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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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QUALITY ASSURANCE WORKSHOP

Holiday Inn Crowne Plaza

Rockville Conference Room

1750 Rockville Pike

Rockville, Maryland

Friday, October 26, 1990

The above-entitled proceedings commenced at 8:30 o'clock a.m., pursuant to notice.

PARTICIPANTS:

John L. Telford

Edward Kaplan

Josie Piccone

Darryl Wiedeman

Anthony Tse

Larry Camper

PARTICIPANTS: [continued]

Kevin Nelson

Anthony Wu

Jonette Roberts

Gerald White

P R O C E E D I N G S

[8:45 a.m.]

MR. TELFORD: Welcome to the Friday session of the makeup workshop. I just want to briefly go over the agenda and show you where we have been, and what we have left to do. We have done everything on Thursday's schedule, so all we have left to do is review the regulatory guide and get your comments there. We have already done the review of the reporting requirements.

Dr. Anthony Tse will discuss the guide with you, and then we will turn it over to comments.

MR. TSE: This morning we are going to continue discussing the guide. Before I go into that, there is a couple of points that I want to make. One is that the guide will follow the rule. Whatever your suggestions on the regulation yesterday when it is adopted, the guide will be automatically revised to follow the changes in the regulation.

The second point is that we will make arrangements to discuss with the professional associations, ACR, APM and JCHO and so on, and comments we will also receive their comments and will be considered in the formulation of the final rule.

Since this guide you have already had that we discussed in the first workshop and you have looked at

information for sixty days, so I am not going to explain each element of the guide. What I am going to do is go to each section, go into each section and ask you to see whether you have any suggestions for modification, addition, deletion and so on. Let's go into the guide.

The first two or three pages are the preliminary discussions, the purpose of the guide, the introduction and so on. Unless anyone has any comments, I will skip that one.

[No response.]

MR. TSE: Then on page four is the Section 1, responsibility, audit and authority. Does anyone have any comments or suggestions on this Section?

MR. WHITE: I have a question about Section 1.2. The second sentence says audits will conducted following approved written policies and procedures by qualified personnel who are not involved with the activity being audited. A lot of facilities would have a problem finding someone who was both qualified and not involved with the activity.

We have a fairly large group, but we don't have anybody -- the hospital just doesn't hire people who are needed to perform those activities. Who did you intend would be doing that sort of thing?

MR. TSE: The activity, for example, if I am tech

I am doing my work myself of drawing up those and so on. I have certain procedures to follow. I cannot audit myself because likely if I do in this way all the time, I will less likely to find errors or problems in what I am doing. The activity, what we intended is a person who directly involved in the activity.

Other people in the department still could audit if their management decides that they are qualified.

MR. WU: Such as who?

MR. TSE: The chief tech.

MR. WHITE: In our institution the chief technologist also cares for patients, draw doses and inject patients. In radiation therapy the physicists for example do dose calculations as do the dosimetrist. We don't have anybody who knows how to do dose calculations but doesn't do them.

MR. TSE: So, how do you suggest -- what do you suggest?

MR. WHITE: I would think that you would either have to delete that part or accept the political overhead that came with having the hospital having to hire somebody just to do that.

MR. TSE: That is not our intent. Dr. Wu, what do you suggest?

MR. WU: It is a problem. In our institution in

terms of radiation therapy our procedures and our implementation of the treatments and everything, the RSO really doesn't know anything about it. They come in treat and audit and all the records and everything but they really don't know what was going in terms of planning, dose calculation, treatment set up and everything.

So, it will be very difficult. The 1.1, the responsibility and authority to establish and implement the basic QA program as well as the audit, it seems to me you put all this responsibility into the one person and that is very difficult. The one who can audit cannot implement it. The one who can audit cannot evaluate the QA program.

MR. TSE: Did you say that Section 1.1 should be modified? Didn't you say that one person -- Section 1.2 says essentially the person should not audit himself because if you do that --

MR. WU: Yes, I understand your intent. What is the definition of the qualified personnel?

MR. TSE: Under 1.2 it says qualified personnel will be determined by the licensing management. They may assign the department head or may assign the QA manager or whoever. That is stated here.

MR. WU: Do you consider that a weekly check and double check the part of an audit?

MR. TSE: No. Audit, what we intend is the annual

comprehensive audit which we talked about yesterday which I don't think is the double check or weekly check. Audit is the QA process and procedures.

MR. WHITE: I would put a period after qualified personnel in that second sentence and delete the -- who are not involved in the activity being audited.

MR. TSE: Okay. That is your suggestion. Are there any other suggestions?

[No response.]

MR. TSE: Now we go to Section 2. Section 2 contains four elements that are applicable to all diagnostic and therapy procedures. Does anyone have any comments on any of those four elements?

MR. WHITE: Section 2.4, one of the things that you mentioned at the startup meeting that we had originally was that an auditable record was not required for that section. I think if that's really the case, perhaps it might be good to put some language to that effect here. I think it would be burdensome to have to perform that task and provide a record of it.

MR. TSE: I think this is the intent of not to have a record. See in the regulation if we need a record you were specifically said what record should be kept. If it doesn't say it, then you don't have to keep it -- for the regulatory purposes you don't have to keep a record. For

your own purposes you might want to.

MR. WU: Section 2.3 said the apparent discrepancy in records, observations -- what do you mean by observations?

MR. TSE: Observations, meaning like the example given that somebody treat the left hip instead of the right hip and somebody observed this is the wrong side.

MR. WU: It is the worker's responsibility to point that out to the physician?

MR. TSE: Right. If the worker notices something that is not correct either in the records not correct or in one record says Ms. Jones and another record says Ms. Smith, then what do you do. This element says that you stop the medical use at that point, the user, and then you try and clarify what is happening and then continue.

MR. WU: The example that you gave is a very clear cut obvious one.

MR. TSE: Give an example that you think is not clear cut.

MR. WU: It depends on the treatment philosophies like treatment of stage one breast cancer. If you are coming from an institution who believed to treat internal mammary for inner-quadrant lesions then they strongly believe that the transential beam should encompass the internal mammary. If you find another institution that

doesn't believe that, then you don't do it.

It is apparent that he or she has to point out that due to observation and tell the physician that as soon as you set up for the press may not catch the internal mammary.

MR. TSE: First of all he says that the kind of case that you said first is the medical judgment.

MR. WU: Yes, medical judgment.

MR. TSE: The physician would say which way I want to treat it. If the technologist believes in her view that something is wrong then he or she should check before completing the treatment.

MR. WU: Before started treatment.

MR. TSE: Yes. If it has already started she should stop. If not yet started she should ask. If the physician says yes that's what I wanted then of course he or she would follow the physician's directives. If he or she believes something is wrong and the worker should stop the treatment and ask first before going on. That is what this means.

MS. PICCONE: Dr. Wu, these are really somewhat things that are easy to see or common sense kind of things and observations. If a technologist sees that the tattoos don't look quite right to the technologist or maybe they are not what they expect, instead of going ahead with the

therapy and instead of treating and using the patient's freckles -- if there is a question of where the tattoos are, check and see what the problem is. That's a real case that happened.

A technologist who noticed erythema knows that there shouldn't be erythema, that technologist or technologists then reported those observations went on, and that's how a whole series of other errors were determined. This kind of observation things -- the bed doesn't hold so they go to you right away and it slips when they leave, the head wobbles or whatever, this kind of thing and not observations that we did it one way here.

MR. WU: I am thinking that in the lawsuit. In the old days I remember if a lawsuit was initiated that the physician takes ultimate responsibilities. Now I think recently physicists are being sued, nurses being sued, technologists being sued. If these words were in 2.3 they could be in suit because they --

MS. PICCONE: Why didn't you --

MR. WU: Why didn't you observe. It is your responsibility to report that. Also, like doses and I think I mentioned it to you yesterday before, the patient that has been treated twice with the full dose, 6,000 RAD and 6,500 RAD for the second time. In any textbook that you look at it is overdose. Physicists know it, technologist knows it,

the physician insists to treat and what would you do.

MR. WIEDEMAN: Let me give a couple more examples of observations. We had a case over at a VA hospital where a patient decided to commit suicide by putting a .45 to his head and part of his brain was gone. The referring physician had ordered -- it looked like bone scan but the technologist looking at the patient said something is wrong. It looks like he needs something with the head.

He went to his authorized user and said they have ordered a bone scan but I think it should be a brain scan. The authorized user came and looked and said no doubt about it, this should be a brain scan. There was a case where a technologist, through his observation, decided something wasn't right.

Another case was over in Cleveland, where they were treating for hemibody therapy the dosimetrist and observing the different calculations, when he saw six minutes he knew something was wrong because at that target skin distance and feel size he knew that it shouldn't be over three minutes. Immediately he went to the authorized user and they rechecked the calculations and found an error.

MR. WU: Those cases are very obvious. There are some borderline cases --

MR. WIEDEMAN: See, you really couldn't report an observation if you really didn't recognize it as being a

problem.

MR. WU: Right.

MR. WIEDEMAN: I don't think that was the intent. It was only to catch the obvious.

MR. TSE: If you recognize there's a problem better not assume this is correct, you check first.

MR. WU: I understand that. It is sort of vague. You can -- I'm sorry I didn't see.

MR. WIEDEMAN: That may happen. It is better to ask than to take a position that that's what the doctor ordered and I'm going to go ahead and do it even if it doesn't make sense. In this way, at least the person has the ability to go back and ask the authorized user is this correct, is this really what you want. I think that was the intent behind that, was to make sure that the staff will ask questions to resolve these discrepancies.

MR. WU: Do they have to document? I ask my staff in quotas over 4,500 I ask them to ask the doctor, is that what you want. They said that is what they want. I ask them to make a note on the treatment planning that the doctor has been notified and then sign it. They are not willing to sign.

MR. WIEDEMAN: Let's assume that you do a lot of lungs and routinely use spinal cord blocks, but for a certain prescription on a patient there is nothing mentioned

about spinal cord block but the technologist knows we always use a spinal cord block.

Rather than just go ahead and give the treatment without the cord block we would want that technologist to go back and ask the physician user, didn't you want to include a spinal cord block.

MR. WU: If they don't they are liable, that's what it is.

MR. WIEDEMAN: If the physician says no in this case I don't want it --

MR. WU: If the tech doesn't ask.

MR. WIEDEMAN: The thing is we just don't want the technologist to take the position that if he didn't write it down I assume he doesn't want it, therefore, I won't put a spinal cord block in.

MR. TELFORD: Dr. Wu, I think you are focusing on what the technologist would actually do and the potential legal case, but I think what we are trying to do here is suggest that there are some rather obvious steps that need to be described in your QA procedures; that this would be guidance or instructions to your technologist that these are the things that should be done. We are not trying to create liability on the part of any workers, but rather -- so that you have every licensee has procedures that would have this sort of good advice within the procedures to capture or

detect the kind of mistakes that are very obvious examples that Josie and Darryl have given.

