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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL

USES OF ISOTOPES

(ACMUI)

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TUESDAY,

FEBRUARY 19, 2002

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ROCKVILLE, MARYLAND

The Advisory Committee met at the Nuclear Regulatory Commission, Two White Flint North, T2B3, 11545 Rockville Pike, at 11:00 a.m., Manuel Cerqueira, M.D., Chairman, presiding.

COMMITTEE MEMBERS:

MANUEL CERQUEIRA, M.D.	Chairman
DAVID A. DIAMOND, M.D.	Radiation Oncologist
NEKITA HOBSON	Patient Advocate
RALPH P. LIETO	Medical Physicist
RUTH MCBURNEY	State Representative
SUBIR NAG, M.D.	Radiation Oncologist
SALLY WAGNER SCHWARZ	Nuclear Pharmacist
RICHARD J. VETTER, Ph.D.	Radiation Safety Ofc.
JEFFREY WILLIAMSON, Ph.D	Therapy Physicist

ALSO PRESENT:

ANGELA WILLIAMSON

JOHN W.N. HICKEY, Designated Federal Official

I-N-D-E-X

P-R-O-C-E-E-D-I-N-G-S

(11:22 a.m.)

CHAIRMAN CERQUEIRA: John should we, I guess we could probably start.

MR. HICKEY: Yes, I believe everybody's here.

Good morning, welcome to NRC. I'm John Hickey, chief of the Material Safety Branch and the designated federal official for the Advisory Committee on the Medical Uses of Isotopes. This is an open transcribed meeting, it will occur in three parts, so I'll explain that.

From now till approximately 12:30, we will have a pre-meeting and then break for lunch and the Commission meeting where the Committee meets with the Commission will be at two o'clock in the other building. It's the main Commission meeting room in the other building. And when that meeting adjourns at approximately four, we do not have any more business planned for today and the Committee will reconvene in this room tomorrow morning at 8 a.m. for an all day meeting.

We thank the Committee for their services and we recognize that with our increased security requirements that it's more inconvenient for you to get

here and the Commission certainly appreciates your services.

For the observers, we will not have any hand outs today. This morning the hand outs will be at the Commission meeting, but tomorrow there will be hand outs made available for the presentations for tomorrow morning. Those hand outs will be available tomorrow.

Just to review the security requirements, if you have a visitor's badge, you should confine yourself just to the immediate area of this room and the elevator lobby, the women's room is on the right, the men's room is on the left and then the elevator to exit.

At lunch if you eat in the cafeteria downstairs you should keep your visitor's badge, but when you finish lunch or if you don't go to lunch there, unfortunately you have to turn in the visitor's badge, exit this building and walk over to the other front entrance of building 1 to go to the Commission meeting. You cannot walk unescorted through the tunnel with a visitor's badge. If you have yellow badges then you can walk unescorted through the NRC space.

If we happen to be here we'll escort you but, unfortunately, we don't have provisions to escort people during lunch unless it's by coincidence because we don't know what people's plans are for lunch.

So that's an overview of the program today. I should also mention that some speakers had conflicts tomorrow so we're having to rearrange some of the speakers for tomorrow and we'll give you a revised agenda for tomorrow before the Commission meeting this afternoon. And with that I will turn it over to Dr. Cerqueira, but we have a question from Dr. Diamond.

DR. DIAMOND: John, for those of us with bags or coats, should we leave them here or take them across for the Commission briefing?

MR. HICKEY: Can we lock this? Okay. We're going to lock this room when we leave so the members can leave things here. The other people when the meeting adjourns, will have to take their belongings with them. That was a good question.

Yes, sir, Dr. Cerqueira?

CHAIRMAN CERQUEIRA: John, just in terms of the changes in the agenda, if we could get that agenda out because I'm sure some of the people that are here just for specific activities tomorrow would probably like to get some idea of when their interested area will be presented.

MR. HICKY: Okay, we'll have that ready by noon. We can get that ready quickly.

Dr. Nag?

DR. NAG: John, also that with the increased security level, we have to arrive in the airport a lot earlier than we normally have to. Is there any way to make sure that we end up -- is there any way to compress tomorrow so that we don't have to be here till five or something like that?

MR. HICKEY: Okay, well I think --

DR. NAG: Because many people will have to leave to make the last flight out tomorrow.

MR. HICKEY: Okay. Well I think Dr. Cerqueira and I will do our best to keep things moving and get done as early as possible.

CHAIRMAN CERQUEIRA: If I cut people off don't get too upset with me because we'll certainly --

Well, again, I'd like to welcome all the other committee members here and all of these precautions are really a sign of the new era that we're all living in. And, again, I'd like to also apologize for the lateness with which we were able to get some of these things together for today's meeting. We compressed it into a short time period, didn't give all of you adequate time to review the material, and part of what we're going to do this morning is actually go over some of the presentations and take comments from people.

So I guess all of the committee members then

have the slides that have been put together for tomorrow's session in the appropriate NRC format. I'd like to thank Dr. Williamson for reducing his, which I know was a daunting task, so John my idea before the briefing was to sort of go through the slides and to basically take comments and get input from the people, both the people that are going to be presenting as well as other committee members. Does that sound like a reasonable plan for the committee?

MR. HICKEY: Yes, and I would add for those that have not been to commission meetings, the five commissioners, or how many commissioners are here today, will be on one side of the table, the five designated ACMUI speakers will sit at the table facing them. There are seats for the remaining members immediately behind the designated speakers and we've provided you, I believe, with a list of the commissioners for those of you who are not familiar with the commissioners.

And some of the commissioners if there's time, before they start the meeting, will actually come and greet you so if they don't do that, please don't feel bad, that's just because for some reason they feel for the time constraints there's not time to do that, but often they will come out and mix it up with you right before the meeting.

CHAIRMAN CERQUEIRA: Okay. Jeffrey?

DR. WILLIAMSON: I take it that the approved and edited slides will be projected for us and we do not need to have our own disks or laptops?

MR. HICKEY: That's correct. The slides have been provided to the Commission and the technical staff and they're ready to be projected and you'll just have to call for next slide or slide 2, or however you want to designate it. There will be people in the projection room to do that for you.

CHAIRMAN CERQUEIRA: Okay. Any other questions or comments?

If not, then I think we can sort of go through and I will be starting off the presentation and I was asked to sort of give kind of an overview of Part 35 NRC revision process, and there's a total of six slides, including the title slide. And I think if we go through, if we look at slide 2, again I thought that the whole approach was really to be risk ~~conformed~~ informed and performance based, those have sort of been the two buzzwords that have been sort of paramount for the entire process.

Having been involved in this from the beginning, I really felt that there was significant stakeholder input, as I will detail in the subsequent

slides, and the ACMUI was involved extensively. Dr. Barry Siegal had sort of initiated this process and also continued to serve as a consultant during the entire revision process and had a significant amount of input into it.

And certainly for the time that I've been on the committee, we've really dealt almost exclusively with the revision process for Part 35.

Slide 3 sort of outlines the openness of the process. There were seven public workshops that were held at various stages, there were 20 professional society meetings between the NRC staff. There were six ACMUI discussion, there were two full panels and then there were two subcommittee meetings that were held both for the diagnostic as well as therapeutic.

The committee and the NRC staff actually traveled to Illinois to meet for one of the sessions there for the therapeutic, and there have been two agreement state workshops to review the entire process, again giving people ample opportunity to input both from the NRC as well as the agreement states.

The states were involved through the OAS, through the Radiation Officers, and there was a Part 35 working group. And in terms of public input, there were 225 written comments that were sent to the NRC at various

times. All the documents were posted on the NRC web site and all of the working groups, full committee meetings as well as the public workshops, were all pretty much open meetings.

And I think the result of this was that there was, you know, and again we could have some discussion, that overall there was a reduced regulatory burden in terms of what was put into the regulations. There was a feeling that there was an elimination of unnecessary rules, and overall there was a decrease in the prescriptiveness which was present prior to this.

And I think all of us were sent copies of the NRC commissioners response to Congress regarding some of the issues that had been brought up, and I think some of the issues that came up where that perhaps the guidance documents were imposing some new rules, and I felt that there was a commitment to basically attempt to eliminate some of those.

Jeffrey?

DR. WILLIAMSON: Well, I think to make the blanket statement that there's decreased prescriptiveness is not correct. I think that you're thinking of it from the perspective of nuclear medicine, where indeed that's true. But I think, if anything, the therapeutic modalities are more prescriptively regulated. A lot of

stuff that was in guidance and licensing space has now been moved into the regulation.

