

Welcome to this Continuing Ed course on Radiation Safety Risk Management Number 2. I'm Tom Shope from the Center for Devices and Radiological Health, and today we were going to hopefully talk about the new amendments to the x-ray standard, if I can make this thing – I did everything but change the slides, huh – there we go. Start out with the usual government disclaimer that this is my position here, and not the federal government's, and having that out of the way, I have another clarification about this talk, and that is when we were asked to present this talk, we were hopeful we would have a final rule with amendments published. That has not happened, and it's still in process, and one of the things about the FDA administrative procedures is once we've solicited comments on a rule, between that time and prior to issuing a final rule, we aren't allowed to give anybody an unfair advantage about what the content of that rule might be, so I really can't tell you this morning what our final decisions are, but I think you'll get

a fair indication of what we're thinking about with the discussion that I give. So, if you had some other session that you were really interested in going to, but because you wanted to hear the final rule and so you came here, I will not feel bad if you go take your second choice. There are some handouts in the back. Yeah, that would be great. I didn't see one. Okay. Handouts in the back – there are two documents. One's just my slides, and the other is the actual proposal we made back in 2002, and it contains the rationale for what we were proposing to do, as well as the regulations as they would exist had that proposal been adopted. There's one ... I guess this mouse does not ... does the mouse advance the slides? I guess not. Here's the outline of what I want to do. I want to briefly review the regulatory environment in which x-ray systems live, talk a little bit about the background of developing these amendments, describe the proposal that we made and the comments that we received on that proposal, which will give you some

idea perhaps of some of the decisions we might have been making, and then talk a little bit about some of the future actions that FDA is currently involved in thinking about. So, what is the regulatory environment? Well, there are sort of a range of things that impact x-ray systems, and I think one of the most important is the professional organizations who develop recommendations, who develop standards of practice or guidelines for practice. Primarily, we think of the NCRP, the National Council on Radiation Protection and Measurements as a group which has been in existence for a long time and upon which our federal standard back in the early 1970's based most of our federal standard on the recommendations of the NCRP. There are also a number of professional organizations, such as the AAPM that make a lot of recommendations and suggestions, but in terms of controls, we get to the state and the local radiation health or control agencies, and they have a wide variety of responsibilities that relate to x-ray equipment.

Clearly, they either license or register the equipment in many states. They are responsible for facility, that is the place that operates the x-ray equipment and the equipment standards, training requirements for people who use x-ray equipment, the qualifications, the licensing of physicians, nurses, x-ray technologists, or the lack thereof. Some states also have requirements for annual testing or periodic testing or the implementation of quality assurance programs in the facility. I think there's a wide variety of activities there. At the federal level, our focus is in the legislation that we have to operate under is a focus on equipment standards addressing radiation safety, and these are standards for the manufacturers, so that they will market a product that complies with the standard. At FDA, we also have some impact on x-ray equipment from our medical device authorities or responsibilities, and this is the review of new products coming to market when they are introduced by the manufacturer, and the manufacturers have to come to

FDA for pre-market review of these medical products, including diagnostic x-ray equipment. Related to that, of course, is FDA's involvement in any clinical trial oversight. If it's a new device, it presents a significant risk to patients during its use, there will be much more scrutiny than there is for a typically non-significant device. X-ray equipment typically falls in the non-significant risk category, and therefore, is overseen by the local IRB, the Institutional Review Board, that monitors clinical activities in a facility. And also at the federal level, something we don't really get into at FDA, which is, of course, controls and influence that is the result of reimbursement issues, so Medicare and Medicaid operations can have a great influence on what people do based on what they'll pay for, but that's a little bit beyond the FDA purview, so that's the regulatory environment that we're talking about. Under our Radiation Control for Health and

