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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

(ACMUI)

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SUBCOMMITTEE ON TRAINING AND EXPERIENCE REQUIREMENTS

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FRIDAY

JUNE 21, 2002

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ROCKVILLE, MARYLAND

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The Subcommittee met at the Nuclear Regulatory Commission, Room T2B3, Two White Flint North, 11545 Rockville Pike, at 8:03 a.m., Dr. Richard J. Vetter, presiding.

SUBCOMMITTEE MEMBERS PRESENT:

RICHARD J. VETTER, Chairman

JEFFREY A. BRINKER, Member

MANUAL CERQUEIRA, ACMUI Chairman

DAVID A. DIAMOND, Member

RUTH MCBURNEY, Member

JEFFREY WILLIAMSON, Member

JOHN W.N. HICKEY, Designated Federal Official

STAFF PRESENT:

ANGELA WILLIAMSON

INDA PSYK

ALSO PRESENT:

PHILIP O. ANDERSON, ABR

JAMES A. BOXALL, JR., ANSC

DR. PAUL CAPP, ABR

PAUL CHASE, AOBR/AOBNM

LYNNE FAIROBENT, ACR

DR. RICHARD FEJKA, BPS/APHA

RANDY FENNIN, SEIC

ANGELA FURERON-LEE, AAPM

SHAWN GOOGINS, ABHP/NIH

DR. WILLIAM HENDEE, ABR

DONNA BETH HOW, NRC

DAVID H. HUSSEY, ASTRO

WILLIAM D. NELLIGAN, CBNC

M. GARY SAYED, ABSNM

KRISTIN SIMONSON

DR. DAVID STEIDLEY, ABMP

WILLIAM R. UFFELMAN, ESQ., SNM/ABNM

DR. WILLIAM VAN DECKER, CBNC

C-O-N-T-E-N-T-S

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

(8:03 a.m.)

CHAIRMAN VETTER: My name is Richard Vetter and I have been appointed by Dr. Cerqueira to be the Chair of this Subcommittee on training and education as it relates to the NEU Part 35. I would like to welcome members of the Subcommittee and Dr. Cerqueira, the NRC staff and our public visitors , here today.

The subcommittee has been working via e-mail to come up with some preliminary recommendations and the purpose of the meeting here today is to discuss those preliminary recommendations and come to a consensus on a recommendation for the training education requirements as spelled out in Part 35.

Dr. John Hickey from the NRC, he and his staff have been supporting this activity, and John has some remarks to make this morning.

MR. HICKEY: Good morning, and welcome to the NRC. Thank you for attending the meeting. I am the designated Federal official for ACMUI, which means that I have day to day responsibility for the interactions between the committee and the Commission.

The function of the ACMUI is to provide advice and recommendations on medical issues to the

NRC, and the Commission appreciates the time that the Committee takes on these matters because they also have very busy schedules at their institutions.

This particular session is as Dr. Vetter said, is on training and experience requirements in the NEU Part 35, which was published on April 24th. The new rule has been published in the Federal Register and is available on our website, and there are excerpts in the handouts that are available on the shelves in the back of the room that include the training and experience requirements that were published.

Prior to publication the Commission was informed of implementation problems related to training by the ACMUI and by other parties. Therefore, the Commission changed the final rule to retain the old training experience requirements for two years in parallel with the new requirements.

And during that two year period the licensees can follow either the older requirements or the new requirements in establishing qualifications for their authorized users and other authorized persons.

In addition, the Commission stated that it would work with the medical community to address

implementation problems and work with the ACMUI. So it was in that context that this subcommittee was appointed. And the Commission looks forward to receiving the recommendations of the Committee.

And the recommendations will be carefully considered, but I want to emphasize that the recommendations to the Committee do not constitute final action by the Commission. The Commission will still need to determine if the changes will be made, and what changes will be made, and if the changes, if they are made, might not necessarily coincide with the recommendations of the Committee.

This is a transcribed public meeting, and so all speakers should keep in mind that they are speaking for the public record, and I will turn the meeting back to Dr. Vetter to introduce the other members of the subcommittee, and proceed with the meeting. Thank you, doctor.

CHAIRMAN VETTER: Thank you very much, John. Dr. Cerqueira, in his capacity as Chair of the ACMUI, at our last meeting appointed the subcommittee to address this training and education issue.

Members of the Committee, besides myself, are Ruth McBurney, who represents the States; Jeff Williamson, representing Therapy Physicists; David

Diamond, representing Radiation Oncologists; and Jeffrey Brinker, representing Interventional Cardiology.

The Committee has worked informally via E-mail and telephone to come up with some preliminary recommendations, and this is our first meeting to actually discuss those recommendations.

I will spend just a moment on the agenda, just so that everyone is in agreement here. The plan is to finish by noon or before. We will start by discussing the charter, and just review that very, very briefly, and then discuss the subcommittee recommendations, the goal being to come to a consensus on what those recommendations would be.

Now, the preliminary recommendations we have written. I'm sorry, I am getting ahead of myself. And we will discuss those recommendations and we will take a short break mid-morning, and then we will open it up for public comments.

Those who wish to make public comments should register. There is a sheet here to register and let the NRC staff know that you do wish to make comments, and then we will open the meeting for these public comments after our break.

We do request that public comments be

limited to 10 minutes. And then finally at the end of the meeting hopefully we will have a consensus that we can review, and that consensus will be presented to the ACMUI for further deliberation. Is there anything that we want to say at this point about that, about that timing and so forth?

MR. HICKEY: Excuse me, doctor, but if I could just interject. Written comments were accepted prior to this meeting, and there are copies in the back. Those will be part of the record. Any written comments can be left today, and we will accept written comments up until June 28th for consideration by the full committee.

And the full committee will be holding a meeting by telecon on July 8th, and that meeting has been announced, and it will be conducted from our auditorium here at the NRC, and people can come to the auditorium to observe that meeting, and Dr. Cerqueira will be here in person to conduct that meeting.

CHAIRMAN VETTER: Thank you. So the public has had an opportunity to input to date, and they will have further opportunity for public input after we arrive at our consensus here today. Okay.

The charter of the subcommittee was to develop the concept for a draft rule that restores

board certifications as the primary pathway for becoming an authorized medical physicist, radiation safety officer, and authorized user.

As the Committee wrestled with that charge to develop some recommendations, there were three areas that basically came out that we needed to focus on. One was the issue of listing boards, and the subcommittee in our preliminary conversations felt that boards should be formally listed, but whether they were listed in the regulations or on the NRC website is a matter that needs to be decided, and perhaps that is more an issue of how that process is facilitated, as opposed to whether it really needs to be in the regulations.

The second area was criteria for recognition of boards, and we wrestled with that, and so hopefully our recommendations will reflect those criteria. And then the third was the issue of modality, specific training. Two issues there really, and that is a licensee hiring a new RSO or medical physicist, or whatever, and assuring that that person who might be board certified actually is experienced using the modalities that that licensee is authorized to use.

And the second issue is a licensee who has

an authorized medical physicist, RSO, or whatever, that gets a new modality, and then assuring that those people get the appropriate training in the new modality.

So that basically was the charge, and as I mentioned, the committee worked by telephone and e-mail to come up with some preliminary recommendations, which we will discuss at this time. Any other comments from members of the subcommittee at this point in time? Yes, Jeff?

DR. WILLIAMSON: I am never without words here. I think that there are a couple of categories of individuals that we have not discussed and maybe should. We have not really developed a framework for 35.300 modalities, and it is not clear to me whether there are not difficulties with the authorized nuclear pharmacy training and experience, and we should clarify whether that needs to be amended, if only to bring the language in line with the revised category.

CHAIRMAN VETTER: I think that is a good point, and I think that my personal perspective is we were charged to work on these three areas, and then secondly to that was the issue of consistently throughout Part 35.

So it was our understanding that if we

came up with recommendations for a particular category -- for instance, just a simple one, the listing of the board. Should boards be listed, and they would not be listed in one category and not in another. So it would be consistent all the way across.

The same thing for criteria for boards. We would develop general criteria for boards, even if we didn't address a specific category like authorized nuclear pharmacy, and we would expect that our recommendation would be applied across the board.

DR. DIAMOND: Just to expand that, Richard. For example, when I was working on 690 for therapeutic uses, we really wanted to try and go and get a consensus on those points, and then the decision would be that once we got that consensus that we would go back and make housekeeping changes for parallel structure, and for example, 392 and 394, and 490, and 491. Otherwise, our e-mails would become even more burdensome.

CHAIRMAN VETTER: Good point.

DR. CERQUEIRA: Another point that has come up is for the RSO. If you are a medical authorized user, should that criteria also allow you to meet the RSO criteria as well, and so I think that kind of needs to be addressed, because as stated, some

of the 290 requirements aren't totally consistent with the RSO requirements.

CHAIRMAN VETTER: Okay. When we get to that. That is a good point, and we be sure to mention that. Okay. Well, let's turn to the draft recommendations that we have. If I could just make some preliminary comments, and I might be repeating myself a little bit as we look at these.

There are -- and let me just say that the intention was to develop a -- the intention was not to develop regulatory language. However, the recommendations look like regulatory language, and that's because the committee simply wanted to pay attention to detail and not leave some stuff out.

But we don't pretend to be those that would write the regulations. So once again, the main thing was that we wanted to make sure that we didn't miss something. So we wrote it in that kind of a format.

So on radiation safety officer, we did list the boards and basically just went back to the old list, and we asked ourselves whether or not that list of boards meets our broad criteria, the broad criteria being paragraph B, as certified by a specialty board, whose certification has been

recognized by the commission and requires all diplomats to.

And then we have several different categories or criteria that we would expect all of those boards to meet, and we have no reason to believe -- even if we have not looked at those in extreme detail, there is no reason to believe that none of them would meet those criteria.

So the issue is -- the primary issue is that there are specific criteria that a specialty board would have to meet in order to be approved to be on the NRC authorized list of boards, the idea again being that anyone who is board certified by one of those boards then would automatically qualify as a person who a license could approve as the radiation safety officer.

The alternate pathway then is separate and the board would not have to meet that alternative pathway. Let me say that the way that we have got it worded here, it looks like they are mutually exclusive, and we certainly didn't intend that.

Certainly if a board -- and I think it would be reasonable if a board chooses to meet the alternate pathway as one of the criteria, and that certainly has to be acceptable, because that is the

alternate criteria.

So we wouldn't want to rule it out. I mean, a board could certainly be listed if it meets those alternative criteria. Then paragraph (b) is an authorized user, and an authorized user of what. We didn't specify there, but we assumed that the next paragraph on modality and specific training would take care of that.

So as an authorized user, and authorized medical physicist, authorized nuclear pharmacist, identified on the license, and then second, has experience with radiation safety aspects of similar types. So an authorized user who is approved to us categories under 200 could be the radiation safety officer for those materials, but would not quality to be the radiation safety officer for 600.

The intent was for all of the sections to sort of follow that general theme, that there is a listing of boards that would be maintained somewhere, either in the regulations or on the NRC website, or somewhere, where anyone who is interested in that list of boards could easily access it.

And then the criteria would be in the regulations. So the boards would understand what criteria they need to meet, or there is the

alternative pathway, and there is the issue of authorized users, and so forth.

And then finally the modality specific training, which I mentioned is intended to assure that even if a person is board certified, they have experience and an understanding of the issues associated with the modalities for which the licensee is authorized. So let me just open it up for comments on radiation safety officer.

MS. MCBURNEY: Just a question. If someone were board certified in, for example, nuclear medicine -- for example, the American Osteopathic Board of Nuclear Medicine -- could they be the RSO for therapeutic material?

CHAIRMAN VETTER: No, because paragraph (e) says that in addition to all --

MS. MCBURNEY: And they have to have the additional training.

CHAIRMAN VETTER: Right. So they could be if they had the appropriate training, I guess, yes. That's a good point. So an authorized user in nuclear medicine could be the radiation safety officer that would include therapy, but only if --

MS. MCBURNEY: If they are board certified.

CHAIRMAN VETTER: If they are board certified, and they have been trained in the safety aspects of therapy in accordance with paragraph (e).

DR. CERQUEIRA: Again, in terms of the cardiology community, the other issue that comes up is the CBNC, which has been recognized in the 290 should be included here as well.

CHAIRMAN VETTER: It should be, yes.

DR. CERQUEIRA: And for Part C on this, for the 290, we sort of break it down into 700 hours without putting specific hours -- you know, here it has got 200 hours, and we had sort of taken that out at some point.

So I think for those people, they may not necessarily meet this criteria if we had the specific 200 requirement in there. So there is an inconsistency between those two, and I think we should try to get that rectified.

MS. MCBURNEY: But if they are an authorized user, they could be --

DR. CERQUEIRA: Well, certainly by board certification, yes.

MS. MCBURNEY: And (d).

DR. CERQUEIRA: And (d).

DR. WILLIAMSON: Yes, paragraph (d), which

says, "is an authorized user, authorized medical physicist, or authorized nuclear pharmacist," there is no presumption that to qualify as an RSO under that provision that you have to meet the board's eligibility requirements if we want to call them that, or board qualification requirements.

DR. CERQUEIRA: Okay. So I guess that would do it, and then if we could just basically add the board to the list.

DR. WILLIAMSON: But I think there is -- I think that Dr. Cerqueira is right. There is a contradiction between (a) and (b) in the proposal. There is not a contradiction between (b) and (d) by definition, and the intent and structure of the old sets of regulations.

But we did say in our covering memo that the intent was that the listed boards, explicitly mentioned boards, would meet the broad criteria in (b).

CHAIRMAN VETTER: And do you think they don't?

DR. WILLIAMSON: Well, that is a question -- I don't think there is any presumption to be, for example, American Board of Radiology certification, does not require you to have six or more years of

responsible professional experience in health physics. So, in that sense I think it would be not appropriate --

MS. MCBURNEY: I think that the boards pertaining to radiation safety officer should only be those that are dealing with health physics.

DR. WILLIAMSON: I think that that is probably true.

MS. MCBURNEY: Because if you are an authorized user, then you go that route.

DR. WILLIAMSON: So actually I think maybe the authorized user certifications at the very least should probably be removed from paragraph (a).

CHAIRMAN VETTER: Okay. Because those people qualify under paragraph (d).

DR. WILLIAMSON: Right. They qualify under paragraph (d). And then, you know, we have to look carefully at paragraph (b), and make sure that it represents kind of the minimum bar for those boards that we do want to include, and I think that at the very least you would want to include the American Board of Health Physics, and probably ABMP certification and medical health physics. And we can discuss whether --

MS. MCBURNEY: ABR.

DR. WILLIAMSON: Yes, ABR medical certification in therapeutic radiological physics, and ABMP certification in radiation oncology physics, should be on that list. And we might want to fine tune these criteria so that there would not be an incompatibility between their eligibility requirements.

CHAIRMAN VETTER: Okay. So what I am hearing is that the list should be focused on those who quality -- the list of boards should be those who qualify in basically medical health physics. So that is the approved list of boards.

DR. CERQUEIRA: Right.

CHAIRMAN VETTER: And they would meet those criteria under (b), but that would not rule out someone who is certified in radiology.

MS. MCBURNEY: In theory.

CHAIRMAN VETTER: In nuclear medicine to be the RSO, and because they would qualify under (d), they are an authorized user. I think that makes sense. Dr. Brinker or Diamond? So the list that we would be recommending to the NRC, wherever they maintain it, would be focused on health physics, and initially at least we would be crossing off the medical boards.

DR. WILLIAMSON: I think if maybe John can

clarify this, but I think the intent of (a) and (b) is to define those individuals who could be RSOs of the very largest licensee organizations is it not?

DR. CERQUEIRA: Right, independent of being an authorized physicist or medical physician.

DR. WILLIAMSON: Right. So that is what the ultimate function or role of this category that we have to keep in mind.

DR. CERQUEIRA: With the provision that there be a sort of specific training in the area in which you are applying, and it is not part of the recognized training requirements.

CHAIRMAN VETTER: Okay. I think we have consensus on that. And the criteria for (b) was basically our minimum criteria that currently are required by the American Board of Health Physics, and the American Board of Medical Physics actually requires a Masters Degree.

And I am not sure about the American Board of Science and Nuclear Medicine.

DR. WILLIAMSON: I don't think that ABMP for Medical Health Physics requires six years experience.

MS. MCBURNEY: It does require a Masters.

DR. WILLIAMSON: It does require a

Masters?

MS. MCBURNEY: I think that can -- I am --

CHAIRMAN VETTER: I think that is a minor point, and we can check on that and be sure that we aren't inconsistent with either of those boards.

DR. WILLIAMSON: I think that both ABMP and ABR may in some cases accept candidates that have two years. As I recall for ABMP, at the function of what kind of a degree you have, and if you have, for example, a doctoral degree in medical physics, it is a smaller number of years of experience, versus having a Masters Degree not in medical physics, would require the most years of experience. I think four. And I think it is 2 to 4.