Is there some exceptions that we can put here or some caveats, or more explanation with some examples of the kind of things that we think you should have guidance for?

MR. WHITE: I think the case where it appears to be good clinical practice and what appears to be good regulatory practice may diverge. The examples that you have given about gosh, it looks like we are treating the patient's foot when his ear hurts, at our facility it something that we would expect the technologist to stop and go ask somebody.

On the other hand the example you gave about the cord block, what we would expect is the technologist to look at the chart and decide if the cord block -- it may not be critical that day and might not be worth interrupting the patient's treatment to find the physician -- if the guy is not around. What we would expect in that case is the technologist to make a judgment about whether that particular apparent discrepancy needs to be resolved prior to the patient's treatment or could be resolved later in the day or the next morning at chart rounds or something like that.

There is no provision in the reg guide for the technologist to exercise that kind of judgment. What it

says is that before you continue to apply the byproduct material you have to stop, and that may not be in the patient's best interest. There is just no provision in here for the judgment of the person who is applying the radiation. Again, leaving out the provision for judgment that is appropriate, you should make the assumption that you are going to have unqualified people doing this.

What I would suggest is that you include a requirement that the people who apply the radiation be qualified to be certified radiation technologists, and then include some provision for judgments. Once again, I think there is an effort here to try to set up a regulatory structure so that people that don't know what they are doing are less likely to make a mistake. It is our position that the best way to do that is to first require that the people that do the work be properly trained and be able to exercise judgment.

MR. TSE: I heard discussions and your suggestions about qualified and training requirements, qualifications and so on. I believe the NRC has an advance notice on the training and experience requirements for all medical personnel. It is on the public comment period and we have not -- we are in the process of thinking about it. Is it the last ACMUI meeting there was discussion about training and so on?

MR. TELFORD: That was brought up at the last ACMUI meeting. Can we go off the record for a minute?

[Discussion off the record.]

MR. TSE: Are there any other comments on Section 2?

[No response.]

MR. TSE: If not, we go to Section 3, which is the specific elements for radiopharmaceutical therapies and diagnostic procedures involving 30 microcurie of Iodine or greater. There is five elements in the Section. Are there any suggestions on those elements?

MR. WHITE: I have a question or suggestion about 3.5, something that we talked about yesterday where it says the authorized user will make, date and sign a written record in the patient's chart. We would normally have that as the radiologist's dictation. Often times they don't actually physically sign that. They may have some computer interaction of authentication.

I look for some word other than sign to reflect the way that people do things with electronic transmission.

MR. TSE: Gerry, first of all, this is a qualified person handling this.

MR. WHITE: In our facility that would be the physician. We would not want -- the technologist would not

normally make, date and sign a written record about the dose.

MS. PICCONE: What about the dose log?

MR. WHITE: They don't generally sign that. I guess they could.

MR. TSE: You think the sign might have a problem with your facility.

MR. WHITE: I just think that the people who keep records by computer, you need to allow them to do all the paperwork needs to be able to be computerized.

MR. TELFORD: What was your suggestion yesterday, to authenticate?

MR. WHITE: That's the word that they use at our hospital. The physician does the computer interaction in which he uses his secret physician computer code, and they say that was authenticated by doctor so and so. I don't know if it's a common word or the guys at the hospital made up.

MR. WIEDEMAN: Let me ask you this: let's assume that in-patient -- normally in a patient's chart there is a medications list. I know many times a physician will, when they administer iodine, they will write in there that so many microcurie or millicurie of I-131 was given on a certain date and sign it.

MR. WHITE: Sure, for therapy, absolutely. For

diagnostic test the referring physician who wants a bone scan might go up and write in the patient's chart bone scan and sign it. If he does that he will also sign the order. He might also sit in his office across town and type in his computer terminal that he wants his in-patient to have a bone scan, and that order will be printed out on the floor on a computer and the nurse will enter a copy of it in the chart, where all you have is a dot printer record of the transmission authenticated by the physician.

MR. WIEDEMAN: Would this really apply for lung scan? This is a pharmaceutical therapy and greater than 30 microcurie of I-131 and 125.

MR. WHITE: It would still apply.

MR. WIEDEMAN: Let's say your diagnostic referral or requisition slip is basically the report that goes back to the patient's chart?

MR. WHITE: It could be any of those things. I just think that in general there's a lot of paperwork that formerly would have required a physician's signature that now has a physician's computer authentication. A hospital would view those two things as equivalent. It is only going to get more that way and not less that way.

I encourage you in the language of this to recognize the fact that what we used to call a signature where a guy takes a pen and writes on a piece of paper may

be obsolete. You should prepare the reg guide to account for that.

MR. TSE: That probably also applies to a signed physician referral possibly transmitted, would that be sometimes transmitted --

MR. WHITE: That's right. You can't read their signatures anyway, so this is probably a good idea.

MR. TSE: All right. Are there any further comments?

[No response.]

MR. TSE: If not, we go to the next section which is brachytherapy. There are nine elements in this section. Does anybody have suggestions or comments on any elements.

MR. WU: In 4.3 when you say verify the radionuclide and source of strength of the sources to be used, you mean physically measure or you mean -- let's say all the iodine -- they give you the strength calibrations. When you say verify you actually take the seeds putting in the calibrators.

MR. TSE: No. I think the note in the back says that gives you some hint of what we mean. Essentially like we discussed yesterday, there are a number of ways that you can verify those are the sources that --

MR. WU: How do you verify this?

MR. WIEDEMAN: Through your transfer record that

you ordered one millicurie iodine seeds and pull out your transfer record and verify that yes, these are the one millicurie iodine seeds.

MR. WU: Okay to just verify by the paper record.

MR. TSE: Right.

MR. WU: Not physically identify it.

MR. WIEDEMAN: That's another way of doing it.

MR. WU: I just want to know if a paper identification is okay.

MR. WIEDEMAN: To me, it would be acceptable. I think the intent is just to make sure you haven't plant the improper seeds or sources that was intended. There should be some kind of a verification system if by color code, serial number, direct radiation measurements, observation, review of transfer records to make sure you received what was ordered. That's a verification.

MR. WU: You say make sure you received what was ordered. If you order -- most of the time you don't receive what you order anyway.

MR. WIEDEMAN: Then you go back to the vendor that you ordered it from and say this is not what I ordered.

MR. WU: You never receive what you order. It is close to what you order but not exactly the same.

MR. WIEDEMAN: Okay, you could be off. Rather than giving you one millicurie of iodine they may have given

you 1.02, once again you go back to the physician authorized user and say we ordered one millicurie but we got 1.02. If he says that is acceptable because that 1.02 is insignificant, document it on the prescription and you are in good shape.

MS. PICCONE: This is if you want a load with three 20's, that you get three 20's and didn't pull out three 5's. That's the --

MR. WU: I am very torn in signing. I totally understand your intent which are good intent -- which really happens in the real world. There are certain areas that it is very difficult if you apply the same standard to the other areas like a prescription -- we spent a lot of time talking about that yesterday -- iodine prostrate implant. The prescription, to read it doesn't mean a thing, permanent implant. Prescription doesn't mean anything at all.

They usually don't prescribe I need 50 seeds, one millicurie per seed. We suggest they don't do that; that you ask them to write down what we suggest and they don't like that. They sort of commit themselves. The second one is that they do the implant they really don't know how many seeds they are going to do the implant. They really don't know what dose to distribution is going to be.

Third, they take the patient with the implant, bring the patient down to take a film, do the dose

calculation. Even at that point they still don't know.

MR. WIEDEMAN: They have no idea how many RADs they want to deliver to the target organ?

MR. WU: That don't mean anything, really. Like Gerry pointed out, they want to put as many as possible to destroy the tumor cells or look at it -- this is several centimeters and they just put in everything. For permanent implant you do the final dose calculations. You have something like in the 16,000 RADs. What does that mean? It doesn't mean anything.

There's no biological conversion from the iodine permanent implant dose to equivalent fractionated external -- none. Also, the dose of 16,000 RADs, it is arbitrary -- the curve he pick. There is no unique way of defining that dose. At that point then he write a prescription, okay? Let's call this 16,000 RADs. What is done is done; you can't change anymore and can't open up and take some few seeds out.

Something like that it is difficult. If you talk about 20 milligram cesium and make sure it's not 15, that's true.

MR. WHITE: If the meaning of the word "prescription" in this case were reduced to what we talked about yesterday where you re-specify the radioisotope and activity of sources, the prescription meant the physician

said Iodine 125 seeds between .5 and .6 millicuries each, period. To us, we think that might be acceptable.

If the definition of prescription were as simple as we discussed yesterday I think that's easier. I think it is easier. If the definition of prescription is more detailed like RADs or number of sources or something like that, then I think the situation is a whole lot more complex.

MR. WIEDEMAN: If your physician said Gerry, I want you to order me some implant seeds, I am going to do an implant next Monday of course, I am sure you would ask what kind of an implant. Otherwise you may order iridium seeds or iodine seeds.

MR. WHITE: True. What I would ask him is what kind of isotope do you want.

MR. WIEDEMAN: There you go, okay. Then you would write that down --

MR. WHITE: Iridium 192.

MR. WIEDEMAN: Iridium 192, and then you would give him the options that they come in so many millicuries per seed.

MR. WHITE: That's right.

MR. WIEDEMAN: He would say I think probably, what do you think, how many seeds should we order. You would probably want to order more than what you think you are

going to use.

MR. WHITE: Actually, those are three questions. The first question was what isotope, and I think having him write that as part of the prescription before he goes into the OR -- not necessarily before he orders the seeds but before he uses them -- I think is okay. The second part about what activity does he want the seeds to be, again, that is reasonable. I want about .5 and .6 and he would write a prescription of 0.4 to 0.6.

The third question is how many seeds, and I think that is irrelevant. We often times just order a whole bunch of seeds, so I don't think that ought to be part of the prescription because the number of seeds that you order or the numbers of seeds that you bring to the operating room doesn't relate to that patient. It is not part of that patient's treatment.

It's the same way as when a patient goes to the OR and they have a drug cabinet on the wall just loaded with all different kinds of drugs. They don't record that as part of the patient's prescription, they only recorded what they administer to the patient. I think the prescription for brachytherapy, seal source brachytherapy is limited to the name of the isotope and the approximate activity of the sources. I think that is a reasonable thing to write down ahead of time.

I think when it gets beyond that, then it becomes a problem there.

MR. WIEDEMAN: So, when does a physician decide 10 seeds is good enough versus 20 versus 50?

MR. WHITE: At our facility it depends on the kind of implant. Generally, when he puts them in or sometimes for a temporary implant like a breast implant, after he puts them in to see how many fit or puts them in to look at them and take some out.