Safety Act, which was passed in 1968, the department was given a role in assuring the safety of radiation-emitting electronic products. This was primarily by means of federal performance standards, again that the manufacturers have to certify their products to meet these standards; FDA has a program to check on that compliance. A second authority and probably the largest activity at the Center for Devices and Radiological Health for a number of years is our authority under the Medical Device Amendments to the Food, Drug, and Cosmetic Act, which makes FDA responsible for assuring the safety and effectiveness of all medical devices. Definition of a medical device is quite broad. I'll turn the timer on. That way I'll know I'm ... time to quit. And sort of colloquially, I say, that, you know, if it's within a half a mile of the hospital, it's probably a medical device. There's sometimes some questions about how far this authority extends, but if it's associated with the care or the treatment of a patient, it's a medical device. And a third

control we have that some of you I am sure are familiar with is the efforts in mammography. This is under a special act Congress passed the Mammography Quality Standards Act, and this gives FDA broad authority to institute standards for mammography, not just the equipment, but the practice, the facility, the personnel involved, and I won't really belabor that point, but it's ... you know ... we do what Congress gives us the authority to do. So, as background for the amendment effort that's been underway now for a number of years, I think we recognize, the whole community recognized in the early 1990's that there were some additional things that we ought to be concerned about with regard to fluoroscopic equipment. We were seeing increased radiation output capabilities, new imaging modes. In the mid-early or late eighties, we had the digital subtraction angiography. Lithotripsy came along. Many of these systems were associated with equipment with rather significant output capabilities. Part of this concern led to an

ACR/FDA conference in 1992, and out of that conference, there was a number of items that there seemed to be a consensus in the community that we ought to pursue to encourage manufacturers to provide some of these features. One of them was the idea of a dose display of some sort associated with the fluoro equipment that was referred to by some as a speedometer/odometer combination that would give you some idea of what instantaneous exposure rate to the patient was. Technology seemed to be available that would allow that without a great cost. And, of course, there were some concerns in the mid-nineties about the radiation injuries from fluoroscopy. So this was kind of the background that was driving us to look at the standard that had been in place since 1974 and to consider some changes. Actually, in 1993, we made a very small change to put a limit on the radiation output during high-level control mode, as we referred to it, and that rule became effective in 1995, and it gave this two-stage limit of either 10 R per minute for

normal fluoro, or 20 R per minute when you were in the high-level mode. When we did that amendment,

there was recognition that there were a lot of other things that needed to be considered, but we needed to do a good bit more work to hone in on what those requirements ought to be, so in the late nineties, there was a kind of a parallel effort that grew out of that ACR/FDA conference, which was the development of an IEC standard, (International Electrotechnical Commission standard, 60601-2-43), which addressed particular safety requirements for equipment that the manufacturer indicates or suggests is for use in interventional radiology or interventional procedures, and that added some requirements in the IEC standard, which, of course, is an international voluntary standard, as far as the U.S. is concerned. It does have some regulatory influence in Europe. Following or in parallel with that activity in the IEC committee, FDA played a role in that activity with the IEC, and I think had some influence in how some of those requirements developed. We published in 1997 then, something we called an ANPR. That's an

advanced notice of proposed rule making that tells the public that we are intending or considering making some changes, and I've given you the reference there for the website where you can pull up that. That really posed some questions about the kinds of controls or regulations that we were thinking about and asked for public input as to whether those were appropriate and were there other things that we needed to look at, etc. The ... didn't get a lot of comments in response to that, I think actually about 12, but some of those comments were very useful. We then talked with our advisory committee, affectionately known as TEPRSSC (Technical Electronic Product Radiation Safety Standards Committee). It's the committee with the largest name in the federal government I think, but we have the discussions with that committee are also posted on our website as we were developing the concepts we wanted to have in the amendments. About that time, though, another problem came along for FDA, which was the Y2K computer problem,

and I have to say a number of us were diverted to that activity, and it really slowed down progress on these amendments as a number of folks were really full-time dealing with that whole issue of what the impact of Y2K might be on all medical devices and medical facilities. We finally got around to proposing our change to the rules in December of 2002. There are several steps one has to do before you propose a rule these days involving a lot of impact assessments, estimates of cost and benefit, other required assessments, such as the impact on federalism and paperwork, and anyway, you have the handout now of the December proposal of 2002. It's also available, and I've put this reference up here. If you go to that web page, that's the home of the federal register, and you can pull up any issue from about 1996, '95, somewhere in that time frame. They are all easily available there, and I think you can even go back further, so if you ever have an issue you want to check up, you can go there. From that link, you'll have to

do a little work to search on the topic or the agency or the date, but that's the place to start. It's where you can find the federal register. Our comment period on our proposal ended in April of 2003, so we're a little bit beyond a year since we got the comments. We've been reviewing these comments. Last fall we developed our final rule, completed all the analysis activity, and this final rule was in its process of wending its way through the bureaucracy to get to the federal registry for publication, so that's where we stand. I would have said last January that publication was eminent, and I still think that. What did we propose? Let's talk about some of the changes that we suggested in this proposal that was published in 2002. The first, of course, was to finish sort of an unfinished task, and that is to go ahead and use the current terminology for units, and so anywhere in the standard where you used to see 10 R per minute, a non-SI-type unit that currently in the standard is in coulombs per kilogram, and it's an awkward unit.

