

Bruce Thomadsen, Ph.D. from the University of Wisconsin has been instrumental in many brachytherapy regulations, the formulation for national and international standards. The task group 152 is currently formed and is working on these regulations and Bruce is here to talk to us about that.

BRUCE THOMADSEN, Ph.D.: Thank you. It's, actually, currently dissolved since we finished our task. And I'll start by saying that this is quite less than ideal. I'm the last speaker, it's after lunch, and they want me to talk to you about regulations. You might as well go to sleep right now. I'll point out I have no conflicts. I do not consult with Xofig; I say hello to them when I see them, that's the extent of our relationship. The task group was charged with designing some model regulations that we could suggest to the CRCPD for their model regulations that they supply to states who are re-writing or writing their state radiation regulations. We were asked to do this, so it wasn't just that we wanted to interpolate ourselves into their process. This is the task group. It's a very big task group; a lot of people were interested in this. And in addition to all those people, the task group's recommendations had to be approved by the task group, by the special brachytherapy modalities working group, the brachytherapy sub-committee, the radiation safety sub-committee, the therapy physics committee, the professional information and clinical relations committee, and the government and regulatory affairs committee. This was a pretty well vetted set of recommendations. The suggestions that we make would be falling under Part X of the CRCPD regulations. If you are at all familiar with the model regulations, they're broken up into all sorts of parts, based on things like industrial radiography and medical diagnostic x-ray. Part X is therapeutic radiation machines, such as linear accelerators. On the suggestions that we made, came along with them some suggestions that we weren't making and that was that the CRCPD add definitions for electronic brachytherapy. Well, indeed, we did offer a suggestion and authorized medical physicists - they don't have that term yet - and to change medical events - change missed administration to the current definitions and terminology for medical event. All of that's just preliminary and now we get to the part where you can go to sleep, the regulations themselves. The presentation that I'm going to give you is very abbreviated compared to what the regulations themselves are. So I'm just - I'm going to list each of the items, but just the highlights of the items. If you have questions, you can ask. I'm not going to go through each of them because that would be incredibly boring and I'll try to just hit the parts that are of most interest. And the scope was the first part that we addressed; it is for electronic brachytherapy operated below 60 kV. At the moment, there isn't anybody operating above 60 kV. If somebody comes into the market and starts doing that, we go back to the writing board. The idea behind having this part was to exempt the equipment from the existing regulations for orthovoltage machines, which are designed to operate at below 50 kVp, such as, what you might use for treating skin cancer in a lot of places. Part B was simply saying you have to have survey instruments, which are appropriate for this type of radiation. Facility designs. We went around with a lot of questions on this and came up with something that was a lot simpler than what was being proposed in the first place. You have to have communications with the patients. As you saw in these particular applications, the patient's right there so you can say, "Hello, how are you?" They can answer back, there you go. The regulations say there needs to be a door to the room and shielding available for personnel. The question of why we have a door, do you really need a door? We felt that the door was there, not for radiation protection, but so that as people were coming in and out of the room, whoever's operating the machine has better chance to recognize that somebody's come in and maybe I should pay attention to where they are in the room and what the radiation levels might be there. One person was saying, "Well, they don't - their therapy

rooms don't have doors and those are for linear accelerators, couldn't we run this without a door?" Certainly you could, but you'd probably want to ask for a variance and they would be likely to give one since the door is only there as controlling who's coming and who's going. And there's a whole bunch of electrical safety references to things like IEC documents, which nobody on the task group, I think, had a clue as to what they were, but they looked good, so we included them. The regulations for the unit itself, that the unit should have a control panel, it's always good to control radiation devices and the control panel should have a power indicator; that is, something saying that you have power to the machine. And an indication that x-rays are being produced, an indication of the x-ray tube potential and current, and a means for terminating the exposure. All pretty straight forward stuff. And as far as the termination of the exposure, I won't go through and read all of these. The idea was that the unit has to have some way to control the termination of the exposure so you get the right amount of radiation to the patient. And that can be with dwell time controls, that can be with a radiation dose monitor of some sort. Whatever it is, it has to have fine enough control that your treatment planning system plan can actually be executed and that's about what that is. The machines that are on the market right now satisfy all this stuff. The authorized medical physics support was something we talked a lot about because we're medical physicists and we care a lot about what we're supposed to do. So what are we suppose to do? We're supposed to evaluate the output of the machine. Calibrate the devices; generate the dosimetric information that's necessary. If you have to feed in that table to PLATO piece by piece, that's our job or at least to see that it's done and correct. We have to supervise and review treatment calculations prior to initial treatment. That is, if you have dosimetrists do the calculations, the physicist has to review that. The physicist has to establish and review the quality assurance. They don't have to do it personally, but they have to review what happens with the quality assurance. Well, the physicist does have to establish the program. The physicist is supposed to consult with the authorized user, give advice on what to do in whatever situation is appropriate. And finally, if something goes wrong, do the treatment - do the calculations and assessment of what happened in that case. Operating procedures. You might have to figure out who should be in the room. And the authorized user, the radiation safety officer or the authorized medical physicist have to approve whoever's going to be in the room. You have to have protective shielding barriers or fluoroscopic aprons, thyroid shields if you deem that they're necessary and appropriate. The medical physicist determines who needs to be monitored in the room. Some of the electronic brachytherapy devices aren't like this. They're used intraoperatively. You don't always have radiation workers in the room, you have operating room people and it's up to the medical physicist to make a determination of which of the people needs to have radiation monitors. You need to have portable shielding of some sort or another to make sure that the radiation levels are acceptable. The FlexiShielding, if it works and is adequate, that's fine. You just have to make sure whoever is the room is adequately shielded. You may want to define areas in the room where people can be and can't be. That's the authorized medical physicists' job. And, finally, this was a big debate. The authorized medical physicist shall be physically present during the treatment. The rationale for that was debated hotly. You'll notice we don't have that the authorized user has to be there during the treatment. It was felt by the - by everybody, eventually. Although, each of the levels where we went for approval, everybody brought the issues up again and it was debated anew, that because this is not a radioactive source and if something goes wrong there isn't the urgency to remove the source from the patient. If something goes wrong, what's going to go wrong, as you saw, the tube's going to fail, the radiation's gone and so there's no emergency and you have time to go get the authorized user and say, "Things aren't

