick to maintain high DQE even at higher diagnostic energies. Photon counting detectors have zero background electronic noise, and so a high DQE is also maintained at the low exposure levels used in fluoro mode.

One of the big advantages of inverse geometry is its low detected scatter. Scattered radiation that reaches the detector adds noise and degrades the signal to noise ratio. This increases the amount of patient radiation required to produce a particular image quality.

In a conventional system with a large area detector close to the patient's chest, a significant amount of the scattered radiation reaches the detector. Even with an anti-scatter grid in front of the detector, there's typically as much scatter as primary or image-bearing radiation at the detector. A 50 percent scatter fraction is typical for normal size patients, and large patients can have significantly higher scatter fractions.

In the inverse geometry system, the detector is small and a long way away from the patient. Since scatter is emitted from the patient in all random directions, the detected scatter is low. An anti-scatter grid is therefore not necessary, and the measured scattered fraction is typically just a few percent.

In a conventional system with the point x-ray source, the radiation is concentrated where it enters the patient's skin. The inverse

geometry system has a distributed x-ray source so that the radiation is diffused at the patient entrance.

There are four main factors that contribute to lowering patient exposure in an inverse geometry system. Minimizing detected scatter, getting rid of the anti-scatter grid and its associated primary transmission loss, a high DQE detector, and spreading the entrance radiation over a large area.

These results were obtained by comparing the inverse geometry system to a well-optimized and calibrated Philips H5000 system that uses an image intensifier and CCD camera. The University of Wisconsin group chose that system so that it could access raw data to be sure they were evaluating the underlying damaging physics rather than any image processing algorithms. The unprocessed data is typically not available from amorphous silicon flat panel detectors.

The two systems were compared at their diagnostic image quality level. Both systems were operated at the same kVp. The chart shows the relative exposure reduction factors between the two systems measured over a range of phantom thicknesses. You will see that kVp increases from 72 kV for a 23-centimeter thick phantom to 120 kV for a 35-centimeter thick phantom. The DQE of the conventional detector decreases with increasing kVp due to the relatively thin cesium iodide scintillator layer. This is necessary to limit optical blurring in that detector. A flat panel detector has the same thin cesium iodide scintillator layer and the same falloff in DQE with

increasing kVp.

The scatter fraction in the conventional system increases significantly with increasing phantom thickness and also with increasing kVp. The relative entrance areas for the two systems varies slightly as a function of phantom thickness and is approximately a factor of 2. The predicted total exposure reduction factor is the product of all four factors.

The contrast to noise ratio of both systems was directly measured using an iodine contrast phantom and by measuring the background noise and the images. The entrance exposure was also directly measured.

These two curves show the close match between the directly measured exposure reduction factor as compared to what is predicted by the combination of the four contributing exposure reduction factors. The exposure reduction of the inverse geometry system varied from about one-third to about one-sixth of the radiation exposure of the conventional system as phantom thickness increased.

The University of Wisconsin group also compared image quality and radiation exposure in a series of direct clinical comparisons. A movable version of the inverse geometry system was brought into the existing cath lab so that patients could be imaged with both systems. Here is an example of the type of same patient, same projection angle comparison images that they obtained. These angiograms were rated as having equivalent image quality by

interventional cardiologists. The inverse geometry system has one-sixth the radiation exposure of the conventional system.

In summary, I have described a new x-ray source and detector and shown the significant radiation reduction advantages that these can have over conventional systems utilizing point x-ray sources and large area detectors. Thank you.

(Applause.)

CDR BOYD: Our next speaker is Tyson Rugenstein. Not here. Next Michael Harsh.

MR. HARSH: Good afternoon. I'd like to just start again by introducing myself. I'm Mike Harsh, vice president and chief technology officer for GE Healthcare. Again, you know, I just thought about it, it'll be 31 years I guess this week I'll be at GE Healthcare and GE, all involved in medical imaging and medical research, both at our corporate headquarters for GE Healthcare as well as our corporate research labs in Upstate New York. I've been involved in medical imaging since right after CT came out. I spent the first nine years designing x-ray systems, and I'm just happy to be here today to have a chance to talk to everybody.

I'm a member of the College of Fellows of AMBI and just wanted to start off a little bit and maybe talk a little bit about fluoroscopy. You know, this morning we talked about CT, and I think the quote I heard this morning is fluoroscopy is not CT. And so when I take a look at the differences

between fluoroscopy and CT, let me just start out by just summarizing a few of them right away.

Fluoroscopy is a realtime imaging modality. You know, it's done at a much lower instantaneous dose rate than the record imaging modes that you have with standard x-ray procedures. It's done in the direct control of the physician, and the imaging is very interactive, and it's based on the dynamics of what you're really trying to visualize. The length of the fluoroscopic exposure is extremely variable when you go back and you look at all the procedures, and it really is dependent on the physician and the patient's diagnostic complexity. So it is a very different thing, as everyone knows, when you look at the difference between fluoroscopy and CT.

So this afternoon, I'd like to just take a few minutes and discuss some of the rest of the key questions that the FDA posed. First of all, I want to say that GE Healthcare is committed to the principle of ALARA. We're compliant to all the regulations. We conform to applicable standards, and we really work at advancement of dose reducing technologies, and we see standardization again as a key enabler in our effort to deliver clinical value and patient safety.

Now, fluoroscopic devices are designed, manufactured, and certified, 21 C.F.R., IEC, and other applicable requirements and standards intended to control exposures and minimize dose.

Now, GE Healthcare already manufactures hardware and

software features to aid users in reducing unnecessary exposure to radiation during each imaging exam.

Now, if you look at the x-ray systems, it's been regulated for decades. You know, examples under 21 C.F.R. Part J, you know, systems are limited to an AKR rate of 88 milligray per minute maximum. Systems default to an automatic exposure rate control, to drive the system to only the radiation levels needed for a particular imaging situation. You know, the automatic brightness control system has been around for quite a while, and it really optimizes the image based on a set of parameters. There's visual indicators for x-ray on. There's audible indicators for x-ray on. There's fluoro 5 minute timers. There's an audible alert when you have a high fluoroscopic exposure going on. There's dose displays. There's last image hold that's been incorporated throughout the years, and there's minimum filtration requirements for fluoroscopy.

Now, for decades, when I look back at what we have done, GE has been advancing technology that really reduces dose and increases image quality. You know, examples here would be x-ray field shaping. We're very precise about how we set the collimation and where do we set the exposure. We've really pioneered dose efficient digital detection, detectors with very high DQE going back to frankly the early '80s when we had started into this.