We've replaced that with a more awkward unit perhaps. You see there, we've put 88 milligray per minute

“vice” to remind you that is in place of the 10 R per minute, so we’ll be expressing our quantity air kerma in the units in milligray per minute in most of the standard. We also had with some of the new technology coming along a need to clarify the applicability of the standard to deal with some of the new developments. One of the things that we wrestled quite a bit with, it wouldn’t seem like it would take a lot of effort, but it seemed to have taken a lot of effort, is trying to clarify when you’re doing fluoroscopy, when you’re doing radiography, particularly with some of the digital units, and our standard was based upon image intensifier technology, and everywhere within the standard, the word image intensifier appeared, we really needed to make that more general and become a fluoroscopic image receptor, because nowadays we have a lot of image receptors and fluoroscopies that were not the image intensifier tubes. A number of definitions were tweaked a bit. We added some definitions to deal with the need to clarify

some of the concepts we were proposing, so you’ll see a number of definitions have been added. Some have been changed. We also propose in addition to the information to users in the proposal, and this had to do with making sure that in the user’s manual, there were some clear explanations of what the modes of operation of the fluoro-system were and some of the dose consequences of selecting that mode of operation. We got some comments on that and have made some modifications of that particular proposal, but I think it will be appropriate when we get the final rule out. One of the changes that we did is recognize the changes in generator technology. Here one of the problems for us in the U.S., is our standard has to be performance-based, so we have to talk about not how you build the equipment, but what the results of the equipment’s performance will be, so where in the IEC standard, they can say things like, “Put two and a half millimeters of aluminum filtration in the beam.” We can’t write our standard in

that fashion. We have to say, “Build your x-ray system so that the beam that comes out of the x-ray equipment has a beam quality that provides a half-value layer in aluminum of the following.” So that presents a little bit of an awkwardness in comparing our standard to some of the IEC standards that aren’t restrained to this performance-type approach. But what we did is recognize that with the new cost of potential high frequency generators, our previous half-value layer requirements were probably ... needed some improvement, so we’ve changed those, and that applies both to radiographic and fluoroscopic systems in our proposal. Primarily our focus was to try to make our fluoroscopic requirements in line with the IEC standard on beam quality. We also propose that the manufacturers on certain systems that have high output capability based on the heat load capacity of the tube provide a provision for adding additional filtration at the user’s option or selection or that was a slight change in the half-value layer

requirements. We address field limitation, looking at what was in the IEC standard, thinking that we can do a slightly better job these days with field collimation, trying to look at the efficiency with which we are using the x-rays incident on the image receptor, and that has a two-step requirement. If the circular image receptors, if the diameter is less than 32 cm, we want the image receptor to capture 80% of the x-rays, and if it’s larger than 32 cm, our proposal was that you have a 2.0 cm total tolerance misalignment across the diameter, and since we now have rectangular fluoroscopic image receptors coming along, we had to clarify what the field alignment would be for those devices, and it’s essentially the same as the radiograph **as far as alignment requirements**. We totally revised the paragraphs current 1020.32 D and E that address limits on maximum entrance exposure rate or air kerma rate. I still say exposure rate, force of habit, but there are no changes in the limits. The numbers are the same. We tried to clarify and simplify

this section as well as to make it clear that the previous exemption that we had in there for analog

recording with an analog recording device such as a video tape recorder, not a digital system, was not exempt from the limits. And we posed in the preamble to the proposed rule questions about, “Should we be looking at entrance air kerma rate at the image receptor rather than the patient, or did people have suggestions for how we might address this? Would this be a better approach?” We got mixed comments on that, and we’ll just have to see how that comes out. We dealt with the question of mini C-arm systems. We’ve had a number of manufacturers come to market with these mini C-arm systems meant – intended for use with extremities or in plastic surgery or athletic event monitoring, and currently, any of these systems that don’t meet the current requirement, they have to come in and ask for a variance. We just propose putting into the regs a requirement that would address the source-to-skin distance for these systems and get rid of this problem of having the manufacturers have to request a variance every time.

