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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

(ACMUI)

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MEETING

+ + + + +

MONDAY,

MARCH 22, 2004

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ROCKVILLE, MARYLAND

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The Advisory Committee met at 1:00 p.m.. in T10c2 of the Nuclear Regulatory Commission, 11545 Rockville Pike, Dr. Manuel Cerqueira, Chairman, presiding.

COMMITTEE MEMBERS:

MANUEL D. CERQUEIRA, M.D.
, Nuclear Cardiologist,
Chairman

LEON S. MALMUD, M.D., Health Care Administrator,
Vice Chair

DOUGLAS F. EGGLI, M.D., Nuclear Medicine Physician

NEKITA HOBSON, Patient Advocate

RALPH P. LIETO, Medical Physicist, Nuclear Medicine

COMMITTEE MEMBERS:

RUTH McBURNEY, State Robinson

SUBIR NAG, M.D., Radiation Oncologist

SALLY WAGNER SCHWARZ, RPh., Nuclear Pharmacist

ORHAN H. SULEIMAN, Ph.D.

Food and Drug Administration Representative

RICHARD J. VETTER, Ph.D., Radiation Safety Officer

JEFFREY F. WILLIAMSON, Ph.D., Therapy Physicist

NRC STAFF PRESENT:

ROGER W. BROSEUS, CHP, Ph.D, NMSS/IMNS/RGB

SUSAN CHIDAKEL, OGC

THOMAS H. ESSIG, Designated Federal Official,

NMSS/IMNS/MSIB

DONNA-BETH HOWE, Ph.D., NMSS/IMNS/MSIB

SAMI SHERBINI, Ph.D, NMSS/IMNS/MSIB

ANITA TURNER, Ph.D., NMSS/IMNS/MSIB

SANDRA WASTLER, NMSS/IMNS/RGB

ANGELA R. WILLIAMSON, NMSS/IMNS/MSIB

RONALD E. ZELAC, Ph.D., NMSS/IMNS/MSIB

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Dr. Malmud

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1:05 p.m.

MR. ESSIG: Okay. This is Tom Essig from NRC. I'm Designated Federal Official, and I have about 1:05 eastern time by my watch, and I think we should go ahead. I've heard a number of key people announce their presence.

So let me just start with my opening remarks.

DR. NAG: Dr. Nag joining in.

MR. ESSIG: Okay. As Designated Federal Official for this meeting, I am pleased to welcome you to the publicly noticed conference call meeting of the ACMUI.

As I said, my name is Thomas Essig. I am the Branch Chief for the Materials Safety Inspection Branch and have been designed as the Federal Official for this Advisory Committee in accordance with 10 CFR Part 7.11. This is an announced meeting of the Committee, it is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission.

The meeting was announced in the March 10, 2005 edition of the *Federal Register*.

The function of the Committee is to advise the staff on issues and questions that arise on the medical use of byproduct material. The Committee provides counsel to the staff, but does not determine or direct the actual decisions of the staff or the Commission.

The NRC solicits the views of the Committee and values them very much.

I'll request that whenever possible we try to reach a consensus on the various issues that we will discuss during this conference call, but I also value minority or dissenting opinions. If you have such opinions, please allow them to be read into the record.

As part of the preparation for this meeting, I have reviewed the agenda for members and employment interests based on the general nature of the discussion that we're going to have today.

I've identified the item related to St. Joseph Mercy Hospital dose reconstruction as posing a conflict for Committee member Ralph Lieto. Because that hospital is Mr. Lieto's current employer, I ask that he not participate in any of the Committee's decision making activities, other formal actions, recommendation or conclusions

related to the dose reconstruction effort for the St. Joseph Mercy Hospital case.

If during the course of our business, other members determine that they have a conflict of interest in matters before the Committee, please state it for the record and recuse yourself from that particular aspect of the discussion.

One administrative point which I would like to raise concerns the need for clearly identifying action items which are being proposed or existing action items for which status information is either sought or being presented. Clearly calling out these items during our discussion will facilitate a search of the transcript following the meetings. The existing process for Committee motions already does this. We would like to establish a comparable process for action items.

At this point I would like to perform a roll call of Committee members that may be participating today.

Dr. Cerqueira, I believe I heard you before?

DR. CERQUEIRA: Yes, I'm on.

MR. ESSIG: Dr. Malmud?

DR. MALMUD: Yes.

MR. ESSIG: And Nekita Hobson?

MS. HOBSON: Yes.

MR. ESSIG: Ruth McBurney?

MR. McBURNEY: Yes.

MR. ESSIG: Dr. Eggli?

DR. EGGLI: Present.

MR. ESSIG: Dr. Diamond, I understand a medical emergency and will not be with us today.

And Dr. Nag?

DR. NAG: Yes.

MR. ESSIG: Sally Schwarz?

MS. WILLIAMSON: She was on earlier.

MR. ESSIG: Sally was on.

MS. SCHWARZ: I'm here.

MR. ESSIG: Oh, you are here. Okay.

MS. SCHWARZ: I'm here.

MR. ESSIG: All right.

Dr. Vetter?

DR. VETTER: Here.

MR. ESSIG: Dr. Williamson?

DR. WILLIAMSON: Present.

MR. ESSIG: Okay. Ralph Lieto.

MR. LIETO: Present.

MR. ESSIG: Okay. And Dr. Suleiman from FDA? Okay. Not present.

And Dr. Schenter, I believe you said you here.

DR. SCHENTER: Yes.

MR. ESSIG: Dr. Van Decker? Who is our other new member, a nuclear cardiologist.

And Mr. Ed Bailey? Okay. Who is our new State Representative.

And I'll now ask the NRC staff to identify themselves. So we could just go around the room where I am and there may be others from NRC who have dialed in from other locations.

As I mentioned, I'm Tom Essig. And I'll go to my left.

DR. HOWE: Dr. Donna-Beth Howe in the MSIB.

MS. WILLIAMSON: Angela Williamson, MSIB.

MS. TURNER: Anita Turner, MSIB.

MS. WASTLER: Sandra Wastler, RGB.

DR. BROSEUS: Roger Broseus, Rule Making Guidance Branch.

MS. CHIDAKEL: Susan Chidakel, Office of General Counsel.

MR. ESSIG: Are there any other NRC staff on the line? I'm sorry.

MR. ZELAC: Ronald Zelac.

MR. ROSEN: Okay. You sound like you're 500 miles away, Ron.

MR. ZELAC: I'm using a headset. I'll try to speak loudly.

MR. ESSIG: Okay. Thank you.

And as far as members of the public, I know beforehand we had indicated that Dr. Carol Marcus, who I've already heard is present, and Dr. Jeffrey Siegel also is present.

Is Gerald White on? Rohsunda Drummond?

MS. DRUMMOND: Yes, I'm here.

MR. ESSIG: Okay. William Uffelman?

MR. UFFELMAN: I'm here.

MR. ESSIG: That was here?

MR. UFFELMAN: I'm here, yes.

MR. ESSIG: Okay. And Fairobent?

MS. FAIROBENT: Yes.

MR. ESSIG: Okay. And Cassandra Foens?

MS. FAIROBENT: No. Dr. Foens had an emergency.

MR. ESSIG: Okay. I believe that that takes care of the preliminary remarks.

And, Dr. Cerqueira, I will now turn it over to you to open the meeting.

DR. CERQUEIRA: Tom, do you have the agenda?

MR. ESSIG: Well, we only have two items on the agenda. One was related to a further discussion of Part 35, specifically the T&E issue and the 35.100. As you recall from our last noticed meeting, we had deferred until the next conference call issues that -- unfortunately Dr. Diamond couldn't be with today because the reason for deferring the issues is because I believe that Dr. Nag had to leave early and Dr. Diamond was not able to be present. And so we wanted to defer certain issues to this call so that we could have the opportunity of Dr. Nag and Diamond to both weigh in on them.

The other item that we wanted to discuss is the dose reconstruction issue, the status of the Subcommittee for the St. Joseph Mercy Hospital case.

So basically it was those two agenda items.

DR. NAG: Right. So the training and experience with -- was now that just related to the 1,000 series?

MR. ESSIG: I know -- go ahead.

DR. BROSEUS: This is Roger Broseus.

I'm understanding is we're actually supposed to be talking -- the aim of the Committee was to talk about 35.390 as it relates to radiation oncologists training experience and qualifications for --

MS. YAK: This is me, it's Frances Yak. Sorry about that.

DR. BROSEUS: So you guys can correct me if I'm wrong, but that was the significant T&E issue from the last agenda and why the radiation oncologists were to weigh in on the call.

DR. WILLIAMSON: This is Jeff Williamson.

That is correct, I believe.

DR. CERQUEIRA: Yes, that was my understanding, too. So, why don't we start with that. And, Jeff, maybe you could lead us through this.

DR. WILLIAMSON: Okay. Let me make a couple of comments.

I did circulate a written proposal to the group, so a little background. Prior to the new Part 35 going into force in October, the radiation oncology certification through the American Board of Radiology was an acceptable credential for being an

authorized user for radiopharmaceuticals, for which a written directive is required.

The new Part 35 basically put in place the old Part 35, or essentially put in place as Board qualification criteria the alternate pathway requirements, and among with perhaps other boards, American Board of Radiology, our old certification, couldn't meet those in part, because the way the Board examine is structured.

So the ACMUI T&E Committee attempted to try to rectify this, and you can see that is in the first half of the proposal I circulated. And what it essentially did was place the requirement for supervised clinical experience with 12 different cases distributed in 4 different categories at the end of the T&E requirement, which would be a common but separate requirement applying to those who are qualifying as authorized users both by virtue of Board certification and alternate pathway training.

So what I have done is, somehow I will mention although I believe it was the intent of the Subcommittee, the final proposal draft was sent forward by the staff, you know, in the Subcommittee's name did not have exactly this draft proposal in place.