If I think back on my career back in the very early '80s, just after '79 when everyone jumped into DSA, you know, out came fluoro noise

reduction and digital fluoroscopy at the time. The whole concept of realtime digital image processing to really go after fluoro noise reduction really started back then.

Pulse fluoroscopy was a follow-on to that where we really optimized the photon utilization that we have in an image so that we made sure that when the x-rays were on, every x-ray that was generated made it to that final image and we read that detector at the appropriate point in time.

And then how did we manage the x-ray filtration so that we optimized the photon energy for the most efficient imaging that the system could have relative to this detection system and everything else?

You know, additionally if I think about it, we are committed to implementing the fluoroscopy DICOM dose SR structure in dose reporting for future product development. Now, DICOM fluoroscopy metrics and structure reporting have not yet been established for the industry. Adoption of a dose metric by a standard body such as IEC will be needed to move this one forward.

I would like to further address additional questions provided by the FDA for this meeting. With regard to question 5, we do not think that exam referral criteria to check for appropriateness belongs on the imaging equipment because physician decision support is most valuable prior to using the equipment. We support these decision-making steps but want it to be at the appropriate time in the decision-making process.

With regard to question 12, which was specific to changes that could be made to products on the market, GE Healthcare will evaluate technical feasibility of changes to devices currently on the market. We anticipate that we will be significantly limited due to technology challenges, such as system architectures, system memory limitations, as well as hardware and software capability and compatibility. When you go back and you look at the rich history of fluoroscopic imaging devices, you know, we've been making fluoroscopic devices since the 1930s. This would be just like trying to integrate autopilot into the Red Baron's biplane.

With regard to the FDA questions 9 and 10, on premarket submissions, GE Healthcare is working with MITA and other industry organizations to provide comments to the FDA to further define premarket submission content. GE Healthcare considers the following information to be relevant: technical data including information for users on dose and image performance, labeling information to include a list of all dose-related warnings and precautions in the user's manual on the system and user interface, and a list of product claims along with the associated substantiation documentation. Demonstration of dose reduction claims and image studies on appropriate phantoms should be provided for substantiation of claims associated with dose and image quality.

So, in closing, GE Healthcare, I want to say, is committed to the principle of ALARA. We're compliant with regulations. We conform to

applicable standards. We're going to continue to push and advance dose reducing technology, and again we see standardization as a key enabler in our efforts to deliver clinical value and patient safety.

With that, GE Healthcare would like to thank you for allowing us the opportunity to provide our comments to the FDA's questions today. Thank you.

(Applause.)

CDR BOYD: We do have another change in the order of speakers. Markus Lendl will be up next.

MR. LENDL: Good afternoon. I'm glad to be here and to have the opportunity to talk to this audience. My name is Markus Lendl. I'm speaking on behalf of MITA, representing the manufacturers, Siemens, Philips, Toshiba, Shimadzu, and GE. Together with my colleague, Sjirk Boon, we will fill the next three time slots.

This talk will have a large overlap to Dr. Balter's talk, but maybe we can give additional details in some slides. Starting with the question for hardware and software features that should be implemented, just as an overview, as manufacturers, we always follow the state of the art through the IEC standards, and we always try to integrate all the latest features that are proposed. The implementation of the DICOM dose structured report has already started. So some manufacturers are ready to add that feature.

The next IEC interventional standard is to be expected to

become mandatory by June 2012 in several states and nations, and this will require the DICOM structured report and other dose saving features.

Specifically addressing the pediatrics environment, there is a requirement for removal of the anti-scatter grids, additional prefiltration, and dedicated protocols. For female patients, there is no scientific ground for specific protocols.

So let's go into some details and discuss the history and what is usually implemented in today's equipment. So there is copper prefiltration or a prefiltration beam filtering of a 2.5 millimeter aluminum equivalent, dose displays at the working precision, last image hold feature, accurate collimation to the extent of the x-ray beam, and there are some features addressing occupational house. So there is a buzzer for x-ray and a visible warning, a red light, when x-ray is on.

Some other features for dose reduction, imaging processing can provide additional dose reduction. If there is a reduction in quantum noise by post-processing, we can reduce the initial dose. So this is an important feature. Additional spectral filtering up to .9 millimeter copper prefiltration. This is especially helpful for saving dose in pediatric environment. Limitation of the maximum entrance exposure rate, for example, for the U.S., we have a limitation on 88 milligray per minute with a possible override to a higher exposure rate to doubled value for fluoroscopy, and usually there is an audible warning that goes with that, with that higher dose rate, and also an

automatic fallback to the normal dose rate when a new patient is registered.

A temporary lockout when using continuous more than 10 minutes of fluoroscopy. So that's just a safety feature since there is no natural limitation on fluoroscopy, and this is limited to 10 minutes. So it's a worst case. Pause fluoro has a feature and retropositioning of the collimator plates. That means if you're moving the collimator plates, then there is a visible indicator where the collimator plate is to be expected when you release the next exposure.

In 2010, this year, there will be a new release of the IEC interventional standard. The number is given here, and this will come with some additional features and additional requirements addressing, for example, the minimum half value layer, the beam prefiltration, a brief audible signal when radiation is on, adjustable threshold for visible warning when there is an exceeding of preprogrammable threshold for the accumulated reference air kerma, removable anti-scatter grids for pediatrics is a must, storage of the last image hold, and additional filtration of 1 millimeter copper or equivalent for pediatrics. So an increase of copper prefiltration and, very importantly, the radiation dose structured report.

For non-interventional equipment, the list is much shorter. Basically the anti-scatter grid and the additional copper prefiltration, and just a note, there is no radiation dose structured report required.

But we are thinking ahead, and Dr. Balter already discussed the

NCRP report on fluoro guide interventions, and we will pick up some features that are addressed in that report. Display the peak skin dose, a regional skin dose. This makes possible that if there's already a high accumulated dose in a certain region, maybe the operator can change the angle and avoid skin burn. So this is a consequence of this regional dose display, and further on, the idea which was mentioned in that report, to trace and track the dose exposure over time. So let's assume there is a follow-up examination, then we can start with that regional dose distribution of the body and avoid skin burn for a second following examination or intervention.

The first speaker, Dr. Goldstein, already addressed ergonomics in the examination room, talking about that heavy lead apron. This is a topic we are working on, and we are communicating to several societies to provide protection for the operator.

That is basically a summary, starting with '94-'95 features that are implemented. This is basically implemented in every or most of the systems in the market. Then 2000, the first edition of the IEC interventional standard with the new features. Then the national requirements for the U.S. 2006, implementing a part of the 2000 standard. And 2010, the second edition of the IEC interventional standard with the features already addressed.

