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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

(ACMUI)

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MONDAY

OCTOBER 29, 2001

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ROCKVILLE, MARYLAND

The ACMUI Advisory Committee on the Medical Uses of Isotopes met at the Nuclear Regulatory Commission, Two White Flint North, Room T2B3, 11545 Rockville Pike, at 9:00 a.m., Dr. Manuel Cerqueira, Chairman, presiding.

Committee Members Present:

Dr. Manual Cerqueira, Chairman, Nuclear Cardiologist

Ms. Nekita Hobson, Member, Patient Advocate

Dr. Subir Nag, Member, Radiation Oncologist

Dr. David A. Diamond, Member, Radiation Oncologist

Mr. Ralph P. Lieto, Member, Medical Physicist

Dr. Leon S. Malmud, Member, Healthcare Administration

Ms. Ruth McBurney, Member, State Representative

Ms. Sally Wagner Schwarz, Member, Nuclear Pharmacist

Dr. Jeffrey Williamson, Member, Therapy Physicist

Committee Members Present:

Dr. Richard J. Vetter, Member, Radiation Safety Officer

NRC STAFF PRESENT:

Donald A. Cool, Ph.D

Angela Williamson

Donna-Beth Howe, Ph.D

Frederick D. Brown

Patricia Holahan, Ph.D

Marjory Rothschild

Susan Frant, Ph.D

Robert Ayres, Ph.D

Mark Sitek

Melanie Galloway

GUEST SPEAKERS

Dr. Jeffrey A. Brinker, Society of Cardiac Angiography & Interventions

Dr. Geoff Ibbott, American Association of Physicists in Medicine

Dr. Prabhakar Tripuraneni

I-N-D-E-X

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

(9:03 a.m.)

DR. CERQUEIRA: I'd like to welcome everyone to the meeting. My name is Manuel Cerqueira, and I'm the Chairman of the committee. We have two new members who are joining us. Are they both official now, Angela?

MS. WILLIAMSON: Yes. It's done.

DR. CERQUEIRA: Well we have American Association of Physicists in Medicine Ralph Lieto who's a medical physicist, who's the newest member of the committee; and Dr. Leon Malmud, who's a well-known entity, but he's here as the Healthcare Administration representative, which is a new role for him. And then we have one vacancy which we're still recruiting for.

A couple of people have informed me that they have flight changes, and so we will definitely try to get through the meeting in a timely fashion. Maybe we should just go on to the remarks that were to be delivered by John Hickey who was unable to make it, and Angela will make some comments and then we'll have Dr. Donald Cool is going to make some comments as well. Angela.

MS. WILLIAMSON: Good morning everyone. I'm going to read the official opening remarks for the

meeting.

I am pleased to welcome you to Rockville for the public meeting of the ACMUI. My name is Angela Williamson. I'm the Project Manager and I am standing in today for John Hickey who is the Branch Chief of the Material Safety and Inspection Branch.

Mr. Hickey is the designated Federal official for this committee. Normally, he would present these introductory remarks, but unfortunately Mr. Hickey is ill today.

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 Federal Register on September 19, 2001 for the October 29, 2001 meeting.

The function of the advisory committee is to advise the staff on issues and questions that arise on the medical use of by-product 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 opinions of the council and values the opinions of the committee very much.

I do request that whenever possible, we

try to reach a consensus on the various issues that we will discuss today or at any other ACMUI meeting. But I also do value stated minority or dissenting opinions. I do ask that if you have dissenting opinions, that we read those into the record.

As part of the preparation for this meeting, Mr. Hickey reviewed the agenda for members and employment interests based upon the very general nature of the discussion that we are going to have today. He did not identify any items that will pose a conflict. Therefore, I see no need for an individual member of the committee to recuse themselves from the discussion.

However, if during the course of our business, you determine that you have some conflict, please state it for the record and recuse yourself from that particular aspect of the discussion. And now I'd like to turn it over to Dr. Cool.

DR. COOL: Thank you and good morning. I'm Donald Cool. I'm the Director of the Division of Industrial and Medical Nuclear Safety, and I would like to welcome you here to White Flint and the meeting today. I'd also like to extend a welcome to the various members of the public representatives from a number of the medical societies and others that we

have here in the room with us today.

Let me particularly welcome Dr. Malmud and Mr. Lieto. Welcome to the committee. We are very pleased that you have been able to join us today. We look very much forward to your being part of this committee, sharing with us your insights, experience, advice as we address a variety of topics, both today and over the coming meetings in your term.

We are in interesting times. The world changed on September 11th. It certainly changed for those of us here at the agency in a variety of ways. I think it has probably changed for each of you in maybe very tangible ways, perhaps more intangible ways.

For the Nuclear Regulatory Commission, we have been on a heightened state of alert and security since minutes after the first plane went into the World Trade Towers. We have had our operations center under continuous activation and staffing since that time, as we have with our regional offices.

We have had the reactor facilities, our fuel facilities under heightened security and safeguards, and have been pursuing aggressively a variety of reexaminations of our current security posture and security of various vulnerabilities and

issues, trying to look forward at the possible ways that other mischief or misuse could take place, and to have in place additional measures that might be necessary or appropriate in order to deal with those threats. Obviously a great deal of that is classified and is not something that we could discuss openly around this room, but there has been a great deal of activity that has gone on here.

As well, there's been a great deal of activity involving the agency with other various Federal agencies and interactions with the Department of Energy, the FBI, the Federal Emergency Management Agency, and you can just keep on going down the list. Add now the Homeland Security office with which we have someone participating, not quite around the clock in their staffing activities, to try and stay involved and be part of the various activities of the Federal family in response to the various events that have taken place.

There certainly have been a number of questions that have been raised about vulnerabilities of various radioactive materials. You've seen a lot of discussion in the press about what people could do. You've seen various viewpoints expressed.

We have, let me assure you, been examining

various issues, interacting with our licensees, providing information to them, as may be necessary providing specific threat information under a couple of circumstances in which we have had at least, over brief periods of time, threats made that we could not determine the exact nature thereof.

We were pleased that they turned out not to have any substance behind them, but it does, as you might expect, get the pulses racing just a little bit when you can't exactly figure out what's going on and you're continuously trying to sift through enormous quantities of information in order to understand exactly what may be going on out there.

I'm sure you're aware that the Federal Government overall continues to believe that the threat in a general threat sort of environment remains high in the United States. You hear that from Governor Ridge who's now the head of Homeland Security, and various other folks on a daily basis, so that should not come as any particular surprise to you.

There have been a variety of issues more recently with regards to anthrax, bioterrorism and including the issues associated with whether radiation has a potential role to play. I'm guessing that a

number of you probably saw the news over the weekend with the Postal Service looking to purchase various radiation pieces of equipment to irradiate the mail. We have been interacting with the Postal Service and the Department of Energy and FDA and AFFRI.

We've been looking into these issues, not directly involved because the technologies that they appear to be looking at and entering into contracts through Ruth McBurney and the states will get the opportunity out as opposed to the by-product materials that are under the NRC's jurisdiction, but we certainly had questions tossed at us early on, how much radiation? What else might it do? And we have interacted with a variety of those folks to try and help pull together an understanding of what is taking place in that area.

So there have been a lot of things that have gone on. There has been a lot of normal activities that would otherwise have been expected to have been worked on and been moving forward, which would have been put on the back burner or worked only very slowly as a result of a very heightened focus within the agency on some of the immediate issues.

Nevertheless, it is with recognition that some of the day-to-day issues and activities need to

continue to be examined that we are here today. Medical care needs to continue. New technologies and activities need to be examined, and we need to make sure that we continue to be in the right place in terms of providing proper oversight, allowing the kinds of activities and developments that are ongoing to be involved, taking a look at some of the emerging issues that are taking place.

Your agenda today has several of those topics, intravascular brachytherapy and some of the things related to mixtures of doses between atomic energy materials and non-atomic energy material, particularly the x-ray fluoroscopy, which at one level ought not to seem to be a problem, but when you start drawing the nice little legal lines and bright boxes that inevitably happen anytime you write down a regulation, suddenly draw you into potential conflicts of how you calculate things and why you calculate things and why that's okay and that's not okay where the two points seems to be essentially side-by-side with each other. So we look forward to some of those discussions early this afternoon.

Likewise, we continue to be in a position where we do not, in fact, have the revised Regulation 35 in place. Dr. Patricia Holahan is going to be

talking about that in just a few moments, so I will not go into detail on those, but she'll give you a review of the current status of the activities there and the various things that are going on and how we are moving forward.

I believe that summarizes the sort of brief overview that I wanted to give you today. I recognize this is a shorter meeting. A number of the topics that we probably would have wanted to discuss were the new regulations going into effect. We're not in the position to discuss these because we really have no idea of exactly how that will all transpire, but we do very much appreciate all of you taking the time and effort, braving the flights or the very other things in order to spend some time with us today.

Dr. Cerqueira, I will be glad to answer some questions or entertain a discussion if some of the members of the committee would like. Thank you.

DR. CERQUEIRA: Dr. Diamond can ask some questions about a discussion we had earlier today to Dr. Cool.

DR. DIAMOND: A few moments before your arrival, we were having a discussion regarding a lot of questions that we members are being asked in our home communities, specifically what type of education

and materials do we have with respect to counseling the public or treating patients, God forbid should there be an intentional release of radioactive materials.

I, as a radiation oncologist despite all my years of medical training, have never received formal training on how to handle these patients. I do know that our professional society's now starting to develop some training materials, but I certainly think it would be useful and productive if the NRC did play a role in helping to coordinate this dissemination of training material in a fashion that does not seem alarmist, and perhaps coordinate those activities with constituencies that we generally don't work with, namely the American Society of Hematology, because of course, they would play an important role should patients be exposed in large numbers.

So, those were some of the thoughts we were ruminating about.

DR. COOL: I think those are some excellent ideas. One of the things that I failed to mention, as I was trying to go through MMI and some of the activities that are going on is that there is an effort within the Federal community to look at and try to have prepared some materials and information

should, as I agree God forbid, someone chooses to use radioactive materials or a nuclear warhead of some type of yield and magnitude.

We have been participating with FEMA and the other agencies. My deputy, Dr. Susan Frant, was at a meeting of Friday of last week with those various groups that are working to try to have some templates in basic pieces of information available for Governor Ridge and others.

So at one level, and a very high level at this moment, there is some work being done to try and have some materials in place. But I would also agree that at a very different level, at your individual levels, it would be useful to have that. I do not have a handy dandy card in my pocket that I can yank out and suggest the three or four things. What little bit of media training I've had, you always try to have your two or three messages and you want them to be fairly short and crisp because CNN will never give you more than five seconds of sound time anyhow.

I think it would be good to be trying to work on some of those things, and we would be pleased to try and reflect on that with you to the extent that the committee either here want to discuss that a little bit, or to interact separately to try and have

some of those things and build upon each other's ideas. So that would be a wonderful thing.

DR. NAG: Don, one thing. You would be able to use your offices to have a more formal training for handling nuclear accidents for the members of the ACMUI and other staff because not just how to respond to the media but if any type of accident happened, whether intentional or not, what are the things that we should be doing? Because we are the ones who are more likely to be called to handle those, and we are basically unprepared to handle them.

DR. COOL: A couple of very good points there. We will have to explore the extent to which we can provide, either providing locations or more directly be involved in providing some training and information. Within the Federal family, there are some other groups that specialize in this down at Oak Ridge REAC/TS Group and some others. I know the Health Physics Society has been doing some things.

At the moment, I'm drawing a blank as to whether you already have some materials that are out there and available. Certainly there are some materials in our operations center that we have available for those within the agency, that the agency

would be looking to as spokespersons to deal with members of the public and some things which our public affairs folks have.

If we can explore, probably not within the scope of the meeting time today, the extent to which we might be able to get some of those and provide some of that to you, we can certainly take that as a possible follow-up item.

DR. CERQUEIRA: Other questions for Dr. Cool?

I think the discussion we had this morning, and again there's a lot of professional medical societies that are involved in there. There's a lot of government agencies, but ultimately I mean, we as physicians working in these areas will probably be contacted, and if we're not that well informed, I'm sure most of our colleagues are probably less informed.

So to try to coordinate the effort would be important, and it would be nice if we could somehow get follow-up on this to try to identify some tangible things that can even be provided to the committee or some sessions, or if those things don't exist, to try to come up with a structure to develop them. And I think the feeling of the committee is we would really like to work with the NRC on some of these issues in

whatever way would get it accomplished.

DR. COOL: Very good. I welcome that suggestion. We'll see what we can do in terms of laying our hands on bits and pieces that are here, and if it pleases the committee, see about getting those to you and get some reflections from you on gaps, omissions, suggestions to try to refine it, because I think it would be useful to us in terms of advanced preparations and certainly useful to various groups in the community. Ruth is waving over there.

MS. McBURNEY: There may be some materials that REAC/TS has prepared and Dr. Ricks (phonetic) or somebody there that could be disseminated to expand.

DR. COOL: Yes, that's what we need to explore, what's already out there.

DR. CERQUEIRA: Would it be possible to get somebody from the NRC staff to sort of help coordinate some of these efforts, or at least a preliminary look to see what's out there or what needs to be done? Could there be a contact person identified?

DR. COOL: We will do that. For the moment, why don't you work through Angela, who's the Project Manager for this committee.

DR. CERQUEIRA: Okay.

DR. COOL: We may modify that at some point

down the line, but that will be a good place to start and someone that you're already familiar with.

DR. CERQUEIRA: Do you have a time line on this? It won't be today, we realize that.

DR. DIAMOND: Yesterday would be fine.

DR. COOL: Yesterday would be fine, okay thank you.

DR. CERQUEIRA: Hopefully the relevance will disseminate over time, but at the same time to sort of get into periods of months before anything gets done doesn't really meet the needs of the committee.

DR. COOL: No, I think this is one which, consistent with the pace of a number of other things we've got going, I would hope would be measured in days to small number of weeks, not in terms of months or the next committee meeting.

DR. CERQUEIRA: Right, because ultimately these bioterrors have medical consequences, and I guess in terms of radiation, this is the advisory committee. Jeffrey, you had a comment?

DR. WILLIAMSON: Yes, I suggest maybe we take some of elective time for new agenda items at the end of the meeting and try to make a more specific focused list of requests from the commission and their

staff, what we as a group would like from them.

DR. CERQUEIRA: That's good. Other questions for Dr. Cool?

DR. COOL: If not, I thank you. I will not be able to stay with you for the majority of the day. In fact, the daily briefing of our senior managers in our operations center up just two floors is in progress and I'm going to go join them next.

DR. NAG: The meeting with the commissioner that was postponed, have we been able to reschedule that at any point?

DR. COOL: It has not been formally rescheduled as in locked down with some new dates. Once we know a little bit more about the time line with Part 35 and looking to see what your schedule may look like in terms of interacting with us on that for the spring meeting, our thought at this point was we would try to arrange that to be more or less coincident with take advantage for a single travel opportunity with the commission at that time. The commission indicated its desire for that to be in the spring.

DR. CERQUEIRA: Okay. We'll work with Angela to try to firm up a date. Obviously getting the five commissioners together is more difficult than

getting the committee today. So, we'll work around their schedule.

DR. COOL: One never knows.

DR. CERQUEIRA: Okay, well thank you very much Dr. Cool. Let's see. We can go on to the next item, which is the follow-up from the April ACMUI meeting.

MS. WILLIAMSON: Dr. Cerqueira, I was wondering if you wanted to briefly introduce the members around the table very briefly.

DR. CERQUEIRA: Of the committee, sure. Okay. Why don't you start Nekita.

MS. HOBSON: I'm Nekita Hobson, and I am the Patient Advocate and my organization is the National Association of Cancer Patients.

DR. NAG: Subir Nag, Association of Oncology, representing radiation oncology and brachial therapy immunity.

DR. DIAMOND: David Diamond, radiation oncologist, also representing the radiation oncology and brachial therapy communities.

MR. LIETO: Ralph Lieto, I'm the new member representing the medical nuclear physicists community.

DR. CERQUEIRA: Manual Cerqueira. I'm a nuclear medicine physician and a cardiologist, and I'm

representing the nuclear cardiology community.

DR. MALMUD: Leon Malmud, the Dean of Medicine at Temple University and the President of Temple University Health System, representing healthcare administration.

MS. McBURNEY: I'm Ruth McBurney with Texas Department of Health. I'm the State Government representative on the committee.

MS. SCHWARZ: Sally Schwarz, representing nuclear pharmacy. I'm from Washington University in St. Louis.

DR. WILLIAMSON: Jeff Williamson, also from Washington University in St. Louis, representing radiation oncology physics.

DR. VETTER: Dick Vetter from Mayo Clinic, representing radiation safety officers.

DR. CERQUEIRA: So, Mr. Brown will do the presentation in place of Mr. Hickey.

MR. BROWN: Yes, absolutely. My name is Fred Brown. I am a Section Chief in John Hickey's branch and I will be trying to cover for him today. So, for instance, I took the requests for information on medical recommendations in the event of a radiological attack, and I'll try to have some information this afternoon during the opening period

for you.

I'm actually going to empower Angela to go over the minutes from the last meeting and the recommendations that you made to us.

MS. WILLIAMSON: Okay, I'll just bend down a little. I have in front of me some recommendations that ACMUI made at our April 18th, 2001 meeting and I'm going to speak to the staff response to those recommendations.

The first recommendation, ACMUI thought that the procedure or felt that the procedure for recruiting and appointing ACMUI members be done more expeditiously to get vacancies on the ACMUI filled sooner. The staff response to that recommendation, we agree with it and we have put into place procedures for filling the vacancies more expeditiously. So, we're addressing that continuously.

The second recommendation that ACMUI made --

DR. CERQUEIRA: Angela, so I guess right now we've got one vacancy, the nuclear medicine physician, and I know that some of the professional medical societies have sent in information. I don't think they've heard, or gotten any feedback to date.

MS. WILLIAMSON: Well when people send in

for the --

DR. CERQUEIRA: Nominations?

MS. WILLIAMSON: When they send in nominations, it's not our procedure to write back every organization that sent in a nomination. What we do is we just collect the nominations and then we proceed with trying to fill the vacancy from there.

DR. CERQUEIRA: All right.

MS. WILLIAMSON: The next thing everyone will hear, the next notice will be a Federal Register -- excuse me, the next thing that will happen after we get the recommendations or the nominations rather, we will proceed to have a panel to screen the recommendations and the commission will make a decision. But we don't reply to everyone.

DR. CERQUEIRA: Well, maybe you could give us an update in terms of when was the deadline for submitting? How many have we gotten to date?

MS. WILLIAMSON: We have five, if my memory serves me correctly, we have five nominations that came in by the deadline and I'm sorry but I don't remember the deadline off the top of my head. We will be having a screening panel meeting in early December -- excuse me, that's wrong, in November, the middle of November. We changed it.

But in any case, in the middle of November we will be having a screening panel meeting and at that screening panel meeting, there will be recommendations made to the commission as to who should fulfill that vacancy. So, by spring of next year, definitely by then we should have the person selected and probably before then as a matter of fact.

But whoever is selected should be able to attend the spring meeting. That's what I want to make clear.

DR. CERQUEIRA: And we have no other vacancies then right?

MS. WILLIAMSON: No, that's the only vacancy that we have.

DR. CERQUEIRA: And in terms of people going off the committee, anticipating another cycle?

MS. WILLIAMSON: Yes, we do look at who's due to rotate off and we address it at that point. If the person is eligible and willing, then of course as you know Dr. Cerqueira, they can serve again, or we can go out and --

DR. CERQUEIRA: Right, but I think Dr. Williamson's point last time had been if we know, and I don't recall who's going to be going off the committee, but if they're going off a year from now,

then if we could start doing some of the leg work for that six months at the latest before that, that would guarantee that we would have somebody in place.

So I think the discussion last time was to try to really have operational definitions of how to do it. Maybe, you know, in terms of follow-up, maybe at the next meeting we could get a listing of when people are rotating off the committee and some time lines for when we're going to -- because we have to publish a Federal Register notice.

MS. WILLIAMSON: Right.

DR. CERQUEIRA: Give a period and so it would be ideal to have the schedule.

MS. WILLIAMSON: I can give you a schedule of rotations.

DR. NAG: Anyone here getting off in April of the people who are here? No.

DR. CERQUEIRA: Does anyone know?

DR. WILLIAMSON: I don't know. I think the major suggestion was recruit in advance.

MS. WILLIAMSON: Yes.

DR. WILLIAMSON: And publish the Federal notice, Federal Register notice well in advance of the member rotating off. So, have you changed your procedures to reflect that?

MS. WILLIAMSON: We have. I mean, sometimes understand that there are snafues, things that just occur that are out of our control. We would have had the nuclear medicine -- we might have been able to fill it sooner, but we have to wait for people to send us nominations and we really have no control over that sort of thing.

DR. WILLIAMSON: No, my point was that if, for example, I am to rotate off in twelve months for example, you would publish the Federal Register notice for my position six months before I rotate off and have basically the selection made by the time my term ends. Have you changed your procedures to do that? That was the major suggestion that was made at the last meeting.

MR. BROWN: Let me interject that we understood the suggestion. We agree with it. That's our plan. As you're aware, there was a change in the management of the committee function about a year ago. We've been in the process of trying to fill the existing vacancies and to get caught up and to get ahead.

We have not updated our internal procedures, but we understood the recommendation. We agree with it. That's our intent and we're moving in

that direction.

DR. CERQUEIRA: Okay, good.

MS. WILLIAMSON: Okay, let's move on to the next recommendation. The recommendation involves a risk-informed reporting limit in which the ACMUI recommended that this risk-informed reporting limit of 5 rem be limited to the reporting of errors made in the release of patients and/or the reporting of errors made in the delivery of instructions to the patient.

The staff in response to this recommendation included it in a paper that --

MR. BROWN: And actually what I'd like to do, Trish Holohan's our next speaker. She can speak to this issue in detail for you. She's the most knowledgeable person. So if we could just defer on that until the next speaker. And actually, the following two recommendations, one dealt with intravascular brachytherapy and we're going to have a speaker shortly in that area.

MS. WILLIAMSON: And the other one is the broad authorizations for --

MR. BROWN: Board authorizations and I'd like to do the same thing, defer the detailed discussion for those speakers.

MS. WILLIAMSON: Okay. For the training

requirements for authorized medical physicists, the ACMUI recommended that the staff involved such qualified member as specialist, consultants or the ACMUI itself in approving these supplementary training requirements that allow Board-certified radiation oncologists and medical physicists to become authorized medical physicists.

In response to this recommendation, the staff agreed with it and will involve outside parties as necessary when guidance is developed.

MR. BROWN: And Dr. Ayres will be speaking to that.

MS. WILLIAMSON: And Dr. Ayres will be speaking to that.

MR. BROWN: And the same with Donna-Beth Howe will be speaking on the last item. So, that was basically all we had for introductory information before we moved into the first presentation, Dr. Cerqueira, unless there are any other ACMUI process questions for us at this time.

DR. CERQUEIRA: No, I guess the minutes are not in the book, are? Or, did I just miss them somehow?