So, as a follow up to the last meeting, I attempted to rewrite 35.390 in the form that you see before you. I hope you all have it. Would it be helpful if I stepped through it bit by bit? Okay.

So the proposal reads as follows: "Except as provided in Sec. 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under Sec. 35.300 to be a physician who:

(a) Is certified by medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section."

Let me make sure I'm reading the right one. Yes, I am. Okay.

"Whose certification has been recognized by the Commission or an Agreement State...To be recognized, a specialty board shall require all candidates for certification to:

1) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of..." so-and-so and so on. I won't belabor all of that. "Or a training program in nuclear medicine or a related medical

specialty that includes 700 hours of training and experience as described in paragraph (b) of this section.

Okay. So notice how it's stated. It basically says complete a 3 year residency in radiation oncology, approved by such-and-so or training in a nuclear medicine or related medical specialty program that includes 700 hours of training and experience as described as in paragraph (b).

So the idea is that there two groups in here. Radiation oncology who defines the appropriate residency, experience by means of this approval mechanism and the nuclear medicine community who defines what constitutes a program by reference to the alternative pathway requirements.

2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct materials; quality assurance, and

clinical use.

So I see that, you know, my version has a mistake. The second line shouldn't say "includes all the requirements of paragraph (b).

Then paragraph (b) is essentially unaltered from the current regulation. It says "Has completed 700 hours of training and experience" and it goes through the classroom, the work experience and lists, you know, the work experiences (A) through (E), whatever they are.

What it does not list now are 12 cases.

Then (c) says, paragraph (c) says: "In addition to meeting the requirements of (a) or (b) of this section, an authorized user of byproduct material authorized under 35.300:

(1) Must have experience, under the supervision of an authorized user, administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories."

And then these categories (A) through (D) are just like they are in the current paragraph

(b) except they're now moved to this new paragraph (c).

Okay. So (c)(1) has the 12 cases of supervised experience. (c)(2) is:

> "Have obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (a) or (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 35.300."

And it basically states the same requirements for authorized user preceptor that is in the current regulation. Basically requiring that the preceptor be an actual 35.300 AU or I suppose partially certified or recognized AUs might also be acceptable.

So that's the proposal. So the essence of it is is that radiation oncology doesn't have to comply with the letter of everything that's in paragraph (b), any other residency experience does.

But no matter which of the two pathways you go through, the board certification or the alternative pathway, at the end there is requirement (c), which is 12 cases plus preceptor stage.

MR. McBURNEY: This is Ruth McBurney.

In the paragraph (a) you said that the requirements in paragraph (b) did not apply?

DR. WILLIAMSON: Yes. What I should have excluded, in paragraph (a) the second line includes all the requirements of paragraph (b) in this section. That should be deleted. I meant to delete it. It's just a mistake on my part. I cut and pasted this from the current regulation.

So that's what I intended to do, so if you would make that correction in my proposal, I'd appreciate it.

DR. CERQUEIRA: All right. Now, Roger, are you on the line? I guess I have a couple of sort of -- and it really relates to part (a) where we actually are listing the boards.

DR. BROSEUS: Excuse me. Dr. Cerqueira?

DR. CERQUEIRA: Yes.

DR. BROSEUS: This is Roger Broseus.

We have a paper copy here that has about five pages. And I wanted to make sure that we were

all the same page.

I'm reading from page 3. It says "Proposed 390 Language: Jeffrey F. Williamson." Is that where you want us to be, Jeff?

DR. WILLIAMSON: Yes.

DR. BROSEUS: Thank you.

DR. WILLIAMSON: And we are talking about the paragraph (a) under the second line, the entirety of the second line as I see it on my screen should be struck out.

DR. BROSEUS: Thank you, Dr. Cerqueira.

DR. CERQUEIRA: Okay. That clarified it I guess for me as well.

All right. Questions for Jeffrey?

DR. EGGLI: Yes. Jeff, are you intending to say that basically everybody but radiation oncologists have to meet the 700 hour training requirement? And if so, why?

DR. WILLIAMSON: Well, the 700 hour requirement basically has inserted in it that the individual supervising it has to be an AU. And, you know, for the same reason that radiation oncologists couldn't be qualified to be AUs, even for their own modalities, it was because the board eligibility process doesn't require or doesn't have a mechanism

for having AUs and preceptor statements in it. So, that's one reason for moving it out.

But I would say the underlying reason is, is that -- and Dr. Nag can correct me. I'm trying to represent his discipline now.

I would say overall about 40 percent of radiation oncologists have a substantial practice in radionuclide therapy. So it is it not radiation oncologists. And they have very successfully pursued it under the existing regulations which doesn't require them to, you know, basically show any of this. Just simply the board certification alone was hardwired into the current regulation. So, what I'm trying to do, I guess the underlying intent is to create a pathway by which graduates of those particular programs that do have clinical experience can become authorized users for this modality and not have an unduly high burden placed upon them.

So the compromise I'm suggesting is that the detailed training and experience requirements, which were deleted by the way from the HDR brachytherapy and gamma knife T&Es, you know, be struck from this and stated in more general form, as I have done in the examine requirements. But then have the clinical experience requirement as a sort

of separate requirement that would allow those individuals to pass through the system of qualification of AU without significantly more hassle than they have now.

DR. NAG: Yes. A simpler possibility would be like if somebody is board certified in radiation oncology, they just have to show that they have done those three cases in those subjects, and therefore a total of those 12 cases.

You know, if you have radiation oncology board only limiting board and you show you had those cases that were done, then you would qualify for the 1000. That would be a shorter way.

DR. EGGLI: Okay. Again, Jeff, the way you have this written nuclear medicine physicians who are the primary practitioners of 390 are held to a different and higher standard than the radiation oncologists. Because in the current system, again, board certification in nuclear medicine without specific documentation of these requirements is adequate training to become a practitioner of 390. And I'm not sure that it's reasonable to set up two different classes of standards: One for radiation oncology whose programs may or may not include all of these requirements and one for nuclear medicine

who, although their programs traditionally do include all of these requirements, have never been in the past required to document that. I don't think it's reasonable to set up two different classes of users.

DR. WILLIAMSON: Well, I'm open to that. The only reason I left it that way is because I thought your community was content for yourselves the way the proposed regulation was written. So I just left it intact so it's exactly the same way as the regulation that was published in the *Federal Register* in December, I guess.

DR. NAG: I guess from a sense of --

DR. WILLIAMSON: I mean, I have no objection whatsoever to changing it and making it more performance based for the nuclear medicine community.

DR. EGGLI: Okay. I just think it's unreasonable to have two different standards. And that whatever the standard for training and experience is, it should apply uniformly and not discreetly.

DR. WILLIAMSON: I would accept that. I think then, you know, there has to be an alternative definition of what kinds of training programs are to

be included in the scope of this regulation.

And, you know, the only reason I left it as what I said in my preamble, is I had this perhaps mistaken assumption that you all, meaning you in the nuclear medicine community, were using these alternative pathway requirements to define what were appropriate residency programs rather than enumerate them.

DR. NAG: Yes. What we can say, anyone who has the nuclear medicine boards or the radiation oncology boards and can show that they have the preceptors in those qualifications will qualify. That makes it: (1) nondiscriminate, or; (2) simpler, and; (3) it ensures that they have, you know, sufficient training and handling in radioactive materials and they have the practical experience as well. I mean I think that would be one --

DR. WILLIAMSON: I certainly wouldn't oppose that.

MR. McBURNEY: And just a question for my own knowledge. The examination for the American Board of Radiology in radiation oncology does include unsealed radioactive materials handling?

DR. NAG: Yes, it does include that.

But it does not go into each specific -- it does require you know about both sealed sources, unsealed sources, but it doesn't categorize and say you must have 12 cases.

MR. McBURNEY: Right.

DR. NAG: So that's why I want to put those number of cases in there.

MR. McBURNEY: Right.

DR. WILLIAMSON: Yes. I agree, in fact.

MR. McBURNEY: No, I was just asking about the examination and (a)(2).

DR. WILLIAMSON: Yes. In physics when we have the didactic lectures to the radiation oncology residents, yes, we have to include lectures on radionuclide therapy, dosimetry, source handling, prescription. So, you know, we cover it in the same way we cover the didactic principles of brachytherapy.

MR. McBURNEY: Right. Okay.

DR. NAG: Yes. I think, you know, the thing is there is also you have written up, it belongs so long that at the end you try to figure out, you know, what is what and what even it capture. You keep it simple and say you need to have a board certification in radiology and

therapeutic radiology on implementing the system and demonstrate -- it makes life a lot simpler and it makes the board to be level --

DR. WILLIAMSON: Well, I certainly would support that. You know, I gave you my reasons for leaving it the way it was.

DR. NAG: Right. Right. I know.

DR. WILLIAMSON: And that I thought the --

DR. NAG: Well, what I meant is if all the other Committee members feel that would make things simpler, we can just have it that way. Make it a lot simpler.

DR. WILLIAMSON: I agree.

DR. CERQUEIRA: So, Doug and Leon, would that satisfy your concerns?

DR. MALMUD: It would satisfy mine.

Dr. Eggli?

DR. EGGLI: Yes. Essentially. I could go either way for either of the two routes, but I think that they should be the same for all 390 practitioners. So, yes, that would satisfy me.

MR. LIETO: I seem to recollect from Dr. Diamond that his concern was that some of the specifics, in particular are listed in Jeff's page 4

under sub item (2) where it lists the specific things like ordering, receiving and unpacking and so forth. His objection was the requirement for generator elution, quality control so forth that really they would never do or have reason to do in radiation oncology. And I think that that was one of the items that he was concerned about being a requirement for radiation oncology program.

DR. WILLIAMSON: That is, indeed. I mean, eluting generator systems, as I naively understand it, has to do with keeping on hand large stores of technetium-99m, I assume.