MR. WIEDEMAN: Like a permanent prostate.

MR. WHITE: He determines that when he is putting them in.

MR. WIEDEMAN: Just put as many as you can get in.

MR. WHITE: Yes, sometimes that's the way it goes. It's not the sort of thing you want to specify ahead of time. You could, but it wouldn't serve any medical clinical purpose, it would only serve a regulatory purpose. I would like to think that we would want to discourage prescriptions that are not for medical use but rather for regulatory use. The real reason you write the prescription is to care for the patient and not to satisfy the NRC.

I think if you have a case where writing a prescription is not something you would do to care for the patient, I wouldn't think that you folks would have an interest in requiring that.

MR. TELFORD: We are interested in tracking the byproduct material here.

MR. WHITE: I don't see anything wrong with that, but I don't see what the prescription has to do with it. The shipping records are a non-patient record that you can use to track the byproduct material. That seems reasonable.

MR. TELFORD: Don't you have these in safe that you keep these in, a source safe, a shipping container.

MR. WHITE: Something, yes.

MR. TELFORD: Some shielded area, and you have a log where you log them in and log them out?

MR. WHITE: Yes.

MR. TELFORD: If you are going to do this prostate case, surely the physician has to ask for a certain number of seeds to be brought to the OR.

MR. WU: That doesn't mean the number of seeds that he is going to do the implant.

MR. WHITE: At our facility, that is determined by the number of seeds that will fit in the applicator. If we have an applicator that has enough cartridges to load 50 seeds, we put 50 seeds in it, everybody.

MR. TELFORD: If we called it a pre-plan as we were talking about yesterday and specified the isotope and activity of each seed, in this case if we ask for a number of seeds you have a standard -- the number of seeds that go

to the OR -- there would be a standard procedure for you -- the prostate -- and you just typically take 50 seeds.

MR. WHITE: I think it's inappropriate. This section here, this whole concept has to do with regulating the way physician's write prescriptions for patients. What I am saying is, that is not part of the prescription for the patient, that's a shipping or bookkeeping record and ought not to be part of the patient's medical record.

MR. TELFORD: It only becomes of interest after --

MR. WHITE: After you use it on the patient.

MR. TELFORD: After the seeds have been implanted. So now, we know the number of seeds and location.

MR. WHITE: That's right.

MR. TELFORD: Or will determine location, and then you can calculate the dose.

MR. WHITE: That's right.

MR. TELFORD: Except for a permanent implant, you are really saying that the best you can do is put in the maximum number of seeds. This applies to any kind of brachytherapy procedure.

MR. WU: In our institution the physicist has some idea of how many seeds, like a physicist has an idea of how to treat the external planting for external things. What I would do is, I will tell the physician that this is one millicurie iodine; to the best estimate the size of the

prostate. You would need total number of millicuries which means if you need 50 millicuries you need 50 seeds. That is my suggestion.

When he opens up the patient or does whatever, another method of doing this is a cartridge or something like that. That's another story. He makes judgment at that point, where he can put 50 seeds. He may want to use more. What we usually do is, I usually order 60 or 70. For institution for iridium, they order 100 seeds for every patient.

I will give you enough seeds so you can do whatever you want. There is no prescriptions prior to the use of the isotopes.

MR. TELFORD: Let's talk about that as a pre-plan to facilitate our discussion.

MS. ROBERTS: I don't know much about brachytherapy, but doesn't 4.6 take care of that?

MR. TSE: That's the intent for why we put it in there. I think their suggestion is that the pre-planning -- before you implant that piece of paper or whatever should not be called as a prescription. They don't want to change -- the physician cannot change his mind. He has not yet determined. If we force him to write down as a prescription, for them to admit there is a change of mind --

MR. WIEDEMAN: I heard your comments on permanent implants with the iridium or iodine, and I see the problem. Let's go back to a gynecology procedure. In that case -- correct me if I'm wrong -- the physician knows what the isotope will be, cesium usually, and he would normally have some idea how he wants that applicator loaded. He doesn't know what kind of an applicator -- Manchester or whatever -- he would know probably how he wants that applicator loaded, two five's and a ten or whatever and the different tandems; is that not true?

MR. WHITE: The question is at what time?

MR. WIEDEMAN: Before it goes into the patient.

MR. WHITE: Before the source of the byproduct material is --

MR. WIEDEMAN: Right.

MR. WHITE: Sometimes he knows that and sometimes he doesn't. Sometimes he will choose the standard loading, put it in the patient and then do the dose calculations and adjust if necessary afterwards.

MR. WIEDEMAN: Okay.

MR. WHITE: What we suggested yesterday is that if a prescription were limited to what you just said -- two fives and a ten cesium 137 -- I think that's reasonable. If he makes that prescription prior -- if, before he put the byproduct material into the patient were required to have a

written prescription that says two fives and a ten cesium 137, I think that's reasonable. I think before we load the byproduct material, if you are required to say 4,500 RADs to point A, I think that is maybe not reasonable.

MR. WIEDEMAN: How about a range --

MR. WHITE: No.

MR. WIEDEMAN: No range?

MR. WHITE: No.

MR. WIEDEMAN: The physician, I am sure, has some idea that he wants to deliver so many RADs.

MR. WHITE: Why do you have an interest in that? You have spent a lot of time telling us that you are not interested in doing the practice of medicine, you are interested in avoiding misadministration. What we suggested yesterday, if the physician dates and signs a prescription that says the isotope and number of sources that he wants and those are what are put in, I think that your concern about the dose to various anatomical points is not important at that time if it's not important to the physician at that time.

What I think you guys are saying is that you want the physician to feel it's important to know the dose to the prescription point before he loads the sources even if it's truly not important to him. I think that's the practice of medicine. If it is not important to that therapeutic

oncologist I don't think it should be important to the NRC.

MR. TELFORD: Let me revisit our thought process of yesterday. I thought that we said yesterday that prior to implant that the parameters of importance were those that you have been talking about, the isotope, the activity and the number of seeds depending on the case. Like the case of using the gynecological implant or a catheter to the lung, it may be important to bring the important number of strength seeds like five, ten or 20's and how many that the physician wants in the OR.

We are interested in the dose but not necessarily at that point, is what we were saying yesterday. It's after the implant that we are interested in knowing the dose because that tells us when the seeds come out. That is really the parameter of importance at that point; is, if you are going to leave the seeds in the catheter for 72 hours or 36 hours and you want them to come out at that point. That's a medical decision that collectively you make and the physician signs off on.

That's the point that we are interested in, dose. We have to be careful, because say in the case of the high dose rate -- the brachytherapy treatments, you need to get everything correct ahead of time, before you actually start dosing the patient because it's all over so quickly. We

understand fully on that, your points about the permanent implant. I think we can have words that follow your guidance there. For the catheter, then I suspect we might be interested in the number of seeds at each activity so that the appropriate ones are delivered to the OR to be used.

What are your thoughts on the high dose rate after load devices where it all happens so quickly and all the input has to be correct?

MR. WHITE: I think that I would agree with your assessment about permanent implant where you specify isotope and activity, but I disagree with your assertion that number of seeds is important or cesium, after loaders and so on. Again, I would say that activity and isotope are the important things to note at the time that you put the source in, dose is not. I just think that is not necessary in medical practice to do that with people who are practicing that honorably and well.

The third aspect about the remote after loaders, I think is exactly the same as the other situations with the compressed timeframes. One of the things that we talked about yesterday is that even for a GYN application you put the sources in and you don't know immediately the actual RAD dose. At some time in the not too distant future you need to know that. We talked a little bit about how long is

appropriate; is it an hour, two hours, 20 percent.

For the high dose rate application I think the question is the same, it is just that the timeframe may be compressed, and maybe it's compressed to have him know that before you put the sources in. I don't know. Quite frankly, we don't do high dose applicators. I think the philosophical question is the same, it's just the temporal scale becomes compressed and maybe it's compressed to zero.

I would hate to think that a rule is made to apply to high dose to account for mistakes made with high dose rate applicators, and is applied to all these other things that have very different characteristics. Maybe that requires a separate paragraph. Paper is cheap.

MR. TSE: Maybe we need several paragraphs, one for each type of -- each kind.

MR. WHITE: It seems to me, speaking from a complete lack of experience, high dose rate brachytherapy has a lot of different problems both in the planning and execution than does ordinary brachytherapy. The way the dose distribution is shaped is different.

MR. TSE: Dr. Wu, do you have something on high dose?

MR. WU: No.

MR. TSE: Are there any other?

MR. WHITE: Yes, I have a question about 4.5.

Again, it may not reflect the way things are done in the clinic. We often times do not take radiographs of the actual sources, and we often times do not even when we do, don't use those as the basis for calculation. An example might be on after loading GYN implant where the films are taken with dummy sources. Another might be a seed implant with a template where we might have 40 needles, where it's difficult to see the seeds on the radiograph but we know where they are at because we know the way the template is shaped and held in place with one-half inch plastic template.

In those cases we might not use the actual radiographs to do dose calculation.

MR. TSE: We have already discussed this one in the earlier workshop, and that is what we will change.

MR. TELFORD: In other words, we agree with your assessment.

MR. TSE: Are there any other elements?

MR. WU: Yes, 4.8.2. Can you elaborate on this?

MR. TSE: For the computer generator dose calculation, the check needs only to be done for the inputs -- the check.

MR. WU: You don't really care what's going on in the black box?

MR. TSE: In this program we do not elaborate

except there's one element later which is in teletherapy that we have something. In this case we say that assuming the program is checked.

MR. WU: By whom?

MR. TSE: It is checked by manufacturer and is checked by the user also. When user receives a program you probably need to run some cases to make sure of the program.

MR. WU: Run some cases. When you say check, they actually check the dosimetry?

MR. TSE: No.

MR. WU: Check physically measure the dose?

MR. TSE: No. Here we do not say check, we check the input. If you have a computer program you use that program to calculate the dose.

MR. WU: I understand what you are saying. Again, it is the same case again. There are some obvious mistakes that people put the wrong input into the computer.

MR. TSE: That's right.

MR. WU: My point of view is that yes, there is a possibility that people may put the wrong input -- people do mix up with millicurie and milligram -- however, the main problem is -- of course this is a problem and is easy to catch. The main problem is that nobody is regulating the accuracy of the computer planning software. That is the main problem.

If the software is wrong, then every time that you have a correct input in you get the wrong answer. There is no governmental regulation on the software package, that's what I tried to say yesterday at the beginning. I strongly believe that it is the vendor's responsibility to be sure that the software package actually -- calculating the right dose. Like you are buying a car, General Motors makes sure that it is safe and it will run.

MR. WIEDEMAN: Yes, we have heard that comment before.

MR. WU: That is the weakest point.