So I think it is not less prescriptive; it is perhaps more in accord with industry standards than it was previously. It's more in accord with ACR and standards of practice and AAPM task group recommendations. That's certainly a positive point that could be made, but it is not less prescriptive.

CHAIRMAN CERQUEIRA: That's a good point. I think certainly diagnostic nuclear medicine modalities that's been true, but in terms of the therapeutic I don't think that was decreased to any extent and, if anything, your feeling is that there may have been some increase.

DR. WILLIAMSON: I don't think that on the part of the regulated community there was, you know, a feeling that it should be deregulated or that it's necessarily inappropriate.

CHAIRMAN CERQUEIRA: Right. But I think that's appropriate.

DR. WILLIAMSON: It isn't necessarily inappropriate.

CHAIRMAN CERQUEIRA: Right. Other comments? Jeffrey? If he's going to be the problem tomorrow, I'll get you all out of here.

DR. WILLIAMSON: While all of this sounds

very good, I do believe that the new regulation is not without deficiency and there are some issues, or examples of important issues, where ACMUI input was ignored.

And I think two examples that come to mind are the medical event reporting criteria, which when in the physician's judgment it's against the medical interests of the patient to receive this information whether or not there's legal guardianship of the patient, the authorized user is forced to pick out somebody amongst the patient's family or friends to impart this knowledge to. And so that basic conflict never went away.

There are problems also with the unborn fetus and embryo exposure reporting rule, too, that are of a similar nature.

CHAIRMAN CERQUEIRA: I think those are both good points. Those are points that we made repeatedly at our own meetings and the commission briefings and at the workshops. And, you know, the response that we've gotten is that certainly in terms of public safety and concerns, that the commission and the commissioners felt it was important to leave that in the regulations.

DR. WILLIAMSON: But still we can state our view that we believe that that's a continuing problem that was not addressed. And there may be others, I

invite the other members to bring forth other issues that might be important enough that we should mention.

DR. NAG: Yes, I think, you know, the way it's written here it seems that mostly in intravascular brachytherapy is basically solved.

I think that the other points that have to be discussed, not necessarily that they have been solved and either say, in brief, that this is how it stands but perhaps there are some practices that have to be discussed without greater detail. But basically I think we can do that in the commission and leave the discussion part for later when the ACMUI members can discuss among themselves.

CHAIRMAN CERQUEIRA: Right. I think that's a good point because in terms of intravascular brachytherapy there were a lot of discussions, and then the feeling was that certainly at the time that we initiated this, there were no approved devices and there were still a lot of uncertainty as to which devices would be approved. And part of that was to put it into the part 1000 which basically sort of emerging technology.

And you're right, we attempted to deal with it but felt that given the lack of approved devices and the uncertainty as to how things would he done in a clinical setting, that we would put it into the emerging

technologies.

Does the committee feel -- again, these points, the medical event reporting, the unborn fetus and the IVB should be brought up again with the commissioners?

DR. NAG: At least to let them know that, you know, these are there, not necessarily that we have the solution or we have the answers.

CHAIRMAN CERQUEIRA: So list it as continuing problems not fully addressed or unresolved issues.

DR. DIAMOND: Well, I think it would be useful to the commissioners for them to understand the points that still need further work and discussions, so they have a more accurate sense of the issues that we're facing.

CHAIRMAN CERQUEIRA: Okay. That's a good point, Niki and then Ralph.

MS. HOBSON: Well, following up on Jeff's point, another area that ACMUI recommended and the recommendation was ignored, was on patient notification. I mean we came down on the side that the patient should not be notified unless there was the potential for harm actually being done.

CHAIRMAN CERQUEIRA: Right.

MS. HOBSON: But we were basically told by the NRC staff, well that's just not the way it's going to be, you know, the commissioners want that in there. So our recommendations were ignored in that.

CHAIRMAN CERQUEIRA: Okay. So in terms again that sort of medical event reporting, yes, it's the same issue. And, again, how do we deal with the fact that the NRC and the commissioners feel that there is a certain amount of public need?

DR. WILLIAMSON: I think let them know what the other point of view is, how it interferes in a negative way.

CHAIRMAN CERQUEIRA: Yes, but we did that repeatedly at all the meetings.

DR. WILLIAMSON: All you can do is keep bringing this to them. I don't think we should just capitulate and say, okay. We shouldn't turn into apologists for the commission.

DR. DIAMOND: To my thinking we have repeated discussions on these issues and we make arguments or recommendations based upon what we perceive is the logic. But what I don't see is the feedback in an official formal way why did they choose to decide otherwise?

In other words, a decision is rendered but

there's no discussion behind that, at least that I tend to see on these issues. So I'd be very interested to see what the rationale was with respect to their reporting criteria. Maybe that would help me understand where they're coming from, and the same goes on the other issues.

CHAIRMAN CERQUEIRA: Again, I think during the meetings we had discussions, not as direct with the commissioners, but certainly with the staff. And, you know, there's sort of the scientific issues of how much risk is involved with the levels of radiation, certainly for diagnostic, and then sort of the public perception fear about the use of radiation.

I think certainly a lot of concerns about cover up. I mean a few years ago they were doing all these investigations into sort of human experimentation with radiation in the past, and there was certainly a lot of public awareness that people early on were not being informed adequately of what the risks were.

And so I think the feedback that we've gotten from both the staff and the commissioners was they felt that, you know, even though you can make a good strong scientific logical argument that the risks are minimal, there's still this concern about cover up, not informing people adequately, and they felt that for that

reason they needed to include it.

Jeffrey?

DR. WILLIAMSON: I believe that that is not the reason why it was rejected. And John can comment on this, he would know better than anyone else in this room I expect. But I believe the concern is that, you know, there are abnormal event reporting requirements that the NRC has made a commitment to Congress to report. And these are specified in terms of dose, absorbed dose levels, and make no reference to the sequellae that ensue.

And so it was sort of an issue between the lawyers who were insisting that the medical event reporting requirement be made consistent with these other precedents versus, I think, a more medically informed and rational approach. And I'm not sure if this is true, but it seemed that the bottom line was that the commission was confronted with having to possibly go back to Congress to amend the AE criteria if they accepted the recommendation of the ACMUI.

Others may remember, but it was a very technically involved explanation.

CHAIRMAN CERQUEIRA: Is that your recollection?

DR. WILLIAMSON: Basically, the NRC

attorneys killed it. It had nothing to do with these rational arguments.

MS. MCBURNEY: I believe it had to do with the requirements for reporting to Congress at certain desk levels. Is that right?

MR. HICKEY: Well, I'm not up to speed because some of these go back a while. I think that both of the issues discussed by Dr. Cerqueira and Dr. Williamson and Ruth McBurney were factors, but I think Dr. Diamond's point is well taken is it is our intent to provide feedback, not just to the committee but to anybody who makes comments. The comments were not ignored. They were considered and the staff or the commission disagreed with the final position, you know, what final position should be taken.

But certainly there's ways we can provide you with better feedback so it's clearer what the reasoning was behind taking the positions.

CHAIRMAN CERQUEIRA: Okay. I think, you know, some of these issues are reasonable issues and certainly after page 6, the results, I think we can include that information as sort of unresolved issues or sort of continuing problems that have not been fully addressed.

And I guess the other thing is we are an

advisory committee and it sometimes is difficult for us to realize that, you know, we feel that we're right about these issues but we can only advise and we don't dictate the policy.

Ralph, I think you've been waiting the longest here.

MR. LIETO: Well, I just had two questions, or a comment and one question. The comments on the involvement of the ACMUI, as Jeff brought up in terms of the reasoning for feedback and so forth, in the Part 35 revision they are eliminating any reference to the ACMUI in revision.

Now the supporting comments and so forth seemed to indicate that, you know, it's not meant that the committee's going to go away or anything like that, but there seems to be the removal of any statutory reference to the committee having to be there. Okay.

The other question --

CHAIRMAN CERQUEIRA: Maybe we should get John to address that and then take your next question, again, I'm not sure that, you know, so just reference until the future existence.

MR. LIETO: Well, I raise that in light of the fact that there seems to be recommendations coming from the committee to the commissioners and staff and yet

they're either ignored and/or there's no feedback as to why that occurs.

And then reading in his support document that went to Congress about the changes to Part 35 referencing the diagnostic portions and so forth, at the ACMUI reference regarding advisory need and so forth, is being removed. Now, it may not be a big thing, and I don't know, but it just seems in light of what the comments are here, it just kind of raises a red flag.