MS. WILLIAMSON: The minutes, I did pass those out. You should have them.

DR. CERQUEIRA: Where?

MS. WILLIAMSON: They may not be in the book but I did pass them out.

MR. BROWN: If there's trouble finding them, we'll certainly get them to you.

MS. WILLIAMSON: We'll get them to you.

(Background conversation.)

DR. CERQUEIRA: Okay yes, it's under Tab, response to April recommendations. That's logically where it should be, yes. Okay, I guess those items are there. We can probably follow up. Angie, you did a great job being put on the spot like that.

All right, so we'll move on with the other items.

(Background conversation.)

DR. CERQUEIRA: Yes, these are just the action items, yes.

DR. WILLIAMSON: The NRC response. There's no minutes.

MS. HOLAHAN: Good morning. I know a number of you but for those of you who don't know me, I'm Trish Holahan. I'm the Chief of the Rule-making and Guidance Branch. No, I'm not John Hickey.

Anyways, I was asked this morning if I could cover the status of Part 35, and some of the

other outstanding issues, so let me walk quickly through that. I was at Cathy Haney's talk at your last meeting in which she gave you some of the status, at which time she had indicated that the Part 35 package had gone down to OMB on March 14th, and on September 19th we did receive OMB approval of the information collection requirements within the Part 35, the new Part 35 package.

We have incorporated all the changes that were in the staff requirements memorandum from the commission in the new Part 35, and there were some minor adjustments based on discussions with OMB to clarify that we were not looking at duplicate records in terms of labeling. Those changes were made.

The OMB did include a number of terms of clearance, which is their phraseology for things that must be addressed at the next time the package is renewed. So, the current clearance expires on September 30th of 2004, and at the time that we submit the renewed package, assuming that we can get the current package out and published, the OMB would like us to first of all consider any new information regarding risk information on uses of medical by-product material and how that new information could then impact the burden imposed by information

collection.

So, they haven't asked us to revisit all the existing risk information, but if new information becomes available, they've asked us to consider and address it in the renewal package.

Also, the second term of clearance requests the NRC to consider whether alternatives, including the use of a third-party accrediting organization would achieve the same purpose, and I do know that in a number of the public meetings and the meetings with the committee here, as Cathy Haney did address the use of third-party accrediting organizations and that was something at that time was put aside for later consideration.

But I think over the next three years, it's going to be something that we are going to be coming to the committee to see whether or not that is a viable alternative, recognizing can you require the use of third-party, and that in and of itself may be a burden.

DR. CERQUEIRA: I don't fully understand what you mean by third-party accrediting organizations.

MS. HOLAHAN: This was a proposal that originally came in, I believe it was from the ACNP and

SNM and I stand corrected if I'm wrong on that, where a third-party such as JCAHO or some other third party put together by the medical organizations would go in and inspect a facility to see if they were in line with the regulations, rather than NRC coming in to inspect.

DR. CERQUEIRA: Okay.

MS. HOLOHAN: Finally, the third term of clearance was focusing on the reporting thresholds we have for a medical event and looking at again whether there is any new information regarding the risks imposed by variation from the prescribed dose, and whether a different threshold would better satisfy the regulations. It may also impose less burden, so they want us to revisit what the actual reporting thresholds are if there is additional risk information available at that time.

They've also requested that we consult with licensees or relevant stakeholders and that would certainly include the ACMUI as we're pulling together that next renewal package.

So that's where the actual rule stands is to say we do have the OMB approval; however, we have not gone forward to publish the rule at this point because, you may be aware that there has been some

discussions up in Congress and the Senate has proposed some language that would impact our expending resources to implement the new Part 35 that is currently in conference session between the House and the Senate.

The House version did not include the language, whereas the Senate version did, so that they are continuing now to negotiate and I know that several of the medical organizations have communicated with both the House and the Senate.

So at this point, we are holding the new Part 35. We have not forwarded it for publication because if we can not go forward and implement it, then we would have superceded the old Part 35 and have nothing on the books, so.

DR. CERQUEIRA: So what are the possible scenarios that could result for this? I mean, so far there's a deadlock and there's no budgetary approval, so where do we go from here?

MS. HOLAHAN: I guess it will depend in part as to what the language finally comes forward, whether or not they are looking for additional information from NRC before we can go forward and publish it or whether we would look to continue with the existing Part 35. At this point, I think they're

negotiating on the Hill and you know, I don't have more insight than that right now.

DR. CERQUEIRA: What if they request a cut and paste? I mean, implement some but not all, would that be something that would be acceptable?

MS. HOLAHAN: That's a possibility, but it would take us again some time to go back through the rule and identify which aspects would be cut and paste and then make sure throughout the statements of consideration in the regulatory analysis that the issues that are moved forward are accurately reflected and referenced. So there would be some work on our part to do that.

DR. CERQUEIRA: We'll come back to get a time line. Dr. Williamson has this.

DR. WILLIAMSON: I wanted to, if you do make a revision of the regulations at the request of Congress, you have to essentially repeat the whole regulatory rule-making process of public comment and so on, don't you?

MS. HOLAHAN: I think it would depend on what they were requesting, because if they were asking us to completely go through and revise Part 35 or aspects of Part 35, yes we would have to go and re-notice it. If it was a matter of just moving forward

with certain aspects that have already gone through the public comment period --

DR. WILLIAMSON: I see.

MS. HOLAHAN: -- that may be a different issue and I think that's what Dr. Cerqueira was focusing on in the cut and paste if I'm correct.

DR. CERQUEIRA: Right.

MS. HOLAHAN: Okay. So anyways, we are on hold at least at this time and as a result, there are a number of other actions that are on hold. Angela addressed that one of the issues that was raised at the last ACMUI was a secondary follow-up rule to Part 35 that would modify 35.3075 which are the reporting requirements if an individual that was released under 35.75, the patient release criteria inadvertently gave an exposure to another individual greater than 5 rem.

I know again in her discussion with you in April, I believe, as Cathy Haney had gone through some of the draft ruling which she had then forwarded you some suggested draft ruling which we received your comments, the comments have been incorporated into a draft commission paper and the draft proposed rule, but right now that action is also on hold and has not gone forward to the commission until such time as we see which way we're going with Part 35.

So, we appreciate your comments. We have incorporated them and we've included them, and we'll certainly get them up in front of the commission when the package goes forward. There are also a couple of other petitions for rule-making that we had hoped that we could move forward to close out, but we are now holding until we see which direction we go with the new Part 35.

So anyways, that's the current status. I apologize and it's very brief, but it's what we have today and as I say, we did make progress. We have moved forward and received the OMB approval, and we are in a -- that's where we are today.

DR. CERQUEIRA: In a holding position.

MS. HOLAHAN: Yes.

DR. CERQUEIRA: I think Dr. Williamson was an instructor when this whole process started out, which kind of dates it and I think for some of us that have been involved, it's a little bit frustrating because the package did sort of go through. But let's -- I sort of time lines and so let's say that if it's -- it could just totally be rejected, correct? Not funded?

MS. HOLAHAN: That's a possibility yes, that it could be totally --

DR. CERQUEIRA: And the consequences of that would be?

MS. HOLAHAN: The existing Part 35 would continue on the books.

DR. CERQUEIRA: So all those years worth of work and Dr. Siegel's time and everything would be lost? Yes?

MS. HOLAHAN: I wouldn't like to say lost. I mean there's still a lot of value there but we wouldn't be able to move forward.

DR. CERQUEIRA: So that's one alternative that I don't think any of us would really look forward to. The other one is it could be approved, correct? That's still a possibility or?

MS. HOLAHAN: That's true. There could be that there is no, I mean the resolution could be such that there is no language in the appropriations bill specific to Part 35, and if that is the case then we could move forward with the Part 35 as it is.

DR. CERQUEIRA: And if that were to happen, what's the time line on that? It has to be published and what would be the time line between Congress' approval and publication in the Federal Register?

MS. HOLAHAN: Realistically, I mean by the time we would go through and do the, I mean we have

the package ready as it would go forward. It would have to be signed off by the secretary of the commission and then forwarded to the Federal Register, so, and the Federal Register could take up to three weeks. That's their time line. I mean, typically they take less time, so I would say within a month or two.

DR. CERQUEIRA: So eight weeks, and then six months after that it would be implemented?

MS. HOLAHAN: And then six months after that would be the implementation date, the effective date of the rule, yes.

DR. CERQUEIRA: Okay, so we've covered both extremes. What about somewhere in the middle? What if there is a compromise in the sense that some things are, you know, approved and implemented and others are not? What constitutes enough of a change that it has to go back through the public notice process?

MS. HOLAHAN: I think if we were changing specific language in the rule, that would have to go back through the public notice comment. If we were moving forward with already approved language, but certain sections, we would have to go back and re-look at the entire rule to make sure that we haven't referenced pieces in certain sections and not

referenced others.

DR. CERQUEIRA: I think the issue comes up is what to do with diagnostic nuclear medicine, I believe, and if that were the only things that were kind of held from implementation, would that require a change or?

MS. HOLAHAN: Well, yes it would because there are several sections within the new Part 35, Subpart A, B and I think C that are general requirements that will apply to all licensees.

So to specifically not have them and then there may be some issues that if you did not move forward with the regulations, you wouldn't have specific regulations; for example, allowing release of patients and things like that for diagnostic, and so you would be in a situation that you may not have applicable regulations to be able to do certain activities.

DR. CERQUEIRA: And what would that mean, so that it would basically have to be republished? It would have to come back to this committee or to the NRC, which would then have to rework the language?

MS. HOLAHAN: Yes. Yes, NRC would have to rework the language on which way we went forward.

DR. CERQUEIRA: And then published Federal

meetings announced, public hearings?

DR. NAG: No public hearings.

MS. HOLAHAN: Well again, the meetings, it would depend on whether or not we went forward with more public meetings on the direction that we would go. And so, you know, until we actually see what the language is, it's sort of difficult to sort of predict which direction we're going to go.

DR. CERQUEIRA: Okay. Jeffrey had a comment.

DR. WILLIAMSON: I wanted to ask about the existence and status of the regulatory guide for the new Part 35.

MS. HOLAHAN: Okay, the guide has been finalized in line with the existing -- no, I'm sorry not the existing, the new Part 35. We have completed the revision of Volume 9 of the 1556 series based on the final rule that's waiting for publication.

DR. WILLIAMSON: So is that available for this committee to look at for example, because I don't recall that we've ever had any input into that. I have never, with all my years of involvement with this process, really ever seen except at very early times a draft of that regulatory guide.

MS. HOLAHAN: Okay, you mean you saw the

draft guide that was published for comment? Is that the one you're referring to?

DR. NAG: I guess so.

MS. HOLAHAN: So then you haven't seen the final guidance document?

DR. NAG: No.

DR. WILLIAMSON: That's right and there's a substantial change.

DR. CERQUEIRA: Is that available on your web site or?

MS. HOLAHAN: No it is not. It's the draft that was published is the one that is still available on the web site; again, because with the rule still not being final, we hadn't published the final guide.

DR. NAG: If we're optimistic and everything went through, what we would like to see is the latest version you have now, so that if everything went smoothly, we would know what is being published. I think that would be rather helpful for us.

MS. HOLAHAN: Okay, you're asking before it was published the committee would like to see it?

DR. NAG: Yes.

DR. WILLIAMSON: Yes.

MS. HOLAHAN: Okay.

DR. WILLIAMSON: In fact, I have a concern

that we've never been asked to look at it because there was substantial changes in the draft rule language since the time, I think, we looked at a draft of the regulatory guide and I believe that must have been two or three years ago.

MS. HOLAHAN: Okay.

DR. WILLIAMSON: So I'm concerned that we have never had an opportunity to have input into the regulatory guide associated with this version of the rule that went to OMB.

DR. CERQUEIRA: Ralph had a question.

MR. LIETO: Yes, I would like to echo Jeff's comments because I think the devil's in the details and that's where a lot of the so-called conditions and what the inspection and enforcement people are going to be looking at is compliance with that regulatory guide if it's adopted by licensees. And so, I think it's really important that we have a change to take a look at this before it goes out.

MS. HOLAHAN: Okay.

MR. LIETO: Because we've never seen it.

MS. HOLAHAN: All right. Well as I say is -- okay, Marjory may I turn to Marjory Rothschild there?

MS. ROTHSCHILD: Yes, I'm with the Office

of General Counsel, and I just wanted to clarify something, kind of put it in perspective. Getting first to the rule, we have a proposed rule that was published for comment. We received comments from the public on it.

Based on those comments, you know, certain changes might have been made. And so, the status of the rule is, it was published for comment or any changes in the final rules of such a nature so significant that you would have to go through notice and comment. I mean it's anticipated that when you publish a proposed rule and see comments, you're going to get out of that process, you know, changes to the rule language.

So, that's a given and not all changes would require, in fact it's just a question of degree. You evaluate changes between proposed and final, and if they are so significant that you feel there wasn't adequate notice, then you may have to republish for notice and comment.

But in a typical rule there are going to be changes in language from proposed to final, and aside from whatever's going on now in terms of Congressional action, the rule still has that status of a proposed rule on which there was comment and you

would only have to republish for notice and comment if you decided that the changes were of such a magnitude between proposed and final that, you know, you didn't give adequate notice. The other comment I had as far as the --

DR. CERQUEIRA: Just in follow-up to that now, is that decision to be made by this committee?

MS. ROTHSCHILD: No. When you say committee, the ACMUI whether you'd have to republish?

DR. CERQUEIRA: Yes.

MS. ROTHSCHILD: That's a legal question.

DR. WILLIAMSON: Would we be able to have -- I guess maybe a more appropriate question is, would we be consulted and be able to express an opinion, since I don't think we have any decision-making authority whatsoever in this agency?

MS. ROTHSCHILD: Yes, I'm sure if you had views you wanted to express, you know, that's certainly a prerogative you have. But whether you re-notice from proposed to final is a legal question. There may be policy considerations also.

DR. CERQUEIRA: Dr. Nag said --

MS. HOLAHAN: I was very actively involved in the development of the draft final rule.

DR. CERQUEIRA: Right.

DR. NAG: I'm not saying that you have to consult us. What I'm saying is that we would like to be consulted upon when you make changes. I know you're getting comments from a lot of people and the staff is going to make the changes. Sometimes some of the changes may be unintentional. It may have some consequences that you may not have thought of.

Even a simple thing like and, and all, make sometimes a big difference, and I think some of you know what I'm talking about. Even a single word, changing an and to an or makes a really big difference, and I think we would like to see that rather than waiting and having the whole thing published and then suddenly be surprised.

MS. HOLAHAN: And you're talking about the guidance rather than the rule-making?

DR. NAG: Yes.

MS. ROTHSCHILD: You're talking about just reg guide?

MS. HOLAHAN: Okay, because I was going to say I was very involved in the finalization as we move forward with the rule. They're asking about the reg guide.

MS. ROTHSCHILD: Okay, well I just wanted to clarify this in terms of the rule, but make it

clear that the ACMUI, as well as members of the public, did have an opportunity to come in on the draft regulatory guide and I know we received a lot of comments. But ultimately what that will say will, you know, depend on: 1) what those comments were; and, 2) what the final rule language is.

MS. HOLAHAN: Right.

DR. CERQUEIRA: Neki, you have a comment?

MS. HOBSON: Well, yes. I think that it would be very useful for us to have the guidance language that we can look at, you know, in connection with Part 35 since some of the comments that I've heard is that the guidance documents that are actually establishing new regulations without going through a regulatory process, and I don't think that's what we intended to do here.

Secondly, and this is nothing new to the members of this committee, but I have expressed in the past my kind of frustration that we seem to spin our wheels and, you know, we give advice and nothing happens. I mean I'm sure we've had some impact on the final Part 35, but I think it's far less than I would have liked to have.

MS. ROTHSCHILD: Okay, we can get copies of the draft guidance for the committee, but I'd just

like to say as one of the things that the guidance does do, and we have taken a very careful look to insure that we're not putting any new requirements in the guidance than is what is in the rule. I mean I think we have to look at that also from an OMB perspective to make sure that there's no additional burden in the guidance other than what is in the rule.

MS. HOLAHAN: But we can check it out.

MS. ROTHSCHILD: We also since the new Part 35 doesn't require the submittal of procedures, we do have model procedures in the guidance, but that's what they are. They are model procedures and licensees can develop their own procedures to meet the requirements. But I think we find sometimes there are some cases where licensees would like to have the model procedures to follow.

DR. WILLIAMSON: So we can count on seeing the regulatory guide soon or do we need to make a motion to the chair?

DR. NAG: At night time please.

MS. HOLAHAN: I think we can get you a copy of the guide.

DR. NAG: Can we have it at night time on that?

MS. HOLAHAN: Pardon me?

DR. NAG: Can we have it at night time on that? When?

MS. HOLAHAN: I don't know if I can get the copies made today but I can get them out to you. We can put it in motion today and get it to you, but I can't --

MS. ROTHSCHILD: Trish, is that the draft final guide you're talking about?

MS. HOLAHAN: Yes.

MS. ROTHSCHILD: Okay.

MS. HOLAHAN: Yes, the draft final.

MS. ROTHSCHILD: Okay, that's fine.

DR. WILLIAMSON: I just had an information question. What version of the rule was the draft guide that we had a chance to comment on based?

MS. HOLAHAN: The proposed rule.

DR. WILLIAMSON: The proposed rule that was published in the Federal Register?

MS. HOLAHAN: Correct.

MS. ROTHSCHILD: Yes, they were both published.

DR. CERQUEIRA: You said you had another comment?

MS. FRANT: I'm Susan Frant and I guess Don mentioned my name and now this is me. I was out

running around trying to find some medicine for impacted sinuses, so I apologize.

Anyway, what I was going to say about the web is our web is down and the only thing on it now are employment kind of things, contract kind of things, the name of the agency, who we are, what our mission is, and how to report a safety concern. So all of the other information that you might send somebody to the web site to get is not available.

The rule-making, proposed rules will go up but the comments are no longer going to be available on the web site. So I wanted you to know that. We decided to do that a couple of weeks ago. The Department of Defense, in fact, asked us to take down our web site and it was more related to the reactors, but there's also some issues related to, and I think Don discussed this, related to radioactive material.

So while we work that through, for instance the Sealed Source and Device Registry is now password protected, and only the states and NRC staff and our master material licensees have access to the Sealed Source and Device Registry when before it was a public registry.

So I heard the conversation "well, what's on the web and what's not on the web." Nothing's on

the web that's related to Part 35.

MS. HOLAHAN: I'm sorry, you're right. I didn't address that.

MS. FRANT: But that doesn't mean that's not available so people can ask for it, but we want to keep track of who's getting what material.

MS. ROTHSCHILD: I just wanted to clarify as far as OMB, the rule doesn't go down to OMB for approval as a whole. What they're looking at is, under Paperwork Reduction Act, the information collection requirements. So, I just want to clarify.

MS. HOLAHAN: Okay, I thought I'd said they'd approved the information so I'm sorry.

MS. ROTHSCHILD: I'm sorry in some of the discussion that might have been blurred.

MS. HOLAHAN: I'm sorry, I meant to say that they -- okay. Doctor Diamond?

DR. DIAMOND: I'd just like to say that when I first learned about this action to go and debate the final rules in Congress, I can not tell you how frustrated and disappointed I was.

Two of the NRC principles with good regulation, I'm reading from the little chart back here, are efficient and clear and we've spent a tremendous amount of time and work on this and I'm

sorely disappointed that this was the method decided by one constituency to go and try and change the final regs. They have the right to do it of course, but that was sorely disappointing to me and just dragging the process that's taken years and years and making it even longer.

The second point is, I would like to fully and very clearly enunciate that when guidance documentation is being promulgated, that this committee have access to this beforehand for comment. The memo that was sent out dated June 12, 2001 regarding IVB, because of a simple use of an operative term, and versus or, as we'll discuss later has generated for me a tremendous amount of questions and confusion which again violates one of your principles.

So the two points I'd like to share: 1) I'd like to see these guidance documents before they go out for discussion; and 2) I was very, very disappointed regarding the type of action that's been taken and it questions the valuable use of my time serving on this committee.

DR. CERQUEIRA: Good comments. Neki?

MS. HOBSON: Is the only OMB report available anywhere?

MS. HOLAHAN: The terms of clearance?

MS. HOBSON: Yes.

MS. HOLAHAN: I can get you copies of those. I didn't get copies made before I came down here. That is to say I stepped in very quickly this morning, but I will get copies and we will get those to you today.

DR. DIAMOND: That's an excellent idea.

MS. HOLAHAN: I can tell you the time line for that. The other thing I would like to say is depending on where we do go is we certainly would like to continue to keep the ACMUI engaged as we see where the final language goes and what the next steps are. So we'll certainly look to the committee as we move forward.

DR. CERQUEIRA: Okay, other comments?

MS. HOLAHAN: Because I appreciate Dr. Diamond's comments and I recognize that you have expended a tremendous amount of effort on the rule that stands today, the new rule.

DR. CERQUEIRA: Okay, well we're at break. Should we take a break and then come back. Let's try to reconvene in ten, fifteen so we stay on time.

(Whereupon, the above-entitled matter went off the record.)

DR. CERQUEIRA: If Mr. Ayres could come

forward we'll get started.

MR. AYRES: Well, thank you. I notice that I'm scheduled for an hour. My presentation is not anywhere near that long, but depending on the questions, we'll see how it goes.

DR. CERQUEIRA: Bob, let me just ask a procedural question. Since some of the people do have to leave early, if we can get through some of these discussions, can we move some of these items up on the agenda or are we committed to doing it at the time that they're on the schedule?

DR. COOL: We should be able to move everything up as we have time available.

DR. CERQUEIRA: Okay.

MR. AYRES: What my purpose here today is to update you on the status. This is my third presentation on board recognitions and my intent is to report on those things we've done and sent the April report to you, and answer any questions that you might have.

DR. CERQUEIRA: Bob, before you get started, I have a question. After the last discussion, you know, on the Part 35 revision, if that doesn't get implemented what's the status of the board recognition?

MR. AYRES: Well the same thing as everything else. We're continuing to work on them but we're holding putting out any formal responses. If you will, we're preparing at a reduced pace, I guess, to continue with the board recognitions, but we're not actually executing the letter.

DR. CERQUEIRA: So, you know, sort of expressing some of Doctor Diamond's frustration, it's been a long process and --

MR. AYRES: It's a shared process and frustration I guess is my comment to that.

DR. CERQUEIRA: Okay.

MR. AYRES: But we are continuing to work on them. Just a quick review. These are the ones that we've talked to you about in the past that have submitted, and what I want to do is now update the status on the individual boards.

American Board of Health Physics, we've come to you several times with the problem we perceive with their application. It's still under review and the two problems we've discussed with you quite a bit in the past are both they come up under board certification process as not mandating the one year of full time radiation safety experience with similar types of by-product materials, and they don't have the

specified written certification of experience signed by preceptor radiation safety officer.