MR. TELFORD: Do you have a suggestion for what we ought to put in the section? Should we say that the program will be demonstrated by use of appropriate sample problems or would you have them prove that it works to a key point or central point before you allow it in your department?

It's okay to give them the responsibility, but how do we -- let's say that we like that idea. What do we say to do some sort of simple prover?

MR. WU: How do we say to whom?

MR. TELFORD: The first question is, should we have something in the section that ensures that the manufacturer's product works and not just assume that --

MR. WU: It is not in NRC jurisdiction to regulating their software packaging.

MR. WIEDEMAN: In a round about way, yes. Part 21 is for -- if you look over Part 21 it says anyone who supplies equipment or supplies to an NRC licensed facility and they find a defect or problem in it, they have a requirement to notify the NRC of what actions they took to correct that problem even though they may not even be a licensee.

MS. PICCONE: FDA has published some proposals on computer programs and whether they are an integral part of an instrument. I am certainly not the right person to speak about FDA.

MR. TELFORD: Take an example here of a brachytherapy program. You have bought a software package and you use it to do calculations, and it results in ten overdoses and it's not your fault --

MR. WU: With those compared with --

MR. TELFORD: Compared to the final prescription, not the pre-plan but the final prescription. Then you have a problem because you have to report ten overdoses, but the problem really is the internal workings of the software that is wrong. I think we would come down on that, no question.

MR. WU: If you are going to record -- you said well, you are more than ten percent or 20 percent over the prescribed dose -- the written down prescribed dose -- I would contest that you prescribe those at the midline or the

pelvis and hey, let's measure it. That's what you mean, right? You mean you deliver 4,500 RADs to the midline or pelvis. Let's actually measure.

It is not what you calculate, it's what you actually delivered to the patient. What you will find out is --

MR. WIEDEMAN: If you basically delivered what was prescribed then you are in good shape, even though the computer may have been wrong.

MR. WU: I bet you even those calculations are correct they are off. I mean, the medicine is not a science yet. It is not in that kind of accuracies.

MR. WIEDEMAN: Let me give you an example. We had a hospital up in the Northern Peninsula of Michigan that they were doing a lot of breast therapy and using a computer generated program to do their treatment planning. They also --they prescribed to a protocol with M.D. Anderson, where you send the patient's chart down to Texas and they reviewed the physics calculations and all that.

They got a call back from M.D. Anderson saying that the computer program was correct; however, they misapplied one of the parameters. I think it was on a block factor or something, they were supposed to either add or take away. Therefore, they had at least 23 misadministration because they had misapplied the computer

program. That would be a case of what we would be looking for in this particular thing, is to make sure that the input and output are correct.

If it's a matter of something that is out of your control like the program was not good to begin with, it's true that you would probably have a report for a misadministration but I don't think we would hold you responsible for coming up with corrective action other than we won't use that program anymore. We would probably go back to the manufacturer of that particular computer program, or at least turn it over to FDA to have them go after it.

MR. WU: I think the dose calculations are a very primitive stage, and I can tell you that the physicists ten years ago tried to convince the physician to take homogeneity considerations -- they would not do that. If you said 4,500 in the middle of the lung, are you talking about 4,500 in the middle of the lung assuming that the whole density of one or 4,500 in the middle of the lung actually measured -- you have a cadaver and you five times your actual measure 4,500. Which one is correct, the prescription is correct or real measure dose is correct.

MR. WIEDEMAN: I like real measured doses.

MR. WU: Then you run into the problem. The measure dose would never be the same as the prescribed dose.

MR. WIEDEMAN: The measured dose would never be the same as prescribed dose?

MR. WU: Yes, because in homogeneity it was never considered.

MR. TELFORD: By how much would it be off? Are you talking orders of magnitude or are you talking a small percent?

MR. WU: I don't know.

MR. TELFORD: Just a statement that they are never the same, we would agree with that because of course they are never the same. It would be very, very difficult to deliver exactly 4,500.000 RADs.

MR. WU: No, we are not talking about -- you talk about algorithm of calculations, never taking into account homogeneity, lung homogeneity. So, 4,500 in the prescription is a fake number. It's a number, it depends on how much you interpret it. Really, literally, say you want a 4,500 to the midline or the chest, then I will say I'm sorry this computer will not give you that kind of accuracy. The same is the brachytherapy. You have ten vendors coming and two or three dosimetries to run the same program on the point A, the people don't even believe where the point A is.

It's very difficult to think that medical is a science.

MR. TELFORD: Let's say the physician said I want

4,500 to the midline of the chest and you said I can't do that.

MR. WU: I will not say I cannot do that. Under these circumstances they understand that, the homogeneity is not corrected.

MR. TELFORD: What is the effect of the inhomogeneity?

MR. WU: It could be as much as ten percent.

MR. TELFORD: The physician's next question might be how close can you get to 4,500, and is it higher or lower?

MR. WU: He doesn't really care, because his mentor taught him that it's 4,500 without incorrections; therefore, he use 4,500 without incorrections. He said my mentor, my teacher gets a good result and why should I change it. Same is milligram hours. Many physicians still use milligram -- regardless of what kind of source filtration is. They use milligram hours.

Forty years ago they use milligram hours and get a good result, why should I change the prescriptions.

MR. TELFORD: You are saying there's a common understanding among physicians that due to inhomogeneities that if you ask for a dose of 4,500 you are likely to get something that is ten percent higher.

MR. WU: Higher or lower, we don't know. It's not

going to be like 4,500 you measure water.

MR. TELFORD: For this section you have this working understanding of that's the way things are. So, the only question here is that you are trying to use this calculational program as well as it can be used.

MR. WU: Right.

MR. TELFORD: So, 4.8.2 just says check the input and the output.

MR. WU: I don't have any quarrel with the 4.8.2. I think I tried to point out that the primary problem is much bigger than you think it is. You don't never assume that the magic box is absolutely correct. You already assume that the prescription is absolutely correct, and they are not. Like I said, you have 100 physicians send patients and ask them to prescribe and maybe you get several different numbers. They are not absolutely correct.

MR. TSE: Dr. Wu, I think we understand that the calculation is the best that they can do under the circumstances to define a dose and to define a number of minutes or hours. When you buy a computer software, what do you do to assure that this is a good software that you can trust; what do you do?

MR. WU: You understand the software and you understand the limit the software can do.

MR. TSE: Do you test the software?

MR. WU: By what way?

MR. TSE: By measurement. You make a simple calculations and you --

MR. WU: No. Not everybody. Like a fracture applicators as to the bladder shields -- all the available software packages right now don't deal with that. They don't deal with the shield.

MR. TELFORD: They don't have the shield in it?

MR. WU: In the calculation program.

MR. WU: When you buy it you have to understand the limitation.

MR. TSE: How do you know the software computes the way you want it to be computed?

MR. WU: They don't. You know the limit, and you know what they didn't do. You know the external -- for instance you do external and you know algorithm how they construct. They have a mathematic model to simulate the profiles, and most of the time they try to fit real well at the central axis. Therefore, there are people who actually do the treatment planning and it just skims through the spinal cord and interpreted within a couple of millimeters this may be 70 percent or 50 percent.

When a physician comes to me and says should I move another one millimeter -- 70 percent to 50 percent -- I said your guess is just as good as mine. I don't know.

MR. WIEDEMAN: Let me ask is it possible, and I don't know what the answer is -- is it possible to do a computer generated program using your ten-ten milligram sources and get an output measurements from your computer and then compare that with a nomogram?

MR. WU: There's no such thing as a nomogram for the cesium source.

MR. WIEDEMAN: There is no nomogram. Isodose curve?

MR. WU: What we do is generate the dose versus the distance against the published -- just the distance. The very difficult to fit the isodose curve in the 2-D dimensions.

MR. WIEDEMAN: You are saying there's a lot of uncertainty. It could be done, but there's a lot of uncertainty in it?

MR. WU: Yes.

MR. WHITE: I think you guys are asking two different questions. I think that what Dr. Wu is saying is that when the computer reports the dose to the physician you start with a set of assumptions that may not be strictly related to reality. Given those assumptions you come out with a certain dose. I suspect that what you folks want is that if you pretend the assumptions are correct, do you get the dose that you expect.

What Dr. Wu is saying is we can do that as long as you don't hassle us about whether or not the assumptions are correct. If we want to pretend the lungs are filled with water or we want to pretend cesium sources have uniform loadings, or want to pretend that we know what the gamma factor for Iodine 125 is; if we want to pretend all that stuff and we get a predictable number out of it.

We don't want to be cited if the let's pretend turns out to be wrong. When we first started to use Iodine 125 seeds we used a certain set of input data into the computer. A couple of years later the guys at Memorial changed their mind. Now what was 16,000 RADs is now 20,000 RADs. To us, that's not a mistake, that's an advance in knowledge. It's the let's pretend part that we think needs to be exempt from regulatory oversight.

MR. WU: That's right. Like Gerry was talking about, specific dose factors. In last five years they changed numbers -- 1.3 something changed to 1.1 or something like that. That's the input data. If you cite me that --

MR. TSE: I don't think that is included here.

MR. WU: I know what you tried to do --

MR. TSE: We state specifically for the patient. The patient-specific input data, not the scientific data which is technical data which is included in the program. The patient, for example --

MR. TSE: So, you really don't care if somebody put in the wrong specific gamma factors or wrong dose tables, as long as you are cranking out the same thing.

MR. WU: I think we do care. The check here is to check the patient-specific input data in this particular section.

MR. WHITE: I would point out that's probably not the example that Darryl used. A lot of the misadministration with brachytherapy have been due to people who have essentially taken these source-specific data and entered it incorrectly. They have misunderstood what the specific gamma ray factor is or what the conversion between milligrams and millimeters are. Those are the big mistakes.

MR. TSE: They have to input at the time --

MR. WHITE: Generally not. Some systems require you to do that, but most -- the ones that are built correctly I think -- leave that essentially difficult to get at. You put it in once and hopefully do it right, and don't present the operator with the opportunity to make that mistake for every patient. We prefer the guy who put in the dosimetry wasn't asked that question. It gives him a chance to screw up weekly instead of once a year.

MR. TSE: I think the intent here to --

MR. WHITE: Patient-specific.

MR. TSE: Whichever the input you need at the time

when you treat the patient, the way you calculate for the patient. If the decay factor needs to put in at the particular time, then that should be double-checked.

MR. WHITE: I would like to point out that it may not be the cause of most of the errors. It's hard to argue that that ought not to be done. Again, I am not sure that is the cause of the real big errors.

MR. WIEDEMAN: Let me ask this: What should we say in the Reg Guide to make sure that the computer generated programs are as accurate as possible?

MR. TELFORD: Or, what do you do?