CHAIRMAN CERQUEIRA: Well I think maybe part of the answer to that is some of this feedback comes during these discussions, it comes during the briefings with the commissioner and all of this, you know, these are dictated minutes that come out of all of this, plus summary, but the problem is it's difficult to get that information.

I think it will be appropriate for the committee, even though we are an advisory committee, we could request that, you know, we could send specific recommendations, and we've tried to do that in the minutes from the last several sessions, and we could request it rather than having staff interactions or discussions, that we get formal, in writing documentation, because Jeffrey and I have a different understanding of why we aren't doing some of this.

So Jeff, do you think that would help clarify it?

DR. WILLIAMSON: Well, we've had an unfortunate lapse where we don't have minutes anymore so I think it's very difficult for the last two years to figure out what this committee's done, unless you wand to wade through the huge stack of transcripts which nobody is going to take the time to do.

I hope we are going to be back on track of having minutes again --

MR. HICKEY: Well --

DR. WILIAMSON: But there were back in the period referred to, minutes that should be available that were prepared by the previous chair people that perhaps we should ask NRC to try to make more available to us on the web site or something.

MR. HICKEY: Yes. Our intent where a recommendation was made to clearly document that recommendation and provide a memo back to the committee on what our response was to that recommendation, and we have done that through I think late 2000 and early 2001.

There was one recommendation made in October that we haven't responded to yet, one reason being because it's still got to be discussed with the commission today, and so I held off responding to that

until after this meeting. But our intent is to clearly document the recommendations and provide a formal written response back to the committee.

Now maybe we didn't do a good job of distributing the responses to those recommendations, but we can do a better job on that.

CHAIRMAN CERQUEIRA: So I think that would be a reasonable message to give out, and I think we could probably include some of that at the end of my comments.

So, Ralph, does that begin to answer the issue? It still doesn't, you know, again the committee, I mean there's always issues when you're an advisory committee to a government agency, the agency is under no obligation to accept those recommendations.

But I think we're putting a lot of work into this and so I think it will be appropriate to request in writing responses, but then that makes it incumbent upon us to ask specific questions, either as a result of, we've tried to take votes at the last meeting so that we can clearly vote upon objects to which we would get a response. And I think we should try to get that.

MR. LIETO: The one other thing that I wanted to ask was do you think there should be any statement to the implementation of Part 35, of issues or concerns to the commission because of the fact that

you're going to be, when it's published, licensees are going to start to convert yet there's not going to be the guidance out there for them or that the guidance is under some controversy in terms of its implementation and finalization.

And that there's sort of this transition period in timing that I don't know if we've got an answer for them but I think that's going to be a real concern for the regions and the licensees in the NRC regions.

CHAIRMAN CERQUEIRA: I think that transition period, and certainly in a response that they made to Congress, they made a commitment to work with the professional medical societies in terms of the guidance documents and to certainly address some of the issues that the SNM ACNP brought up. But there really is no time line on that and I think that certainly sooner rather than later is the appropriate request. So I can make that in the statements as well.

DR. DIAMOND: I also do think, I'm sorry.

DR. WILLIAMSON: Go ahead.

DR. DIAMOND: I also do think it was a very useful decision for the commissioners in their letter to Congressman Callahan to decide not to do a partial implementation but wait for a unified implementation based upon the review of the SNM issues. That would have

created tremendous confusion and I applaud them for that decision.

CHAIRMAN CERQUEIRA: Okay. Dr. Nag and then --

DR. NAG: I realize that the AMCUI advisory body and we do make a lot of recommendations. What I think we should ask is (a) the summary recommendation be separately be put forward. I mean we will have the entire transcript, but just the summary of the recommendation be made in one, two, or three page document.

No. 2, if the NRC had to go through a lot of things and you have to try everything, but if they are either going against the recommendation of the ACMUI, it should be a requirement that they respond why they are they not following.

They don't have to follow us but they have to tell us why they are not following us. I think that's all we ask.

CHAIRMAN CERQUEIRA: I think it's appropriate and what I've tried to do at the last couple of meetings is, you know, sometimes we have discussions ad nauseam and then don't reach anything, so I'd like to sort of make motions, take votes on motions, and those things specifically we would want the commissioners

through their staff, their individual staff and any NRC staff that supports this committee to respond to us. So I think we could make a --

DR. NAG: But that I'm saying the recommendations be taken out and at the end have a separate section. We had a two day meeting, these were the recommendations. I mean they will be in the body of a 100-page document, but at the end there would be a two page document.

CHAIRMAN CERQUEIRA: Yes. Well that's Jeff's point. The minutes of the meetings are where that information needs to be extracted and I think we should work for that and, clearly make note of areas where we made motions, we took votes and we want to get a response.

MR. HICKEY: Yes, the staff agrees with that also. It's been our intent to do that, so we will make every effort to do that.

CHAIRMAN CERQUEIRA: Okay. Niki?

MS. HOBSON: Well I just want to follow up on Ralph's comment on the timing. I mean how sure are we that, okay, you publish Part 35 in 30 days and then it will be implemented in six months. How sure can we be that the guidance documents are going to be revised and approved? I don't even know what process we have to

follow, that has to be followed.

But, just having seen how long it takes to do anything, I'm wondering is six months enough to get that huge document revised and commented on and so forth? Or should we maybe encourage the commissioners to delay publication for another 30 days? I mean we've waited this long, couldn't we wait another 60 days, just to make sure that the guidance is there, when the rules are going to be implemented?

CHAIRMAN CERQUEIRA: Yes, I guess John, what's the process for the guidance documents in terms of getting them written, approved and implemented?

MR. HICKEY: Well, first of all with respect to allowing enough time, I think the mechanism if a decision was made to allow more time, would be to delay the effective date of the rule, not the publication date of the rule. I think we would want to get the rule published. It's essentially already been published, in the sense of being made available to the public, but it hasn't been published as a formal agency action.

It is a challenge. The mechanism will be to issue NUREG 1556 as a final document, but it is a challenge because we've now agreed to take a harder look at it and have meetings and have written comments come in which will have to be dealt with.

So the direction from the commission, and feel free to comment on this to the commission, the direction is to have that guidance revised reflecting comments, including more comments from ACMUI but also the public and other stakeholders within that six month process.

CHAIRMAN CERQUEIRA: Okay. Jeffrey?

DR. WILLIAMSON: Well I think maybe when you raise this issue or talk about your bullet about it being risk informed and performance based, it's only going to be performance based if it's implemented through inspection and licensing procedures in a performance based way.

There's enough specific prescriptive regulation in this new Part 35 that they could completely tie up and hamstring anybody by finding some small paperwork or mission or detail. But performance based means that they look at the licensee's overall performance in achieving broad safety targets and are emphasizing less small paperwork infractions.

I think in some ways it's not just having this done in time, it's the quality of this document and the quality of the training efforts for the inspectors that go behind its implementation.

So I think to emphasize, there's a risk here

if they don't do this right.

CHAIRMAN CERQUEIRA: Yes, the problem we have is we're talking about, what, 32 agreement states and 18 NRC states so that basically the people that are going to be impacted by this immediately are 18 out of the 50 states. And I think part of the reason to try to get this out there is to try to get more agreement, because the agreement states have up to three years, and we'll hear Ruth's presentation.

But I think these are good points and I'm not trying to convey the fact that this is a perfect document but just in terms of the process that we went through, I just don't know another alternative method where we could have gotten input from people. I suppose there were other things that could have been done but it's taken long enough as it is and it's not perfect, and I think certainly we've identified other areas that we can bring up that are unresolved issues and I think we should, you know, basically hammer home those points to the commissioners as Jeffrey has suggested.

And then maybe, again within the role of the committee of the process and the whole interaction with the NRC, I think we're sort of evolving towards trying to capture the critical discussion items that occur and trying to get specific feedback from them. We should

definitely move in that direction.

Richard?

DR. VETTER: I just wanted to underscore what Jeff said about implementation, and rather than focusing too much on what happened in the past, look forward to how this is implemented. And therefore the guidance does become very, very critical. And to get the most out of the regulations, to truly be risk informed, performance based, the guidance needs to emphasize that and the NRC in fact will set the tone for the states.

If the whole process holds the licensee accountable rather than focusing on the prescriptive nature of the regulations, we can still gain as much benefit as possible out of the current Part 35.

CHAIRMAN CERQUEIRA: All right. This has been helpful to me and I think probably we should go on to the next section, otherwise we're going to be here up until the time of the briefing.

Thank you for your comments and input and, again, I would have preferred to have circulated these ahead of time to people so we could all get the input and modify them, but we just didn't have the time to do it. So Ruth, do you want to go over your --

MS. MCBURNEY: Yes. Basically mine is just going to talking about the implementation of Part 35 in

the agreement states. As Dr. Cerqueira mentioned a majority of the states are agreement states. In fact, probably about 70 percent of the medical facilities that would be impacted by this change are in agreement states.