MR. LIETO: Right. It didn't have any relevance --

DR. WILLIAMSON: Yes, it doesn't have any relevance to this.

MR. LIETO: And so that was one of the things that, if my memory serves right about his concern, was that 700 hour piece.

I don't think there was an objection to the 700 hour requirement.

DR. WILLIAMSON: Well, I think there are several objections to it. One was missed by the original ACMUI Subcommittee on this business. And first of all, it says that it has to be under the

supervision of an authorized user that meets the requirements of 35.390(a). Okay. Now, that is not going to fit with the ABR paradigm of doing things, because even in brachytherapy and in gamma stereotactic, which are in the province very uncontroversially of radiation oncology, that requirement couldn't be met.

MR. LIETO: Yes. I don't object to that particular phrase being removed, Jeff. I think my point was that just the 700 hour requirement itself, I don't think there was an objection of that by --

DR. WILLIAMSON: Well, there is. If it's understood that the 700 hours devoted exclusively to radionuclide therapy. As I mentioned, at least half of the radiation oncology training programs do not have a significant component of this in their training program. And so if you can make the case that even one individual will be allowed to sit for the boards without having all of this, then it disqualifies the whole board from being a default credential for this process. So you have to really careful.

I think the proposal to get around the requirements is a good one, which is let's not be so prescriptive. Let's, you know, basically try to be

more performance based and just basically say you have to have this clinical supervised experience plus you have to have the board certification, which gives you a general and good training in radionuclide handling. And that plus the case experience will be enough for all applicants for 35.300 AU status, then we don't have to worry is this a good requirement, but that one a bad one. And simply leave paragraph (b) intact for the alternative pathway.

DR. NAG: I think I would agree. I mean I think we should make the simpler, easy to swallow and also make sure we cover the bases but yet not be too overly prescriptive.

MR. LIETO: So, Jeff, if I understand you correctly, then what you're suggesting also is that in your proposed paragraph (a)(1) that you would remove that last couple of lines there stating includes 700 hours of training and experience?

DR. WILLIAMSON: That's correct. So what we would do is replace training program in nuclear medicine or related medical specialty that includes 700 hours of training and experience that's described in paragraph (b) with some kind of enumeration of the appropriate residency training

experiences that, I guess, we will rely on Dr. Eggli, perhaps, our nuclear medicine colleagues on the Committee to supply. Because I don't know how to do it.

MR. McBURNEY: I think there's a ACGME residency, I mean, for that as well.

DR. WILLIAMSON: Yes. So I think that the good proposal is just to enumerate the appropriate residency experiences; diagnostic radiology, accredited residency would do as well as however many different kinds of specific nuclear medicine residency experiences there may be. Again--

MR. LIETO: What you're saying then, though, that all the nuclear medicine and radiology programs have to fit into the alternate pathway?

DR. WILLIAMSON: No, I'm not, at all.

MR. McBURNEY: No.

MR. LIETO: Well, you're striking it out of (a).

DR. WILLIAMSON: We're striking it out of paragraph (a) entirely. So in paragraph (a) there will be no reference to paragraph (b). That's what Dr. Nag and Dr. Eggli's proposal amounts to.

MR. LIETO: Well, if I'm reading it

right now, (a)(1) says: successfully completes a 3 year residency training in a radiation therapy program approved so forth and so on. So where do the other programs comes in?

DR. WILLIAMSON: Well, we're going to have to come up with language describing each one of them, like that. Okay. So all of the radiation oncology AU descriptions all have this phrase in there. They define themselves by using the words radiation oncology and residency program approved by the Residency Review Committee of the ACGME or Royal College of Physicians, or Surgeons, whatever it is. So we have to come up with a similar list for the other nuclear medicine and related medical specialties. And then, you know, they are no longer going to be defined by a reference to paragraph (b). And I think that's what Dr. Nag/Eggli proposal amounts to.

And paragraph (b) would remain, maybe with the removal of the elution of generators.

MS. SCHWARZ: I think that will be a good idea.

DR. WILLIAMSON: For a definition of the alternate pathway only. And so we would have then the criteria for (a)(1)(2) would be the criteria for

board recognition. Then paragraph (b) will be the sort of equivalence training and experience for alternate pathway. And then paragraph (c) is the common requirement for documented and supervised clinical experience with 12 cases plus preceptor.

And that way, you know, I think certainly would I think satisfy the needs of the radiation oncology community and allow my clinical colleagues to remain in this practice.

DR. VETTER: I think I like that proposal, but I have another question for Drs. Eggli and Malmud.

I don't know if you know the history. Where did three years of residency come from and is that an appropriate amount of time? Do you really need to be in a residency 3 years to use radionuclide therapy safety?

MR. UFFELMAN: If I may intrude on the Committee's discussion. In SNM's letter responding to the rule, we pointed out that when in fact when the radiation oncologists were added that the 3 year just in order in which it appears, the 3 years of radiation oncology got in there which made it appear that the nuclear medicine physicians were in fact subject to that, when in fact their residency is a

two year residency. And so we had actually suggested some alternate punctuation that made it clear how it should have been when that was first added by the ACMUI last summer.

MS. FAIROBENT: We did the same thing in our letter from us and the other associations. Basically it was to clarify that the 3 years residency applied to radiation therapy, that there was 2 years of nuclear medicine residency program or, any other program in a related medical specialty that includes the 700 hours.

One of the concerns in listening to this discussion I have of completely taking out any tie, and I throw this back to Dr. Cerqueira, I think that if you take out any reference at all to another related medical specialty including 700 hours, what does that do for the nuclear cardiology?

DR. CERQUEIRA: Well, this is for 390.

MS. FAIROBENT: Okay.

DR. CERQUEIRA: So our people would not really be involved in this.

MS. FAIROBENT: Okay.

DR. CERQUEIRA: And I guess the endocrinologists would not be covered by this because they're not using doses in this amount. Is

that correct, Jeff?

MS. FAIROBENT: Yes, that would be the 80 training under 392 and 394.

DR. WILLIAMSON: Yes. They have their own sort of single indication I-131 AU definitions.

DR. EGGLI: In response to the 3 year residency issue, if that 3 year just were removed altogether and it would be defined as a residency program approved by ACGME, the Residency Review Committee of the ACGME, then ACGME for radiation oncology determines that the residency is 3 years, for nuclear medicine 2 years, and is it necessary to have a reference to the time or just to the fact that the residency is approved by the Residency Review Committee of the ACGME?

DR. NAG: I was going to add that similar suggestion that let's not make one three year and one two year. We know that the residency program have their own standards. And so it let it be what the residency standards are and so long as they're are board certified, they are board certified. Let the board certification. Now radiation oncology 4 years. So we don't need to say how many years.

DR. WILLIAMSON: I agree with Dr. Nag's

suggestion. I think there's no reason. In fact, the requirement is now for 4 years of radiation oncology.

MS. DRUMMOND: This is Roshunda Drummond with ASTRO.

And I just wanted to point out that in the joint comment letter we also highlighted that point that the radiation oncology residency program far exceeds what's already stated in 35.390. So we also support that contingent that the 3 years just be taken out altogether and just to say what the program actually requires, the residency program already requires.

DR. CERQUEIRA: So it seems like the general agreement, yo know, leaving it up to the programs, the ACGME accreditation, would be the appropriate way to do it. And does anybody object to do doing it that way, to not specifically state a time period?

DR. MALMUD: I don't object, but I have one or two questions.

The first one is this: Is board certification a requirement or eligibility for board certification adequate?

DR. WILLIAMSON: It's board

certification.

DR. MALMUD: So we agree it's board certification?

DR. WILLIAMSON: Yes. I mean, there's two requirements; having the residency and passing the examine.

MR. McBURNEY: That's the A path, yes.

DR. MALMUD: All right. So then if that's the case, then under 35.390 subheading (a) and under that subheading (b) and then under (b) number (1) that should read: "To successfully complete ACGME board certification in radiation oncology, nuclear medicine, or a program in related medical specialty..." etcetera. Is that the wording that is discussable?

DR. WILLIAMSON: I think that in this definition you can't have the word "related medical specialty." I think it has to be more specific.

DR. NAG: Yes. I believe that, too. Because, you know, radiation oncology and nuclear medicine we know that they do cover all of this.

DR. WILLIAMSON: And radiology, too.

DR. NAG: Yes. If you say and related specialty, someone may say well, I am in thyroid disorders and it's a related specialty and so I

claim a background.

So, the word related becomes very vague.

DR. MALMUD: Fine. What is the wording that is preferred? Could someone read subheading (b) paragraph (1) to me so that I can agree or disagree with it?

DR. WILLIAMSON: I suppose successfully complete a residency training program in a radiation therapy program approved by X, Y or Z. I guess, no. A radiation oncology, nuclear medicine, or radiology program approved by blah, blah, blah. But it may not be able to be so simple. I think you might have to have a separate phrase for each one, because I'm not sure necessarily all the nuclear medicine, radiology and radiation oncology programs are approved by the same entity.

DR. EGGLI: I think it actually is pretty much similar.

DR. WILLIAMSON: Okay.

DR. EGGLI: There's a ACGME, there's the Royal College of Canada, and there's the osteopathic group for nuclear medicine.

DR. WILLIAMSON: Okay.

DR. EGGLI: And I believe they're quite similar for diagnostic radiology as well.

DR. WILLIAMSON: Okay. Well, if that's so, then it could read --

MS. FAIROBENT: My only concern is trying to identify these, I'm looking back at the original language in subpart (a)(4) this type of stuff. And because, in fact, the certification titles have changed over the years, I'm a little concerned that if we start specifying and calling out certification areas, that we may in fact disenfranchise some people who have older certification titles.

In subpart (j) --

DR. WILLIAMSON: But hold on, Lynne. We're not enumerating certifications. We're enumerating residency experiences that are eligible that make a certification process eligible.