MR. WHITE: I suspect I would suggest two things. One is that at some time the operation of the program, including the specific gamma ray counts and all that sort of stuff, be approved or signed off on by a certified medical physicist. I don't know how the language would be. You have a teletherapy physicist and maybe there was some talk in one of the proposals that I saw for a brachytherapy physicist definition.

I think that has happened at least one place where the input data was put into the computer by somebody who wasn't a physicist and didn't understand. Not that it couldn't be done by a physicist that didn't understand, but fortunately for our profession in that case it was done by somebody else. I think that's one thing. I think, although

I really hate to admit it, I think that the double-check of the input data is a good idea. It is something that I think is difficult to do because not only do you have to double check it, it has to be double-checked quickly by somebody else who is qualified. Those three things simultaneously are hard to do.

They are hard for us to do in a group that has three physicists. We have a guy that is at a hospital for two days in a row and we have an implant, we have to send somebody else -- another physicist there that next day to check the implant. That is difficult.

MR. WU: Also, are you considering that digitizing is an input data? You have 50 iodine seeds, you digitize 50 iodine seeds into that computer --

MR. WHITE: Location.

MR. WU: Location. Is that input data? Do they have to be double-checked?

MR. TELFORD: How can you double-check those?

MR. WU: I am asking you.

MR. TELFORD: Theoretically, yes.

MR. WU: Theoretically yes, but practically not possible.

MR. TELFORD: Practically not possible.

MR. WU: Yes. There is no double-check mechanism. Either you wipe it out and start over again and that's good

as the first time.

MR. WHITE: What we do for that is a more casual check. We have a prostate implant, the guy who checks the second time will essentially look at it with a ruler and say yes, this is four and one-half centimeters by three centimeters by two centimeters, it's about what the doctor said. It looks about right.

We have had one case where he measured it and the prostate was one and one-half by two centimeters by one and one-half centimeters, and we knew that the guy who put in the seeds had done it wrong. I think that kind of casual check is probably appropriate. Checking the source coordinates for each source is just not possible. As I say, it does become a double-check and it becomes - doing it again --

MR. WU: Doing it again.

MR. TELFORD: Gerry, you started talking about you would do two things.

MR. WHITE: Yes. The first thing was to have the input data approved by somebody who knows what they are doing. The second thing is, I think this double-check is a good idea. I think it's going to be difficult to do in practice. If it's hard for us to do with three physicists in a group that covered two hospitals, it's going to be very difficult for some guy who is all by himself.

MR. TELFORD: What do you do with new programs that you get, how are your programs checked out?

MR. WHITE: We check them by comparing them with published data for simple geometric situations; one seed, different positions, different places off axis. Then we check combination of seeds. If it works for one seed, what happens if you put ten seeds in the same place, you get ten times the dose. Then we hope for the best.

That sounds simple, but it takes us -- we have done three of these new computers so far. The brachytherapy part probably takes about 40 hours to check.

MR. TELFORD: One program.

MR. WHITE: That's right. It's usually seeds and linear sources are usually separate. It takes us a long time because it's a lot of detail. It's not the kind of thing that lends itself to regulatory description.

MR. WU: I think Gerry's first point is very well taken. I think for unqualified person to enter those dose tables, attenuation factors, all these in systematic fashion, all the patient is done on that computer. They have to really be entered with a tremendous amount of care. If you screw up one number all the patient will be.

The outcome is the same. It doesn't matter the output -- your input and output coming out the same. Like cobalt decay factor, if you put the wrong decay factor it

doesn't matter. You put input and output and do 100 times, and you have the same. That digitizer position of the source, it is not possible to double-check. In our institution we double-check the activities to make sure it's correct and make sure it's no screw up in milligram and millicurie.

Then we plot on the transparencies the position of those seeds and superimpose on the film and they look at it, this is all right in general, not every seed to make sure they are correct. That is the extent.

MR. TELFORD: Gerry described a sort of gross over check of the rough, overall dimensions.

MR. WHITE: I think that's fine. What you need to avoid is determining those source coordinates, the X,Y,Z coordinates the second time. I think some rough double-check is appropriate for that sort of thing.

MR. TSE: Are there any other comments on brachytherapy?

[No response.]

MR. TSE: It's 10:10, so perhaps we should take a break for about ten minutes. We will come back at 10:20 to continue to teletherapy.

[Brief recess.]

MR. TSE: We will resume our discussion of the regulatory guide. Now we will discuss Section 5, which is

the specific elements for teletherapy. Who wants to start comments?

MR. WHITE: I get as far as 5.2 before I have a question. That has to do with approve a treatment plan that includes -- and then it describes a number of items. One of the treatment volume, I think, is problematic. I think it's something that has specific meaning that is not always determined in advance of administering the teletherapy dose.

The total dose at a specified location is also not always determined at the time the initial treatment is done. Nor is the number of fractions, although often times prescribed is an interim dose which is quite different from the total dose. The treatment volume is a big problem in there I think.

MR. TSE: I think the intention here should be treatment site, like the regulations. You can look at treatment site as volume.

MR. WHITE: I see how you define treatment volume. I mean, there is an official radiation treatment volume.

MR. TSE: They call target.

MR. WHITE: Target volume, yes. I think there may be some confusion in what you mean.

MR. TSE: If change to treatment site, you would avoid the confusion.

MR. WHITE: I think that would be a little bit

better.

MR. TSE: You also mentioned the total dose and the dose per fraction.

MR. WHITE: The dose per fraction generally we have to specify, but the total dose may not be there. The physician may have an intention to treat 4,000, 5,000 or 6,000 RADs, but often times will say he will treat 180 RADs a day anterior, posterior to 1,800 RADs and re-evaluate, or pending a plan. The physician will put that on our desk and say I have written a prescription for 1,800 RADs. You have two weeks to figure out what we are really going to do.

I think in normal practice there are a number of times when the total dose is not prescribed.

MR. TSE: The prescription would not have the total dose in there. What do they have in addition to the fractional dose? What would the physician say how many total dose -- how many dose he wants to give?

MR. WHITE: It might a partial total.

MR. TSE: Partial total.

MR. WHITE: He's going to give a prescription that is good for two weeks, so write in the dose that the patient had after that two weeks.

MR. TSE: Yes, 5.3 can take care of that if there's a change of those. I know what you are saying. In our institution you see cross it out and write another one.

MR. WHITE: Interim total, do you think that would be acceptable?

MR. TSE: Yes.

MR. WHITE: He intends to go to 6,000 and writes 2,000 the first day?

MR. TSE: Yes.

MS. PICCONE: What you are describing sounds to me like he changes his prescription based on --

MR. WHITE: No. His intent -- it doesn't change his intent. His intent is to treat to say 6,000 RADs, and the first day he writes prescription for the first 2,000 of it. Is that acceptable under this?

MR. WU: I think what you are saying is the first one is a plan, he plans to treat at 6,000 and the second one is a prescription, 2,000 and re-evaluate. Like medicine, they ask you to take two weeks and if they feels there is a need they take another two weeks.

MR. WHITE: A little different than that. It's not actually re-evaluation. He knows basically the prescription is going to be -- the total dose is going to be say 6,000 RADs. He has not yet prepared to prescribe the entire 6,000 RADs. He has prescribed the first 2,000.

In 5.4 I make the same thing about sign. We are looking at computers that are going to do that. The other is that I think it's not an easy thing to do to request that

the person who does that record the agreement or lack thereof between the administration and the prescription each day. You have to write in 180 RADs delivered, yes this is what we wanted. I think it ought to be sufficient to record what you did and not to have to record you did what you wanted.

MR. TSE: I think we discussed that point previously. Are there any others?

MR. WU: The 5.6, I have difficulty with that. I can tell you what we are implementing in our hospital. In regular fractionation the calculation has to be checked before two working days. If it is more than 500 RADs per fraction, the calculation has to be checked before the administration of radiation but not 25 percent.

MR. WIEDEMAN: You can always do it before. I think 25 percent is after. You can do it the first hour or the first day.

MR. WU: If 25 percent -- let's see. I remember we rant into the problem during the 60 day trial.

MR. WIEDEMAN: I assume you do a three day treatments on high dose.

MR. WU: Yes, three day treatments.

MR. WIEDEMAN: You do those within --

MR. WU: Some per fractions.

MR. WIEDEMAN: You do your double-check before the

treatment is given, so that would be okay.

MR. WU: That would be okay.

MR. WIEDEMAN: When you are going to administer 6,000 RADs total, 200 fractions, 200 per fraction --

MR. WU: That's no problem, because we check even before 25 percent.

MR. WIEDEMAN: Is there any situation that you would go over the 25 percent?

MR. WIEDEMAN: Suppose you only have a three fractions --

MR. WIEDEMAN: He does the double-check before the dose is administered.

MS. PICCONE: Only if it's greater than 500.

MR. WU: Only greater than 500. Let's say 400 times four, then the calculation has to be double-checked before the administration.

MR. WIEDEMAN: Four hundred times four, that would be the 1,600?

MR. WU: Yes. The first treatment would be 25 percent. In other words, any single fraction regardless of the dose, they have to be double-checked.

MR. TSE: You mean only one fraction and double check before --

MR. WU: Yes, regardless of the dose.

MR. TSE: These are the guidance. We really

should not be interpret as 25 p it is a regulatory requirement. I understand there are some other people may hold as that, so we will look at it and modify it into a more general kind of wording.

MR. WU: You relax the requi ements. In other words, if you deliver 6,000 RADs then you don't have to check the calculation until 1,500, rignt?

MR. TSE: Yes, right, 25 percent of that.

MR. WU: To me, that's practice.

MR. TSE: What would you suggest then?

MR. WU: We always check within two working days.

MR. TSE: Okay, but some people may not have the staff availability like you have.

MR. WU: They have to double-check anyway, 25 percent or two working days, right? They have to have somebody to check.

MR. TSE: No, because this is a guidance. Somebody can say I want to check at 50 percent.

MR. WU: You are confusing me.

MR. WIEDEMAN: They could turn it around and say I want to do it the first day --

MR. WU: I understand that. I am saying that you regulate some things are not as much more relaxed than most in common practice.

MR. TSE: This is the minimum. We suggest that

you should do it before that.

MR. WIEDEMAN: That's like Tony said. If you want to do it at 50 percent or the first day --

MR. TSE: No, you cannot do 50 percent.

MR. WIEDEMAN: Sure you can. This is not a regulation, this is only to provide guidance to the licensee as a minimum.

MR. WU: You know how the licensee fees when the NRC comes in. They try to at least in talking -- we try to implement everything you want us to input. That is the regulation. If you want to leave it to us you really don't need this.

What I am trying to say is that in the general practice -- I don't know how Gerry's institution how they check the calculation -- in our institution we check the calculation within two working days which has a much stricter quality assurance standard.

MR. TELFORD: Is that the standard within two days or within --

MR. WU: Yes, the NRC.