Requiring that these systems that meet this new shorter SSD also have to be labeled “for extremity use only.” We propose requiring a last image hole requirement on all fluoroscopic equipment, so that people would have the benefit of being able to look at images without exposing the patient. Probably the biggest change is the proposal we made for a display of exposure time, air kerma rate, and cumulative air kerma. This is the old speedometer proposal that was discussed in 1992. One of the things about this is our proposal would delete the current five-minute timer that has to be reset, and the proposal – we had two proposals in the notice. One was that you’d get a warning after five minutes, but it would just be a brief warning, and you could continue to go about your business without having to reset a timer. The other proposal was allowing people to set the interval at which this warning would occur. If you knew you were going to do a long procedure and you wanted to be reminded after ten minutes, you could set it for the

ten-minute reminder. The main part of this proposal, though, was to have the display of this time at the fluoroscopist position, not back out in the console room, and we got a number of comments on that. We’ll see how that turns out in the final rule. With regard to the display of exposure or kerma rate information, this would be at the fluoroscopist operation, the fluoroscopist’s operating position. It would be like in the IEC standard, a display of something we call the dose at the reference location, and the reference location is, thinking of a C-arm system, 15 cm toward the source from the isocenter of the system, thinking that the isocenter is typically located about where the organ of interest is and back toward the source would be the location of the patient’s skin. So this is meant to be a crude indication of entrance skin exposure/exposure rate - air kerma, or air kerma rate. This is the idea here in this crude ... crude drawing. The operator here would have a display associated with something that he can see from his position,

which would give information about the output of the system. Again, you’d go to the isocenter and back up 15 cm. This is not a very good to-scale drawing, but typically this location here from the source would be somewhere in the neighborhood of the patient’s skin entrance for the beam. We had some comments about how this display should work, what should it be displayed appropriately, what kind of units. I hope we’ll give the manufacturers a little bit of flexibility in how this is done. One of the things that we proposed in our proposal was to make it clear that if you have a fluoro equipment that was manufactured under the previous standard before these amendments, the amendments come out, and you’re interested in getting your system upgraded somehow, that we make it clear a process for doing this, so that the owner of the equipment could have somebody come in, do the upgrade so that it complies with the new requirements, and have a mechanism for making clear how to do that. One of the things we did was

modify the warning labels, some suggestions from our advisory committee that this warning label should

say more than just “to be used by the physician carefully – can produce radiation.” It also should emphasize the need for knowledgeable operation for maintaining the system appropriately. So the words to the warning label have changed slightly. We had a number of other housekeeping changes and corrections and clarifications. We have a problem in the current standard dealing with mammography or mammographic systems. An effective date in one paragraph was left out, so we’ve tried to clean up some of the things that have been there. So, what kind of comments did we get on our proposal when it was published? We heard from 12 different groups, two state agencies, three professional associations, including the AAPM and the American College of Radiology, a large industry association, NIMA, a couple of manufacturers in addition to the comments we got from NIMA, and a number of individuals including a medical physicist and a radiation effect researcher. So we didn’t get a lot of comments, you

know. Sometimes the FDA gets thousands and thousands of comments on a proposal, so I guess we think we lucked out here and we didn’t have to analyze thousands of comments. In general, they were in favor of what we were doing. There were, however, some objections to specific details of some of the proposals. So we’ve looked at all those comments, and a number of the comments suggested that we do things we hadn’t proposed doing, and that presents a bit of a problem because normally if you make a significant change, that has to be in a proposal first, so we can’t just implement some of these suggestions if we agreed they were good ideas without going out and making another proposal and giving people a chance to comment on it. However, there were some minor changes suggested that we have addressed. Some of these were clarifying definitions or adding definitions. A number of comments suggested that, you know, we get in line with what the IEC is doing, and that’s been our goal all along to the extent