MS. FAIROBENT: Okay. But if you looked up in the old language under subpart (g), the ABR certifications were in radiology, therapeutic radiology or radiation oncology.

DR. WILLIAMSON: But those are the certifications.

MS. FAIROBENT: I would assume the residency programs pretty much back at those times, went along with it.

DR. CERQUEIRA: This probably falls into the area of grandfathering. I think what we're proposing is basically applicable to people who are starting training or currently in training. In some of these other issues, what do we do in terms of people who are currently practicing? But shouldn't they already be qualified, Jeff?

MS. FAIROBENT: They may not be on a license.

DR. WILLIAMSON: But, Lynne, why then aren't the 600 and 400 rules also subject to that criticism, and ACR never commented on that?

MS. FAIROBENT: The 600 and 400 was only the -- in fact, we did comment in the past on those, Jeff.

DR. WILLIAMSON: But it does say, it uses the word "radiation oncology residency" to define them. So why would it be wrong to use the word radiation oncology residency in 300 if we use it in all the other regulations?

MS. FAIROBENT: I'm not questioning on the oncology side. I'm trying to be sure we're all inclusive on the diagnostic radiology and nuclear medicine side. And just saying simply nuclear medicine, I don't think we are all inclusive for ABR

radiologists that are also certified and authorized users under 300.

DR. WILLIAMSON: So it probably means a little research needs to be done.

MR. ESSIG: Okay. You going to do it, Jeff?

DR. WILLIAMSON: Well, I thought the NRC had a staff?

DR. CERQUEIRA: Tom, any staff that can help Jeff out on this?

MR. ESSIG: Is the question whether or not we can do the -- I wasn't quite sure what Jeff's reference was to.

DR. WILLIAMSON: Well, I think the concern is that some research needs to be done to identify all of the types of residency experiences on the nuclear medicine side that we would want to put in the scope of this regulation. And --

DR. NAG: Well, one question is that, you know, they always have the alternative pathway to provide. If they are only going to be, you know, one or two or very few numbered, they can always use the alternative pathway.

DR. WILLIAMSON: Well, I think it's a legitimate question that Lynne raises. I think,

though, I'm basically a therapy physicist. I don't know the details of nuclear medicine certification and programs. So I think that this is a much better question for our representatives on the nuclear medicine side of the table to opine on.

DR. EGGLI: I mean, basically there are a limited number of certifications that effect nuclear medicine. There is American Board of Nuclear Medicine, there is the Canadian equivalent, which is the Royal College of Surgeons, there's an osteopathic equivalent. And that's straight nuclear medicine.

I think what Lynne was addressing was diagnostic radiology. But again, in diagnostic radiology, there's the American Board of Radiology certificate in diagnostic radiology. There is the certification in diagnostic radiology for the Royal College of Physicians and Surgeons.

MS. FAIROBENT: Right.

DR. EGGLI: And there's also a certification in diagnostic radiology for the post graduate training of the American Osteopathic Association.

So I think if diagnostic radiology is listed, then the only issue is to go backwards to

deal with the historical titles which have changed. And, again, I think the issue raised was maybe the grandfathering process takes care of that. And if the person hasn't practices in a time frame that's old, they may have to retrain anyway.

DR. BROSEUS: Dr. Cerqueira?

DR. WILLIAMSON: That's correct.

DR. BROSEUS: Dr. Cerqueira, there's a hand raised here by Roger Broseus. May I be recognized?

DR. CERQUEIRA: Yes.

DR. BROSEUS: One of the things that we tried to do when we were writing the proposed rule is to be less specific and use language that was nonprescriptive and general enough that would capture different areas.

And so the idea that I have is it sufficient, and this is a target maybe that I'm throwing up, to say radiation therapy and not say radiology and radiation oncology and a whole bunch of qualifiers that limits things overly? Is it sufficient to say that?

DR. WILLIAMSON: Well, remember that what has to be qualified in this paragraph (1)(a) is not the name of the certification and not really the

specialty that the practitioner is in, but it's the residency experience that you do have to delineate.

DR. BROSEUS: Okay. Thank you.

MS. FAIROBENT: Right.

DR. WILLIAMSON: So that's the key issue. So it's basically, you know, who approves residency programs for radiology and nuclear medicine, and within the 7 year time frame are there any ones that are left out?

I do think the argument that if they're more than 7 years old, it should be a nonissue.

DR. MALMUD: May I go back to a very concrete issue, and I'll try and reread section (b) line (1) again? About to successfully complete ACGME board certification or equivalent certification by the Canadian, British or Osteopathic Board for residence training in radiation oncology or nuclear medicine training program, or a program in a medical specialty that includes the 700 hours of training experience as described.

Now, it is true that ones that argue that an unrelated field may say it's related, but they would still have to document the 700 hours.

DR. WILLIAMSON: Maybe it's better to

have some sort of an out for a new program that might come along. I mean maybe, who knows, urologists of the future will find radionuclide therapy becomes a central modality in their field and --

DR. MALMUD: Well, they have qualified.

DR. WILLIAMSON: Yes. And then this provides then if they can show that it does have this amount of activity, 700 hours, then they could qualify.

DR. GOLDBERG: I think --

DR. MALMUD: Excuse me, but what I wanted to say is that if they are urologists and they are ACGME approved, and they can document that they've had 700 hours, they will qualify under this hypothetical in the future.

DR. WILLIAMSON: Okay. I think so. But you know the intent was to not have the nuclear medicine radiology or radiation oncology programs have to have -- live up to the letter of paragraph (b).

DR. MALMUD: The nuclear medicine residence training programs exceed the 700 hours of training.

MR. McBURNEY: Right.

DR. MALMUD: So the nuclear medicine programs are not threatened by it. What we were concerned about as practicing or former nuclear medicine physicians is NRC not become prescriptive in demanding training requirements for board certifications, since that is a board certification issue and not an NRC issue by tradition.

DR. WILLIAMSON: Right. I think that's a reasonable point.

So I think your language with the exception of maybe adding in radiology would be a point appropriate.

DR. CERQUEIRA: Is that a motion, Jeff?

DR. WILLIAMSON: Yes. I guess with the addition of diagnostic radiology, I move that we accept Dr. Malmud's rephrasing of paragraph (a)(1).

DR. CERQUEIRA: Do I have a second?

MS. SCHWARZ: I second the motion.

DR. CERQUEIRA: Okay. And any further discussion?

MR. LIETO: I thought Dr. Malmud's, correct me if I'm wrong, I thought you were say was B as in boy (1) that you were rephrasing?

DR. WILLIAMSON: No. No. Successfully complete a residency training program approved by

the Residency Review Committee of the ACGME or Royal College of Physicians and Surgeons of Canada or the Osteopathic one in radiation therapy, nuclear medicine or diagnostic radiology. Period. I think you have to say, and then or in any related medical specialty that includes the 700 hours of training and experience as described in paragraph (b) of this section.

MR. McBURNEY: There you go.

DR. WILLIAMSON: So that's a separate sentence.

DR. MALMUD: That is correct, Dr. Williamson.

DR. WILLIAMSON: So that's how he has stated it, I think.

Yes?

MR. McBURNEY: I think that will work because their certification still has to include it to be accepted item (2) as well.

DR. WILLIAMSON: That's correct. So item (2) then, (a)(2) is: "Pass an examination," which basically then lists these things in a more sort of generic fashion.

MR. McBURNEY: Right. To be accepted as the board --

DR. WILLIAMSON: I should say, in a less descriptive fashion kind of lists all the things that are covered in a very prescriptive fashion in paragraph (1)(b).

DR. MALMUD: That is correct. I did want to specifically ask Mr. Eggli as a practitioner of nuclear medicine whether he's in agreement with this?

DR. EGGLI: Yes, I am.

DR. VETTER: I have a question. The residency program in diagnostic radiology, does it currently include radiation therapy using unsealed radioactive materials?

DR. MALMUD: The answer to your question might come best from a member of the ABR, but my understanding is that in the past and even into the future no fewer than 3 months would have been required. Is that correct?

DR. VETTER: Well, I think their rotation through nuclear medicine is changing to three months. I think that is correct.

DR. MALMUD: Yes.

DR. VETTER: Now will that include all of these therapies?

DR. WILLIAMSON: Well if it doesn't,

they'll fail to qualify on part (c) then. Okay. Remember (a) or (b) and (c). So if the individual does not actually have the 12 cases of documented and supervised experience, that individual won't. But if any radiologist who presents their board certification certificate in evidence of a preceptor statement and the 12 cases, will then a AU.

DR. MALMUD: At our institution, which is not meant to be a template for the country, we are requiring that the residents document and keep a record of the specific cases with which they were involved in order to meet the requirement.

DR. EGGLI: We do exactly the same thing with radiology residents. We provide in diagnostic radiology residency all this subpart (b) requirements. And then it's up to the individual to determine whether they want to garner all the necessary cases to demonstrate the direct case related experience in subpart (c).

And so I think that the statement is correct that you need that subpart (c) experience as well, and that's where different radiology residents within a residency program choose whether or not to participate in the unsealed source therapies.

MS. FAIROBENT: Dr. Vetter, that's my

understanding from my discussion with the nuclear medicine board trustees from the American Board of Radiology as to what the diagnostic radiologists are, pardon the pun, exposed to during their nuc med rotation. And I do think that you need a preposition between (a)(1) and (a)(2), Jeff, in your draft. You did not have an "and," and I believe that you mean paragraph (a)(1) and (a)(2) to reply.

DR. WILLIAMSON: That is correct.

MS. FAIROBENT: Okay. So I think you are missing an "and" there.

DR. WILLIAMSON: Well, I'm an amateur rule writer.

DR. CERQUEIRA: A little qualification. It's 3 months of nuclear medicine now.

MS. FAIROBENT: That is what they're going down to, which is roughly the 700 hours.

DR. CERQUEIRA: Okay. Three months of nuclear medicine total for everything. Okay.

All right. Any further discussion on this?