What they do have is six years of professional experience and a code of ethics. What they're trying to do is say, well we put those two together and we get the equivalent. It doesn't seem to quite work out that way. Any discussion on the American Board of Health Physics? I'll happily take comments on the individual items or wait until the end.

DR. CERQUEIRA: Jeffrey?

DR. WILLIAMSON: So has the American Board of Health Physics actually submitted a letter claiming that they meet at least the intent of the rule, or exactly -- I understand they had actually sent a letter saying they don't meet the rule.

MR. AYRES: They've submitted several pieces of correspondence, one of which says that they don't meet the letter of the language but they feel they meet the intent through their six years plus their code of ethics. But unfortunately with rule language, intent usually doesn't quite get you there.

DR. CERQUEIRA: Neki, you have a comment.

MS. HOBSON: How is this going to be resolved? From your comments, it almost sounds like

you've kind of made up your mind that they don't qualify?

MR. AYRES: That's correct. That's the way it looks at this time but the letter hasn't gone out so that's subject to change. But basically as a role of staff member, my position is to determine whether they do or do not meet the rule requirements.

MS. McBURNEY: And that's only for the RSO?

MR. AYRES: I'm sorry?

MS. McBURNEY: This is only for the RSO?

MR. AYRES: That score yes, of 35.50 for radiation safety officer, and in particular in the past the board has been the main source of your large institution radiation safety officers, broad scope medical licensees and multi-disciplinary treatment facility.

What's the out? The out is to go back to the training and experience and maybe another possible way is American Board of Health Physics board certification plus the preceptor statement showing that they have met the one year of full-time radiation training and experience in a medical facility, so they have the requisite experience.

DR. CERQUEIRA: Ralph -- go ahead Dick.

MR. LIETO: If I could just go Dick. Yes,

if I could comment on that since I'm on the board.

DR. CERQUEIRA: Yes.

MR. LIETO: One of the reasons the board has resisted going that direction is because that would force it into a sub-specialization and they're just trying to keep one single certified health physicist which is comprehensive, certifies across all areas, and then the ethics force you to practice in an area of expertise. So the board recognizes they do not meet the letter of the law and they were simply commenting to the NRC they thought that the way they practiced met the spirit of the law and so it's in a state of discussion.

MR. AYRES: Yes, I think we come up with some unattended consequences in the rule language and the public comment period and the whole process maybe didn't get where everybody thought they were.

But now we have the language, and assuming it goes forward, what we're doing in our letters and you have one of them in your package, the one we did send out recognizing the American Board of Nuclear Medicine, but not totally, I'll point that out in a moment, we say you appear to meet all of our requirements and we'll grant recognition for this and then we ask questions about those things. We don't

say we're denying recognition. We haven't been able to resolve whether they do or do not meet the rule language.

So often our letters, once they start going out, will go out with questions and there are several areas. More of them will come up as we go through the different boards, but the American Board of Nuclear Medicine, that letter of June 29th is in your package.

DR. CERQUEIRA: We had another question from Ralph.

MR. LIETO: Mr. Ayres, back with the American Board of Health Physics, a question. You made a point that most of the RSOs with broad scopes, large medical centers and so forth are RSOs that were approved meeting certification requirements under the current Part 35.

MR. AYRES: Right and the board is recognized under the current Part 35.

MR. LIETO: Right, now assuming that the new Part 35 is approved and goes into effect, are those --

MR. AYRES: They'll be grandfathered.

MR. LIETO: Okay.

MR. AYRES: Yes, everybody that holds an

existing appointment, authorized user, medical physicist, RSO, et cetera, grandfathers. If they're listed an authorized user, that authorized user status will transfer. I know there may be some questions on that.

So, the only thing else with the American Board of Nuclear Medicine as well as three or four other boards come in asking for recognition under 35.50-A. Maybe they didn't understand the ruling, but 35.50-A is for the full broad scope RSO type of appointment that's traditionally done by AB, the American Board of Health Physics right now, and it has the same requirement.

I mean the requirements are the same. They don't change. That one year of full-time experience in the RSO statement, plus the other training experience issues. So it didn't look like to us that the American Board of Nuclear Medicine met that, but there's an alternate pathway for almost all authorized users, 35.50-C which says if you're an authorized user, a physician or a medical physicist or a radiation pharmacist, you can be an RSO of a facility working as an RSO for those materials for which you have experience.

So a nuclear medicine authorized user

could readily be appointed under 35.50-C as the RSO for a diagnostic nuclear medicine facility. I don't know if their request for broader authorization was an error or not, but what we did in the letter and it's in your package is said "well, it doesn't look like you meet, we won't recognize you under 35.50-A, but you're already granted the authority and recognition under 35.50-C."

The Board of Pharmaceutical Specialties, that's also under review. It looks like we've got to go back to them and ask some questions about their written certification of training and signed preceptor statement. Those seem to be an issue at least in the letters that we've got and looking on their web sites, on their board processes, that we don't see evidence that they exactly meet the rule on this and we have to go back and ask. Yes.

DR. WILLIAMSON: I guess I have a general question. What sort of verification do you subject these written claims to?

MR. AYRES: Written certification from the board officers.

DR. WILLIAMSON: But if the board officers say "we certify X" do you just accept that or do you have some sort of a procedure for validating that

claim against independent information?

MR. AYRES: I'm speculating here but I think the way it works, we accept it. If somebody questioned or complained to us that this board you approved and it doesn't meet this requirement, we're probably going to go out and inspector check.

So the policy now, as I understand it, we'll accept their verification but we reserve the right to question it if it becomes an issue.

DR. WILLIAMSON: Okay.

MR. AYRES: I think that's a fair way. So that's the status of radio pharmacy. One of the more problematical ones, this one really applies as we later get on to ABR and their certification of medical physicists also. The exact same issues exist. It's currently under review. We in fact have a letter drafted, but again pending the outcome of Part 35, we're sort of sitting on that one.

We also have a letter that we got on these issues from AAPM and that is in your package. And like I said, it's under review. The central issue is the lack of a requirement to complete the training for specific modalities, such as -- well, not such as, specifically remote afterloader teletherapy and the gamma knife. Like I said, the AAPM letter is in your

package.

There are certainly some alternatives here to go and maybe we might end up in a position that might not be too different from what we are doing now in that we again recognize board certification plus, and that's kind of what the letter addresses, plus evidence of specific training experience in these modalities. So you could be an authorized medical physicist for remote afterloaders or remote afterloaders and gamma knives or any combination of the three.

I expect that that's probably the way we'll grandfather if a person is currently authorized for teletherapy and remote afterloaders that would be their authorization and grandfathering. It would not include gamma knife until they come in to demonstrate specific training and experience which we really need on the gamma knife.

DR. WILLIAMSON: What's your basis of that? 35.51 does not express any such qualification.

MR. AYRES: Well, it's a training and experience requirement. What I'm saying is I'm hoping. There's two ways to go, to not recognize the board whatsoever, okay -- well, three ways, recognize the board and that would give them all the

authorization.

DR. WILLIAMSON: I think there's two issues maybe being collapsed into one issue. I guess I heard you addressing both in the same sentence, 35.51 which is the perspective credentialing for medical licensees and 35.51 which is the grandfathering clause for those currently on licenses and it seems to me they're very different.

MR. AYRES: Right. Well, they are. They may be. They could be very similar and they could be very different. There's two issues and one, you've raised the points in correspondence.

One is what does grandfather? How do we grandfather authorized users and medical physicists that have current authorizations that do not encompass the full range of the board certification process? And as written now, 35.51 if we recognize and granted recognition for board certification, we say that the board certification encompasses all of these modalities and the medical physicist is authorized to perform them all, which is the problem that we're running into.

What we have with current medical physicists, we have them authorized for one or two or there may be some where they're authorized for all

three. None come to mind, but it's certainly possible. And so how do we -- do we just have a general title of authorized medical physicist or do we grandfather authorized medical physicists for modality A, B and not C that they currently are authorized for.

DR. CERQUEIRA: I'd like to hear, you know, comments from Jeffrey and Ralph on these points because it's a critical issue.

MR. AYRES: Yes, there's certainly a lot of correspondence going on.

DR. WILLIAMSON: Well, I think the 35.51 and 57 have to be clearly distinguished from one another and I think that we have a system that's in place now where there basically is only a definition in the regulations of teletherapy physicists.

MR. AYRES: That's correct.

DR. WILLIAMSON: And in some cases by license amendment, radiation safety committees and so on have had to review the credentials of individual physicists to do high dose rate and gamma knife.

MR. AYRES: Exactly.

DR. WILLIAMSON: And perhaps in even some specific scope licenses there might be a commitment to provide certain QA functions for gamma knife and for high dose rate therapy by someone who meets the

teletherapy physics requirements.

MR. AYRES: Yes, there's usually some --

DR. WILLIAMSON: So I think it's a rather confused situation.

MR. AYRES: Yes.

DR. WILLIAMSON: I think now you're starting a new system and the system's not going to function very well unless you create artificially a pool of authorized medical physicists who can provide the preceptor function. So --

MR. AYRES: Well.

DR. WILLIAMSON: Let me finish. My strong advice would be that 35.51 should be interpreted without qualification, that if someone is named or endorsed as a teletherapy physicist on an agreement state license or NRC license or via act of a radiation safety committee for any modality whatsoever, that credential should be accepted, that person should be accepted as a fully qualified AMP without restriction, thereby creating the pool of individuals you need to do the credentialing prospectively.

MR. AYRES: Well.

DR. WILLIAMSON: Every board or certification mechanism faces this problem, and I think the fact that qualifications were not written

into the rule language gives you the option to prevent, I think, what could be a catastrophe in the community.

MR. AYRES: I'm not sure on that. At a minimum, and I didn't want to really get into the grandfathering issue, but at a minimum everybody would retain their authorizations they currently have, at a minimum. But I hear and I really didn't intend to address, except for some similar issues, the grandfathering.

DR. CERQUEIRA: But this is an opportunity to hear from two respected physicists in this area. Ralph.

MR. LIETO: I agree that you got to keep the two issues separate. I think the grandfathering has to occur across the board, because you're going to end up disenfranchising a lot of physicists from performing duties that either they assumed that they're qualified by their board certification, and their institution to perform. The main population that's going to suffer is the patient population that may not be able to get the medical physics support that's needed for that modality.

You're already stating that you're going to be grandfathering the RSOs and the authorized users

as they're approved right now. This sub-specialization so to speak of subcategories are being created by the new rule, okay. It's not something that exists in the old rule.

MR. AYRES: Well it's something that exists in policy because the old rule only covers teletherapy.

MR. LIETO: Right, but if a teletherapy physicist was approved on a license or by a radiation safety committee or so forth, to my knowledge I know of none that have not been approved to perform remote afterloading and some of these other new modalities as they're coming up.

MR. AYRES: The way we do it now so it's the same way, basically we've always viewed the teletherapy physicists and their involvement in manual break therapy was a given and we never had any questions about that. But we required specific authorizations and training for them to be authorized to work with remote afterloaders, high dose rate remote afterloaders and stereotactic radiosurgery. They did have to come in and have a specific authorization put on their license for that, and provide training and experience, any additional training and experience requirements.

DR. WILLIAMSON: Did you require that for authorized users in the license?

MR. AYRES: No, don't believe so. Don't hold me to that. I'm not absolutely certain on something like stereotactic radiosurgery.

DR. WILLIAMSON: But they didn't.

MR. AYRES: I don't think they did at all.

DR. CERQUEIRA: Maybe we can get some comments from Dr. Nag and Dr. Diamond on this issue. I mean, how would you propose to deal with the issue of specific modality.

DR. NAG: Yes, I think again I agree that the grandfathering should be kept separate from the new one. For the new one yes, you can go ahead and do it the way of the posting. But in the grandfathering, the way we have our medical physicists if they are doing teletherapy, let's say we never had remote afterloader in our department and we bought one today, they would get the short training course from the manufacturer on how to use that but they would not require any other separate 500-hour job training.

The way it's written, the 500 hours is not taking into account the overlap of the training that you already had for taking care of your other radioactive material. So, my suggestion is anyone who

is currently a medical physicist should be allowed to use any of those modalities.

MR. AYRES: Well, what you said what they do is what -- basically we require primarily for remote afterloader is our main additional requirement for a teletherapy medical physicist to be named as a remote afterloader or a high dose rate brachytherapy authorization is to get the manufacturer's training. We require it for the authorized user too, so there is a case there where we do it in policy, okay. I'm not absolutely current on the stereotactic radiosurgery, but we do have a little more extensive requirements. There's an apprenticeship training program run by the manufacturer and that includes both the authorized user and the medical physicist.

DR. WILLIAMSON: So why are you singling out the physicists for special treatment like this?

MR. AYRES: We're not. We haven't got to the authorized users. There's some places in there, okay.

DR. CERQUEIRA: David, do you have a comment?

DR. DIAMOND: Yes.

MR. AYRES: Okay.

DR. DIAMOND: Every time I hear these

discussions, I keep on asking myself how can we not be enslaved to regulations that are well-intentioned but not perhaps worded the exact way they were intended? And this would be an example of it. What I'd like to explore is whether, just like we've done in other areas, without our advice and consent I may add, some type of guidance document be promulgated that exactly reflects the spirit of this discussion.

MR. AYRES: Well, generally we issue guidance documents in the absence of regulatory language.

MR. DIAMOND: This would be an example of a guidance documents in the place of bad regulatory language.

MR. AYRES: When we have regulatory language, we can't issue guidance language that gets around the regulatory language requirements. We can only issue -- we can and do and that's a reg guide that you want to review, issue language in how to meet the regulatory requirements, but there's no way we can alter the regulatory requirements through guidance.

DR. DIAMOND: Well, I don't know. I think one of the most productive at last meeting was a methodology in the guidance document that allowed us to use IVB for indications off label without that

being mis-administration. I would consider this to be in exactly the similar vein.

MR. AYRES: No, because there's no regulatory requirements relating IVB, so we're free to regulate it and we do and we must because there's no other mechanism through guidance. Once it's in the rule, we don't have any flexibility anymore. Well, the only flexibility we have is granting requests for exemption, specific requests for exemption on a case-by-case basis.

DR. CERQUEIRA: Neki had a comment.

MS. HOBSON: Yes, from a patient perspective what we are really talking about here is a transition period of a few years I'm assuming.

MR. AYRES: No, if the new rule becomes effective, it becomes effective completely on the date, which would be six months from publication.

MS. HOBSON: But you're grandfathering everyone who's current licensed.

MR. AYRES: Only on training and experience.

MS. HOBSON: Oh, on training and experience.

MR. AYRES: So anybody new applies the day after the new rule becomes effective has to meet the

new requirements.

MS. HOBSON: Okay, but the currently licensed or authorized medical physicist, even though his certification doesn't include specifically remote afterloader teletherapy and gamma knife, he would be able to conduct those efforts?

MR. AYRES: Well it does right now. It is specific to what he's authorized for. If he's been there a long time and has done nothing else, it's for teletherapy only. Then, you have to come in to be added either, well through a master material license broad scope and through ourselves for the other modality, yes.

MS. HOBSON: I'm concerned that the patient is going to be caught in a situation here where, you know, they'll just fall through the cracks because there won't be anyone at that particular institution or facility who can give them the treatment that they need if the license is so restrictive.

MR. AYRES: There's no change in the authorization -- when the new rule becomes effective, there's no change in the authorization of the medical physicist from what exists now, and exactly how the grandfathering will be done, we've kind of gotten in to that which I'm not addressing and there's two

routes, full recognition or recognition for the modalities that they currently have.

MS. HOBSON: That's my concern.

MR. AYRES: I'm not sure. I would have to review the rule language a little myself.

MS. HOBSON: I think there's a --

DR. CERQUEIRA: The recommendations of the committee are to basically grandfather them generically for all of those modalities for the people that are currently licensed. Does anybody disagree with that?

DR. WILLIAMSON: No. I think we need a motion.

DR. CERQUEIRA: All right, do you want to make a motion Jeffrey?

DR. WILLIAMSON: Yes. The ACMUI moves, recommends to the commission that 10 CFR 35.57 be interpreted to mean that medical physicists listed as teletherapy physicists on any agreement, state or NRC license, be understood to be fully qualified authorized medical physicists without limitation to modality.

MS. HOBSON: I'll second that.

DR. CERQUEIRA: Second that. Any further discussion?

MR. AYRES: The rule is quite clear on it.

MS. HOBSON: Yes.

MR. AYRES: They can be authorized only for those medical uses which they're authorized on the date the new rule goes in effect. I wasn't prepared to talk on 35.51, so I hadn't reviewed the language, but it's quite clear. So, it's kind of a moot point.

MR. NAG: I'm not quite sure, what does that mean?

MR. AYRES: Well, it means if they're only authorized for teletherapy, that's all they're going to get grandfathered for.

MR. NAG: Right, but not here today. We have Dr. Williamson who is taking care of the teletherapy at his institution, but tomorrow he goes to an institution that has teletherapy and a remote afterloader. The manufacturer provides usually a three or four-day course on how to run the remote afterloader. Would he be able to use it or not?

MR. AYRES: No, he'd have to submit to be named as authorized user for remote afterloaders based on the training he received and that would probably be readily granted.

DR. WILLIAMSON: Could I read the regulation just to make sure I understand the

consequences.

MR. AYRES: Sure.

DR. WILLIAMSON: An individual identified as a radiation safety officer, a teletherapy or medical physicist or a nuclear physicist on a commission or --

MR. AYRES: Pharmacist.

DR. WILLIAMSON: Well, it says "or medical physicist."

MR. AYRES: Well they should have nuclear -- well, never mind.

DR. WILLIAMSON: "Medical physicist or a nuclear pharmacist on a commission or agreement state license or master material license permit or by a master material license permitee," a broad scope, "before insert date six months from publication of final rule need not comply with the training requirements of 35.51 or 55."

MR. AYRES: Right but then the language I was referring to is in B. "Physician then or authorized user" and you go on down and it says --

DR. WILLIAMSON: Where does it say physicist?

MR. AYRES: "To perform only those medical uses for which they are authorized on the date need

not comply with the training requirements of Subparts B and A."

DR. WILLIAMSON: Where does it say physicist? It says physicians, dentists, or podiatrists.

MR. AYRES: Okay.

DR. WILLIAMSON: It doesn't say physicists in there.

MR. AYRES: All right, I wasn't prepared to talk on this but we -- clearly on the physician all right.

DR. CERQUEIRA: We're not going to be able to resolve all this.

MR. AYRES: Yes. I certainly understand your recommendation and certainly review it in looking at the rule. I wasn't prepared to discuss the grandfathering which seems relatively straightforward in most cases.

DR. CERQUEIRA: So we still have a motion on the floor. Is it still relevant Jeff? Do you want to keep it?

DR. WILLIAMSON: I think it's relevant.

MR. AYRES: Oh, it could be. Well, certainly advice we'll take it and look at it.

DR. WILLIAMSON: I would like to say one

thing in it's defense or it's articulated rationale for it. I think that the idea of grandfathering is to basically for a population of professionals that are working before a certain date is to be able to guarantee that they will be able to pursue their livelihoods under the existing training and experience regulations as of that date.

MR. AYRES: Yes.

DR. WILLIAMSON: And as of that date, you know, right now if someone is a teletherapy physicist doing just teletherapy, all they have to do is satisfy the conditions of the license to be an authorized HDR physicist which in this case simply means undertaking the, you know, accepting a commitment to have vendor-supplied training or perhaps, you know, annual training provided by another physicist within the institution. It depends how your license is written really.

MR. AYRES: Yes.

DR. WILLIAMSON: So I think the intent clearly is, is that that's the rule that should be followed in the future for somebody that's listed as a teletherapy physicist prior to the changeover.

MR. AYRES: Yes.

DR. WILLIAMSON: I'm not trying to suggest

that this should be a way of getting around license commitments.

MR. AYRES: Traditional grandfathering is you retain the rights you had when the rule changes, and on that basis they are --

DR. WILLIAMSON: To say that somebody who's just a teletherapy physicist who's board certified and so on can only be a teletherapy physicist without satisfying the new 35.51 for HDR and gamma is actually then imposing an additional and different set of requirements which are rather different than the ones they work under now.

MR. AYRES: What I'm saying is not really because we have that type of requirement as part of -- only it's in guidance --

DR. WILLIAMSON: But I don't think it's identical to the one that's in 35.51-B. It's not the same.

MR. AYRES: Well, I understand your recommendation.

DR. CERQUEIRA: I think we should vote on this and move on. You said an hour was too long.

MR. AYRES: I was hoping it would be.

DR. CERQUEIRA: Training and experience is never.

MS. McBURNEY: I can support what Jeff is saying if the license conditions are going to stay the same after the new rule goes into effect.

MR. AYRES: They won't.

MS. McBURNEY: Right, so if they're not going to stay the same, I mean there needs to be some commitment that they have that additional training from the manufacturer.

MR. AYRES: In the therapy area they're fairly similar but there is of course changes.

DR. CERQUEIRA: Do I have a motion for a vote on this, because what I'd like to do, and Jeff has brought up this point a couple of times. We have a lot of discussion.

MR. NAG: And nothing goes.

DR. CERQUEIRA: Sometimes we don't make motions. Well now, we're going to try to make the motion and what I'd like Angela to do is, at the next meeting give us follow-up. And by follow-up, I want like what's been done, when it was completed, and if it hasn't been done, what's the problem?

DR. WILLIAMSON: Not that we're thinking about it or we heard what you said.

DR. CERQUEIRA: Okay, so --

DR. VETTER: One more, I just would like to

support what Ruth said. If the conditions of the license change, then that becomes problematic.

MS. McBURNEY: Right.

DR. VETTER: Relative to the motion.

MS. McBURNEY: Right, so he can add.

MR. LIETO: You're going to change all the licenses when the new Part 35 goes through? I mean, that's kind of what it sounds like.

MR. AYRES: You're getting a little outside my area. I've never made this major transition on a rule, but there is rule language in there on how the rule transitions the new part and what governs if you have more restrictive license conditions in the new rule, those stay. Yes.

MR. BROWN: What I'd suggest is that the committee go ahead, make the recommendation. As with all recommendations, the staff will take that, look at how implementable it is and we'll get back to you with the decisions that we've made.

DR. CERQUEIRA: So Ruth, one final comment.

MS. McBURNEY: I would like to amend the motion to include that when transitioning to a new modality that they still be required by license condition to receive the manufacturer's training on the new modality.

DR. WILLIAMSON: I guess I would like to maybe suggest that we have an alternative amendment. Instead of that, basically include in the motion that not only teletherapy physicists' qualifications as articulated in the current Part 35, but also the training and experience guidelines in the existing regulatory guidance for gamma stereotactic and HDR, which would be more general and would pin it down to a document that is now in place.

MS. McBURNEY: That's exactly it.

DR. CERQUEIRA: So why don't you --

MS. McBURNEY: Restate the motion.

DR. CERQUEIRA: So what are we voting on?

