

DR. O'SHAUGHNESSY: So we have a few minutes for questions. I will repeat the question just because we're trying to capture them for on the video tape and we don't have a mic to go around the room. And then I'll direct it if you want to direct it to a specific speaker, please let me know. Yes?

Q: [1:07:43]

DR. O'SHAUGHNESSY: Okay, so the question is what is the effective length of the source and it was for George. There were a couple of different numbers floating around in the different presentations. And how is it measured? George do you want to just come up here?

DR. MARDIROSSIAN: I can answer that from my point of view as I did treatment planning. The nominal number is 0.1 cm or 1.0 mm, however, effectively, effectively, the effective length is zero. And I think based on that, maybe Mark can elaborate on this more. The TG 43 parameters were reduced accordingly. Well that is perhaps Tom can elaborate – How do you measure the length of the source itself?

DR. RIVARD: It's not magic how, well it's actually pretty magical how the tube works, but it's a known design. We know where the electrons are hitting the anode so we know the spatial distribution of where photons are being produced via bremsstrahlung. Furthermore, we say length; I think that's not an appropriate parameter to be thinking about. It's the size, so if you were to imagine if it was a spherical distribution, right? So if you're beyond the sphere it would be, you know, a readily point-wise approximated. So it's not, the radiation source itself is not spherical, it has a conical shape and the area over which the radiation's being emitted is somewhere between 1.0 and 2.0 mm, but the point is that because it doesn't have a length to it, which then feeds into the variation of the dose-rate distribution as a function of angle, because of that and also because planning systems can only, at this time, do point or line source geometry function approximations, and then for yet another point, because we're also at distances certainly, certainly for the breast application at distances where you're much further than the active length of the source, it's very reasonable to ascribe the geometry function as a point wise approach.

DR. O'SHAUGHNESSY: Yes, another question?

Q: [1:10:48]

DR. O'SHAUGHNESSY: Okay, I'll let Mark Rivard answer this. The question was given that the spectrum of iridium, which is a line spectrum in a Xoft source, which is a broad bremsstrahlung spectrum, is so different, how do we go about assuming, or how do we know that the TG 43 formalism is appropriate for that type of source?

DR. RIVARD: You're going to love the answer. Dose is dose. So how the radiation is produced and what energies, etc. are creating the dose, that almost does not even matter. If it was, you know, the limit of infinite discreet lines or the bremsstrahlung distribution of photon energies. So it's more important to characterize the dose distribution for the clinical implementation. The salience of what the spectra are does not effect at all the measurements and the calculations and then subsequently, you know, the ability to transfer it into the planning system.

Q: [1:12:24]

DR. O'SHAUGHNESSY: Sure, one comment on that.

Q: [1:12:28]

DR. O'SHAUGHNESSY: Do you want to summarize it for me?

DR. RIVARD: Yes, the summary is that if, perhaps in reality, it's not a point source, how can you get away with in a planning system using a point source model, when perhaps,, in reality it is not? Maybe the length is 0.12 mm or 1.2 mm. The magic of the way that planning systems work is that all we want them to do is reproduce the dose calculations accurately. So if you put, and if the investigators – those dosimetry investigators, those that measure and calculate the dose-rate distribution – if they were to use a different length than what you had done, you would get these parameters and then you would use a geometry function, perhaps with a specified length, and then reproduce dose-rate distribution, then calculate dose rate distributions. If a different length was used between the investigator and yourself, there would be a conflict. In fact, the wrong dose-rate distribution would be determined by the planning system. So, it's somewhat arbitrary, the decision of what length to use as long as it roughly approximates the reality of it and there's a lot of simplicity to the approach of using this length equals zero, because I would say for every other brachytherapy source, it's distributed in a line sense. This is not at all distributed along one axis.

DR. O'SHAUGHNESSY: Maybe we could have you come up afterwards. We can get the details. I'd like to get some more questions in, thank you. Yes. Yeah, you.

Q: I wanted to find out, what, hear more about what is the average lifetime of one of these sources?

DR. O'SHAUGHNESSY: Sure, the question was what is the average lifetime of the source? This, I'll answer that because it's more of a company generated question. The average lifetime, the specification is for two and a half hours of on time. So we've put in about a factor of two over the typical amount of time you're going to need to do both calibrations and treatment time. A typical treatment time to deliver 3.4 Gy is going to be between five and ten minutes, depending on the size of the applicator that you're using.