CHAIRMAN VETTER: We can check on that. We can check on that.

DR. CERQUEIRA: Richard, under (b)(3), it sort of comes again to the written certification and what does that mean. You know, part of the charge of the committee was that the preceptor concept should be modified to become documentation of successful completion of a training program, rather than a testimony to clinical competence.

CHAIRMAN VETTER: Right.

DR. CERQUEIRA: And we had tried, you

know, during the initial discussions over the course of the last six years, we wanted to put a little bit of bite into the preceptor statement, in the sense that we didn't want people to just sit through a program, but that they have had some mastery of the material, and whether competence is too strong a word.

But at some point, we are going to have to deal with or address the issue of whether just having completed a program, versus some requirement for the preceptor who is signing for this person, and saying that this person not only has completed the program, but has mastered the material in some way.

DR. CERQUEIRA: That is what the exam does.

CHAIRMAN VETTER: That is what the exam does, but this is the alternative pathway.

DR. CERQUEIRA: No.

MS. MCBURNEY: No, this is the requirement of (a).

CHAIRMAN VETTER: Okay.

DR. WILLIAMSON: Perhaps you should delate paragraph (b)(3). Why is it necessary to have a preceptor statement in the board certification criteria if they are already passing an exam. Isn't that a sufficient credential?

DR. CERQUEIRA: We will come back to that later on, because in order -- you know, what are the eligibility criteria for the board, and are we going to require some sort of a preceptor statement as to mastery of the material.

MS. MCBURNEY: Most board certifications do require some sort of reference or supervisor reference, or something like that.

CHAIRMAN VETTER: They do, but I think the point for us to wrestle with would be whether or not we want someone to testify that in fact the person was around going through some training, or did they simply read a book.

It is a matter of being in contact with the material, and with the environment, because that would be the issue. Do we think that the regulations should require that, or --

DR. DIAMOND: I see that kind of like a letter of reference almost that that person was around performing that supervised experience, because again at this point they are not in a formal degree program, let's say, if they are going through (b)(2).

You need someone to sign off that this person was there and they did fulfill these

responsibilities.

CHAIRMAN VETTER: Right. Okay. Well, let me present sort of a principle by which we may be able to decide what to do, but I think the principle is, is that the boards as currently configured that are nominally accepted as valid credentials for these roles are doing a good job, and that there is no threat to public safety by virtue of these boards not working well.

So therefore we should not or we are not in the business of imposing criteria that forces them to make certain changes. I mean, the NRC should only do that if they believe there is a threat to public safety from the existing credentialing system.

So I think that the consequence of this principle, if we accept it, is that we want to very carefully -- that we want to recommend to the staff that they very carefully tailor the wording of this preceptor statement so that inadvertently well-functioning boards that do a good job of identifying competent practitioners aren't inadvertently excluded from the process.

So maybe we can sort of leave it to the staff to worksmith this according to the ball of the principle that I just articulated.

DR. WILLIAMSON: Right. I agree with that. But if the consensus to leave that paragraph 3 in there or delete it?

DR. DIAMOND: I would suggest leaving it in.

CHAIRMAN VETTER: Okay.

DR. DIAMOND: I think it serves a useful function.

CHAIRMAN VETTER: Okay.

DR. CERQUEIRA: Getting back to Jeff's point then, so if we take it out of the board requirements do we want to leave it in for the alternative pathways? So that if somebody is meeting this by training and experience, that sort of preceptor statement, which doesn't require board certification, would put a little bit more pressure on the person certifying them, and not only that they have sat through the program, but they have been in the environment and have some master.

DR. WILLIAMSON: I think that is reasonable, since they are not taking an examination, and this is not a formal or structured certification mechanism, that there be more teeth in the board free, or boardless alternative pathway requirements.

But I think that we have to recognize that

the board requirements and the alternative pathway requirements can be different.

So a more or a tougher preceptor statement would probably be warranted in that.

DR. DIAMOND: I would concur with that. For example, in 690, we tried to use language such that the alternative pathway was a little more prescriptive, and a little more enumerative if you will, of these details.

CHAIRMAN VETTER: Okay. So we are recommending that to the alternative pathway we add some sort of written certification or preceptor statement, something of that sort. All right. Moving on, and we need to move through these reasonably quickly. We can't spend all day on this particular section.

And let's do or focus a moment on paragraph (e), because this would be something similar throughout. Simply saying that whoever this individual is who the license wants to appoint as radiation safety officer needs to have experience.

We don't specify or we don't get into detail what that is, and I guess I don't think we should. That should be left to guidance. But we specify that the individual must have training and

experience in the materials that are being used by the licensee, and if they don't have it, there is a pathway to get it.

For instance, you get a new modality. If a licensee gets gamma knife and has not had one before, then the radiation safety officer can get training in the emergency preparedness, et cetera, from the authorized medical physicist, or another RSO who is authorized to use that material. Jeff.

DR. WILLIAMSON: Yeah, I think we should recognize that the level and intensity of training for an RSO is different than what would be required for an authorized, an authorized medical physicist.

There is on presumption that the RSO is a hands-on person and has to operate the device and treat patients. They are kind of a level up in the management structure, and so that is one point. I think the second point is that to my knowledge there really are not formal mechanisms or training programs.

I don't believe other than supplying installation guides and licensing guides for these devices that the vendors really don't provide a mechanism that gives the appropriate introduction.

And so I think we should be on the record as stating that in defense of the vagueness or

looseness of these requirements.

DR. CERQUEIRA: I guess in terms of (b) as well, we are saying that it is supervised by an authorized medical physicist or radiation safety office. And in the case of diagnostics, could that supervision be by an authorized user physician?

DR. WILLIAMSON: I think that is a good point.

CHAIRMAN VETTER: Sure. I think so. So we will add, "or authorized user" in there.

DR. WILLIAMSON: Probably as appropriate maybe should be also put in there.

DR. CERQUEIRA: Yes, to make certain that if you are an authorized user for diagnostics, then you are not going to train somebody in therapeutics.

DR. WILLIAMSON: That's right.

CHAIRMAN VETTER: So AU/AMP, or radiation safety officer, as appropriate.

CHAIRMAN VETTER: Good point. Other discuss on paragraph (e)? Okay. So we will add authorized user as appropriate. All right. Let's move on to training for authorized medical physicist.

And once again, trying to carry the same theme through the entire recommendations, first would be a listing of the boards. Jeff, do you want to --

and again we don't want to nitpick on words that carry the basic concept through.

So on the listing of the boards that would be maintained by the NRC, this would be limited to boards that certify medical physicists specifically.

DR. WILLIAMSON: That's right. So, we would define the general phrase, "radiation oncology physics," which refers to the core material covered by paragraph (a), those boards.

CHAIRMAN VETTER: Right. Do you want to explain why (b) is different? Why is--

DR. WILLIAMSON: You mean why is (b) a separate paragraph?

CHAIRMAN VETTER: Yes.

DR. WILLIAMSON: It could be changed, but it is because the American Board of Radiology has historically had a number of credentials, and some of them very broad. So, for example, radiological physics actually includes examinations in nuclear medicine, radiation oncology, and diagnostic x-ray imaging.

So it was just time saving. You know, there were four board certifications maintained by the ABR, and so I made an ABR section,a nd then an ABMP. But we could change it and have paragraph (a).

CHAIRMAN VETTER: I don't think we need to worry about level of detail.

DR. WILLIAMSON: It is detail, and I don't think it is important.

CHAIRMAN VETTER: I agree.

DR. WILLIAMSON: But we could collapse (a) and (b) into one paragraph if that were desired. No problem.

CHAIRMAN VETTER: Well, they probably won't be in the regulations anyway. They will be maintained on a separate list. And so just that it is clear what the intent is. So the intent is the American Board of Radiology and those four areas, the American Board of Medical Physics, and Radiation Oncology Physics.

DR. WILLIAMSON: That's correct.

MS. MCBURNEY: And just again, and pardon my ignorance, but are we then saying that if the physician is certified by the ABR that they could then quality as an authorized medical physicist?

DR. WILLIAMSON: No.

MS. MCBURNEY: So there is a separate ABR examination for a physicist?

DR. WILLIAMSON: That's correct

MS. MCBURNEY: And is there some way that

we can separate that out? Otherwise, it could be somewhat ambiguous.

CHAIRMAN VETTER: They are there, those four areas.

MS. MCBURNEY: It says these things.

DR. WILLIAMSON: It says specifically therapeutic radiological physics; roentgen ray and gamma ray physics.

DR. CERQUEIRA: But those are separate examinations that are given?

DR. WILLIAMSON: Yes.

DR. CERQUEIRA: They are? Okay.

DR. WILLIAMSON: Well, it is very similar to the old Part 35

CHAIRMAN VETTER: Okay. Let's move on to paragraph (c). These are the general requirements that we would expect, or our general criteria that we would expect to recognize a board. Do you want to say anything about that, Jeff?

DR. WILLIAMSON: Yes. I will mention that there are -- there is a move in radiation oncology to have formal two year clinical training programs, which we call radiation oncology physics residences. But they are not widespread, and I don't think the market penetration of those training vehicles is great enough

that they could form the basis of a regulation at this time.

So this was quite a difficult task to figure out what to do. So I went through and I compared the ABMP and ABR eligibility requirements and tried to distill the common subset, which is basically a graduate degree in a physical science or engineering, a Masters Degree, and a minimum of two years of supervised experience.

And to make sure that this was experience in an appropriate facility, I included in here that it had to occur in a radiation oncology facility that provides mega-voltage external beam therapy and brachytherapy.

And that I further, to make sure that this experience doesn't occur in Bermuda, or some place that does not follow customary -- and I mean no slam against Bermuda.

But some place that does not follow the standards of practice characteristic of North America, and that I put that it had to be under the direction of physicians who meet the requirements of 35.400 or 600, which would have effectively I think limited it to experience in the U.S.

And so how to do this certainly is open to

debate, and whether Canada should be included, for example, and Europe. I don't know how exactly. So there is an issue there that I want to point out, and that is why I included this paragraph (c)(2)(ii), because otherwise I felt that some very marginal experience in something peripherally related to health care could be substituted, and I didn't want that.

And so the intent was to restrict this training and experience that occurs in a reasonable full-service radiation oncology department.

DR. DIAMOND: So, Jeff, right now the specialty boards that are granting this radiation oncology physics certification, is it just ABR, or ABMP, or --

DR. WILLIAMSON: Well, ABR and ABMP both have diplomates that are in the field. Recently there has been a negotiation between ABR and ABMP, and ABMP is going to not in the future certify radiation oncology physicists in competition with the AABR.

DR. DIAMOND: And you did not want to enumerate ABR or ABMP in this paragraph because it may be evolving to include other certified positions?

DR. WILLIAMSON: Well, the whole purpose of paragraph (c) is to allow for other certification mechanisms that might arise in the future. You know,

we had made the decision, or it was suggested to us that one way or another we had to include broad criteria that defined what were acceptable boards in the different areas.

And to do that by enumerating physics boards would be a circular definition. So you can't define what is an acceptable radiation oncology physics board by saying it is one of these boards. You have to have an independent list of criteria. So I made an independent list.

It doesn't mention physics certification or any specific certification mechanism. It indirectly by 35.400 and 600 reference refers to the certification of the authorized users presumably, but they could be alternative pathway physicians, too.

Then finally pass as an examination administered by diplomats of the board in questions that assesses the following broad list of functions and skills.

MS. MCBURNEY: The term megavoltage, external being therapy, would that include materials?

DR. WILLIAMSON: It would include materials, but it would include linacs, and I think that is important because there are actually very few cobalt 60 teletherapy units operating in the country,

and it would be completely unrealistic to expect that physicists, authorized medical physicists for taking care of Cobalt 60 teletherapy would have Cobalt 60 in their training experience, and this is one of the central efficiencies of the old set of requirements that I think we were asked to address.

CHAIRMAN VETTER: All right. And then the alternate pathway is pretty much as it was before, and you do have the written certification from the supervising medical physicist.

DR. WILLIAMSON: Yes, and I put here satisfactorily completed.

CHAIRMAN VETTER: Right.

DR. WILLIAMSON: And I assume that means more than just sleeping or sitting there.

CHAIRMAN VETTER: Right.

DR. WILLIAMSON: And again we could debate exactly how that --

MS. MCBURNEY: Usually there is an exam involved in that training.

DR. WILLIAMSON: -- should be. But this is the alternate pathway, and so there is not necessarily an exam. Remember that there is no --

MS. MCBURNEY: Right, it is not board certification, but a lot of times with training there

is some sort --

DR. WILLIAMSON: Only in a formal structured program, and again we talk about requiring a physics residency here, but I really do think that would be contrary to the intent of either the old or current set of regulations.

CHAIRMAN VETTER: Any other comments on the alternative pathway? Okay. Then paragraph (e) is the modality specific training. Any comments there, Jeff?

DR. WILLIAMSON: Just to say that the basis was to put the burden of defining the content of this curriculum really on the vendor, and use the sort of training that the vendor typically supplies to a new purchaser of a unit. This will of course vary with the type of unit.

For HDR, it may be on the order of several days, and for stereotactic it is a week usually at a facility treating patients, or for Cobalt 60, it might be an hour.

MS. MCBURNEY: I would suggest removing the phrase, "that is equivalent to instruction provided by the vendor to new customers," because I think it is covered in the next sentence. Whereas, if you just say in addition to meeting the requirements

of (a), (b), (c), or (d), an authorized medical physicist must have training in the modality for which authorization is sought, that includes device operation, safety procedures, clinical use, and operational treatment planning system.

And then I think the next sentence that this may be satisfied by a training program provided, et cetera.

CHAIRMAN VETTER: I agree. I think that is a good point. In the first sentence, we don't want to limit it to some level of vendor provides. We might want to exceed that.

DR. WILLIAMSON: All right. So just strike, "that is equivalent to instruction provided by the vendor to new customers."

MS. MCBURNEY: Right.

CHAIRMAN VETTER: And then the second sentence allows that pathway for other training through the vendor. Other questions on (e)? Yes, John.

MR. HICKEY: I wanted to go back to (c) when we are done with (e).

CHAIRMAN VETTER: Okay. Any other questions on (e)? All right.

MR. HICKEY: I wasn't clear. Paragraph

(c) would not have a written certification, but paragraph (d) would?

DR. WILLIAMSON: Well, as I think we have made -- we have decided by consensus that some kind of a letter addressing the performance of the candidate for the board examination is required.

MR. HICKEY: Okay. Because it seems to me when someone presents their credentials that they provide some testament that they actually have completed those credentials.

DR. WILLIAMSON: That's correct, and I think that both physics boards that I have experience with would have no difficulty meeting or in fact do require letters of reference to attest to their satisfactory completion of this experience.

So we could put it in there. At the time that I did this, I didn't think it was necessary because the examination seemed to be a substitute for assessing confidence.

CHAIRMAN VETTER: So we will put something in. Go ahead.

DR. CERQUEIRA: The default statement that seems to be coming out that we have both for the 290, as well as for the medical physicist, is that the individual has satisfactorily completed the training

and experience described above.

So do we feel that is the way that we want to go, rather than saying it is competent or is mastered?

DR. DIAMOND: Yes.

DR. CERQUEIRA: So we basically would make it uniform for all RSOs, medical physicists, and authorized users?

DR. DIAMOND: I think that is good verbiage to use.

CHAIRMAN VETTER: Okay. Just looking to know that or for some one to testify that in fact a person really was here, and really did train.

DR. WILLIAMSON: And did an acceptable and satisfactory job, and wasn't incompetent, I think. You know, satisfactorily completed, it seems to be a broad enough statement, I hope. Maybe in the public comments the representatives of the different board organizations can address this, but if we go back to the principle I enunciated we want, whatever the verbiage is.

It has to be common enough that all of the boards that are currently accepted as credentialing those functions would be able to satisfy that requirement.

CHAIRMAN VETTER: Well, if we use as an example the current preceptor statement, or I'm sorry, the old -- yeah, the current preceptor statement that is required by the NRC, it simply lists the hours of training and the number of generators alluded, and that sort of thing, and it is signed by the preceptor.

The preceptor doesn't have to testify whether the person did a good job, a bad job, an indifferent job, but completed those requirements.

DR. CERQUEIRA: I think what this does, and again when we started this process we wanted to take the NRC out of the practice of medicine, or responsibility upon the boards, or the physician, or medical physicist.

And I guess this will do it. Basically, the NRC will accept either the boards or a statement from an authorized user, but it really makes it incumbent upon the boards to make certain that the people have had some mastery or competence of the material.

CHAIRMAN VETTER: So satisfactorily completed. Those are the words that we are looking for? Does that sound okay?

DR. CERQUEIRA: Yes. But I guess the public comments will be important later on.

CHAIRMAN VETTER: Right.

DR. CERQUEIRA: And to see what the boards can tell us.

CHAIRMAN VETTER: Okay. John, did that answer your question?