possible. However, there are a couple of things that if we do, we’re going to have to encourage the IEC probably to make changes in their standard, because we feel strongly like the five-minute timer is not really what you need in fluoro these days, and the IEC has requirements for five-minute timers, so we may need, if that becomes the final rule, to do some work with the IEC to perhaps bring theirs into line with what we think is an appropriate standard currently. Some of the comments - modify definitions. A couple of the organizations were very interested in having closer interaction or consultation with FDA, particularly on the topic of some of the things we propose for suggestions or comments but not a specific proposal on our amendments. This has to do with, you know, additional requirements we might consider for imaging – fluoroscopic imaging receptors, such as the new flat panel displays or the question of the requirements for entrance skin – excuse me – entrance air kerma rate at the image receptor, and I think

FDA would certainly want to do this were we to go forward with these kinds of additional requirements in the future, so we’re – we’d welcome interactions with these groups if we do do any further amendments in the future. One of the things pointed out is the attenuation block we have in our reg is a little bit small for some of the imaging systems that we currently have, so we’re addressing that. One of the comments we had was our discussion about modes of operation of fluoroscopic assemblies. It was pointed out that in the IEC standard, mode of operation is restricted to some operational mode of the fluoro system that you get by pushing one button or selecting one control. We had a little difference of opinion about that, so we worked on straightening that out. We defined C-arm fluoroscopes. We, in the standard had the normal definition of exposure as the quantity, and we, colloquially perhaps, in the U.S. use “exposure” in the same sense that the IEC standards use as the term “generator loading” or “loading,” that is to mean the

actual production of x-rays. So, we’ve modified our definition to think about adding that to it. Isocenter

needed to be defined. Solid-state extra imaging device needed a definition. Visible area had a comment or two, so there were a number of other suggestions that we've attempted to deal with. One of the significant comments, perhaps, was some concern that we were requesting in our proposal that manufacturers describe the intended use for certain specific modes of operation in the user's manual. In other words, the manufacturer had in mind that this mode of operation would be for this clinical purpose. We wanted them to make that clear to the user. Some folks were concerned that having this specified in our standard would somehow preclude the user from using that mode for something different, and we addressed that issue. The manner and the accuracy of the dose display was of concern. One of the things that noted is we propose an accuracy of this dose display of plus or minus 25%. The IEC standard currently has a slightly larger tolerance, and we debated about what we really need there, what's feasible technically. So we've

made a decision on this, and you'll see that in the final ruling. Like I said, we talked to about getting modifications initiated by the user or the owner. The owner is ultimately responsible for that, but he, you know, should through contractual relationships, employ somebody who can do that job correctly and assure the owner that the system continues to meet the standard. I mentioned this conflict about the audibles— no, I'm sorry – this is different from the timer. There's a concern here about knowing when fluoroscopic exposures are being made. And so, we've looked at that. The idea here is ... in the good old days, perhaps, you knew fluoro was going on because there was an image being produced, but nowadays with a lot of recording, you're not clear that that's a live image or a recorded image or a displayed image. The IEC has a requirement that the generator provide a place you could connect to get that warning out, but it doesn't require that there be a warning being given, so we're working with that requirement. A

couple of comments said, "You know, this dose display is a great idea, but do we really need it for the small systems or for some of the systems maybe that aren't used in interventional procedures?" And so we dealt with that comment. We had a number of suggestions, again, for things that we hadn't proposed really, and that we would have to do considerable evaluation and really do a re-proposal to make these things part of the standard. A number of folks wanted FDA to require manufacturers to provide tools that would assist in troubleshooting, repair, servicing, testing, things that the medical physicist might be interested in, or the third-party servicers might be interested in. I think one of the issues for us if we were to propose such a requirement like this is: how do we make the connection to radiation safety performance of the equipment, so we had a comment like that, but of course we can't go with the final requirement on this particular amendment, but we'll continue to think about those things. It was a concern

that when we talk about KBP in the standard, we haven't specified that the waveform for that KBP be described, and so that was a comment that we got. A number of times we got the comment, "You should just adopt the words from the IEC standard for this requirement." There's a problem with doing that because of the structure of the two standards, some differences in definitions, some requirements in writing a performance standard the way we do, that makes this sort of difficult, but we will continue to think about these issues as we work with the IEC. There was one strong comment from the interventional radiology community that the dose display of exposure or air kerma rate and cumulative air kerma or cumulative exposure is not enough. What they really were seeking is a display that tells them something about where on the patient the dose was being delivered and how much, something that's been referred to as a skin-dose map. This is very much like a feature that was previously available on some Seeman