There was considerable involvement of state personnel in the rule making process. In fact, two people on the working group and one or two on the steering committee as well felt that it was a fair process that allowed for input from all the stakeholders.

As he also mentioned, the agreement states normally have three years to implement a rule once it's adopted by the NRC. During the rule making process, a parallel process was going on to provide suggested state regulations and so they're ready to be published as well and provided to the states as soon as the Part 35 is published.

Some of the states have seen that several of the rules are needed now, some of the rule changes, for example on the brachytherapy, the high dose rate low dose rate brachytherapy requirements, the provisions for new technologies, especially in some of the larger states where the new technologies are coming in fast and furious.

So the scheduling of the rule changes will vary from state to state. Some of the states have

already implemented some of the provisions of the proposed changes that aren't impacting their compatibility with the Nuclear Regulatory Commission. And some states will just wait and may not meet the requirements until that three years is up, because some of the rule making requirements in some of the states is more onerous and takes longer than in other states.

For the training and experience requirements for the MD authorized users, ACMUI has recommended that NRC cooperate with the states to get sooner uniformity, more immediate uniformity in the requirements, because this can cause cross boundary issues with physician training programs, And also to approve the boards as soon as possible to facilitate that uniformity.

Board certification acceptance makes the approval of users a more efficient process.

The Nuclear Regulatory Commission has mentioned on several occasions that they are having workforce issues with a maturing workforce. The states are likewise having those same issues with people that have been trained, have been health physics training and so forth, are getting to near retirement age and there's a lack of trained personnel to take their place in licensing and inspection work. And attracting new staff at the pay scales that the states can offer is really

difficult.

CHAIRMAN CERQUEIRA: All right.

MS. MCBURNEY: Comments on that?

CHAIRMAN CERQUEIRA: Comments?

DR. DIAMOND: I just would like to mention what I told Ruth privately. The states, particularly my state, Florida, is having tremendous workforce issues so I applaud you for emphasizing that and I believe that this manpower issue may only increase in the next three to five years, as I believe there will be a dramatic increase in the use of radio-pharmaceuticals for therapeutic purposes in the next couple of years.

MS. MCBURNEY: We've seen our work load in licensing, in medical licensing, already starting to go up because of some of these newer modalities.

CHAIRMAN CERQUEIRA: One of the charges we got from the commission was to basically try to give them ideas, not just Part 35 revision issues but sort of anticipating problems in the next three to five years. And I think this manpower thing that we've all identified is going to be very critical because I mean all of us, no matter what part of, what area we work in, we're all having difficulties so I think it will be an important --

MS. HOBSON: Well, I just wondered if the

states or the committee, are there recommendations on how to remedy this? Are there programs that should be implemented, funding that should be --

MS. MCBURNEY: We have in the past recommended that NRC reinstitute paying for training for state personnel. They used to pay travel and tuition for certain courses but, of course, they've had cutbacks as well and once they were put on a fee-based system, that all had to go into the fee basis, and it was difficult then for them to provide training for agreement state personnel when it was their licensees that were having to pay for that.

We in the states are having to sort of train our own. We were fortunate in Texas to have Texas A&M put on a five week course for us, similar to the one that Oakridge does for state and federal personnel.

CHAIRMAN CERQUEIRA: I think we can identify this. Dick had a --

DR. VETTER: Yes, back in the late 50s or in the 50s through the 60s and into the early 70s, the federal government pumped considerable dollars into training programs and fellowship scholars in radiological health.

In the late 70s through the 80s and 90s, those programs have struggled and today the number of

health physicists in the system being trained numbers in the ballpark of 100. And so all those people who were trained in the 50s and 60s are gray haired, like me, and we're going to be retiring and there just aren't very many people to replace us.

So in health physics alone, let alone the other areas, this is going to be a very critical issue. And someone at a very high level needs to become aware of this and begin asking what they're going to do to try to resolve it. These training programs are going down the tubes.

CHAIRMAN CERQUEIRA: That's true for radiation safety officers, health physicists to technologists. I mean certainly all of us that are doing diagnostics, it's a key issue that needs to be addressed and obviously is going to need some resources to solve it.

MS. MCBURNEY: There is some legislation in Congress that would provide more scholarship funds for that but nothing that we can --

CHAIRMAN CERQUEIRA: Yes, unfortunately, a lot of the training programs, certainly for technologists, have basically closed and there's plenty of jobs out there, but even though there may be scholarships, if the programs aren't available it's going

to be a problem. John, you had a --

MR. HICKEY: Yes. If I could go back to your previous point, when you used the phrase "immediate uniformity" --

MS. MCBURNEY: It was --

MR. HICKEY: I'm anticipating, maybe the commission won't ask, but what do you see as the role of the commission? Is it to encourage the states to do things as quickly as possible?

MS. MCBURNEY: Encourage, right.

MR. HICKEY: And I think people are aware that the reason that I'm asking that is the states are allowed three years to implement the rule and they generally resist overtures from NRC to try to get them to implement the rules faster than that as a requirement. Now some of the states do implement it but other states, for one reason or another, can't implement things as fast as we would like.

MS. MCBURNEY: Yes, that was my previous one. Dr. Cerqueira was this a slide that you added?

CHAIRMAN CERQUEIRA: Well I did, I added some of that material about, you know, and we've got sort of these, from my constituency, the training and experience are going to be a big problem as people go across state lines.

I guess the other question, too, John is that I think the Glenn Commission in the early 90s identified the fact that the NRC doesn't really have the authority to make the states compliant with federal policy. There's no mechanism in place by which they can, you know, get compliance from the states.

So what if Texas decides it doesn't like some of these changes and it's just not going to do them period. Is there anything that the NRC can do, short of going to Congress?

MR. HICKEY: I'd rather not comment on that at this time.

MS. MCBURNEY: That's incompatible with --

MR. HICKEY: Well I can tell you my personal understanding is that the NRC can revoke a state's agreement and take jurisdiction for the licensees in that state. That would be unlikely but generally if NRC's unhappy with the way the states are implementing important regulations, the result is the states eventually implement those requirements.

CHAIRMAN CERQUEIRA: But again, and I don't recall all the details, but the Glenn Commission did find that that was a major problem that you couldn't get a consistent implementation.

DR. NAG: What authority does the NRC have?

Do you have the authority to do that or not? I mean if you find a state inconsistent, either they are more lax or over restrictive, can you do anything?

CHAIRMAN CERQUEIRA: We have the authority to revoke the agreement and take jurisdiction of the licensees.

DR. NAG: But that's almost unlikely to happen. But only this portion you are overstepping your boundary or something like that, can you do just anything short of revoking an entire license?

MR. HICKEY: There are lots of things we do to get states to be compatible, but I'm not a lawyer, I don't know what the legal significance of those things are.

MS. MCBURNEY: Every few years each agreement state has a review done, it's called an IMPEP review, Integrated Materials Program --

MR. HICKEY: Performance Evaluation Program.

MS. MCBURNEY: Right. Right. And as part of that they review the rules, the procedures, the training and experience of the staff, all that, to make sure that it is adequate to protect public health and safety and is also compatible with the program at NRC.

Now, certain rules have a higher or lower compatibility level than other rules, and of course

certain things like Part 20 has to be almost essentially identical. And then there will be certain parts of Part 35 that will have to be identical, or essentially identical. And then there will be other parts of it that the states have more flexibility on.

CHAIRMAN CERQUEIRA: But there were different levels of compliance and some of these things, I know with training and experience we basically said it had to be level C compliance.

MR. HICKEY: Yes, we call them compatibility levels.

CHAIRMAN CERQUEIRA: Yes.

MS. MCBURNEY: I think it's a B.

CHAIRMAN CERQUEIRA: It's a B?

MS. MCBURNEY: Meaning essentially the same.

CHAIRMAN CERQUEIRA: The same. But the implementation for that is still within a three year period after six months following the publication in the Federal Register.

MR. HICKEY: Correct.

CHAIRMAN CERQUEIRA: Okay. Any other questions for Ruth or points that people would like to make? Okay, if not then --

MR. HICKEY: If I could just interject, Mr. Chairman, we have the revised agenda here so we will be

able to hand it out to all the members and the other attendees before they leave today.

CHAIRMAN CERQUEIRA: Okay. Again, I think we're sort of captives. We're definitely going to be here tomorrow for the whole meeting, but some of the other people are only here for sections so if you make it available that'll be good. Sally, do you want to go over the sort of nuclear pharmacy issues?