Q: Are you saying it's a one time use?

DR. O'SHAUGHNESSY: It is a disposable one time use device. You would use it once per patient, that's what our FDA clearance was for. Yeah, it's a little bit different model for people to think about. Go ahead, a question in the front here.

Q: Actually I wanted to ask Mark if he would elaborate on this lack of a NIST standard. I think it's more of a comment, but perhaps I misunderstood your point.

DR. RIVARD: The question's being asked by Steve Seltzer of NIST. And Steve is asking, I suppose, a brief elaboration on lack of a standard at NIST. I think when I was mentioning this, the topic was on high-dose rate iridium standard, as well as a current standard for the calibration of these sources and please correct me if I'm wrong, but I understand that there is no primary standards laboratory calibration for high-dose rate iridium 192 sources.

STEVEN SELTZER: That is correct.

DR. RIVARD: How about then for at least today, for this source, for this Axxent source?

STEVEN SELTZER: NIST has a primary standard for that x-ray beam, if you will, that x-ray energy since, oh it's more than fifty years.

DR. RIVARD: Oh, for teletherapy, right.

STEVEN SELTZER: No, no, no, for x-ray. For 50kV beam. We've had it for...

DR. RIVARD:,...I'm not denying the, that NIST has standards for, you say for beam, for teletherapy. This is for brachytherapy, so, so are you saying then that we could ship our source to you and you could calibrate it?

STEVEN SELTZER: In principle we can, but you can talk with Tom about setting up the manipulation because this source has got some unique features so it wouldn't be easy to do in our room. But what I'm trying to suggest is that the primary standard instruments have existed for at least five decades. It's just the set up and you know, and I appreciate the work that went in at Wisconsin to, you know, make it a good set up. We haven't done that yet because we weren't approached, but it's a different concept than saying that there's no instrument that will measure it.

DR. RIVARD: I guess I wasn't saying that there was, I didn't mean to say that if I did, I was just simply saying that today, I mean when you say you could build it for this, today there's nothing set up today. Right, so I was only speaking about today.

DR. O'SHAUGHNESSY: And certainly our plan is to work towards developing that, in particular, obviously we need a calibration standard that will facilitate the calibration of the well chamber that you're going to use prior to every treatment, so that's what we have been working on with Wisconsin and yes, we are working with NIST to figure out and establish a new standard. Yes?

Q: I don't quite understand what even a standard would be in this case. Are you saying that the output for micro, I mean, your calibrations, you didn't actually say but I think the calibrations have to be sort of micoramps from a well chamber per micoramp on the source, I assume, how constant is the output of the source per microamp? And how constant is the number of microamps? You would think, any one of your sources, are they all giving exactly, I don't know, 50 microamps...

DR. O'SHAUGHNESSY: ...no there is some variation from source to source in the output of each source. We allow a certain range on the manufacturing side and then we have certain requirements on for a given source and I think this relates to some of the measurements that Julian showed. For a given source, how stable is it from fraction to fraction? So, so the calibration is to take you from the current that you're measuring in the well chamber to an air kerma strength; because the air kerma strength is what your treatment planning system is based around. Again, how you tie in the calibration and the output of the source into your treatment planning and because we're using the TG 43 parameter formalism, which is tied to an air kerma strength, we need to make that connection. So that's where the connection comes from. And that's, Larry DeWerd is nodding his head so I hope I got that right. Other question, here, yes.

Q: Another question, from my experience, so the current may stay constant, but the radiation dose may be decrease within minutes. Do you have any radiation dose control during treatment?

DR. O'SHAUGHNESSY: The question is do we have any radiation dose control over the treatment even though you're monitoring the current within it. We do not have a system built in, although we have made measurements of the output of the source during actual use. I think that's one of the measurements that we'll continue to get more data on. In our own animal studies, we showed a poster, I believe it was last AAPM on that data and we have those available. You could also, if you prefer, measure, you know, output dose, skin dose, if you wanted for a given patient to monitor the dose going forward. I think some of the physicists at the early sites had mentioned that they would like to do that, but it's not a requirement for the system.

Q: I'm coming from Europe. We have dealt with a large number of difficulties with the Regulatory Boards in this case.

DR. O'SHAUGHNESSY: The question was a comment about European Regulatory Boards in terms of assuring the dose that was delivered. It's a question, I mean, we've made a lot of measurements with that, but you certainly could opt to make an output measurement. It's very simple and we've had various different exposure meters you can measure to show the constancy if you don't need an absolute value. Question here?