MR. HICKEY: Yes, thank you.

CHAIRMAN VETTER: Okay. Jeff, any -- I guess that takes care of your section, right?

DR. WILLIAMSON: Yes.

CHAIRMAN VETTER: Moving on to 35.190, training for uptake, dilution, and excretion studies. Ruth.

MS. MCBURNEY: Okay. The first section there is just to put back in the boards that had previously been accepted for uptake, dilution, and excretion studies.

These would be the board certification requirements for acceptance of a board. The question here arises for consistency do we want to add requirements for some sort of residency, or have that as an optional pathway for acceptance of the board certification process.

Otherwise, it would just be a board certification whose process includes the requirement for (b)(1), and success completion of the exams, and

has been recognized by the commission. So that is basically just a minimum of 60 hours training experience.

And certification by an authorized user that the person has successfully completed those requirements.

CHAIRMAN VETTER: So the question that you were asking under paragraph (b) was whether we thought a residency should be completed?

MS. MCBURNEY: Option.

CHAIRMAN VETTER: Oh, an option.

MS. MCBURNEY: Or an option for uptake and dilutions, since these are low risk.

CHAIRMAN VETTER: So they have completed a residency and approved by the American --

MS. MCBURNEY: Nuclear Medicine.

CHAIRMAN VETTER: Right.

DR. CERQUEIRA: But I guess that would sort of look at people who have completed a residency, but are not necessarily board certified, but wouldn't they meet the requirements under (d)?

MS. MCBURNEY: Oh, yeah. The question is of course that the residency should include those 60 hours and a minimum of that, but whether we want to put into rule space an option would be that one has

completed something similar to what is in --

DR. WILLIAMSON: If you look at subpart (j) 35.190, it has three options. You can be certified in one of the listed boards, or (b), have the classroom and training experience, et cetera, as listed here, or (c), have successfully completed a six month training program in nuclear medicine as part of a training program that has been approved by, et cetera, et cetera.

It seems to me that we should probably follow the old regulation.

DR. CERQUEIRA: But there are no six month training programs in nuclear medicine. I mean, that has been pointed out quite often.

MS. MCBURNEY: Right. That is an issue.

CHAIRMAN VETTER: But as I interpret the question, do we think it is appropriate for a new medical specialty board to come along to certify candidates for 190, and the only requirements for the board are that you have 60 hours of training experience?

MS. MCBURNEY: I don't know that any specialty board is going to come along to do that.

CHAIRMAN VETTER: And we don't know what anyone might do, might or might not do. So I guess

the question is do we feel that would be appropriate if that in fact -- that they are meeting the minimum requirements for the alternate pathway.

MS. MCBURNEY: It will become more important when we get to 290.

CHAIRMAN VETTER: Right. But the way it reads now, a board could come along to offer a specialty specification. Even ABR could offer a specialty certification in 190. Of course, ABR requires more than that.

But let's say a new board would come along and only require 60 hours of training experience to qualify for the board.

DR. WILLIAMSON: Well, this individual would have a medical degree, and has to have completed an internship just to have basic licensure, right?

CHAIRMAN VETTER: Right.

DR. WILLIAMSON: Basic licensure as a practicing physician, and so is this uptake and dilution considered sufficiently low risk that the NRC does not have to require them to have a residency in something? I guess that is the issue.

CHAIRMAN VETTER: Right. I am not arguing that one way or another. I just wanted us to feel comfortable with what this says. This says a board

could do that.

DR. WILLIAMSON: I think Dr. Cerqueira is the closest to a nuclear medicine practitioner. What do you think?

DR. CERQUEIRA: I would feel uncomfortable having somebody with a one year internship as is only medical training, be able to use this, even if they met the hourly requirements. I just don't know how --

MS. MCBURNEY: Well, I guess the medical specialty board whose certification process requires the successful completion of a residency program in nuclear medicine, approved by --

CHAIRMAN VETTER: Well, again, we need to focus on the safety aspects, and not --

DR. WILLIAMSON: Right.

MS. MCBURNEY: And the board certification process and not the alternate pathway.

DR. WILLIAMSON: Well, let me be a contrary in here for a minute. I think that when back when, in the last six years, the ACMUI and the NRC made a determination that nuclear medicine type imaging applications, and those areas using relatively small doses of radioactivity, were considered sufficiently low risk that all the NRC had to concern itself with was the technical and safety training of

the individual, and not the clinical competency, whether they will competently execute these dilution and uptake procedures, and so on.

And so it seems to me that our scope is to fix problems, and not to overturn major -- how should I say -- principles that were decided on long ago as being the basis of these regulations. So it would seem to me that since neither the old regulation that the NEU Part 35 has superseded, nor the NEU Part 35, requires a residency in something.

And that we should look very carefully at this, and ask the NRC to produce a list of what kinds of specialists have availed themselves of 35-190, and make sure that we are not unnecessarily disenfranchising some segment of the practicing community, unless there really is a public health issue at stake.

MS. MCBURNEY: I think like a lot of endocrinologists and so forth, and clinical pathologists, go through the alternate pathway usually.

DR. CERQUEIRA: I think we also decided that we would leave a lot of this up to credentialing bodies at hospitals at the State level.

DR. DIAMOND: Exactly.

DR. WILLIAMSON: That's right.

DR. DIAMOND: I was just going to make the point in response to what Manny said that in a circumstance where you have some disillusioned individual that just finished an internship in pediatrics and wants to go and start doing these studies that there is no way that any credentialing subcommittee in a hospital is ever going to grant privileges to do this.

CHAIRMAN VETTER: So I guess we are okay with the way that it is.

MS. MCBURNEY: Okay. So that covers the certification, and certainly if they are an authorized user under 290 or 390, they can do the 190 stuff. Once again, (d) with alternate pathway, requires some sort of written certification that the individual has satisfactorily completed the requirement. And then to 290.

DR. CERQUEIRA: So I guess we are all comfortable with the concept that if a cardiologist meets the 290 that he is not going to be treating patients for thyroid disease, but that is going to be sort of regulated by the medical community.

CHAIRMAN VETTER: Right.

DR. BRINKER: But this isn't treatment?

MS. MCBURNEY: Right.

CHAIRMAN VETTER: No.

MS. MCBURNEY: Going on to 290 then. One again in (a) was the certifications that had been accepted in the old rule, and then (b), certified by a medical specialty board. The certification process includes the minimum training experience that is in alternate pathway.

The question becomes here do I add an option for a residency program in nuclear medicine. Of course, the residency program would include all the training experience requirements in (b) probably if it was --

DR. WILLIAMSON: Wait. I'm not sure I understand your question.

MS. MCBURNEY: Okay. In 690, Dr. Diamond has included a residency program as a requirement.

DR. WILLIAMSON: That's right.

MS. MCBURNEY: The question is do we want to add a residency program in nuclear medicine as an optional --

DR. WILLIAMSON: As a criteria --

MS. MCBURNEY: For criteria for a board certification process acceptance.

DR. WILLIAMSON: I would make the same

argument that I did for 190, that we went through this ad infinitum for two years, and decided that the break point was 200 versus 300 and above, and for 200 and 100, we were not going to require a demonstration of clinical competence, and that the requirements should focus more on safety, and technical competence, and handing, et cetera.

And I am afraid that if we open that up again that it will cause a big controversy, because that took a lot of effort, and compromise, and negotiation, to sort out.

So it seems to me that we should apply the principle that if it is not broken, let's not fix it.

CHAIRMAN VETTER: And so we are okay with the way it is worded now. Anyone disagree with that and the way that it is worded now?

DR. WILLIAMSON: I think we do need to make sure that we have identified all the things that are broken, and make sure that these changes do fix it. And it is obvious from the comments that some of these things are very controversial with the community.

MS. MCBURNEY: And then going along with that, and this sort of went back and forth, but the nuclear cardiology certification in nuclear cardiology

does include all of those requirements.

Now, the fact that they are limited by their scope of practice -- and not under a license, but under what they are doing in practice would be just nuclear cardiology.

DR. CERQUEIRA: The practice of medicine would probably propose the appropriate restrictions on it.

MS. MCBURNEY: And then you would be going after in-bone scans and that sort of thing.

DR. CERQUEIRA: Right.

DR. WILLIAMSON: Yeah, I agree with that.

MS. MCBURNEY: Since we are focusing just on the radiation safety issue and handling techniques.

CHAIRMAN VETTER: Okay. Continuing on, is there anything else?

MS. MCBURNEY: Let's see. (d)(1) with parallel structure, and having the certification by the preceptor that they meet the requirements in (d)(1).

CHAIRMAN VETTER: Right.

DR. WILLIAMSON: Now, are we -- do we know whether all these certification boards in fact do meet the proposed requirements in (d)(1), or have we fixed the problem for --

MS. MCBURNEY: Oh, of the current board?

DR. WILLIAMSON: Yeah, of the current boards. For example, diagnostic radiology by the American Board of Radiology. Would their eligibility requirements include the requirements in (e)(1)?

MS. MCBURNEY: Has the NRC --

DR. WILLIAMSON: John, could you maybe fill us in on that?

MS. MCBURNEY: On what requirements each of these boards has?

MR. HICKEY: Yeah, and I think don't I can do that off the top of my head. The only one I recall is the Board of Nuclear Medicine meets the requirements, except that there is a possible question about the preceptor statement.

But I might be able to check during the break to see what the other ones are and where we are on those.

MS. MCBURNEY: Okay.

MR. HICKEY: I would also ask again on paragraph (b) for both 190 and 290, is there going to be a requirement for some sort of a certification that the training was completed?

MS. MCBURNEY: Yes. Oh, I see what you mean, because (d)(1) --

DR. CERQUEIRA: You mean a preceptor's statement?

DR. WILLIAMSON: Well, it depends on how you define a preceptor statement, but it was what before we were calling a preceptor statement.

MS. MCBURNEY: Rather than (d)(2).

DR. WILLIAMSON: So why don't you just paragraph (d), and delete or cross out the (1).

MS. MCBURNEY: Both 190 and 290 and cross out the one?

DR. WILLIAMSON: Yeah.

CHAIRMAN VETTER: In that regard, I would like to -- I don't want to get into a long detailed discussion of this, but relative to the option of a residency, why don't we allow the boards to require either a residency or (d)?

MS. MCBURNEY: That way if there is some question on the number of hours, and if it is a residency --

CHAIRMAN VETTER: So the American Board of Radiology would not have to determine that in fact the person had 700 hours of training, but that they had in fact completed the residency?

MS. MCBURNEY: A two year residency program.

DR. WILLIAMSON: Do we know that this is a problem that we have to fix? I thought 700 hours was selected because it is the number of hours that a radiology resident typically spends in nuclear medicine. I am not a specialist --

DR. CERQUEIRA: Yeah, I think that is how it was decided. There was a lot of discussion about whether to put in specific hourly requirements for the classroom, and didactic it, and come up with like 80 hours at one point.

But then I think the Nuclear Medicine Society basically felt that it should just be 700 hours in the environment. And I think that is what the radiologists are required to do, 6 months, 4 to 6 months.

MS. MCBURNEY: Maybe we could get into from the board's comment period.

CHAIRMAN VETTER: We will ask that during the comment period.

DR. WILLIAMSON: Again, I think we should be careful and not change it.

MS. MCBURNEY: But even if it is an option

CHAIRMAN VETTER: What I am trying to do is to add some flexibility to the process for the boards.

MS. MCBURNEY: Right.

DR. WILLIAMSON: Well, you want to make sure that somebody doesn't substitute a pathology residency or something.

MS. MCBURNEY: No, it would be a residency in nuclear medicine or in radiology.

CHAIRMAN VETTER: And approved by ACGME. We will ask that question later as to what would be -- whether or not that would be problematic. Okay. So mainly the only changes under (b)(1), to include the requirements of the entire paragraph (d).

MS. MCBURNEY: Yes, and the same with back on 190, the same way.

MR. HICKEY: Dr. Vetter, on that change, I just want to point out that that paragraph calls for the certifier to be an authorized user. So you just need to make sure that is your intent.

CHAIRMAN VETTER: Good point. I think that is their intent isn't it?

MS. MCBURNEY: I believe so.

DR. WILLIAMSON: Do we want it to be an authorized user, or someone who meets the requirements for an authorized user?

CHAIRMAN VETTER: Why wouldn't it be an authorized user?

DR. CERQUEIRA: Right. I think --

MS. MCBURNEY: To provide the training?

DR. CERQUEIRA: I think we all felt that being an authorized user was essential. Otherwise, there is no way of identifying that that person has the hourly requirements to sign off.

CHAIRMAN VETTER: Everybody okay with that? Then let's move ahead to 35.690, training for use of remote after-loader units, teletherapy units, and gamma stereotactic radiosurgery units. Dr. Diamond.

DR. DIAMOND: Okay. Yes. So, again the general framework of this is authorized user status granted through a board pathway, which is paragraph (a), and board alternate pathway, paragraph (b). The currently approved boards are listed in paragraph (c).

And then a specific delineation for modality specific training in Part (d). Problems or changes in paragraph (a) would be the fact that currently certification requires the successful completion of a three year residency programming radiation oncology approved by the residency review committee on the ACGME.

It was pointed out to me that all of the American Radiation Oncology Residency Programs have

now moved to four years. However, if you change that verbiage from a 3 to 4 years, that may not be consistent with some of the foreign boards that are currently recognized; Canada, the World College, and Great Britain.

So my suggestion would be to leave it at 3 years to prevent that problem.

MS. MCBURNEY: At a minimum.

CHAIRMAN VETTER: Add the word minimum? A minimum of?

DR. DIAMOND: A minimum, that's fine. Continuing on that same paragraph (a)(1), is this is the only section that we have discussed thus far in which we do not delineate that the residency program must satisfy the requirements enumerated in paragraph (b)(1), and in the final draft, which we are looking at today, several members of my stakeholder community said that it became onerous on the residency programs to keep track of the number of hours of classroom time and laboratory training, and suggested that that specific reference be deleted.

I don't have a specific problem in removing that language, except that it makes this inconsistent with the other sections that we have just discussed.

DR. WILLIAMSON: I am confused. I don't think so. It is not with medical physics.

DR. DIAMOND: If you take a look --

CHAIRMAN VETTER: It is consistent with the diagnostic.

DR. DIAMOND: Correct.

CHAIRMAN VETTER: But not with the RSO or authorized medical physics.

DR. DIAMOND: That's correct.

DR. CERQUEIRA: I think it's fine.

DR. DIAMOND: Okay. I am just pointing out key differences. We included the examination of paragraph (a)(2), and the alternate pathway is essentially unchanged from the current regulation.

Going on to paragraph (b)(2), that is unchanged. And paragraph (b)(3) is the preceptor statement, which has the parallel verbiage of having written certification that the individual has, "satisfactorily completed."

So that is parallel to what we discussed a few moments ago, and the caveats there is that the written certification must be signed by a preceptor who meets or who has experience in that particular modality.

In other words, you need to have that

preceptor statement signed by someone who knows what they are doing in that particular area.

CHAIRMAN VETTER: Right.

DR. DIAMOND: It would be ridiculous to have a preceptor statement signed that this person has satisfactorily completed training in the use of gammaknife when that person who is offering that statement has never seen a gammaknife unit.

So that is why that is written in that fashion. Paragraph (c) represents to the best of my knowledge the board's currently recognized by the commission, and we would probably want to modify that to be specific, and that it is radiation oncology training within ABR, the American Osteopathic Board of Radiology, and so forth.

In other words, to make it clear that someone can't just be a diplomate of the ABR in diagnostics.

MS. MCBURNEY: It has to be in whatever it is.

DR. DIAMOND: Right.

MS. MCBURNEY: Radiation oncology.

DR. DIAMOND: Right. Radiation oncology training in.

DR. WILLIAMSON: Why did you choose to --

you know, all the other statements have up front as option (a) board certification in X, Y, or Z by so and so, and you have kind of put it down here in (c).

CHAIRMAN VETTER: It won't really matter because they are not going to be in the regulation. They are going to be listed separately from the regulations.

DR. WILLIAMSON: Well, we don't know that. That was something to be discussed wasn't it?

CHAIRMAN VETTER: We were going to discuss that, right. Well, we are not writing the regulation either.

MS. MCBURNEY: Right, and they will do the parallel work.

CHAIRMAN VETTER: If the NRC wants to maintain them in the regulation, they will place them in whatever paragraph they wish.

DR. DIAMOND: And finally in paragraph (d), my only suggestion for the modality specific training paragraph is that the second paragraph, which states that this includes training in device operation, common safety procedures, common clinical use, and so forth, I would just go and end the sentence there, and delete the phrase, "that is equivalent to that instruction provided by the vendor

to new customers."

MS. MCBURNEY: Right.

DR. DIAMOND: And with the same rationale that was discussed a few moments ago. So I think that is a good start for us. I would again remind the staff that if these principles are accepted, that we need to go back and make parallel changes to other sections, including 392, paragraph (c)(3); 394, paragraph (c)(3); 490, paragraphs (a) and (b)(3); and 491, paragraph (b)(3).