Let's move to question 12. What changes should manufacturers make to devices currently on the market? So basically what

can we do to provide dose reduction to the installed base?

It's important, first of all, that there is a continuous education of users of the installed base. So with every feature, there should be a training, and the user should get aware of it, how to use the new features and what are the changes to appropriately use the equipment, but that refers to tomorrow and will be discussed in detail.

Interventional equipment manufactured prior to 2006, so that was the date the U.S. regulation went active, which is presumably not compliant with that U.S. regulation shall be upgraded or replaced prior to June 2016. That is a recommendation. So there is a 10-year period. After 10 years, every single equipment should be able to have the new features, and it's similar with the latest features mentioned in the 2010 and older, of course, older standards, that features should be integrated into the equipment during a typical serviceable product lifecycle. So a lifecycle, until the service contract is finished. So it's usually 10 years or 12 years timeframe.

If the systems are not upgradable, then we would recommend a replacement which will support the manufacturers to do, to make some business.

Addressing the DICOM dose structured report, we looked up which of the older equipment can be upgraded pretty easily, and we came to the conclusion that there is around 2007 manufactured equipment can be upgraded pretty easily. So then the dose structured report, a very important

feature, is available even for the old equipment.

I want to thank you, the audience, and want to hand over to my colleague, Sjirk Boon.

(Applause.)

MR. BOON: So let's move onto the other questions. We will basically deal with all questions in view of time.

Question A2 was about incorporating access control specific on fluoroscopy equipment as well. There are some differences with interventional equipment mainly in the area that you always want to be able to do emergency uses in the middle of night. Doing, for example, a STEMI procedure wouldn't really be helpful if you're going to have to look for a user name and password to get into the system. So there should always be an override. But as of now, in order to help our customers to comply with HIPAA rules, there is already access control foreseen in current systems, although our practical experience is that for most sites, they choose to switch that off for the normal clinical users because of emergency reasons.

And then there are now specific tools to change protocols and to be able to change things, and those are typically limited by passwords or other access control means. And with respect to the audit capabilities, we think that by introducing DICOM structured reporting is sufficient to be able to audit which physician did which case with what amount of dose, and there's no other audit necessary for clinical users and for the service part.

That is something that is indeed logged per user.

So the levels then of users or regular user is basically that the clinical user, they can choose a specific protocol based on anatomy, patient type, patient size, et cetera, and they also have the freedom to choose different fluoro dose rates. So depending on what phase they are, are they in the beginning where they only have to position the catheter, or are they really at the phase where they do the intervention, and depending on that, vary the dose rate.

Then there's another group classified as super users which can do things like deleting images and change patient names. Administrator, so at certain sites, there's a preference that the local physicist or the local biomed engineer has responsibility to go into service modes as well, and that is possible after receiving training and certification, et cetera. Then there's a certain amount of changes which you can do, like limit the changes on filtration or frame, and then there's the real advanced access like being able to control kV/mA curves, milliseconds, et cetera, and the next one, air kerma rate which is variable in different countries, and that is something that is only allowed for people if they undergo proper training, service training. Okay. So this is our answer to question.

Question 3 is about the look out. Well, it has been discussed a number of times before that real look out is not a good idea in interventional system. And that's also in the new IC norm. We do think it's important to at

least alert the user that, for example, the general accepted threshold for skin burn is approaching, and indeed like Dr. Balter said, make it more bigger on the display instead of very small part so that it really is clear to the user that is going to occur.

Well, question 7 is about the recording of dose metrics. We think by introducing the DICOM structured dose reporting, that that is sufficient to do this. As soon as you have the dose area product and skin dose, then you can also put it in the electronic patient record. Some subtleties here are if you really want to do peak skin dose, then there needs to be more consensus also from the scientific community on how to do it and what kind of accuracy would be required for that, and then the question is, if you, for example, want to compare the CT scans that a patient underwent and the fluoro examinations and you need some common metric and then you get into difficult discussions, what are suitable units for that in order to compare CT radiation with fluoro radiation? So there is basically waiting on consensus from the scientific community, and as soon as it's there, then it can be incorporated into the DICOM structured reporting as well.

Question A4 is about the diagnostic reference levels. So, yes, they are mainly targeted at diagnostic procedures because they have less standard deviation and more predictability. In intervention, it's very much dependent on factors that are outside scope of the imaging manufacturer. It's about case complexity, patient anatomy, disease state, but we do think it's

important that while doing the case, the user can have some kind of visual feedback on how he relates to what is a commonly accepted dose reference level, and we see also in a lot of countries development of dose reference level standards.

So what we propose then is that we just make room in our system where the users can put in their own reference values, and it can be like local standards of base -- experience or national or even international, all based on literature. So basically as a manufacturer, we don't determine what the dose reference level is, but we do think it's important that you see it displayed while doing the case and getting reminded if you are at 50 percent or already above the dose reference level.

This illustrates why it's such a difficult problem. This is from a study in France, from Dr. Bar, who basically looked at the spread in average dose area product, and this was just for PTCAs, and he looked for 19 -- what the ratio was between minimum and maximum, and it shows that the spread is huge, and it's more than 2 orders of magnitude difference, and that shows you that it will be very hard to go to small dose reference levels.

And also this shows because the difference per hospital and the difference per user is so big, that the whole usage factor also plays an important role, and by having that dose structured report available, facilitating these kinds of studies will be very easy and will be quite standard then.

So there are things we think are important and which also need to be standardized amongst industry and scientific community is to alert the user how much dose is left. So indeed next to the skin dose, which is about deterministic effects, also for stochastic effects, for the depth level, and warning you visually if you are at halfway or at 100 percent or really above the dose reference level. And some example of countries who already have now implemented those reference levels are Switzerland and the Netherlands.

Question A6 is about whether fluoroscopic equipment should also enable peak skin dose display, make it available to the operator. Well, we already have some kind of estimation according to the IC norm, but it's not differentiated in position. It's just basically assuming that it's uniformly distributed over a sphere, a sphere which measures 15 centimeters around the isocenter. However, we think it is very useful to be able to have a better display of skin dose because it's actually something you can influence during the procedure by displaying it, that the operator can adapt his working angle and in that way really lower the peak skin dose that occurs during a procedure. So, in that sense, it's an important parameter to display.

However, as already discussed in previous talks, it's not very easy, and there's questions on how accurate does it need to be? Do you really know the position of the patient compared to the table? Do you need to know the patient size? What kind of accuracies are required, for example, if

the table is bending? How should you take that into account, et cetera? So for that, we think it's very important to standardize and harmonize among the different manufacturers. So if we are going to display something as a peak skin dose, that it's also then comparable and independent of the vendor.