going so well, maybe you want to come down and take a look?" As long as the medical physicist is there that probably is fine. The question came up, does the medical physicist even have to be there? Can the operator be there without a medical physicist? There were arguments on both sides, saying once again, this is not an emergency situation, the authorized medical physicist probably doesn't need to be there. And there was the argument well, who knows what's going to be happening, somebody of the authority of the medical physicist should be there to keep track of everything. Let's see if there's anything here that's particularly exciting. You have to have - down about in the middle - You have to have procedures developed and implemented and maintained for abnormal situations. That is, you have to have instructions available for responding to equipment failures and the names of whoever you should want to get there if something happens. And one of the strange things - one of the little inconsistencies in the regulations, is that the names and telephone numbers of the authorized user, the medical physicist and the RSO have to be there. Of course, the medical physicist is right there, so it's not clear why you need their telephone number right there. Maybe it's the cell phone and the operator wants to get them from the other side of the room, I don't know. If the patient has to be held, only mechanical devices shall be used. You shouldn't have one of the people hold them. If the patient dies, you've got to inform the radiation safety officer or the medical - and the authorized user and either the radiation safety officer or the medical physicist have to inform the manufacturer and probably the state and other people, but you have to notify in case something happens. We're not assuming they're dying because of the treatment, it's just you've got to notify all these people if the patient dies while you're there or while they're there. Calibration is an important part of the model regulations. The physicist has to verify the output of the machine and you have to do that with calibrated chambers; the chambers have to be calibrated at NIST or one of the accredited dosimetry calibration labs. That implies that there has to be a national standard for these sources. The calibration has to be verified on each x-ray tube before you use it or if it's been repaired or anything like that, when the spot checks indicate they - it should be checked. And the calibration validation must include, as applicable, a value for the output within 2% of the expected value or the determination of the output that you're going to be using, the timer accuracy and linearity, the operation of backup exposure control devices that they're going to operate within the allowed dose range, and evaluation of the relative dose distribution to within 5% of what's expected. That is that the TG 43 dosimetry values are applicable still. And I've already said you use calibrated dosimetry system and the calibration should be in accordance with a recommendation by a national professional association, such as the AAPM if there is one. If not, you can use the manufacturer's recommendations and you have to, of course, maintain records of that. Spot checks. You have to have spot checks, that's part of the physicist's job is to design the spot checks. You do them at the beginning of each day or when the unit's used in a different room or after each x-ray tube installation. The physicist establishes the written protocol for the checks. You don't have to do them, as I said, but you have to - as a medical physicist - you have to review them. Let's see, a lot of this is not too interesting. The spot checks, of course, have to verify radiation exposure indicator lights, things like that, that just are pretty routine and you know. And they have to have - check on the output of the machine within 3% of the expected value that is what you got when you calibrated it. And your spot checks have to have some way of checking the consistency of the dose distribution. This is a little bit looser; it's just to be consistent with the dose distribution that you found when you checked the dose distribution at the time of calibration, so this is just a consistency check. And that wherever you're putting the source is going to be there within 1.0 mm and, finally, that all the treatment components are in good order. Records. You don't

want to know anything about records, that's boring. Treatment planning. The medical physicist performs acceptance tests on the treatment planning system. We just had a good talk on checking all these - what you have to do in checking all those, so I'm not going to repeat all that training. You want the people to know what they are doing so you have to provide initial training to all the operators. The authorized user and medical physicist will get training by the manufacturer initially and from trained people annually and the training should be specific for the unit, just not general brachytherapy training. Well, thank you. That's - we got through that pretty quickly and it looks like most of you have woken up after the talk. I hope you're refreshed. Thank you.