And just as far as language regarding competency and just minor housekeeping changes.

CHAIRMAN VETTER: Okay. Ruth.

MS. MCBURNEY: I guess parallel language in 300 as well.

DR. WILLIAMSON: Yeah, and in that there are going to be some more substantive issues.

CHAIRMAN VETTER: Okay. Questions for Dr. Diamond? Good job.

DR. DIAMOND: Thank you.

CHAIRMAN VETTER: Okay. And then the other issue that we were simply asked to consider and I think we all agreed, that we simply want consistency in all of the sections relative to requirements, or criteria, that is, that boards would need to meet in

order to be listed, or whether or not we need to look at each one of those and go through and develop criteria is another matter.

We were not asked to address nuclear pharmacist, authorized nuclear pharmacist, for example. But we would expect that it would simply be consistent throughout, and the same for the other, the radiopharmaceutical therapy.

We would want consistency in those sections as well, but we were not asked to address them specifically. But that takes us through those sections that we were asked to address. John.

MR. HICKEY: Yes. If I could just ask one question back on 690. Again, on the preceptor statement, I believe there still are questions that are parallel to the concerns about the medical physicist.

As written, I believe that the authorized user -- first of all, the authorized user would sign the preceptor statement. And second of all, there would have to be coverage of each type of unit. So in order for someone to be certified on a gammaknife, they would have to have training on the gammaknife and the preceptor would have to be authorized for the gammaknife.

And all of this would have to be part of the board process in order for the board to be recognized, and I think there are some issues there that parallel the issues that were raised with the medical physicists.

CHAIRMAN VETTER: Right. That's a good point. We don't mean to constrain the boards to that point, to that extent. We want to be sure to capture all of the requirements for training in the paragraph that addresses training in specific modalities.

But we don't mean to constrain the boards to require that everyone who is going to be certified have gammaknife experience.

DR. WILLIAMSON: I don't think that Dr. Diamond's write-up does that. He basically gives the requirements for boards in Section D of 35.690(a). And I think what needs to be done to make it parallel to the others is that you have to add a four, and it includes a preceptor statement testifying to satisfactory completion of the above-requirements.

MS. MCBURNEY: Of the residency.

DR. WILLIAMSON: Yes, basically the residency. But the intent is to -- and the description of what the examination contents include, they include radionuclide handling, and stereotactic

radiosurgery, high and low dose brachytherapy, which are all topics that the boards do cover.

But then the contact with actual units and actual experience with a given unit is cast on to Section D, the modality specific training. So in that sense it is parallel to the medical physicist. And it is only in the alternative pathway, Section B, where the preceptor is attesting to specific competence of the physician in the modality being requested.

And that is also similar for the medical physicist, and seems consistent with our principal that the non-board certification route alternate pathway requirements can be a little stiffer and more focused than the broader requirements of the boards.

MS. MCBURNEY: Does the board certification require that the residency -- that whoever is in charge of the residency program, send in a letter?

DR. DIAMOND: Yes, your residency program director has to send in a letter.

MS. MCBURNEY: So if we add that as a requirement under the board certification process, a written statement of the completion of (a)(1) --

DR. DIAMOND: Right, and so we will make that (a)(4), preceptor statement, which could be

interpreted to be a residency program director statement indicating or certifying that the above requirements have been satisfactorily met.

MR. HICKEY: Thank you.

DR. CERQUEIRA: And John, I guess the staff is going to go through the minutes and all of these changes will be put into the revised version of this.

And I think it is really incumbent upon us before the main meeting on July 8th that we go through it and check it, especially all of the ands or ors, as well as the parallel nature between the various groups.

CHAIRMAN VETTER: Right. I think they are expecting us to provide a report to you, that this subcommittee would provide a report to you with those changes in it.

DR. CERQUEIRA: Right.

MR. HICKEY: Yes, and we can assist with the administrative review, in terms of noting editorial inconsistencies and things like that.

DR. CERQUEIRA: Well, we have got like two weeks.

CHAIRMAN VETTER: Right. So it is not a lot of time. That takes us through the sections that

we were asked to address. Are there any other additions or questions on these sections? If not, John, are there any other additions or questions at this point from you?

I know that you have not had a chance, or you and your staff have not had a chance to discuss any changes that we have made here. But any questions at this point?

MR. HICKEY: No, I think the discussions and conclusions this morning hold together very well. I want to emphasize though that the subcommittee recommendations should be clear on the list, or on the issue of the listing of the boards, and the rationale.

It is my understanding that the subcommittee believes that all of the boards should be reevaluated against criteria, and there should not be any presumption that any boards that are currently listed in Part 35 meet the criteria, and that those have to be reevaluated.

And there will be a lot of people who are not in this meeting that will be asking that question; is there any presumption that any board that was listed in the old rule does not have to be reviewed again.

CHAIRMAN VETTER: We are a little ahead of

schedule, and so let's go ahead and discuss that point right now.

DR. WILLIAMSON: Well, I argued for the explicit mentioning or listening of the currently recognized or accepted boards in the revised rule making that might come out of this. So we had I guess a tentative consensus that was reasonable, or at least we would go with that initially.

But I would agree that there was also the presumption that to be so listed that the listed boards would have to meet the broad criteria for being an eligible board.

But the rationale was that as part of the package of writing this regulation that it would force the NRC and the staff to go through and comb the eligibility criteria of these boards very carefully and compare them against the proposed criteria. So that a terrible error wouldn't happen again as it has happened now with the recently published rule.

And secondly that as soon as the rule hits the streets, then those boards are mentioned, and so there would be no disruption. So that is the rationale from my perspective.

CHAIRMAN VETTER: Ruth.

MS. MCBURNEY: Given that information and

that all of these are going to have to be relooked at to see if they meet the new criteria, and going back to 35.50, the way the written certification of the supervising or RSO that an individual completed for training and experience, would the American Board of Health Physics still meet that.

CHAIRMAN VETTER: Yes.

MS. MCBURNEY: Because it doesn't mention that it is specific in medical physics.

DR. WILLIAMSON: Right. Well, this is health physics now?

MS. MCBURNEY: Yes, in (b).

CHAIRMAN VETTER: It says professional experience, and it does not say professional experience in medical.

MS. MCBURNEY: Right. Because I think they do require a residency signed by the supervisor.

CHAIRMAN VETTER: They do. They require 2 or 3 residences, yes, and one of them signed by the supervisor. And the American Board of Medical Physics is somewhat similar to that.

MS. MCBURNEY: Yes.

DR. DIAMOND: I must happened to note, Richard, that when I was doing paragraph (c), which enumerated the boards, included was the American

Osteopathic Board of Radiology. I am not even sure if the American Osteopathic Board of Radiology has a radiation oncology training program in existence. I don't know, but I am not aware of it offhand.

CHAIRMAN VETTER: I think that gets back to John's point. We would not presume that any board at this point in time meets these criteria. This would require the NRC staff to go back out to the boards, and similar to what they did before, two years ago, and ask them do you meet these requirements, and demonstrate that you do.

And presumably they would be able to simply send the literature back to the NRC, the literature that the candidates received that spell out what is expected of the candidate, and what the minimum requirements are.

DR. CERQUEIRA: Yeah, I think we do have a history on this, in the sense that Bob Ayres was sort of detailed to go through the boards, and there were some issues that arose more related to the preceptor statement rather than the content was my understanding.

But we really need to look at that, and if David brings up the point that the American Osteopathic Board of Radiology, that if they don't

provide that training, then they definitely should not be listed, because it really opens this up.

DR. WILLIAMSON: Well, if they don't provide the training, then nobody will be a diplomate of their board, and it is kind of a moot point. I mean, it does no harm. It sort of is unnecessary.

But the one concern that I have is that this process of the American Board of Radiology applying or trying to get a definitive answer from the NRC about whether they are going to be recognized or not has taken two years, and to my knowledge, still the boards do not have definitive answers and have not -- and so this is a major reason why I would like to see the reasonable collection of boards listed up front in the regulation, because it will stop all this nonsense, and it will force them in the process of crafting this regulation to ensure that there is not a contradiction between those board eligibility requirements.

And to give them an opportunity to fine-tune these criteria so that everything will work out, and I am afraid that if they just ignore that issue, and go ahead with some criteria, some little conjunction, or disjunction, or some turn of phrase, will be incorrect.

And then we will find ourselves in the position that the Office of General Counsel, based on some legal technicality, disenfranchises some part of the community for no reason at all.

So this way by putting or listing the board's explicitly, the task of once and for all definitively figuring out if these criteria fit the boards will be done before the rule is cast in concrete.

CHAIRMAN VETTER: We will actually arrive at our answer to that question at the end of the day after we have heard public comment, but are there any other comments at this point in time that anybody would like to make in that regard? John.

MR. HICKEY: I just wanted to add that there are a couple of boards that have told us that they do not want to request recognition until they know what the criteria are.

CHAIRMAN VETTER: Right. Okay. Good point. Any other comments or questions at this point in time? If not, we will take our break 15 minutes early, and when we come back from the break, we will hearing public comments.

So once again, any members of the public who wish to make comment, if you have not already

registered with the NRC, be sure that you do that.

DR. CERQUEIRA: We should check just to be sure, because we are changing the schedule, and there may be people that are coming and expecting to start at a certain time. So by starting early --

CHAIRMAN VETTER: That is a very good point.

MR. HICKEY: Let's get the list and read it off and take attendance here.

DR. CERQUEIRA: Just to make sure that everybody is here. And basically we are going to have quite a long period, and so if people --

CHAIRMAN VETTER: They will still have time. But let's look anyway. Let's look at the list and let's see if those people who have registered are in fact here, and then we will take our break and get to the public comment when we come back.

(Discussion off the record.)

CHAIRMAN VETTER: We did not give specific times for anyone to speak. We simply said they needed to sign up to speak and they would be given up to 10 minutes. Now we have eight people signed up. So that would be 80 minutes.

So we are hoping that people wouldn't take a full 10 minutes, but could we just see if these

people are here. William Van Decker?

MR. VAN DECKER: Yes.

CHAIRMAN VETTER: William Hendee?

MR. HENDEE: Yes.

CHAIRMAN VETTER: David Steidley?

MR. STEIDLEY: Yes.

CHAIRMAN VETTER: Paul Capp?

MR. CAPP: Yes.

CHAIRMAN VETTER: Richard Fejka?

MR. FEJKA: Here.

CHAIRMAN VETTER: Gary Sayed?

MR. SAYED: Yes.

CHAIRMAN VETTER: Bill Uffelman?

MR. UFFELMAN: Yes.

CHAIRMAN VETTER: Paul Chase?

MR. CHASE: Yes.

CHAIRMAN VETTER: Okay. They are all here. So what we will do is come back at a quarter-to, and have a 15 minute break, and come back and begin hearing public comment from Dr. William Van Decker.

(Whereupon, the Subcommittee meeting was recessed at 9:30 a.m., and resumed at 9:45 a.m.)

CHAIRMAN VETTER: Okay. Here we are all back again. Thank you all very much. We are at the

point in the agenda where we are ready to receive public comments.

We now have nine people signed up, and we had originally said you have up to 10 minutes, and you still do have up to 10 minutes, but we would urge you if you can make your points in less time than that to do so.

We would also ask that you leave a minute or so for the subcommittee to ask you questions, and if you could do that, please. The first person who has signed up is Dr. William Van Decker. His affiliation is with the CBNC. Dr. Van Decker.

MR. HICKEY: Let me suggest that the speakers join us up at the table for more comfortable.

CHAIRMAN VETTER: That would be good, yes.

DR. VAN DECKER: Good morning. As an affected stakeholder in this process, I want to thank both the NRC and the ACMUI subcommittee for allowing us to be present today. I would just like to touch on five quick points if I could.

Number One, the CBNC would like to thank the NRC for its written May 21st, 2002 notification that the Board meets the requirements for being an authorized user, the board has worked very hard over the past few years to make sure that this is true, and

we appreciate that in writing, and we appreciate the ACMUI Subcommittee recognizing that in its drafts for where we are going from here.

Secondly, we wanted to note with some bemusement that the CBNC has always been aboard and has had strict criteria that a person sitting for authorized user status before sitting, because it had not had board status in the old subpart (j).

And therefore we want everyone to at least notice now how exactly and painstaking a process this can be if that is part of the issue going in. But it is something that we have done for years, and so it is not that much of an issue, per se.

The third point that I would like to make is at least a thought provoking point. In regards to .290, if you look at the current draft, passing a board actually makes the alternative pathway as a building block for authorized usership actually moot.

Because just passing the board on to itself will give you the ability to be an authorized user. Therefore, I think it is important obviously that all the boards have relatively industry standard means for sitting the boards.

I also want to raise the point to remember that whatever the boards are now, they may not be 10

years from now, and assist them where we try to do innovative things for patient care.

So a board changing its criteria five years from how, and another one changing its criteria eight years from now, by the end of 10 years, you may have multiple boards with multiple boards, with multiple diversity of how you become an authorized user.

And some consideration needs to be given to how you address that type of a consideration. The fourth point that I wanted to touch on I think was touched on quite heavily this morning, and so I won't spend too much time on it, but that was the issue of radiation safety officership.

We are a little less bemused by the fact that the draft specifically lists 11 different boards, which is a fairly diverse community, and did not list CBNC.

We recognize that most people involved in nuclear cardiology would have been covered under the nondescript paragraph (d) for that use. But certainly an authorized user should be able to be the RSO for a single modality diagnostic imaging type setup, if that is what their expertise is in, and if they should so desire.

And leaving that board out, and just to point out the political sensitivities of life, and make somebody feel like a second citizen to somebody else whose board is listed in some way.

And I think that happens in any of the different categories when you begin to board lists. And the last thing that you want to do is look like you are restricting the scope or practice of medicine in ways that are beyond just radiation safety, and I think that is something that we all need to keep in mind as we go about dealing with this type of situation.

And I guess that is the last point that I want to talk about, is number five. Coming from a constituency who has always sensed in some way that subpart (j) was used as an unequal restriction of the scope of practice among physicians, and this may be a point to remember when we talk about having alternate pathways with more teeth and quotes from those people who are quotes are already in.

And we are particularly sensitive to rule wording, and that really places the NRC in the position of regulating the practice of medicine. Certainly we have had a lot of workshops on the guidance and inspection documents, and talking about

being more risk informed and performance based, and how we just go through inspections, and guidance, and licensing.

I think we need to be taking that same type of thoughtful process to everything else that we do. The key role here is that the NRC wants safe authorized users, and not to be involved in the regulation of medicine.

And therefore any wording of any ruling must allow room for new paradigms, for patient care, and even new boards that meet industry standards, remembering where we have come from.

And new training and experience for emerging technologies. That will be thought out in the future since it is -- and perhaps such as intervascular brachy, and that the alternative pathways should not be super restrictive to the practice of medicine, but should looked at as building blocks to the other boards.

And anything less than that probably begs for stagnation and antitrust arguments as board shift criteria as time goes by and everything else, and I think we should just be trying to do this in an appropriate manner for everyone involved in the community. And I think that I will end my comments on

that note, and I thank You very much for the time.

CHAIRMAN VETTER: Thank you, Dr. Van Decker. I appreciate it very much. Does anyone on the subcommittee have questions or comments?

DR. WILLIAMSON: Well, we certainly apologize for inadvertently leaving out your board, and I think you can see that we have reversed our mistake by taking all of the specialty physician imaging boards out, and that was not the intent.

DR. VAN DECKER: I understand that it was not the intent, but I am just trying to say that we recognize how difficult this is once you start listing specific things as to who you include and exclude kind of thing.

DR. WILLIAMSON: Let me ask my question. The way the proposed. draft statements are worded now, it says that you can be an authorized user if you are a diplomate of one of these listed boards, or a diplomate of a recognized board meeting the following broad criteria.

And then we do have to work on the problem of how to make sure that the listed boards maintained their adherence to that criteria. But would you find the combination of those two statements acceptable from the scenario or the perspective of your board and

the struggle that it has had to be recognized?

Do you think that this sort of alternate board pathway is a reasonable framework for recognizing new boards that come along in a field?

DR. VAN DECKER: I think that in all things the devil is in the details, and so as long as the review process is reasonable, and that there is a clear cut building block of what needs to be there and what doesn't need to be there, and that that building block is not four times the standard for whatever anyone else in the rule is, that that is something that could probably be worked with.

CHAIRMAN VETTER: Any other questions? Manny?

DR. CERQUEIRA: You brought up one item about change in requirements for boards, and I guess once we started listing boards, we are assuming that there is a criteria for -- that eligibility criteria is going to stay the same.

And I guess in terms of the committee, do we have any mechanism in place which would allow us to look if a board all of a sudden decides that they are not going to have requirements for certain things?

Is there some way that we can take them off the list and do we need to develop some sort of a

process for that.