But as soon as that has been done, it's also possible to not only display, but also put it in the dose DICOM dose report and store it in the patient record file, et cetera, for later use.

So that was I think the last question.

(Applause.)

CDR BOYD: Thank you. Unless Rugenstein or Lewis has joined us, we have some time remaining this session and can entertain questions for any of the speakers if members of the audience would like to pose a question.

MR. YATES: Robert Yates, FDA, Division of Medical Imaging. I got the impression from both this morning's session and this session that we're confusing two problems. I mean one problem is the problem of accidents where patients are grossly overdosed, such as the patient who went in for a CT and got essentially a sunburn on his head and his hair fell out. On the other hand, there's the problem of the dose that people routinely get when they're having these studies which we want to reduce to as low as possible.

So I was concerned when several people said they're against having a level of dose at which the machine would completely shut down and

couldn't be overridden. I mean you wouldn't want to do that with any dose that would ordinarily be given to a patient if they were very obese or for some other reason, but certainly there's a dose level beyond which you wouldn't want to give to any patient, and for that dose level, you know, to prevent an accident, you'd want to have some kind of device, some kind of thing in the device that would prevent you from doing that, you know, to prevent you from giving such a high dose with a CT scan that a patient's hair would fall out.

CDR BOYD: Thank you for your comment, and maybe we'll get into that more as we go through the round-table discussion and hear from various industry members because I don't know that there is one person who has an answer to that question.

Are there other specific questions to individual speakers that would get to how FDA or industry can improve fluoroscopic equipment? Dr. Tenfordy (ph.).

DR. TENFORDY: Sean, I don't actually have a question, but I did want to make one comment. There was a lot of discussion this morning about what would be the best mechanism for producing a uniform set of DRLs, particularly suitable for the United States, and I wanted to point out that NCRP has initiated that effort. A gentleman on my left, Dr. Jim Brink, is chairing a distinguished committee of scientists who is preparing a DRL report, and it is being funded by the National Cancer Institute as part of our

five-year grant with them, and so I think that's an appropriate way to fund it. I heard suggestions of industry funding and so forth and so on, and I have some concerns about people so close to the manufacturing process and maybe those using the DRLs in a clinical setting actually developing specific DRLs. I think we can stand aside and produce an objective set of DRLs, and it will be totally peer reviewed very rigorously. And it will be made available for public comment at the time of Council review. So that's forthcoming I would say, well, hopefully within another 12 to 16 months we'll have a draft suitable for Council review. So that's just a point of information.

CDR BOYD: Thank you for the comment. Other comments or questions specific to this session?

MR. RAUCH: With the autopilot for the Red Baron aside, I'm really curious why the vendors are reluctant to retrofit the DICOM structured report for say five, six-year-old equipment that's installed. Is that true for other vendors as well?

CDR BOYD: Maybe we'll have a discussion about that issue during the round-table as well.

Well, if there are no other comments, we can give you back five minutes. We will break for the next 15 minutes and resume at 4:25. Round-table participants, come up here for instruction and, again, if you have specific questions, you can hold them for the mic or jot them on a note card that we can ask once the round-table convenes.

(Off the record.)

(On the record.)

CDR BOYD: If round-table participants could come to the front of the room and take their seats, and everybody else could take their seats in the audience.

Welcome back. We're going to begin our round-table discussion, and the purpose of this discussion again will be to answer questions that have not been fully addressed that were posted in the Federal Register notice and to address other issues that would help inform FDA decisions or industry actions to improve safety of fluoroscopic equipment specifically, and we will also open it for questions from the audience within a few minutes.

Before we begin, I wanted to have everybody on the round-table introduce themselves with their name and their affiliation.

DR. BARNES: Gary Barnes. I'm not from the American Hospital Association. I'm from X-ray Imaging Innovations and also UAB Medical Center.

DR. BRINK: I'm Jim Brink. I'm from Yale University. I'm co-chair of Image Wisely campaign and chair of NCRP Scientific Committee 4-3 for defining reference levels for the U.S.

DR. GOLDSTEIN: Jim Goldstein. I'm a cardiologist at William Bowman Hospital in Royal Oak, Michigan, and I'm a member of the Society of

Cardiac Angiography and Interventions.

MR. HARSH: Yes, I'm Mike Harsh, chief technology officer, GE Healthcare.

MR. JOHNSON: Medical physicist, Cleveland Clinic, Cleveland, Ohio.

DR. MILLER: Don Miller. I'm an interventional radiologist and vice chair of NCRP Committee 2-3 representing NCRP.

MR. LENDL: Markus Lendl. I'm with Siemens. I'm an image quality specialist.

MR. STRAUSS: I'm Keith Strauss. I'm the Director of Radiology, Physics and Engineering at Children's Hospital in Boston, and I also serve on the steering committee of Image Gently.

MR. BOON: I'm Sjirk Boon. I work for Philips in the R&D Department in the Netherlands.

DR. KYPRIANOU: I'm Jake Kyprianou. I work with the FDA. I'm a medical physicist.

DR. SMITH: I'm Robert Smith. I'm a radiologist and a medical officer at CDRH.

CDR BOYD: And the first question or a question that was left unanswered immediately following the open public participation or open public presentations was the first question I wanted to ask that the round-table discuss, the importance of upgrading existing or the installed base of

equipment, what is possible, what is not likely possible from an industry perspective, and what is most important to be done from a provider or operator perspective?

MR. LENDL: So let me try to answer that question. It's a matter of cost. So basically every piece of equipment can be upgraded to the latest level, but it's a matter of cost, and the cost may be as high as replacing the equipment. But if there is sufficient need to implement a certain feature to older equipment, then basically we can spend some effort on developing that and introducing features for older equipment, but it's a matter of how many systems will get that new feature.

MR. HARSH: I would like to add one other thing, you know, based on what the standards and the requirements are, and at that point, we'd really have to go back into our installed base. Some of this equipment does date back many years. In some cases, you know, we found equipment still in operation before computers even existed to control a system. So we really have to go back and understand just from a system architecture standpoint any limitations that we might have in terms of if it is a computerized system, what type of memory it might have, its limitations and its processing capability, hardware capability, and bounce that off against what the regulations are and just see what's possible. I mean we will do what's required, but we have to understand what's possible from a technical feasibility standpoint and what's being asked.

MR. JOHNSON: I would say once we have an understanding from MITA or the manufacturers on what can be done and the cost associated with that, I think we could get a lot of bang for our buck with training in those areas that would be too costly to upgrade equipment-wise, hardware, software, maybe hit the safety issue a little heavier, the training end. That might not be as costly.