DR. WILLIAMSON: Okay, I think we are voting on a motion which reads as follows: The ACMUI recommends that NRC interpret 35.57 to mean the following; that medical physicists who are listed as authorized teletherapy physicists on any agreement, state or NRC license, or by any act of a radiation safety committee within a broad scope licensee, be allowed to be authorized medical physicists for all modalities without qualifications, provided that they satisfy the supplementary training requirements contained in the current regulatory guides for those modalities extent on that date.

DR. CERQUEIRA: He doesn't have John's knack for resolutions.

DR. WILLIAMSON: I'm sorry. He is sorely missed.

DR. CERQUEIRA: But I think you'll get the gist of it. We should take a vote. All in favor. Opposed? Okay, and then Angela if you could transcribe that off the transcript.

MR. AYRES: Yes, that actually sounds pretty workable.

DR. WILLIAMSON: I would be happy to help edit my motion before I leave.

DR. CERQUEIRA: Okay Bob, what's next. The American Board of Radiology.

MR. AYRES: A similar one and the American Board of Radiology, ABR, has applied for recognition under all three of their disciplines which are diagnostic radiology. They've applied for 31.190, 290 and 390 and they've stayed away from the specific applications for thyroid work on their applications, and 392 and 394 they didn't ask for.

Under radiation oncology, 392 and 94, which they are putting the thyroid cancer ablation applications under, 490 the brachytherapy, 491's the stronium I applicator, and 690 which encompasses all

the high-dose stuff, the gamma stereotactic radiosurgery and the high dose rate and teletherapy and so forth.

Under radiological physics, they again applied for the broad 35.50 and the 35.51. Again, we're reviewing that. We have some issues. Again, with all the board, we're looking at and confirming that they do, as part of the board application process, have a preceptor statement requirement.

Now Jeff raised an issue under 35.690 on our specific modality requirements for authorized users, and under 693 at the bottom of the page here, B-3, it says it has obtained written certification that the individual has satisfactorily completed the requirements above in this section and has achieved a level of competency sufficient to function independently as an authorized user in each type of therapeutic medical unit for which the individual is requesting authorized user status.

So there is a requirement for the authorized user to demonstrate experience with gamma stereotactic and radiosurgery, high dose rate, standard manual brachytherapy, teletherapy, et cetera. Yes.

DR. NAG: What is the language requirement

on this? Is this the same? For example, like 30 years or 20 years ago --

MR. AYRES: I think the grandfather requirement on this is much more straightforward because we do not at present put authorized user radiation oncologists in bins as we do medical physicists. So, there's no bins to sort the existing pool and they would just get the full authorization.

DR. WILLIAMSON: I'm not sure you really have that for physicists. I mean, you only have the one legal category which is teletherapy physicists, and there's a requirement in guidance that for HDR and gamma stereotactic that you have a physicist do these things who satisfied the definition of teletherapy physicists in the current Part 35, plus has these additional trainings. I think you do exactly parallel language for the authorized user if I'm not mistaken.

MR. AYRES: We have authorized for 35.600, 35.400, and 35.300. There's three bins if you would for a therapy authorized user. For authorized medical physicists we have the same three bins. They're authorized for either teletherapy, high dose rate or gamma stereotactic radiosurgery. That's how they're currently binned. Now how it ends up, well let's not go back there.

DR. WILLIAMSON: It currently refers to the current Part 35. I mean, how they will be binned is what you mean.

MR. AYRES: Under the current Part 35, there's no binning of the authorized user for therapy except in the broad 600, 400, 300. The medical physicists are usually not involved in 300, the ones that are working in therapy, they may or may not be. There's no requirement that a medical physicist be there, so that's not an issue. But they are binned 400, 600, and 300 in six bins. We heard your recommendation and hopefully we can move on here.

DR. CERQUEIRA: We've got to think about the physicist and Dr. Nag do you have a comment?

DR. NAG: Yes. We had a long discussion in the last meeting and since I'm not clear what portion of our discussion was acted upon, I would like clarification here. One of the major discussions we had was what the radiation oncologist, the 500-hour requirements and those 500 hours, it was not clear were they to be 500 hours separately for high dose rates, separately for gamma knife, and separately for --

MR. AYRES: I can head that off quickly. The answer's in your book, the letter from the

chairman to Dr. Hendee I believe. It gives our position on that and it's that they will be aggregated in a single 500 or whatever expansion task that is to meet the necessary training.

DR. CERQUEIRA: While people are looking at that so they can comment, since they haven't seen it, the confirmation of preceptor statement, that's been something that showed up on all of these, but if you make that an eligibility requirement for the board, shouldn't that satisfy your requirements as well?

MR. AYRES: Yes, and the issue is whether the boards require it or not. It's not certain that ABR does. The draft letter back to them will ask them "well, what do you require in the way of meeting this objective of the rule?" Their initial submission didn't go into that.

DR. CERQUEIRA: Okay.

MR. AYRES: They may or may not. We'll get down to the bottom and then there's the broader issues, but you're already getting into most of those.

The medical physicists we have the same issue that we had with the Board of Medical Physicists, which is the three specific modalities. Again they ask for the RSO qualifications. It's the same issue. They really don't meet the one year

specific training and experience requirement and the preceptor statement under 35.50-A but they come in under 35.50-C again.

And the letter from the chairman to Dr. Hendee really does give our position I think quite clearly on the 500-hour, whether it sums for 400, 500, 600, 300 you end up with 2,000 hours and their answer is no. It's 500 plus and the plus would be if you couldn't stuff it all for all those modalities in 500. Yes.

DR. WILLIAMSON: Could you go back to the radiation oncology slide application?

MR. AYRES: We're still on it.

DR. WILLIAMSON: No, there was one where you listed all the things that ABR had requested. That's the one I wanted to just make a comment on.

MR. AYRES: Oh, okay.

DR. CERQUEIRA: Just go backwards for the sake of time.

MR. AYRES: There we go, okay. I was figuring out if it was up, down, right or left.

DR. WILLIAMSON: Under radiation oncology, Dr. Kapp's (phonetic) letter, you know, December 26, 2000 actually includes 35.390 which is the general radiopharmaceutical authorized user status.

MR. AYRES: Yes, you mean under oncology?

DR. WILLIAMSON: Under oncology, yes.

MR. AYRES: Okay, I may have -- if it includes it, it includes it and it's just an error on my preparing the slide. But certainly addressing everything that's asked for, and I just omitted one. I had it up here. I didn't move it down here.

DR. CERQUEIRA: So Dr. Nag, did you get a chance to look at the letter?

DR. NAG: Yes.

DR. CERQUEIRA: And you're in agreement with the response?

DR. NAG: Yes.

DR. CERQUEIRA: Okay.

DR. NAG: That includes now.

DR. CERQUEIRA: Right. Now Bob, where do you stand? I mean, you know the ABR was preapproved in the past, so have you responded to them with these issues and have they gotten back to you?

MR. AYRES: Well, we're holding the response.

DR. CERQUEIRA: So you haven't sent responses out to any of the boards at this time?

MR. AYRES: Well, only two communications went out, yes, the letter out to the American Board of

Nuclear Medicine which went out before we found out there was a problem with getting the rule out in a timely fashion, and the letter from the chairman to Dr. Hendee which partially clarified some of the ABR issues.

DR. CERQUEIRA: Right. Well, I think the suggestions of the committee would probably be that once this gets resolved that hopefully we'll be able to go forward with this. We'd really need to notify them because to make some changes in the eligibility requirements for preceptorship statements and everything can take a year or two. I wouldn't hold up boards pending the actual language in their eligibility requirements.

MR. AYRES: Well understand there's no deadline on this. If the rule becomes effective and they haven't met the requirement and it's the decision of the board whether they choose to alter the board. We're getting ahead in the discussion item, where they wish to alter their requirements in a sometimes major, or sometimes minor way to meet the requirements. There's no deadline. There might be a period of months or weeks or years that they wouldn't be recognized, but once they do they can go on the list.

DR. CERQUEIRA: But I think you can

minimize that. It would be in everybody's interest to do that.

MR. AYRES: Yes it would be --

DR. CERQUEIRA: It would minimize the transition period.

MR. AYRES: It would be a big administrative burden on us. This guy was certified in this time period which means he's not eligible for this time. That would be really -- it would be nice to avoid.

DR. CERQUEIRA: I guess what we're suggesting is once the decision's been made and you've already done the work and there's issues, and if these boards don't know that there's issues, they're not going to be able to respond.

MR. AYRES: The boards know the issues because they in fact identified them themselves in their letters to us.

MR. BROWN: This is Fred Brown. I can speak for John Hickey. We agree, Dr. Cerqueira, these need to go out as quickly as they can once we know the status of the final rule and that's our plan.

MR. AYRES: Yes, we're continuing to work on them and; in fact, I have several of them all drafted and ready to go once we know which direction

we're going.

DR. CERQUEIRA: Hopefully that will be soon. MR. AYRES: Yes.

DR. CERQUEIRA: Why don't we go on to, what's the next board? Go ahead Jeff.

DR. WILLIAMSON: What are your responses to the radiation --

MR. AYRES: We did --

DR. WILLIAMSON: -- excuse me, what are the responses, your proposes responses in the letters for radiation oncology?

MR. AYRES: Well, they're draft right now.

DR. WILLIAMSON: Can I ask what they say?

MR. AYRES: I basically reviewed them and we got to go back with questions, particularly with regard to the preceptor statement. I got to look at -- I haven't prepared that letter yet. That one's under preparation, but I need to look a little more closely about their training and individual modalities too, whether they certify that.

The American Board of Cardiology is under review. It looks like, well they meet everything. It looks like it's no problem, no outstanding issue, one clarification. I talked with their manager.

There is a -- in the preceptor language it

says a preceptor has to have training -- or be an authorized user for 35.190 and 290 and the question came up, do I need the 190 authorization if I'm serving as a preceptor to only grant 290? It seems obvious that you wouldn't if you're only going to write a preceptor statement for 290, 290 would be all that you should need.

I think the rule more or less anticipated that the nuclear, the pure diagnostic nuclear medicine side where almost all of them ask for both 190 and 290 and many of the 300s. So there's no outstanding issues that we can see there at this time.

The American Board of Science and Nuclear Medicine look like they have a lot of problems because they're -- well, I don't want to go into what the composition board -- they're only asking for authorization under 35.50-A. They have no other available authorized user path, so 35.50-C is not available to them and they clearly look like they have difficulties in meeting the one year and the RSO preceptor statements.

So right now I've got to write back to them and, you know, ask for clarification on this. But if they don't meet that, it looks like they would not gain recognition.

DR. CERQUEIRA: Is anybody familiar with this board?

MR. AYRES: It's kind of affiliated with SNM or the American Board of Nuclear Medicine, and it's a board of science professionals, Ph.D. chemists, electrical engineers and other related medical professionals that are kind of aggravated into this one board.

DR. VETTER: I'll give you an example of the type of person who might be certified by them who then practices radiation safety, and that would be a consultant. They've never actually practiced at a medical center but they consult for many medical centers, so there's no way to get the one year of experience under a certified RSO.

MR. AYRES: Unless you go back in their training which is by the board by now. Anyway, they would certainly, those of their individuals who currently are authorized as RSOs would retain that under the grandfather provision. But it looks like they will have difficulty gaining recognition.

Points for discussion. I think we hit most of them. Those are the boards the work's been done on since I last spoke to you.

DR. CERQUEIRA: How many others have

submitted?

MR. AYRES: I had the whole list at the start. There's seven boards I believe that have submitted.

DR. CERQUEIRA: So and we went over all seven of those?

MR. AYRES: It's in the handout. The first two slides are all of the boards that have submitted.

DR. CERQUEIRA: All right, so there are no others then. Then basically you're up to date?

MR. AYRES: Yes, there are other boards that haven't submitted and, in fact --

DR. CERQUEIRA: Well, if they haven't submitted then --

MR. AYRES: Two osteopathic boards I've spoken to. I didn't put slides on them because they have not submitted. They intend to submit once the rule goes out.

DR. CERQUEIRA: Okay.

MR. AYRES: So there's others that plan to submit but have not.

DR. CERQUEIRA: So we had discussions in the past that there might be hundreds of boards that would be applying, but the reality is the number has been relatively small.

MR. AYRES: Yes, in fact the number of boards that have currently applied are far less than the number of boards that are currently recognized. I think we currently recognize twelve, seven have applied, and one of those is a new board.

MR. LIETO: But aren't some of those foreign boards, like the Canadians and the British?

MR. AYRES: Yes.

MR. LIETO: So they wouldn't --

MR. AYRES: There are two British we list and I'm not too sure that hasn't co-listed a single British board. The Canadians, there's three foreign boards in there. The Board of Nuclear -- the Certification Board of Nuclear Cardiology is a new one, and so we have six -- well four -- basically six currently longstanding boards that have applied to us for recognition.

DR. CERQUEIRA: Good, well maybe we could save five minutes for the intravascular brachytherapy discussion which I'm sure will be. Any other questions for Bob?

MR. AYRES: I think we've dealt with these.

DR. CERQUEIRA: Jeffrey.

DR. WILLIAMSON: I understand this issue's going to come up again this afternoon, is that right?

MR. AYRES: I'm going to be at -- this afternoon, so I won't be here. I'm scheduled to give a talk this afternoon.

DR. CERQUEIRA: Come up in what way? Under new business?

DR. WILLIAMSON: Well I understood there was going to be a speaker from the AAPM who was going to address the issue again with a proposal.

MS. McBURNEY: That's correct.

DR. WILLIAMSON: Since Bob won't be here to hear that person, you know, it might be appropriate to discuss what the AAPM speaker has said. We have the slides distributed here.

DR. CERQUEIRA: What are the wishes of the committee, do it now rather than part of new business?

DR. NAG: We can do it now. It's the same line.

DR. DIAMOND: I think it would be fine to do it now. Bob is here.

DR. CERQUEIRA: Do we have the representative then?

PARTICIPANT: He was told he wasn't on until 2:00, so he left.

DR. DIAMOND: So wait until 2:00.

DR. CERQUEIRA: Okay.

MR. AYRES: I managed to get dual scheduled. Jeff is familiar with the competing meeting. One of the items there is, Jeff is on the committee, but we're working on, I think it's an important point to note when you review the guidance document is one of the things NRC is encouraging in the new regulations is adopting of industry standards.

I have a committee working with Jeff on one and there certainly could be more. Unfortunately, APM does a lot of good work but they don't develop industry consensus standards, and I think they're looking towards doing something in that area. And so what, for example, was pointed out in the guidance, you can accept the model program, develop your own, or accept an industry standard.

DR. CERQUEIRA: Good. Well, thank you very much. The next discussion is on update on intravascular brachytherapy and Donna-Beth Howe.

MS. HOWE: I don't have a microphone. Okay, can you hear me? I'm essentially going to be giving you an update on the guidance that we put out for intravascular brachytherapy. I don't have any slides because I'll be speaking to the handouts in your notebooks, and at the end I'll give you just a quick update on mis-administrations that have occurred since

the last time we met.

What you have in your handout is the June 12, 2001 letter memorandum to the regions from Don Cool, giving updates on guidance. It supercedes two memos that went out, one was February of 2001, which was addressing the Novoste beta cath and the other was January 26th which was discussing the Cordis system.

The major differences are that we have kind of written things in a little bit more general and concise manner. Primarily in training and experience, that's the same. We're still requiring 35.940 for intravascular brachytherapy for these particular devices. Intravascular brachytherapy is not one field. It may be many different field depending on what the device is. So, what I say for these two devices may not apply for the next device coming down the road, okay.

We're still requiring vendor training for the authorized user, the interventional cardiologist and the medical physicist. We are no longer really defining things as a team but we're saying that the authorized user is responsible for the procedure and that the authorized user will consult with, an intravascular cardiologist or that could also be an interventional radiologist, and the medical physicist.

And then instead of requiring in the earlier memos all three members of the team to be physically present during the procedure, we've indicated that you must have the physical presence of the authorized user or the medical physicist. That in sort, we assume the cardiologist will be there, but there is some optional leeway there. Dr. Nag?

DR. NAG: I think I have very strong reservations about that. We had a lot of discussion at the last meeting.

MS. HOWE: You did.

DR. NAG: And there was no final consensus that this should be an or. Just changing that one word from and to and/or makes a huge difference without consulting or without talking back to the ACMUI.

The reason I have great reservation is that by changing this to an or, you would have a scenario that you are having an interventional cardiologist present who is very good in putting in catheters and taking care of the interventional part of it, and you may have a physicist very good in calculation, but does not have the anatomical know-how of blood vessels inside, and if there is a problem you don't have that one person there who has both the radiation safety knowledge in their head as well as the medical training

required to intervene with that second part. That very much concerns me.

So this should not have remained an or without getting back to us. This should have remained as an and and not an or. So it's that one word. And the other thing that concerns me is that you can make -- this is not a regulation, but this is what, an amendment? No.

MS. HOWE: This is a guidance.

DR. NAG: Yu can make a guidance where you make a slight change of the word and that changes the entire meaning and entire substance of the whole ruling and that very much concerns me, and I would like to have some feedback from some of the other members of the committee about this.

MS. HOWE: I reviewed the transcript from the last meeting several times before in preparation for this and it appeared to us that in the last meeting, there was pretty much a consensus that the committee did not want to require all three individuals to be there and that the flexibility of two individuals would be more acceptable to the committee members.

What we tried to do in specifying the authorized user and the medical physicist is to insure that we will always have someone there that has

radiation safety knowledge and the ability to do dose calculations in brachytherapy.

It can either be the authorized user or if the authorized user is not available and it's just the interventional cardiologist, the interventional cardiologist has substantial experience in, or the interventional radiologist because it may not be the coronary arteries, has extensive experience in the medical aspects, can recognize when the patient's having a medical problem, can take care of that, while at the same time, the medical physicist can supplement that information as far as the dosimetry, so he can know pretty quickly whether he's got a radiological concern in addition to whatever the problem is.

DR. NAG: But the concern that I have, you don't have that one person who has them both. Because in an emergency what you need is somebody who's familiar with both.

Let me give you a scenario. The major scenario I'm worried about is the fact that source is now inside the patient. The physicist can do the calculation and say well the set amount. But the physicist is not familiar or not very competent about handling anatomical stuff.

So now it goes back to the interventional

cardiologist who is very good at the interventional procedure but is not very comfortable with handling radioactive material. So who is going to handle it now?

DR. CERQUEIRA: Dr. Brinker is in the audience and he was actually at the last meeting. Maybe we could get him to come to the microphone and make some comments as well. But while we're waiting to do that, maybe Dr. Williamson, you wanted to make a comment?

DR. WILLIAMSON: I think we didn't come to a consensus that there should be an and, and some of the considerations that were involved is that the radiation oncologist is still the authorized user. The regulations are very clear that that individual has responsibility for the conduct of the procedure and has the ability to be there, require himself or herself to be there, or designate a resident of, if appropriate, if the physician has confidence in the physicist and the rest of the team to handle it, then just that group.

I think the intent was to provide some flexibilities to licensees, recognizing that the devices have very different levels of complexity, very different levels or probabilities of error and problems

and that one size doesn't fit all. And we did have quite an extensive discussion.

DR. CERQUEIRA: Yes, we did.

MS. McBURNEY: I don't think it was a consensus one way or the other.

DR. WILLIAMSON: Yes, I think we couldn't achieve a consensus on the and, that's for sure.

DR. CERQUEIRA: Dr. Brinker, do you want to make any comments?

DR. BRINKER: Well obviously I appreciate the opportunity to speak to you all again and I configured myself between my colleagues, radiation oncologists. I'd just like to say that the logistical problems that we discussed at the last meeting were accompanied by a suggestion and that is that we don't preclude situations where there is an agreement between all three members of the team that a cutting edge approach to this might be taken to solve a potential logistical -- not a potential, a real logistical problem in many areas.

This by no means meant to disenfranchise any member of the team, all three of which we consider to be very important. The background of some of this is the fact that this scenario of having a radiation oncologist aware of a particular case or situation but

not necessarily physically present has been used pretty frequently in Europe, which operate under a number of constraints, some of which don't pertain to us.

But, the concept is not unreasonable. My thought when I proposed this the last time was that in certain institutions where you have the three members of the team agree to this configuration, and who will put the necessary monitoring and checkpoints in motion, that this could be done. I don't think in proper reflection that this should be a problem for anybody, because if the radiation oncology arm of the team doesn't agree at that institution, that should be respected, and that was the gist of the comments.

I thought actually when I left that people pretty much agreed to that concept. The wording may be a little bit less precise and it could certainly be corrected by just saying when all three members of the team agree, and I hope everybody would be happy.

MS. McBURNEY: I think I'd also like to point out that just because we say the authorized user or the medical physicist have to be physically present, that does not exclude the cardiologist from being physically present.

DR. NAG: I don't think that answered my question at all. My concern was somewhat different.

MS. HOLAHAN: You want the authorized user there at all times?

DR. NAG: If the authorized user, like now the authorized user is the only person who is most confident, familiar with both components, the radiation component as well as the medical anatomical component. I would like to invite Dr. Tripuraneni who has been doing interventional brachytherapy longer than I have and see what you think this would do to your practice. He's a pioneer in this, and I invite -- Manny, can I invite Dr. Tripuraneni to say a couple of words?

MS. HOLAHAN: I would like --

DR NAG: It is very important.

MS. HOLAHAN: I'd like to point out that in the last meeting, one of the major concerns, and I think the committee discussed it for a significant amount of time was the fact that, at many of the hospital, they could not get the radiation oncologist for 24/7 coverage. They couldn't get the medical physicist for 24/7 coverage and so there was tremendous discussion about the fact that all three members of the team at many hospitals weren't available for 24/7. So there needed to be some kind of flexibility, some kind of compromise that the team could go ahead and treat patients without all three being present.

DR. NAG: Except that it's much easier because radiation oncology and medical personnel and who are already on medical standby, it's much easier to get a radiation oncologist immediately than to get a medical physicist immediately. The other thing is, if you have a situation where they are so understaffed and they can not have center coverage, then that center should not be doing treatment with high dose radiation where there's a potential for severe problems.

DR. CERQUEIRA: Well, I think that some of the discussion related to the fact that some of these devices are much more straightforward in terms of the administration, the dosing and everything else. There was a lot of discussion, I think Neki made some points, that if you're going to be denying access to some patients for a technique which is valuable, then that really kind of limits the care.

I certainly would entertain, make a three-minute comment period if you'd like to make it about your experience with intravascular brachytherapy. This is obviously a difficult question. We'd like to get everybody's viewpoint and I think what the staff was trying to do was just trying to be pragmatic to make the service available in a way that would help the patient and clinicians. If you could come to a

microphone. Do we have one back there?

DR. TRIPURANENI: Thank you for recognizing me.

DR. CERQUEIRA: I'm going to watch the clock, so I don't want to be rude, but this is an add-on, so three minutes.

DR. TRIPURANENI: We started vascular brachytherapy in March, 1995. We have done about close to 1,200 cases of it so far. We have experience with just about all systems that are currently approved and also currently going through the investigational procedures. I think it's probably important to have all three members of the team and this was the point of Dr. Nag.