CHAIRMAN VETTER: David, did you --

DR. DIAMOND: I was just thinking of the same thing as Dr. Van Decker was speaking. There are a lot of advantages to enumerating the boards for clarify sake, and for removal of all of these nitpicking questions that may occur.

But then you have to have a mechanism for updating them, and for deleting boards should they for some reason they not adhere to. So if you are going to do that, it works both ways.

DR. WILLIAMSON: Well, I have a suggestion. Actually, we could put in that paragraph (a) that it is certified by Board X, by Board Y, Board Z, et cetera, provided that the diplomates sitting for these boards adhere to the minimum requirements in paragraph (b).

CHAIRMAN VETTER: Yeah, I don't think that we have to worry about the words, but the point is well taken.

DR. WILLIAMSON: And that would automatically nullify, even though they are mentioned explicitly, that if they somehow change the residency requirement from 2 to 3 years, it would automatically disqualify those diplomates.

CHAIRMAN VETTER: And the point is well taken. We don't want words in here that would restrict the growth of the profession.

DR. VAN DECKER: And new paradigms. And this just jogged my memory. This residency issue is frequently a matter of clinical competence and time of patient selections, da da, da da, da da. And I think that the goal here is to be focused on what is the radiation safety, and what makes the States and the NRC comfortable that a physician can appropriately handle ionizing radiation.

And coming from the City of Philadelphia, I can guarantee that if you want to worry about clinical competence, there are plenty of lawyers who will find you. I guarantee.

CHAIRMAN VETTER: Okay. Thank you very much, Dr. Van Decker.

DR. VAN DECKER: Thank you very much.

CHAIRMAN VETTER: Dr. William Hendee, representing the American Board of Radiology.

DR. HENDEE: I would like to ask that Dr. Capp join me and we will do ours together.

CHAIRMAN VETTER: That will be wonderful.

DR. HENDEE: And Dr. Capp has a very brief statement.

CHAIRMAN VETTER: Sure.

DR. HENDEE: So that will cut down one of your speakers.

CHAIRMAN VETTER: Okay.

DR. CAPP: Thank you. My name is Paul Capp, and I am the Executive Director of the American Board of Radiology and have been for nine years, and the former president of the board prior to that time. I am an old physicist from way back, and then went into nuclear physics.

And then I realized that I wasn't bright enough and so I had to go into medicine. So, if you will excuse me for that, but I speak as a medical doctor and a radiologist.

I don't have to tell this group that our board from way back realized that the serious effects of radiation caused the board beginning in 1934 to start examining in 1934 about radiation effects.

And so it has been high on our list in the examination process over the many, many years. So much so that in 1947, and in view of the increasing technology, we brought in physicists to the board at that time and started the certification process in radiologic physics.

And which is still recognized today by the

ABMS, and that is important. The ABMS is medical board's only, but the ABMS has allowed for the ABR to continue to certify radiologic physics up until this day.

Whereas, they do not allow certification for non-physicians in any other field except for medical genetics due to many, many other reasons. We think so seriously about this topic that we have separate examinations in the diagnostic radiology today, and we have a three hour examination, written examination, in both radiologic physics and radio biology for the diagnostic resident who has just completed five years of training.

And in radiation oncology, we have a three hour examination in radiologic physic, and therapy, and a three hour examination in radiobiology, besides the basic science clinical examination.

And this of course all precedes the oral examination that occurs if they are successful with the written examinations. So we are very serious about radiation safety, and we have specific examination committees.

Dr. David Hussey from San Antonio, who is the head of the examination committee in radiation oncology, and he feels strong enough, and he is here

in the audience today, to perhaps answer your questions.

And Dr. Phil Alderson from Columbia is in the audience who runs our nuclear medicine section, and Dr. Steve Thomas is here, who is a nuclear physicist, in charge of the nuclear medicine part, and he is representing another or wearing another hat, and representing the AAPM.

And I am pleased to say on our board of trustees we have three physicists, which is unusual for a medical board, but that is also how strongly we feel about this topic. And I am pleased to say that we are probably the only medical board in existence that has a non-physician as president now.

So our president for the next two years is Dr. Bill Hendee, who will give the points that we would like to get across. Bill.

DR. HENDEE: Thank you, Paul. I think everyone in this group and so there is no point in telling you who I am, other than the fact that I did want to mention one credential that you may not know about.

I am the secretary of the National Patient Safety Foundation and a founding board member , and I wanted to state that just so you will know that in

addition to coming at this from a professional point of view as a medical physicist, and health physicist, I also come at it from the point of view of having a great interest in the protection of the health and safety of patients who are provided health care in institutions across the country.

It is a pleasure for me to be here as well, and I am here to state the unqualified support of the American Board of Radiology for the June 14th statement that has been developed by this group, by the ACMU subcommittee, and which has been discussed here today.

This statement restores board certification as the default pathway for individuals to become authorized as radiation safety officers, and medical physicists, and nuclear pharmacists, and authorized users of byproduct material.

We endorse this restoration of board certification as the default pathway. We strongly encourage the acceptance of each of the certification of boards that are identified in these subcommittee's report as they relate to Parts 35.50, 35.51, and 35.190,and 35.290, and 35.690.

And we would also point out that we would also hope that they would be identified as they

pertain to other relevant sections in the revised Part 35, and that would include Parts 35.390, 35.490, and 35.590.

In the development of the position of support for the subcommittee's report, the American Board of Radiology consulted three other certification boards; the American Board of Health Physics, and the American Board of Medical Physics, and the American Board of Scientists in Nuclear Medicine.

All of these boards are represented here today, and you will hear from all three; David Steidley representing the ABMP, and Gary Sayed representing the American Board of Scientists in Nuclear Medicine, and Shawn Googins representing the American Board of Health Physics.

I am pleased to tell you that these three certification boards have joined with the ABR in unqualified support of your statement. In arriving at this position of unqualified endorsement of your report, the ABR and the other boards examined the five assumptions on page one of the subcommittee's report, and we agree with these assumptions and acknowledge that the boards specifically identified in your report meet the criteria referenced in the second assumption of your subcommittee's report on page one.

Why did the American Board of Radiology and its companion boards feel strongly that about board certification as the default pathway? There are several reasons and here are some of them.

And I will express these on behalf of the American Board of Radiology, and the other committees can make their own statements. As you have already hear, the ABR has spent 80 years defining the criteria for the safe and efficacious use of ionizing radiation, including radiation from byproduct materials in diagnostic and therapeutic medicine.

These criteria are infused into the certification examination process and by extension into the education and training programs for diagnostic radiologists, nuclear radiologists, radiation oncologists, and medical physicists.

Certification by the ABR is a direct indicator that the individual is technically competent to use ionizing radiation safely to diagnose and treat disease, and in the case of medical physicists, to provide medical physics and radiation protection services in a safe and responsible manner.

The ABR and its companion boards recognize the futility of attempting to equate competence with hours of training and experience in any discipline,

and an acknowledgement that is shared by virtually all experts in higher education.

Consequently the ABR and its companion boards do not wish to accommodate a specific requirement of hours of training and experience, because we think it is not relevant to the evaluation of competence.

Further, the ABR and its companion boards wish to assure the NRC that board certification is a more acceptable criteria than hours of training and experience in evaluating the competence of individuals using radiation for the diagnostic and therapeutic diagnosis and treatment of disease in humans.

Now, as I have listened to your deliberations today, there are three issues that I would like to comment on specifically. The first has to do with the discussion of Part 35.50, training for radiation safety officers, at which there was some discussion about the desirability of removing from the list of qualified certification boards, the American Board of Radiology.

We believe that would be a mistake, because if you remove the American Board of Radiology as a default pathway to become a radiation safety officer for individuals, especially for individuals

training in medical physics, then the only way that a medical physicist could serve as a radiation safety officer is to meet the definition of authorized user, which is confined to radiation oncology physicist.

But the American Board of Radiology certifies not only radiation oncology physicist, but it also certifies medical nuclear physicists, who are extremely well qualified to serve as a radiation protection or radiation safety officer in institutions.

And it also certifies diagnostic radiologic physics, who have a lot of training in radiation protection and radiation safety, and for small hospitals that don't have an extensive program in radiation oncology, they might be the best choice to serve as a radiation safety officer.

So we would ask that you reexamine that discussion to be sure that you don't disenfranchise individuals who could do a great service to the community by removing the American Board of Radiology as a default pathway for certification, leading to recognition as a radiation protection officer.

My second point comes to the discussion about letters of reference and whether those letters of reference should address whether an individual has

completed a training program, has satisfactorily completed a training program, or has competently completed a training program.

And we obviously have had great discussion about this within the American Board of Radiology. Our belief is, number one, that it is the certification process that assures competence, and not a letter of reference from an individual.

And therefore, we don't pay much attention to letters that attest to competence. We want letters that attest to what can quantitatively be evaluated by an individual, namely the degree of training and whether it has been completed or not.

We don't know what satisfactorily completed means as compared to completed. If you want to leave satisfactorily in there, I suspect that it will be interpreted as completed.

Another issue is that if someone were to write a letter that stated that an individual is not competent, we would not pay much attention to that letter, because once again it is the certification process that evaluates competence and not letters.

And we do not want an individual to be accepted or rejected into the certification process based upon the opinion of one individual evaluating

competence. And if we did and rejected the individual on the basis of letters that declared that he was competent, I suspect that we would be ending up in court because we had disenfranchised a potential applicant from practicing his profession.

So I think that letters of attestation or letters of reference really have to only address those things that can be evaluated by people in a quantitative way.

There was a discussion on Part 35.290 related the certification and diagnostic radiology by the American Board of Radiology by the American Board of Radiology, meet the requirements of Section d-1 in Part 35.290.

And I would like to say an unqualified yes, as we have already stated in a letter dated June 26th, 2000 from Dr. Paul Capp, the executive director of the ABR, to mr. Donald Cool of the NRC staff, and in which we addressed specifically that specific question.

I think that all of us here -- the Nuclear Regulatory Commission, the American Board of Radiology, the ACMUI, and its subcommittee, all the companion boards to the ABR. We all share a common objective.

The common objective is using ionizing radiation safely and effectively in the diagnostic and therapeutic applications of human disease. And we propose that the NRC and the professions work together as we are now towards this objective to improve human health, medical diagnosis, and therapy.

A good start, a very good start in this direction by the NRC, would be the acceptance of the statements of its own subcommittee of the advisory committee on the medical use of isotopes related to the training and experience requirements, and we would like to thank this subcommittee for your hard work.

We think you have done a great service to the people of this country, and what you have accomplished through this statement, and we appreciate it very much. Thank you.

CHAIRMAN VETTER: Thank you, Dr. HENDEE. Anyone have questions for Dr. HENDEE or Dr. Capp? Yes, Ruth.

MS. MCBURNEY: One of the MRC staff persons brought up that if the certification process requires a signature by an authorized user attesting to the completion of the training and experience requirements that that might pose a problem.

What sort of letters of reference are

required for sitting for the diagnostic board?

DR. HENDEE: At the present time, we require two letters of competence, and I can ask Dr. Capp to address this as well. They are letters from individuals who are certified by the American Board of Radiology.

MS. MCBURNEY: And they would already be authorized users or maybe be qualified as authorized users, maybe if they are program directors, or something like that.

DR. CAPP: If you are talking about, say diagnostic radiologists.

MS. MCBURNEY: Diagnostic, right, the 290 physicians.

DR. CAPP: At the present time, as in most ABMS boards, the program director is required to sign off, and in our particular application, the program director must state that an individual is professionally qualified, is the term that we use.

Now, in the 193 diagnostic radiology programs in this country, virtually all of them have multiple individuals who could be qualified to be authorized users. So I am sure that they have one, two, or three in each institution.

MS. MCBURNEY: So the wording of that is

not a problem.

DR. CAPP: It is not a problem, except on the other hand most program directors in diagnostic radiology are probably not authorized users, because there are people in nuclear medicine, or a radiation safety officer, a health physicist, et cetera, fulfill those criteria.

And so what we would have to do would be to put another line in there, and so the signatures that would be required would be not only the program director, but an authorized user if that is your intent.

CHAIRMAN VETTER: But the program director would be as equally qualified as the authorized user to testify that the individual had completed the training?

DR. CAPP: Yes.

MS. MCBURNEY: So we could add some wording there.

DR. CAPP: Yes, program director, or authorized user. Go ahead.

DR. DIAMOND: Well, I was just going to state that if the program director must already make an attestation for that candidate to be professionally qualified to sit for the boards, then it is entirely

moot to add another sentence.

For example, what we were going to do in paragraph (a)(4), a preceptor statement or residency program statement, which is entirely redundant and moot as far as I can tell. My question for Dr. HENDEE would be would you also recommend based upon the grounds that you cited that a preceptor statement be deleted from the alternate pathway?

You made an argument for deleting a preceptor statement from the board certification pathway, and would you recommend on the same principles delineated from the alternate pathway?

DR. HENDEE: I wasn't making a statement to delete the preceptor statement. I was making a statement that says that the preceptor statement should verify that the individual has completed the required training, and we do require preceptor statements as you have already heard for entrance into the certification examination.

My comment was on asking that individual to attest to the competence of the individual, and I think that is not a wise thing to do.

DR. DIAMOND: All right. So, for example, the language that is currently there, which is, "satisfactorily completed," you just told us that that

is meaningless to you, and --

DR. HENDEE: Completed is not meaningless, but satisfactorily completed, and I don't know what satisfactorily means in that context.

MS. MCBURNEY: I think that means that they didn't fail.

DR. HENDEE: Well, if they failed, they would not have completed it, right? I mean, you can leave satisfactorily in there. I don't think it is a big issue. Competently is the issue.

CHAIRMAN VETTER: Jeff.

DR. WILLIAMSON: Well, two comments. I think in 35.290, we should be really careful not to overly define the qualifications of the preceptor so that we get the radiology boards in trouble. I think it is nitpicking, and there is no reason to do that.

And I think that in the description of the broad criteria for being an acceptable board, we have to make it general enough that a residency program director who is primarily a diagnostic radiologist, and who had been overseeing the program, that that person's statement can be accepted as a preceptor statement.

The second comment, because I think that Dr. Hendee is right, and we should go back and look at

the RSO category, and do something to address the possibility of these specialty physics certifications being able to practice as RSOs, at least in limited context, and I think he is absolutely right.

CHAIRMAN VETTER: I agree, and I wanted to ask a question with regard to your radiological physics exams, do you have two exams; one for diagnostic, and one for oncology?

DR. HENDEE: We have three exams actually. We have one for diagnostic radiologic physicists, and we have another exam for medical nuclear physicists, and we have another exam for radiation oncology physicist.

There is a part one, which is common to those, but then there is a Part II written exam, and an oral exam, and they are separate exams all the way through.

CHAIRMAN VETTER: So relative to 35.50, it is those three subspecialities that we are talking about?

DR. HENDEE: Yes. Right.

CHAIRMAN VETTER: Thank you.

DR. WILLIAMSON: And I think somehow we need to distinguish between an RSO that has broad authority to be an RSO for a broad scope licensee,

versus an RSO who is limited to kind of single modalities or some smaller collection of modalities.

MS. MCBURNEY: For example, for a radiation oncology program that is separate from a large hospital, a lot of times the medical physicist is also the radiation safety officer.

CHAIRMAN VETTER: Good point. Okay. Other questions for Dr. Hendee or Dr. Capp? Thank you both very much. We appreciate you taking the time to come here and address us. Thank you. Next is Dr. David Steidley, representing the American Board of Medical Physics.

DR. STEIDLEY: Good morning.

CHAIRMAN VETTER: Good morning.

DR. STEIDLEY: My name is David Steidley, and for identification purposes only, I am the Chief Physicist, as well as Radiation Safety Officer, at St. Barnabus Medical Center, in Livingston, New Jersey. I am a Diplomate of the American Board of Radiology, of the American Board of Medical Physics, the American Board of Health Physics.

I am a Fellow of the American College of Radiology, and a Fellow of the American Association of Physicists in Medicine. I am here today in my role as a member of the Board of Directors of the American

Board of Medical Physics, and I also serve there as their panel chair for medical health physics.

The official position of the American Board of Medical Physics is identical to the American Board of Radiology as expressed minutes ago by Dr. Hendee.

I would like to stress the painstaking path that our board has laid out for its diplomates. You must have an advanced degree. You must have multiple years of experience. You have to have letters of reference.

You have to pass a rather arduous written exam, which is divided into two parts, and you have a notoriously difficult two hour examination before a panel of three experts.

Only then do you become qualified, and are able to be a diplomate on the American Board of Medical Physics. We have heard a number of hours of training and education bandied about -- 200 hours, 500 hours, 700 hours.

A typical candidate here has a minimum of 16,000 hours of training and experience. So I think those other numbers pale in comparison. So given all this background, I think you have to conclude that we need a default pathway that says you are boarded.