DR. VETTER: I'm satisfied with that answer. I think that takes care of the concern I had about -- I was a little concerned that the 3 months residency would not include these therapies

but, in fact, if a resident wants to include them, he simply has to make arrangements to include them.

MS. FAIROBENT: And provide the documentation.

DR. CERQUEIRA: And provide the documentation.

DR. VETTER: Right. Yes. I think that's reasonable.

DR. CERQUEIRA: Shall we call the question?

All in favor of the motion by Jeff.

ALL: Aye.

DR. CERQUEIRA: Opposed? So it's passed.

All right. We've spent 56 minutes on this one item.

DR. BROSEUS: There's a virtual hand here from Roger Broseus.

One of the questions that the Commission directed us to ask when we published the proposed rule, are the changes being proposed adequate -- I'm going to paraphrase -- to protect health and safety? And I personally feel that it would be useful to make sure that I understand for the record of these deliberations the ACMUI people who are speaking, the

members of the Committee feel that there is adequate health and safety protection built into the training programs, the certification programs, the residency programs that AUs are getting sufficient training as well as being tested on this. That would be a useful sort of thing to discuss very briefly for the record, I believe.

DR. MALMUD: The 700 hours is adequate from my perspective. The testing, of course, is variable from institution to institution but is consistent at the time of sitting for the boards.

DR. NAG: I think while we were discussing all this, we were keeping in our minds about the safety and the training be enough. So I think I'm satisfied.

MS. SCHWARZ: I do have one question about the training. Jeff had raised it earlier. I don't know that it's an issue, but it might be something is to take off (H) under the training section.

DR. BROSEUS: Who is speaking, please?

MS. SCHWARZ: Sally Schwarz.

MR. ESSIG: Sally, this is Tom Essig.

The only thing that I know our previous discussion focused on generators for technetium-99m,

but then we were wondering if there aren't other generators that might come into play, and even those that may be tagged some other compounds, some other radiolabeled compounds that may be other than diagnostic.

I was only raising it because that (H) may be broader than just the normal technetium-99m generators.

DR. MALMUD: Sally?

MS. SCHWARZ: Yes.

DR. MALMUD: May I address the issue? I agree that it's a technique which is not used in many departments today. However, with the future being uncertain as to what will be coming down the pike, including other generators, it is practical to send the resident for several sessions to a radiopharmacy house to witness and participate in the experience of eluding a generator for those the departments that now receive unit doses and don't have resident generators any longer.

It is something which few of us have done since our years of training, but I think the experience will resonate in our minds as to what we did and by participating in it at the time.

MR. LIETO: I would like to support

Sally on removing that section (H) from the radiopharmaceutical therapy training and experience. If I need to make a motion, I will.

My reasoning is that the generators are more important for the training experience for diagnostic and imagining uses. And really I think, at least the impression I got also from Jeff, was that really is not apropos for radiation oncology. And I think that is the section that it's under.

MS. SCHWARZ: Excuse me. I just wanted to mention, I do agree that there are generators in the pipeline essentially for therapeutics. But they are much different in terms of operational capacity than -- not much different, they are different.

But I think that the focus on the training is really the comment on safety issues, seems better addressed time wise not necessarily involve eluting generators, but I mean I think that belongs in diagnostic.

That was my thought.

DR. WILLIAMSON: Yes. I agree, too. I think that if we were to put such a requirement in there, it must be made much more generic and somehow refer to appropriate packaging and preparation of the radionuclides.

MS. SCHWARZ: Right.

DR. WILLIAMSON: Rather than -- this is sort of -- you know, really obsolete sort of requirement and I agree with Sally. I think the time could be better spent in didactic or practical training with real radioactive drug preparation.

DR. CERQUEIRA: I support those comments as well. But I think do we need a motion to remove it?

DR. WILLIAMSON: Well, maybe we could amend the motion that we have on the floor, which is essentially to remove what is called paragraph (b)(2)(H).

DR. MALMUD: I have a question for Eggli.

Eggli, do you agree with removing it?

DR. EGGLI: Yes. I really think that the generator stuff is -- and we still use generators in my practice. That's 200 series and at the current time there's certainly nothing in 300. And I think it might be appropriate, as Dr. Williamson suggested, to modify the statement to include a training in the preparation that's appropriate for the therapeutic radiopharmaceuticals.

DR. MALMUD: Oh, it's covered under

(2)(c). (2)(C) says: "Calculating, measuring and safely preparing patient or human research subject dosages." So I think that covers it.

DR. EGGLI: Yes, I think you're right, Jeff.

So I fully agree with removing (H). That's a 200 issue.

DR. MALMUD: I remove my objection.

DR. WILLIAMSON: Okay.

So then if it's removed, so perhaps --

DR. HOWE: You have a virtual hand raise.

DR. MALMUD: -- would be helpful if I may summarize what the regulation now says. So (a) says it's certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a residency training program in radiation therapy, nuclear medicine or diagnostic radiology approved by the Residency Review Committee of

the ACGME, Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; or alternatively a residency training program in a related medical specialty that includes 700 hours of training and experience as described in paragraph (b) of this section, and" and then (a)(2) is unmodified.

And then paragraph (b) is unmodified with the exception of deleting paragraph (2)(H).

And otherwise it reads as I have written it. So I think that's the motion.

DR. CERQUEIRA: Okay.

DR. HOWE: Dr. Cerqueira?

DR. CERQUEIRA: Yes.

DR. HOWE: This is just kind of an historical. I think (H) was put in there by the group that wrote the rule so that it was clear that the 35.300 physicians had training and experience in preparing radiopharmaceuticals and therefore could

be recognized as someone that could prepare radiopharmacueticals under 100 or 200. Because the old Part 35, the 300 physicians were specifically excluded from preparing radiopharmaceuticals because their training was only 80 hours.

So I don't know how that's going to fit into your elimination of (H).

DR. CERQUEIRA: Jeff, do you care to comment?

DR. WILLIAMSON: I would prefer to defer to those with more expertise.

I'll only say that, you know, it seems that the specific technical requirement is really irrelevant to the modern practice of radiopharmaceutical therapy.

DR. HOWE: I don't think --

DR. WILLIAMSON: And the staff should perhaps come back with a more up to date phraseology or requirement that captures their concern.

DR. CERQUEIRA: Donna-Beth?

DR. HOWE: I think one other point was I don't think (H) was specifically for the technetium-99m generators. I think they were talking about the other generators that were coming down the line for therapy.

MR. LIETO: No. That's just taken right out of the old requirement. There was, I don't think, anything to do with -- it's nice that you would think that we had all this future foresight, but that wasn't really the intention. This was just a rephraseology of the old requirements.

DR. WILLIAMSON: I don't think that the word generator is appropriate for the way, you know, even fairly complex preparations are done.

MS. SCHWARZ: I agree with that.

DR. WILLIAMSON: I mean, it makes no sense. It refers specifically to a mother/daughter radioactive decay manufacturing process, as I understand it.

DR. CERQUEIRA: Does anyone support keeping that language in there from the Committee?

DR. EGGLI: I do not support keeping the language in there.

MS. SCHWARZ: I don't think it's necessary at this part of --

MR. McBURNEY: If there's a concern about that they know how to actually measure and test for the purity and the nuclides measurements and safety prepare the dosage, if taking out age is a concern to staff, maybe if they could modify (c)

to include whatever concerns were there.

DR. WILLIAMSON: But I'm trying to think of the radioactive, the radiopharmaceuticals I've had contact with in radiation therapy. If there's any where, you know, where there was a purity test that's part of the state of practice?

MS. SCHWARZ: Currently there aren't any that are available.

DR. WILLIAMSON: Yes. So any it's too speculative a requirement.

MR. McBURNEY: Okay.

DR. WILLIAMSON: I mean, I'm trying to think. And I certainly haven't had the broadest experience, but we did use seven or eight radionuclide preparations.

MR. McBURNEY: And the tagged antibodies are not --

MS. SCHWARZ: Typically it's iodinated antibodies and the iodine is not produced as part of the generator system.

MR. McBURNEY: Right.

MS. SCHWARZ: So, I mean, yttrium, those are not available as generator products radionuclides.

DR. EGGLI: Not only is a throwback to

technetium generator, but it's a throwback to the early day of technetium generators when there was an issue with radiochemical purity of what came off the silica column. And, again, even with modern generators, that's almost never a problem. We teach our residents about it for historic interest only.

MS. SCHWARZ: And really the wording here is and processing elute with kits to prepare labeled radioactive drugs. And I really don't think it will be useful in therapy at this point in time.

DR. CERQUEIRA: I think you've got the sense of the Committee that there is not much support for keeping this here and for their reasons. Given the time, I suggest we call the question with Jeff's new proposal.

MR. ESSIG: Call the question. Go ahead.

DR. CERQUEIRA: All in favor?

ALL: Aye.

DR. CERQUEIRA: Opposed? Anyone abstaining?

Okay.

MS. WILLIAMSON: Dr. Cerqueira?

DR. CERQUEIRA: Yes.

MS. WILLIAMSON: There's going to be a

phantom person named Mary-Beth on the transcript now.

MR. McBURNEY: Donna-Beth.

DR. CERQUEIRA: Oh, I'm sorry. I've done that before. Okay. Sorry, Donna-Beth.

DR. WILLIAMSON: Okay. I have edited this document, so I will send it forward then so the staff has something to -- and the Committee members to look at to determine whether this is -- it keeps a detailed record of what we voted on.

DR. CERQUEIRA: Okay. That's good.

MR. ZELAC: Dr. Cerqueira?

DR. CERQUEIRA: Yes?

MR. ZELAC: This is Ronald Zelac. Could I just interject for the previous from the Advisory Committee about the fallout of taking out the generator elution aspects of the 390 requirements. Currently, as Donna-Beth pointed out, one can become an authorized user after 290 if in fact they are authorized user under 390.