MS. WAGNER SCHWARZ: Yes. Actually, along the same lines in terms of numbers of individuals in the field and if their pharmacy kind of faces the same situation, not so much that we're dwindling number wise but that the requirements and, I mean the field is expanding. The need for pharmacists generally is expanding.

And so one of the largest growing areas in nuclear medicine for pharmacy personnel is PET and that's not an NRC concern but it certainly does impose a difference for the agreement states. They regulate both byproduct and the accelerator produced materials, but for the NRC regulated states essentially it's the issue of PET isotopes or accelerator isotopes, as well as byproduct material in dealing with dispensing firms. In centralized nuclear pharmacies this issue is already bearing essential increases in hand dose.

I know that within our field we've always tried to work at the ALARA level of 10 percent and so I know that's not a mandate, it's just what we attempt to do in terms of hand and body exposure. But with the introduction of PET, the 511 keV photons essentially bring a difference to the field compared to the 140 traditional energy level of most nuclear medicine handling isotopes.

So with that thought in mind I just really wanted to do this kind of as an issue that needs to be addressed, for ALARA in using PET we're talking more like 35 to 40 percent of the allowable exposure that's being incurred by personnel in working with PET isotopes.

So from the inspectors' standpoints, from the NRC who are reviewing these personnel, even attempting to keep things as low as reasonably achievable, this becomes an issue. And it's not that we're not working safe, it's that we are again working with higher energy, and it's not if we could just hire people and have more pharmacists that might be one way to improve the situation, and again there is this shortage of pharmacy personnel that's apparent.

And the reason for the shortage, there's a couple of reasons. Pharmacy programs have recently gone from a five year undergraduate degree program to now a

six year program, and the numbers essentially of pharmacy entrants are about flat. I mean there's not an increased number, but there certainly is an increased demand and not just from PET but from other areas that draw pharmacists in general.

So I think that in other words, in order to maintain ALARA levels we do need more pharmacists, at least the lower ALARA levels we do need more personnel. So how are we addressing the shortage as far as pharmacy is concerned? Some pharmacy curriculums, specifically Purdue I am aware of, that is trying to include sufficient electives within their curriculum so that they would be essentially certified with the required training to be able then to go out in the workplace and get the training, on site training hours that are needed for board certification.

And, additionally, there are certificate programs available for already graduated pharmacists. These are only three that I list here, Purdue, the University of New Mexico, University of Arkansas, all of which are the larger programs. Some of the actual centralized pharmacies, such as Syncor, does have their own programs so they hire pharmacists and then send them to various training programs.

So they do have methods available to

essentially train individuals, but again we're still short of people to train even having those programs.

The next thing that's essentially in the works is the technician training. There always have been pharmacists technicians who have worked in regular pharmacy settings and actually in 2000 there were guidelines actually prepared by the APHA section nuclear pharmacy practice in 2000, guidelines for nuclear pharmacy technicians. So, again, there are certificate programs through APHA for these technicians to be certified.

So, again, this may allow us to share dose by bringing more of these technicians to be supervised by the pharmacists on board, but again the issue of money really is something, too. I mean programs again have for nuclear pharmacy gone by the wayside. The particular program I went through at the University of Southern California is no longer available because of funding. I mean it's just gone.

And so, again, it's an issue of people, lack of monetary ability, it certainly would be helpful if that was reinstituted but most likely it won't be something that will be on board in the near future.

DR. DIAMOND: Sally, are you concerned about the potential for some of your workers actually reaching

or exceeding allowable worker limits, for example. There are some centers where a PET center may be a stand alone center in which all they do all day long is PET at very high volume. And that radio pharmacist or technician will only be handling this particular material and will not have access during the day to mixing it with other types of perhaps even lower risk material. Are you seeing that at all?

MS. WAGNER SCHWARZ: Yes, we are seeing that. I would not say probably at the limit but certainly you have to continue to change practice, to upgrade, you know, as far as, yes, it's problematic.

DR. DIAMOND: For example, at our institution we have a dedicated PET center and that raises a concern perhaps there should be mechanisms in place to ensure that these workers do rotate. Not just for experience and training to keep their skills up at all levels, but also for their own individual --

MS. WAGNER SCHWARZ: We currently actually at our institution do try to essentially distribute that dose to the best of our ability. And, again, all of these personnel chemists, technologists and again the shortage of technologists presents a pharmacy issue, too because often technologists have been hired because they've been trained in handling radioactive materials,

to be able to do, you know, the PET production, distribution as well. But they are not really available a lot of times.

CHAIRMAN CERQUEIRA: Jeffrey?

DR. WILLIAMSON: Well I think that maybe in the course of Sally's presentation would be a good time to mention in general the mixed dose issue, which is very important for interventional cardiology, and any group of people that's getting a larger amount of superficial radiation from non byproduct sources but also handles byproduct radiation, and that is the problem that for the purposes of complying with Part 20. They're forced to use, what is it the deep dose, the DDE, deep dose equivalent, which is defined as the maximum dose to the whole body rather than the effective dose equivalent which can be averaged and weighting factors can be applied to.

So that is a major problem that maybe one of us ought to chime in and suggest it really needs to be solved, either by a regulatory initiative or through reinterpretation of the appropriate regulations in Part 20.

CHAIRMAN CERQUEIRA: So the issue of mixed dose tied into the fact that, you know, we're having sort of a shortage in all the areas of workers. We can't sort

of divide things --

DR. WILLIAMSON: Well that it's exacerbated that because NRC is essentially applying a definition for calculating whole body dose with mixed modalities. That's out of step with what the community is doing. Is that a fair statement?

MR. HICKEY: Yes, and in fact the commission has given some direction to remedy that and that's what we're going to discuss tomorrow. That's on the agenda for tomorrow.

MS. WAGNER SCHWARZ: At NCRP.

CHAIRMAN CERQUEIRA: Right. So this is a separate issue, this is something to a great extent out of the hands of the individual licensees but as the, you know, penetration of technology changes and maybe the diffusion of liquid radio nuclides and non byproduct materials into radiation oncology increases, we could also have the problem.

MS. WAGNER SCHWARZ: Yes, absolutely. That is definitely where this is --

MR. HICKEY: Right now we don't because we get such low exposures in general that it's not an issue.

CHAIRMAN CERQUEIRA: So I think if you could bring that point up Sally. Even though it's going to be

discussed tomorrow, I think it's important for the commissioners to hear it.

One question I have. This change in the requirements from five years to six years, was that made by the programs? Was that made by regulatory agencies?

MS. WAGNER SCHWARZ: It's actually been a work in progress since I graduated from college. At the time that I graduated, which was 1971, California had a six year program. Really, we've grown over that interval into the six year program, and that really was to accommodate increased training in clinical areas generally as part of total pharmacy, so that graduates are required essentially to increase their --

CHAIRMAN CERQUEIRA: Right. Now we can make all of these, you know, make them aware of the concerns about manpower in training. We've identified the problem, but what's the solution? Do we just need more money for this? Is that all it takes? I mean because there are jobs out there but people aren't going to them. Jeffrey?

DR. WILLIAMSON: Well, I suspect the radiation safety officer and health physicist part is a little different. Maybe what NRC does or doesn't do could have more impact on that, and that really is a serious crisis.

I think the others the therapists needed, the staff radiation oncology nuclear medicine and other things that probably will be solved by marketplace incentives, you know, you pay those people out of clinical fees garnered by the hospitals. So there is a source of funding for that and it's necessary to get supply back in alignment with demand.

But radiation safety officers and health physicists don't generate patient billings. And so I think that is a major issue. They really are, I think, desperately in need of subsidization of some kind or another because they don't enjoy the same benefits as the other para professional people in radiation medicine.

DR. DIAMOND: Why -- I'm sorry, go ahead.

DR. WILLIAMSON: So I think another, it's probably related to the board certification issue, too, they've managed to undercut the value of American Board of Health Physics certification, that's surely not going to help at all.

CHAIRMAN CERQUEIRA: Okay. David?

DR. DIAMOND: Certainly I think the marketplace will at some point go and correct those inequities. We certainly are paying our technicians a lot more, technologists, than we formerly had paid and, you know, that's how the system works.

With respect to their agreement states, in the state of Florida we have certain regulations which dictate how much starting employees can make. Unfortunately, they are out of step with the technical qualifications of these individuals. That, plus the cutbacks in state funding because of our declining economy following 9-11 have all really produced issues. So, again, it's a multi factual process, the states have their own financial issues, there's a marketplace set of issues, and then with respect to the RSOs there's a set of experience and training and board certification issues.