systems, that during a procedure would give you basically a mapping. This is a picture that would appear at the operator's console, but down here we taken and split the skin down the middle and unfolded it, so this is the back which is the center here and off to the sides is the front of the patient. But it gives you a graphical display, color-coded as to where the beam is impinging the patient, and the color tells you something about the magnitude of the cumulative dose at that point. This feature is no longer offered, but there was strong encourage that FDA require something like this on fluoro from one of the comments. Technology to do that is a little bit of a challenge, and we've taken that under advisement, let me say. One of the suggestions was that we have a feature that allows the location of the collimators to be shown without actually producing a radiation, in other words, an electronic display of where the collimators are

set, allow setting of collimators without having a beam on. That was something we didn't propose. We would have to do a proposal to require that. Again, this question about indicating the beam is on and which image is live – one comment raised the question, I think it's one that we need to think a little bit about, but in the whole area of digital imaging, what do you store versus what image do you produce in terms of the area impinged by the x-ray on the patient, something that some people refer to as image propping. If you take a, you know, 14 x 17 image but to save space, you save the central 9 x 9 portion of that, is that an issue? Do we need to think about those kinds of things, does it permit going back and thinking about how well the x-ray beam is adjusted to the image receptor size? I don't think there's been much discussion of that issue. As I said, we had some omissions and some clarifications that were needed. We addressed the issue of what is a unique mode of operation and the dose information. We had an

effective date missing. One of the things that was pointed out and we have a table, Table 2 in the requirement, that deals with the attenuation allowed for materials that will be between the patient and the image receptor, and we changed the half-value layer for the KBP at which this is measured. We, through oversight, didn't change the amount of attenuation allowed in these materials, and that's now going to be measured with a beam of higher beam quality, so this Table No. 2 in there, in the proposal clearly needs some adjustment, and we will be working on that. It will be cleared in the final ruling. Some questions, again, about the tolerance on the dose display – what we had in one point in the preamble early on, we talked about the manufacturer describing the uncertainty in his dose display. We later changed out proposal and somehow didn't kill that paragraph in the preamble, so we had a confusing thing of saying in one place plus or minus 25% and in another place in the preamble it said, "manufacturer will specify the

uncertainty." So the option for the manufacturer to specify the uncertainty shouldn't have been there in the proposal. We had just a regular typo in the description of what we were proposing dealing with the alternate location of the reference point. If you read the preamble describing this change, there's a couple of sentences there that don't make any sense at all, and we've recognized that. I don't know how that happened. So that's the kind of proposals we made, the kinds of comments we received. I just might mention that one of the things we've had to do, of course, is to look at what this might cost the community and what the benefit of it might be. I'm not going to go into this into great detail, but just to say that we looked at the cost. This is primarily our FDA estimates of what it's doing to cost the manufacturers to add these feature to equipment, the number of those kinds of equipment sold each year, what that might do to the annual cost of x-ray equipment, etc., a little bit of the cost for FDA to administer

the program, nothing about what it may cost the facilities because that just gets too complicated. But anyway, we came up with an estimate of about \$31million as an annual cost for these requirements to be implemented. If you want to see that document, this is the web location where it's posted. It's shown there

as “draft,” but we really aren’t going to change that in the final sense. The second thing that we had to do was look at the benefits. This is, I think, even a more tougher issue to do, which is, “What’s the benefit of saving dose to patients or avoiding exposure to patients?” The requirement is that we do this and do it in dollar terms. So, we made a valiant attempt to do this. There’s a document on the website that describes our analysis. We really looked at about three aspects of the requirements. We didn’t attempt to deal with all of them, but the three major that have dose impacts, we looked at, tried to estimate what that impact would be from a number of aspects of what will it mean to have a dose display, how might that influence