And I've heard several statements to the effect that although it's not as normal these days or as prevalent, there is still some aspects of generator elution that's important for diagnostic work.

So what I'm really saying is that the fallout of removing the elution requirements of 390 is going to put into question the ability for someone who is recognized under 390 now be recognized as an authorized user under 290 if generator elution still has relevance for diagnostic work. I'd just like some feedback if possible from the Committee on this issue, which is a secondary issue to the one that's just been discussed.

DR. CERQUEIRA: Well, I guess one way to phrase that is should it be taken out of 290? What's the Committee's feeling on that?

MS. SCHWARZ: No.

DR. CERQUEIRA: Sally says no. Okay.

MS. SCHWARZ: Well, no. I'm thinking about that statement, actually.

And as far as taking it out of 390, I mean if it's an historical problem, maybe it just needs to be reworded.

DR. WILLIAMSON: Well, now are you speaking with respect to 290 or 390, Sally?

MS. SCHWARZ: Well, I'm trying to see what kind of confusion he's talking about people not being able to be licensed in 290.

DR. WILLIAMSON: Well, the issue is that

now apparently somebody who qualifies for 300 can automatically qualify for 200, which is imagining with localization.

MR. ZELAC: That's correct.

DR. WILLIAMSON: That's the way it's structured now. I guess that's a question I would have to defer to the nuclear medicine community on.

DR. VETTER: I think we have just created an inconsistency between 390 and 290.

DR. WILLIAMSON: Well, not necessarily. I mean, the localization and imagining could potentially pose different safety --

DR. BROSEUS: Oh, it's true. It does. It does. But if we require that anyone authorized under 290 -- or that the training authorized for 200 under 290 -- the training requires eluting generator systems, then why would we allow anyone else to be authorized under 200 who hasn't had that training.

MR. LIETO: Would going back to that subitem (c) under part (b)(2) would in guidance space could we say that calculating measuring and "safely preparing patient or human research subject dosages must involve the elution process of measuring and preparing."

MS. CHIDAKEL: And from a legal

standpoint we can't make any requirements in the supplementary information that are not in the rule. We cannot say any "musts" unless they're supported the regulations.

MR. LIETO: No. What I'm just saying is that safety preparing dosages in guidance space would be described as including eluting and preparing dosages from a generator.

DR. WILLIAMSON: I think that that's unreasonable. We've just said that for 300 uses, that's not a reasonable requirement. So I think the question is now if some proaction of the community that, say, a radiation oncologist might be a good example. So are there any radiation oncologists who are going to be disenfranchised by virtue of doing radio oncology rather than say passing the examine and doing 12 cases, and then they're going to be unhappy that they can't do nuclear medical localization and imagining because their program didn't including eluting a generator?

This is really the issue, I guess. Maybe there are other examples that perhaps Dr. Zelac can give.

DR. BROSEUS: The relevant item in 35.290 includes requirements in 35.390. And one

could fix the problem at issue by saying 390 and incorporating in this paragraph by reference 290(g) which includes eluting generator systems appropriate blah, blah, blah.

DR. WILLIAMSON: So 290 basically refers to the 390 paragraph (b)(1), is that correct.

DR. BROSEUS: That's correct.

DR. WILLIAMSON: Oh, I didn't realize that.

DR. BROSEUS: It refers to 390. And if one incorporates a back reference to the experience -- the work experience eluting generators in 35.290, I believe that would fix your problem.

DR. CERQUEIRA: Jeff, are you in agreement that it would?

DR. WILLIAMSON: I guess so. Yes. I mean, I'm a little out of my area here. I haven't actually read the 290 one for a long time.

DR. CERQUEIRA: Dr. Eggli, would that be acceptable? Would it solve the problem?

DR. MALMUD: I think that it would.

DR. VETTER: I think it would also.

MS. FAIROBENT: Dr. Cerqueira. I just want to be sure I kept the right tie from Roger.

Roger, you suggesting then under

35.290(b) to add a statement? As currently written it is "As an authorized user under section 35.390, or, before October 24, 2000, section 35.920 or a group equivalent --"

DR. BROSEUS: No.

MS. FAIROBENT: --"and" paragraph and then it was would be (c)(1)(ii)(GG)?

DR. BROSEUS: I was referring to the last paragraph in 35.290. We might have to go back and look at paragraph (G) also.

I think that for the purposes of our rule writing, if the ACMUI were to indicate that by way of motion that this is their intent that we could look at the rule language and adjust it appropriately to make sure that the inclusion of 35.390 authorized users with experience eluting generation systems as enumerated in 35.290 now would qualify them.

DR. WILLIAMSON: Yes. Here's what it says under 290 now, as I understand it. Is that except as provided in the -- the licensee shall require authorized user of byproduct material for 35.200 to be a physician who is certified by a medical specialty board or (b) is an authorized user of 35.390 or equivalent Agreement Statement

requirements or (c)(1) has completed 700 hours of training.

That's the one you're concerned about?

DR. BROSEUS: Well, it's in two locations. In paragraph (b) and in paragraph (c)(2).

MS. FAIROBENT: Yes. Roger, under paragraph (c)(2) I say where you're at. I think that the incorporation by the reference to paragraph (c)(1)(ii)(G) is going to have to go into both places if that's what ACMUI is requiring. Because I think you're going to have to have a preceptor authorized user from 390 be somebody who has the experience with eluting the generator.

So I think you've got to look at it at both places. That's why I was asking for where you were sticking it, because I was looking at the other place.

DR. BROSEUS: Thank you.

MS. FAIROBENT: You're welcome.

DR. CERQUEIRA: All right. So, Jeff, where do you go with this next?

DR. WILLIAMSON: Okay. Are we through with this or -- well, this seems awfully complicated. And since even for nuclear medicine

imagining, doubts have been raised about the relevance of this requirements. Maybe the nuclear medicine representative should consider a proposal to strike it from 35.200.

DR. EGGLI: Although there are fewer now, there are still processes which use generators, including mine. So I'm reluctant to strike it from the 200 series.

MS. SCHWARZ: I agree. It should not be struck from the 200 series for certain. I'm just concerned now that having it taken it out of 390, that it's a bigger problem than it solved.

DR. CERQUEIRA: And from the perspective of the nuclear cardiologists, nearly all of the new unit dose pharmacies which really generators are usually not part of the normal practice setup. So for that group it is not a big requirement. Currently most of them will go a radiopharmacy and spend some time there, you know, getting the exposure. But in their daily practices, it's not something that they have to do.

DR. MALMUD: We agree it's something they don't have to do, but we certainly believe that it is something that should remain with the 200, do we?

MS. SCHWARZ: Yes, I agree.

MR. McBURNEY: I agree that it needs to stay as part of the training in 200. The old generator type, the technetium or the new one coming on board and a lot of facilities still use them.

DR. MALMUD: Right.

DR. CERQUEIRA: Okay. Then that's fine.

We should probably move on.

Now, Tom, let me get some clarification. What's the duration of the conference call? this thing could go on forever?

MR. ESSIG: Until 3:00 p.m. eastern. So another 40 minutes.

DR. CERQUEIRA: Okay. All right.

So what's the next item on the agenda that you would like our input on?

MR. ESSIG: Roger needed to raise one question.

DR. BROSEUS: Dr. Cerqueira, was there a motion from the Committee on the issue of eluting generators?

DR. CERQUEIRA: I don't think there was a motion. There was general agreement that it should be kept in 200, and we have -- and essentially we were just the 390. Do we need a motion on it? Or I

think you've got the feeling on the Committee. I was the only one who had any sort of objection, and nobody else supported it. So I think there's pretty much uniform agreement.

MS. WILLIAMSON: So you're saying there is a motion to eliminate an (H)?

DR. WILLIAMSON: Yes, we've passed a motion to eliminate H from 35.390.

DR. BROSEUS: I understand that the remaining question was for nuclear medicine physicians to be qualifying under 390 if the striking from 390 of that paragraph (H), if that's still is a problem that needs to be addressed in the final rule.

DR. VETTER: I have a motion. Be it resolved that the ACMUI wishes to include under 200 the requirement that any authorized user who qualifies must have had experience in eluting generators. End of motion. And then the NRC can put in whatever words are necessary to accomplish that.

DR. CERQUEIRA: So do we have a second on the motion?

DR. WILLIAMSON: Second.

DR. CERQUEIRA: Okay. Further

discussion? There being on, I call the question. All in favor?

ALL: Yes.

DR. CERQUEIRA: Opposed? Okay. So that passed And it's an official motion.

DR. BROSEUS: Thank you.

DR. CERQUEIRA: So what next?

MR. ESSIG: Yes. The only other item that we had on the agenda was to briefly discuss the Dose Reconstruction Subcommittee efforts and basically a status report where they are. this is in conjunction with the St. Joseph Mercy Hospital dose reconstruction.

Right now we're marching toward a milestone of having the Subcommittee complete its effort and provide a report by March 30th to the full Committee. I should say not later than March 30th, to clarify that. And then the full Committee not later than April 9th provide its report which considered the Subcommittee's report to the staff so that we can act on it and replay to the incoming letter from the Society of Nuclear Medicine President.

So at this time it might be appropriate for Dr. Malmud to provide us a status of the

Subcommittee efforts and if he is on track to getting a report to the full Committee by March 30th.

DR. MALMUD: Thank you.

I have sent a memo to Dr. Williamson and copied it to the other members of the Committee. And I invited comments from the members of the Committee regarding the memo. I hope that all the members of the Subcommittee on the call now did receive did receive my memo and also Dr. Williamson's response to it, and Dr. Nag's comment.

ALL: Yes.

DR. MALMUD: Okay. And so it looks as if, and I then sent a follow up note to Dr. Williamson indicating that I appreciated his comments and additions or deletions in both cases, to my recommendation. And if I may, I'll read the memo as amended by Dr. Williamson's comments. Is that okay?