DR. MILLER: I think from the user's standpoint, the most useful feature would be a display of cumulative air kerma at the operator's working position, which has been a FDA requirement since mid-2006, but I would note in passing that an interventional fluoroscope that we installed in my hospital in 1996, that capability was available as an option and was installed. So certainly going back at least a decade and a half, some equipment can be retrofitted without enormous difficulty because it was designed for that capability as an option.

MR. STRAUSS: I'd like to make a suggestion. Obviously a manufacturer is going to work on a state-of-the-art platform when it works on its installed base on coming up with an improvement, but as a guideline, if a manufacturer has done that, and less than 50 percent of the manufacturers installed base still doesn't have that feature, I would think that maybe the manufacturer needs to do more, you know, if they work on their state-of-the-art platform and maybe one generation back, and they've captured the majority of their installed base, I think that's probably a reasonable

compromise, but if they've only captured a minority of all their installed base, I think they ought to think about doing more despite the cost.

DR. BARNES: I would think also the cumulative dose output would be useful so it can be recorded and put into the databases.

DR. MILLER: It's necessary not only as something that you can record after the procedure, but as really the only useful guide you have during the procedure to tell you how much radiation you've used. Fluoroscopy time is a very poor indicator of radiation dose, and if that's all you have, then you really have nothing.

MR. STRAUSS: One of the other things I might add as a function of patient size, as manufacturers are looking at this, it's great to have the air kerma, but as it's been mentioned, that's certainly not skin dose. That's not patient dose, and to make estimates of what skin dose or patient dose might be, it's imperative that you know something about the patient size. So as manufacturers are trying to address that problem, if there would be some way to provide that kind of information, that would be very helpful.

DR. BRINK: I found it interesting in Don's words previously that patient size, when you looked at a broad group of patients, either averaged out or it wasn't as critical as perhaps some of the factors, and I don't know if you might want to comment.

DR. MILLER: For interventional fluoroscopy procedures, patient size is important, but it's markedly overshadowed by other factors. The

principal ones are complexity and operator technique, but patient size does play a factor. It's not as great a factor as it is in say, for example, in CT where the procedure algorithm and the protocol is well defined in advance. There is no such thing as a standard interventional procedure. Every patient is different. Every patient anatomy is different, and so what you do depends on what you see when you get there.

CDR BOYD: There was a lot of discussion this morning about justification of diagnostic imaging exams when using CT equipment, but there was no discussion basically this afternoon about justified use of interventional fluoroscopy procedures, and it was described as a dynamic procedure. A medical doctor is using the equipment in realtime to inform their decision on what they're going to do for a surgical procedure. Can the panel discuss what role, if any, referral criteria or other guidelines for how much fluoro should be used and when fluoro should be used during interventional fluoroscopy procedures or interventional surgical procedures?

DR. MILLER: You should use just enough and no more.

CDR BOYD: We heard that.

DR. MILLER: Justification for interventional fluoroscopy procedures is different than for CT. For one thing, the interventional fluoroscopy procedure is normally done by a physician who has already independently evaluated the patient, not merely a request but the patient, and determined on the basis of his or her understanding of the patient's

underlying condition and the therapeutic goal that the procedure was indicated on the basis of a benefit/risk analysis. That's one.

On another, the benefit/risk analysis for an interventional procedure is very different than it is for a diagnostic procedure because in a therapeutic procedure, we're accomplishing a therapeutic goal. It's not a question of merely providing information. We're performing an intervention.

And, thirdly, the risk of a diagnostic procedure is largely limited to the radiation risk and the risk of contrast material administration, if there is any. The risk of an interventional procedure is substantially -- well, not substantially; it's greater because it is an intervention. You're introducing something through the skin and into the body, and the risk of the procedure complication is considerably higher than the risk of a radiation problem, whether that is stochastic or deterministic. Radiation risk is a risk but markedly outweighed by procedure risks, and therefore we don't really think about radiation risks in terms of the benefit/risk ratio unless we're dealing with a very young patient or a pregnant patient or someone who has already had a great deal of radiation and we're going to be reradiating the same area.

MR. JOHNSON: I would agree with that. One thing I could see for an electronic medical record standpoint for the clinician for non-emergent cases, because of the skin effects, to look at that and see if it could be postponed to a longer date, that would be more readily available if possible, that you could postpone it for a few months. That would be one benefit of

having more consolidated dose information or exposure information.

CDR BOYD: Other comments?

Another speaker presented a slide on, I guess, after a certain point, the question of how much information do you need during an interventional fluoroscopy procedure, and after a certain point, I think the point was made that it's overused in some cases, and another speaker spoke about alerts that are provided by equipment need to be meaningful. Maybe it's not meaningful to have an alarm every five minutes that you're going to ignore just because the fluoro is on. What kind of alerts would be meaningful? And some of them described included alerts that were triggered once a threshold was hit that's established locally by the facility or by the provider. Can the round-table participants discuss the importance of alerts, what type of alerts would be useful for fluoroscopic equipment specifically?

DR. BRINK: I think Jim Duncan's presentation earlier really highlighted some of the key issues there, and one is that, you know, to really have an alert, you have to have a benchmark that's reliable, meaning you have to measure something that's measurable, and I think the example he showed of even measuring locally through a monitoring system that tracked the exposure among a wide range of rooms within his facility I thought was a very good step forward. I guess the question, how we could leverage that on a more broad basis, because again the alerts have to be based on reference levels that we can define both nationally, locally, and what have you, but

without really collecting that data in one repository, it's awfully hard to establish meaningful alerts.

MR. BOON: I think in general, alerts need to be something where you can have influence on. So, for example, because of the peak skin dose, you would choose a different angle, then it has meaning because then you can decrease peak dose or other things like decreasing the SRD, choosing a different dose rate. So there are certain things that an operator can influence, and I think all the things you need to display are things that you can do something about. Otherwise, it doesn't make sense to display it.

DR. MILLER: The Society of Interventional Radiology and the Cardiovascular and Interventional Radiology Society of Europe have produced the document that was published last year which deals with this specific issue, and what is recommended is that some member of the staff, a nurse, a technologist, someone who is present during the procedure, have the responsibility delegated to them of advising the operator at specific points, determined by radiation dose, of what the radiation dose is on the theory that the operator is busy doing the procedure and not necessarily paying attention to the radiation dose. That document provides recommended levels based on whether you're measuring kerma area product, cumulative air kerma, peak skin dose, assuming you can do that, or fluoroscopy time, although the use of fluoroscopy time is discouraged.