MR. TELFORD: Is that what you do, Gerry?

MR. WHITE: That's our goal. We generally accomplish it.

MR. WU: Yes, we are very strict about this.

MR. WHITE: It's a case where I would prefer the

regulation to be looser and allow us to make the mistake without being cited. You are right, the appropriate clinical practice is to check typical doses within two days and small total number of fraction doses immediately. That's what good practice is.

MS. PICCONE: How would you define small fraction?

MR. WHITE: At our facility, anything less than three fractions has to be checked before the patient is treated. It's different every place.

MR. TSE: Any suggested changes, or just comments? Do you suggest Dr. Wu, do you suggest change anything in 5.6?

MR. WU: I would change to two working days or any fraction dose greater than 500 or less than three or four fractions should be checked before the administration of the radiation.

MR. TSE: Would you think that is something small hospitals can do?

MR. WU: Yes.

MR. WHITE: I think that there are small institutions that would find that difficult, but one of the purposes of these regulations is to change that behavior. If you wrote regulations that were not a burden to anyone and didn't make anybody change, then you could just skip the regulation part. Does that make sense?

MR. TSE: You also need to consider the impact to the operations if people cannot do it.

MR. WHITE: We all have personal biases tied up in this from our history of our practice. The feeling is uniform among the three members of our group is that a facility that is treating patients with radiation and has a physicist that comes once every other week to do these kind of dose checks is on the frontier of malpractice; that if you want to treat patients who have cancer with radiation you need to have people on-site. If you don't have the people on-site then you can't afford to be doing it.

One of the advantages of living in a rural area is that you have fresh air and cows. One of the disadvantages is that if you get sick you are in trouble. You have to keep that in mind. I live in a State that has lots of rural areas. I live in a state where our facilities draw cancer patients from 200 miles away. I understand that. We have two facilities in our state that practice that way. Somebody flies in every other week, and it sure makes me nervous.

MR. TSE: Are there any other comments?

MR. WHITE: On Section 5, yes. I was wondering about this 5.7.2(2) about using the TLD -- I don't have a cobalt machine. Are there other commercial TLD services that provide that; is there somebody that you can --

MR. WIEDEMAN: M.D. Anderson --

MR. TSE: They are not commercial.

MR. WIEDEMAN: Those are the RPC's. You have to be on a protocol or something. You can sign up for it and it costs money.

MR. WHITE: Can anybody sign up or are they open to anybody? We do that in connection the research protocols that we are not -- if we weren't on those research protocols would we have access to that?

MR. WIEDEMAN: I am not sure. I know that at one time it was available. We had a listing of like five different nationally recognized laboratories or facilities that offered this service, but I am not sure if it's still available to everyone.

MR. WHITE: You may want to look into that before you suggest it. If that were not available I think that the other alternative might be a little more difficult.

MR. TSE: I have discussed with M.D. Anderson and they said if it becomes final rule they will --

MR. WHITE: They thought that five percent was reasonable.

MR. TSE: Yes.

MR. WHITE: If they could report the five percent. In 5.9 I guess we have a problem with both of those; one with the treatment distances and the other with beam

modifying devices except blocks, boluses or stock material. That seems like a big problem. Compensators come to mind.

MR. TSE: Let's take one at a time. Number one says that the field sizes or treatment distances that fall outside the range of those measured.

MR. WU: What do you mean, outside the range?

MR. TSE: Outside the range when you have a calibration you measure your dose output, output up to like 100 centimeters. Now you want to use 120 centimeters distance, which is outside the range that you measured. You measure from certain centimeter up to 120 centimeters. Within the range you don't have to do the measurement because --

MR. WU: Do you know how they calibrate a cobalt?

MR. TSE: Not personally calibrate before.

MR. WU: Therefore, what you are saying is the range is not --

MR. TSE: How does it calibrate?

MR. WU: If they calibrate in air they have a chamber placed at the 80 centimeter and that's it. There is no range. In anything other than 80 has to be checked.

MR. WIEDEMAN: When you do your annual full calibration, do you go through all the different established field sizes -- 80 sonimeter source skin distance or source chamber distance. You will make a bunch of measurements,

maybe a six by six or eight by eight or ten by ten and so on. All of a sudden let's assume that you get it to your largest field sizes -- I don't know what it is.

MR. WU: We do from almost -- not exactly -- almost nothing. For cobalt yes, five by five is the smallest.

MR. WIEDEMAN: Five by five is the smallest.

MR. WU: Yes. We measure all the way to whatever 30 by 30 or something, large as the field, the whole range. Suppose somebody coming with a spinal cord five by 20. We can never make measurements.

MR. WIEDEMAN: I don't think that was the intent of this. Our intent was because of the unique treatment modality such as hemibody and whole body, where they do a full calibration and they just use a certain source chamber distance or certain field size. Now, all of a sudden, they have the patient lay on the floor and bring the therapy unit up as high as they can so they can cover the largest area.

Yet, a physical measurement was never made --

MR. WU: I would relate to that kind of malpractice to the so-called qualification of the physicist or whoever is doing it. A qualified physicist would not just take it for granted. I think it's going to be inverse square and I think it's going to be the TMR table --

MR. WIEDEMAN: This happened at one of the largest

facilities in the Midwest. All of their medical physicists were all certified and AAPM and ACR.

MR. WU: AAPM is not to certification.

MR. WIEDEMAN: Right, members.

MR. WHITE: I think the point is that what your intent is differs from what you write in the Reg guide. Other examples of things that I would say would fall under that is if you had a patient you wanted to treat isocenter, lateral pelvis 40 centimeters wide and the doctor asks for the de max dose. Gosh, that is set at a distance of 60 centimeters and it may not have measurement there.

There are a wide range of distances at which the physician may request a dose, even though the patient is nominally treated at 80 centimeters. I think that generally people would consider that above and beyond to do inverse square measurements at any rate -- that large a range of distances where you could potentially place the patient's -- generally what folks do is measure it 80 centimeters and a couple of inverse square measurements a little farther down in case you want to do 100 centimeters or something like that.

That is generally considered good practice. The obvious exceptions, if you are going to treat somebody for a real big distance, you may measure again which I think is what your issue is for that treatment distance.

MR. WIEDEMAN: Also keep in mind wedges, filters that were never considered or measured during the annual full calibration.

MR. WHITE: The question that comes up, aside from the treatment distances, I think it is something that you need to clarify a little bit of what you mean there. Filters and things like that that may be made out of some sort of compensator, would that fall under this?

MR. WIEDEMAN: Anything that modifies the beam.

MR. WHITE: It excludes blocks, excludes boluses. I guess if it excludes block material, would that exclude compensators?

MR. TSE: If a compensator is made out of stock materials.

MR. WHITE: Something that we have in the warehouse. If you put a wedge in that's made out of brass -- I think that's a little unclear basically. If I make a compensator out of a -- plastic is exempt because it's a stock material -- then a wedge made out of brass is not exempt even though they do the same thing.

MR. WIEDEMAN: To a different degree though.

MR. WHITE: Not necessarily.

MR. WIEDEMAN: Brass versus plastic?

MR. WHITE: That depends on how much. We make a lot of compensators that change the distribution more

significantly than a 15 or 30 degree wedge. There was a time when wedges were supposed to move the isodose curves to 15 or 30 or 45 degrees, and now I think with computers people view those as just one way to shape the dose distribution that is unfortunately limited to four selections.

MR. TSE: Under distance, I thought that in your full calibration how many distances do you use in your full calibration; like 80 centimeters? I thought you mentioned several different distances.

MR. WHITE: When we had a cobalt machine we measured -- we calibrated our full calibration at 80.5. On one occasion you get a new source we would recheck the inverse square lot dependence, but we wouldn't do that every year.

MR. WU: When you do annual calculation for inverse square, if it the first time meets the inverse square you are assuming every time thereafter will obey the inverse square. The reason for first time measurements right after the installation of new sources you may find there is some impurities, something is there that doesn't really obey the inverse square.

MR. WIEDEMAN: Let me ask a question. If you do your annual full calibration at 80.5, and all of a sudden your physician asks for this particular treatment modality

he wants to use 100 centimeters. Would you ever -- you would calculate the dose by inverse square or a combination of inverse square and a physical measurement.

MR. WU: You calculate dose by inverse square.

MR. WIEDEMAN: But no physical measurement?

MR. WU: I don't think you measure --

MR. WHITE: If the source was new we would measure that one time, but we would not have done it within a year unless the source had been replaced within the year.

MR. TELFORD: What would you do with the case where you put the head at the maximum distance and the patient on the floor, would you make a measurement there?

MR. WHITE: Yes, but not necessarily actually within a year. When we had a cobalt machine and we treat on the floor we measured one time -- actually measured more than one time, but we didn't do it ever year. Once we had that number we assume that we put the head in the same place and same source, same geometry, the dose rate was going to be the same if it was the same at 80.5.

MR. TELFORD: The only thing that happened during the meantime was decay.

MR. WHITE: That's right. The only thing that happened was either decay or something that would have changed the dose rate at 80.5, either of those things.

MR. TELFORD: But you had been checking the dose

rate at 80.5, so --

MR. WHITE: With regular calibrations. We assume that if something that -- I guess our assumption was that nothing happened that would have kept the dose rate the same at 80.5 but yet caused it to be different than 120 or 130, which we felt was a reasonable assumption.

MR. TSE: So, those distances should be measured but only at the first time when the sources change or some spot check that those is not correct.

MR. WHITE: What we do is, we measure it one time or if the source changes we assume that anything could be different we check as much stuff as we can think of.

MR. TSE: Is that what your institution does?

MR. WU: You are talking about the annual full calibration, and this is not part of --

MR. TSE: I know. I am just trying -- the wording here says if you do not do it last year full calibration --

MR. WU: When you do an annual calibration you essentially very much depends on -- you can calibrate any other possibility of the shape of the beings; therefore, assuming that the square, small square to the large square and then you do the measurements. Anything falling between the example that I give it to you, five by 20 spinal cord, then it depends on the calculations. It depends on the table provided to you, inverse square calculation table.

God knows how accurate -- we did check it but the table is very commonly available for other physicists. If you want us to measure the five out of 20 then it would be very difficult because almost all the fields are different from the square field.

MR. TELFORD: But you handle that routinely.

MR. WU: Every day.

MR. TELFORD: The five by 20, you would -- you had the five by five, and you had greater than 20 by 20, so you feel perfectly competent to do the [illegible] because it's within the range of what you have been operating in.

MR. WU: Yes. The five by 20, I never check measure that in my annual report.

MR. TELFORD: I don't think we mean to capture that, so we will have to make sure in the language that we don't.