Q: A question on regulatory issues. With HDR you're talking about licensure and you're talking about requirements for physicists to be there and radiation oncologists to be there, had you looked into those issues and are the fears that somehow they would be bypassed somewhat realistic?

DR. O'SHAUGHNESSY: The question was regarding licensure and in particular presence of authorized users, physicists in the room during treatment. It has come up with almost every regulatory body I've spoken to and I've spoken to most of them. I think, you know, most of the agencies, once they recognize both the energy, the ability, there's a lot of interlocks, ways you can turn the system off, that I don't know which way each body will go, but as we work with the different national groups, I'm certainly, we feel that it's not necessary to have the physicist in the room with the treatment. It's very different from an HDR iridium source, where you have no way of turning it off if something happens and you want to stop treatment and it gets stuck. So, I don't know which way the conversations will end up. I think there's a lot of work being done. As Mark mentioned, the national group, CRCPD is drawing up some draft guidelines and I know they, in particular, mentioned this issue as one they wanted to discuss and we're working with various states, as well. So, we'll see how it goes. We're more concerned with making sure the appropriate people are trained and available, whether they're in the room or not, but that people understand the radiation that's coming from the system and appropriately use it.

Q: Just a comment. In Europe, the physicist has to be in the room present.

DR. O'SHAUGHNESSY: A comment, the European, in Europe the physicist has to be in the room present for an HDR treatment of for electronic...? Yeah for a similar device, I think you're saying, yes, yeah. Our system hasn't been used yet in Europe. One more question here, yeah.

Q: **[1:22:59]**

Dr. O'SHAUGHNESSY: Yes we have. Tom do you want to handle that one? Dose to the operator? Tom Rush is one of the founders of Xoft and has been traveling with the system and obviously that's one of the series of measurements that most of the sites made in terms of exposure for the operator.

TOM RUSH: As Julius pointed out, I was also the photographer in at least one of the images. What we've done is we've measured the source both in air, totally exposed with no shielding and at one meter, the typical exposure rate you get there is about 8-10 R per hour. It's a very intense source. If you put it in a tissue phantom or in, when we were doing the animal studies, in goats, with the flexi-shield in place, then at one meter we were getting exposure rates on the order of around 12-15 mR per hour. In many of the treatment facilities, the idea of having an operator, as George is mentioning, with an apron or standing behind a portable shield, then we're getting exposure rates that are in the order of 0.05-0.1 mR per hour and so during a ten minute treatment, you would end up with significantly less than an exposure of 1.0 mR.

DR. O'SHAUGNESSY: Yes, a question over here.

Q: [1:24:36]

DR. O'SHAUGNESSY: The question is if there is a material in the wall of the balloon that is attenuating enough for CT so that you can see it, then what does that do to your dose for your therapy that you're planning? It's a very good question. The good part about the fact that the material is built into the wall is that it's a very consistent amount of material. So, in the controller itself, it actually applies a correction to your treatment plan because your treatment planning system, as Mark has pointed out, is in water, it doesn't accommodate that. It's about a 6% attenuation of the radiation. We took an average based on, you know, the varying different locations of the balloon, so that 6% is applied automatically to your treatment plan in the controller.

Q: [1:25:44]

DR. O'SHAUGNESSY: The question is, if you have patients where the balloon is deformed different amounts in different directions, do you have to go back and recalculate and readjust your treatment plan based on that? The answer is no. We did look at that fairly carefully and the amount of variation you get by stretching the wall different amounts, again the fact that the 6% is an average over all balloon sizes means that covers the range from the smaller balloon at 3.8 cm to the larger ellipsoidal balloons which could be 7 cm. That would be equivalent to the amount of variation; I mean I'm assuming it's an upper limit, to the amount of variation that you would get within a patient. And so the 6% was chosen as an average and then the error that you get, using a 6% value, is folded into the overall calculation of the, the dose delivery error. So it turned out to be a fairly small contributor to the actual error in delivering a dose to 3.4 Gy at 1 cm. But we could, if you want to come up, we could talk more about the details about how that was done. More questions, anyone? Well I very much appreciate your time. I apologize for going over. Enjoy your, "Go Seedless" t-shirts. If you didn't get one, there's probably still some at the front door and thank you very much.