And those alert levels are set so that after three alert levels,

you have reached something which that document refers to as a significant radiation dose, which is a dose that is high enough to potentially cause deterministic effects to the skin and which would require that you follow the patient.

I think it is a very, very bad idea to use reference levels to set alert levels. Reference levels are exclusively and solely designed to allow you to compare the dose to your population of patients to the dose to a larger population of patients, whether from the same type of facility or whether from the same country or whether internationally, but a reference level is designed so that you can look at typically the average dose for a series of patients and compare that to the 75th percentile of dose to another series of patients and find out if, in general, the dose distribution is such that your doses are higher than they need to be.

Dose reference levels are not and were not and should not be used to look at individual patients.

DR. GOLDSTEIN: I just want to add on to Don's comments, as a practitioner, in an analogous way, I'm tuned in on every single case to contrast dye, particularly in my patients who have heart failure or any renal compromise or diabetic, who I know more x-ray dye I use, the greater the risk that I'm going to have a complication afterwards. So I'm constantly watching the bottle dye and watching it go down and asking the nurse, how many ccs have we used, and one of the problems with radiation is like carbon

monoxide. It's odorless. It's tasteless and, you know, it doesn't really hurt, you know, unless you look over a long period of time. Again, what the metric is, I don't have the expertise to comment on. There are many experts who have done so. But having some kind of a feedback -- I mean physicians get it, not only do they not want their patients to be radiated, but they don't want to be radiated, and if there's some kind of a monitor that told you, you know, you've got this much and, you know, you can even color it green, yellow, red, when it gets to levels of concerns, it's relatively easy to train physicians, particularly when not only is their patient at risk but they are as well.

DR. BARNES: Well, we do have the cumulative dose or air kerma that's tabulated, and in my experience, it's a matter of educating the people at what point do they need to be concerned. You might make it a little easier with a bar graph or something but, you know, hospitals generally set up a value and say at this value, you need to start being concerned, and when you start approaching that, you need to look at that, and it's educating the operators to that.

MR. STRAUSS: We have the advantage in our institution of recording all our fluoroscopic interventional case doses, cumulative doses, and we implemented about a year ago the policy that Dr. Miller referred to that was written up in a document and essentially notify our users of that at set points during the cases, and what we've noted as a result of that is that the maximum doses in our facility have significantly declined. Interestingly,

our average doses for typical cases haven't declined that much, but the maximum doses have because I think in part because the operators have been made aware of the fact that the case is continuing and maybe they need to think about wrapping it up, but that's the trend that we've seen as a result of implementing that type of policy.

DR. MILLER: I also would point out that the methods and the numbers in the document that I referred to before have been incorporated into the draft NCRP guidance document as well.

CDR BOYD: Question from the audience?

DR. DUNCAN: So, Dr. Goldstein, your comment about contrast, I mean most of us start a case and we have a contrast budget that, you know, there's a certain value that we don't really want to go over, but we will. You know, it's like jet fuel that you have to go into if you have to. But the same thing to me applies to radiation dose, that I probably should start the case with an idea for this particular patient, that this is the dose that I'd like to be under, and if I can stay under my budget, all the better. If I have to go over, I have to justify why I went over. It's sort of like writing grants.

DR. BARNES: I think we have that now with education of what the values are. It's a question that Steve Balter mentioned, that sometimes the cumulative skin dose or air kerma, I should say, is hard to see, but that's one thing that needs to be made more readily visible to the operator, but that's there, and it's educating what that value means.

MR. BOON: Do we propose then for a need for air kerma so for the deterministic effects or the dose area product, which will be another possibility, because I believe that most of the dose reference levels where we express as a dose area product and also as air kerma.

DR. BARNES: I think the air kerma is probably more meaningful for most of the cases, you know. I think the dose area product, for fluoroscopy, is a little less useful.

DR. MILLER: If you look at the correlation between kerma area product and skin dose, it is good overall but very poor in specific individual cases. If you look at the correlation between cumulative air kerma and peak skin dose, it is also very good overall and somewhat better than kerma area product for individual cases.

The European literature tends to give reference levels almost exclusively in kerma area product. There is relatively little actual literature for interventional procedures, and for the ones that are given this, only relatively few procedures, there is limited information in the U.S. There's only one paper I'm aware of that provides proposed reference levels for interventional radiology procedures, and that provides it in units of kerma area product, also in cumulative air kerma and in fluoroscopy time.

CDR BOYD: Question from the audience?

MR. BANASIAK: I do have one. Hi, my name is Gene Banasiak. I'm from Clinical Microsystems. We've manufactured dose monitoring

equipment and databases for the last 16 years. One of the panel members said that, you know, you should really be aware of the radiation in the room, and as you adjust different things, it could increase the dose. Libby Brateman illustrated the point where if you lower the table under the same conditions, you'll have an inverse square increase in the dose because you're getting closer to the source, everything else the same, and this is true. When you're in a fluoroscopy room and because of the IEC standard that said, well, you should have dose area product meters, maybe even some index dose meters there, if you're looking at those meters as guidelines, and this is true for all your fluoroscopy rooms that have these meters, if you lower the table and the patient's getting more dose and she knows that, what does the meter say? Does it say that the patient's getting more dose? No. How are they supposed to know that? That's a big gap in the dose index system. Now, you know, and it's like she was saying, it's like a factor of 2. I think everybody sees this.

Another thing I'd like to point out, too, is that the JCAHO in 2006 in a question and answer session said is cumulative defined as a lifetime dose? Now, their answer is no, it's impractical. But it should be monitored -- monitoring a cumulative dose over a period of six months or a year would be reasonable.

Now, what they're talking about here is a sentinel event. I have a patient on the table. We give them 500 milligray, comes back in a week. The clock starts all over again. That's what they're trying to avoid. Now, how

can we avoid that? Anybody there?

DR. BALTER: The answer to the first part is probably the most neglected piece of the entire dose meter story. The IEC standards from 2000 requires dose rate to be displayed while the fluoroscopy is active. So if you change the table, you will see a change in dose rate.

DR. MILLER: With respect to the second part, if you have more than one procedure on a patient during the same hospitalization, you can design your EMR to accumulate that, although I don't know of any that does it now. The problem that I don't see a work-around for short of a national EMR is if you have a procedure at hospital A and then a week later go to hospital B and have another procedure in the same area.

MR. BANASIAK: Well, even in your own institution, within the walls, how can you satisfy the JCAHO requirement? I mean, you know, the requirements are there. A lot of times, you know, you can't do anything about it, but it's there in black and white.