CHAIRMAN CERQUEIRA: Subir?

DR. NAG: Yes. In terms of funding, I think what we have to see is (a) whatever the radiation safety officer is providing. Is this a direct benefit to the patient. If it is, then just like any other group, you have to lobby the HCFA that, you know, radiation survey is a procedure that has to be done for the benefit of that patient, and there should be a charge associated with that.

And if you do it that way, then you get reimbursed for that and then you, you know, with more regulation you will then generate your own income. So that is something I think the radiation safety officers

group should try to lobby the HCFA.

CHAIRMAN CERQUEIRA: One of my other non-paying jobs is to serve on this CMS, which used to be HCFA and AMA and just looking at what practices should be paid. And I can tell you nothing is going up, it's going to continue to go down. I think again we can identify this issue is that there's increased utilization in all aspects, certainly in PET for diagnostic studies and we're really finding a short that's multifactoral, certainly the maturing or aging or graying of the workforce and failure of people coming into the work environment.

The other that's happening, too is there's a shift, and certainly if you're hospital-based you can't pay people what people in private practice can do. And the conditions in an out-patient cardiology practice doing nuclear cardiology are a lot better. There's no call, the patients are usually healthier, so there's issues of distribution as well.

I think we can make these points at the commissioner's request. Okay, Sally. Any other comments for Sally or --

MR. HICKEY: I'd just like to make a procedural suggestion. Remember that you're speaking to a broad audience of people in this meeting. There's

going to be other people there besides commissioners so when you use an acronym the first time, like LDR or PET, say what it is. You can generally assume everybody in the room's going to know what ALARA means, but it's better still to explain the acronyms. And for PET, it may be worthwhile to just take a moment to make clear that that's an accelerator technology that's not under NRC jurisdiction, so that that's clear to everybody that this is an influence. It impacts medical care but it's not something that's directly under our jurisdiction.

Also, call the slides, like say next slide please, or slide 5 please, so the people who are showing the slides will know where you are in your presentation.

CHAIRMAN CERQUEIRA: Okay. Jeffrey?

DR. WILLIAMSON: Okay. Well I want to start out making the point that everybody in the community and within the ACMUI I think is pleased at the introduction of the concept of the Authorized Medical Physicist or AMP. That recognition that the physicist plays a much broader role in promoting the safety and efficacy of radiation medicine than calibrating Cobalt 60 units is an important step forward in aligning the regulatory point of view with clinical reality.

But, unfortunately, there is a major conflict between the training and experience requirements

specified for AMP in 35.51 and the community's definition of qualified medical physicist.

The community's definition is that the individual be certified in the appropriate specialty by the American Board of Radiology or American Board of Medical Physics, plus satisfy certain continuing education requirements.

The 35.51 specifies a number of requirements, a graduate degree, years of training, but also requires specific experience and training with byproduct modality such as Cobalt 60, teletherapy and stereotactic and high dose rate or HDR brachytherapy.

The ABR and ABMP criteria for sitting for the boards as a little different. In many ways they're similar, they require the same graduate degree essentially, require between two and six years of experience to sit for the boards, but they do not require specific experience with byproduct modalities, that's not included.

So their emphasis is on assessing the candidates' clinical judgment, knowledge base and ability to independently practice the profession of clinical physics for all modalities.

So this is the essential conflict so it does appear that neither American Board of Medical Physics

certification nor American Board of Radiology certification will become one of the approved boards for authorized medical physicists.

The unintended consequences are, firstly, this can serve to undercut and marginalize board certification. The essential issue is why bother going through the board certification process if it's not going to help you become an authorized medical physicist. I think overall this is a very bad consequence. It certainly does nothing to help promote safety and it may in fact undermine public health.

The underlying reason why this is so is that board certification is essentially the only industry standard or credential that defines a qualified medical physicist. Unlike other areas, such as radiation oncology where there are well established residency and training programs, there is no established and accepted single pathway for achieving this level of experience.

So the board certification process is really the only quality mechanism to ensure that this experience is of high quality. It may exacerbate AMP shortages by preventing qualified medical physicists from practicing in licensed institutions. There are relatively few opportunities, especially for Cobalt 60 and gamma stereotactic to achieve this training.

So that the remedies listed here are I think short term, two things the ACMUI has recommended, one is unconditional grandfathering of current teletherapy physicists as full AMPs without qualification and without limitation of what modality they can practice, to create a pool of AMPs that can serve as preceptors.

The second short term remedy would be to accept board certification as evidence for complying with as many of the 35.51b requirements as possible. So, for example, implementation and guidance space require evidence of supplementary training, for example in Cobalt 60 gamma stereotactic, plus board certification, as grounds for becoming an AMP in that area.

And, of course, the long term fix is a rule making initiative which addresses this problem and essentially puts the boards back in rule space and replaces the and with an or.

CHAIRMAN CERQUEIRA: Okay. And then there's some back up slides for Jeffrey. Subir?

DR. NAG: Yes. The requirements that Jeffrey was talking about are no different than that for the authorized user. Quite simple, in the authorized user you have radiation oncology boards, you have general training in radiation oncology, you don't have to have cobalt experience in radiation oncologies without cobalt

experiences, they are all parallel.

I don't think that any major difference between the AMP, authorized medical procedures, and the authorized user. They have very similar problems, and in the authorized user that has been solved by saying you have to be board certified and show that you have experience in any of these special modalities like gamma knife or Cobalt 60. I think they're all very similar.

DR. WILLIAMSON: Well, actually that's a good point and it is quite possible, it seems to me, that radiation oncology certification may not be accepted as the default pathway for becoming an authorized user because the regulations in 35.600 do in fact make reference to byproduct modality specific procedures. So indeed radiation oncologists could find themselves in the same boat as the physicists. So that's definitely a point I wanted to make if I have a moment.

I think there is a difference, and that is first of all there are state licensing requirements, which encourage and promulgate the incentive to undergo board certification and hospital credentialing requirements that do and, with the exception of a few states, physicists don't have this and, secondly, radiation oncology does have a uniform clinical training program that by either the alternative TNE or the board

certification pathway you have to have. And physicists don't have that, so that's why I view it as a greater risk to the physicist than the radiation oncologist.

But I think it is important that board certification is in doubt for physicians, too.

MR. LIETO: I was just going to make the point or make a suggestion that the short term remedy you're suggesting really is just to maintain the status quo.

DR. WILLIAMSON: More or less. It's exactly what we do as an industry standard that we undergo a few weeks, or hours in some cases, of supplementary training on top of board certification.

If I have the opportunity I'll try to make a comparison of the regulatory paradigm of how one learns and the clinical reality. I think underlying all of this is the unrealistically mechanical concept of how people learn to become competent. Somehow this information, knowledge is downloaded into you from a vendor and then you go off and practice correctly. But that simply is not right. You rely on the judgment, skills and knowledge base of the physicist to essentially set up these specialty procedures, design form, design procedures, implement training programs for the staff to make them work.

So it's not that a, you know, specific bit of knowledge is going to make all of the difference between having a successful program or a dangerous program.

CHAIRMAN CERQUEIRA: Jeff, can you remind me why we put and and not or in the current regs? You're saying that the long term, just a rule making initiative, to replace and with or.

DR. WILLIAMSON: Well, John may have a more informed opinion.

MR. HICKEY: Do you want me to go first?

DR. WILLIAMSON: Yes, you go first.

MR. HICKEY: Well, the intent was that the board certification be subject to criteria that the board certification would just without review be accepted, so that now there would have to be a criterion by which the board certification actually included a process such that the people were qualified. So that's the distinction between the old rule and the new rule.

With respect to Mr. Lieto's comment on the status quo, that's not quite true. The status quo would be that people who are currently on licenses as authorized teletherapy or medical physicists could continue under their current authorizations. The proposal here is that they would be allowed additional

authorizations that they currently don't have.

For example, if they weren't currently authorized for gamma knife, under this proposal they would be authorized for gamma knife.

DR. NAG: Can you tell me what you mean by this "and" and "or." I mean was not really clear.

DR. WILLIAMSON: Okay. Maybe I should take a stab, I have to present it. The new regulation states --

CHAIRMAN CERQUEIRA: Here again you may want to make it clear to the commissioners because I'm not sure that they'll really be up to date on it.

DR. WILLIAMSON: That's a good point. So the issue is the new regulation states that an authorized medical physicist is one who has board certification by an approved board that meets the following requirements, which is the years of experience, the degree and acquaintance with certain byproduct material modalities.