And I am happy to see that this committee is making progress in restoring that, and in conclusion then, I think that we can say that we stand totally in support of your subcommittee's draft of 614.02 on training and experience as amended today. Thank you.

CHAIRMAN VETTER: Thank you, Dr. Steidley. Any questions for Dr. Steidley? You said years of experience. Could you be more specific about that? A person needs an advanced degree, and so a minimum of a Masters degree.

DR. STEIDLEY: That's correct.

CHAIRMAN VETTER: And so many years of experience.

DR. STEIDLEY: Yes. It depends on the -- if you have a Ph.D., the experience is four years in order to sit for Part III; and it then takes an additional year for you to go into the oral examination. So with a Ph.D., you would need a minimum of five years.

Now, if you do a specific Ph.D. in medical physics, and there only a handful of programs that have that requirement, it is a total of four years. But most of your work at that point, if you are in one of those programs will be hospital related.

Your research project will probably or undoubtedly have something to do with medical physics. So you are quite a bit more involved than a standard candidate taking a Ph.D. in physics. We lightened that up.

If you come from a medical physics program that is accredited, and now you are talking just 2 or 3 in the country, then we would reduce it to a total of 3 years. And with Masters degree candidates, you have to add about 2 years to each of those numbers, in terms of total experience.

CHAIRMAN VETTER: So with a Masters, a minimum would be five years experience, plus a Masters degree?

DR. STEIDLEY: Well, if you are in an accredited medical physics program, you could get away with as little as 4 years after you have got your Masters degree. But if you are in an accredited Masters physics program, those 2 or 3 years that you have spent have been just 100 percent medical physics.

CHAIRMAN VETTER: And for the medical health physics?

DR. STEIDLEY: The same

DR. WILLIAMSON: And for -- this is years of experience before you can successfully apply to

take the first level of the written exam?

DR. STEIDLEY: We have -- well, for the part one exam --

DR. WILLIAMSON: Yes, the Part I test.

DR. STEIDLEY: -- you don't need to have professional experience. It is a generalized test. Then for Part II, you would have to wait another 4 years, but that is not a usual pathway.

CHAIRMAN VETTER: Other questions?

DR. WILLIAMSON: Well, one question. How does this compare to the ABR?

DR. STEIDLEY: Excuse me?

DR. WILLIAMSON: How does the years of experience for ABMP compare to the American Board of Radiology for radiation oncology physics?

DR. STEIDLEY: I don't think I could speak to an exact comparison.

CHAIRMAN VETTER: Are Dr. Hendee or Capps still here that could answer that for us?

DR. HENDEE: Okay. I could answer that. The question is what are the experience requirements or the total requirements for certification in radiology oncology physics by the American Board of Radiology, and the answer is that you have to have three years of experience.

If you have a Masters degree, you can count up to six months of that education towards the three years, provided that it is real experience in the clinic as part of your educational process.

If you have a Ph.D., and the Ph.D. and the Masters have to be of course in relevant scientific fields, then you can count up to 12 months towards the 3 year requirement, but again it has to be in clinical relevant experience as part of your education and training.

CHAIRMAN VETTER: Okay. Thank you. Any other questions for Dr. Steidley? Thank you very much for taking the time to come here and visit with us here today. The next on the list is Dr. Richard Fejka, representing the Board of BPS and APHA. That is pharmacist.

DR. FEJKA: Good morning, and thank you for the opportunity to appear in front of the board and offer some comment. Specifically, I am here representing the Board of Pharmaceutical Specialties, and specifically their nuclear pharmacy specialty council.

As well as a dual hat of representing the American Pharmaceutical association. Specifically, myself, I am a practicing nuclear pharmacist for the

past 21 years, and I am board certified, and I am currently serve as a member of the Nuclear Pharmacy Specialty Council within BPS.

Although the subcommittee was not specifically asked to deal with the training and experience requirements for an authorized nuclear pharmacist, in reviewing the proposed regs that were submitted here for radiation safety officers, authorized medical physicists, and training for authorized users, we are encouraged to see that board certification is listed, specifically listed, and that it is an excellent move to list particular boards as being or meeting the qualifications to become authorized.

However, the aspect of putting a preceptor statement into a board, we are not so sure that it meets the requirements that we see as authorizing someone to be a board certified nuclear pharmacist.

As Dr. Williamson stated, if you sit to take an examination and don't pass, obviously you are not going to become board certified. And in our particular case for recognizing, and we are sitting to become board certified in nuclear pharmacy, we require a minimum of 4,000 hours of T&E, which far exceeds the NRC's statement of 700 hours.

So obviously one could become recognized as an authorized nuclear pharmacist under the proposed NRC regs if you just meet the 700 hours. But board certification is also another area which could represent that pharmacist who truly wants to go above and beyond the minimum, and to state that you understand the work that you do, and that you are a recognized expert in your field.

As a nuclear pharmacist, and representing APHA, the alternative pathroad that was proposed in the April 24th regs of 700 hours is acceptable to us for meeting the requirements of mathematics and chemistry, and the manipulation of pharmaseuticals, and to be able to safely operate a nuclear pharmacy.

And the preceptor statement there certainly is appropriate, and as a nuclear pharmacist, again, I believe that we wouldn't have any real problem with accepting that.

As a possibility to recognize future boards, although being in the field for this large numbers of years that I have practiced, I understand the importance that the NRC would want to be able to have criteria to recognize future boards.

And maybe to do that, certainly be a member of the Board of Pharmaceutical Specialties, we

have as a minimum our 4,000 hours, and maybe that might be an acceptable figure to use.

But as Ms. McBurney stated in her review of the proposed draft regulations, a board that would meet the NRC's minimal requirements of 700 hours in the various areas of training might be a standard whereby the NRC could use to judge future boards that were to come down and be recognized.

That basically summarizes what I wanted to state with regard to nuclear pharmacists, but since we are not sort of, so to speak, dangling out there, we are not exactly sure finally what the NRC is going to state.

We have the April 24th regs, and we have the regulatory guide, Chapter 9, which lists specific things, but does not go into detail as to what was proposed here that the subcommittee was specifically asked to look at.

So again as a nuclear pharmacist, we certainly would be encouraged or would like to see what the final draft, the final rules, would come down as it affects us. But if you use what this committee did as an example of what we might be able to be applied to, to specifically put back the Board of Pharmaceutical Specialties for recognition without a

preceptor statement, would be acceptable.

And the other alternative pathways to being recognized as an authorized nuclear pharmacist of the 700 hours would be acceptable to us also.

CHAIRMAN VETTER: Thank you very much, Dr. Fejka. Questions?

MS. MCBURNEY: I think we mentioned earlier that we would recommend that the NRC make similar consistent ruling language throughout all this T&E requirements.

DR. FEJKA: I did hear that, and I was encouraged to hear that from a member. But once again, with some speculation or apprehension until we see the final rules, at least we are encouraged to see that if we are treated similar to the other authorized user areas, then we probably will be happy.

MS. MCBURNEY: Good.

CHAIRMAN VETTER: A couple of questions.

DR. FEJKA: Sure.

CHAIRMAN VETTER: Focusing on the preceptor statement first of all. It is going to be our recommendation that -- or at least the sense that I have so far is that our recommendation is that we not require boards to require candidates to provide a preceptor statement that testifies to their

competency.

But rather that they have completed a training program, and could you tell me what you mean by a preceptor statement?

DR. FEJKA: Well, that was again a thing in the April 24th publication, and in Reg Guide 9, the proposed Reg Guide 9. It was, I'm sure, exactly what that meant to us. Now we have had further information that delineates that the NRC basically was concerned about an individual from the radiation safety standpoint.

Now, the preceptor statement, and trying to apply that with regard to our certification examination, since to sit for it requires 4,000 hours, two years of training in the area of nuclear pharmacy, we would think that somebody who would become board certified would eventually learn something concerning radiation safety issues.

CHAIRMAN VETTER: I'm sorry, but I just would like a very specific answer as to whether or not you would object to a statement that required candidates to provide the board with a letter that said they had in fact completed the training, or do you assure that in some other way?

DR. FEJKA: We assure that in some other

way. If you sit for our exam and you don't pass it, you don't become board certified. But the alternative is that before you would even get to our examination, that you would have the NRC's 700 hours of experience.

MS. MCBURNEY: But you don't require a statement from the training institute?

DR. FEJKA: No, because the training that a pharmacist would have, 4,000 hours, two years, could occur over working at several different facilities. And again not having much to go upon as to what or who would certify, who would sign ultimately saying that you worked and satisfactorily met the requirements --

MS. MCBURNEY: So they would just self-attest to it?

DR. FEJKA: Self-attestment is another thing, and maybe it could work, but if you don't past the tests --

CHAIRMAN VETTER: But you do have a mechanism that demonstrates that the individual has completed the training; is that correct?

MS. MCBURNEY: Just the exam.

DR. WILLIAMSON: Do you have some way to verify that they completed the stated number of hours of training?

DR. FEJKA: Okay. We ask them to attest

to that either through providing evidence of taking course work, of where they have worked in their experience, and what facilities, and whether or not they have gone on to take graduate level programs or degrees.

So to that extent, we have that requirement. The Board of Pharmaceutical Specialties did submit that to the NRC and the NRC felt that we met the requirement, providing the information with regard that our board is a satisfactory board.

However, their comments did come back that the preceptor statement was missing. And it is that preceptor statement that we feel under the pathway that would exist, 700 hours, comes before our examination.

You could maybe go that way. However, if you did choose to become board certified and not an authorized nuclear pharmacist first, although I can't understand someone would go down that pathway first, that it might serve as a moot point.

CHAIRMAN VETTER: Okay. Other questions? So your minimum requirements are basically two years of training in nuclear pharmacy?

DR. FEJKA: To become board certified.

CHAIRMAN VETTER: To become board

certified, right. Okay. If there are no other questions, thank you very much, Dr. Fejka.

DR. FEJKA: Thank you.

CHAIRMAN VETTER: I appreciate you coming here today to visit with us. And next on our list is Gary Sayed, representing the American Board of Science and Nuclear Medicine.

MR. SAYED: Good morning. For reference, I am Gary Sayed, Professor of Diagnostic Imaging at Thomas Jefferson University, in Philadelphia. I am the past president of the American Board of Science and Nuclear Medicine, and I am here to inform you that the formal position of the American Board of Science and Nuclear Medicine is identical to the position expressed by Dr. Hendee on behalf of the American Board of Radiology.

The ABSNM is a board established and founded to certify scientists by the Society of Nuclear Medicine, the American College of Nuclear Physicians, and the American College of Nuclear Medicine.

The board has been certifying scientists in radiation protection, medical nuclear physics, and nuclear pharmaceutical science, for the past 25 years. In order to sit for the examination, the candidates

with a Masters degree are required to provide letters of evidence from two preceptors, one of whom must be a certified nuclear medicine scientist; and the other a board certified nuclear medicine physician for 5 years of training.

And for the Ph.D. candidates, we require 3 years of experience. In closing, I would like to thank you for this opportunity to participate in this process.

CHAIRMAN VETTER: Thank you very much. Questions? Yes, Jeff?

DR. WILLIAMSON: For what category in Part 35 would your certification be applicable; to just radiation safety officer?

MR. SAYED: Specifically for 35.50, yes.

DR. WILLIAMSON: And probably for nuclear medicine applications, and not broad scope licensees? Or would you claim that one of your diplomates could be an RSO for a broad scope licensing?

MR. SAYED: Yes. Under Part 35.50, as RSOs for broad scope licenses, particularly our diplomates who are certified in the radiation protection specialty.

CHAIRMAN VETTER: And does your board assure or does your board examine in any safety

aspects of radiation therapy?

MR. SAYED: Yes. The radiation protection exam covers all aspects of radiation safety practice in nuclear medicine, particularly with respect to safety practice in nuclear medicine, particularly with respect to unsealed sources involving therapeutic applications.

DR. WILLIAMSON: But not brachy therapy?

MR. SAYED: No, we don't cover that.

DR. WILLIAMSON: Or Cobalt 60 teletherapy?

MR. SAYED: No.

MS. MCBURNEY: And then under that, they would need to go into items under 35.50 about the other --

CHAIRMAN VETTER: We do have a mechanism to cover that. They would have to have modality specific training in those areas over and above their board exam?

MR. SAYED: That's right.

CHAIRMAN VETTER: Now, could you review again what the minimum requirements are? Three years experience, plus a Ph.D.?

MR. SAYED: For candidates who have or whose terminal degree is a Masters degree, we require five years of experience.

CHAIRMAN VETTER: Okay. And do you allow anyone with a Bachelors degree to sit for your exam?

MR. SAYED: The minimum academic requirement is a Masters degree.

CHAIRMAN VETTER: Okay. Thank you. Any other questions for Dr. Sayed? If not, thank you very much for coming and visiting with us today. And next on our list is Bill Uffelman from the Society of Nuclear Medicine, the American Board of Nuclear Medicine.

MR. UFFELMAN: I am Bill Uffelman, and I am General Counsel and Director of Public Affairs of the Society of Nuclear Medicine and I guess by default I am appearing for the American Board of Nuclear Medicine as they did not send anybody today.

As an attorney, my comment on all of this is that words do matter. Particularly, I have concern over the presumption that a program director's signature does satisfy the preceptor requirement.

I would want to see language that specifically says that. The grandfathering in 35.57 -- my concern is that the preexisting board certifications, because those conceivably a board for whatever reason may not choose to meet the new requirements, but somebody who is currently working

under the old board certification, that they in fact somehow don't lose their status.

I mean, the irony is that they were good enough in the old rule, but not perhaps they are not good enough. And at the same time, there is a seven year recentness of training requirements. Somebody in fact may have been an RSO, and may have been gone into academia, and that they are not an RSO.

But they are teaching the course that is training the people to be the new people, and I guess perhaps obtaining continuing education in the whole process, or a lifetime of education.

But in fact that they could return to that status, because the way that the language is currently written, it says that you have to be an RSO today, and you have to be a teletherapy or medical physicist.

You have to be a nuclear pharmacist today on somebody's license, when in fact whatever path you follow you may have moved off of the license at this moment in time.

Then I guess my last comment may be very specific and probably could be asked away from this, but I will ask it on the record. John, the timing on some of this, the ABSNM and ABMN were both given until Monday to respond to the letters that you sent them.

I got back from L.A. last night from our annual meeting of the Society of Nuclear Medicine, and I know that our office is closed today and that there is nobody there cranking out a letter for Monday.

You did get an e-mail or an e-mail was sent from ABNM, which I believe as I read it, at least responds to the two specific questions that you asked, and Gary of course has gone on the record on behalf of ABSNM, and I would ask that until we can get actual signed letters in with those documents be considered, and those statements be considered sufficient to respond to your questions.

MR. HICKEY: Yes, that's fine, and I wanted to clarify that anybody who wants to submit comments for consideration by the subcommittee or the full committee has until June 28th to submit those comments.

MR. UFFELMAN: As far as my letter to you, you can respond at any time.

MR. HICKEY: Okay. Thank you very much.

CHAIRMAN VETTER: Thank you very much, Mr. Uffelman. Questions?

MR. UFFELMAN: Yes, Ma'am?

MS. MCBURNEY: Just a comment on this recentness of training, and that has been one of the

issues that we have been grappling with, and I don't know if they are addressed in the new NRC rules. John, do you know?

MR. UFFELMAN: John, 35.159.

MR. HICKEY: It is there.

MS. MCBURNEY: Okay.

MR. UFFELMAN: It has been seven years.

MR. HICKEY: It is there.

MS. MCBURNEY: Because we do have some people returning to different aspects of user status, or RSO status that have been out of it for a while.

DR. WILLIAMSON: Well, it says seven years, or the individual must have had related and continuing education and experience since the required training and experience was required.

CHAIRMAN VETTER: Well, that is not in our charge, but we will certainly pass that comment on, right.

MR. UFFELMAN: I think it is, and it is obviously related, and you are worried about the new people coming in and I am worried about the people who are already here.

CHAIRMAN VETTER: Absolutely. Right. Any other questions for Mr. Uffelman? If not, thank you very much. We appreciate you coming over to visit

with us. Next on our list is Paul Chase from the American Osteopathic Board of Radiology.

MR. CHASE: Dr. Vetter and members of the committee, I am happy to be here to make some comments. I am Paul Chase, and I am Chairman of Radiology at the South Jersey Hospital System. I am the radiation safety officer for the system, and I am not on the Board of Osteopathic Radiology, but I am here representing the American Osteopathic Board of Radiology, and the American Osteopathic Board of Nuclear Medicine.

I am on the Board of Nuclear Medicine. I am the past president of the College of Radiology, and I am certified by the American Osteopathic Board of Radiology, by the American Osteopathic Board of Nuclear Medicine, and by the American Board of Nuclear Medicine.

The American Osteopathic Boards have a long history of working together with the NRC. We go back to 1982, when our diagnostic boards were actually the first boards recognized by the NRC in Categories 1 and 2.