DR. NAG: Is that the one from March 17th?

DR. WILLIAMSON: As amended earlier today.

DR. MALMUD: Yes. As amended earlier today. And in the chaos of this meeting, I lost

that memo. Hold on a second. I had it right in front of me at the beginning of this call.

It begins with the following: "The calculations derived by Dr. Williamson estimate the range of radiation exposure to the patient's daughter, a "member of the public" to be forward to diagram in a best case-worst case scenario. The methodology is summarized in the slides presented by Dr. Williamson but does not include an additional radiation burden from the urine bag, whose radiation burden was presumed not to be additive.

Even at the lowest estimate, that is the best case, of 4 rem the radiation burden exceeded the 100 rem allowed.

Paragraph two: The calculations of 4 to 9 rem that Dr. Williamson submitted to the Subcommittee of the ACMUI would mean that the NRC Regional office overestimated the exposure to the daughter by 3.75 to 1.67 times Dr. Williamson's calculations.

Paragraph three: The reasons for the differences in the estimated radiation burden has to do with the assumptions of the time and distance of exposure of the daughter to the patient.

Paragraph four."

DR. NAG: I hear a lot of wind or some other noise. Is that the same for everybody?

ALL: Yes.

DR. MALMUD: It sounds like somebody's breathing really heavily. Breathing heavily into our phone. I didn't mean the call to be anything but serious business.

We now move to paragraph number four: "There was agreement among members of the Committee that the calculations performed by the regional office of the NRC which produced a radiation burden of 15 rem were overly conservative because they assumed extended close contact between the patient and the daughter at an unrealistically close distance and ignored the use of local shielding. More specifically, the use of Monte Carlo simulation to reconstruct the bedside measurement distance came up with an unrealistically short distance for mean patient center-to-daughter surface distance."

I'll reread that: "The use of Monte Carlo simulation to reconstruct the bedside measurement distance came up with an unrealistically short distance for mean patient center-to-daughter surface distance. And the use of continuous decay would lower the dose estimate by about 10 percent.

Most importantly, the license post-incident interviewers and dose reconstruction lead to a different scenario regarding the use of body shields and daughter dwell time distribution than that derived from the Region III interview. The Subcommittee strongly feels that these differences should have been outlined in the inspection report and used to define lower and upper exposure bounds." In other words, a range.

Paragraph five: "Perhaps prompt contemporaneous notification to the NRC regional office of the unwillingness of a member of the public to comply with the directions of the RSO would have had the desirable effect of assisting in the better documentation of the event.

Paragraph six: A concern of the committee is how such a similar situation in the future might be handled in a more optimal matter for both the public and the licensee. Therefore, the Subcommittee recommends that the ACMUI recommend to the NRC one of several options:"

First one: "That the NRC develop an information notice regarding contemporaneous notification of the regional NRC office of noncompliance by a member of the public despite the

best effort and advice of the licensee."

Second bullet --

DR. WILLIAMSON: Well, there is an addition I made there.

DR. MALMUD: Oh, I'm sorry. "That the IN should summarize all available guidance on exposure limits and licensee options when a family insists on attending a radioactive patient."

DR. WILLIAMSON: I meant to say "family member."

DR. MALMUD: All right. "That the IN should summarize all available guidance on exposure limits and licensee options when a family member insists on attending a radioactive patient." And the word "member" will be inserted between "family" and "insists."

Next bullet: "That a modification process be developed by the NRC to allow the enforcement policy to grant exemptions based on humanitarian grounds, thus when a licensee after having made a best effort to inform and enforce the regulations is unable to do so (such as for humanitarian reasons), that the licensee might have recourse in collaboration with the NRC for dealing with the issue and without unduly alarming a member

of the public regarding the consequences of exceeding the allowable radiation burden when exceeding the limit is deemed not to have serious medical consequences." In other words, we remain concerned about the psychological well being of the public as well as its physical well being by unduly making them anxious.

That is the recommendation of the member of the ACMUI Subcommittee which was circulated. The comments of Dr. Williamson were then incorporated. And those of you who have received his comments, will see the gray lining in addition to the text that I sent to him.

And we present that to the Subcommittee for its recommendation to the Committee.

So, if I may, I will present as a motion of the Subcommittee. May I do that.

DR. NAG: Yes.

DR. MALMUD: Yes.

DR. NAG: One thing. Did you want to just briefly mention what I had -- the comment I made about having a signature something akin to a patient going out on their own will against medical advice?

DR. MALMUD: Yes. Did you all receive a

copy of Dr. Nag's memo?

MS. SCHWARZ: Yes, I did.

DR. MALMUD: All right. I only heard one yes, so let me read it to you if I may. It's dated March 17th and it was emailed to me.

"I am not a member of the Subcommittee, however one suggestion regarding item six reproduced below is to treat the matter similar to the way we treat patients who leave the hospital against medical advice. I suggest that the licensee have the patient's relatives sign a form indicating that they have been warmed that the time spent in proximity to the radioactive patient is likely to exceed the amount permissible under current regulations, that they are voluntarily exceeding the permissible amount against medical advice.

We may have to design a suitable form to paraphrase this in simple language. This could be placed in the patient's chart."

MR. McBURNEY: Excuse me. I'm going to need to leave for another conference call. Thanks.

DR. MALMUD: Okay. Thank you, Dr. McBurney.

DR. VETTER: What happens when the patient's relatives refuses to sign. Could we

accomplish the same thing by simply dictating a note in the chart that the patient has eloped, and prior to that of course during patient instructions they were given this information?

DR. NAG: Yes. Basically like a patient who is a hardship risk who we ask them to sign, but if they don't sign, we cannot tie them down.

DR. VETTER: Right.

DR. NAG: If a patient leaves the hospital, we say this is what we told them.

DR. VETTER: Right.

DR. NAG: Similar thing.

DR. VETTER: Okay.

DR. MALMUD: Any other discussion of this recommendation by Dr. Nag?

DR. VETTER: I think it's a good characteristic or a good concept to tie into the Committee's report. I'm not exactly sure about the words, but the concept I think is good.

MS. SCHWARZ: I do agree with that.

DR. MALMUD: Any other comments regarding the spirit of the paragraph, though we'd have to refine the words a bit?

DR. EGGLI: I agree with it conceptually.

DR. MALMUD: So, Dr. Nag, shall we accept that as a motion?

DR. NAG: Yes, I think we can make that a motion and make the comment part of the Subcommittee report. Because this will be dispersed in the whole Committee and, you know, this can be added, this paragraph would be modified. I'll leave it to you to modify it and add it as part of the amended Subcommittee report.

DR. MALMUD: Dr. Williamson, did I hear you getting ready to say something?

DR. WILLIAMSON: Oh, no, I agree with that. I'm wondering, though, whether this report fulfills completely our mandate. You know, I thought we had three mission. One mission was to review Mr. Marcus' and Siegel's letter and the NRC dose calculation for being overly conservative, etcetera.

DR. MALMUD: We did that.

DR. WILLIAMSON: Which, we did. Okay. The third one was to make recommendations about the future management of patient's relatives who insist on being present with their relatives and receiving more than the 100 or 500 mR exposure limit they are allowed.

And the second one, which I don't think we've done, was actually to give some more general advise to the NRC to follow in future dose reconstruction efforts so that, you know, scientific credibility or loss of confidence doesn't occur again.

DR. NAG: And I think -- because you have to inject the feature there should be minimum and maximum and legal range rather than one and two say that the NRC should -- you know, real-case scenario rather than being overly conservative. You did mention all those points in your letter that I saw.

DR. WILLIAMSON: Yes, in my letter that I saw, they're not -- you know. It just might be necessary to summarize them as a separate set of bullets in our final report.

DR. NAG: Yes, I think I agree with that. I think, you know, many of the points that you made that I looked at this afternoon were points that should be brought up to the whole Committee's notice.

DR. MALMUD: When the Committee met in Washington, we discussed the concept of a best case/worst case/most likely case scenario. And some

of us felt that when data, though calculated precisely are based upon estimates, that there should be a presentation of the results based upon three different scenarios; the most likely, the least likely and -- well, best case/worst case and intermediate situation.

And I think that, Jeff, you incorporated that in your bullet two under paragraph four. But I will take your advice and more specifically tease that out into a separate item.

DR. WILLIAMSON: Yes. I think that one thing especially that the major source of discrepancy between my lower limit estimate and that of the NRC regional office actually had to do with a very distinct difference in opinion between the licensee and the NRC inspectors who, both groups did interview to some extent the same group of people and they came up with different conclusions. And I thought that the final report should have reflected these differences and that these different assessments of who was where when behind what should have been used to form upper and lower limits.

DR. MALMUD: Thank you. Any other comments for addition or deletion of this Subcommittee report to the Committee.

DR. MARCUS: This is Dr. Marcus.

Dr. Cerqueira, may I make a comment?

DR. CERQUEIRA: Yes, please.

DR. MARCUS: I think the Committee or the Subcommittee has done a very good job making suggestions to the NRC how to more accurately do the calculation to the daughter's upper arm. But this is not really a trunk dose, and it's the trunk dose of the true whole body dose that is really used for risk assessment.

And in situations where the dose to the upper arm is not indicative of the dose to the whole body, there needs to be an additional calculation at least done that is to be used for risk assessment. Because the dose to the whole body is really what you want know and what you want to use for risk assessment and is going to be a lower number.

DR. SIEGEL: Yes. Before everybody responds, I'd like to commend the Committee and Jeff's report. It was terrific. And up until the point of regulatory definition of TEDE, that's right. We went beyond the regulatory definition because in terms of a risk assessment, one needs more than a regulatory value. One needs a value more reflective of the situation, and that's how we

got from 4 down to 1 because the trunk and the arm were different distances, plus there's more attenuation in the truck.

So I'd like the ACMUI to contemplate --

OPERATOR: Your conference is scheduled to end in 15 minutes.