I do agree that there are multiple systems, and even though some systems may seem straightforward and simple, some of the difficulty in administering and mis-administration seems to happen with one system more than the other. It's probably the design of the system rather than actually the isotope, et cetera, right in there.

That's when I think it's important to have all members of the team for the safety of the patient more than anything else. By giving the leeway, I think what you're doing is you're really not asking the

institutions to develop policies and procedures.

I do respectfully disagree that actually the this is really not a 24 hour and 7 days procedure. Most of the institutions have developed policies and procedures how to actually integrate there day-to-day practice between interventional cardiology and radiation therapy. For example, we have not denied a single patient so far, even though technically we do only two periods of this procedure, and then we're doing corporate emergencies that come in because it's for instant regional cell only.

So I don't think it's really a 24/7. We can work out these things into the day-to-day procedures sir. I think the European candidate training is somewhat different and actually they are much more broad-based. In some of the European countries, you really don't even need a radiation oncologist, and in fact, to give chemotherapy, you don't need a chemotherapist, a radiation oncologist can give chemotherapy. So you really can't extrapolate experience from there to here.

So in summary, I think from our experience having used all systems, I do think actually having all three members at the table is helpful.

MS. HOLAHAN: What facility are you from?

DR. TRIPURANENI: Scripps Clinic in La Jolla.

MS. HOLAHAN: Okay.

COURT REPORTER: I'm sorry, could the speaker identify himself for the record please.

DR. TRIPURANENI: Prabhakar Tripuraneni and I'm a radiation oncologist at Scripps Clinic in La Jolla, California.

DR. NAG: For your information, Scripps Clinic was the first institution and that institution has a long list of experience in intravascular brachytherapy in this country.

DR. CERQUEIRA: Dick?

DR. VETTER: I have just a little bit of problem with the patient who is on the table. You're doing angioplasty and the cardiologist decides that this patient would be ideal for IVB. The cardiologist can get a hold of the physicist and the radiation oncologist but both can't come there immediately to do the procedure. They agree on what the prescription should be, but the only way they can do the procedure is to pull the catheter and do the patient again tomorrow, and that introduces more risk.

DR. NAG: I think I'd like to -- you've had several of these. Can you tell me how you responded to

this situation?

DR. VETTER: And while he's on the way to the phone or to the microphone, it introduces more risk and we're asking the regulator to make a decision about that risk. Personally, I think it ought to be the medical team that's making the decision about whether or not to reintroduce a catheter tomorrow.

DR. CERQUEIRA: I'd like to add as a clinical cardiologist, for me to take a patient out of the cath lab, a lot of these people come in with instent restenosis with an unstable course. They're having symptoms and to basically have to leave them on anticoagulation for 18, 24 hours adds a certain amount of risk, leaving the sheaths inside add some additional risks, taking the sheaths out and then having to put in new sheaths adds even more risk on the anticoagulation. So it's not an ideal situation.

If you can basically get somebody there who has the experience and the knowledge to calculate a dose and do the procedure, that's optimal for patient care.

DR. NAG: And I have had that situation happen to me much more frequently with the intra operative radiation where the surgeons are taking too much out and they need me immediately, and that happens

at a much higher frequency than ever happened to me in intravascular brachytherapy. Radiation oncologists because they are doing so much brachytherapy for cancer work, are much more readily available than apprentices. Apprentices at night are more difficult. Radiation oncologists are always available for radiation emergency. If in twenty minutes you can not remove radiation from an implanted patient, that hospital should not be doing any brachytherapy at all.

DR. WILLIAMSON: But do the Federal regulations require you to be present to do an intraoperative implant?

DR. NAG: We are the one doing the intraoperative, no one else.

DR. WILLIAMSON: You are the one doing it, but you're able to staff that in the way you want without a Federal regulation that requires only you and you alone to be there.

DR. NAG: For high dose rate brachytherapy yes. The authorized user has to be present and intravascular brachytherapy at the dose rate is apparently given this high dose rate brachytherapy.

DR. WILLIAMSON: Yes, but the treatment for high dose rate brachytherapy yes, but not for laying down the catheters in the operating room. There's no

NRC requirement that requires --

DR. NAG: That's fine. You can lay the catheter for intravascular brachytherapy, just don't put the radiation source in.

DR. CERQUEIRA: Some of the discussion that occurred last time also related to the fact, we're talking right now about very specialized centers with expertise with a lot of bodies around, but if you're really going to do this, in not such a prestigious institution and especially as you identified the fact that radiation oncologists are getting busier. They're doing more things in the operating room which makes availability more of an issue for clinical sites.

I can tell you at our center, we have to electively schedule these two days a week and sometimes we've got patients coming in and the radiation oncologist has an emergency of some sort that we basically can't do the procedure. So I think the discussion last time was, if you're going to have a technique that's been official and you're going to make it available to do the greatest good for the patients, you need to streamline the process in such a way that you can make it available, while at the same time guaranteeing safety.

DR. TRIPURANENI: The great majority of the

patients with instent restenosis, at least in our institution, are scheduled procedures. That's where this has been approved to use in radiation therapy. I would say in excess of 95 percent of them.

We do an occasional emergency that actually could not wait. For example, somebody comes in let's say on a Friday morning, we certainly don't wait until next week. We actually go in and do the case at Friday noon or whatever. We do want to take care of the patients first there.

The second thing I think is one the situations that the chairman talked about is somebody at their periphery. For example, several small centers where they do a diagnostic angiogram find an instent restenosis and actually ship the patient as of that point in time, we actually accommodate them within the next several hours to actually take care of those patients.

And as they're getting comfortable, they actually go into angioplasty at that point so that the patient is unstable. However, they do not have radiation therapy available at that center. They actually ship the patient to regional centers such as our site and elsewhere.

In the beginning we did not know what to

do, but I think with the recent June 12th NRC guidance document, we actually decided to go ahead and offer radiation therapy at that point, within the first 48 hours, rather than wait for the next instent restenosis. Where there is a way, you can find ways to actually do it and I think having to do this vascular brachytherapy with the two members should be an exception rather than the rule.

DR. NAG: The other thing that concerns me is that if you having the procedure being done in centers that are doing very few of them, in centers that are not well equipped to do this, you are going to end up with poor results. And once you start getting poor results, you tend to wipe out an extremely good technique because it's not done well.

So, I would prefer these to be done in centers that have the experience, that have the know-how and that have the safety to back them up. If you're doing only it only once in a blue moon, you can not respond to emergency.

The other thing that concerns me, I am doing intravascular brachytherapy and let's say at my center, because of a new ruling, the cardiologist says well, we will be doing this with a physicist only. Now, I'm the authorized user. It is going under my

license. If there's a problem, I'm not doing it but I'm responsible for it but I have no way of supervising, no way of knowing what is going on under my own license. I am not prepared to have things done under my license when I have no control over what's going on.

And also, if I don't do it often enough, let's say the cardiologist says well, we have to do it now, they don't call me. They do it with a physicist. I would not be keeping abreast and later on when I have to go into it, I will just like a hospital where I'm doing one a year and I have no idea what I'm doing.

DR. CERQUEIRA: Let's sort of go around the room. This is obviously a complicated issue and we haven't heard from some people. Why don't we sort of start at this end and float around. Dick.

DR. VETTER: Number 1, I am a firm believer in efficacy but I do not believe that's within the purview of the NRC and I don't think we want it there. Number 2, at any institution the authorized user is responsible, and if the authorized user's uncomfortable with the way things are done or proposed, the authorized user simply must say no.

DR. WILLIAMSON: I think the other thing I would like to point out is we have a long debate during

the development of the new Part 35 over the staffing of remote afterloading procedures and the community pushed very hard to relax the attendance requirements for high dose rate brachytherapy, from requiring a medical physicist and an authorized user to be present during the whole treatment, to medical physicist plus a physician trained to undertake emergency applicator removal under the supervision of the authorized user.

So you know, we do have precedents where we attempted to sort of put in place a guidance that was a little more balanced, that respected patient safety, but gave some flexibility in staffing so that in an institution. Where you have a senior resident that you trust to delegate this responsibility to, you don't have to be there every minute and you can write the written directive, have your designee be there.

So I think this kind of a guidance allows you to, I think, tailor the staffing policy to the complexity of the procedure and the risk.

DR. NAG: I'm telling you not the way this guidance is written, not saying that you must have less than -- it doesn't allow me to have a designee there.

DR. WILLIAMSON: Sure it does.

DR. NAG: I have no problem if I have a designee there.

DR. WILLIAMSON: It's consistent with that.

DR. CERQUEIRA: Let's sort of go around and we'll give everybody a chance to -- Sally.

MS. SCHWARZ: I believe that within an institution certainly, you have to have guidelines and I think for the NRC to regulate all of these issues, I think it becomes more inflexible. I understand your concerns but I think each institution will have to essentially -- I think that the regulation can't be so constrictive and that it's better to allow within the institution you to make choices and set up a guidance that allows you to operate safely and effectively, rather than to be regulated.

DR. CERQUEIRA: Okay. Ruth do you have anything?

MS. McBURNEY: Yes. Right now most of the states, agreement states, are requiring the three-person team approach. I think leaving it in guidance will allow more flexibility than certainly to put any rule in place. This is a relatively new area and we need to see how that approach is going to go and whether we can pull back and be a little more flexible as was mentioned, a delegated type approach for the medical end.

In some cases, not this particular case,

but we've allowed for the supervision to be available in the facility in case of an emergency type situation rather than to be actually, physically present in the room at all times. But what I think that we need to do is kind of see how we're going and what sort of problems arise and how to address those, but leaving in guidance.

DR. CERQUEIRA: Leon, do we have enough time?

DR. MALMUD: I'll be very brief. I think that the credentialing process of the Joint Commission for Accreditation of Health Organizations is one which gives this responsibility to the medical staff of the hospital, and this should be a credentialing issue within the institution.

It would be a mistake for us to assume that the NRC with all of its wisdom should be the party to declare who should and who should not participate. Having said that, it would be extremely wise for each healthcare institution that will be doing brachytherapy to have participating in the process someone who is either the licensee or the designee of the licensee to make certain that your concerns are addressed. But I don't believe it should be through the NRC. It should be through the individual institution.

DR. CERQUEIRA: Okay. Ralph.

MR. LIETO: I feel that with the guidance that it should remain guidance. I agree that it shouldn't be a rule, that the authorized user determines the team components. I think having it stated that the cardiologist or interventional radiologist be there is really kind of a moot point. They're going to be there no matter what because of the fluoroscopy that's done.

And so basically what I think it comes down to is the authorized user and/or the physicist aspect and I think that depending on the facility that the authorized user is the guy in charge. He's the one that's accountable to the radiation safety committee or the NRC and they should determine the team components.

In some institutions, they physicist is mainly there. He's not there to do treatment planning or time and so forth. That's all been done beforehand. They're mainly there to handle if there's an emergency removal that things are done safely, that surveys are taken care of, and it very well could be that you could have in some institutions a very qualified dosimetrist that could perform that aspect that's been trained.

So to say that it has to be the specific team players, I think that the authorized user should

be the person that's placed in charge and determine what those team components are and who needs to be there and so forth. I agree, I mean if the facility staffing does not allow 24/7 coverage, they shouldn't be doing 24/7 coverage, okay. But it's the authorized user that has the say in that.

DR. DIAMOND: I agree with a lot of the statements that were just mentioned. We discussed this at our hospital at great length. We're the largest cardiovascular hospital in the country, and in the past year I myself have done 300 of these cases.

Basically what we decided is that our policy will be that we would wish that all three members be present at all the cases unless there is some circumstance which made it physically impossible, some extenuating circumstance, and that allows us this flexibility if a person's coming on in for an emergency case and either the physicist or the radiation oncologist, you know, has an accident or has a problem. It gives you flexibility to proceed without incurring some type of therapeutic misadventure.

But again, this was an issue that we discussed amongst our medical staff. We have our bylaws for the Department of Cardiology reflective of this, and we feel very comfortable. I myself would not

feel comfortable treating a person with a high dose rate procedure without having an opportunity to discuss the risk and benefits with the patient in advance. And again, this is just how we decided to do it at our institution. We feel very comfortable with this approach, and this flexibility.

My one reservation regarding this whole process was that the guidance document which was promulgated on June 12th, I don't think reflected that sense. I don't think it reflected the sense that: 1) we had not reached a consensus at the last meeting or that, 2) if one allowed this to proceed without all three members present, perhaps the best argument would be some sort of an exceptional circumstance.

But in any event, I think most of the discussion is moot in that the authorized user is the ultimate person responsible for the management of the procedure and that each medical staff needs to discuss this and develop policies that are commensurate with what they feel comfortable with. I should also say that of the 300 cases that I myself have helped perform, only one has been a middle-of-the-night case thus far.

I guess one other thing that perhaps would be useful for the advisory committee to know is that my

personal sense is that this field is going to continue to evolve in that what we're seeing is that perhaps in the next year or two, these new coded stents may be a wonderful boon for our patients in reducing the primary rate of restenosis.

Many individuals think that perhaps what we're going to be seeing is a shift from many of our patients having fairly straightforward lesions, meaning big vessels, large diameters, that's to say short lesions, non-diabetics, to a shift towards treating these folks with the most complex of lesions bifurcations repeat treatment, patients that have had perhaps radiation procedures before.

So the field really continues to evolve and, if anything, I think we're going to be leveling off on the number of cases that we perform at our institution on an annual basis, but shifting it toward the high-risk patients.

DR. BRINKER: I don't have anything to add to the cogent comments made by everybody else here. I think that the key is flexibility and leaving the responsibility to the authorized user for his or her appropriate delegation when they're confident it can be carried out.

I would just like to take the opportunity

to thank the commission for two other pieces that were in that guidance that have greatly facilitated all of our work in terms of not feeling bound to the specific FDA indications, and the step back procedure. I think that that has done a great service to us all, and I want to thank you for that.

DR. NAG: Well, I think now having heard from all of you, I think what people are saying is reasonable but then the wording that you have here has to be changed slightly to reflect that, just like the and and or wording. I think this should be changed so that it's authorized user or designee and the designee could be under exceptional circumstances, and I have no problem with that.

The other thing is that this has to be recognized that interventional brachytherapy is nothing but high dose rate brachytherapy because the definition of high dose rate brachytherapy is 12 mR per hour. Anything more than 12 mR per hour is high dose rate brachytherapy and if we did not have the specific technically staff for brachytherapy, this whole thing would have been under the definition of high dose rate brachytherapy and that's how we would have managed it.

So, almost everything that's under high dose rate brachytherapy should be applied to this as

well, and therefore it is nothing but high dose rate brachytherapy.

MS. HOWE: I think that was Jeff's point is that in the HDR, in our guidance required all three people to be there.

DR. WILLIAMSON: I think there's a technical difference between many of the systems available for intravascular brachytherapy and conventional high dose rate brachytherapy.

The latter is photon emitting, has extremely high activity sources, and involves an entirely different overlay of technical complexity, having to do with the single stepping source device, the need to have a remote afterloading versus -- so the 35.600 section was crafted very carefully to be focused on existing high dose rate devices.

And, I think if one of those devices were used for intravascular brachytherapy, such as in the peripheral vessels, I think you'd be absolutely right that NRC, you know, without question should use the 35.600 guidance in determining what the attendance and various technical restrictions are. But I don't think, for example, the Novoste device that would be completely appropriate.

DR. NAG: But then intravascular

brachytherapy under which all of these things go, also include iridium at more than 500 milicurie and that will be the problems with a high energy gamma emitter, the same or similar as iridium.

DR. WILLIAMSON: But it's not remote afterloading, so --

DR. NAG: It's manual.

DR. WILLIAMSON: It's manual.

DR. NAG: Yes.

DR. CERQUEIRA: Okay, we'll give Neki the last word.

MS. HOBSON: Okay, you know my stand on this. I do not want to see treatment of the patient denied or delayed on some technical regulatory technicality. I mean, I think it's the medical care, the medical profession is obligated to give that patient the very best care, and if that involves three people or two people, you know, I'm not going to be counting heads.

I would assume, and I agree with the comments that have been made around the table, that the medical institution and in this case the authorized user, would be responsible enough to make sure the expertise is available to do the procedure. But I don't want to leave the patient dying on the table

while we go run for someone else.

DR. CERQUEIRA: I guess a lot of what we're saying is the practice of medicine is something that's already regulated at the hospital level, and radiation's covered under a lot of that. But obviously there's inherent risks and so we want to stay within those guidelines provided that we can give the patients what they really need. Now Ralph, you wanted to make a comment?

MR. LIETO: Yes, I was just going to say that when we consider this guidance, Dr. Nag's point is well taken that we can't separate, you know, beta midicurie versus gamma midicurie because of the guidances being written to apply to all the systems. So, I think this is one thing we need to be careful of there.

MS. HOWE: I think as you look through the guidance, you'll see that for those things that are common --

MR. LIETO: I'm referring to the issue of the team presence.

MS. HOWE: Yes, those particular issues.

DR. CERQUEIRA: Yes, Neki.

MS. HOBSON: Well is it too late to, you know, maybe Dr. Nag has some substitute language that

would clarify the guidance if it isn't too late.

DR. NAG: My suggestion would be as I said, authorized user or designee. If you put that in there, I have no problem. Then if the authorized user in charge, if he feels that a certain person has a similar level of expertise, he can ask that person to come and I have no problem with that. For example, if I'm busy, I'm doing an intraoperative case, I can ask a senior resident, who is most expert in radiation and expert in the anatomy, to be there to be able to take that out if necessary in an emergency. That's not the problem.

But the way this language is, it leaves open that in one center, you may not have authorized users in any of the cases and that center would be in severe trouble if there was an emergency and neither of those personnel were very familiar to handle an emergency in that circumstance.

DR. WILLIAMSON: I think if that's so, you know, it should be amended in such ways to make it symmetrical between the physicist and the physician so that it's one or the other, or designee.

DR. NAG: Or designee, yes.

DR. WILLIAMSON: Or designee of either. I mean, because you know, as Ralph pointed out, it would be appropriate under some circumstances for the

physicist to designate a therapist or dosimetrist to cover the case.

DR. NAG: I agree with you.

DR. CERQUEIRA: But I guess the one thing is so that means -- I think some of the gist that came up, you obviously need the cardiologist there, and if the medical physicist is there and can deal with some of the issues, can the team just be the medical physicist and the cardiologist? Could that designee be the cardiologist who's appropriately trained?

DR. NAG: No, because the cardiologist is appropriately trained in the anatomical positioning, the isotope positioning, but is not adequately trained in the radiation safety and handling of radiation material in an emergency. We do this as a team in our department. If I were not there, the cardiologist would have a difficult time trying to assess under what situation they could take it out, when they could take it out, handling radioactive material.

I have great regard for them in that adequately placing the catheter. I depend on them to do that, but I would not depend on them to be taking out the source in an emergency. I have no problem having a senior resident do that because I have taught him for three years.

DR. WILLIAMSON: I agree completely with Dr. Nag on this point. I think first of all, there's a problem of having sort of a board certified individual in another field being the designee, because I'm not sure it satisfied the supervision requirement. And secondly, there's a virtue in having redundant personnel available whenever you're doing, I think, a procedure like this.

So I think it would be surely a mistake not to have one person who is in a formal sense under the supervision of the authorized user and who has mainly sort of a technical safety background that can be a counterbalance and a separate pair of eyes and hands to the cardiologist.

DR. CERQUEIRA: Maybe I misunderstood some of the discussion because I think some of the points that were made was that we're dealing with a cardiologist who's been through three years, four years of medical school, three years of internal medicine training which includes oncology, three years of cardiology which includes a lot of radiation and nuclear cardiology, nuclear medicine, and then he's got a fourth year of training in interventional cardiology, which is very extensively involved.

So we've got four years, plus three of

internal medicine, that's seven; three years of cardiology is ten and an extra year as an interventional cardiologist, that's eleven years beyond college, can't we train that person somewhere in there to deal with some of these issues or -- I mean, what have they learned during all that?

DR. WILLIAMSON: Why don't you count up the years of training of a radiation oncologist and an authorized physicist as well and then ask, is the cardiologist going to, you know, absorb that additional training?

DR. BRINKER: Can I just make one point --

DR. CERQUEIRA: Go ahead.

DR. BRINKER: -- that I think is germane to this? I think that if we're interested in supplying the best service and the greatest flexibility, I think it's naive to think that if the authorized user feels that the cardiologist at his or her institution is adequately trained in bailout technique, that he could designate that person.

In some places, there is no resident and in other places it's an affront to have, you know, an interventional cardiologist. I've done hundreds of these procedures and for them to be -- and at none of them as there ever been a radiation oncology resident

in when a time when the authorized user can't be there for him to say "well, I'm sending this resident to be there." It just doesn't make the same sense.

So I want to take this away from a turf issue and make it more a patient safety and patient efficacy oriented issue, and I think that putting too limiting a wording on this will not really change the issues which prompted our concern about this.

DR. WILLIAMSON: So are you arguing that the existing wording should remain or some additional modifying the word as it sits.

DR. BRINKER: I wouldn't mind the existing. I want to keep the authorized user in the place that he is, but I want --

DR. NAG: It is all.

MS. HOWE: The authorized user --

DR. BRINKER: No, what I'm proposing --

MS. HOWE: The authorized user, it says in the beginning that the procedure will be conducted under the supervision of the authorized user who will consult with the interventional cardiologist, physician, medical physicist prior to initiating treatment. So the authorized user is still responsible. He is still providing the supervision. It's his decision whether that supervision is in the

physical present or more remote.

DR. DIAMOND: I think that this last two or three minutes of discussion truly is moot with respect to what Dr. Malmud has said and what I have said. I think this gives the flexibility for unforeseen or exceptional circumstances for the procedure to go ahead.

And I think it also makes it very clear that the authorized user is the ultimate responsible party, and that that institution under the direction of the authorized user needs to develop policies on how they wish to proceed with regard to this technique and this technology. And, I feel comfortable at this point, keeping it the way it is because I don't think the language we could come up with is going to be any better.

DR. CERQUEIRA: Let's go around. Richard, what do you?

DR. VETTER: I'm comfortable with the way it is.

DR. CERQUEIRA: Jeffrey?

DR. WILLIAMSON: I think under the circumstances, yes I'm comfortable the way this guidance documents reads. It might be appropriate to add some more sort of, I wouldn't say paragraphs --

explanatory paragraphs, thank you, that would be the word, maybe getting the spirit across. But, I think to sort of have hard and fast rules with more teeth and more different details and options is probably inappropriate at this time.

So, I just want to say two more things. You know, I would like to echo the comment that I think the added flexibility in using the device for stepping for slightly different indications and so on, I think is a great boon to the medical community and to the ability of the community to develop, you know, new and different indications for this technique and improved techniques for treating the existing indications.

And secondly, I think also to echo the comment to leave this is guidance phase for awhile so that the results of this approach can be observed, because I think it's going to be really very difficult to get a consensus what we should do in terms of a final regulation at this point.

DR. CERQUEIRA: Sally?

MS. SCHWARZ: I agree. I think the authorized user has to be the individual in charge. The institution at hand has to be able to develop policies that fit. That's where I think it should stay, the way it is.