It's also possible that, you know, one can be an authorized medical physicist simply by complying directly with these alternative pathway requirements.

So in the old regulation it was be certified by one of the following boards, or comply with these training and experience requirements. So now it's have

board certification that includes all of the following requirements.

CHAIRMAN CERQUEIRA: So this was just an oversight on the committee's part?

MR. LIETO: You know, I --

CHAIRMAN CERQUEIRA: Ralph?

MR. LIETO: I was just going to say, I seem to recollect that when the proposed Part 35 came out, the intent was that the NRC was going to set up potentially its own exam to approve authorized users, RSOs and so forth. And then the final revision that came out sort of said we're not going to be doing this.

And I'm just wondering if, in that that process of getting away from doing that process, somebody forgot to change an and to an or or something like that. Because what was originally proposed in Part 35 in what, 1998?

CHAIRMAN CERQUEIRA: Yes.

MR. LIETO: Especially regarding training and experience, has gone through a couple of major iterations. In all the public forums that I attended, the and/or were never discussed, I mean it was basically that you were going to have board certification and then there was going to be these alternate pathways without naming the board certifications.

DR. WILLIAMSON: I think the assumption was that the alternative pathway requirements were a fair statement of the existing prerequisites to sit for the boards. I don't think anybody examined it closely.

MR. HICKEY: Yes.

DR. WILLIAMSON: And my private conversations with staff, even those in leadership positions in this organization, is widely admitted this was an error, both on the part of the staff and failure of the community to notice this discrepancy between the alternative pathway requirements and the board eligibility requirements.

MR. HICKEY: Yes, that's the NRC's understanding also.

CHAIRMAN CERQUEIRA: But is it too late to correct a typo?

DR. WILLIAMSON: We've been there.

MR. HICKEY: It's too late to correct it before the rule is published. I don't know if it's correct to characterize this as a typo.

(Laughter.)

CHAIRMAN CERQUEIRA: I was being facetious. Richard?

MR. HICKEY: I understand.

DR. VETTER: Just to add one more point to

this, I agree with everything that's been said relative to the past history and how this occurred, the NRC originally was going to more or less accredit the boards and one thing they were considering was the exam process.

All of that we had an opportunity to comment on, and I assume there were comments. I don't know what they all were.

Then the published rule came out this way where the or was changed to an and, so that the boards would be held to some sort of a minimum requirement and everybody would be on a level playing field. But I think the crucial point here is that we never had an opportunity to comment on that and. That came out in the published rule.

DR. WILLIAMSON: Is that true, John?

MR. HICKEY: I didn't attend the meetings and we could review it with the people who did another time. But my understanding was it was made very clear in the meetings and to the professional boards what the rule said, what it was going to say and we didn't get any comments objecting to that wording.

DR. WILLIAMSON: Could we find out during the lunch hour?

MR. HICKEY: No.

CHAIRMAN CERQUEIRA: Well, you know, again the whole issue of a separate board that would test not clinical competence but just knowledge of radiation issues and day to day practicalities was entertained and the NRC looked at it, decided it was cost prohibitive in terms of setting it up, administering the exam, and the decision was made not to go that route but rather to let boards apply, you know, the currently existing boards, as a way of letting the NRC out of the requirements for setting their own board standards.

And I guess certainly for the diagnostic, I always thought that there was still an alternative pathway, if you didn't have boards you could still have that 700 hour training and experience.

MR. HICKEY: That's correct. If it were just a question of a misunderstanding of what the boards required, that could be corrected but there's a substantive issue. The proposal on the table is a person who has no training or experience in a modality should be deemed quality in that modality. That's what we have to wrestle with. Somebody who has no dealing with a gamma knife is going to be deemed qualified to work on a gamma knife. Somebody who's never been in a medical facility can be qualified to be an RSO in a medical facility. That's the part that would take more time to deal with.

CHAIRMAN CERQUEIRA: So we want it to be sort of isotope or technique specific training and experience?

MR. HICKEY: Yes.

CHAIRMAN CERQUEIRA: Richard?

DR. VETTER: John, how do you reconcile that for a licensee who has not had gamma knife and now they are getting a gamma knife, and no one there has any experience using the gamma knife?

MR. HICKEY: Well, they bring people in that had training from another facility, either from the vendor or another facility, I mean is what I've been told. But that's part of, if that's not practical that's part of what we would have to consider.

DR. VETTER: No, that is in fact what happens.

MR. HICKEY: Right.

DR. VETTER: So they do get the training?

MR. HICKEY: Yes.

DR. WILLIAMSON: They get some training.

MR. HICKEY: Right. They gain most of it by experience so they get the training once the device is on site.

DR. WILLIAMSON: But I think the flip side of this, the concern is that if you only get people that

have that kind of training and not the broader base of knowledge and experience provided by board certification, what you've done really is undercut the quality of what goes in the --

MR. HICKEY: Yes, I understand.

DR. WILLIAMSON: This is the problem that somehow if you discourage or create a disincentive to have the broader and more important credential, you are not serving public health.

MR. HICKEY: I understand that. My own view is that people will still get certified and if they needed to get additional training they would do it. I don't think they would say I don't want to get certified because of what NRC says. But I understand that that's a concern and it's reasonable to raise that with the commission.

CHAIRMAN CERQUEIRA: Yes. Subir?

DR. NAG: I think that the same thing again or as an oncologist, if I never had the gamma knife and I'm board certified, when I get the gamma knife or when our department got the gamma knife, I still don't treat on the gamma knife unless I go through a separate training on the gamma knife. And even in that training I'm still not superb on the gamma knife until I start working on it a few days.

And even in intravascular brachytherapy, when you came from one intravascular system to the other, the training was entirely different. So just because you've been qualified for intravascular doesn't mean that you are going to know everything about another system that is intravascular but using different equipment.

DR. WILLIAMSON: Well this also gets back to -- that's all correct I believe and this gets back to the issue of risk informed and performance based regulation that, you know, to think you through your criteria have identified a reasonably competent body of professionals to do the procedures, you rely on essentially their level of professionalism, training and experience to be able to meet the broad safety performance targets that are laid out in the regulations.

CHAIRMAN CERQUEIRA: Okay. I think this is a point that you can bring up and I'm sure that they'll have discussions, but I think they may not understand all the background in this and you may want to go into a little bit of basic --

All right, shall we go on to Dick for the last portion of it, but we'll try to finish by one o'clock which will give us an hour for lunch and to make it over to the meeting. Dick?

DR. VETTER: The point I wanted to make is that it certainly was unintended, but the proposed Part 35 actually exacerbates the problem of a shortage of available, potential available RSOs.

And I wanted to review the current Part 35 in which it details how a person might be qualified as a Radiation Safety Officer, or approved as a Radiation Safety Officer for a medical licensee. And in fact there is an alternate pathway. One pathway is to be certified by a board from a list of pre-approved boards, which are actually published in the regulations.

The other pathway is to meet some specific training requirements that are detailed in the regulations and have one year of experience under the supervision of a Radiation Safety Officer.

In the slide three, the proposed regulation, a Radiation Safety Officer, or a person may be approved as a Radiation Safety Officer if they are certified by a specialty board or if they have training requirements. But in reality there is no alternate pathway because the certification process requires the board to have adopted the training requirements and preceptorship. So there is no alternate pathway. You must meets Parts B and C no matter what, whether you're certified or not.

And in fact none of the boards that I'm

aware of specifically do have entered in their qualification requirements the specific hours of training that are specified in the regulations. Rather, they require degrees in physics or medical physics or whatever. And they require several years of experience, not one year in a preceptorship but several years experience.

So what's the problem here? Well, in fact a medical licensee under the new regulation a medical licensee would not be allowed to hire a certified Radiation Safety Officer who had many years of experience working as a consultant to hospitals, because in fact that person never served a preceptorship. And, in fact, the person may not even have the specific training requirements that are outlined in Parts B and C, even though that person had a master's degree or Ph.D degree in medical physics or health physics or something.

Well, the unintended consequences of this are actually an increased burden on the NRC staff because for any Radiation Safety Officer, because none of the boards meet the specific training requirements, the staff will actually have to look at the specific training hours that each candidate has when they fill out their application.

As mentioned under Dr. Williamson's

presentation, this does marginalize board certification, that is for purposes of becoming a Radiation Safety Officer at a medical facility you don't need to be certified and it doesn't help to be certified for that narrow purpose.

It also does undermine an effective industry standard in which there are several boards whose sole purpose in life is to raise the credentials and competencies of those who practice as radiation safety officers and those boards basically don't serve a role in this process.