MR. LENDL: Addressing that question, I mean what you can do is the dose display and the product called for, for DAP and accumulated dose is available. So you can put it in the patient record, not necessarily an electronic record, and just move that record with the patient from one hospital to the other hospital. So it's a manual tracking of dose and a manual accumulation, until an electronic patient record is available, and I think the dose structured report is a feasible tool for establishing an electronic dose

record.

MR. STRAUSS: I would like to just underscore what Dr. Miller said. We're fortunate enough at my institution to have interventional doses recorded for five years, and in the one case in our interventional labs where we literally burned a patient because it doesn't happen that frequently in pediatrics because pediatric patients are small, we didn't anticipate that that was going to happen because indeed the patient had had a significant procedure outside our hospital. So we had a five-year history on that patient, and we knew based upon what we had done that there should be no issue with the procedure that we were planning to perform. And the patient still sustained a burn because of something that was done outside our institution. So, again, until we have some kind of a national database, it's going to continue to be a problem.

CDR BOYD: Other comments?

DR. BARNES: I just think manual writing down things is problematic. I think we should have electronic transfer of that dose information so that it can be imported into the report on that patient. I just think manual recording, it can be done, but it's not the way to do it at this time.

MR. STRAUSS: Well, another problem with dose data is we have all our dose data in one database. You certainly need that capability if you're going to find your frequent flyers, but the problem is that technically

that's not in the patient's medical record, and getting that information into the patient's medical record is another big step, once you have all that data in a combined dose database. So certainly it's easier to get all of the data in a combined dose database than it is to get it distributed actually into the patient's medical record.

DR. MILLER: Actually the dose data needs to stream in three different ways. It needs to stream in conjunction with the images, it needs to stream into the electronic medical record for each patient, and it needs to stream into an institutional QA database so that you can do the database analysis that you need to do, and at the moment, those three are entirely separate data streams that are not combined at any point.

MR. HARSH: You know, I just want to comment on that. When I look at DICOM structured reporting for fluoroscopy or any DICOM SR for dose, you know, when you look at the binding of that dataset, the dose data, it really wants to be with image set. So, you know, I've got to look at it. We'll look at the PACS. The way I would look at it is that the PACS is really where the binding point is of that dose data, and from there it can serve this data up to whatever EMR or other IT system that needs the data, but I think that's the way we have to look at it because that dose is associated with an image set. So let's keep it bound there. So I look at the PACS system as being really the primary actor to be able to distribute that dataset.

MR. STRAUSS: I don't disagree with that comment. However,

it's almost impossible to find your patients that have had multiple exams over a short period of time through your PACS system, but I certainly agree. That's the place where you want the information really to be for the sake of the patient, but it doesn't help you managing QA issues on the frequency with which you're conducting examinations on patients.

MR. JOHNSON: At the Cleveland Clinic, obviously we all know that manual tracking is laborious. What we do for our interventional patients, we take an effort at sending non-emergent patients' information, to please provide us with any interventional procedures you've had within the last six months anywhere in the country or in the world for that matter. It takes a little effort, but I think if we can get an electronic medical record, we keep hammering that, to track this, it'll just go a long way, and then any procedure, we log every fluoro procedure at every facility currently, and our quality committees, we look at it quarterly, and anything over 5 gray air kerma, we sent take-home instructions to our patients to be aware of potential deterministic effects. It's not perfect, but automation would go a long way in being more efficient.

CDR BOYD: Question from the audience?

DR. FERRELL: Yes, thank you. Dr. Bev Ferrell. I'm an interventional cardiologist and now work in policy, Hope Policy in Washington. I just wanted to pick up on this theme that has been talked about of not only the importance of recording cumulatively the episodic

dosage exposure, but I think another very important variable that needs to be recorded with regard to interventional procedures is the angulation. Certainly in interventional cardiology, the issue with frequent flyers is often that they will come back with a recurrent lesion in the same artery and, in fact, virtually the same angulation will be used so that rather than skin exposure being spread over a variety of angulations and distribution over the skin, in fact, it's tightly focused on exactly the same spot. So I would hope -- I liked the comments very much about what different institutions are doing currently to try and address that and educate patients, but I would hope that in the DICOM standard, that there is also data collection for interventional procedures that actually records and relates either dosage spent at specific angulations or at minimum and not as good fluoro time at different angulations. Thank you.

MR. LENDL: Thank you very much for that comment. Just a note, the DICOM structured report will record the angulation. So basically the data are available. There has to be established some tools to evaluate that, and in the DICOM standard, we are talking about different roles, and the role for the equipment manufacturer is called acquisition modality. So to provide all the data, and the next step is to implement managing roles to collect all the data and analyze the data and calculate, for example, the distribution over the body, so a regional distribution of dose based on the angulation and the accumulated skin dose.

DR. BRINK: As was mentioned this morning, the FDA and Image Wisely campaign is looking to try and develop a dose card, if you will, that at least would track inter-institutional exposures, both interventional and diagnostic. So this may be one sort of analog way around this problem until a more robust electronic means is developed to track inter-institutional dose.

DR. BARNES: My concern would be if we track too much, you'll get information overload for the people. In my working with them, I think you probably want an average angle or some couple of pieces of information, but if you have all kinds of stuff, it just simply won't be useful for people. They need a few nuggets of information and not a fire hose.

CDR BOYD: And our efforts to look at an individual's medical x-ray history is really limited to documenting occurrences of exams and not getting into specific data elements that a patient isn't going to understand or know what to record necessarily, and that's something that we're working with the Image Wisely folks and ACR on.

MR. LENDL: May I just comment on that? Would it be useable to have just a graphical display, let's say a simple model of the body colored, the surface colored with green to red?

DR. MILLER: Both the FDA and the ICRP, I think a decade ago, recommended that for procedures with high skin doses, that a skin dose map be included in the medical record. That has never been done essentially because there was no way of doing it, but that would be the ideal method for

following these patients and for ascertaining whether or not you were likely to get into trouble with the next procedure.

DR. BARNES: So as I understand it, what you're advocating is a distribution, so you have the total dose and then the relative distribution of that dose across the skin.

DR. MILLER: Well, the skin dose map would be a graphical representation of the skin surface with an indication of the skin dose at every point on that surface as well as a numerical indication of what the highest dose is at any point on the skin surface, the peak skin dose. And this system actually was available briefly from one of the major manufacturers of fluoroscopic equipment and was discontinued because there was no interest in sales, but while it existed, it was an extraordinarily useful tool for those of us who had it available.

DR. BARNES: It must have been an option.