DR. CERQUEIRA: Okay. Ruth.

MS. McBURNEY: I agree.

DR. CERQUEIRA: Ralph.

MR. LIETO: I guess I was trying to figure out a way to maybe improve this along the lines, and I'm wondering if that last sentence and the guidance, if that was just struck out, and just leave it as "procedures will be conducted under the supervision of the authorized user who will consult with the interventional cardiologist, physician and medical physicist prior to initiating a treatment," and then he determines whether he's going to be there or the physicist because the cardiologist is going to be there anyhow.

To say that they're going to be there or not is really immaterial. They're going to be there regardless period, whether you do the procedure or not. They're going to be the one putting in the catheter and taking it out. They're going to be there from beginning to end. So the issue really sounds like it's the issue between whether the physicist and/or the authorized user is going to be present. And I think just striking that last sentence might, you know, solve that issue.

DR. CERQUEIRA: Well, we'll come back to that.

DR. DIAMOND: Again, for the reasons I explained, I feel comfortable with the language within the guidance document. I wasn't happy with the way it was promulgated, but I'm happy with the way it is, given the reasons I expounded upon a few moments ago.

DR. CERQUEIRA: Jeff.

DR. WILLIAMSON: I have nothing to add.

DR. NAG: What I'd like to know is after this was sent out in June, how many centers are doing interventional procedures without an authorized user being present? Do we have any idea? That would give me an idea whether it can be routinely done or whether even though we have that, it's not been used, and that would be of interest to me to know. And, you know, if it's not being done that's a moot point what we have in here anyway.

DR. WILLIAMSON: Yes. At Washington University, the radiation safety committee took it upon itself to basically say "we want both to be there, you know, for the time being."

DR. NAG: All three you mean?

DR. WILLIAMSON: All three, well yes essentially all three.

DR. NAG: Yes.

DR. DIAMOND: It's always been all three at

my institution. I'm not aware of it being done with just the cardiologist and one or the other in the State of Florida.

DR. VETTER: The Mayo Clinic also requires all three, but I'm not so sure we'd want the NRC dictating that to us.

DR. CERQUEIRA: Yes. Neki?

MS. HOBSON: I guess I'm comfortable with the way it's worded but I do think this is an issue that we should review periodically to see are we having any problems.

DR. CERQUEIRA: Yes, I think that's an important point because it's only been in the last year that these devices, two of them, have been approved certainly for cardiac applications, and you've got a couple of problem cases of details.

Now, do you have any numbers how many of these are being done?

MS. HOWE: NRC always has difficulty getting the denominator.

DR. BRINKER: I called, I took it upon myself to call the vendors and it's roughly 20,000 since approval between the two of them. That's what they said.

MS. HOWE: 20,000?

DR. BRINKER: 20,000.

DR. CERQUEIRA: Since March `99?

DR. BRINKER: This is since approval.

DR. NAG: November.

MS. HOBSON: November of 2000.

DR. CERQUEIRA: And of those 20,000 do we have any information on those outcomes or adverse events?

MS. HOWE: We have the individual case studies and the in med and Bob Ayres is keeping track of them, so he has the preceding mis-administrations and then I've got the next four mis-administrations here. We don't have a lot of mis-administrations, but we don't tend to have a lot of mis-administrations period, and mis-administrations are in order to see trends or to identify problems before they get out of hand.

DR. CERQUEIRA: Right. I guess the feeling of the committee was to keep the language as is, is that it? Okay. And basically we feel it's being done at institutions and certainly it sounds like at least the two that you've reported on, it's being done as prescribed, but it does give sort of the medical community the opportunity to regulate itself.

MS. HOWE: And that essentially was our

intent.

DR. CERQUEIRA: I think Dr. Brinker --

MS. HOWE: That essentially was our intent. The other parts I think are pretty easy to go through. We have the written directive follows more the HDR type brachytherapy. We have to give the site and the dose. It is high dose. We require independent measurement prior to being used on a patient. We have emergency procedures. The idea that -- in the earlier guidance we had that it was for native coronary arteries for instent restenosis.

We talked about it last time. We were going to go to a much more general authorization and you'll see that under the Cordis and also under the Novoste, we have gone to that general authorization where it says "for the use of" and then lists the device for intravascular brachytherapy. So, it's not tied to the specific approval given by the FDA.

In the Novoste, we had required an introducer sheath. Now we've said they shouldn't use it unless it's contraindicated for the individual patient. And we had the same thing for the dual syringe system, unless it's contraindicated for the patient.

And we've noted that in the mis-

administrations, those two aspects come to light as being our most prominent mis-administrations. They run out of fluid. They have a kink where the valve is and the sheath would have prevented a number of these mis-administrations and the dual syringe would have provided an extra safety margin also.

We were a lot more specific on the source train and size and also the stepping. We said, we've put the stepping up into the quality management program. We have concerns whether you can provide a high confidence that what you're prescribing can be done in some of these systems with stepping, because it's difficult to tell where you are. But if the facility can come up with a procedure that gives them high confidence that they can do stepping, then that's part of 35.32, the Quality Management Program.

I think that's probably about all that I had. Any other comments on the guidance? And the guidance was put out because we are dealing with licensees everyday and applications everyday. This is not rule-making. Our licensees don't have four years for us to figure out a rule and go out, so we needed some guidance to help patients be treated with these devices. So that's why a guidance letter went out in June, as soon as we felt we pretty much knew what the

committee was thinking in terms of it and if we could come up with the flexibility.

DR. CERQUEIRA: One last final short comment Jeff.

DR. WILLIAMSON: I understand the guide in P32 System, approval by FDA is imminent. So what are your plans for developing product-specific guidance for that device?

MS. HOWE: We'll look at it and we'll see how it fits into the scheme, where it fits with things that are common to practices already done. We'll leave those as is. If it needs additional, we'll add it. If it doesn't we'll delete.

DR. WILLIAMSON: Can you consult this committee with your proposal, at least entertain our feedback?

MS. HOWE: We can always entertain your feedback.

DR. WILLIAMSON: Not if you don't ask for it, you can't.

MS. HOWE: The committee meets --

DR. WILLIAMSON: I guess I'm asking, can you make a commitment to share your preliminary guidance once you've drafted it but before it's finalized, for this committee to review, if nothing else remotely?

MS. HOWE: We can consider it.

DR. NAG: The remote afterloader, it will be a stepping source. It has basically no difference from any other HDR afterloader other than the energy and I think it highly appropriate if at least the people, the apprentices and the radiation oncologists who deal with this every day at least get the chance to look at it before you send it out to the whole world.

DR. WILLIAMSON: Have a conference call with a subcommittee. No, you can't do that I guess. We have to announce it.

MS. HOWE: We have certain requirements for the government advisory committees and we'll have to work with those and we'll try to be as flexible as we can.

DR. CERQUEIRA: We have in the past, we've actually broken up into two separate committees.

MS. HOWE: Yes, that was when you were working on rule-making, right.

DR. CERQUEIRA: Right.

MS. HOWE: This isn't quite rule-making, but within the guidelines of the Federal advisory committees, we'll work something out.

MR. BROWN: This is Fred Brown. I guess I would request and I believe you are probably more

knowledgeable than we are about the new treatment system. If you have recommendations for us today, please give them to us, either now or after 2:00. You know, we can include that going forward as we try to respond promptly to the request for licensing actions.

DR. CERQUEIRA: Sure.

MR. LIETO: I know that people are antsy to hit the food line, but I got two issues regarding this that I'd like to bring up regarding how licensing is being done and being approved. They've created I think some real issues at the license amendment stage at the regional levels, and I'd like to address that if we can at a later point.

MS. HOWE: I won't be here this afternoon, so if you --

MR. LIETO: Well, I guess my quick question is why does everybody have to go back and get their license amended when the sources are FDA approved? For example, the Novoste. You approved the sources. They were in the source registry and just simply because of the source linked to the training, everybody's got to go back and amend their license and it created a huge bottleneck at the licensing regional level. And to say that there were a lot of short fuses being lit is an understatement.

DR. CERQUEIRA: What did they do at the agreement state, do we know? Because right now, you're only regulating what, 18 states, 17?

MS. HOWE: It's a small number.

DR. CERQUEIRA: Ruth, do you know what they did at the agreement states?

MS. McBURNEY: I don't know with all the states. We don't have the same configuration in the rules, so all of these devices are, for specific licensees, would be separately authorized.

DR. CERQUEIRA: So people have to apply for an amendment then in Texas?

MS. McBURNEY: Yes, right.

DR. CERQUEIRA: Yes.

MR. LIETO: Well, I mean for the device, but --

MS. McBURNEY: For the device.

MS. LIETO: Whether they got a source of x-strength or y-strength, as long as they were under their possession limit, it's not an issue.

MS. McBURNEY: We didn't have to amend for that.

MS. HOWE: That was an issue to start out with because one of the manufacturers did not have all of their sources in the original PMA, and so not all of

the sources that were in the device registry had FDA approval, so those that didn't had to be under INDs.

MS. LIETO: No, the issue specifically has to do with Novoste okay, and that the sources were approved, and that basically the issue is whether how many sources you have in the train, whether it's 20 millimeters or 40 millimeters.

And when the FDA approved the 20 millimeter source strength in the original device configuration, when they got the FDA approval for the longer source strength, everybody had to go back and amend their license to get that longer source strain, although the sources, the individual source type had not changed. It was just the number of them. That's really, I think, inconsistent.

I mean, you didn't have brachytherapy departments going back if they wanted to get so many seeds for Iodine ^{125}, they didn't have to have approval based on the number of seeds they had. It was a possession limit issue.

MS. HOWE: I think probably Dr. Ayres can address that since he was more actively involved.

DR. AYRES: Those two different length trains were not approved at the same time. Otherwise, if we'd incorporated, they'd have been the same

guidance, first the 30, then the 40. The 60 is not yet approved.

MR. LIETO: But you have given specific guidance to them to state that they can not license it based on the condition that it's FDA approved. In other words, it would save a hell of a lot of problems with licensees and time and with the regional staff if you would just state and allow them to state on the license that they could have any FDA approved source. So when the 20 came out, boom it's approved. When the 40 came out and it was approved, automatically they could use it. And they are under specific guidance not to do that, and I think that's wrong.

MR. BROWN: I think I understand the point and we'll take that for follow-up.

MS. HOWE: I think we have another issue though and that's that our General Counsel a number of years ago, in looking at the sealed sources, indicated that we used to have a very general way of writing on a license what sealed sources you can use, and this is not just medical, this is gauges, this is radiography, this is everything.

So they said we have to list specific manufacturer model numbers on the license, and so that gets you into the concept that as something gets

approved you got to change model numbers. But we'll look into the issue, but I just wanted you to know that's another complexing factor.

DR. CERQUEIRA: Maybe you could look into it and then, you know, provide Ralph with some feedback and I think the feeling of the committee is whatever we could do to simplify it, especially since the states seem to have kind of resolved the issue without additional paperwork. So, I think we should break for lunch now because we're going to try to quit early.

DR. NAG: When do we come back?

DR. CERQUEIRA: 1:00.

(Whereupon, the above-entitled matter went off the record.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:03 p.m.)

DR. CERQUEIRA: The first presentation's going to be on regulation of mixed occupational doses involving both NRC-regulated material and fluoroscopy. Mr. Brown will be doing the presentation.

MR. BROWN: Thank you, yes. Before I jump directly into the technical aspects of the issue, I'd like to start by saying I know that this is the first time we've brought this to you. You don't have detailed copies of the regulations or any of the procedures I'm going to discuss.

So what I'm really interested in is feedback from you on how in your facilities you deal with mixed dose issues, and then the practical ramifications of some of the various options or the options that you have in place. What I'm really looking for, as we work our way through the mixed dose regulatory issue, is a better understanding from you about what impact we're having in the license community.

So I guess I'll start by saying, obviously the NRC regulation is limited to by-product material. The states typically, well the NRC and agreements

states limited the by-product material. The states have regulatory jurisdiction over fluoroscopy and other sources of radioactive material used in the medical community.

There is certainly no intent in this area to change that or modify it in any way, but on the flip side, the human body that's absorbing the radiation is indifferent to what its source is. It knows only the biological effect from that radiation.

So Part 20 is written to apply dose limits as they're applicable to NRC licensees to a cumulative dose for the individual from both licensed and unlicensed sources. If you look at the history of Part 20 at the time of the revision, and it was quite an extended period that Part 20 was being revised, there were several issues of concern.

One was workers at DOE facilities where the dose is not NRC regulated, coming to NRC regulated facilities and doing work. Another was that employees on a contract basis could go from an NRC regulated facility to NRC regulated facility, and if each were limited to 5 rem during the time of employment, then you could obviously end up with much greater doses over the course of a year.

So Part 20 encompasses all dose received

during the year by an individual for comparison to the 5 rem limit. We've looked at this as a pretty simple thing with the blinders on, that people do NRC regulated work and they may do work regulated by somebody else, but the licensee could always add the values together to come up with a dose of record.

What we've become aware of recently this year, is that there are applications, especially in the medical field, where doctors and other professionals are exposed to NRC regulated dose, they're exposed to state regulated dose, and for instance in intravascular brachytherapy, especially with the Iridium sources, they may be exposed or they will be exposed to both sources at the same time. The concept was always easy. Now though, we're trying to deal with the practical ramifications of how the employer or the licensee attributes or assigns dose for the individuals.

Quickly where we are at today, we became aware of a couple of hospitals in NRC regulated states or jurisdictions where doctors had received greater than 5 rem whole body dose as computed under the NRC regulations, which is basically the TLD at the collar, even when fluoroscopy is performed with a vest. The doses that the hospitals were assigning were less than 5 rem because of methodologies approved by the states

relative to the fluoroscopy dose.

As the regulations, Part 20, are written that is a violation of NRC requirements because we require deep dose equivalent for the part of the whole body receiving the greatest dose. That's not a consequence that we had intended, so we have informed at least two licensees that we are exercising discretion for those violations, and that the staff is working on a methodology that will be communicated to the industry on how to avoid this unintended consequence.

So the issue before the staff is to work through the legal mechanism for doing that, and we've been doing that internally very aggressively. Once we have worked through the legal mechanism to achieve the desired results within Part 20, we will issue guidance to all of our licensees on acceptable methodologies to look at an effective dose equivalent approach for whole body dose when fluoroscopy is involved and aprons are worn to reduce the dose.

The hope today is to get your input, I said, on practical ramifications of this issue and recommendations that you would have on how we proceed with issuing a guidance.

DR. WILLIAMSON: Can I just ask a question

of clarification?

MR. BROWN: Certainly.

DR. WILLIAMSON: I think I'm just sort of confused what the technical issue is. As I understood in Part 20, the 5 rem equivalent is in terms of the quantity EDE, Effective Dose Equivalent. It's not --

MR. BROWN: I know.

DR. WILLIAMSON: And so the definition that's in Part 20 is something more like the maximum dose of penetrating radiation is the one that's supposed to be carried as the quantity that's supposed to be accumulated for the body dose?

MR. BROWN: Right, the limit for whole body is stated in terms of total effective dose equivalent. The definition of total effective dose equivalent is the deep dose equivalent plus the committed effective dose equivalent, and the deep dose equivalent is further limited to that portion of the whole body receiving the greatest dose.

Just for context to help you understand that, on the other side of the NRC regulated fence for a worker in a nuclear power plant entering a steam generator, the radiation field on the portion of the body inside the generator may be orders of magnitude greater than the proportion outside of the steam

generator. So, the standard has always been, deep dose equivalent portion of the whole body receiving the greatest dose, and that's actually consistent also with OSHA's approach and other Federal approaches for external radiation.

DR. WILLIAMSON: How does that agree with ICRU and ICRP and NCRP?

MR. BROWN: Looking at Part 20 when it was issued, the ICRP 60 guidance had not been finalized. Right in the statements of consideration we addressed the absence of recognized Federal waiting factors for external radiation sources. And, in the rule we do indicate that as we move to an accepted standard for waiting factors, that the agency will look at adopting those or responding to them. That's actually the approach that we're looking at now from the legalistic end.

MS. McBURNEY: Just to explain just a little bit about how the states are addressing this. In the suggested state regulations in what we've adopted, if there are two film edges, one under the apron, one outside the apron, there is a waiting factor to actually determine the effective deep dose equivalent. This was based on some work, I think the AAPM or somebody did.

DR. VETTER: I think it was published by NCRP.

MS. McBURNEY: It was in the NCRP, right.

DR. VETTER: Originally it was Rosenstein & Webster.

MS. McBURNEY: Right.

DR. VETTER: It was work originally conducted by Rosenstein & Webster and it's now in NCRP. I've forgotten the report number.

MR. BROWN: 122.

DR. VETTER: 122, thank you.

DR. CERQUEIRA: Other comments? Dr. Nag.

DR. NAG: No comment but a question. I'm not very familiar with this so I need some clarification from the witnesses. How are you differentiating, by having one film under and one over? I mean, if I have to go and do a procedure, I have to have three films then, one for my ring because I'm handling the radioactive material in my hand, one because I'm also at the same time doing fluoroscopy. I have one that I wear over my lab apron and one under my lab apron?

MS. McBURNEY: That's correct.

DR. NAG: And minusing the two that you have, can you explain one of you?

MS. McBURNEY: There's a calculation.

DR. VETTER: NCRP 122 also allows a single whole body badge in which you can estimate the fraction that penetrates the apron, but the apron if you're looking at like 80 to 100 KBB (phonetic) stops almost 98 percent of the scattered radiation. If you're at 100 and above, it's 95 percent. So, the apron is very effective at stopping x-rays.

DR. NAG: No, it will stop the fluoroscopy but not the Iridium.

DR. VETTER: That's correct but not the Iridium, right.

DR. WILLIAMSON: Can you give us an idea what would be, for a typical say interventional cardiologist or other person that made extensive use of fluoro, what could be the discrepancy between the two measures, the deep dose equivalent as defined by NRC and NCRP 122?

DR. VETTER: Just talking practical levels, what really happens at our institution, the interventional radiologist receives zero from Iridium because they leave the room. So, it's easy.

DR. WILLIAMSON: That's what we do too.

DR. VETTER: Yes, so it's easy. But we do have several who exceed 5 rem per year on their badge

but the state allows us to use the NCRP 122 methodology to estimate the effective dose.

DR. NAG: Where do they wear their badge, outside or inside the lab coat?

DR. VETTER: Outside the apron.

MR. BROWN: The reduction factor, in looking at the doses we've seen, is approximately 5-1 when you compare the deep dose equivalent at the part of the whole body receiving the greatest dose which would be the collar badge, and the assigned dose using what's been referred to as the Webster Formula, which is one and a half times the value of the badge under the apron and .04 times the value at the collar added together.

DR. WILLIAMSON: Will this eventually, are you planning a rule-making initiative to adopt something equivalent to the NCRP 122 methodology?

MR. BROWN: We feel at this point that there is latitude within the regulations for us to adopt guidance and publish it uniformly that will not require a rule-making change. A rule-making change may long-term be the best way to go, but what I'm interested in right now again is the practical inputs on especially any facility that's counting doses differently for different regulators to be able to get the quickest response out, which is not rule-making.

DR. VETTER: A very practical way to handle that is to require the issuance of a separate badge when they are being exposed to Iridium, and that badge not then be worn for the fluoro portion.

DR. NAG: But the problem is many times you are doing both, you are checking, you are putting the Iridium in. I'll be putting the Iridium in and then I'll be checking with fluoro to make sure that the Iridium is going in, so I'm exposing both at the same time. And immediately after that I might be doing a case with Iridium and another case with fluoroscopy and Iodine.

DR. VETTER: In that case, then you have to wear a badge under the apron.

MS. McBURNEY: Yes.

DR. WILLIAMSON: You have to wear three badges I guess, one for the non by-product material, one for the by-product material and one for both, so you could do the appropriate subtractions. I guess we handle it typically in radiation oncology as we do have some non by-product sources that we are concerned with, we have fluoro because we have simulators. We have linear accelerators which contribute a small amount of whole body exposure to our personnel, and we have other radionuclides, such as Paladium ^{103}, which is largely a

cyclotron-produced radioisotope.

But I think in general these are well managed sources of exposure. The exposures are quite small and we simply, as a matter of practice, we don't make a distinction. We just sort of report one quantity which is the sum of all these radiations, and we don't attempt to distinguish it. But I think there are different settings in our institutions, such as the cyclotron. Maybe Sally might want to address where this approach is not possible.

Certainly I think in the cath lab it's a problem, and our solution has been to try to separate. And as long as the cardiologist is willing to stand in the control area, you know, where the Iridium sources are being used, we've not had the problem.

MS. SCHWARZ: We have produced isotopes and our personnel that handle all of our accelerated produced isotopes are badged and essentially similar to NRC-regulated materials. But they're looked at separately when we are inspected, because we're maintaining a single exposure for the individuals but certain individuals are only exposed to cyclotron produced and some are exposed to both and those people are under NRC auspices. So essentially, the records are kept separately for those who are essentially

accelerator produced individuals, but it's the same badging technology.

MR. BROWN: Right, thank you.

MS. McBURNEY: I don't think that you'd want to separate for an individual the dose that they got from by-product versus non by-product sources, because the rules are talking about total occupational dose.

MS. SCHWARZ: If our individuals are exposed to both, it is a single badge.

MS. McBURNEY: Right.

DR. WILLIAMSON: But we would have different levels of concern in terms of ALARA investigations, wouldn't we? Potentially for somebody that was exposed just to by-product material who has very relatively low exposures versus somebody that has the potential of higher exposures from the accelerator, plus some exposures to by-product material, we might adjust the ALARA level. So we wouldn't in that sense manage it as sort of a compromise between the sort of working standards that I guess prevail in the accelerator world versus the by-product material world.

DR. CERQUEIRA: Ralph.

MR. LIETO: As far as ALARA reporting, I guess it kind of might vary from institution to institution how they maybe make their reporting and so

forth, but most places pretty much have a standard reporting level. It's usually around 10 percent of the dose limit or some other fraction, like 30 or 50 percent. So I don't think it will affect ALARA reporting that much.

I think the practicality of having like three badges to try to separate the radioactive component from the fluoroscopy component with no fence to our cardiologists is really, I don't think they're going to buy into that. I think with a lot of times it's real difficult just getting them to wear badges period.

So, to get into issues of trying to separate the components -- but I think you could probably do that by looking at, you know, overall trends of areas. There's going to be a fair number of them that just do fluoroscopy and granted there might be certain expertise differences, but I think on the average you can get some idea of what fraction of their exposure is from just fluoroscopy.

And by the same token, looking at just your radioactive material handling side, say your nuke-med techs for example, they're going to probably be an upper estimate though in terms of whole body exposure from that side.

So I think there's ways you could get an idea as to what fractions are from radioactive material handling versus the fluoroscopy end, especially in the cardiac area.

MR. BROWN: So that approach which would be to look at the dosimeters at the end of the year, and then assign fractional values for whole body using deep dose, and then whole body using computational methods, such as Webster. Is anyone doing that?