physician practices, and what would be the benefit of the dose reduction from that. You can see that you build quite a ... quite a house of cards, and we came up with a mean, and sort of the range of what this benefit might be, and there’s the numbers – \$88 million to over \$1 billion dollars with the mi- ... sort of the middle estimate there is roughly ten times what we saw as the cost. We got not much comment on either one of these analyses. The manufacturers didn’t have much to say to help us with the cost estimates. We did get a comment from one state that said, “Based on our experience, you’ve way underestimated the benefit.” And we got another comment from an individual who said, “Radiation is a whole lot more risky than you think, and you’ve way underestimated the benefit.” So that was our two analyses. What are we going to do to finish this job? Well, we’re trying to patiently wait the review process to wend its way through the department final to OMB. Because this has a potential benefit of more than \$100 million

dollars, it will get scrutinized at OMB more than a typical rule would. Again, I was anticipating this publication early in ’04. It’s now middle ’04, and I’m still anticipating, so that’s about the best I can tell you. Let me talk a minute about refocusing of our radiological health program that FDA is doing, and I see I left out the big R right there. We want this to be a big R program. One of the things that FDA has experienced over the last few years, of course, is tremendous increase in our responsibilities related to all types of medical devices, and sort of a diminishing in the resources that can be applied in the radiological health area. So we are trying to look at what is the place that FDA for the public can get the biggest bang for our buck or of effort expended, and so we want to look at the important public health issues related to radiation- emitting electronic products. Back when this law was passed in the sixties, people were concerned about, what’s the microwave oven going to do to your elderly parent that has a pacemaker and

is trying to use the microwave oven or the televisions that are radiating the kids that sit four feet from the front of the T.V. screen. A number of products had real concerns, and I think there were no standards in existence, and our efforts probably have contributed to public health, but with the current state of the industry in many cases and the needs in the radiological community of things that might ought to be done, we want to try to focus on the things where we can make a real contribution. That may require looking carefully at some of the current things we are doing and deciding those aren’t the most effective things. We want to have sort of a public process to identify what the concerns are of the public, the users, and the manufacturers of all these electronic products that emit radiation, help use that input to focus our efforts. We will engage the state **co-holders**. We have some plans for doing that. It’s started already, particularly in discussing these things with the state radiation control agencies. We recognize, of course, that products

evolve, and standards are sort of static, and it takes a lot of work to change a standard and keep it up with current technology. Another thing that’s changed is the manufacturers’ capabilities and knowledge about such things as quality assurance programs and quality systems. A number of those things have come to the fore that makes the industries in many cases quite different than the situation we had in the early seventies. One of the questions we have to ask is, “What’s the role of our mandatory standards in a global

economy where manufacturers are trying to make products for the entire world, and they are faced with competing standards in various countries?” We have had an active involvement in the international standards process contributed to the IEC standard for interventional systems actively in the IEC standard for CT systems. We may want to continue our role there and look at what the current role of mandatory standards should be. Mandatory standards are difficult when technology is changing rapidly. Usually you

can write a standard after you have some experience with the product, and as I mentioned earlier, manufacturers now have, I think, much more sophistication with making sure their products are being produced as designed, and that the designs are appropriate for their intended use. So in our area of constrained resources, we’re posing some questions for ourselves. What are the current benefits of our compliance and inspection programs, not just with x-ray equipment, but with microwave ovens or televisions or sun lamps or all the products that we have standards for? One of the questions I think are, “Are there really significant equipment-related problems currently that deserve the attention that they are getting or should be getting and the resources that are being expended on those kinds of issues. Perhaps the question would be better focused if we looked at things such as: training of users of the equipment, qualifications of the users, maybe the approach for diagnostic x-ray equipment ought to be more of focus

on making sure medical facilities or users of this equipment have a continuous quality improvement program in place. Some of these things that are listed in this bullet are not things we have the authority to require. They are things that we could do by influence, by recommendation, by working with the other stakeholders to help those things be possible. Some states do have requirements on quality assurance programs. Perhaps, you know, we should be less focused on, “Does the equipment meet the collimation requirements? Does the equipment meet the linearity and reproducibility requirements?” and look more at, “Is the facility doing the things it needs to do to assure that its equipment continues to operate and function appropriately?” So that’s my story. I will just tell you that we have a lot of stuff on our website that you can look up if you’re interested, and you can also get a daily bulletin from us about anything new that’s happening if you go to this place and subscribe to the e-mail newsletter, and I’d be glad to entertain any questions. Let me back up and give you that.