MR. WU: Also, the distance range we don't check -- like Gerry says we may check once every five years but we never check the distance. Assuming that if you would then -- I think the physicist s trained or educated so that maybe they can judge it within certain distance inverse square law holds you can do the calculations. However, if you are treating the TBI's with a sound judgment, they should check it.

They should check that these things are 300

centimeter away from the source, whether it is still inverse square base.

MR. TSE: Some suggestions from another workshop says inverse square lies so you always have to check it. Suppose somebody has never been measured a large distance away from the source and they use inverse square a lot because they say that always hold and use --

MR. WU: They may be correct.

MR. TSE: Would you do it, or would you check it?

MR. WU: I would check it.

MR. TSE: You would check it.

MR. WU: Yes. But it doesn't mean they --

MR. TSE: It doesn't mean they are -- why would you check it?

MR. WU: Why would I check it, because I don't know.

MR. TSE: Just to make sure.

MR. WU: Yes. I think within the therapeutic distance we know very well. But you turn 500 centimeter away -- I don't know. Therefore, I would have to check.

MR. TSE: You too, right? Would you check it?

MR. WHITE: Yes.

MR. TSE: How about the Item 2, modify the wedges. If a new wedge never been measured before should be measured?

MR. WHITE: Yes.

MR. TSE: So, you have no problem with that. You only have a problem with the compensator --

MR. WHITE: I would put it the other way around. If you wanted to make number two to say wedges -- and we sort of all know what that means and I pretty much agree with that -- if you wanted to make number two an inclusive listing of separate items, I think we would look at each item. You have done it somewhat differently. You have said everything except all these things.

I think I would feel more comfortable if you did it the other way around and picked the things that you thought were important. I think everybody would agree that if you get a new wedge you should measure it. There are a lot of things that someone might include in that list that I think might not be appropriate there.

MR. TSE: Which kind of a device -- beam modifying device would you think should be checked other than wedges?

MR. WHITE: Block trays -- just common ones would be block trays. Personally, I would include the new kinds of blocks. If we introduce a new kind of block we measure them before we use them. I have to wonder about patient restraint devices, that one might be confusing. I don't know if that was your intent or not, filters.

MR. WIEDEMAN: If we said wedges, wouldn't that

include filters or is filters inappropriate.

MR. WHITE: Yes. The problem that I have with that is the consistency with the stock material. I would hate to have to measure separately -- I would hate for there to be a regulation that said we had to measure separately compensators that were applicated to the patients. That is one that comes to mind, although generally we do that.

There have been cases where we didn't think it was necessary and wouldn't like to have to do it especially before the treatment. That's another issue. This is before 25 percent of the total prescribed.

MR. TSE: That's right.

MR. WHITE: I think wedges I wouldn't disagree with. Block trays I wouldn't disagree with.

MR. WU: Other than -- I can tell you that in an emergency case a patient that has a spinal cord block and the patient can't even turn, there are times that we treat them -- do I have to measure?

MR. WIEDEMAN: Emergency is covered elsewhere.

MR. TSE: Five-eleven covers the physical --

MR. WHITE: I think our point -- we are in the situation that some of that stuff we would never measure.

MR. WU: You would never measure. You make a judgment right there, is that important to that patient. Not measuring, would that present any harm to that patient.

MR. WIEDEMAN: Let's see if I understand. Because the patient is immobile you would shoot up through the table. Your question is, should that include the table; is that --

MR. WU: Not the table. We have about one inch just padding.

MR. WIEDEMAN: Styrofoam?

MR. WU: No.

MR. WHITE: Cushions or boards. Sometimes we have the backboard and the patient will come down on some --

MR. WIEDEMAN: It wouldn't attenuate that much of the beam, would it?

MR. WU: No. Therefore, there judgment is that it's not worth it.

MR. WHITE: There's other stuff. Sometimes there will be a board. Sometimes the patient will have some kind of incredible contraption attached to their body. If somebody is really sick that is probably not going to be with us next week, we would irradiate them and send them back upstairs. I would not like to have to take time at 7:00 the next night to see did I measure within two days requirements.

I think that this is sufficiently broad. I think listing what you meant by beam modifying devices takes care of that problem. If you could come up with some stuff that

everybody could basically agree on, yes, that's something we ought to measure and not have to worry about this other stuff.

MR. TELFORD: A board is not intended to be a beam modifying device.

MR. WHITE: It may not be intended but it sure is. Block trays are not intended to be beam modifying devices but they are. There is stuff that you put in the beam because you want to, to change the beam and there's stuff that you put in the beam because you have to. The importance of the knowledge of their effect on the dose distribution doesn't depend on the intent, it just depends on their presence.

MR. TSE: The suggestion is that 5.11, after the emergency measurement may not be necessary.

MR. WHITE: I guess my suggestion would be in number 5.9, to Section 2. To make the changes we suggested in one and two, and two to specifically list the beam modifying devices that the NRC felt was important.

MR. TSE: I already marked that one. In the discussion of emergency when you were saying that the guide stated that the measurement will be performed within two days after the emergency, did you suggest that those emergency cases the patient is in emergency and such a measurement may not be necessary.

MR. WHITE: I think that's true. My objections would be satisfied if 5.9.2 just excluded the stuff that we thought was irrelevant. Quite frankly if we had a patient that we treated with some -- if we had a spinal cord patient down and for some reason we treated him with a new wedge -- I'm just wildly speculating -- even if the patient died the next day we could probably go back and measure what dose he got so that the record was correct.

I don't think I have a problem with the things that you think ought to be measured -- actually measuring them, irrespective of the patient's condition. There are some things that we might want to agree that don't need to be measured.

MR. TSE: If it's a 5.9 if it's modified, then you wouldn't have a problem with 5.9.

MR. WHITE: That would be my opinion.

MR. TSE: How about you, Dr. Wu?

MR. WU: Yes. I think 5.9 should have some sort of qualification on the one. On the two I agree with Gerry, it should be specified what kind of things you mean beam modifying devices.

MR. TSE: What kind of suggestion do you have is, essentially, the distance -- the measurement should be done once. That is what --

MR. WU: In routine clinical practice. We are not

talking about TBI's and this. One does not check every SSD you use on a patient, but there is a formulation that you can use to do the calculations.

MR. TSE: Every SSD meaning all sizes?

MR. WU: No, every SSD mean if we just calibrate one point. Gerry says 80.5, and in our case 80 centimeters. We don't check the other distance. If the patient treat a 90 according to th'• we have to check it, right, to measure?

MR. TS[illegible] If you have not measured --

MR. WU: If we have not measured, right. I don't think that's necessary. To give you an example, if you treat a patient isocenterically then SSD change every time. We don't do that. We have a formula to do the calculation, and we believe that the formula is reasonable. Like if you say five by 20 and it's the inverse -- equivalent square table, we believe that equivalent square table is reasonably correct.

I don't want to check all this irregular fields, fields other than the square.

MR. WHITE: What if you put a period after outside the range of those measured, period.

MR. TELFORD: Since the source change?

MR. WHITE: You might add source change. I wouldn't feel badly that at some time someone has measured that, but it seems excessive to have to do it every year. I

don't have a cobalt machine anymore -- do you guys still use that?

MR. WU: Yes.

MR. TSE: Some states may take this one to be --

MR. WHITE: I'm thinking along those terms. How is this going to affect your gamma knife; have you thought about that?

MR. WU: Gamma knife is different ballgame.

MR. WHITE: But it will fall under all these regulations.

MR. WU: That's true. That's very true. Gamma knife, we don't have a change of distance. We do have different block patterns. In other words, 200 of one sources that we may block 10 of them. Does that mean we have to be calibrated?

MR. TELFORD: Probably the section over here where we are checking the input is probably the most important thing for the gamma knife, where you are checking the distances and inputting that to the computer for the gamma knife. Those are probably the most sensitive points.

MR. TSE: Are there any other comments on any other elements?

MR. WHITE: Five point ten, are we up to that?

MR. TSE: Yes.

MR. WHITE: We were talking about this the last

time. I just think it ought to be done right, which is probably a couple of hundred pages or abandoned.

MR. TELFORD: Is there an ACR Report Number 24 that talks about things like this?

MR. WHITE: I know the AAPM has been working on some kind of document on this, but I haven't seen even a draft yet. Do you know where that is?

MR. TSE: No, I don't.

MR. TELFORD: We will be talking to both of those organizations in the near future, like next month. We hope to get some specific advice from them on the sort of checks you should do after you change sources and before you first use a computer program.

MR. WHITE: My gut feeling is that it is highly unlikely that the level of detail required for that procedure will lend itself to inclusion in a regulatory guide.

MR. TELFORD: What if we just make some general statements here about what we are really after and what our intentions are, and leave the specifics up to --

MR. WHITE: It's hard to speculate about that. I don't know. Just general statements can be scary. I don't know. We have a new computer system that we are testing out and have probably 200 hours into it already before we can use it clinically.

MR. WU: This will take a tremendous amount of time and expertise to do that. There are only a handful of centers in the country who actually can do this.

MR. TELFORD: After you change the source, Gerry talked about -- say for brachytherapy -- use one seed on the axis and off axis and then ten seeds on axis and off axis. What do you do here with your cobalt machine after you change the source, what sort of measurements do you make to it?

MR. WU: The standard routine practice that I think is a good practice is, you measure the few sizes versus the output and you measure the wedge factors, tree factors, measure absolute output at the isocenter and all the safety features. It's a pretty comprehensive calibrations but not even close to the work that is required by 5.10.

In the 5.10 -- let me give you an example. Like a cobalt, nobody has measured the depth dose. You know that.

MR. WHITE: The depth dose?

MR. WU: Table. People take BJR 17.11 which used to be 11 and have a new table, BJR 17. You use it on that dose tables, assuming they are correct. You don't use water to actually measure the depth dose of the cobalt. I don't think any institutions do this. If you are asking for -- you require some sort of scanner, you require some sort of

waterproof chambers to do that. I just don't see -- I think only the few hospitals, major medical centers have the equipment and the qualified person to do that.

MR. TSE: When you change a source in your institution, how do you make sure all the computer programs which have source terms in them be changed accordingly?

MR. WU: You assume the depth dose table doesn't change, right?

MR. TSE: No, the depth dose -- the number of curies change.

MR. WU: You make absolute dose calculations at the reference point.

MR. TSE: What does that mean?

MR. WU: That means you measure -- if you want to measure in air you put a chamber in at the isocenter and measure.

MR. TSE: And then, you compare with your computer calculations? I am thinking about if you computer program--

MR. WU: Our computer program does not -- have nothing to do with dose output.

MR. TSE: Your computer is a relative calculation.

MR. WU: A relative calculation.

MR. TSE: How do you get the number of dose?

MR. WU: Then the dosimetry has a larger tables, curves, which provide the physicist who did the

calibrations.

MR. TSE: It is a hand calculation?

MR. WU: That's correct, from the treatment planning computer.