Remedies. Again, I realize in terms of the regulatory infrastructure this is a problem, but short term simply accept health physics certification by several different boards. Here are the ones that I'm aware of that offer certification in health physics. In long term there simply needs to be rule making that would fix this problem specifically changing the and to an or under 35.50b.

CHAIRMAN CERQUEIRA: -- your back up slides.

MR. LIETO: I was going to say in your remedies, Dick, would it be appropriate to state accepting certifications in those boards plus a documented preceptorship of experience?

DR. VETTER: No, my point is the boards

already require you to have I think the minimum, if you have a Ph.D you only need four years experience, that's already required in the board process.

MS. MCBURNEY: And the ethics?

DR. VETTER: Yes, they all have ethic statements that you shall not practice in an area in which you are not certified.

MR. LIETO: Not competent?

DR. VETTER: Not competent, yes, not competent. Thank you, that's a better way to put it.

CHAIRMAN CERQUEIRA: Now the commissioners, if I were the commissioners I would come back and say, you know, you've just detailed this four year process of revising Part 35, you've had all those meetings that were sort of listed at the beginning, why didn't we catch this sooner?

MS. MCBURNEY: This I think was brought up.

CHAIRMAN CERQUEIRA: But did, was it just failed to be changed?

DR. VETTER: The and or, I don't believe, I wasn't on the ACMUI at the time but I don't believe the and or came to this group. For a radiation safety officer.

CHAIRMAN CERQUEIRA: Right.

DR. VETTER: I think the issue that was discussed before ACMUI was the accreditation process where NRC would accredit boards. And at one time they were talking about an exam and I believe they came to realize that this would be a burden for the NRC to go out and accredit these boards and so they wanted to turn that around, make the board accountable for meeting certain minimum requirements.

And the easy way to do that was to change that or to an and, because that would put everybody on a level playing field. That's the minimum.

The point that I'm making is that a master's or a Ph.D in health physics, sorry, the point I'm making is to pass one of these exams, a board certification exam, demonstrates that you understand material, whereas going to 200 hours of training, you may not understand anything when you're done with that. No, really. I mean we've heard horror stories of people going to these wonder courses and they get their certificate, not pointing any fingers, but they get their certificate and they meet the requirements. They have not demonstrated any competence by going to those trainings, whereas sitting in on a board, those of you who have taken even part 1 of Health Physics or American Board of Health Physics, you know you have to understand the material

pretty well.

DR. WILLIAMSON: Now the failure rate is quite high for the American Board of Radiology as well, especially the oral. And I believe it's fair to say this committee through the entire process was against the idea of independent NRC administered exams, and for the idea of recognizing board certification as evidence for being qualified to practice in these categories period without qualification. That has always been the case.

DR. VETTER: Now one thing I don't think any of us wants to do is point the finger at anybody for having made an error, whether it's the NRC or this committee or whomever. The point is here we are, we're in a pickle, and it's going to exacerbate the shortage of candidates for radiation safety officers at medical facilities in the coming years because there's a shortage of health physicists period.

And I'm not suggesting that we lower our standards. I'm suggesting that there are many people out there who are qualified to be radiation safety officers but who will not qualify under the new rule.

DR. WILLIAMSON: And the people who qualify under the new rule, since board certification won't be there as even an alternative pathway, are less qualified than the diplomates of these boards.

DR. DIAMOND: But again that raises the issue how do we remedy this? We've said in the past several times good guidance does not make up for bad regulations.

DR. WILLIAMSON: Rule making initiative to make a new rule.

DR. VETTER: Ultimately, that's what needs to be done.

DR. WILLIAMSON: I think we need to kick the ball off and do that.

CHAIRMAN CERQUEIRA: Well that may be the message. But it's taken five years for this or longer. John, is there another solution? I mean can't we just say we made a mistake?

MR. HICKEY: Well, regardless of that there still would be rule making required, but as I say there's the substantive issue of the training or experience of some sort in a certain modality, whether that's going to be required or whether you would accept generic. I mean you can be certified by the American Board of Health Physics without ever having worked with radioactive material for example.

Is that going to be acceptable? So it's not just a simple matter of fixing, you know, typographical errors or something like that.

CHAIRMAN CERQUEIRA: I understand. And certainly with you know some of the other boards that have been looked at, I mean some of them I know have changed their requirements so that people who sit for the boards would be required to have a certain amount of training and experience. Is that something the boards could do?

DR. WILLIAMSON: Well, it's not practical for Cobalt 60 teletherapy and stereotactic because there aren't enough facilities to guarantee everybody has it.

MR. HICKEY: It was not our intent that the board have to change their process. That definitely was not the intent. And that again is a difficult process, just as NRC's rule making is a difficult process.

MS. HOBSON: Is the current rule making process so absolutely set in cement, in concrete now that if you extended, say, the publication date there would not be a chance to go back and revisit these two issues? I mean are we too far along that we simply can't make a change?

DR. VETTER: My impression is that it's a done deal and we have to make a new rule making after this is implemented. Now that could be done in, I don't know, a reasonably short period of time whatever that is, one or two years. But it is a done deal.

MR. LIETO: I have a question. I mean let's say recognizing this, could either through a petition and/or staff development of a revised rule regarding these sections, couldn't that go out for comment? And potentially be reviewed and approved by the implementation date of the Part 35 as a whole? After publication of the Part 35?

MR. HICKEY: I can't rule that out. That would be unusual to do something like that that quick but I can't rule out that that could be done.

CHAIRMAN CERQUEIRA: Again, I think the commission was against partial implementation as had been requested by several groups, and I think this would be just be another sort of scenario.

DR. WILLIAMSON: I don't think it's a matter of being for or against it. I don't think there's a mechanism that would allow it to happen.

MS. MCBURNEY: Not in six months.

DR. WILLIAMSON: If you ripped out 35 100 there wouldn't be a coherent rule, it would not be implementable.

CHAIRMAN CERQUEIRA: And I guess getting back to your question, I think there's enough improvements and changes and what's been done already that to delay that further may, certainly for some of the

stakeholders, cause more hardship and problems. And maybe trying to get this thing implemented and then dealing with some of these issues, some of these things I think some of the other complaints can be dealt with in terms of the guidance documents. But some of these are more substantive and they basically would need new regulations. And I think that would take a much longer time.

DR. VETTER: Just one --

CHAIRMAN CERQUEIRA: Yes, Dick?

DR. VETTER: Just to add something that John Hickey said a moment ago about demonstrating experience working with certain modalities. As Jeff mentioned, there's only a certain number of gamma knifes for instance in the country. We happen to have one where I work. If we wanted to hire, under the new rules or new thinking there, if we wanted to hire a radiation safety officer from another broad scope medical licensee who had everything except a gamma knife, would that person not be qualified then?

MR. HICKEY: Not necessarily. We have to go in more detail. The words for medical physicists are different than the words for RSO are different than the words for authorized user, and each one has their own nuances. The most obvious problem is with the medical

physicists and the RSO wording. But the RSO wording does not say that you have to have experience in individual modalities. It says you have to have experience at a medical facility, whereas the therapy physicist says you have to have to experience in the modalities.

CHAIRMAN CERQUEIRA: Okay. Well I'd like to thank the committee members for working on the slides. I think we've gotten some helpful input and so John?

MR. HICKEY: We apologize that the committee was rushed in preparing for this meeting and we appreciate the effort that goes into that. And I would also note that the commission generally starts their meetings on the dot. So I would try to get there about ten or 15 minutes early, particularly if you're a speaker, to make sure you're oriented and situated when the meeting starts.

MS. WILLIAMSON: I have an administrative announcement before everyone leaves.

MR. HICKEY: Are we done, Dr. Cerqueira?

CHAIRMAN CERQUEIRA: We are done, yes.

MS. WILLIAMSON: Very quickly, for the ACMUI members, anything that you want, that you think you're going to need at the commission briefing as far as your briefing books and your personal items, take those with you to lunch and take them with you to the briefing room.

For anyone else who does not have, it looks like all the committee members have, well I'm sorry, at least one committee member doesn't have an NRC badge and also this announcement is for members of the public. I need you to meet me down in the lobby of this building, Two White Flint, at 1:30 so that I can escort you en masse over to the other building. You will not be allowed to walk without an escort.

That doesn't give you very much time for lunch so I highly suggest that if you want to eat that you just go down to the cafeteria in this building to eat. And I'll meet you down in the lobby area at 1:30.

And also for the ACMUI members, if you'll hold tight just for a second I'll give you the latest iteration of the agenda.

(Whereupon, the above-entitled matter went off the record at 1:02 p.m.)

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