DR. MILLER: Of course it was.

MR. LENDL: Actually it was sold three times.

CDR BOYD: Question from the audience?

MR. LAUNDERS: Yes. My name is Jason Launders, and I'm from ECRI Institute. I just got a comment really, and maybe something to think about regarding legacy equipment, and we realize that this is a cost to manufacturers to manufacture or to design something to go back on older equipment, but I'm not sure how it would fit into 510(k) review type

regulation because if you're changing an existing product, presumably you have to make a new submission, but if you're on a new product, and you're putting a new dose saving technology in there, should the manufacturer at that time discuss within 510(k) whether that technology can go back to legacy equipment, and what are the justifications for either not doing that or doing it? I'm not sure how it will fit into the 510(k). So maybe I'm just naïve. Thank you.

CDR BOYD: Comments from our FDA folks on how that might fit into the 510(k) process? I'm not a 510(k) guy. So --

MARY: We can discuss that at a future time.

CDR BOYD: Okay. Thank you, Mary.

So thank you. One of the reasons we're gathered here is to help inform us on questions that we still have yet to answer, and if we need to consider the impact of retrofitting or upgrading the installed base of equipment, the impact of that on 510(k), or the appropriateness of including I guess backward compatibility of such enhancements or upgrades on previously cleared devices, we will talk about that and develop a position.

Other comments or questions from the audience regarding how we might improve fluoroscopic equipment?

DR. KYPRIANOU: I had a question for the panel.

CDR BOYD: Yes.

DR. KYPRIANOU: Most modern CRM systems also have

calibrated for CT. Should CT images and CT dose from those systems be considered separately or as air kerma as well?

DR. BRINK: That's a good question. I would think that CT should be tracked through CT metrics and fluoroscopy metrics tracked through fluoroscopy personally.

MR. JOHNSON: I would say with CT used properly, it's more of a stochastic, long-term effect issue and deterministic effects that we're worried about. It's a different set of dynamics that we want to follow for the dose with interventional versus CT.

DR. MILLER: On the other hand, consider the poor interventional radiologist who is already having trouble with kerma area product and then is trying to figure out to add in CTDIvol into that to figure out how much dose his patient got.

MR. LENDL: This problem is of a certain interest in the neurosurgery department. There was a study tracking a patient over different modalities and adding up dose, and doing some analysis on what is the major contributor for neurosurgery, it was DSA imaging and the CT. So there is a certain need to combine dose and a certain metrics, and I think there is a certain requirement to evaluate skin dose in a CT environment to make it more comparable, and then maybe we end up at the skin dose map finally to combine everything.

DR. BARNES: In head CT, if you know the CTDI volume, you

basically know the dose to the skin. So, you know, it's not a major issue. You can get a reasonable estimate, and I think that's what you need to have, reasonable estimates rather than high degrees of precision here.

MR. HARSH: I guess if we're using C-arms for this, I think it is another record mode. It's generally a limited field of view, tomographic reconstruction. The beam is quite different when you really look at what's going on with one of our C-arms compared to a CT scanner. So I just think, you know, it is another category completely that would need to be taken a real hard look at, but I don't think we can just bin it either in fluoro or CT, but we really have to take a look at the variables independently and see what's going on.

MR. STRAUSS: I do though think the key is we need to keep it simple. AAPM Task Group 111 certainly has had a lot to say about errors in our estimates of dose associated with large field CT and scatter contributions to our current CT dose indexes. So, you know, our estimates are not as accurate as we'd like them to be. So let's keep it simple so that we don't overtax our poor operators that are trying to keep it all straight.

MR. BOON: And if you are only interested in stochastic effects, why not just use the dose area product over a 3D scan and then maybe use that conversion factor, but otherwise just keep track of the dose area product because it doesn't matter which angle you use for that.

DR. BARNES: I think the issue in fluoroscopy and interventional

procedures is the skin dose is the issue, not the dose area product.

MR. BOON: Yeah, but specific for the question of about 3D and CT, like capabilities on the C-arm.

CDR BOYD: Other comments or questions from the audience?

Things that the panel would like to discuss?

MR. STRAUSS: I'll just make a quick comment. It's been a long day, and it's heartening to still see so many people sitting out in the audience. One of the things that we've said and we've harped about for many years is that kids are not small adults, and just before this panel sat down, I heard that comment in a different way that I thought was quite clever, and it was said that, no, it's more like adults are just big babies. So I got to attribute that to the author. He's sitting two chairs down from me, and he has less hair on the top of his head, but I won't name him, but that's his ingenuity, not mine.

MR. JOHNSON: I would just like to say thank you again to the FDA and for the people here. It is heartening to see there is so much concern about it, and that from my experience and my years in this field of radiation safety and dose management, there's a lot of dedicated individuals out in the United States working on this and colleagues from across the pond. It's a process. We're going to keep working at it, and a lot of us have dedicated our lives to radiation safety, to our families, our friends, and we're just going to keep working at it.

DR. MILLER: I would like to thank the FDA, but I also

appreciate, and as does the FDA, that the FDA is not the answer to this problem. There are things that FDA can do, but there are many, many things that FDA cannot do, and that is up to other governmental entities, some of them at the federal level, some of them at the state level. One thing the FDA could do that was mentioned briefly earlier this afternoon was to be more involved in IEC activities. 2-43 which has been mentioned a number of times this afternoon, there was only one U.S. Representative on the committee that revised that. There was no FDA representative, and the IEC, that document will go into effect, well, it'll be adopted sometime this year and will go into effect for legal purposes, I believe, in Europe and some other countries in 2012. If the FDA decided to regulate today, the regulation would probably not go into effect for a decade. So this is a much more rapid way of accomplishing the goals.

DR. BARNES: I would just like to comment that in my experience in the hospital, that the equipment usually is not the problem. It's the operator training and the education of the operators. I think we're going to talk about that tomorrow, but that to me is a critical factor, and credentialing, making sure the operators have had some training. Those are key factors in minimizing interventional incidents.

CDR BOYD: Well, with that, I think thank the round-table participants for their discussion.

(Applause.)

CDR BOYD: And that concludes today's agenda. We will resume tomorrow morning at 8:00 a.m. Thanks, everyone.

(Whereupon, at 5:20 p.m., the meeting was adjourned.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

DEVICE IMPROVEMENTS TO REDUCE UNNECESSARY

RADIATION EXPOSURE FROM MEDICAL IMAGING

March 30, 2010

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were held as herein appears, and that this is the original transcription thereof for the files of the Food and Drug Administration, Center for Devices and Radiological Health, Medical Devices Advisory Committee.

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