MR. TSE: Is any computer have curies included?

MR. WU: Curies, no I don't think any computer including the curies. They include absolute output at the reference point. I think there are some.

MR. WHITE: Yes.

MR. TSE: Essentially when the source changes the output changes.

MR. WU: Sure.

MR. TSE: The computer program -- some have output in there.

MR. WU: Then you have to change --

MR. TSE: That's right. How do you ensure these output being changed in computer program?

MR. WU: You need some qualified physicist to do that, like a brachytherapy. There are many parameters in there. You need a qualified physicist to enter those parameters.

MR. WHITE: I think the whole 5.10 ought to be abandoned. If we are going to talk about it, let me make the point that you ask for tests for two different kinds of conditions here. One is a test before the first full use of

the computer program for dose calculations, and I am depending on the computer program. We have computer programs that tell the field size and stuff like that, tells you the time. That's a short check.

We have other computer programs that are radiation therapy treatment planning computers, and that's a month of work and those are different. But the philosophy of checking them is basically the same. I think the approach for that is different than for the second part about after performing full calibration measurements pursuant to all that other stuff. And, if all that has changed is the source activity -- you have a new source and do a full calibration measurement -- you don't need to check all that other stuff again.

For example, the things that you have mentioned there, the open field at angles at the isocenter and that sort of thing, is independent. The calculations in all the systems that I know about, the results of that are independent of the source activity. It does all those calculations and internally within the computer it comes up with some relative number. And then, the computer software will then look in a box somewhere and see what the cobalt dose rate it and apply it to that. It applies it in generally the same fashion whether you have a single ten by ten field or multiple fields of incredible complexity. If

it makes a mistake it does it the same all the time.

So all you really need to check is, is it handling that number correctly. If you put in the new cobalt output, does it give me the same dose rate in the same way as it did with the old source. I think that's fairly easy to check. If that's your goal, I think you could write something that talked about that. If your goal is to check the proper function of the treatment planning system, I think that's too complex for this kind of document.

MR. WU: I think it should be the vendor's responsibility to check before they can sell that.

MR. TSE: I think the goal here, at least initially, is to check the Cobalt 60 output is correct and incorporate the new Cobalt 60 output is in the computer program.

MR. WHITE: Then I think that it ought to say that before first use after source change or change in the calibrated output -- that is something that differs from the predicted output of decay by more than five percent -- that you do that. You check the output data for what you said was perfect and I can't remember what you said -- basically you check the output data from the Cobalt 60 source to see that it changes as expected.

I think it's a test for something different than what you want to test for. If that's what you want people

to check then say that yes, you have to check that. All the computer programs that you use, you need to check the Cobalt 60 output and see that it is correct.

MR. TSE: Okay. Do you have any comments or suggestions, Dr. Wu? Just check the output?

MR. WU: Yes.

MR. TSE: You agree?

MR. WU: Yes.

MR. TSE: There is one elements after 5.10, but are there any other comments on any elements in this section?

MR. WU: The 5.6.2, when you say input -- is it subject to the independent double-check?

MR. TSE: Yes.

MR. WU: Okay. How do you check the patient's counter? Do you mean the counter has to be taken twice?

MR. TSE: No.

MR. WU: Digitized twice?

MR. TSE: No, I think that's the same as the brachytherapy --

MR. WU: Brachytherapy.

MR. TSE: Yes.

MR. WU: As the licensee when we look at this, we literally interpret this as we have to have two people to go into the room and take the counter twice. In this last two

days here it is now you are in ten. The licensee's, they try to avoid any kind of misadministration or any kind of violation and they are willing to do that.

MR. TSE: That is why this workshop discussion is very useful, so we can think about. Are there any other comments?

[No response.]

MR. TSE: If not, thank you very much for your suggestions.

MR. TELFORD: We have covered everything on the agenda. The only thing we have left is to give you some individual air time. I suggest you take three, five or ten minutes, whatever you want to take. I think I have it listed here at the end of this viewgraph here, summary comments, just your thoughts and conclusions on the proposed rule and guide and reporting requirements.

Anything that you would like to say, just feel free to say it. I think we started with Dr. Wu last, so we will start with Jonette this time.

MS. ROBERTS: Well, I don't know too much about the teletherapy and brachytherapy, although I know more today than I knew two days ago. I think it's a good idea for the QA program based on these proposals. I think it promotes awareness on the technologist's part, although it is a lot of paperwork. Maybe some way it will help protect

the public.

MR. TELFORD: Gerry.

MR. WHITE: You sure get excited about regulation when you come here and shuffle all these papers for two days. I think a couple of thoughts that we have had about the program is one that the pilot program has certainly been an interesting idea and one that there was a lot of enthusiasm about that, both from the opportunity to try out the rules to get a feel for what the rules really meant; that is, the difference between what we read here and what you folks intended, which has been real enlightening.

Last, the ability to give some kind of input that really seems substantive. I am very fortunate to have had the opportunity to have done that. It's not often that you can have effective input. A lot of times you can write letters and you don't have somebody sitting across the table from you taking notes. It's really gratifying to see that.

We have made a lot of specific comments about the rules and how they work for us and how we would project that they work in the future if they actually became effective. We have some more general philosophical concerns about the whole idea; that is, what I said yesterday about how serious is this problem really. Again, I would refer you to the paper that I brought about misadministration for stable pharmaceuticals. I think that the risk from

misadministration of radiopharmaceuticals, while creating problems that we would all like to avoid, needs to be put into perspective with the risks that patients incur from other types of medical procedures or other types of activities which people perceive as relatively risk free.

If the risks from these misadministration in fact significantly exceed the risks from other things that people perceive as risk free, I think some regulatory effort is probably appropriate for that. If in fact they don't exceed that sort of thing, then I would ask you to reconsider the whole project.

Given that in fact I am wrong and that these are really significant risks compared to others that patients face in the hospital, then I would ask that you consider doing two things that we feel certainly and certainly our technologists feel are important to reducing the risk to patients. The first one is to require that technologists be properly qualified; that people be educated both in medicine and in nuclear science. There are certain programs that do that and certify in a performance-based fashion that people have done that, and those are the registry boards for nuclear medicine people.

The second is that -- this is a prescriptive requirement -- performance-based requirement. I am hesitant to recommend stuff like that because I think your other

approach is really good. I think that for diagnostic nuclear medicine there is no substitute for putting the dose in a dose calibrator before you give it to the patient. When I talk to technologists uniformly, they are astounded that it is not a rule. They thought that it was an act of Congress. At the May meeting I was told that it is not a rule.

MR. TELFORD: Not for all states.

MR. WIEDEMAN: The NRC.

MS. PICCONE: It is for NRC.

MR. WHITE: That you have to own a dose calibrator?

MR. WIEDEMAN: Yes.

MS. PICCONE: Not all the agreement states.

MR. WHITE: That seems to be a prime candidate for an item of compatibility. Again, I just want to say that everybody was really enthusiastic about the opportunity to do this program.

MR. NELSON: I just simply would like to thank all the participants for coming here and sharing with us your ideas. I think they were very valuable, and the NRC will look at them and hopefully make a very good rule from this.

MR. TSE: I thank you for your suggestions. The discussions should not be stopped here. If you have any other comments or suggestions and would like to let us know,

please give me a call. My phone number is in the Federal Register Notice. Thank you again for your effort to help us.

MR. WIEDEMAN: I would say basically the same thing. I appreciate your comments. It is very important to get that type of input. I feel that it is essential when we start talking about passing rules and regulations that could affect the medical community, and it's important to get that feedback so that we know that the impact will be minimal if any at all. Once again, thank you very much. We really appreciate it.

MS. PICCONE: Just to reiterate what has been said before, you can get another thank you for your participation. I think the workshop certainly has been very productive, and we do appreciate your time -- not just your time in the workshop, but we realize that it did take a lot of time and effort in the course of the 60 day pilot in submitting a program for review and actually participating in the pilot.

As you mentioned, we were taking notes as we have with all the participants. We certainly are serious in considering your comments in the rulemaking process. Thank you very much.

MR. KAPLAN: It has been very interesting to sit here quietly taking notes having gone through your QA plans

first and hearing what you had to say here. It now begins the interesting part for us, but I am very glad that you feel the way you do about the enthusiasm about participating in the pilot program. I think it is something very important, and I thank you.

MR. TSE: I am really thrilled, because there are six NRC manager level personnel coming here. I thought there would be at least 50 people here and coming here and listening to just three of us. That is really a thrill. I have beer very frank and very direct. My comments after these two days is that -- the first one is very similar to what Gerry brought up. This morning when I was having breakfast and jotting down some numbers, I think I asked John how many misadministration we had last year. There was 14.

Then there are 2,000 facilities in the country, okay? Let's say that average of them have -- let's say one cobalt machine per facility -- I don't know whether this is true. Let's say one cobalt machine, and then you have let's say 22 to 25 patients per treatment -- patients per treatment is about 250 patients treated, new patients treated on the cobalt. Each treatment there are at least five to ten operations which may be potential to cause misadministration. So I multiply them together, and it's in the order of ten to the seventh or ten to the eighth. That

means that every ten or 100 million operations is potentially to cause misadministration you only have 14.

The amount is 14 misadministration, and then you ask yourself how many of them actually harm to the patient. Some of them may be and some of them may be not. We are talking about the a very small kind of risk. I really don't think there is something such as a risk-free society. Like I stated in the beginning, we really have to set up the limit which has certain risk factors about which we have to accept.

Darryl -- we have dinner together and Darryl said many years ago Congress wanted to monitor something and said well ten percent of total dose. It turned out to be very good. There is a biological reason for that, and since we have this current rules in existence more than ten years, we can analyze that data and see whether we are -- these rules are too strict, we need a more stricter regulations because we have more violations. It becomes a risk factor which is not acceptable to the public.

Along this line we have to really to be very careful before you can set a limit -- a certain percent or twice as much the fraction or whatever the number you put it down. I hope that there is some sort of scientific reason behind that.

The second point is that the basic assumption of

this regulatory process is the prescription is 100 percent correct, and we measure against the prescriptions. That is not true. The prescription could be deviation of the prescription of the amount of the physician by as much as 20 percent. Like you telling me that the table is ten feet minus 20 percent, then you require a ruler accuracy of two percent to measure that table, you are never going to get anywhere.

Over regulation -- you can do it for the sake of regulation, but whether that will improve the care of the patient or decrease the radiation hazard to the public, I am not quite sure about that. That's my comments.

MR. TELFORD: Thank you very much for participating in the pilot program. We certainly appreciate your comments, and we will use them. The meeting is adjourned.

[Whereupon, at 11:59 a.m., the meeting concluded.]

REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission

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were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken by me and thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing proceedings.

Mary C. Larkin

Official Reporter
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