And radiation oncology in categories five -- or in Groups 5 and 6 at that time. Over the years our basic standards for training have been modified,

always trying to keep up with the requirements of the NRC.

For example, at that time in 1982, I believe that they changed the requirements from 3 months to 6 six months of training, and we increased our training to six months at that time.

In the osteopathic profession, the American Osteopathic Association is the certifying board. The training requirements are established by the College of Radiology. Certification, however, and examination is by the boards. In the college we have a committee called the EESC, Education, Evaluation and Standards Committee.

And that committee sets the training requirements, and submits those to the committee, and to that Board of the College, and they then go to the Committee on Post-Graduate Training of the AOA, and eventually to the Board of Osteopathic Specialists.

But the power to certify comes from the American Osteopathic Association. Neither the Boards nor the College are autonomous. In a letter just a day or so ago, we are asking for -- and I won't go through the whole letter, but again we have been certifying since 1940 in radiology, but the names of the boards have changed over those years.

And we are included in most of the sections in the NRC requirements for authorized users, but we need to have some updating in Category 35.930 and 35.940, and 35.950, and 35.960. And I think -- and I am not going to go through that, as the letter is on file, but most of it has to do with housekeeping and bringing things up to date.

I would like to support all the comments that were made by Dr. Hendee and by Dr. Capp, and also say that the American Osteopathic Board of Radiology has been working with the ABR to keep our standards and requirements for examination at that level.

Now, as regards to the radiation oncology question, I don't think there are any programs, Dr. Diamond, in radiation oncology at this time, but I would say that it is very important to keep the board qualification in there in order to protect those people that are already certified.

The basic standards are available, and I would be happy to provide those to you for diagnostic radiology and radiation oncology, and even if there are no programs, they are constantly being updated, and they were updated in '99, and 2000, and 2001, and they are available for review at any time.

Pam Smith is our executive director, and

she would be happy to work with anybody in the NRC program. Thank you.

CHAIRMAN VETTER: Thank you, Dr. Chase. Any questions? Jeff.

DR. WILLIAMSON: I think in the proposed draft rule language for authorized user of 35.600 modality, specifies that the boards have to require of the candidates who sit for the examination a three year residency that is approved by the radiation oncology residency review committee of the ACGME. Do you meet the language of that standard for your radiation oncology?

I was looking at that

and I think further down doesn't it mention the osteopathic boards?

MR. CHASE: The osteopathic boards are listed I think in Part A, aren't they, as one of the explicitly recognized boards and then Part B, or whatever, as I can't remember the numbers, lists the broad criteria that all the boards, both current and future, have to meet.

And the major requirement that is in there is the three year residency requirement. So my question to you is --

DR. WILLIAMSON: Yes, we do, because it is

a four year program.

DR. DIAMOND: ACGME.

DR. WILLIAMSON: ACGME.

MR. CHASE: No, it would not be recognized by the ACGME because like I said initially the power to board certify in our situation comes from the American Osteopathic Association.

CHAIRMAN VETTER: It is a different pathway.

MR. CHASE: It is a different pathway.

DR. WILLIAMSON: Okay. So if we want to fully recognized the osteopathic credential in radiation oncology, we might have to modify that paragraph. That is my point.

MS. MCBURNEY: There is the -- what was it, the C-O-P-T?

MR. CHASE: Yes, the Committee on Post-Graduate Training.

MS. MCBURNEY: Right. The osteopathic equivalent.

DR. DIAMOND: What was that again?

MR. CHASE: The Committee on Post-Graduate Training.

MS. MCBURNEY: C-O-P-T-A-O-A.

DR. DIAMOND: The Committee on Post-

Graduate Training?

MS. MCBURNEY: Or the Council on -- the Committee or Council on Post-Doctoral Training at the American Osteopathic Association. We have that in our Texas rules.

MR. CHASE: I am glad you mentioned that. If I can make one more comment. It is very important for us to have recognition at the Federal level because in those States that are not agreement States, they will look to the Federal Register for how they are going to act.

We had that problem in Rhode Island, where there was no recognition at all, and there were only two osteopathic radiologists in that State, they would not have been able to practice nuclear medicine.

CHAIRMAN VETTER: Okay. Other questions for Dr. Chase? If not, thank you very much for coming to visit with us today. And our last registered speaker is John Googins, representing the American Board of Health Physics.

MR. GOOGINS: Good morning. I am Shawn Coogins, a member of the Board of American Health Physics, and I will keep my comments brief. For the record, I would like to note that at the June 14th and June 15th, 2002 meeting of the American Board of

Health Physics, we unanimously endorsed the ACMUI Subcommittee draft recommendations on training and experience requirements.

I would strongly urge the NRC to accept the recommendations of this subcommittee. As far as some brief requirements for certification at the American Board of Health Physics, requires for someone to be able to sit for the exam, a minimum of a Bachelors degree and six years of experience, which not strangely enough on the Part B requirements may be substituted no more than two years of experience for an advanced degree in health physics.

As far as the statement regarding written certification from a supervising physicist or RSO, the board certification requirements do have requirements for recommendations and signatures, and evaluation of the training and experience requirements for the individual to be able to just sit for the certification exam.

CHAIRMAN VETTER: Thank you very much. Questions for Mr. Googins? Jeff.

DR. WILLIAMSON: Does the examination cover modality specific issues of radiation oncology, nuclear medicine, and so on? Is there any content that the candidates are expected to master?

MR. GOOGINS: Yes, the examination covers a number of what we call domains of practice, which cover anything from oncology, nuclear medicine, general biomedical research, that the individual is expected to know and be able to sit to pass the examination.

One thing for the record to note is that when an individual practices in a particular area the code of ethics that the American Board of Health Physics requires everyone to sign requires them to not practice in an area which they are not competent to practice in.

DR. WILLIAMSON: Do you have an opinion about how we should phrases the requirement for modality specific training and education? Do you like the one that we have?

MR. GOOGINS: Personally, I think that as far as modality specific, that is really covered within the inherent ethics statement that we sign for people to be able to practice and supervise a specific modality. So I don't have a particular problem with the statement as it is written.

MS. MCBURNEY: I think as you mentioned that the Code of Ethics and the requirements, and for the modality specific training, would involve the

radiation safety regulatory issues, and emergency procedures, and clinical -- some sort of knowledge of the clinical procedures of any modality they would not have had previously.

MR. GOOGINS: Correct.

CHAIRMAN VETTER: So your code of ethics basically would require someone who is certified by your board, if they are working at a medical center, and you get gammaknife, they requires that they get the training in order to properly serve as Radiation Safety Officers for that modality.

MR. GOOGINS: That is correct.

CHAIRMAN VETTER: Okay. Other questions for Mr. Googins? I thank you very much, and I appreciate you taking your time to come visit with us.

MR. GOOGINS: Thank you very much. That comes to the end of our list, and just let me make sure that I have not missed anyone. Is there anyone who had signed up with the NRC to speak today and who I have missed?

(No audible response.)

CHAIRMAN VETTER: If not, I would like to take this opportunity to thank all of you. We know that you all have very busy schedules, and we know that this topic is important to you, but it is very

important to us, and we absolutely needed your input, and we very sincerely appreciate you taking the time to come here to visit with us here today.

The next -- let's get back to our agenda and see where we are here. The next item, I believe, is the additional discussion. The summary of meeting -- I'm sorry, additional discussion. So we have according to the schedule about 45 minutes to further discuss.

And with the input that we received from the members of the professional community, are there issues that the subcommittee would like to discuss and air out a little bit more?

MS. MCBURNEY: I think we can go back and revisit the types of certification that would be accepted for the radiation safety officer, or rather the types of board certification.

I think that we had eliminated all except those that were in health physics, but after hearing the comments, I think the ABR physics certifications probably would be --

CHAIRMAN VETTER: And ABSNM as well.

MS. MCBURNEY: ABSNM, yes. Right.

CHAIRMAN VETTER: So basically what we are looking for on our list are boards who specifically

examine in medical or health physics, to list them there, and if --

MS. MCBURNEY: And partly aimed at authorized user status.

CHAIRMAN VETTER: And basically that's it, and remove those that are aimed specifically at authorized user status and nuclear pharmacy, because that would -- there is an alternate pathway for them.

DR. CERQUEIRA: Richard, let me just ask a sort of procedural question from John in terms of the issue of whether to list the boards or what we had decided in the past was to let the NRC have a listing of boards that would not be specifically detailed in the Federal regulations.

So if we have a published rule in the Federal Register which lists boards, and then if we want to add another board, do we then have to go back to this whole revision process to the Federal Registrar, or how would that be handled?

MR. HICKEY: Well, the way the old rule is that you would have to go through the full rule making process to add a board. But there is a way to write the rule that it will list -- the rule could say these are the currently listed boards, and they are acceptable, plus any

other board that is subsequently recognized.

So that could be handled administratively without having to go through the rule making process.

DR. WILLIAMSON: That would address many of the concerns of the community if we could do it like that, so that when the package is submitted it is very clear who qualifies and who doesn't.

CHAIRMAN VETTER: Okay. So for 35.50, paragraph (a), we are going to recommend that the boards that are currently considered to be listed, of course we have to confirm that in fact they do meet paragraph (b).

But those that we would recommend be considered for the original list would be those that examine in health physics and medical physics. And nuclear medical physics as well; the American Board of Science and Nuclear Medicine.

DR. WILLIAMSON: Well, I think it is more complicated than this. It seems to me that there is an ambiguity in this regulation, and actually the two preceding regulations, too.

My impression seems to be that (a), and (b), and (c), really define the minimum criteria for who can be the RSO in the most complex of institutions.

And that the broad scope licensees that have the full range of modalities, and it sounds like to me that some of these certifications are very focused on certain modalities, such as -- and it sounded to me like the American Board of Science and Nuclear Medicine, Dr. Sayed had stated that they did not examine for knowledge --

MS. MCBURNEY: On sealed sources.

DR. WILLIAMSON: On sealed sources, or in radiation oncology, and I am not sure compared to the American Board of Health Physics that that certification is appropriate without qualification.

Maybe one could make the same arguments for the American Board of Radiology certifications in Nuclear Medicine Physics, and in Diagnostic X-Ray Imaging, that those should be limited to those uses, which are not in the content of the examination.

So I am not sure exactly how to do it, but it seems to me that we need to create a category of RSO that is focused on more limited range of byproduct medical services.

CHAIRMAN VETTER: Well, I think it would be my position that the purpose of listing the boards is to list those that examine candidates to determine that they are competent to practice medical health

physics without knowing all modalities.

MS. MCBURNEY: Right.

CHAIRMAN VETTER: And Paragraph (e) captures that.

MS. MCBURNEY: Right.

CHAIRMAN VETTER: Also, the purpose is not to distinguish between a small medical licensee and a broad scope, and that is what guidance is for. So this would just satisfy that if you want to be an RSO, there are several ways that you can do it.

One of the ways is to be certified by this board and have modality specific training, if that is required.

MS. MCBURNEY: Because basically in radiation safety what you are really wanting is what do you want the certification to cover, and basic radiation protection and instrumentation, and mathematics, and radioactivity, and radiation biology, and shielding, and those sorts of things, without getting into a lot of the medical physics, the treatment planning, and those sorts of things, because those are not included in radiation safety.

DR. WILLIAMSON: Okay. So then maybe what all needs to be done is to remove American Board of Radiology and replace it by a more detailed list of

physics boards.

CHAIRMAN VETTER: Right.

DR. WILLIAMSON: And ABR certification and therapeutic radiological physics, and in nuclear medicine, and the diagnostic x-ray, et cetera.

MS. MCBURNEY: Right.

DR. WILLIAMSON: And take away the physician authorized user boards from this list altogether.

CHAIRMAN VETTER: Right.

DR. CERQUEIRA: But we did accept the fact that authorized physician users would be eligible to be RSOs.

MS. MCBURNEY: Right, and that is under (d).

DR. CERQUEIRA: Okay.

DR. WILLIAMSON: Okay. So that seems like a reasonable argument. Then the Part B or paragraph (b) requirements have to be looked at very carefully.

MS. MCBURNEY: Yes, in conjunction with those.

DR. WILLIAMSON: And not so specifically focused on American Board of Health Physics that the other ones failed to quality.

CHAIRMAN VETTER: Right. We need to look

at the years of experience, and that is the main one, I think. And then under (c) we are going to add what we have been calling a preceptor statement, a statement that would ask that the candidate provide evidence that they have in fact completed some training.

DR. CERQUEIRA: And so we have agreed that we are going to just have completed training rather than satisfactorily completed, or competently completed?

DR. DIAMOND: Or professionally qualified.

MS. MCBURNEY: Well, I think you can define this as satisfactorily completed.

DR. CERQUEIRA: But Dr. Hendee said or made the point that that would be very difficult to do.

CHAIRMAN VETTER: What does that mean? They completed it certainly for the boards, and he was referring to I think on behalf of the boards.

DR. CERQUEIRA: And he didn't answer the question for the alternative pathways.

CHAIRMAN VETTER: Well, for the alternatives, that is up to us, and that is different.

DR. WILLIAMSON: I think there is more flexibility, and I think it is reasonable that all of

the speakers have indicated that board certification subjects the candidates to certain rigorous standards, and for someone who has not gone through that process to have a slightly stronger teeth in the preceptor statement doesn't seem unreasonable to me.

DR. DIAMOND: Right.

DR. WILLIAMSON: But it does seem to me that we want to craft a preceptor statement fairly carefully so that based on the legal technicalities that we don't exclude boards unnecessarily for no good public health reasons.

DR. DIAMOND: I have a couple of questions or comments. Firstly, fairly shortly there will be a process beginning whereby the currently enumerated boards will be reviewed by the NRC to ensure that they meet the current standards.

How is the NRC going to respond to a board that doesn't have a residency training program? Does that mean anything to you? For example, when the AOBR submits to you its requirements in its training program, will it be of any concern to you that they don't have a residency training program, or is that really a non-issue to you?

MR. HICKEY: Well, if the criteria don't state that that is a requirement, then that will not

be a concern, in the sense that as part of our process of listening to the ACGME and making the final decision we will have decided that that is not a criteria to make the decision.

DR. DIAMOND: Okay.

MR. HICKEY: Now, there may be individual people inside and outside the NRC that might be concerned about it, but it would not be the basis for the decision.

DR. DIAMOND: All right. My second question is with the language that we are adopting as an example, if you go and take a look at Section 35.390, unsealed byproduct material for which (inaudible) is required go down to paragraph (b)(2)?

As an example, with parallel language, this is parental administration of -- this is actually for iodine 131. Currently, it writes that the individual has satisfactorily completed the requirements of the above paragraph, and has achieved a level of competency sufficient to function independently as an authorized user.

My sense is that phraseology of level of competency can be deleted, and completely struck out. Fine. Number 3, just since we are all together, I think what we will do is for 35.690, based upon what

we talked about, I think the best place to put this preceptor/residency program statement, is actually not in (a)(4), but put that directly under (a)(1), just as a writing issue, a preceptor for residency program, director statement, that the above requirements have satisfactorily been met.

It makes no sense to put it as a paragraph (a)(4) if that person has no bearing on whether a certification has been recognized by the Commission and so forth.

MS. MCBURNEY: Right. And those being part of those requirements.

DR. DIAMOND: Right. And lastly if based upon what John just mentioned about AOBR, and it really not being an issue to him, and that they don't have a current radiation oncology training program.

And probably the best place to include the Council on Post-Graduate Training of the American Osteopathic Organization would be on paragraph (a)(1), and this included residency review committee of the ACGME, or -- and that is probably the best place to do it.

CHAIRMAN VETTER: Excellent point.

DR. DIAMOND: I am just trying to save us some e-mails.

CHAIRMAN VETTER: Right.

MS. MCBURNEY: We had heard comments that the person signing off on the training experience for board certification might not be an authorized user, but they might be the program director for a residency program.

So I was thinking that we may need to add language in 190 and 290 that to allow for that in Item (d)(2). Right now we have, "has obtained written certification signed by a preceptor or authorized user that meets the requirements."

CHAIRMAN VETTER: We could say preceptor, or. Is there something better than program director? Residency director

DR. WILLIAMSON: Training program director?

MS. MCBURNEY: Well, a training program director could be --

DR. WILLIAMSON: Well, let me ask a question. Is this for the criteria for accepting a board as a credentialing process or the alternative pathways?

MS. MCBURNEY: Both, because now that we are saying includes all the requirements of paragraph (d), unless we break that out.

DR. WILLIAMSON: And probably authorized user, or residency program director, would be reasonable and would cover both cases. Now, I am wondering --

MS. MCBURNEY: Now, will those program directors meet the requirements of 35.190, 290, or 390, or should we put that after --

CHAIRMAN VETTER: We are not asking that they do.

MS. MCBURNEY: Okay. So that would come after the 190, 290, 390.

CHAIRMAN VETTER: That's a good point

MS. MCBURNEY: Or equivalent.