MR. LIETO: Probably not according to that. I think probably the method that Dick mentioned earlier is doing it on an individual basis, based on the fact of the two dosimeters that are worn. But then there are some states that don't allow it.

MR. BROWN: Right.

MR. LIETO: And that can be a problem. But I think if the NRC came out with guidance that this was an acceptable methodology to follow, using NCRP as maybe a precedent, I think it might be easier for those states that don't allow it to justify the individual licensees to do it.

MR. BROWN: Ruth, do you have a comment on that or is the NRC going to be in the position of --

MS. McBURNEY: I don't think that they'll be forcing the states to do that, but I think they will

be, I mean we'll kind of encourage those that haven't adopted the methodology to go ahead and do so.

Because if on one hand, you know, the state is coming in to review the occupational doses under their x-ray registration and are using a different methodology than the NRC is allowing when they come in to do their radioactive material inspection in a non-agreement state, that could be problematic. So hopefully, it will encourage states to become a little more uniform if it becomes a national standard.

DR. CERQUEIRA: Yes. Jeff.

DR. WILLIAMSON: Well, you know, I guess the solution for most of us is we really try to avoid the problem where we have to apply a different sort of correction to one whole body dose than another, but clearly intravascular brachytherapy and maybe a few other applications maybe make that very difficult to do and we're left with this quandary.

So, I suppose a technical question is, does there exist a single badge which has some filter in it or something and could distinguish between diagnostic quality exposure and a gamma, which would be higher energy and hence bear the maximum, as you call it, body dose? It would be a good indication of the whole body dose.

MS. McBURNEY: I think there are some energy compensated badges.

DR. WILLIAMSON: I think that's a question for the physics people.

DR. VETTER: The current badges will distinguish extremely low-energy photons and that adds to the skin dose. It's a shallow dose.

MS. McBURNEY: Right, but I don't think there's incremental things.

DR. VETTER: But whether or not -- how far up in energy they could go, I don't know.

MR. LIETO: I think it's mainly for the algorithm that's used for converting the dose into a dose equivalent.

DR. WILLIAMSON: So there's, other than a dual badging procedure, there's no technical solution to this problem?

DR. VETTER: There might be. We just don't know. We would need LCN or Landau or somebody like that here to answer that question.

MS. McBURNEY: Right.

MR. LIETO: And even if the technology's there, then you'd have to have the vendor adopt that.

DR. WILLIAMSON: Ralph, you think there isn't such a technology that's been developed by a

vendor at this point that's widely available.

DR. VETTER: Well the other complication is a Nav-Lab. They have to process their badges in accordance with Nav-Lab.

MR. BROWN: Going back to the comment, thinking through it a little further, if we adopted an approach that said for the portion of the exposure that's fluoroscopy and even the portion that's a combination of fluoroscopy and Iridium intravascular brachytherapy, use two badges. Calculate them under the state standard that's applicable. Add that value to a separate badge that would be worn only with by-product material alone. Do you see practical concerns with getting a second set of dosimetry put into use in some cases or not?

MR. LIETO: I don't. I think you're probably doing it as a standard anyhow for physicians or workers using fluoroscopy, table-side fluoroscopy. Just thinking out loud here, you could maybe use, if you can demonstrate that there's a high likelihood that less than 10 percent of it is from radioactive materials, that you could use this as a methodology.

Now, if you're above that, I don't have an answer for you. But, that might make it easier, because generally speaking, if they're getting dual

exposure, just a very small fraction of it is due to the radioactive material aspect of their work.

DR. CERQUEIRA: Okay.

MR. BROWN: I guess I would comment as an inspector following up and doing the end-of-the-year dose reviews, trying to decide whether it was 9.5 or 10.5 though is the dreaded task. But that is actually something that we're looking at as well.

MS. HOBSON: I have a question. Say you found a situation where the combined dose exceeded the NRC standard, would the licensee get a violation or would they be cited for that?

MS. McBURNEY: Yes.

MR. BROWN: yes.

MS. HOBSON: So you're really bringing fluoroscopy kind of in under the NRC mantle of regulation?

MR. BROWN: Well, I would say no. What we're doing is insuring for the health and safety of the individual, in this case the doctor or the medical worker, that they aren't exposed to more than the legal limit in an annualized period. As I said, the body really is indifferent to the source, the nature of the source, so if it's occupational exposure we apply the 5 rem limit without regulating the non by-product

material, but in essence by reducing the allowable dose from by-product material.

So in simple math, if the limit is 5 and you've received 4 rem annual exposure from non by-product material, what you really have is an annual dose limit of 1 rem for NRC regulated material.

DR. CERQUEIRA: Dr. Williamson.

DR. WILLIAMSON: Well, you know, I think that maybe it's not quite fair to call this mixed exposure. It's really -- the only problem is when one exposure is relatively superficial and governed by a different set of rules than is in Part 20 and the other component is a more penetrating component.

So your proposal, you know, is to offer some regulatory relief to those people so that they can apply, you know, the what would the word be, I guess the less conservative methodology in a sense, which is now a well-regarded and how should I say, is not just sort of a procedure that's been dreamed up, but the various advisory bodies such as NCRP stand behind it.

So since you're accommodating them by allowing them to use this more liberal strategy, it seems that it's incumbent upon those that avail themselves of this strategy to develop a method of keeping track of the two. And perhaps, in cases which

Ralph has mentioned where one can come up with a ballpark estimate that demonstrates that the penetrating component is quite low, maybe dual badging might not be necessary.

But if in a sort of rare scenario where you have somebody that's doing a whole bunch of fluoro plus a significant amount of brachytherapy with Iridium 192 or some other penetrating field, you know, then I think they simply are going to have to bite the bullet and wear two badges and have one under the apron and one on the collar, and apply a set of corrections and they will just have to accommodate themselves. And, I think that's not an unreasonable demand to make on the part of an institution, because I think it's probably a small cohort of workers.

DR. CERQUEIRA: Any other comments for Mr. Brown?

MR. LIETO: Well, I've got one related to this dose limit issue and maybe I have this wrong, but it relates to extremity monitoring and that I seem to recollect that reactor people have said that exposures to the upper arm would be considered like whole body limit values, and I'm just wondering if you would be running into a similar issue, let's say they're wearing an extremity monitor and because the lead aprons don't

cover any portion of the arm, would we be running into a similar issue here also?

MR. BROWN: Actually, the way the Webster formula was developed applies the whole body exposure portion as part of -- the upper arm, excuse me, is considered within the whole body for EDE as calculated or as determined by Webster.

MR. LIETO: It's in the correction factor.

MS. McBURNEY: Right.

MR. BROWN: Yes.

MS. McBURNEY: The portion of the body that's still exposed, even with the lead apron on, is taken into account in those calculations.

MR. LIETO: Right, okay.

MR. BROWN: Well, thank you very much. This helps considerably.

DR. CERQUEIRA: Thank you. I guess the next item is new business.

MR. BROWN: Yes new business and I guess -- let me go over a couple of things. We have available for the members of the committee, copies of the Volume 9 guidance for Part 35, and I'll warn you Melanie Galoway can probably hold up a visual to help you appreciate the scope of the package.

MS. GALOWAY: So if anybody would prefer to

have it mailed to them, we can do that. I do have ten copies available for anyone on the committee who would like to take one home with them. They're not too heavy. The staff and I were able to sweet-talk the xeroxing department to make it a priority today for you. Does anybody else prefer to have theirs mailed?

(Background conversation.)

MR. BROWN: I'd like to just kind of introduce a concept as you look at that too because there's been a fair amount of discussion at the last two meetings around the role of guidance, and the regulations and licensing. I'm sure you all know this better probably than I do, but just to reiterate. The regulations are enforceable and we inspect against the regulation. Licenses are enforceable and we inspect against the licenses.

This guidance document is to facilitate the licensing process so there are pre-approved standards in this guidance document that will facilitate rapid issuance of licenses, but it does not preclude any licensee from choosing an alternate means to demonstrate compliance. So if you see, for instance, it was mentioned the model procedures. If you see model procedures that you don't think are consistent with how the new rule should be applied, that does not

mean that we have placed a new regulatory requirement in place via this guidance. Go ahead.

DR. WILLIAMSON: I was going to actually comment on the licensing guidance for remote afterloading brachytherapy which is FC 86-4. My own personal experience is that license reviewers are loathe to entertain any alternatives to those procedures. So I find your comment rather difficult to reconcile with my own personal experience.

MR. BROWN; Well, I on the other hand deal with the requests for alternate methodologies as a major portion of my job so I know that they do come in and we, in fact, end up approving not a small share of those requests, and I think both are probably true. That I think license reviewers would prefer to have licenses that come in that they can turnaround in a very short period of time without any additional headquarters review. But by the same token, where licensees feel strongly that they do not want to proceed in exact conformance with the guidance, we do approve many of those.

DR. WILLIAMSON: Well, you know, I think it's one thing to state that. It's another to make your administrative structure and procedures be friendly and not make it an intolerable burden so that

in practice the licensees really don't have access to that benefit.

That is the concern I'm stating, and I think this is not just the way, you know, a matter of how these things are written, but it's a sort of a function of the roadblocks, procedures that you set up to implement these. You can either make it sort of something nice you can say which you sort of show, or you really could have a system set up that is fairly robust and does, in fact, seriously entertain alternatives without imposing substantial burdens or costs upon the licensee to have access to alternatives.

MR. BROWN: I think it's a good point and I don't disagree, and then getting to the practical application of it is, of course, the devil in the details.

DR. CERQUEIRA: Exactly. Any other comments?

MR. BROWN: There was at least one other follow-up from this morning as well. We've had a staff member looking into existing guidance and recommendations on medical follow-up for anyone exposed to radioactive material that might seek medical attention. At 2:00, I hope to be prepared to give you a quick overview of the NRC role, the existing

documentation that we have, one or two references that you might find useful, and then some discussion about where we can go to address the more specific interests that you had. So that should be ready in about 20 minutes or so.

DR. CERQUEIRA: Okay. So in the meantime we're probably going to go on with new business. Yes, Geoffrey.

(Pause.)

MR. IBBOTT: Thank you and good afternoon. I appreciate your giving me this opportunity to speak with you this afternoon. I'm representing the two organizations listed on this slide, the AAPM and the ACR, and I'm a member of both.

My name is Geoff Ibbott. I'm a medical physicist at the Anderson Cancer Center in Houston and I have a number of years of experience in medical physics, and I'm here to relay concerns to you in two areas regarding Part 35.

First let me explain to you that our organizations recognize a term we've dreamed up called "qualified medical physicist" and all three of the organizations listed here, the AAPM, the ACR, and the American College of Medical Physics, have agreed on essentially identical definitions. Our definition of

a qualified medical physicist is somebody who is board certified and who then meets certain continuing educational requirements.

We believe that board certification is important and under the board certification pathway in the new Part 35, the NRC would expect board certification to address all of the training and education requirements that are specified in 35.51-B. And, we're concerned that strict interpretation of this requirement could ultimately diminish the importance of board certification.

Let me explain to you why we believe that. Firstly board certification is, in our field, the only widely-accepted credentialing system for clinical medical physicists. For 50 years, medical physicists have been certified by the American Board of Radiology and the American Board of Medical Physicists, and it is a process that indicates a certain level of competency that people in our field have come to recognize and take confidence in.

Unlike with physicians, a residency program is not a requirement for board certification. In addition, the demographics of our field require that physicists be able to transfer from traditional physics fields into medical physics by getting some additional

training and then board certification.

We are very concerned that board certification be preserved as a key element of any other credentialing requirement through the NRC. But as has been discussed earlier, I believe the certification boards do not require specific experience with Cobalt 60, gamma stereotactic radiosurgery or remote afterloading brachytherapy.

We believe that any move that diminishes the importance of board certification, could ultimately jeopardize public health. This is because certification is recognized as an indicator of competency. We have a number of examples. In Texas, I'm licensed by the state, essentially by virtue of being board certified. MQSA is another example, where great importance is placed on board certification.

We would hope that the NRC would accept board certification as a default or accepted pathway for demonstrating some of the individual requirements in Part 35.51, such as the existence of an advanced degree and of certain training.

There's also been some discussion about grandfathering earlier today I understand. We believe, again, that previously and currently licensed medical physicists should be recognized as meeting the

requirements for an authorized medical physicist. This is consistent with NRC practices. We believe it to be appropriate that this authorization be awarded without limitations, and we think it's essential that this be done to build up a cohort of authorized medical physicists to continue the process of awarding authorization to other medical physicists.

Now, the existing wording proposes a single AMP category. We think this could be a problem. Our estimates are that there are approximately 100 Cobalt-60 teletherapy units in clinical use. That's clearly about two per state, but they're not distributed that way and so there are many folks who are quite some distance from a Cobalt ^{60} teletherapy unit.

Similarly, there are only a few dozen gamma stereotactic units, not enough for potential AMPs to get experience with these devices. So we propose that subcategory AMPs be defined, that again emphasize the importance of board certification but enable the awarding of the AMP authorization.

So our proposed solution to this is to define three subcategories of AMP. As shown here, the teletherapy AMP, remote afterloading AMP and a gamma stereotactic AMP.

Now for the teletherapy authorized medical

physicist, a physicist who is already board certified, could then show his special skills with Cobalt^{60} teletherapy by performing a complete calibration, a full annual calibration of a Cobalt unit and then a monthly spot check which would then be scrutinized by an AMP who would then sign off to indicate that the procedures were in agreement with the AMPs own procedures.

I'd like to point out that, while my slides says "under the supervision of", this is not intended to mean a sort of teacher-student relationship. It may well be that the person seeking the authorization is more experienced and more capable than the AMP, but the point is that the AMP who has first calibrated the unit to meet with the NRC requirements then compares the measurements of the person seeking accreditation with his own to insure that the procedures were done correctly and the results are in agreement.

Now, this is a physicist who is not already certified. A physicist who is not board certified would have to have a graduate degree and have a year of full-time training in therapeutic radiological physics, and an additional year of experience under the supervision of an AMP physicist at a facility using a Cobalt teletherapy unit. This would bring us into

agreement with the legal requirements established by 35.51.

Similarly, for remote afterloader system, a board certified physicist would demonstrate his ability to operate and calibrate the unit by performing a full calibration and a spot check, and that would be signed off by an AMP and a non-certified medical physicist would go through the pathway I described just a moment ago, with the appropriate degree and training, followed up with experience on that particular device.

And likewise for the gamma stereotactic AMP, a board certified physicist would demonstrate his ability to calibrate the unit appropriately. A non certified physicist would have again the degree and training requirements, followed up by experience at an institution with such a device.

So I'd like to conclude by stating that I've intended to make two points here. One is that we believe certification is a very important credential in our field and that the requirements for an authorized medical physicist should not in any way detract from the importance of certification, and should take advantage of the certification processes we have in place.

Second, that we propose that there be three

subcategories of authorized medical physicists to make it more practical to bring people in under this credential. And I'd like to finish by saying that the AAPM and ACR are both willing to work with the NRC in any way we can to help with this ruling and with regulations that would follow. Thank you and I'd be happy to answer any questions.

DR. CERQUEIRA: Dr. Nag.

DR. NAG: You mentioned three subcategories. Where would you put the category that exists in many places where the physicist is certified and handles Caesium, Iridium, has not had training in either gamma knife or high dose rate or cobalt teletherapy? How would you characterize that person?

MR. IBBOTT: Well, if that person is not working with cobalt teletherapy or cobalt gamma knife or the remote afterloading devices, then it's my understanding that the AMP criterion doesn't come into play.

DR. NAG: No, but then how would you handle caesium and iridium? What will you call him? He's not a teletherapy AMP. He's not a gamma knife AMP and he's not a high dose rate AMP. So, what kind of an AMP is he?

DR. WILLIAMSON: I think the answer is, is

that in 35.400 the only requirement for the involvement of an AMP is to perform decaic calculations for strontium^{90} I applicators and that's it. So essentially, the role of the AMP is limited to 35.600 devices, except for that one indication.

DR. CERQUEIRA: I don't think that's what he was asking.

DR. NAG: No, how are you handling, you know, many patients are using a lot of caesium, iridium.

DR. WILLIAMSON: But the NRC basically does not regulate the role of a physicist in those modalities with the exception, you know, the NRC staff can correct me, but my understanding is, is that the AMP is not required for 35.400 modalities except for the strontium^{90} I applicators and in the case where low dose rate sources are used in a remote afterloading device.

DR. DIAMOND: Jeff, I don't think you understand what Subir was asking. I think his question is, with the new rubric that Geoff just explained, whether it be an AMP with these three different qualifications for the individuals coming through the training now, I think Subir was asking what about those individuals who are grandfathered in. Would there be

specialized designations indicating their training? Is that what you're asking?

DR. NAG: No, I was saying what about those physicists who have training in low dose rate, all right, but do not have training in any of these three. You only have three top categories. What about the fourth category which will be applicable to a lot of physicists who don't have training in any of these three.

DR. CERQUEIRA: So he's saying a general physicist who wouldn't be specifically trained in those three but --

DR. NAG: That means they can't handle radioactive material if they don't have a category.

DR. WILLIAMSON: NRC doesn't have such an entity, that's the answer Subir is there is no AMP for manual afterloading brachytherapy with the exception of strontium^{90} decaic calculations.

DR. NAG: Oh.

DR. WILLIAMSON: If you read the definition, it basically says AMP has this degree and so on, and gets the experience at an institution and then there's a list of section numbers out of Part 35 and they refer to all of the things Dr. Ibbott mentioned, which are the full, basically full calibrations and spot checks

of the three 35.600 modalities, plus I think leak testing and strontium^{90} decaic calculation.

DR. NAG: No, if someone is doing interventional brachytherapy and does not have any of these three, he's not an authorized medical physicist.

DR. WILLIAMSON: I think he can become one depending upon the proposal that's used. Now, in Dr. Ibbott's proposal, if this person were board certified, he would have to go and fulfill these supplementary training requirements that he just mentioned in this scenario, and then he could become an authorized medical physicist.

DR. NAG: No, but -- okay, under the interventional brachytherapy procedure, it has to be done in the presence of a physicist or authorized user and so forth. Now, if it is not high dose rate, since this is not gamma and this is not cobalt^{60} he's not a physicist.

DR. WILLIAMSON: Well, it says actually in this guidance, I hate to be argumentative, but it just says medical physicist. It doesn't say authorized medical physicist.

DR. NAG: Oh, okay.

DR. WILLIAMSON: So there still is a concept of medical physicist and there still is a concept of

board certified medical physicist and that is quite separate from the current category of teletherapy physicist which is going to turn into the category of authorized medical physicist.

So, I think the way to see this is in the old regulation that we now have, the only mention of the physicist in the regulations is for calibrating cobalt^{60} teletherapy and that's why he's called a teletherapy physicist. And there are other mentions or other references to the physicist, but only in regulatory guides.

DR. CERQUEIRA: Dick, you understand this. You're going to explain it, right?

DR. VETTER: Oh yes, Jeff is absolutely right and I do understand the question. But it's sort of like the old cliche, when is a dose a dose? Now we have a new one. When is a physicist a physicist?

DR. NAG: Right.

MR. IBBOTT: And I have to say we were responding to the wording in the revised ruling, and sort of took it point by point.

DR. NAG: Thank you for the clarification. Now I know when you're a physicist and when you are an authorized physicist.

DR. VETTER: And a qualified medical

physicist.

DR. NAG: And a qualified physicist.

DR. WILLIAMSON: I mean it really is confusing. We have actually the same trouble in our radiation safety committee. We had nearly an identical discussion. It was very confusing because we even had a third definition which was authorized by the radiation safety committee to do such and so which is different yet. So, it's very confusing.

DR. CERQUEIRA: Any other questions for Dr. Ibbott? Yes?

DR. WILLIAMSON: If I can make a comment and I think what this proposal amounts to is accepting the rule language as it is and is suggesting a procedure which would be implemented more in guidance space rather than rule space. The essence of the idea is to make board certification cover as many of the 35.51-B requirements as possible, so from a regulatory point of view, there would be desirability of board certification, and the willingness of physicists in the field to undergo the rigors required to earn this certification would not be diminished.

So you know, I think in view of how controversial this is, I think it would be maybe a good idea if this committee considered a motion to support,

you know, this type of proposal.

DR. CERQUEIRA: Well, why don't you work on a short motion and Dick you wanted to make a comment?

DR. VETTER: Yes, just one brief comment more or less in support of the whole discussion here, and that is we all together hold some responsibility for the dilemma we find ourselves in relative to the interpretation of the requirements, not the requirements to be uncertified, but the requirements for certification to be recognized. So anything we can do in guidance phase to try to clarify that to encourage, at least to not discourage board certification will help improve the safety of patients in my opinion.

DR. CERQUEIRA: Yes, I think that's true for not just medical physicists, for all the groups we've addressed today. Dr. Nag.

DR. NAG: I would like to know if, I know there has been some problem between certified physicists from the American Board of Radiology certified physicists and I think the American Board of Medical Physicists. Would this involve both or would it resolve the issue for both or not? I'm not really up to date with the two, but I know that there was a controversy. Someone who is either a member of both,

or not a member of either, I think should address this position.

MR. IBBOTT: Well, I think I can address it if you will. There are two answers. One is that we are saying board certification without specifying ABR or ABMP.

But the second response is that an agreement has been worked out between those two boards and physicists certified by the ABMP can request and will receive a letter from the ABR stating that their certification is equivalent to ABR certification. It will be a time limited certificate and at the appropriate interval, they will then be able to become recertified by the ABR if they so choose. Otherwise, they can become recertified by the ABMP. But the boards have recognized the equivalency of the two mechanisms, so I deliberately did not state which board I was talking about. We consider them equivalent.

MS. HOBSON: I assume you've discussed this proposal with NRC staff?

MR. IBBOTT: We have written to the NRC staff.

MS. HOBSON: Right, have you had any indication as to what their position might be?

MR. IBBOTT: Not to my knowledge.

DR. CERQUEIRA: How's the motion coming Jeffrey?

DR. WILLIAMSON: Oh, I'm working on it here. It's three pages long, so.

DR. CERQUEIRA: Good grief.

DR. WILLIAMSON: It's hard for me to write it down. I'm not nearly as good as our departed colleague at this.

DR. CERQUEIRA: That's right.

DR. NAG: You're better on your computer typing.

DR. WILLIAMSON: I'm better at just ad-libbing it actually. Maybe I should just do that. Well, I think the motion would read: ACMUI recommends that NRC accept ABR or ABMP certification in radiation oncology physics as prima facie evidence for satisfying as many of the 35.51-B training requirements as possible.

DR. CERQUEIRA: That doesn't -- it has to translate into the boards, you know, the application process that we talked about earlier.

DR. NAG: Yes, the three subcategories.

DR. WILLIAMSON: Okay, well we could make it more --

DR. CERQUEIRA: But there seems to be a

mechanism in place, although --

DR. WILLIAMSON: It's really sort of three components to it, I guess. We've already had one motion which endorses the idea of broadening the grandfathering.

DR. CERQUEIRA: To grandfather it in in three levels.