DR. SIEGEL: Oh, thanks. To contemplate, yes, one needs to based on NRC regulatory requirements to calculate the one centimeter DDE, that's true. But if this value is to be used for risk assessment at some point, is it or is it not appropriate, especially in this case, to use that value?

DR. MALMUD: Okay. Thanks, Jeff.

Dr. Williamson?

DR. WILLIAMSON: Well, you know, I certainly can't disagree with that. In my initial report to the spring ACMUI meeting I did calculate that by Monte Carlo simulation. I don't have the figure in front of me, but I think it would drop these estimates by an additional factor of four if one averaged the exposure over the daughter's entire body.

And I agree for medical risk assessment where there is a question of stochastic or

nonstochastic injury to the daughter, that would be appropriate. And that's worth pointing out. But in terms of addressing the sort of narrow regulatory issue that we were asked to address, that is not really relevant.

I mean, we have the definition of TEDE in Part 20, and that's the regulatory conclusion will be based upon. And I think at this level, even if it is 15 rem, that is I don't think anybody was claiming that there was an enormous or any significant risk a bodily injury to the daughter based on even the highest estimate.

DR. SIEGEL: Well, with respect that's exactly the point. In the Adams' document, a medical consultant wrote back that essentially there was very small medical consequences. But in order for that expert to have made that assessment, I would think it would be important for that medical consultant to know that a 15 rem was to the arm as opposed to 15 rem was to the total arm.

DR. WILLIAMSON: Well, I'd certainly agree with that, and you know like I said, that was definitely one of my comments to the full Committee.

DR. MALMUD: And we should add another bullet to our letter in that there seems to have

been a lapse in fully informing the medical consultant?

DR. WILLIAMSON: Well, I don't know if there really was a lapse. But I certainly think that it is a good piece of advice, and yes. If the NRC is going to ask a medical consultant was there any medical risk to this patient by virtue of the exposure, it certainly is appropriate to supply them with a more relevant physical endpoint than the regulatory TEDE. It's only common sense. Even though it has in this context no regulatory significance.

DR. NAG: Yes. I agree that as a clinician I would like to have an estimate of the total body combined exposure for me to make any decision about the medical -- any of the medical degree.

DR. MALMUD: An other comments?

Reporting as the chair of the Subcommittee to the Committee, and we will clean up this document and get it out to the Committee members today, to Subcommittee members today so they can review it and then make a final report to the Committee based upon a draft and the additions as a result of today's discussion.

Is that acceptable?

ALL: Yes.

DR. MALMUD: Are there any other comments that anyone wants to make about this.

DR. EGGLI: Yes.

DR. MALMUD: Yes.

DR. EGGLI: I didn't get those whole exchange of emails, although I agree with everything that you read and was discussed. Could you send me this whole chain?

DR. MALMUD: Certainly.

DR. EGGLI: Thank you.

DR. MALMUD: Okay. Any other comments?

MR. LIETO: Dr. Malmud?

DR. MALMUD: Yes.

MR. LIETO: It was my understanding that the second charge that was described earlier by Jeff of the ACMUI regarding this matter was something that was going to be done and completed in the future, which was to come up with I thought a specific --

OPERATOR: Your conference is scheduled to end in 10 minutes.

MR. LIETO: We'd come up with specific suggestions for guidance to the NRC. Are we saying

that our charge regarding that is completed with this Subcommittee report?

DR. WILLIAMSON: I think that Dr. Malmud said he was going to take another pass at it, break out a set of bullets that address the problem more generally.

MS. SCHWARZ: Dr. Malmud, when you do complete your bullets, will you then mail us a copy of your --

DR. MALMUD: Yes. I want to get the amended report out to each of you so that we can present it as a Subcommittee to the full ACMUI.

MS. SCHWARZ: Right.

DR. MALMUD: But simply an ad hoc or subcommittee of the ACMUI.

And let me just review with you before we sign off, what tasks you have given me at the moment. And that is point out that a major source of discrepancy existed between the licensee calculation and the NRC inspectors, that was one point.

And the other one was that if the NRC would ask the consultant to look at the medical risk, then that consultant should be given relative data, than simply the TEDE. They really need the

whole body.

Does that cover the additional items that you wanted me to include?

DR. WILLIAMSON: Yes, I believe so.

There's a small change about having to do with the urine bag. That's I don't think quite accurate. I didn't take an explicit count of the radioactivity that was in this urine bag, but assumed it was included in the bedside readings and one meter readings that I did work with. So it was implicitly included. So I'll have to make a little comment about that.

DR. MALMUD: What I said, Jeff, is that you had mentioned that at the meeting, and that what you had done was to assume that because the urine bag was hanging there, that it was part of the activity that was monitored at a distance?

DR. WILLIAMSON: Correct.

DR. MALMUD: And you are consistent. You did say that then, and you are reiterating it now.

DR. WILLIAMSON: Right. But I think that the point one makes it seem like I ignored. And, you know, I don't think that's quite true, either. But it wasn't independently considered as a source, but it was assumed to -- I didn't think

there was enough information available to separately treat it as a source.

DR. NAG: I think if you would just put back as an amendment note

DR. WILLIAMSON: Yes, I think when we revise it, we can edit this a little.

DR. MALMUD: We can just add on to that sentence which ends "Whose radiation burden was presumed not to be added exclusively, but included in the moderate dose."

DR. WILLIAMSON: Correct. That would be perfect.

MR. ESSIG: Mr. Malmud, this is Tom Essig. I need to raise one other administrative issue relative to the receipt and action by the full Committee on the Subcommittee's report.

I think what we'll have to do so that there is a formal acceptance of the report by the full Committee is we'll have convene another conference call, perhaps in two weeks after the full Committee has received the report and had a chance to read it. And then we will for the record have amotion to accept the report of the Subcommittee and forward it to the NRC.

DR. CERQUEIRA: Leon, is that fine with

you?

DR. MALMUD: That's fine with me. We could even do that next week if you wish to. I'm going to be out of town and then unavailable for a bit. But we'll do it whatever time is convenient. Because I think that Jeff and I could probably polish this up today if he has a few minutes.

MR. ESSIG: Okay. If the full Committee can review the report in a fairly timely fashion, we're up against a noticing procedure, however, and we've got to allow two weeks for the *Federal Register* notice. So even if we manage to get the *Register* notice out tomorrow, I think the earliest we could have the call is April 6th. That would be two weeks from tomorrow.

OPERATOR: Your conference is scheduled to end in five minutes.

DR. MALMUD: All right. May I read this to you and see how this sounds to you?

"Under item six we another bullet which says that we recommend to the consultant that the medical risk be evaluated based upon whole body exposure rather than using the TEDE." Is that acceptable?

DR. WILLIAMSON: Yes.

DR. MALMUD: Okay. That's one line.

The other line would refer to the fact that the data, that when there is a discrepancy between the licensee's report and the NRC's report, that both sets of data are presented for evaluation to the -- who are they presented? The NRC?

DR. WILLIAMSON: Well, I mean, I think that the discrepancy should be described in the final inspection report and basically unless there's some real reason, clear reason for discrediting one or the other, the two alternative reconstructions should be used to bracket the two exposure to be used for defining upper and lower limits.

DR. MALMUD: Discrepancy should be described in the final report and a high dose/low dose estimated from the two variables.

DR. WILLIAMSON: Right.

DR. MALMUD: Okay. Does the Committee wish to move on this? We'll get you the final wording today, but you've got what I'm going to be saying.

MR. LIETO: Quick question?

DR. MALMUD: Yes.

MR. LIETO: Jeff, would it be unreasonable to put in what the ratio or the facts

of difference between the TEDE and the whole body from a risk standpoint to an individual?

DR. MALMUD: Who is speaking?

MR. LIETO: I'm sorry. This is Ralph Lieto.

DR. WILLIAMSON: I mean it certainly could go in there. I have no problem putting it there.

DR. VETTER: That may work for this case, but the ratio would be potentially different for any other case.

DR. WILLIAMSON: And one involving much larger distances, it might be fairly minor contributing factor or for a little hotter radiation.

DR. SIEGEL: Excuse me. That's exactly why you do a dose reconstruction in a specific case, because no two cases are the same.

DR. WILLIAMSON: That's correct. So, yes, I mean in the context of this particular incident, you know, I think that even the highest exposure estimate was well below any threshold for medical injury to the patient. And I think putting a factor of four in the general discussion of what the recommendations should be is inappropriate,

because it only applies to this case.

DR. MALMUD: But that the discrepancy should be described in the final report. The discrepancy, if any, should be described in the final report and presented in a manner which provides a high dose/low dose burden estimate?

DR. WILLIAMSON: Yes, I think that's reasonable.

DR. CERQUEIRA: Gentlemen, we're going to have to end soon.

DR. MALMUD: As the Chair to the Subcommittee, do these sentences meet with the Subcommittee's approval.

MS. SCHWARZ: Yes, I think they do.

DR. MALMUD: Does someone on the Subcommittee want to make a motion.

DR. WILLIAMSON: Okay. So moved.

DR. MALMUD: So moved, is there a second.

OPERATOR: Your conference is scheduled to end in one minute.

DR. MALMUD: All in favor? Subcommittee?

ALL: Aye.

DR. MALMUD: Any opposed?

MR. ESSIG: We don't know what the motion was, Jeff, that you said I so move. The record won't show what your motion was.

DR. MALMUD: The motion was the memo that sent back to me by Jeff, dated March 17th referring to the conference call of March 15th.

DR. WILLIAMSON: Well, Leon, I think the time has run out and we really can't present this to the full Committee for a vote. I think the simplest thing is to basically send it to all of us.

OPERATOR: Your conference time has now expired. Thank you.

DR. MALMUD: Thank you, all. We will send it by email, Jeff.

DR. WILLIAMSON: Okay. Thank you.

(Whereupon, at 3:00 p.m. the meeting was concluded.)

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