MR. HICKEY: Could I just clarify? Is that -- is the term, residency program director, that is a recognized term that everyone will understand what that means?

DR. DIAMOND: Yes. So, Dick, what is our next step?

CHAIRMAN VETTER: The next step is that we have a conference call coming up and I would assume that before that time that we should each go back and craft a revised verbiage for each of the sections that we have discussed, and resubmit them to you.

DR. DIAMOND: Would that be helpful?

CHAIRMAN VETTER: Right. Our next step was to -- that when we are finished with our discussion here, go have lunch, and then come back and meet unofficially to talk about the mechanics of that, and how exactly we would take care of all of that.

MS. MCBURNEY: And some time-lines.

CHAIRMAN VETTER: And remind ourselves, and have the NRC staff remind us what the deadlines are and when we have to have things done, because we are going to need to have to write a report to Dr. Cerqueira and the ACMUI with what our recommendations are. And then we will be done.

And then they will meet by conference call on July 8th, or we will.

DR. DIAMOND: And then is the next step after that to start working on guidelines for these details of board recognition. In other words, we were having a discussion before about having to have language for allowing boards to have evolutionary changes.

I think Dr. Van Decker was alluding to that. Do we need to do any work along those lines?

CHAIRMAN VETTER: Our subcommittee does not.

DR. DIAMOND: Okay.

CHAIRMAN VETTER: Our charge is --

MS. MCBURNEY: This is it.

CHAIRMAN VETTER: So ACMUI will have to determine whether or not we want to do more in that regard. Any further discussion at this point? Yes, Jeff.

DR. WILLIAMSON: Is this an appropriate time to raise the issue of 35.300?

CHAIRMAN VETTER: Sure.

DR. WILLIAMSON: Okay.

CHAIRMAN VETTER: In terms of consistency?

DR. WILLIAMSON: Yes. Well, I think that some decision has to be made about the role of the radiation oncologist as an authorized user for radio-pharmaseuticals.

So I think we should think about that, and consider making a recommendation to the ACMUI and to the NRC about that. In the past, the old regulation included ABR certification and radiation oncology as one of the default credentials.

In the new regulation, the one that was just published in April. None of the boards were listed, and a far more focused set of requirements were put in that had the 700 hours of training and so on, and for the full unqualified right to practice

radiopharmaceutical therapy.

You know, 12 cases, a case experience of 12 cases distributed in four different categories is required, and then of course there were the single indication, more focused authorized users.

And I think we should give some consideration when we make the list of boards for 35.300 that we consider including certification in radiation oncology because there are a number of radiation oncologists that are very involved in the development of radio-immunotherapy.

And depending upon how nuclear medicine service is structured in various institutions, such as ours, for example, the radiation oncologist actually do administer all of the radionuclide therapy for malignant indications, and nuclear medicine does it for benign indications.

So one option is to think about the pattern that we have developed, which is board certification meeting these criteria, or alternative pathway, and modality specific experience.

So what we might do is craft the list of boards to include radiation oncology and have the 700 hours and so on that make it general. And then put as the "and" the 12 cases.

DR. DIAMOND: Would you enumerate the boards in this case again?

DR. WILLIAMSON: Yes, if we are going to do it with the others, we have to do it for this. So I think we need to make a decision about whether to recommend radiation oncology as was done in the past.

DR. DIAMOND: I think we need to do that, because as we change 690, some of those changes by the letter of the law may not allow you to do some of the things in 35.390. So we will have to make that change.

MS. MCBURNEY: Does radiation oncology and board certification include radiopharmaceutical therapy?

DR. DIAMOND: You are examined in that, and it depends on your residency training program how much experience you have. Where I trained, for example, we do all the therapeutic radionuclide administration.

So , for example, in my particular training program, I had extensive experience in the use of iodine for thyroid cancer, and some of the newer agents such as Zevalin and Bexxar for the use of refractory recurring non-Hodgkins lymphoma.

And in other training programs, you may be

not exposed to that. You will certainly be examined on it, but you won't have hands-on experience. Again, one of the other reasons that it is so important to have this modality specific training, we don't want a physician who may have passed a board on what these agents represent, and how they are used, has never seen it or handled it before, and all of a sudden is starting to use it, unless they have had some experience and some oversight in their use.

MS. MCBURNEY: Now, we are facing it in Texas with the introduction of some of these newer therapeutic drugs, such as the zevalin and the bexxar.

DR. DIAMOND: And the other thing is that I really don't think it is a turf issue at all, because again we are not in the business of saying who can and can't do it at a particular institution. That is the physicians of institutions themselves that have to work it out. This is simply a matter of being authorized.

DR. WILLIAMSON: So you would support then having as the modality specific "and" clause, the distribution of the 12 cases as is given in the current regulations on top of all of the certifications?

DR. DIAMOND: Yeah, I think so.

DR. WILLIAMSON: So we have a broad agreement and we could write that paragraph in that way.

MS. MCBURNEY: Okay.

CHAIRMAN VETTER: Yes. Other comments? If we don't have any other comments, I am going to suggest that John Hickey be given the opportunity to make any comments he has, and then I would suggest that we take an early lunch, and then come back and talk about the details of what our next steps are, and the mechanics, and so forth.

DR. DIAMOND: Richard, would it be inappropriate to perhaps suggest that since it is so early to just move on before breaking, because that may allow some of us to catch an earlier flight home?

CHAIRMAN VETTER: Sure. We can do that.

DR. CERQUEIRA: Is that going to be an open meeting or is that the committee?

CHAIRMAN VETTER: That's just the committee.

DR. DIAMOND: That's just the committee.

CHAIRMAN VETTER: Will that work, John?

MR. HICKEY: Well, if you want to continue, we will just continue to keep transcribing the meeting. There is on reason to stop the

continuity. I am not sure how long it will take.

CHAIRMAN VETTER: Okay.

MR. HICKEY: As far as your -- to give me the opportunity just to make some remarks, I think the discussion from my perspective -- and I think I can speak on behalf of the staff, has gone well this morning. I think you have hit on the key issues.

In particular, you have addressed the issue of preceptors, which affects almost all of the boards, and the issue of different modalities, and I think that you have come up with some good ways to address that.

I think you are also positioned on what you are going to recommend as far as listing the boards. I can't predict how that will actually come out, but I view that more as an administrative issue, rather than a substantive issue.

I think you have gone a long way in addressing the substantive issues, and you have some constructive and viable ways to address those.

CHAIRMAN VETTER: Well, the first issue is that each of us doing some minor revisions. It looks to me like it is minor, minor revisions of each of our sections, and then sending those to the entire subcommittee.

And as long as we don't have any debate on those minor issues, I will simply assemble all of those and forward those to Dr. Cerqueira for the ACMUI conference call on July 8th.

So that is the first issue. The second issue is the issue of continuity, and I guess I would raise the question do we need to draft sections for 390 and so forth, or can we assume that our intent is going to be carried forward, or will ACMUI draft those, or what?

We weren't specifically asked to address those issues, but only to address the issue of continuity.

DR. DIAMOND: It is probably -- and not that I have a particular desire to do any more work than I need to, but it is probably useful for me to go and work on 390 and send out a draft, and let us fine tune it around. It goes much faster that way.

DR. WILLIAMSON: I think it would be wise given the complexity of the 300 that it we take it on and at least come up with a draft.

CHAIRMAN VETTER: So which sections need to be done yet? There is a 390?

MS. MCBURNEY: There is a 390, the radiopharmaceutical therapy.

CHAIRMAN VETTER: Radiopharmaceutical therapy, right.

MS. MCBURNEY: Right. And Dr. Diamond --

DR. DIAMOND: Right, 390. I have a whole list of them.

DR. WILLIAMSON: And we have a 490?

DR. DIAMOND: So there is a 390 that needs some extensive work actually. And 392.

MS. MCBURNEY: And that is?

DR. DIAMOND: And 392 would be just the competency issue. So, 392, paragraph (c)(3), which is just deleting the level of competency phrase. Then I have 394, paragraph (c)(3), which is the same exact thing. Then I found 490.

MS. MCBURNEY: And 490 being?

DR. WILLIAMSON: Brachytherapy.

DR. DIAMOND: Brachytherapy. Which is (b)3), level of competency, and also you would have to go and change that parallel structure, right?

MS. MCBURNEY: Right.

DR. WILLIAMSON: I actually think that the 392 and 394 are going to be as much work as 390, because one you have the pattern of all of the boards, you have got to do it the same way.

DR. DIAMOND: Right. It is going to be

just repetition.

DR. WILLIAMSON: You can sort of recopy it, I think.

DR. DIAMOND: Right. Right. I will do that, and so that was 490.

DR. WILLIAMSON: And then there is 500.

DR. DIAMOND: And 491, again level of competency for -- and I am going to use Strontium-90, and that is paragraph (e)(3). I was really bored on the plane.

DR. WILLIAMSON: You have a lot of work.

CHAIRMAN VETTER: Are you volunteering to do all of this?

DR. DIAMOND: Well, once you do it once, you can cut and paste.

MS. MCBURNEY: Yes, cut and paste.

DR. WILLIAMSON: And then 590.

DR. DIAMOND: I may have created myself as the only authorized user for most of these modalities.

MR. HICKEY: Dr. Vetter, if I could just make a suggestion. If it turns out that you are running into time problems in wording the rules, if you could at least state what the principles and objectives, and rationale are that you are trying to get out with 390, and 490.

And at least the full committee could deal with that, and then the staff could follow up with the committee.

MS. MCBURNEY: Right. Is anybody going to do anything with the nuclear pharmacy issue?

CHAIRMAN VETTER: Yes, that is what I was hoping to ask, because that issue was brought up, and do we need to make any changes as a result of the presentation?

MS. MCBURNEY: Apparently they have done a preceptor issue on the acceptance of --

CHAIRMAN VETTER: Right. You have someone at your institution --

DR. WILLIAMSON: Yes, maybe I could speak with Sally Schwartz. It seems to me that we ought to do something. It seems unreasonable to discredit or marginalize the nuclear pharmacy board on what seems to be a technicality, and I suspect that they have good reasons for not requiring or requiring what they do.

And again unless there is a major public health issue with the way that they do it, it would probably behoove the NRC to adapt to them, rather than try to force the community just for technical legal reasons to conform to them.

So maybe I can talk with Sally and see if she can work up something.

CHAIRMAN VETTER: Right. If you could visit with her, and you are volunteering to look at all of those other sections during --

DR. WILLIAMSON: I think that someone else should take on 500.

CHAIRMAN VETTER: Yes, that is the diagnosis. Would yo be willing to do that, Ruth? That one is fairly straight forward, I think.

DR. WILLIAMSON: With the exception of the 190 and 290 series, where we have agreed that we are going to include in the criteria for recognizing boards, a preceptor statement that states satisfactory completion of a training program, I guess.

Many of the statements, or some of them anyway, have that the preceptor must be a diplomate of the board in question. Is that reasonable or unreasonable, or should we delete that?

Or is this a technical detail that we should leave for the staff to work out?

DR. CERQUEIRA: We probably should leave it out, because we are dealing with the radiation safety aspects and that is sort of what we are concentrating on.

DR. WILLIAMSON: For the therapeutic applications, let me remind you that the ACMUI made the determination in its recommendations that you could not separate safety from clinical competence, and that the proper selection of patients, and not giving high doses of radiation to wrong patients and so forth, resulted in the fact that safety and competence were sort of bound together.

So this is mainly an issue, I think -- and I specifically excluded 190 and 290, where the alternative pathway and the board recognition criteria are really the same. But for the therapeutic modalities, they are different.

CHAIRMAN VETTER: So how would it leave it then? You would require a preceptor statement if the person had completed the program.

DR. WILLIAMSON: Right. A preceptor who is a diplomate of the board in question tests to satisfactory completion of the training program by the applicant. I mean, that is how it is written now, the authorized medical physicist one.

CHAIRMAN VETTER: Cold it be a program director who is not necessarily boarded? I mean, we have kind of allowed that for the radiology.

DR. WILLIAMSON: Well, you see, medical

physics is an exception, where the formal structured training program is not a uniformly available structure.

CHAIRMAN VETTER: So we are talking just about the physicist rather than the authorized user?

DR. WILLIAMSON: Well, for the physicist, it is very special, and I thought -- I think for the physicist that you can make a really good case that it should be there, because it is one of the few items that really determines the structure,or places some bounds on the training program. So I think it is very reasonable to have it there.

CHAIRMAN VETTER: For the physicist.

DR. WILLIAMSON: For the physicist. For the physician, I am not sure that it really matters. I don't think so, because really the weight of the regulation, or the regulation really relies on the residency review committee to ensure that it is a proper training program.

CHAIRMAN VETTER: Okay.

DR. WILLIAMSON: So we leave it for the physicist, I guess, who is the consensus.

CHAIRMAN VETTER: Okay. Deadlines. Working backwards, we need this material for the conference call, and also for publications. So when

do we need a report to whom?

MR. HICKEY: We would like to have it to me by the 28th, next Friday.

MS. MCBURNEY: So does that mean that we would need to get it to you by the 25th?

CHAIRMAN VETTER: Yes, I would say that I would like to have everything by Wednesday, and preferably earlier to give us a chance to react to anything.

DR. WILLIAMSON: So Tuesday is what date?

MS. MCBURNEY: The 25th.

DR. CERQUEIRA: The 25th.

CHAIRMAN VETTER: The 25th, by five o'clock.

DR. CERQUEIRA: Eastern Standard Time.

DR. WILLIAMSON: Now, another general question. You know, the bulk of our report is actually draft language. Is there a need for some more discursive or explanatory material that discusses the rationale, or are you prepared to synthesize something based on all the comments that are made, or do we need to expand the first couple of pages?

MS. MCBURNEY: Or would that be after July 9th?

MR. HICKEY: I would say maybe a few more

sentences in the front to address the rationale is appropriate, but not an extensive -- I think you did a good job of preparing a short introduction, and then the wording as illustrations, the way it is drafted now.

DR. WILLIAMSON: So that has to be done by the 25th, too?

CHAIRMAN VETTER: Right. I will take that assignment, and I will expand that a little bit to take into account what we have done here today.

MS. MCBURNEY: And the public comments?

DR. WILLIAMSON: Do we need to react to the public comments?

CHAIRMAN VETTER: We all have those, and we have all heard them, and we all have copies of the written. I think when we write our sections that we need to review those.

DR. WILLIAMSON: But do we need to --

MR. HICKEY: You don't need to document or respond specifically to the comments. You just have to consider them as part of your process.

CHAIRMAN VETTER: Okay. The plan, David, is for us to -- for those of us who are doing some writing, to have it to me by five o'clock next Tuesday, at 5:00 p.m. Eastern Time, Tuesday. And if

it goes over into the evening, then that would be okay.

I will assemble everything in the form of a report, and get it to you by five o'clock Wednesday. You will have Thursday to react, and by five o'clock on Thursday, you need to send an e-mail to John Hickey. He needs it by the 28th.

DR. DIAMOND: Should these e-mails that we send back, should they be directed just to the subcommittee, or should they should be sent, CC'd, to the other organizations that have provided comment already

CHAIRMAN VETTER: No, just the subcommittee.

DR. WILLIAMSON: And the NRC.

CHAIRMAN VETTER: Well, just like we have been doing before. We have been copying the staff.

MR. HICKEY: After Dr. Vetter transmits it to us, we will transmit it to the attendees, and speakers, and stakeholders, and put it up on our website, and then it will be ready to go on July 8th for the full committee.

DR. CERQUEIRA: Now, John, once Dick has finished his portion, it would be good for the staff to go through to look for consistency. Again, the

"ands" or "or" requirements that are in there. Is that possible?

MR. HICKEY: Yes, we will do that. I don't think that we can do that before we post it, but we can note that by the time that the full committee meets, or even after if necessary.

MS. MCBURNEY: And fix those editorials.

CHAIRMAN VETTER: So are we okay with all of that? Questions? If there aren't any questions, I think we are done aren't we?

DR. CERQUEIRA: Yes.

MR. HICKEY: Okay.

CHAIRMAN VETTER: Thank you all very much. You have been an extremely task-focused subcommittee, and I appreciate that very much, and we have not wandered too far astray I don't think. And we are going to have our job done on time.

MS. MCBURNEY: And under budget.

CHAIRMAN VETTER: Was there a budget?

DR. WILLIAMSON: Actually, there is some money involved?

MS. MCBURNEY: No.

CHAIRMAN VETTER: Okay. So in terms of adjourning the meeting, I want to thank all of you for all the time that you put on, and for the time that

you will continue to put in on it. I would like to thank the support of the NRC staff. I have had extremely good support from John Hickey, and Linda Psyk in moving materials around, and getting us the public comments, and all that sort of thing.

And I would also like to officially thank the members of the public who took their time or the time out of their day to come here and share their perspectives with us. If there are no other comments, the meeting is adjourned.

(Whereupon, at 11:35 a.m., the meeting was concluded.)