DR. WILLIAMSON: We need to have essentially two recommendations. One recommendation would be that NRC utilize a modality specific definition of AMP which allows separate credentialing of teletherapy AMP, remote afterloading AMP, and gamma stereotactic AMP. That would be one component of the recommendation.

DR. CERQUEIRA: But shouldn't part of this be incorporated as part of the board approval process because in a sense that's what we're -- I mean, how would that be -- I mean, we could make the motion.

DR. WILLIAMSON: No, this first part is independent of the board certification to some extent I think, the idea of having multiple modality AMPs is not necessarily, I think, connected with the board certification.

DR. CERQUEIRA: But it's a concept of --

DR. WILLIAMSON: The second component would be is that I think to sort of iterate the essence of

Geoff's proposal, you know, the basic idea is that: ACMUI recommends that NRC accept ABR or ABMP certification in radiation oncology physics as evidence for complying with all of the requirements of 35.51-B except the modality specific requirements not covered by the board eligibility criterion, which is in essence the various types of calibration. Would that cover it?

MS. McBURNEY: Rather than this being a motion, could it just be kind of a consensus that we support the idea outlined by Jeff?

DR. CERQUEIRA: Dick?

DR. VETTER: I agree. In fact, I think in the material that was in our packet, I think it's pretty well outlined, board certified physicist plus demonstrating the modality specific training. It's really well-outlined there and if we could simply transfer to the NRC our consensus that we support this concept, it doesn't have to be the exact words, this concept. I think that would work.

DR. CERQUEIRA: I think consensus opinion is probably right.

DR. WILLIAMSON: I think it would be interesting to hear what the NRC reaction to this proposal is.

MR. BROWN: Well I tried to operate by the

standard. If I don't know what I'm talking about, I shut up, and unfortunately in the room right now, you don't have any of the people dealing directly with this issue, so I can't offer you anything more than that. I would observe that if the issue is trying to modify the rule language for blanket recognition of the board certification, that's more difficult than if how this is implemented is as a standard acceptable for license amendment request to add an authorized medical physicist to a license which is quite simple and readily amenable.

DR. WILLIAMSON: I think it's guidance for identifying those physicists that comply with 35.51-B that basically, if a candidate comes to you that has one of the two specified certifications, you don't have to ask them where they got their degree and what it was in.

You don't have to ask them about their year of training and their year of experience, because you have already concluded that the board certification adequately covers those requirements, and the only additional ones you have to go after are those that the board does not include.

So I think this is the idea and that the idea is this would be something that exists in guidance

space and would not require a reworking of the regulatory language itself, which requires a rule-making initiative which I think should be discussed sometime soon, I hope, to rectify the problem long-term.

So I guess what it would require is, is that the boards would basically write to NRC and say our requirements include this, this, this and this but not this, and that could be used as the base by radiation safety committees of broad scope licensees for credentialing AMPs and I guess would be used by NRC license reviewers in assessing the suitability of applicants offered as authorized medical physicists file license amendment.

DR. CERQUEIRA: The more you keep talking about it, the more confused I'm getting here. Again, I understand the point that you're making, but I'm not certain why we shouldn't make this point for all the other authorized users, whether it's physicians or whatever. So and I think this is covered adequately within the certification board review process. I think that would get it into, you know, out there and enforced much sooner than anything else we could do. Dick, am I misperceiving it?

DR. WILLIAMSON: I'm not sure I understand

your point.

DR. CERQUEIRA: I understand your points though.

DR. VETTER: See I think one of the problems is the way the language has been finalized. There's nothing in the language that prevents someone from becoming a qualified medical physicist or radiation safety officer apart from being certified. Just fill out all the paperwork. You send it in to the NRC and you get approved. I think what Dr. Ibbott is saying is that there is value in the certification process in helping to assure safety of the medical use of radioisotopes, because certification is one very strong indication of competency, and the more competent our physicists are, at least we would hope, the safer -- this is true for physicians as well, I assume.

DR. CERQUEIRA: See but that's kind of a generic.

DR. NAG: I think one way or the other, for the authorized user, for the radiation safety officer. I think the only difference I can see here is that in addition to you having a certification, they should show competence in these three --

DR. VETTER: Right, and his proposal does that.

DR. NAG: Right.

DR. CERQUEIRA: Right, but the way to get this through is part of the application process that they've already initiated that we discussed this morning. I mean, isn't that correct? I mean, David help me out here? I mean, what am I missing?

DR. DIAMOND: Well, I was just laughing to myself. Perhaps if the Society of Nuclear Medicine has its way and this whole Part 35 rule-making is scrapped, we have now learned some important lessons next time we do this as to how to write these regulations.

DR. CERQUEIRA: Dick?

DR. VETTER: The problem that we have is that the current language requires the board to certify that the person has had the appropriate training and experience. And the boards don't do that.

DR. CERQUEIRA: Well, they do in their eligibility requirements and that's one of the things that the board review process is looking at is they're looking at the requirements for those candidates for certification, and they're supposed to meet the NRC requirements.

I know that the cardiology community basically changed their rules to be in compliance with the proposed changes. Now unfortunately, it's already

been done and if it just doesn't go through, they're in trouble. But Jeff, briefly, how am I going to, what am I missing?

DR. WILLIAMSON: Well, I think three points I'll try to make.

DR. CERQUEIRA: Quick points.

DR. WILLIAMSON: I think what you're saying is why can't this comment be generalized or essentially this recommendation of Dr. Ibbott's be generalized to cover all of the various individuals that are mentioned in the regulation.

Well, I think the first reason is, is aside from the health physics certification, I think medical physics has been the sort of only individual where it appears that we definitely know for sure the board certification process has failed to meet the NRC definition. I think at this point in my mind, all I've heard it's very cloudy.

DR. CERQUEIRA: Wasn't the discussion this morning that we would basically break it down into categories, and shouldn't that meet the board's eligibility requirements?

DR. WILLIAMSON: Let me try to finish my answer.

DR. CERQUEIRA: Okay.

DR. WILLIAMSON: So that's one point. The medical physics, the definition for authorized medical physics very clearly does not agree with the board eligibility requirements that exist now. There probably is no practical way ever to make it agree completely with those requirements due to the demographics and how people enter the field and the distribution of some of these modalities, which is actually quite rare.

I think the second point is, is that board certification is especially important to, I think, quality of radiation medicine delivered because it's sort of really the only credentialing tool we have. If board certification in radiation oncology, you know, ceases to have the significance that it does now, that's not as serious I would argue because there is the residency requirement, which is the sort of real teeth of the regulation.

And again, due to the fact that residency programs are a new concept in medical physics and do not have the market penetration, it is not practical at this time to insist on a uniform training experience. So we really have to rely on the board certification mechanism in order to weed out people, and it does have teeth. It's rather difficult to pass in the sense that

30 or 40 percent of those who take the exams flunk them. So it is an effective tool I think.

I think those are really the two main points. I've lost track of what the third is, so I think the idea was to make -- the third idea is or the third argument was, is that the fact that board certification for physicists has been the criterion used in the current Part 35, I think has been very important in making it have the universality of acceptance that it now has and the concern is, if it completely disappears as a tool for selecting who can be an authorized medical physicist, that they'll be little motivation for physicists in the future to become board certified and there will be an influx of people into the field who do not have the certified credentials.

DR. CERQUEIRA: I'm president of a certification board, so I understand a need and a concept of why we want to do it. I'm just not certain how this committee's going to advance it. But tell me what you would like to do and we should probably take a vote and move on.

DR. WILLIAMSON: The proposal is that I think this committee should pass a motion which endorses the separate modality AMP concept and I think

the second proposition I think this committee should support is the idea that, even though board certification at this time can not be accepted as sort of the sole credential for getting through the process, it should be utilized as much as possible in determining who has satisfied the alternative pathway requirements in 35-1B.

So, the board certification is not evidence that the person has had specific experience in gamma stereotactic, but it is evidence that the person has the two years of training, the Graduate Degree.

DR. CERQUEIRA: See, that's just too many -- you got to make it simple.

DR. WILLIAMSON: What is your point?

DR. DIAMOND: The point is you made a very good case just now that this is a special situation in which there's a disconnector or dichotomy between current training with respect to the board and what the new regs have, a special case in that there's no residency training so that the certification is really integral, and number three, it's a special case because it's the historic certification which has carried weight.

So you made a very good argument with these three points. How do we get these points over here and

make it workable so for the next three years, we don't have to spend a lot of time dealing with this?

MR. BROWN: I think that I suggest that there was a proposal brought to the committee in the form of the slides which will be part of the record.

DR. CERQUEIRA: Plus the letter.

MR. BROWN: And the letter. And I think if the intent of the committee is to suggest to the staff that we pursue this avenue to achieve a methodology of getting authorized medical physicists into hospitals, then you could simply so recommend to us and then we'll work out the mechanism on how to make it work.

DR. WILLIAMSON: The recommendation is this, that the NRC accepts board certification as having satisfied all of the 31-1B requirements, except for the specific experience with remote afterloading, gamma stereotactic and $Cobalt^{60}$.

DR. MALMUD: I have a question.

DR. CERQUEIRA: Yes.

DR. MALMUD: Are there enough board certified physicists to handle the clinical load nationally or are we creating a possible obstruction to patients getting care?

MR. IBBOTT: I don't believe there's any evidence that there are not sufficient numbers.

DR. MALMUD: But I was asking the other question. Is there evidence that there is a sufficient number?

DR. NAG: You have the alternative pathway. The pathway is there. I mean, this is a way to streamline or make it faster, so you don't have to go through and examine every training requirement. If you don't have a board, you can always use the alternative pathway with equivalence.

DR. WILLIAMSON: I think one answer is, I'm not sure if there's direct evidence, but certainly the current regulation and the current licensing guidance basically requires board certification as the sole criterion essentially for being authorized to do all of these things. So this represents actually a change where board certification is no longer going to be used as part of an assessment.

MR. IBBOTT: But Jeff, could I follow up on that? At the moment, yes board certification is recognized as that level of competency in practice. In institutions that have say a gamma knife, a physicist does get training administered by the manufacturer or by a practitioner of that field that's acknowledged by the manufacturer, and so does get some special training in that field.

So, I think the answer is that yes, we do have people out there now who are meeting the needs because there isn't a clamoring for four people. Now, we're experiencing some shortages just like all other medical specialties are, but the fact is that hospitals aren't prevented from delivering these treatments because they don't have qualified and experienced medical physicists to calibrate the equipment.

DR. CERQUEIRA: I'm not sure we're going to get consensus, so unless somebody feels very strongly that we need to take a vote on it, I think we've gotten information to the NRC staff. I also think, you know, in terms of Dr. Malmud's point, we should get some numbers. I mean, how many certified physicists are there out there? How many people are currently employed as medical physicists were certification would be a necessity? That would give us some idea of the numbers and the scope of the problem, and I think that could be discussed at the spring meeting.

So, unless somebody feels really strongly, I vote --

DR. WILLIAMSON: Well, I feel quite strongly and I think this is a seminal point in time which, you know, the role of physics board certification in the regulatory process is really in doubt, and I think it

would behoove this committee to send a strong signal to the NRC staff that this is an important credential and should be used.

DR. CERQUEIRA: Maybe let's go around the room and just short comments in terms of whether you feel we need to have sort of a motion or whether we need more information.

DR. NAG: I felt that, the way the ruling now addresses that and that's true for all the others, I mean authorized user a board requirement is there and all the others and we have an alternative pathway for those who are not board certified.

DR. CERQUEIRA: Yes, Neki?

MS. HOBSON: Well, it seems to me that if we endorse Dr. Ibbott's proposal, it would just hopefully give it more weight when it's being considered by the NRC staff and hopefully, eventually a commission. So, I would agree with Jeff that I think it's something that we could go on record now as being in favor of it.

DR. CERQUEIRA: As endorsing, okay. David.

DR. DIAMOND: As I suggested, I'm in favor of endorsing Jeff's points.

MR. LIETO: Same.

DR. MALMUD: I agree.

MS. McBURNEY: I too am in favor.

DR. CERQUEIRA: All right. So, shall we take a vote for endorsement?

MS. McBURNEY: Yes.

DR. CERQUEIRA: All in favor? Opposed? It's unanimous, good. Thank you very much.

MR. IBBOTT: Thank you.

DR. CERQUEIRA: Any other new business before we --

MR. BROWN: We are prepared.

DR. CERQUEIRA: To do?

MR. BROWN: To talk about the other subject.

DR. CERQUEIRA: All right, some people have to jump ship momentarily, don't they?

DR. NAG: Yes, actually right now.

DR. CERQUEIRA: Okay, well maybe I think we could let the three jump ship and then this is -- is there any way we could send in the material?

MR. BROWN: We certainly can hand you what we have.

DR. WILLIAMSON: What is the topic that's being proposed, I'm sorry?

MR. BROWN: This is the follow-up to your request this morning for information on recommended treatment.

MS. McBURNEY: Medical update from accident?

MR. BROWN: Accident, right.

MS. McBURNEY: And non accidents.

MR. BROWN: Mark Sitek from our staff will go through the slide. I'd like to just introduce the topic by pointing out that within the NRC obviously, is as you have pointed out to us quite often, we're not involved with the practice of medicine or recommended medical efficacy issues with respect to patients. We're interested in radiation safety occupational specifically, as well as to the patient from the treatment.

So we don't have a large in-house medical capability to make the sort of recommendations or provide you directly with the information on how you would treat citizens who came to you with specific concerns or specific exposures. Having said that though, we do have some things that we can share with you, including who we think the best people in the Federal Government to address the issue are.

So, I'm going to let Mark go through that, and then I'll kind of wrap it up at the end by letting you know how we intend to proceed based on your concerns.

MR. SITEK: Again, my name is Mark Sitek and I work for Fred. I quickly went through some of our

internal documents and did a couple searches for other Federal agencies or government entities that can offer assistance. Internally, in one of our inspection manuals, we have very brief and generic guidance on when we recommend individuals exposed to radiation be referred to a physician. This procedure is currently under review, but as it stands now, we have basically two group.

Group A, those women that are pregnant that receive or are believed to receive in excess of 500 millirem, we recommend that they see a physician. The second group is everybody else, men, children and non-pregnant females when they receive greater than 5 rem, we recommend that they see a physician, and these dose limits are based on Part 20 dose limits. Five rem is of course the occupational worker limit and 500 millirem is the limit for pregnant females.

MS. McBURNEY: Question, this is a single dose?

MR. SITEK: Acute, yes.

MS. McBURNEY: Acute instantaneous.

MR. SITEK: Yes. And then if anybody receives greater than 20 rem, we recommend that the physician follow up with cytogenetic studies. But in all cases when we refer it to the physician or ask the

individual to see a physician, we recommend that they contact REAC/TS which is through the Department of Energy and is the Radiological Emergency Assistance Center/Training Site, for those individuals are truly the world experts in all aspects of assessing radiation exposure and have the state-of-the-art and the most current expertise on how to deal with and treat internally, externally wounds associated with radiological contamination.

Their web site is pretty good in providing very general or generic guidance on how to treat externally contaminated individuals, externally exposed and internally contaminated individuals, but it does not go into great detail on how to step through the process like in a cookbook format. It doesn't say, Step 1, administer 100 milligrams of potassium iodide for example. It's just very general and provides to some degree various drugs or blocking agents and chelating agents that are in existence that can be used.

This center is available 24 hours a day, and like I said, they are the world experts and are called upon all the time. They also provide training to physicians on how to treat and recognize signs of radiation.

But the underlying message from them is, these types of events and these patients should be treated on a case-by-case basis, and if you don't know what you're doing, then you should definitely contact the experts, which in this case is this group of people.

They also refer you to, there's a national counsel on radiation protection and measurements report which is #65 which goes into a little more detail on the recommendations and on how to treat, and other drugs that have been used in the past. But again, it's also a very general and the overall recommendation is to seek expert advice.

MR. BROWN: This obviously goes hand-in-hand with the function that we have more directly, which is in the event that there is either an industrial accident or a terrorist event, we'll be working with the other Federal agencies involved and key players, the states, to make recommendations on protective actions and over the course of the long-term, decontamination of any exposed area.

So, that effort is actually right now being coordinated through the Homeland Security Office and I believe FEMA is the lead agency. So what we plan on doing is to recommend to the commission and senior

agency management that we forward to that organization the issue that you raised, that the medical community in general may expect to be asked about what are protective action guidelines, what should they do if they're directed to a physician. And so that we'll propose that those branches of the government with the lead on this be responsive, and then we'll keep you informed as the ACMUI as we hear back to that need.

So, I guess I should first ask whether we scratched your itch at all here, or if we're totally off target.

DR. CERQUEIRA: I think this is a start in terms of once again -- I think the point we were getting at this morning again, is just some general information. Again with the anthrax concerns, our medical center has been having almost daily briefings for staff and physicians on what knowledge do we have about anthrax? What are some of the issues that are going to come up? How do we treat it? And just try to keep it very current with what's going on in the public media, because that's what patients come in and ask about.

So, the whole issue is, you know, obviously sort of nuclear bioterrorism is a concern and how do we sort of alert ourselves and the other physician

communities. It sounds like REAC/TS is the group that we need to go to. Leon.

DR. MALMUD: There is a rich literature on the subject. It tragically evolved in the same way that the literature for anthrax evolved. Anthrax came out of the Swerdlovsk incident in the Soviet Union, and our information has come from our own effort to close World War II at Hiroshima and Nagasaki and then with one or two radiation accidents that have occurred.

The individuals who would be involved in treatment would be certain radiation oncologist, environmental health and safety people, radiation safety people. But then hematologists, burn specialists and then the areas that are affected would require intensive -- for patients who were subjected to large radiation burdens externally but may or may not be externally burned, they would have the typical reaction of patients who got too much whole body radiation, begin sloughing their gastrointestinal tract and have bone marrow shutdown.

But there's rich literature on it. It's not timely, fortunately, and we hope it will never have to be timely, but it is available and I suspect it's probably accessible through those numbers that you've given us in that page. The data will be updated as the

Federal Government gets to work on preparing us for possible nuclear terrorism.

We have the largest emergency service in the City of Philadelphia at Temple, and we've begun the process of preparing for both biologic, chemical and nuclear incidents. We're further ahead with biologic and chemical than we are with nuclear because we wanted to deal with those two first.

We would be remiss in a facility of our size, treating the volume of patients that we do in the city, not to be prepared for this as well. And I suspect as you well know, that's why we have the itch. I could respond to you that you did help scratch it a bit. That list is very useful. Thank you.

MR. BROWN: Thank you.

DR. CERQUEIRA: Ruth.

MS. McBURNEY: For those, as I mentioned this morning, for those facilities that are in the vicinity of nuclear power plants, they are geared to treating exposures and contaminated individuals from the plant. But in the case of a large-scale attack, you're talking about having to take people to higher populated because most of the power plants are in lower populated areas and having to go into bigger facilities in the city, which may or may not have had the training

to deal with that.

DR. CERQUEIRA: Ruth, or Neki?

MS. HOBSON: Aside from, you know, the technical and professional problems that the medical community would need to address, and maybe someone's already done this, but there should be put together by some very credible organizations a packet of basic information on radiation and radiation exposures that you can hand to the media and try to keep -- you know, the media just goes hysterical and I think it would be really helpful if we had that kind of information available that we can just distribute to dampen that hysteria a little bit at least.

DR. CERQUEIRA: Yes, I think that would be very important, and obviously even if word got out that some government committee had started asking about these questions, then there would be concern it's imminent.

But I think just having information is useful, and whatever the NRC could do to come up with it. Maybe, you know, the REAC/TS people seem to have all the information but maybe it needs to kind of be distilled and made available for the medical community as well as for the general public. Certainly, I think, that's within sort of the mission of this committee to

advise you that that's a need, that people are going to come to the NRC and to committee members in general to address.

MR. BROWN: And we took our web site down where we had some of that general information. So, I guess the other option --

DR. CERQUEIRA: Well, if it was there, maybe you could provide, I mean -- it wasn't closed because of that type of information. So if that could be made available, that would be useful.

MR. BROWN: I guess the other obvious reference are the BEIRs studies to go back to the best science as we know it for dose effect relationship, but your point's well taken Dr. Cerqueira. I think that's what we'll pass on.

DR. CERQUEIRA: Yes.

DR. MALMUD: The Soviet literature too from Chernobyl.

DR. CERQUEIRA: Chernobyl, yes.

MS. McBURNEY: The Conference of Radiation Control Program Directors is putting together a sort of a series of links or referenced web sites for the general public and on different topics, one of these being general information on radiation. Also, even terrorism type links that they've -- anyway, I'm on the

committee that's putting this together for public information type information that people can go to to find information on the various related -- you know, to get information, general information on radiation and radiation effects.

DR. CERQUEIRA: The information is there. All these things that have been mentioned have all the information, but it's not distilled in a form that can be easily presented to, certainly to lay people or even to medical physicians. Okay. Thank you, that was very useful. Other new business? I guess the next meeting is?

MS. WILLIAMSON: Before we discuss that, I just want to mention to the committee members that if I can get specific travel information and other information. This is really committee business, more than public business, but I just want to remind the committee members that if I can get all of your travel information, your professional pay information before you leave, that will expedite the process of getting those reconciled. So, if you can get those to me that will be helpful to us both.

DR. MALMUD: Is there a standard form?

MS. WILLIAMSON: Yes. I might have to speak with you and Mr. Lieto offline since you're new to the

process, but the other members know exactly what I'm talking about.

MS. McBURNEY: It's just the little expense form, or do we need to have a voucher to sign as well or would we be sent that?

MS. WILLIAMSON: Well, I thought -- if you don't have both of the forms that you need, I can get you both the forms.

MS. McBURNEY: Okay.

DR. WILLIAMSON: We might not have all of the receipts and some of our expenses are yet to be incurred, so it's sort of difficult to.

MS. WILLIAMSON: Okay.

MS. McBURNEY: Yes, the end of the night tonight.

DR. WILLIAMSON: I think all we have to do is fill out the simple form and give you the receipts that are required, including the airfare information and such, and then as I understand, your office generates some more complicated voucher that comes back to us and then we sign and then we send it back to you.

MS. McBURNEY: Is that right?

DR. WILLIAMSON: That's how it works.

DR. CERQUEIRA: Good, okay. So the next meeting, I think everyone felt it was important to have

the meeting with the commissioners which we tried to schedule this time but were unable to do so. But, we were supposed to meet in April and hopefully we will have some resolution on Part 35 by then, the revisions. We should probably get availability for the commissioners in April?

MR. BROWN: We'll use April as a target to work with the commission staff.

DR. CERQUEIRA: Okay, they can't project that far I guess. I think otherwise first to try to settle on a date without knowing when they're available is futile and a waste of time.

Okay, any comments from the staff? Well, then I'd like to thank everyone for coming and participating and giving us their input. And I'd like to again welcome Ralph and Leon to the committee and hope they weren't too discouraged by this first meeting. It gets better I think. And with that, we'll adjourn. Thank you.

(Whereupon, the above entitled matter was adjourned at 2:39 p.m.)

1